

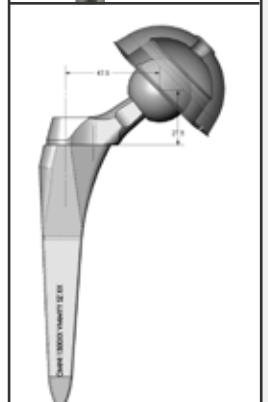
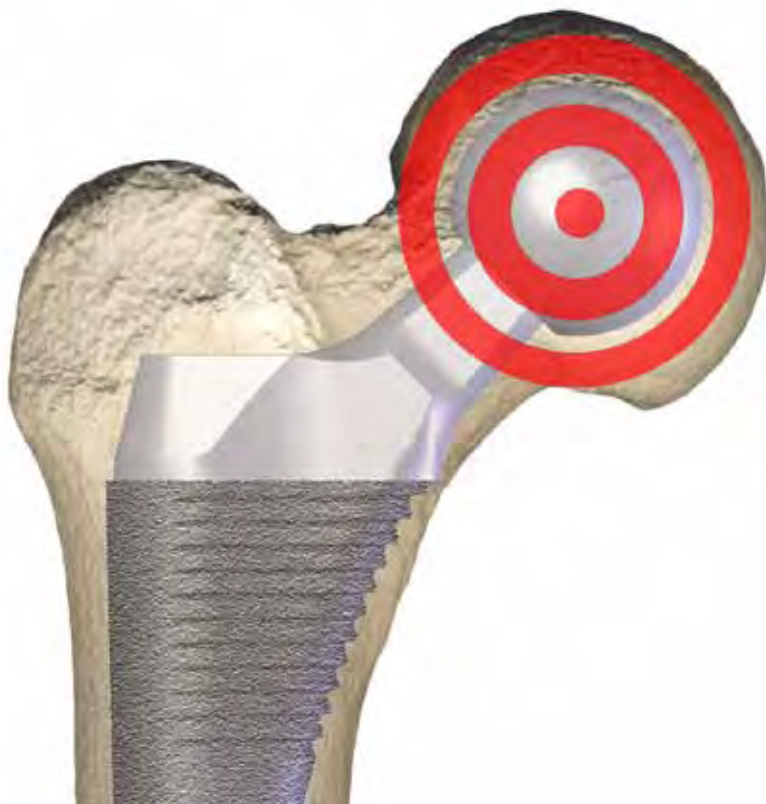


Joint Implant Surgery & Research Foundation

Dedicated to the Advancement of Total Hip, Knee, and Shoulder Surgery

Reference Book on Total Hip Modularity

Compiled by:
Timothy McTighe, Dr. H.S. (hc)
Executive Director, JISRF



Third Edition, January 2009



Published by the Joint Implant Surgery & Research Foundation in 2008
A Non-Profit Scientific and Research Foundation (Founded in 1971)

Timothy McTighe Dr. H.S. (hc)
46 Chagrin Plaza #118
Chagrin Falls, Ohio 44023
440-785-9154
Web site: www.jisrf.org
email: tmct@jisrf.org

Acknowledgements:

I would like to thank my mentor, Dr. Charles O. Bechtol, Founder of JISRF (1971), the Board Members (Louise Bechtol, Hugh U. Cameron, Ian Clarke, Kristaps J. Keggi, Dave LaSalle, John M. Harrison, Edward J. McPherson, Richard "Dickey" Jones, and H. Del Schutte for their continued interest and support to the Foundation. In additional thanks to our clinical/surgical research advisors: Louis Keppler, Thomas Tkach and Allen Turnbull.

Special thanks to all the contributing authors and co-authors of the research papers contained within this reference book.

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1994 Bruce D. Shepherd, M.B.

1995 James E. Bateman, M.D.

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The tradition continues as established by Professor Charles O. Bechtol, M.D.

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Joint Implant Surgery & Research Foundation

Dedicated to the Advancement of Total Hip, Knee, and Shoulder Surgery

“Cutting-Edge Developments on Proximal Modularity in THA”



**Mini-Symposium held at the Annual AAHKS Meeting
Friday, November 7, 2008, Dallas, TX
11:30 AM - 2:45 PM**

American Association of Hip & Knee Surgeons
Hyatt Regency DFW, 2334 N. International Parkway, DFW Airport, Texas 75261
For immediate registration visit www.aahks.org

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“CUTTING-EDGE DEVELOPMENTS ON PROXIMAL MODULARITY IN THA”

Satellite Symposium held at the Annual AAHKS Meeting, Dallas Texas
Friday, November 7, 2008 at 11:30 AM - 2:45 PM

A CME activity (3.25 Credits) sponsored by the Postgraduate Institute for Medicine
and the Joint Implant Surgery and Research Foundation

**Course Directors: Timothy McTighe, Dr. H.S. (hc), Executive Director of JISRF &
Thomas Tkach, M.D., Clinical/Surgical Research Advisor**

Course Overview

- Historical Review • Pre-Operative Planning • Intra-Operative Assessment
- Surgical Technique • Surgical Approaches
- Target Restoration are Large Heads Necessary?
- Does Proximal Modularity Reduce the Need or Aid the use of Hip Surgical Navigation?
- Bearing Surfaces Does it Matter with Proximal Modularity?
- Does Stem Modularity Aid in Revision and Conversion Surgery?
- Post-Operative Results
- Clinical/Surgical Impressions

Learning Objectives

- Indicate a basic knowledge of modular total hips
- Describe the various designs and material limits of modular hip designs
- Define indications and contraindications for the use of modular hip designs
- Review the efficacy of new design options through evidence-based data

Proximal modularity is being used worldwide with different levels of success. It is important that one recognize the strength and weakness of these designs and the required techniques to use them.

After completion of this mini-symposium attendees should have a better understanding of the indications, contraindications of proximal modularity. The different designs, materials available and the required techniques to implant and retrieve these designs.

Session I

Moderators:

McTighe and Tkach

Introduction:

Historical Review
by McTighe

Key Note:

My Experience With Proximal Modular Stems
by K. Keggi

Discussion



“Modularity”

Target joint restoration of biomechanics make it work.

Session II

Moderators:

Mackel and Turnbull

Restoration of Joint Mechanics by Cameron

Femoral Offset How to Measure Pre-Operatively
by Schutte

Effects of Modularity on Acetabular and Femoral Positioning in THA
by T. Clyburn

The Value of Intra-Operative X-Rays by Keppler

The Lack of Need for Surgical Navigation
by Woodgate

Intra-Operative Techniques in Using Proximal Modular Stems by Low

Discussion

Session III

Moderators:

D. Stulberg and Donaldson

The Use of Cemented Stems With Modularity
by Cameron

Target Restoration With Proximal Modularity
by Tkach

Indication for a Straight Stem vs. Tapered Stem
by John Keggi

Are Large Heads Necessary With Proximal Modular Stem Designs by Walter

Tapered Stems Comparison With and Without Modularity by Turnbull

Discussion

Session IV

Moderators:

Cameron and McPherson

New Approach to Neck Sparing Stems by McTighe

Short Stems With and Without Modularity
by Stulberg

Neck Sparing Stem Design Early Experience
by Woodgate

Neck Sparing vs. Hip Resurfacing by J. Keggi

Tissue Sparing Conservative Approach for Neck Sparing Hip by Keppler

Discussion

Closing Remarks by Tkach and McTighe

Faculty (* Denotes International)

Hugh U. Cameron, M.B.C.H.B.S.*
Terry Clyburn, M.D.
John Keggi, M.D.
Kris Keggi, M.D.
Louis Keppler, M.D.
Warren Low, M.D.

A. Mackel, M.D.
Ed Mcpherson M.D.
Timothy McTighe, Dr. H.S. (hc)
Thomas Donaldson, M.D.
H. Del Schutte, M.D.
S. David Stulberg, M.D.

Thomas Tkach, M.D.
Allen Turnbull, M.D.*
William Walter, M.D.*
Ian Woodgate, M.D.*

Target Audience

This activity has been designed to meet the educational needs of orthopaedic surgeons involved in the care of patients with total hip arthroplasty.

Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and Joint Implant Surgery & Research Foundation. PIM is accredited by the ACCME to provide continuing medical education for physicians.

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John Keggi, MD	Royalties, Consulting, Ownership Interest: Omni Life science
Kris Keggi, MD	Royalties, Consulting, Ownership Interest: Omni Life science
Louis Keppler, MD	Consulting fees, Stryker, Omni life science
Warren Low, MD	Royalties, Consulting Fees, Ownership Interest: Omni Life Science
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Thomas Tkach, MD	Ownership Interest: Omni life science, royalties: Omni life science
Allen Turnbull, MD	Consulting Fees: Stryker and Global
William Walter, MD	Royalties: Stryker Consulting Fees: Stryker & Finsbury Contracted Research: Stryker / Finsbury / Ceramtec / Global Ortho
Ian Woodgate, MD	Ownership interest: Global orthopaedic
Thomas Donaldson, MD	Royalties & Consulting Fees: Biomet /Contracted Research: DePuy, Encore, Smith and Nephew, Zimmer
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"Cutting-Edge Developments on Proximal Modularity in THA"
Mini-Symposium AAHKS, November 7, 2008 Dallas, TX

Course Co-Directors

Timothy McTighe, Dr. H.S. (he),

Executive Director

Joint Implant Surgery & Research Foundation (JISRF)

Chagrin Falls, Ohio

&

Thomas Tkach, M.D., Clinical / Surgical Research Advisor, (JISRF)

Orthopaedic Surgery and Joint Reconstruction, Bone & Joint Hospital, OKC, OK

Joint Implant Surgery & Research Foundation



The Foundation, through the leadership of Prof. Bechtol, its Founder, was pioneering in many areas of hip and total joint surgery as far back as 1954. His first Endo stem design in 1954 introduced steps on the proximal stem, for the transfer of hoop strain into compressive forces. He went on to design: "The Bechtol Total Hip System", The Bechtol Total Knee System", The Bechtol Total Shoulder and the first Patella-Femoral Total Joint System.

In 1952 he presented the first lecture to the AAOS relating engineering principles to orthopaedic surgery. He was a founding member of the P4 Committee (biomaterials) of the ASTM. He was Professor of Orthopaedics at both Yale and UCLA and Established the Yale Biomechanics Laboratory.

JISRF Founder: Professor [Charles O. Bechtol, M.D.](#)

Formed in April, 1971, the mission for the Foundation has remained the same:

"The specific and primary purposes are to operate for scientific purposes by conducting medical research of improvements in medical and surgical methods and materials for preserving and restoring the functions of the human body joints and associated structures which are threatened or impaired by defects, lesions or diseases."

JISRF started sponsoring C.M.E. courses on Total Hip Surgery (first course "Total Hip Arthroplasty" November 1971, 55 surgeons attended. Since then the Foundation has sponsored hundreds of seminars with thousands of surgeons, nurses and industry personnel in attendance.

We are pleased to be able to continue the work and vision of Prof. Charles O. Bechtol, M.D. (www.jisrf.org)



Course Faculty

Hugh U. Cameron, MB, C.H.B.S., Orthopaedic & Arthritic Institute, Toronto, Canada, Joint Implant Surgery & Research Foundation, Board Member

Terry Clyburn, MD., Clinical Associate Professor of Orthopaedics, The University of Texas at Houston, and The Baylor College of Medicine.

Thomas Donaldson, MD. Assistant Clinical Professor, Loma Linda University, Loma Linda, Ca., Director and Founder Donaldson Arthritis Research Foundation (DARF)

Kristaps J. Keggi, MD. Professor, Yale University, New Haven, CT, Founder Keggi Orthopaedic Foundation, Middlebury, CT, Board Member (JISRF), Chagrin falls, OH

John Keggi, MD. , Director, Department of Orthopaedics, Waterbury Hospital, Waterbury, CT.

Louis Keppler, MD. Co-Director Orthopaedic & Spine Institute, Cleveland, Ohio, Clinical / Surgical Research Advisor, (JISRF), Chagrin Falls, OH

Warren Low, MD. Orthopaedic Surgery and Joint Reconstruction, Bone & Joint Hospital, OKC, OK

Audley Mackel, MD. Chief of Orthopaedics St. Vincent Charity Hospital, (UHHS) Huron Hospital (Cleveland Clinic) Associates in Orthopaedics, Cleveland, Ohio

Ed McPherson, MD. Clinical Associate Professor, Department of Orthopaedic Surgery Center for arthritis and Joint Implant Surgery California Hospital Medical center, LA, CA., Joint Implant Surgery & Research Foundation, Board Member

Timothy McTighe, Dr. H.S. (he), Executive Director, Joint Implant Surgery & Research Foundation (JISRF) Chagrin Falls, Ohio

S. David Stulberg, MD. Professor, Clinical Orthopaedic Surgery, Northwestern University Feinberg School of medicine, Chicago, IL

H. Del Schutte, MD. Chief Adult Reconstruction at MUSC Bone & Joint Center, Charleston, NC, Board Member, JISRF, Chagrin Falls, OH

Thomas Tkach, MD. Clinical / Surgical Research Advisor, (JISRF) Orthopaedic Surgery and Joint Reconstruction, Bone & Joint Hospital, OKC, OK

Allen Turnbull, MD. Orthopaedic Surgeon, St. George Hospital, NSW, AU
Clinical / Surgical Research Advisor, (JISRF)

William Walter, MD. Orthopaedic Surgeon Waverton, NSW, Australia

Ian Woodgate, MD. Associate Professor Clinical Orthopaedics, St. Vincent's Hospital, NSW, AU

Friday, November 7, 2008

Agenda

Session I	Moderators	McTighe & Tkach
11:30 AM	“Historical Review”	McTighe
11:40 AM	“My Experience With Proximal Modularity”	K. Keggi
11:50- 12:00	Discussion	5 minutes
Session II	Moderators	Mackel & Turnbull
12:00 AM	“Restoration of Joint Mechanics”	Cameron
12:10 AM	“Femoral Offset How to Measure Preoperatively”	Schutte
12:20 AM	“Effects of Modularity on Component Position”	Clyburn
12:30 AM	“ The Value of Intra-operative X-Rays”	Keppler
12:40 AM	“The Lack of Need For Surgical Navigation”	Woodgate
12:50 AM	“Intra-operative Techniques in Using Proximal Modular Stems”	Low
12:50–1:00 PM	Discussion	10 minutes

**“Cutting-Edge Developments on Proximal Modularity in THA”
Mini-Symposium AAHKS, November 7, 2008 Dallas, TX**

Session III	Moderators	Donaldson & D. Stulberg
1:00 PM	"The Use of Cemented Stems With Modularity"	Cameron
1:10 PM	"Target Restoration With Proximal Modularity"	Tkach
1:20 PM	"Indication Straight Stem vs. Tapered Stem"	J. Keggi
1:30 PM	"Are Lg. Heads Necessary With Proximal Modular Stem Designs"	Walter
1:40 PM	"Tapered Stem Comparison With and Without Modularity"	Turnbull
1:40- 1:50 PM	Discussion	10 minutes
Session IV	Moderators	Cameron & McPherson
1:50 PM	"New Approach To Neck Sparing Stems"	McTighe
2:00 PM	"Short Stems With & Without Modularity"	D. Stulberg
2:10 PM	"Neck Sparing Early Experience"	Woodgate
2:20PM	"Neck Sparing vs. Hip Resurfacing"	J. Keggi
2:30 PM	"Tissue sparing Conservative Approach To the Hip-Posterior Approach"	Keppler
2:30- 2:45 PM	Discussion	15 minutes
	Adjourn	Thank You

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“Historical Review of Stem Modularity”

by

Timothy McTighe, Dr. H.S. (hc)*, Hugh U. Cameron, M.B.C.H.B.S.,**

Louis Keppler, M.D.*., & Thomas Tkach, M.D. *

***Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio**

****Orthopaedic & Arthritic Institute, Toronto, Canada**

*** Orthopaedic Spine & Joint Institute, Cleveland, Ohio**

*** McBride Clinic, OKC, OK**

Introduction

This review will look at modular stems designed for both cementless and cemented application. Both of these design applications are dealing with the restoration of the joint mechanics and aseptic loosening. The goal of biomechanical restoration of the hip is the same regardless of the type of stem fixation used. However, due to the inherent properties of materials, limitations can and do occur for specific design features. Example: specific designs that are acceptable and reliable for cobalt chrome alloy might be unacceptable for titanium alloy designs.

The early nineties saw a number of first and second-generation modular stems come and go. It is important to understand the specific design features and goals of Modular Total Hip Stems and not to lump all designs into one simple category “Modular Stems.” In-fact, modular sites, designs, features, material and quality can be quite different in nature and sophistication.

Modularity Classification

- > Proximal
- > Mid-Stem
- > Distal

Design Review

> Proximal



Head/Neck

Tapers are now considered state-of-the-art for most total hip stems. The opportunity to correct for vertical height has provided significant advantages in achieving enhanced joint stability over monoblock head stem designs. However, this modular junction does not allow for independent adjustment of femoral offset from vertical height.

We now see Co-Cr-Mo alloy heads used on titanium alloy stems, Co-Cr-Mo alloy on Co-Cr-Mo alloy stems and Ceramic heads used on both titanium alloy and Co-Cr-Mo alloy stems. The use of Ti alloy as a bearing material for femoral heads has all but been discarded by the early 1990s as a result of increased wear.

The potential risk of fretting corrosion in the Morse taper region of modular junctions has been attributed to the presence of gaps between taper surfaces and differential metallic alloys. One way of reducing the potential fretting corrosion of tapers is the use of ceramic as the femoral bearing material.



Recent retrieval c.c. head on Ti stem with black staining on the trunion of the head taper. Keppler 10/08

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Ceramic heads have had some problems with fracture as shown in this two year post-op THA.

Improvement in material and fabrication has reduced this situation but demonstrates that there is concerns and considerations when selecting modular devices.



Biolox forte: 0.02% reported failure rate 2/10,000
Biolox delta: 2 in 100,000

Neck Extensions

Trunion sleeves offer increased neck length adjustments, however, tend to reduce range of motion.



> Helpful in revision situations

Modular Necks

These designs allow for adjustment of hip mechanics in a mono-block stem. In addition, they provide the option for stem insertion prior to cup preparation, thus reducing operative blood loss.

While modularity has its advantages especially in fine tuning joint mechanics, modular junctions can and do fail.



Examples of failed Ti modular necks



Examples of failed c.c. modular necks



Examples of varied modular necks

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Modular Collars

These designs increase collar/calcar contact. Their clinical advantages has not been proven and usage has all but stopped.



Proximal Shoulders (bodies)

This area of modularity has the largest differential in design styles. Significant influence comes from European experience dating back to the 1970s. These devices are more than just a neck, but less than a metaphyseal body. They have the design option of increasing their proximal body height to compensate for bone loss. Some of these designs, also allow for variable body height and version orientation.



Intra-operative fine tuning of joint mechanics (both version & offset can be a valuable tool with these design style proximal bodies.

It is however important to know the specific design features and required technique for these individual designs.

These designs all feature different locking mechanisms for the modular components.

Anterior / Posterior Pads

This design allowed for adjustment of fit & fill in the A/P dimension of the implant. They were criticized for not having circumferential porous proximal coating. While the design allowed for adjustment of fit & fill gaps allowed for migration of particulate debris resulting in bone lysis.



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Stem Sleeves

Note: ACCME guidelines are to be neutral as possible in acknowledgment of trade names and commercialism.

However, one cannot describe this section of modularity without recognizing the significant contribution of the S-Rom™ modular stem design. This is not done out of any sense other than pure historical contribution that this design has made to the overall outcomes of THA. This has been recognized by all of industry as has the Charnley stem design for cemented arthroplasty.



Stem sleeves offer the advantage of fit & fill with adjustment of hip mechanics. Some designs like the S-Rom™ require removal of the stem to correct offset or version, while newer designs allow for correction with the stem *insitu*. All of these designs feature a modular site located within the femoral bony cavity. This has a higher concern of fretting wear debris being delivered directly to the implant / bone interface versus designs with modular sites located out of the femoral cavity. Dr. Sivash is credited with creating the first stem / sleeve cementless total hip stem introduced in the United States by the U.S. Surgical Corporation. The Sivash total hip system never received major clinical or market success, partially due to the difficulty of the surgical technique, and the positioning of this constrained device. We must, however, not overlook its major areas of contribution.

- Titanium alloy for femoral stem and chrome cobalt for head articulation
- Cementless (threaded) petalled acetabular component
- Titanium alloy proximal sleeves for enhanced collar calcar contact
- Constrained articulation (metal on metal) In 1975 Noiles and Russin redesigned the Sivash stem to improve its function in cementless THA. Adding eight longitudinal flutes similar to that of the Samson intramedullary rod reduced torsional forces on the implant/ bone interface.

Dr. Hugh Cameron started his clinical use of threaded sleeves and the S-Rom™ stem in July 1984. Due to demanding surgical technique, an array of press-fit porous taper-lock sleeves were developed. This evolved into the current stem sleeve combination and is now considered the gold standard for modular cementless stems.

Evolution from the 1960s Sivash to the 1970s SRN, to the 1980s first generation S-Rom™ to its current design and the varied style sleeves along the way.



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Design changes were made as a result of clinical / surgical concerns.



Groove acted as a gutter providing direct path of poly debris resulting in progressive lysis. Engh

The ultimate compliment is that of copying. Many of today's devices both modular and monoblock have copied the geometric shape of this cementless stem design.



Revision (stem-sleeve) & other modular junctions designs

Allow for significant bone loss and different designs feature different style modular junctions.



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> Mid-Stem Modularity

These designs offer versatility in correction of sizing mismatch between proximal and distal femoral anatomy. This feature has been very helpful in complex revision cases.

Mid-stem modularity has a potential for more mechanical failures in part to the complex nature of revision surgery and often lack of proximal bone support. Not all mid-stem modular junctions are equal in mechanical features (fatigue properties). Generally, larger and longer taper junctions are stronger.



> Distal Modularity

These designs allow for distal stem fit with different distal style options (smooth, fluted, or porous). One of the more interesting designs is the distal bullet design. This stem features a polished distal stem tip. The design goal was to improve load transfer and minimize the thigh pain associated with a poor fitting or toggling distal stem. Some devices that featured distal sleeves had other under-designed features including the lack of circumferential coatings, poor locking designs on modular cups, and titanium femoral heads, resulting in increased particulate debris (bone lysis). The combination of problems certainly affected the acceptance of distal sleeve designs. Possibly, with current technology, distal sleeves could be designed with minimal abrasion wear problems. However, we believe distal sleeves would have great difficulty gaining acceptance in the marketplace.



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➤ Multi-Modularity

Excess modularity on the stem in addition, to the modular sites for its cementless porous cup and optional screws, could end up with over six sites. From a fit & fill point of view this system was a very novel approach that offered significant versatility in addressing surgical and anatomical situations. However, it faced too many problems in the market and has been discontinued.



Summary

These stems represent some of the current trends in both design and marketing efforts. This tendency is no doubt due to both the clinical and market success of the proximal modular stem-sleeve design of the 1980s and competition attempting to improve upon that stem by offering different design features. These designs attempt to offer features for fit & fill of the implant to the bone and some adjustment of joint mechanics.

Certain modular designs' goals have changed over the past 20+ years. In the early 1980s fit & fill was the principal objectives. Today aseptic loosening does not have the same concern. The reduction of particulate debris and restoration of hip mechanics are the focal point.

In 1995, a chapter in the *Encyclopedic Handbook of Biomaterials and Bioengineering*, "Design Considerations For Cementless THA" McTighe, Trick & Koenman. That chapter reviewed the use of modularity and made some predictions as to product design features in-the-near future. The main focus of future design direction was for the stem to incorporate a proximal modular body that would allow for correction of version, offset and vertical height without disruption of the stem body from its bone-implant interface. Proximal bodies of different sizes and shapes would be available that provide for versatility and retrievability with little or no bone destruction.

No one would argue that restoration of hip mechanics is critical to a long-term successful clinical outcome. Today designs exist that allow the correction, or fine-tuning, of the hip mechanics after the stem has been implanted.

Standard cementless modular stem designs offer significant value and we believe improve outcomes, however technology (material, design & surgical techniques) does evolve and the future holds as reflected by the past significant opportunity for advancement and improvement in clinical outcomes.

The future will continue to be focused on modularity. There will however be a new focus with tissue sparing designs that save both hard and soft tissue. Example this neck sparing stem with a modular head and neck. Also, this novel bearing material Polycarbonate-urethane (PCU) which reduces wear debris.

Modularity is here to stay!



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"My Experience With Proximal Modular Stems"

By

Kristaps J. Keggi, M.D., Dr. Med. (h.c.)
Professor of Orthopaedic Surgery and Rehabilitation
Yale University School of Medicine

The first total hips I started using 38 years ago were one-size femoral components with one neck length and a fixed head. There have been many improvements in surgical techniques and femoral prostheses. It has been an exciting period in hip surgery with more improvements in materials and designs that present continued surgical challenges and promise better outcomes for patients. Modular femoral components are an integral part of this story of continuum of improvements.



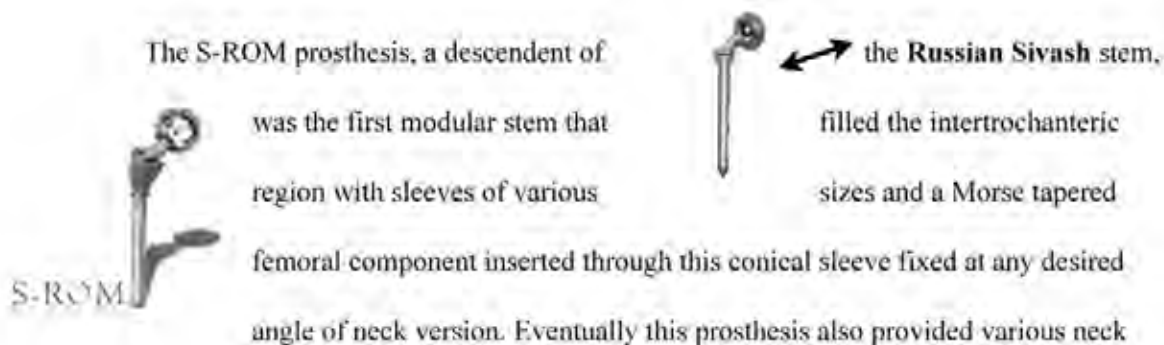
Modular hip replacements for chronic arthritis or acute fractures of the femoral neck will be popular as surgeons and patients learn of their advantages. They are easier to insert and cause less tissue damage as they are inserted. The variety of stems and necks that can be mixed, matched and selected for optimum prosthetic placement at the time of surgery also leads to faster recovery and better outcomes. These are also factors that decrease the cost of the procedure, which is a major consideration as we face an aging population with a greatly increased need of hip replacements for degenerative disease and fractures.



The first modular prostheses that I started using were femoral components of different sizes and neck lengths that could be adjusted by "modular heads" impacted on the

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trunions of the main components. These became available in the mid 1970's and represented a huge improvement in the reconstitution of femoral neck anatomy and hip stability.



lengths, offsets and calcar replacements. I was enthusiastic about this device in the 1980's, and it has been very successful over the years and has proven itself in long-term results. My experience with this prosthesis both in primary and revision surgery has been good, but it was cumbersome to insert through short skin incisions and muscle sparing approaches.

Short skin incisions with preservation of muscle innervations and muscle tissue has been our interest since the 1970's, and within the last few years there has been much interest in the subject frequently referred to as "minimally invasive surgery" or MIS. We have been doing all of our total hip arthroplasties in patients of all ages and sizes through a short anterior skin incision and the Smith Petersen muscle sparing internervous interval since the early 1970's.

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This time-sparing approach has been clinically successful with rapid post-operative recoveries and excellent outcomes. Most recently Dorr (JBJS 06/07) has confirmed our experiences that rapid recoveries and excellent outcomes are indeed related to soft tissue sparing and short incisions if possible. The post S-ROM generation of modular hips relate to these basic surgical principles. Even though our own approach has been anterior with secondary stab wounds or incisions, modular hips facilitate all approaches to the hip joint.

In the pursuit of less and less soft tissue trauma in hip replacements, we have considered and hoped for a femoral component that would be relatively short (bone preserving) and could be inserted without the fixed protruding neck requiring a longer skin incision and causing unnecessary muscle damage (soft tissue sparing). I had discussed this with several orthopaedic manufacturers in the late 1980's and 1990's, but it was not until 2002 that hips of this type became available in the United States as FDA approved implants.

They were the **Cremascoli** prosthesis introduced by Wright Medical as the Profemur Z, the **OTI now Encore Medical R-120**, and the Apex, now a product of Omnicore life sciences. Since then I have become aware of a multitude of implants of the modular type manufactured by American and European companies.



Smith & Nephew, Inc. introduced a micro stem with modular necks this fall, and I started to implant this latest femoral prosthesis 6 weeks ago. All four of these modular hips have femoral components that can be inserted without an attached neck. The femoral component can be introduced through a short primary incision or in the case of anterior approaches in large patients, a second stab wound. Once in place the femoral

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neck or the femoral neck-shoulder (Apex/Omni) is then fixed to it. During the last two years we have used primarily the K-2, a modified Apex hip design. It is a flat prosthesis with a rectangular cross-section and a circumferential ingrowth surface over its proximal one third. The neck-shoulder is connected to it with the Apex reinforced dual Morse taper (Dual Press TM) and an anti-rotation locking pin. Our total modular hip experience (Kristaps J. Keggi, John M. Keggi and Robert E. Kennon) consists of some **1,100 devices – Cremascoli 65, OTI 241, Apex-1 163, Apex-2 216, K2 410, and 5 SNR mini modulars.** We have been pleased with these devices because of the a traumatic, simple insertion of the femoral component and the variety of femoral necks that can be used to adjust anteversion, retroversion, height and offset for accurate reconstruction of proximal femoral anatomy, achieve stability and equal leg lengths. Even though its assembly is more complex than the Cremascoli neck, the K-2 has the greatest number of reconstructive options. The operative times have been short, post-operative pain has been decreased because of the decreased soft tissue operative trauma and no post-operative dislocations. In our series of modular hips, there have only been two dislocations, and these have occurred in very unusual circumstances such as an elderly patient twisting her leg getting out of a bathtub. Rehabilitation has also seemed more rapid. Since the publications on modular hips are still few, the exact results on these joints have not been quantified, but it is my opinion that our initial impressions about improved outcomes will prove to be correct.

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I have also been using shorter ("micro") stems to decrease proximal femoral canal invasion and to make revisions easier should they become necessary. The conservative hips now known as resurfacings were designed to avoid long stems and cement filled canals making revisions extremely difficult. In the early 1980's we were enthusiastic proponents of resurfacings through an anterior approach, but I have been reluctant to resume them because of the metal-on-metal bearing surfaces and my preference for totally inert ceramic-on-ceramic. The short non-cemented stems that we now use sacrifice a little more bone stock but are easier to use, can be used with ceramic, are easy to remove and can be converted to any other revision prosthesis easier than the cemented stems of the 1970's. Short modular and mini stem hips seem to me a good alternative to resurfacing. I believe they will prove themselves on a larger scale.



The modular prostheses have also been labeled as being resident-friendly allowing a relatively inexperienced surgeon to correct potential errors by the adjustment of the modular components. Based on some of the recent revisions I have done, this feature becomes even more significant as we are entering an era of primary total hip replacements for femoral neck fractures that may be done by residents or by physicians other than hip surgeons.

The main concern with the modular components is the stability of the neck-body junction. In our series of 163 Apex-1 prostheses, we have had five failures of this junction. The first one of these in my patients came in the spring of



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2004. I stopped all further insertions of this device until it was strengthened by a rotation pin and reinforcement of the Dual Press™ junction with a bolt passed through the shoulder of the neck device into the main body of the prosthesis. This modified design was extensively tested and we resumed its use during September 2004. We have now done over 600 of these reinforced hips (Apex-2 and K-2), and four years later I have not had any failures of the neck-body connection. There is also some subjective evidence that there may be fretting and continued cold welding of the Dual Press that make the titanium-to-titanium bonding stronger with time. I continue to use the K-2 device with a growing sense of confidence in its strength, flexibility and options it offers my patients.

I have similar confidence in the "Cremascoli" type junction that I have used with the Wright Medical components and the most recent Smith & Nephew mini modular hip. It is extremely easy to assemble which is a major advantage, but its neck length has to be kept relatively short to avoid abnormal mechanical forces on the portion of the neck fixed into the body of the prosthesis. A short neck will have to be adjusted by "higher, proud" placement of the femoral component.

We have had 9 OTI neck failures either due to fracture of the relatively thin neck or dislocation of the cobalt chrome neck from the same metal femoral component. We have stopped using this particular design.



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Even though there have been some failures in the early series, I continue to be enthusiastic about the use of the modular devices since they do allow for precise reconstruction of the proximal femoral anatomy with its related musculature. They allow insertion of the devices with minimal soft tissue trauma. They are also bone sparing since some of the devices are very short and can be easily revised.

With the patient supine and the direct anterior approach giving us an anatomical view of the acetabulum and proximal femur, we have not had to use fluoroscopy or navigation systems to achieve proper placement of the components. Simple navigational and robotic devices are being studied and produced, but for the time being in our hands they have not been necessary.

Modularity has made the anterior approach more reproducible with less soft tissue trauma.



Proximal modular necks provides for smaller incisions.



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"Restoration Of Joint Mechanics"

By

Hugh U. Cameron, M.B., CHBS.,* & Timothy McTighe, Dr. H.S. (hc)**

***The Orthopaedic & Arthritic Institute, Toronto, Canada**

****Joint Implant Surgery & Research Foundation**

Introduction

ACETABULAR CONSIDERATION

The hip joint is not a perfect ball-and-socket joint; the femoral head is oval in shape and the articular surface of the acetabulum is horseshoe shaped. The dome of the acetabulum, which has been considered a weight-bearing area, is in-fact flexible. The horns of the acetabulum can thus close up and contact the femoral head when the joint is loaded.

The degree of this movement is dependent upon age, load, and femoral anteversion. This mobility of the acetabular horns could explain biomechanically the development of aseptic loosening that occurs around acetabular components.

Pauwels describes a radiolucent triangular space above the dome of the acetabulum. The shape of this triangle is subject to modifications that are dependent upon femoral loading orientation. In advanced osteoarthritis of the hip the surface area of this triangle decreases and vanishes. It is interesting-to-note that with age, the hip becomes more congruent and the radiolucent triangle disappears while a trabecular pattern becomes apparent.

Apart from the initial stability at the acetabular implant bone interface some time after initial implantation is needed for the acetabular horns to become mobile again. This corresponds to radiographic evidence of radiolucent lines in zones 1 and 3. In - fact, clinical analysis of cemented devices demonstrates considerable progression of acetabular component loosening beyond the 12th year and even earlier in young, active patients. This mobility might further explain finding little or no bone-ingrowth on retrieved cementless implants. Mobility of the

acetabular horns must be considered in design parameters if long-term fixation is to be achieved. Fixation is enhanced if the prosthesis is set in a position of less than 45° abduction to promote compression and eliminate tension at the interfaces.



The acetabulum is generally spherical in shape and its opening is oriented closer to 55° than 45°, downward in the coronal and sagittal plane, and anteverted approximately 15° to 20° in the midsagittal plane.

Initial acetabular component stability is affected by the cup's ability to engage with the host bone. This is a function of cup design, size, and surgical technique. Cups of a true hemispherical design are more stable than low-profile designs.



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FEMORAL CONSIDERATION

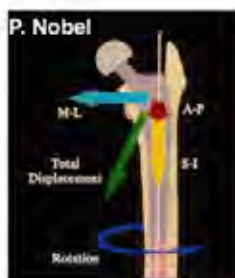
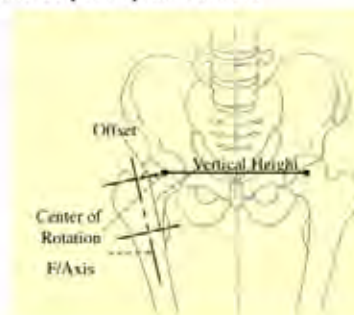
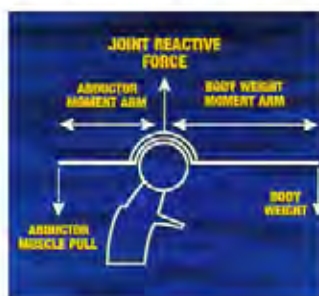
The femoral head is slightly larger than one half of a sphere, and the shape is more oval than spherical.



Mechanical Considerations

The stresses on the femoral head usually act on the anterior superior quadrant, and surface motion can be considered as sliding on the acetabulum. Two important angles need to be considered: the neck shaft angle and the angle of anteversion. In addition, to these two angles, the joint reaction force is affected by femoral head offset. It is also important to remember that while static force is considerably greater than body weight, even greater force is generated posteriorly in dynamic situations such as acceleration and deceleration: manifest in negotiating stairs or inclines, in changing from a sitting to a standing position or vice versa, and in other routine activities of daily living that load the hip in flexion.

Routine activities can result in significant forces acting on the hip joint and the bone-implant interface. Historical torsional loads have been published demonstrating patient related activities can generate loads in the 12-23 Nm range. However, patients can easily generate excess loads that can and do put implants at risk.



> Stumbling 30-40 Nm it only takes 30 Nm of torque to put implant stability at risk

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What are the objectives of hip replacement?

- Pain relief
- Restoration of function
- Longevity.

Young patients will live > 50 years

- Bearing Surface longevity
- Currently this is possible using hard/ hard bearings
- Optimal current couple (?) yet to be determined.

Stem Longevity

- Currently there are several stems with a more than 20-year survival and show no signs of loosening.
- However osteolysis, especially of the Greater Trochanter may lead to pain, fracture and loss of function.

Prevention of osteolysis

- Osteolysis is particle disease
- All bearings produce particles.
- Hard/ hard produce many less particles than hard/ soft, but they still produce particles, especially with component malpositioning.



Increased particle production. Squeak is an indicator!

- Impingement between neck and cup. If severe will result in subluxation/ relocation which produces impact and destroys fluid film lubrication.
- Failure to give adequate offset will allow micro-separation.
- Vertical cup placement allows the head to ride out of the cup thus destroying fluid film lubrication.

Cup Placement

- In an effort, to protect ceramic liners many companies inset the liner.
- This means that while the center edge angle of the outer shell may be at 45° the liner is then at 55°.
- Think of 35 therefore as being the new 45 i.e. with hard/ hard bearings the cup must be inserted more horizontally than previously.

Preventing impingement

- During trial reduction check that the head is centered in the cup.
- The neck must not hit the cup edge, especially in external rotation in extension.
- With the stem/sleeve stem I could always do this
- What surprised me was that when I got a modular neck cemented stem I ended up putting the neck in retroversion in 75% of cases.

Impingement is important in heavily X-linked poly.

- The fracture toughness is reduced and repeated contact with the neck may result in rim fracture with subsequent liner separation.
- As well as of course, increasing particle production.

Micro separation – now recognized as being a problem

- Increase of wear may produce noise by cavitation and loss of lubrication.
- Currently there is no way of checking this intra-operatively. The Shuck test does not really help.
- The more closely offset can be restored, probably; the less likely it is to happen.

Major challenge is joint stability and leg lengths

- Joint stability takes precedent over desired leg length



Difficult to balance the joint mechanics

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Remember even if you are using pins and a ruler that unless there is the same flexion, rotation and offset you are likely only accurate to within a cm or so. I use the GT/FH, the knee test, and the reduction test, and the Shuck test.

The biggest problem with leg length is pelvic obliquity.

- If the patient is elderly, I assume that the obliquity is fixed and therefore balance the apparent leg length.
- If they are young, without any obvious spinal problem, I assume that they will correct, and therefore balance anatomical length.
- Warn the patient however, and if they do not wish to risk, do not do it.

When you have done a big leg lengthening

- The glutei will be tight and pull the hip into abduction, producing an apparent over lengthening.
- These patients must be kept away from physiotherapists who will give them a lift. If the patient is given a lift in the first 4 months, the glutei will not stretch out.
- So warn the patient no lift

Gluteal avulsion – an ignored topic

- Spontaneous Gluteal avulsion is like a rotator cuff tear. It may produce a sudden increase in symptoms or it may be completely silent.
- If it is large and not repaired the patient will limp after the operation both surgeon and patient will be disappointed.
- This is easy to identify with an antero-lateral approach.
- It is difficult to see from a posterior approach.
- This is a problem especially in revision surgery.
- We call it the Bald Eagle.

One of the most sever problems is femoral anteversion

- The surgeon puts in the acetabulum in retroversion.
- He compensates by putting in the stem in anteversion. This means that the patient in-toes. They hit the other leg in swing phase and fall.
- These case all need revision.
- In Japan I do see in-toeing on a congenital basis. If a girl has had this deformity all her life she can live with it, but do not do it to a Caucasian.

Restoration of joint mechanics is and will continue to be our major challenge for total joint arthroplasty. A better understanding of surgical techniques, device related techniques and patient related activities should aid us in restoring joint mechanics and improving clinical outcomes.

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"Femoral Offset How to Measure Pre - operatively"

by

H. Del Schutte, MD*,

N. Romero, MD., J. Conrad, MD., W. Barfield, PhD., W. Conway, MD., T. McTighe, Dr. H.S. (hc)**

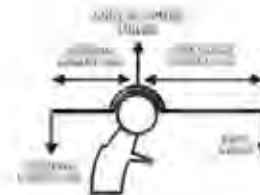
*University of South Carolina, Charleston, SC

** Joint Implant Surgery & Research Foundation, Chagrin Falls, OH

Femoral Anteversion and Accurate Offset Measurement

Introduction

The importance of proper offset in total hip arthroplasty is well known. Inadequate offset causes a shortening of the proper abduction lever arm leading to a limp, lateral hip pain, increase joint reactive forces, impingement and possibly hip dislocation. Patients with increasing degeneration of the hip joint will have a progressive loss of range of motion which seems to affect internal rotation more than external rotation. In-fact, most patients with severely degenerative hips will fall into external rotation. When an attempt is made to obtain preoperative anteroposterior (AP) radiographs of the degenerative hips the perceived offset will be much less than the actual offset. The purpose of this study is to assess how much the rotation of the limb affects the measurement of offset.



Methods

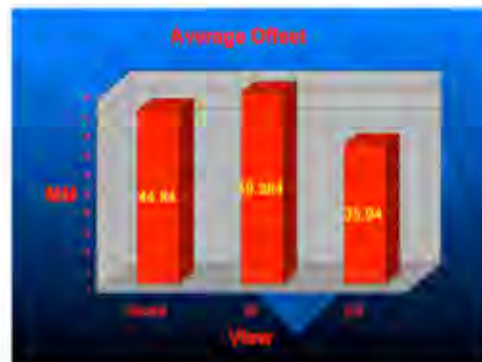
We took 10 cadaveric femurs and placed a steinmann pin in the center of the femoral head, through the neck and to the later cortex. We obtained radiographs of each femur in neutral, 20 degrees internal rotation and 20 degrees of external rotation. Offset was measured from each of these radiographs to assess the variability of offset in varying degrees of rotation.

Numerous author's have attempted to assess anteversion and femoral offset at the hip *in vitro* and *in vivo* with plane x-rays, special devices and modern imaging techniques including cross-sectional computed tomography. In each instance the technique has demonstrated some measurement error due to the anteversion of the proximal femur. The goal of our study is to assess the role that limb rotation plays in changing the inclination and offset in a cadaver model. Traditional AP and lateral radiographs taken in neutral, 20 degrees of internal rotation and 20 degrees of external rotation will alter the inclination and femoral offset. This may have clinical applicability to preoperative planning for total hip arthroplasty.

Ten cadaveric femurs had a steinman pin placed through the femoral head through the femoral neck to the lateral cortex of the femur using Wright medical Hemi-Resurfacing Guide.

Radiographs taken in neutral, 20° internal rotation and 20° external rotation were taken:

Offset was measured by five senior residents and three orthopaedic staff faculty. Pin length was also measured.



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Results

There was a statistical significant difference in measurement between raters, cadavers and rotation ($p < .001$).

After controlling for rater and cadaver there was statistically significant variation between the different view measurements ($p < .0010$).

Pin length measurement was also statistically significant in comparing the different views ($p < .001$)

Discussion

Cadaveric femurs in 20 degrees of internal, external rotation and 0 rotation will change the angle of anteversion and femoral offset, thereby, impacting applicability to patient imaging prior-to surgery. Essentially the literature has surgeons templating to a model that underestimates the offset due to a combination of the anteversion angle and the increasing loss of internal rotation which is dependent on the severity of osteoarthritis and changes as a result of limb positioning prior-to x-ray.

Results from our study indicate patients with radiographs taken in neutral or external rotation position will underestimate the actual femoral offset.

Reconstruction of the anatomic femoral offset is essential if restoration of the abductor moment arm and optimization of leg length, stability and implant load is to be achieved.

Note: Femoral offset can be underestimated by as much as 1cm depending on views of x-rays.



Note: paper presented in part at the ISTA 2003, San Francisco meeting

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“Effects of Modularity on Acetabular and Femoral Positioning in THA”

**By
Terry Clyburn**

- I. Introduction; Total hip arthroplasty is one of the most successful orthopaedic procedures with very high success rate as measured by pain relief, improved function and patient satisfaction. There has been an evolution of designs beginning with the monolithic stem of Charnley utilizing cement fixation for both the stem and the one-piece polyethylene Acetabular component. Charnley taught the principles of proper leg length and offset and he clearly understood the effect of hip center on the joint reaction force. He also understood the effect of lateralization of the greater trochanter on the abductor lever arm and thus the effect on joint reaction force. He taught the proper position of the Acetabular component in both abduction and anteversion and he taught the proper anteversion of the femoral component in order to achieve stability.

He was able to address all of these issues using a monolithic stem with a 22 mm head and a one-piece all-poly cup! Today, orthopaedists possess a constantly expanding armamentarium of equipment including modular Acetabular components with shells designed to accept a variety of inserts including polyethylene with or without “hoods” or rim elevations, ceramic and metal articulations. Modern stems come in a vast array of designs, but virtually all have a modular head neck junction. The S-Rom and multiple newer primary stem designs incorporate modularity in the proximal stem such that length and offset are adjustable even after the stem is fully seated. There are potential advantages and disadvantages to this modularity, which we shall discuss.

II. History

- a. The first “modularity” was at the ball-neck junction. Monolithic stems were implanted with cement leaving the only means of adjustment of leg length as the depth to which the implant was potted within the femur. Surgeons learned to adjust the leg lengths at the time of stem insertion using various “tricks”. Offset was primarily set by the neck-shaft angle of the implant and the astute surgeon determined preop what implant design would best benefit the patient. If abductor lever arm was an issue, the trochanter could be advanced as described by Charnley. The modular head neck with the Morse Taper design offered the surgeon the option of intraoperatively adjusting length and offset simultaneously. However, dependent on the neck-shaft angle, the gains in one parameter may be at the detriment of the other.
- b. Metal back shells were initially designed to offer greater support to the polyethylene component and of course ultimately offered the capability of porous coating and bone ingrowth. The markedly improved survivorship of bone ingrown cups is irrefutable. Evolution of the acetabulum included the “increased offset liner”, the “hooded” or “elevated rim liner” and ultimately alternative bearing inserts. The increased offset and hooded liners were offered as a means to increase stability at a time when 22, 26 and 28 mm heads dominated the market.
- c. The Cutting Edge; We have been using product in the hip revision arena for some time now which have midstem modularity allowing for better distal fit and proximal fill, often with anteversion, retroversion adjustability at this junction. We continue to have the head-neck adjustment for length and many of these designs incorporate proximal segments with variable “offset” options. While widely used and accepted in the revision stem market, the more extensive modularity is just now gaining popularity in the primary stem market.

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- III. The Problem of Instability
- a. The incidence of dislocation of primary hip replacement is quite variable but remains a significant problem. A number of factors have resulted in a decrease risk of dislocation including smaller and improved neck designs, greater head to neck ratio, greater surgical options for length and offset and soft tissue solutions such as the “Mayo” repair and increased popularity of the anterior approach.
 - b. Clearly however, implant malposition remains a primary cause of recurrent hip instability.
 - i. In our own reported study in which we evaluated the Range of Motion of two different constrained cups utilizing a cadaver model, the cups were implanted by a single, experienced surgeon, with extensile exposure of the pelvis, but yet there was variation in the abduction and version angles.
 - ii. DeHaan et al reported in the JBJS-BR in 2008, that 27 of 42 revisions of a metal on metal resurfacing were done for malposition of the acetabulum. The most common issue was with increased abduction with a mean of 69.9 degrees, range 56-98. They also found issues with anteversion and retroversion. They noted an increase in serum metal ions and metallosis in these malpositioned cups.
 - iii. DiLima et al in JBJS- Am, 2000, used a computer model to study prosthetic impingement secondary to poor positioning. They determined that less than 45 degrees of anteversion would result in decreased flexion and abduction and reduced abduction would limit extension and rotation. They also noted that the addition of a “modular” sleeve would reduce the range by 1.5- 8.5 degrees, dependent on the direction of travel. They pointed out also, that the position of the Acetabular component may be dictated by the bony anatomy of the pelvis and that the version of the femoral stem was often dictated by the bony anatomy of the proximal femur, thus limiting the surgeons control over these variables.
- IV. Modularity and the Modern Cup
- a. As mentioned above, the metal shell maybe used with a wide variety of inserts, which may contribute to over all stability of the total hip arthroplasty.
 - b. Use of bone grafts and the use of available metal augments may allow the surgeon to improve cup position for optimal placement.
 - c. Large ball options with head to neck ratios not dreamed of just a few years ago offer a range of motion without prosthetic impingement not dreamt of just a few years ago. Multiple studies have clearly shown the reduced risk of dislocation with these large heads, but concerns exist with regard to metal ion release.
- V. Modularity and the Modern Stem
- a. Cameron et al reported in the J Arthroplasty, the results of over 20 years experience with the S-Rom Hip. The noted that there is no mathematical relationship between the intramedullary canal of the metaphyseal region and the diaphyseal region of the human femur. Thus, it would be impractical to attempt to design a monolithic stem, which would provide distal stability and proximal fill. Thus, the concept of “midstem Modularity” developed in which the metaphyseal and diaphyseal parts could independently fit and fill the patient’s femur. In that the proximal segments of some of these designs offer the option of variation in height, offset and version, the surgeon gains control over the anatomy and is able to achieve a combined anteversion, which will result in stability.
 - b. The S-Rom hip can be locked into any degree of version relative to the proximal metaphyseal sleeve and has been a favorite to address the unique challenges of the Developmentally Dysplastic Hip. Others have used it as their primary hip.
 - c. Other manufacturers have used similar design philosophies. The Link MP and the MRP-Titan are examples of stems, which can be used to change length offset, and anteversion. Kang et al in J Arthroplasty 2008 reported the use of these stems to treat cases of recurrent instability. Kwong reported in the J Arthroplasty in 2003, only 3 dislocation or subluxation in 143 cases of recurrent instability using the Link MP. This compares very favorably to the

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report of Paprosky (CORR 1999) with a dislocation rate of 7.1% using a one-piece revision stem.

d. Failures

- i. Concerns exist with regard to failure at each and every modular junction.
- ii. The great majority of reported failures are in cases of revision in which proximal bone stock is lacking and as such there is inadequate support about the mid stem modular junction as has been seen in the Zimmer- ZMR (Pierson et al AAOS 2005).
- iii. Primary cases with adequate bone stock should not be at significant risk
- iv. There are however reported failures at these junctions. (Kop and Swarts J Arthrop 2008 and Patel et al J Arthrop 2008).

VI Summary

- a. There has been clear improvement in the longevity and the stability of total hip arthroplasty as modularity has become available.
- b. Modularity of the Acetabular component is widely accepted in both the primary and revision total hip.
- c. Head neck modularity is universally available in all total hip systems, and the benefits have proven to be immeasurable over the risks of fretting, corrosion and failure, which simply have not been a major issue.
- d. Midstem modularity is widely used and accepted in revision stems and has gained acceptance in the primary hip.
- e. Femur-neck modularity is available in several forms and offers options for improved offset, length and version.
- f. Dislocation although significantly reduced over the last decade remains a significant cause of total hip failure.
- g. Dislocation is often the result of component malposition
- h. Malposition may result due to anatomical variation of the acetabulum, the femur, or both.
- i. MIS surgical exposure may limit the surgeon's ability to place the components in the optimal position.
- j. Head-neck, Mid-stem and the neck-stem modularity allow the surgeon to adjust leg length and offset via the head-neck taper and adjustment of femoral anteversion via the neck-stem taper.
- k. The benefit is stability and reduced dislocation.
- l. The risk of dissociation and failure in primary cases is extremely low.

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"The Value of Intra-Operative X-Rays"

By

Louis Keppler, MD* & **Timothy McTighe, Dr. J.S. (hc)****

*Co-Director Orthopaedic & Spine Institute, Cleveland, Ohio,

*Clinical / Surgical Research Advisor, (JISRF), Chagrin Falls, OH

**Executive Director, JISRF, Chagrin Falls, Ohio



Introduction:

Overall the technique of total hip arthroplasty continues to improve but technical complications still occur. Improper restoration of hip mechanics can lead to a number of clinical problems: limb length inequality, soft tissue laxity, weakness of the abductors, mechanical impingement, accelerated wear and increased risk of dislocation. Improper stem sizing and positioning may cause fracture, subsidence, and thigh pain.

Methods:

Approximately 1500 primary cementless THA were performed over the past twenty-four years by the senior author at two hospitals. Three different stems were used, two being modular and one being monoblock. A variety of cups head sizes and bearing material were used. All cups were implanted cementless. All surgeries were performed using a posterior approach. A cross table AP x-ray was obtained with the acetabular component and trial femoral components in place. Analysis of this x-ray was used to determine if changes in stem position, size, neck length or offset were required and if acetabular position was satisfactory. Necessary changes were made prior to implantation of the final components.

Results:

Cup revisions have been the biggest problem to-date secondary to anticipated polyethylene wear. There have been no cases of clinically significant limb length inequality. There have been no stem revisions for malposition or undersizing. There have been no known intraoperative fractures.

Over the past four years large head metal on metal bearings have been used employing a monoblock acetabular component. There have been two recent events of aseptic loosening. One occurring after a fall in a previously well functioning hip and another discovered at the six week visit. There was no evidence of cup malposition in these cases.

Discussion and Conclusion:

Advances in implant design allow precise restoration of hip biomechanics. Modern modular femoral components allow adjustment of length and offset in 2-3mm increments. Hard on hard bearing materials are unforgiving of cup malposition. Proper stem sizing and position lessen the risk of post operative thigh

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pain. Achieving equal limb length is an achievable goal and eliminates a leading source of patient complaint.

Using the information from an intraoperative x-ray necessary adjustments are made with confidence in choosing the final implants.

By making it part of the operative routine no time is wasted obtaining the x-ray and the x-ray technicians become familiar with the technique lessening the need for repeat films due to improper position of the plate or poor exposure.

Flexion or version of the monoblock metal on metal acetabular component is sometimes difficult to assess and a marker system is being devised to remedy this.

A few surgeons like Keith Berend, M.D. go as far as to use intra-operative fluoroscopy to reduce implant malposition.



The following are a few examples of intra-operative usage:



⇐Starter rasp



Final Broach⇒

>Surgical evaluation of neck sparing technique then converted to a proximal modular tapered stem.



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➤ MOM cup too vertical 55° with trial broach and neck in place

➤ Cup repositioned to 45° with final stem and modular neck in place



➤ Stem orientation and size was corrected along with adjusting proximal modular neck offset

We strongly recommend the routine use of intra-operative x-rays.

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"The Lack of Need for Surgical Navigation in THA."

***Prof. Ian Woodgate, MD., & **Timothy McTighe, Dr. H.S. (hc)**

***St. Vincent's Hospital, Sydney, Au**

**** Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio**

Introduction: There is growing interest in surgical navigation in THA due in part to continued problems with dislocation and difficulty in restoring joint mechanics. This paper will clearly demonstrate that there are proximal modular implant designs, large MOM bearings and techniques that are more practical, cost effective and reproducible than surgical navigation.



Methods: The authors selected two stem designs that permit independent selection of lateral offset, version and leg length. 300 primary consecutive THA were performed since 2003 by the senior author.



Third modular stem will be reviewed in additional paper "Early Experience w/neck Sparring Design"

All were performed using the posterior approach. 28 mm - 54 mm diameter heads (metal & ceramic) were used. Anatomical landmarks were used to aid in preparation and insertion of implants with extensive trial ROM to determine joint stability and a simple reusable hip calibration device was then used to confirm restoration of joint mechanics.



Results: There have been no dislocations, no leg length discrepancies as defined as plus or minus 5 mm. One late infection, zero revision and no gait abnormalities.

Discussion and Conclusion: Restoration of joint mechanics was possible using these combined techniques. Short term benefits as to reduction of dislocations and improved functional ROM was clearly demonstrated. Author's are encouraged that these techniques will provide additional guidelines to the orthopaedic community in a reproducible, practical and cost affordable approach to THA.

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"Intra-operative Techniques in using Proximal Modular Stems""

by

*Warren Low, M.D., *Thomas Tkach, M.D. ** Timothy McTigue, Dr. H.S. (hc)

*McBride Clinic, OKC, OK

**Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio

Introduction

PREOPERATIVE PLANNING

Preoperative planning, which requires templating, of the patients x-rays and important communications of the potential needs to the operating room with additional notification to implant companies can and does save valuable time, improve efficiencies and outcomes for each individual case.

The proper staging of surgical procedures is often neglected or taken for granted resulting in added OR time and risk for the patient. Example: will allograft or autograft be needed? Will intraoperative x-rays be needed? Will certain non-standardize instruments (Explant) be needed? Will additional personnel be needed and will there be a change of personnel if the case drags on? All of these and more can effect the flow and outcome of the surgical procedure.

Templating



Work from Accurate Radiographs. Ensure that the pelvis is centered over the pubic symphysis for the A/P Pelvis radiograph. For the lateral radiograph use a Lauenstein technique (frog leg lateral). It is recommended to use a radiographic marker or scale.

Note: In standard A/P x-rays often the patient is placed in neutral or external rotation resulting in less than idea position for measuring femoral offset. When possible try to get 20° of internal rotation. You might have to consider templating from the contra-lateral side.

Notice the OA hip can't rotate in you and you see the Lesser Trochanter: Templating from the non effective hip allows internal rotation and more accurate measurement of femoral offset.

Determine Hip Center of Rotation. Size the acetabular component using the porous shell templates. If medializing the acetabular shell, the native center of rotation may be slightly different from the center of rotation for the templated porous shell. Place a small mark on the radiograph at the center of rotation of the selected porous shell. **Determine Preoperative Leg Length Correction.** Using the A/P Pelvis radiograph determine the leg length discrepancy from the contralateral hip or other clinical methods.

Select a stem size that fits the intramedullary canal and fills \ the proximal metaphysis. Position the selected templated size on the A/P pelvis radiograph and select a modular neck size that places the "0" neutral femoral head at a position to correct the leg length discrepancy. In some cases a larger proximal body may be needed if large length discrepancies are presented. **Determine Neck Resection.** Note the distance from the shoulder of the selected femoral stem to the lesser trochanter. Templates are printed with graduated markings for reference.

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Broaching

Start with the broach that is one or two sizes smaller than the last conical reamer. Attach the selected broach to the broach handle and then attach the appropriate stem pilot. Advance the broach to the depth established by the conical reamer and the neck resection plane. As with the conical reamers, reference marks to the greater trochanter are also provided on the broach handle. Once the final broach is used it should be seated into the final implant position. Assess the stability of the broach. When satisfactory purchase has been achieved, detach the broach handle and leave the broach and stem pilot in place to serve as the femoral trial. Trim the neck resection using an oscillating saw or Rongeur as needed for proper seating of the neck trial. Mark the medial calcar even with the midline of the broach to aid prosthesis alignment during insertion.

TROCHANTER CLEARANCE

Trochanteric Reamer

A trochanteric reamer is provided in the instrument set to facilitate the placement of modular neck trials and neck implants. The distal face of the reamer body contains a cavity that accepts the stud on the broach. To use the trochanteric reamer, attach it to a driver and slide this cavity over the stud with the reamer's shaft angled medially as shown. Gradually apply power and lever the handle laterally until the appropriate amount of relief has been attained.



Trochanteric Reamer

Gradually advance laterally until relief is attained

TRIAL REDUCTION

The modular neck trials slide onto the stud on the proximal end of the broach. Select the neck trial based on preoperative planning and on the previous intraoperative assessments. Slide the neck trial onto the broach, taking care to establish the proper version (0 or ± 13 degrees anteversion). Affix a modular head trial onto the neck trial and reduce the hip. Assess leg length, range of motion, and stability. Adjust as necessary by choosing a different neck / head combination, or by anteverting, or both.

Color Neck Trial Head Trial

Black or Brown Long - 3.5
Gray Short + 0
Blue Medium 3.5
Green Short 7

Leg length and offset may be fine tuned by changing the neck and/or head. Often stability can be enhanced by choosing an anteverted neck ($\pm 13^\circ$).



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Implant Assembly

Device may be assembled on the back table or *in situ* depending on surgeon preference or surgical indication. The important feature to remember is that the surgeon has last minute opportunity to fine-tune joint mechanics without disruption of implant-bone interface.

If assembled on the back table selection of appropriate proximal shoulder / neck (neutral or version 13°) is then assembled and inserted on the stem as a monoblock stem would be. If necessary proximal modular neck can be removed and any adjustments made prior-to closure.

Important! Care must be taken to ensure that the mating surfaces of the stem and neck are clean prior-to and during assembly. Entrapped bone or soft tissue may result in incomplete seating of the neck.



Independent selection of femoral offset and vertical height is possible and we feel that restoration of joint mechanics is more reproducible with the use of proximal modular devices as compared to monoblock stems.

The use of proximal modular stems has in our clinical practice reduced dislocations as compared to monoblock stems and in the rare occasion post-operatively has allowed us to disengage the proximal modular junction for improved access to the hip joint. We find this device to be safe and effective and believe proximal modular junctions will become available by all manufactures as has modular heads.

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"Target Restoration of Hip Mechanics in THA"

by

Thomas Tkach, M.D.^{*,†} Warren Low, M.D.,
George B. Cipolletti, MS.[‡] Ed Cheal, PhD.[‡] Timothy McTighe, Dr. H.S. (hc)^{**}

^{*}McBride Clinic, OKC, OK

[‡]Omnilife science, Raynham, MA

^{**}Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio

Introduction

THA continues to improve but complications still occur. Dislocation continues to be a significant problem.^{1,2} The causes for dislocation can be multi-factorial, and include: mal-positioned components, soft tissue laxity, component design, head size, component orientation, surgical approach and impingement of component-on-component or on fixed obstructions such as osteophytes.^{3,4,5,6} Weakness of the abductor muscles due to improper reconstruction can also be a contributing factor.^{7,8} In countering these factors, stability is often achieved at the expense of limb lengthening.

Over lengthening or shortening of the joint center can result in limp, back pain, increased risk of dislocation, revision and legal problems. We see a number of trends that indicate hip joint instability remains a significant concern in THA outcomes: Big Heads, increased use of constrained sockets and development of expensive surgical navigation.

The Goals of THA:

- Eliminate Pain
- New Hip
- Restore Function

Reproduce Hip Mechanics

1. Femoral Offset
2. Neck Length
3. Version Angle



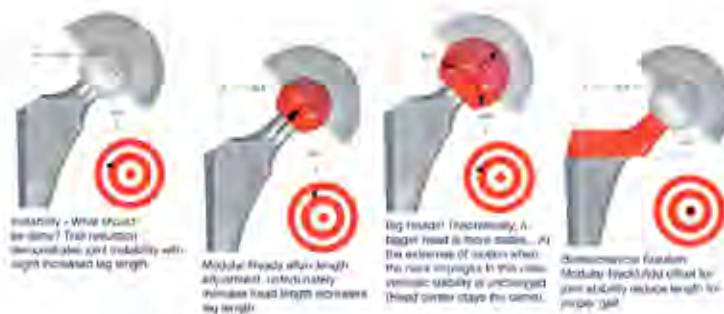
Methods

To study the influence of implant geometry on tissue balancing and joint stability, the authors selected a stem system that permits the independent selection of lateral offset, version and leg length. This study presents the short term results of this experience. 2000 THA's were performed using the Apex Modular™ Stem, beginning in May 2001 - March 2006. 957 available for review - primary stems and 115 were revision cases. All were performed using the posterior approach. Acetabular implants from a variety of manufacturers were employed. All cases were fully cementless. Data on stem, neck and head selection were available for 800 of these cases. Head centers were plotted in bubble chart format.

Reality in the O.R., you are faced with the following situation! What to do?

Results

Discussion



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- Restoration of normal joint mechanics on a consistent basis was possible with this modular design.
- Provides for intra-operative fine - tuning of biomechanics without disruption of implant - bone interface.
- Provides for increased exposure to the hip joint in case of revisions.
- Provides for intra-operative options in case of dislocations, due to muscle laxity and mechanical impingement.
- Significant number of small (10mm/11.5mm) stems required > 45mm offsets.
- The head center data suggest reconstruction benefits from the availability of many head centers for each stem size.
- This unique modular design allows for a large selection of proximal modular bodies to enable restoration of proper soft tissue tension and joint biomechanics.

Dislocation rate by the senior-author for monoblock stems has run between 2-5% for primary THA. Since using the proximal modular style stem dislocation rate has all but disappeared. We are encouraged and remain enthusiastic about the features and benefits of proximal modularity.

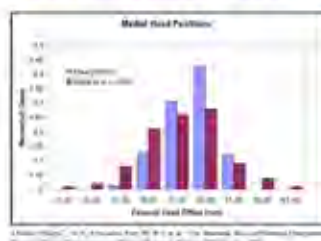
2,000 Proximal modular stems implanted 2001-2005

AAOS 2006 Scientific Exhibit

957 THA's Performed (2001-2005)

842 Primary/115 Revisions

Data collected on 800



- Center of bulble/head location
- Dia. Indication of frequency
- Several values are listed



Typical 15 - 40° more ROM with neck anteverted.



Anteverted neck used 18 times in the first 200 cases.

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"Indication for a Straight Stem Vs. Tapered Stem"

By

John Keggi, MD.,

Kristaps J. keggi, MD., Robert Kennon, MD., & Timothy McTighe, Dr. H.S. (hc)



Straight stems (AML®, S-Rom®) have been used successfully in THA for the past twenty-five years as have tapered stems (Taperlock, Zwymueller). Besides specific stem features each style straight stem and tapered stem designs offer additional features. Example an AML is a porous straight stem with proximal parallel sides and is considered a distal fixed stem. The S-Rom is a proximal modular stem/sleeve design that provides distal torsional stability but is considered a proximal fixed stem with a porous proximal sleeve..

Tapered stems all feature a mid-stem fixation point but might have some additional design styles like lateral trochanteric flares (torsional stability), porous coating levels etc.

All appear to work with reasonable reproducibility as to aseptic loosening. There is however a significant movement into adding proximal modularity for adjustment or fine-tuning of joint mechanics to both these designs.

Over 1,000 modular stems have been implanted by our group over the past 8 years with close to an even split between straight and tapered stem usage however, the trend in the past few years has been towards the K2 Tapered stem style. We have found in our practice that the use of tapered stems has been increasing especially with the use of proximal modular stem designs. As a general-rule we go by Dorr's classification of A,B,C bone.

In type A-bone we still prefer to use a straight stem which allows us to fit & fill without over reaming the distal canal. Keppler, Cameron and McTighe in a 1996 AAOS exhibit reported thigh pain in type C-bone with the use of straight stems. Keppler has moved to a tapered stem in type C-bone and Cameron still uses cement for this indication.



We agree with their findings and have adapted the same basic indications. Type A bone = straight stem. Type B & C bone = tapered stem.

We have seen well fixed straight stems in type C bone that encounters progressive thigh pain. These can be successfully treated by-the-use of on-lay grafts which will decrease the modulus mismatch between implant/bone interfaces.

The impaction broach technique of tapered stems also reduces the surgical time and cost of instruments required for this style stem. In addition, the proximal modular neck design is very helpful in the anterior approach resulting in less soft tissue trauma and ease of stem insertion.

We feel there is an indication for both styles stems however the tapered stem design appears to have a slightly broader indication, requires less inventory and saves time in the O.R.



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"Design Considerations and Results for a Modular Neck in Cemented THA"

*Hugh U. Cameron, M.B., CHB, FRCS., †Chris Leslie, D.O., & **Timothy McTighe, Dr. H.S. (hc)

*Orthopaedic & Arthritic Institute, Toronto, CA

†Leslie Orthopaedic & Sports Medicine, Camdenon, MO

** Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio



Objectives:



Cemented stems are still widely used in THA, however, there remains concerns with hip dislocation and wear debris. Restoring joint mechanics is essential for soft tissue balance and reduction of mechanical impingement. These concerns have lead to the development of a modular neck for cemented THA. This is an update of previous data from ISTA paper presented in 2003.



Materials and Methods:

200 R-120™ cemented stems were implanted in 190 patients since 2001. The shape of the stem is trapezoidal with a large collar that provides for impaction and compression of the cement. The stem collar is made with a cavity where a self-locking taper and a positive indexing mechanism provide 12 different positions to ensure proper restoration of joint mechanics.

One to seven years follow up with a mean of 3.5 years. Two-thirds were female and one-third male. Age ranged from 39 to 87 with a mean of 73. Majority were treated for OA. A c.c. 28 mm or 32 mm head and poly bearing were used for all patients. Selection of neck position was recorded for all patients.



Results:

63% of all head-neck positions were other than neutral. There were 0 dislocations, no significant leg length discrepancies (± 5 mm), and 0 infections. There was one stem removed due to a post-op peri-prosthetic fracture at 3 years that was treated with a long cementless stem. One death due to a PE ten days post-op. 1 intra-operative calcar fracture wired and healed uneventfully. 1 intra-op greater trochanter fracture that was treated with screws. Two neck fractures revised to cementless stems. Note: Verbal communication from the Keggi group Waterbury, CT. 150 Old style necks in both cemented and cementless stems implanted since 2002 with 10 neck fractures.



The Keggi group has discontinued using this device.



Fatigue Testing Results

Fatigue Strength @ 5,000,000 cycles

Old Design 520-700 lbs.

New Medical Design > 1200 lbs.

40% increase in surface area (taper length & dia.)

Conclusions:

Modular neck design aids in fine tuning joint mechanics after stem insertion, and allows for ease and access in case of revisions. This modular neck design has eliminated (to date) hip dislocations and we remain optimistic about its long term potential to improve clinical outcomes. Fatigue properties have been significantly improved and no additional neck fractures have occurred

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"Are Large Heads Necessary with a Proximally Modular Stem?"

Bill Walter, M.D., PhD.

Sydney Hip & Knee Surgeons, Sydney Australia



The first widely successful hip replacement – the Charnley hip was not modular either in the femoral or the acetabular component. Modular heads were introduced by Boutin in France introduced to enable the use of Ceramic heads on metal stems for ceramic-on-ceramic bearings. There is now a wide range of modular options available in femoral components offering the surgeon the intraoperative flexibility to address different clinical situations. Modularity has benefits but also introduces new risks. Modular junctions inevitably reduce the strength of a device in the highly corrosive and dynamically loaded environment of the body. Changes in stiffness and materials can create the potential for fatigue failure, crevices increase the possibility of corrosion, and movement at the junction may cause fretting. To reduce the risk failure engineers designing modular femoral stems may limit the offset to reduce the bending moment on the modular junction thereby creating other problems for the surgeon. The challenge for engineers is to design a modular junction that has an adequate range of positions, is strong enough and ideally can be disassembled at revision surgery, which may be decades later.

Creating the correct length, offset and anteversion is a challenge for the hip surgeon. Data from several of our own analyses of ceramic-on-ceramic bearings shows benefits in terms of wear and stability if the acetabular component is anteverted more than 15 degrees. Acetabular anteversion is limited by impingement of the neck of the femoral component on the posterior rim. Excessive femoral component anteversion will limit the acetabular anteversion available to the surgeon. Similarly inadequate femoral anteversion can make a hip unstable in flexion and internal rotation by causing anterior impingement, which may be prosthetic, bony, or soft tissue impingement. Furthermore, femoral offset, if inadequate may lead to impingement and instability. When using a stem with inadequate femoral offset surgeon may be faced with the choice of leaving a hip unstable and with inadequate offset and inadequate soft tissue tension, or creating a leg length discrepancy. Modularity may offer a solution to these surgical problems.

We studied 3682 patients with a primary total hip arthroplasty for a diagnosis of osteoarthritis with at least one year of follow-up. We measured cup inclination and anteversion as well as femoral and acetabular offset. 1.6% (60) of hips dislocated and one-third of these (20) required revision due to recurrent instability. We found no difference between the risk of dislocation with 28 mm and 32 mm heads when analyzed as cumulative survival. Age greater than 70 was associated with a 3.2 relative risk of dislocation. When we compared the dislocated hips to a matched control group there was no difference in leg length, acetabular offset or acetabular inclination. However, acetabular anteversion less than 15 degrees were associated with 3.0 relative risk of dislocation and dislocated group had a greater mean increase in femoral offset than the control group (5 mm compared to 1 mm, $p=0.03$).

Modularity of the femoral component is an attractive option for the surgeon allowing fine-tuning of the mechanics of a hip replacement during the procedure, particularly with cementless fixation where the surgeon may have little control of the position of the implant within the bone. This is especially true where there are variations of the femoral anatomy. Modularity, however introduces risks, which must be weighed by the surgeon against the benefits. We have experience with a number of modular stem designs and are in the process of evaluating, as they relate, to joint stability. Our principle head diameter has been 28 or 32 mm diameter due to our preference to use ceramic-on-ceramic bearings as we feel that the benefits of this bearing material outweigh the benefits of larger head sizes available in metal-on-metal bearings. On occasion we have used large M-O-M and they do improve stability and may be a benefit in our 70 year old plus population that has been associated with a higher dislocation rate.

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“Tapered Stems – Comparison With and Without Modularity”

by

Allen Turnbull, M.D*, Timothy McTighe, Dr. H.S. (hc)**

***St. George Hospital, Sydney, AU**

**** Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio**



Monoblock



**Dual-Press™
Modular Shoulder/Neck**

Introduction

Hip arthritis is a common and disabling condition. Efforts to replace the hip joint have always been confounded by the problems of fixation of the components to the skeleton and wear of the articulation.

The problem of fixation although still present, has to a large degree been overcome with methylmethacrylate or modern ingrowth surfaces.

New bearing surfaces such as ceramic on ceramic and metal on metal and the new highly cross linked polyethylene have introduced problems of their own but have greatly lessened the incidence of wear related problems that were encountered in the past.

As the issues of fixation and wear have lessened, physicians are focusing on more subtle issues relating to total hip arthroplasty. One such issue is restoring a patient's normal hip biomechanics during the hip replacement procedure. Leg length and femoral offset are two such issues.

Standard hip replacement components are based on anthropometric studies. Neck offset and neck lengths are based on averages but not all patients fit within the average ranges.

Most femoral components available have neck lengths and offsets that increase with increasing stem sizes. The options available do not accommodate patients with small canals and large offsets, or large canals with small offsets or abnormally valgus or varus neck angles.

To accommodate all the variables stem inventories would have to be impossibly large.



**Failed Ti
modular neck**

Modular stems have been introduced. These modular stems allow for many variations in stem geometry while keeping inventory levels down. While modularity has these advantages, it does come with its own problems. Modular junctions can fail, fretting at modular junctions can occur and component fractures have been seen.



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Discussion

Taper wedge stems have been shown to give excellent long term clinical outcomes. Developing modularity in these stems has been difficult because they normally have small AP dimensions which do not allow enough metal bulk for traditional modular junctions of the female male type. This proximal modular stem has a unique junction design (Dual Press) that when assembled is strong and has the biomechanical strengths of a monoblock stem.



Narrow A/P dimension



> Tapers are side-wall loading devices and have a smaller surface area for load sharing



> Dual Press™ large surface area provides medial support thus allows greater offsets



> Independent correction of offset & vertical height

Comparing a standard stem to modular stem we have found that the modular stem reproduces a more favorable restoration of patient biomechanics. We hope that by restoring more normal biomechanics patients will benefit because of reduced energy requirement for walking, and less fatiguing, more stability and less dislocations, and a greater chance of having legs of equal length.



Version adjustment



Offset adjustment



Target Restoration of joint mechanics

We have had very good results with monoblock tapered stems however we do feel this is the next generation of cementless THA. We continue to evaluate our clinical results and are conducting mobile gait analysis comparing our clinical outcomes and will report on our findings in the future.

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“New Approach to Neck Sparing Stems”

*Timothy McTighe, Dr. H.S. (he);

*Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio

Ian Woodgate, MD, Allen Turnbull, MD, John Harrison, MD, Declan Brazil, PhD, Sydney, AU.

Kristaps J. Keggi, M.D., John Keggi, MD, Robert Kennon, MD, Middlebury, CT.

Louis Keppler, MD, Cleveland, Ohio & Hugh U. Cameron, MB, CHBS, Toronto, CA, S. David Stulberg, MD, Chicago, IL

Introduction

Architectural changes occurring in the proximal femur (resorption) after THA (due to stress shielding) continues to be a problem ^{1,2}. Proximal stress shielding occurs regardless of fixation method (cement, cementless). This stress shielding and bone loss can lead to implant loosening and or breakage of the implant. ^{3,4}

In an attempt to reduce these bony changes some surgeon designers (Freeman, Whiteside, Townely and Pipino) have advocated the concept of neck sparing stem designs. ^{5,6,7,8}



Freeman, in describing the biomechanical forces in the reconstructed hip went as far as to say: “the design of all conventional arthroplasty is made worse since the femoral neck is routinely resected.

He further stated:

“This is done for reasons that are purely historical. Drs. Moore and Thompson designed stems for the treatment of femoral neck fractures, and for this reason, the femoral neck had to be discarded. In the typical arthritic hip, the neck is intact and therefore it can be retained. There is significant mechanical advantage in retaining the femoral neck, which results in a reduction of torsional forces placed on the implant / bone interface.”

Methods: Review of previous published work was evaluated along with FEA modeling in creating a new approach to neck sparing stems for primary THA.

One needs to review the European history in this area and certainly not only the past twenty years but more recently the work of Pro. Pipino in reestablishing the viability of neck sparing and tissue conservative approaches to THA.

Examples of short and neck sparing stems



Note: Not all short stems are neck sparing and not all neck sparing have short stems.

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To-date most if not all neck-sparing stems have been somewhat disappointed in their long-term ability to stimulate and maintain the medial calcar. Partially for that reason a new design approach was undertaken to improve proximal load transfer and to create a bone or tissue sparing stem that would be simple in design, amenable to reproducible technique and provide for fine tuning joint mechanics while stimulating and maintaining compressive loads to the medial calcar.

In theory neck retaining devices provide for:

- Bone and/or Tissue conservation
- Restoration of joint mechanics
- Minimal blood loss
- Potential reduction in rehabilitation
- Convertible to standard THA in case of revision
- Simple reproducible surgical techniques
- Opportunity to pick modular options for appropriate bearing surface
- Opportunity to select optimum femoral head diameter
- The selection of any standard surgical approach to the hip

There are a number of trends occurring in THA that are worth noting that can be selectively addressed with the MSA™/ NSA™/ TSA™ Neck Sparing Stem System.

- Hip resurfacing is getting more attention with Metal on Metal bearings and the demand from patients requesting a device that allows them an opportunity to get back to their active lifestyles.⁹
- Large head diameters provide a sense of hip stability and appear to be reducing short-term dislocation. There is more awareness to restoring joint mechanics providing for better long-term results.
- There is a movement to bone and tissue sparing approaches.¹⁰



Does hip resurfacing really address these concerns?

- Hip resurfacing requires a larger soft tissue approach vs. small or MIS conventional surgical incisions
 - Most hip resurfacing is done by the posterior approach, which has been shown to significantly affect blood flow to the femoral head
 - Currently only Metal on Metal and Metal on Poly are available for resurfacing and Metal on Ploy in the past has demonstrated drastic clinical results
 - Most surgeons do not recommend Metal on Metal for woman of childbearing age
 - MOM has been shown to be contraindicated in post-menopausal women
 - Current resurfacing has a high demand learning curve
- Hip resurfacing is not bone conserving on the socket side
- Hip resurfacing does not allow for adjusting or fine tuning femoral offset
- There is concern as to long-term systemic reaction on metal ions



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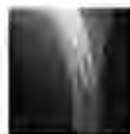


The MSA™/ NSA™/TSA™ Stem is a combination of a simple curved stem with a unique lateral T-back designed for maximum torsional stability, ease of preparation and insertion. The proximal design has a novel internal conical shape designed to stimulate and transfer compressive forces to the medial calcar. A modular neck provides for fine-tuning joint mechanics without disruptions of implant bone interface and a distal sagittal slot reduces chances of lateral cortex perforation. In case of stem removal a threaded hole is provided for a solid lock with a slap hammer for retrievability.



Note:

Risk of short stems is varus stem position resulting in perforation of cortex.



Surgical Technique



Pre-operative templating is helpful making sure that x-rays are taken with 20 degrees of internal rotation. This will provide reliable data as to femoral offset and medial neck curve.

Any surgical approach will work with the MSA™ Stem System. The femoral head is cut at the isthmus of the neck, perpendicular to the cervical axis. The distance between the osteotomy and the base of the greater trochanter is approximately 1.5 cm so this conserves the existing femoral neck.



Anterior Approach J. Koski



Posterior Approach L. Koppert

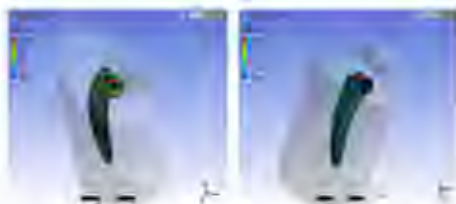
The femoral canal is opened with either a starting awl or curved curette. A flexible reamer may then be used to open the femoral canal or selection of the smallest starting broach. The stem is designed for simplicity in preparation and impaction broaching is used in sequence to the proper fit. The final implant is line-to-line with the broach and the proximal porous coating and later T-back design provide for a tight press fit. The final broach is selected by checking for torsional and axial stability. Trial stems are provided along with modular trial necks and heads ensuring restoration of joint mechanics. Trials can also be done off the definitive implant providing for last minute fine-tuning of joint mechanics.

Results

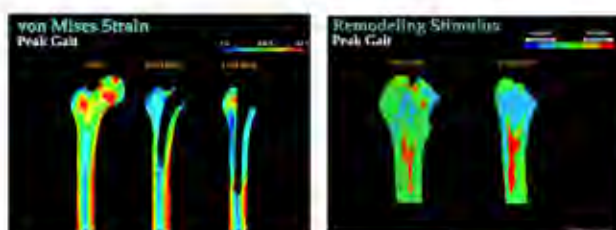
FEA modeling was conducted to look at stress in the modular neck when assembled and subjected to loading prescribed by ISO 7206-6.



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Illustrations show a change in stress in the stem with the increased load capacity of the extended taper and changed taper angle from 3.5m to 4° included. Stress is reduced from 662MP_a to 538MP_a.



Strain patterns for the MSA™ stem demonstrated better patterns vs. long stems or the short Biodynamic neck sparing stem.¹¹ We are encouraged with testing to-date. Additional FEA modeling and mechanical testing is underway.

Discussion and Conclusion

In theory neck retaining devices provide for⁹:

- Bone and/or Tissue conservation¹⁰
- Restoration of joint mechanics
- Minimal blood loss
- Potential reduction in rehabilitation
- Convertible to standard THA in case of revision
- Simple reproducible surgical techniques
- Opportunity to pick modular options for appropriate bearing surface
- Opportunity to select optimum femoral head diameter
- The selection of any standard surgical approach to the hip

We encourage and believe there are significant advantages in the concept of neck sparing stems. Clinical / surgical evaluation is now underway and will be reported on in the future.

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6. Freeman, M.A.R., "Why Resect the Neck?", *JBJS* 1986
7. Townley, C.O., "Interview in Orthopedics Today" Oct. 1990
8. Whiteside, J., S.E. 630b, Annual Meeting AAOS Feb.22-26, 1996

Note: Presented in part at AAOS, 2008 and the Australian Arthroplasty Society, 2008, 10th Annual Update in Hip & Knee Arthroplasty (IARF) Meeting, 2008, Annual Advances in Arthritis, Arthroplasty & Trauma, 9/2008, and ISTA-10/08.

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“Short Stems With & Without Modularity”

By

S. David Stulberg, MD

**Professor, Clinical Orthopaedic Surgery, Northwestern University Feinberg
School of Medicine, Chicago, IL**

Introduction:

Cementless femoral stems of many designs, reflecting a broad range of bone attachment rationale, provide dependable long-term fixation. However, a number of issues related to cementless stem fixation exist which might increase their safety, versatility and durability. These issues include the: 1) optimization of load transfer to the proximal femur to maximize bone preservation and restoration; 2) elimination of the potential for a mismatch in proximal-distal fit (Such a condition might exist in the presence of an excessively bowed femur, or one deformed as the result of a fracture or developmental abnormality. Young, active, large patients, who require hip replacements, may have large proximal femoral metaphyses and very narrow intra-medullary diaphyses. The use of cementless implants with stems of conventional length in such patients carries with it the risk of early and/or delayed fracture); 3) facilitation of various minimally invasive surgical exposures, especially those incorporating an anterior exposure of the femur; and 4) the preservation of proximal femoral bone stock in young patients who might ultimately require revision of their primary components.

In order to develop short stem implants that achieve these goals, it is desirable and necessary to evolve from the principles that have been the foundation for the fixation success of cementless femoral implants with standard length stems.

The purpose of this presentation is to: 1) Describe the design rationale and characteristics of uncemented, metaphyseal (<100mm) primary THA femoral stems which incorporate these principles; 2) Present the initial 2-4 year follow-up clinical and radiographic results achieved using stems with these principles; and 3) Propose the characteristics of future, short, cementless metaphyseal stems based upon this initial experience.

Methods:

Two groups of patients have been studied in which stems with similar design characteristics have been used. In the first group, sixty-five custom-made uncemented metaphyseal engaging femoral stems were inserted in a sequential series of 60 patients between March 2004 and March 2005. The indications for inserting these implants were all patients less than 70 years of age. No patient was excluded based on femoral bone quality or body mass index (BMI). A minimum of two-years (average 32 months, range 24-44 months) clinical and radiographic follow-up was obtained for the patients in this study. The average age of the patients at time of arthroplasty was 56 (range 16 - 69). There were 37 procedures performed in men and 28 procedures performed in women. The diagnoses were osteoarthritis in 62 patients and avascular necrosis in 3 patients. The average BMI was 29.1 (range 26.3 – 54.6). The metaphyseal engaging femoral stems were customized to each patient based on preoperative computed axial tomography scans. The implant was designed to fit closely against the endosteal metaphyseal bone along the anterior metaphysis, medial calcar, posterior femoral neck, and metaphyseal flare at the bottom of the greater trochanter. The femoral stem was made of titanium alloy with a hydroxyapatite coating on a titanium plasma-spray in the proximal 1/3-1/2 of the stem. The average stem length was 90 mm (range 70-125 mm) and the average stem diameter was 14 mm (range 9-23 mm). A porous coated acetabular component was used in all cases. The bearing surface in was metal/highly cross-linked polyethylene. The femoral head size was 32 millimeters. All of the arthroplasties were performed through a less invasive posterior-lateral approach. Full weight bearing was allowed immediately. Clinical and radiographic data were collected preoperatively, in the early post-operative period, and at subsequent examinations. The clinical evaluation consisted of an assessment of pain, functional parameters, and a physical examination to provide a composite Harris hip score (HHS). Specific inquiries were made with respect to thigh pain at each visit. Standard anterior-posterior radiographs of the pelvis and lateral radiographs of the hip were obtained at all visits. The implants were evaluated for subsidence in a standardized fashion by measuring from the tip of the greater trochanter to a fixed point on the femoral stem. A modification of the criteria described by Engh was utilized to determine the stability of the femoral prosthesis. A stem was considered to be stable if there was evidence of bone bridging or endosteal condensation, no evidence of subsidence, and no lucencies or reactive lines surrounding the stem.

In the second group of patients, 230 off-the-shelf primary short stem implants were inserted in consecutive patients from January 2005 – March 2006. These stems were inserted in patients of all ages regardless of bone quality. The off-the-shelf implants had design characteristics based upon and very similar to the custom-made implants. The surgical technique for implantation, the peri-operative management and the post-operative surveillance were identical to the custom group.

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Results:

In the custom group, the average preoperative Harris hip score was 49 (range 23-68). The average Harris hip score at most recent follow-up was 93 (range 73-100). There were no complications in this group attributable to the femoral stem. There were no intra-operative or postoperative fractures. Two patients underwent an acetabular cup revision for recurrent dislocations. At the time of revision surgery the femoral stem was noted to be stable in both cases. In the off-the-shelf group, the clinical outcomes were similar to those of the custom group. There was one intra-operative undisplaced intra-operative fracture which was recognized and treated and was associated with an uneventful post-operative course. There was one post-operative minimally displaced peri-prosthetic fracture, which was treated successfully non-surgically.

Preoperative radiographs were evaluated for the quality of bone based on the method described by Dorr. In the custom group, twenty-one hips (32 percent) were found to have type-A bone; 39 hips (60 percent), type-B bone; and 5 hips (8 percent), type-C bone. In the off-the shelf group, 30 per-cent of hips were Type A, 40 per cent were Type B, and 30 per cent were Type C. There was no radiographic evidence of subsidence on the postoperative radiographs. (fig. 1)

All stems were radiographically stable with no signs of reactive lines or loosening on the most recent radiographs. There was no evidence of calcar atrophy or lucencies surrounding the stem. The radiographic pattern that demonstrated bony ingrowth in these stems was that of bone bridging and endosteal condensation.

Discussion:

Cementless metaphyseal engaging femoral stems with a proximal hydroxyapatite coated porous surface are associated with excellent clinical and radiographic outcomes at 2-4 years. The potential benefits of these short stems include: 1) increased ease of insertion (broach-only); improved proximal femoral bone remodeling; avoidance of proximal-distal femoral diaphyseal mis-match; ability to accommodate variations in proximal femoral diaphyseal anatomy, and facilitation of less invasive surgical approaches.

The stems used in this series were designed to identify the characteristics of short stems that would be necessary for successful, reliable results that were comparable to those achieved with currently available off-the-shelf cementless implants with stems of conventional length. Based upon this experience the next generation of short stems should include the following: 1) extensive femoral metaphyseal bone contact; 2) ingrowth and/or on-growth coatings in the metaphyseal engaging portion of the stem. Off-the-shelf short stems of the future are also likely to have modular necks and accommodate femoral heads of all sizes and materials (fig 2).

Instrumentation must be developed to assure that short stems are inserted accurately and reproducibly. In particular, the tendency to place these devices into varus must be minimized with proper instrumentation. Finally, to be truly bone conserving, instruments should be developed to remove these short stems with minimal proximal femoral bone loss.

Selected Reading:

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3) Röhrli SM, Pedersen E, Ullmark G, Nivbrant B. Migration pattern of a short femoral neck preserving stem. *Clin Orthop Relat Res*. 2006;448:73-78.

4) Kim YH. Cementless total hip arthroplasty with a close proximal fit and short tapered distal stem (third-generation) prosthesis. *J Arthroplasty*. 2002;17:841-850.



Fig 1: Custom made metaphyseal engaging short stem: Pre-operative x-ray, pre-operative c-t reconstruction with pre-operative plan, actual implant and post-op x-ray, 4 years post-op, demonstrating excellent bone remodeling.



Fig. 2
Small curved stem with modular neck will allow tissue sparing (hard & soft) techniques.

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“Neck Sparing Stem Design Early Experience”

by

***Prof. Ian Woodgate, MD.,**

Allen Turnbull, MD., John Harrison, MD., Peter Hanaford, MD., Steve Banks*, **Timothy McTighe, Dr. H.S. (Jic)

*St. Vincent's Hospital, Sydney, Au

* Orthopaedic Surgeons, NSW, AU

*Global Orthopaedic Technology, NSW, AU

** Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio



Introduction:

Neck sparing stems have been around since 1948 with the Thompson stem. However it was Freeman in the 60's and 70's that began to popularize this concept for routine use. Following in his footsteps was Whiteside who developed both modular and monoblock neck sparing stems built off the Freeman design. Townley followed with a straight stem with a broad flat collar but Pipino has advocated the design concept of tissue-sparing. There is significant mechanical advantage in retaining the femoral neck, which results in a reduction of torsional forces placed on the implant-bone interface the challenge comes in loading and maintaining the neck.

Methods:

Review of previous published work was evaluated along with surgical approaches in creating a new neck-sparing stem for primary THA. A new stem design along with a new surgical approach that would be simple, reproducible and provide for fine-tuning joint mechanics without disruption of implant-bone-interface was utilized. Five patients were selected for use of a custom neck sparing stem to prove the viability of this concept. Patients were three females and two males. Ages were youngest 22 - 55. All patients' lead active lives both professionally and privately. The senior surgeon using a small conventional posterior approach performed all cases.

Results:

Operative time was reduced in every case from 115 minutes to 105 minutes. No blood transfusions were needed, no infections, DVT or dislocations. One case of over correction of leg length was encountered. Case number one was lengthened 5 mm (not clinically significant) the other four cases were all corrected to pre-operative measurement. HHS scores improved for all patients.

Discussion and Conclusion:

These early cases clearly demonstrated that neck sparing THA provides for bone and tissue conservation, restores joint mechanics, minimal bone loss, and simple reproducible surgical technique. Provides for modular options for bearing surface and selection of head diameter. Standard surgical approaches to the hip can be used without compromising exposure. We are encouraged and believe there are significant advantages in this concept of neck sparing stems. Clinical / surgical evaluations are now underway and will be reported on in the future.

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“Neck Sparing vs. Hip Resurfacing-Anterior Approach”

By

John Keggi, MD.,

Kristaps J. Keggi, MD., Robert Kennon, MD., & Timothy McTighe PhD (hc)



Back to the future! Hip Resurfacing (HR) and Neck Sparing (NS) seems like we have been here before. “Lets not forget the past or we are likely to make the same mistakes.”

Three key point made by the UK Joint Registry with-regards to HR:

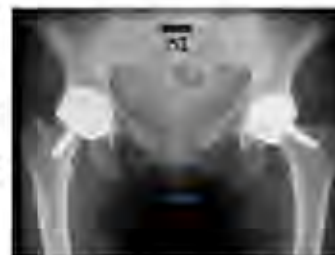
- UK Joint Registry (2005) RH accounts for about 9% of all hip replacements.
- <55 years old HR accounts for 34%.
- HR has highest failure rate

Recent paper by R.T. Steffen et. al. J Bone Joint Surg Br 2008 90-B:436-41

“The Five Year Results of the Birmingham Hip Resurfacing Arthroplasty” 93% good to excellent results

“Hip Learning Curve may be longer than thought for placing hip resurfacing components “55-60 cases” reported in Orthopaedics Today 2007: 27:12

British and Australian researchers collaborating on a prospective study identified a longer-than-expected learning curve to accurately perform hip resurfacing arthroplasties. Hip surgeons taking part in the study, all of whom had performed more than 1,000 hip surgeries, found they had to complete three-times more resurfacing surgeries than they expected in-order to place femoral components within 5° of the desired neck/head angle. “Based on the results, she Diane L. Back, FRCS told others to expect their margin of error to be high for the first few years, no matter how skilled they were.”



The implants in this post-op radiograph were 15° off in the patient's left hip and 5° off in the right from where the surgeon originally intended to place them.

In the United States where orthopedists begin practicing after completing fewer hip replacements than surgeons in the United Kingdom or Australia, “It actually, means their learning curve may take them 10 years to get out of,” Diane L. Back, FRCS

Mr. Duncan Whitwell reported 95.3% survivorship at 8 years at the 2007 DARF meeting in Palm Springs.

So we are seeing between 93-96% survivorship of 10% indication for HR and 97% for cementless THA at 15 years on all indications. This is a clear indication that something other than HR must be added to our treatment plan.

Australian Joint Registry 2005 “ HR procedures have a higher number of early revisions as compared to conventional total hips.”

Hip resurfacing even with the anterior approach is more invasive than conventional or neck sparing THA.



Early impression is that short neck sparing stems will be more tissue preserving than compared to HR and not require any special instruments to be done in a reproducible manner with the anterior approach. We are optimistic about this emerging new technology.

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“Tissue Sparing Conservative Approach To the Hip-Posterior Approach”

By

Louis Keppler, MD* & Timothy McTighe, Dr. H.S. (hc)**

*Co-Director Orthopaedic & Spine Institute, Cleveland, Ohio,

*Clinical / Surgical Research Advisor, (JISRF), Chagrin Falls, OH

**Executive Director, JISRF, Chagrin Falls, Ohio

“It is important to know where we came from less we forget the mistakes of the past.”

It is also important not to lose sight of our goals and not be unduly influenced by current trends. Successful surgery is simple, reproducible and predictable.

THA has been and continues to be an excellent surgical treatment for diseases of the hip joint. Current clinical results demonstrate 97% good to excellent results at 15-17 years as compared to 95% at eight years for hip resurfacing (HR). At first glance, one would think these results were comparable. However, we must remember that indications for HR are at most 10% of THA.

So what is the driving factor for HR?

We believe that this is patient driven. Patients are under the impression that this is a conservative surgical approach as compared to traditional cementless THA because of less femoral bone resection.

Hip resurfacing however requires a more extensive soft tissue exposure which has consequences.

Most hip surgery in the United States is done via the posterior approach which has been shown to significantly affect blood flow to the femoral head in HR.

The direct lateral and modified lateral approaches have been associated with an incidence of postoperative abductor weakness and slower recovery.

The anterior approach provides good exposure of the acetabulum but can be challenging in mobilizing the femur for proper exposure. Some advocate the use of traction tables and or special retractors in combinations with a second incision to provide adequate exposure.

Current HR employ a MOM bearing. Contraindications for HR and MOM bearings include:

- Women of childbearing age
- Osteopenia
- Patients with metal sensitivity
- Patients with renal disease
- AVN

Additional concerns with HR are:

- Steep learning curve
- Extensive soft tissue exposure
- Acetabular fixation
- Very sensitive to implant malposition (femoral and acetabular)
- Long-term exposure to metal ions

Recent developments and past-experience in neck sparing designs may offer a truly tissue sparing (both bone and soft tissue) approach to total hip arthroplasty.

Dorr has clearly demonstrated that the MIS posterior approach has better early pain relief and function as compared to conventional posterior surgical incisions. However bone conservation in-the-form of neck sparing designs goes back to the 1980s and is credited to Michael Freeman.

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Freeman's design concept was a neck-sparing stem that would have the following objectives:

- minimize the incidence of aseptic loosening
- conservative femoral bone resection
- Reduce tensile and shear stresses at the implant-interface and transfer hoop tension into compressive forces at the implant-interface.

Freeman in describing the biomechanical forces in the reconstructed hip went as far as to say "the design of all conventional arthroplasty is made worse since the femoral neck is routinely resected." He also stated: "This is done for reasons that are purely historical". Drs. Moore and Thompson designed stems for the treatment of femoral neck fractures, and for this reason, the femoral neck had to be discarded. In the typical arthritic hip, the neck is intact and therefore it can be retained. There is significant mechanical advantage in retaining the femoral neck, which results in a reduction of torsional forces placed on the implant-bone interface.

As you can see by this illustration, since bone now extends upwards to reach the inferior surface of the femoral head, the area of bone available to resist downward migration of the component is increased (by a



factor of about three), while the length of the moment arm, is reduced by a factor of about four.

Two additional papers by Freeman back up his concept of neck retention: Freeman, M.A.R., Rasmussen, G.L., Cannargo, J.N. and Burton, K.C. "Cementless Fixation of Prosthetic Components in Total Hip Arthroplasty" In "The Young Patient with Degenerative Hip Disease", ED. J Goldie. Pub. Almqvist & Wiksell International Ltd. 1985 Freeman, M.A.R., "Why Resect the Neck? JBJS 1986

Dr. Charles Townley, of Port Huron, Michigan entered the market with a neck-sparing device called the Horizontal Platform Stem marketed by DePuy in the 1980's. This lead to his current device the PSL which is basically the same stem however manufactured and distributed by a company he Founded "BioPro". "The prosthesis must load the supporting bone over the largest possible surface area of the remodeled cortical arc, and in the normal direction ordained by the trabecular pattern" (Townley, Orthopedics Today, October 1990).



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Professor Pipino from the Department of Orthopaedics and Traumatology, Policlinico of Monza, Milan, Italy has been working with neck sparing stems for the past 25 years. His original design series spanned from 1979 to 1996. His original stem was a cobalt chromium alloy, straight stem, 4 sizes, with a single CCD angle of 135°. He has strongly advocated a tissue-sparing approach for both soft tissue and hard tissue (bone). "This is achieved, in THA, by conservation of the femoral neck through-the-use of a mini-stem." (J. Orthopaed Traumatol (2006) 7:36-41)

His updated design the CFP stem maintains many of the original design concepts. However, he has changed material to titanium alloy to reduce stiffness of the stem and has added additional sizes and surface texturing to improved torsional resistance. In his March 2006 paper he reported on 943 stems demonstrating a high percentage of excellent clinical results and good radiographic appearance.



CFP Stem

Leo Whiteside, M.D., from the Biomechanical Research Laboratory St. Louis, Missouri has been another strong advocate of neck sparing stems. Dr. Whiteside started his research in the early 1990's and he remains enthusiastic about the advantages of this concept. Some of his biomechanical studies clearly demonstrate the initial advantage in torsional resistance and stability of the stem. Although some proximal remodeling is observed with this design he continues to use the Quattroloc stem.

"Changes in direction of principal strain in the substance of the medial femoral bone show how bone must adapt to the bone-implant-interface." (Whiteside, 63rd Annual Meeting of the AAOS Feb. 22-26, 1996)



The NSAT™ (Neck Sparing Approach), MSA™ (Muscle Sparing Approach™) stems are curved, short, neck sparing designs. Their design incorporates both head and neck modularity, a sagittal distal slot, and a proximal design based on finite element analysis to load the medial calcar.



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Posterior Surgical approach

MIS has been defined as an incision length 10-12 cm or less. The senior author has evolved slowly into this small incision approach as a natural progress of experience. At no time, has he promoted the use of MIS or small incisions over conventional surgical exposure, and still feels that adequate exposure is of vital importance. The posterior approach is familiar to most surgeons, requires no special instruments and has not added any additional time for the procedure.



It should be noted that intraoperative x-rays are our standard routine and we feel this is a vital aspect to the success of our past, current and future outcomes for THA. Certainly there is evidence that malpositioning of implants has increased since the increased use of smaller surgical incisions. Future developments in surgical navigation could also prove to be of benefit.

As with Dorr's technique, the patient is positioned in the lateral decubitus position. The skin incision is a short oblique incision centered over the posterior aspect of the greater trochanter. The fascia is divided in line with the fibers of the gluteus maximus. The gluteus maximus muscle is split for about 10 cm. At this point a Charnley self-retaining retractor may then be placed. The abductor musculature is protected and the piriformis tendon is released. The remaining short external rotators and gluteus maximus tendon insertion are not disturbed. The posterior capsule is incised at the base of the neck superiorly, posteriorly and inferiorly and "T" posteriorly. The acetabular insertion of the capsule is preserved. Incising the anterior capsule superiorly is often performed to release contractures.

The subcapital high neck resection in no way restricts acetabular exposure.

Femoral exposure is simplified without the need to dissect the soft tissue of the piriformis fossa, resect the lateral femoral neck or disturb the medial greater trochanter and abductor insertion.

The femoral canal is entered with a small curved Mueller rasp. The curvature mimics that of the natural medial curvature of the femur and preserves the proximal lateral cortex of the neck.



Medial

Note:
The higher the neck resection the smaller the size of the stem.



Lateral

abductor musculature is protected ⇒



Surgical approach with prototype instruments that clearly demonstrate the ability to convert a high neck resection into a conventional cementless THA without difficulty.

A standard box chisel is used to open a direct line into the femoral canal, followed by a short tapered hand reamer then impaction broaches used in incremental sizes. A standard proximal modular tapered cementless stem is inserted, intraoperative x-ray taken to confirm targeted restoration and case closed.

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Excellent acetabular exposure, preparation, and monoblock cup insertion



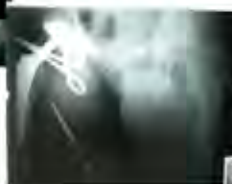
⇐ Neck resected for conversion to conventional hip design



⇐ Typical box chisel for in line preparation of femoral canal



⇐ Typical starter reamers need to be positioned lateral



⇐ Well positioned stem can damage lateral structures

We are excited about the potential this technique is going to provide not only to our younger more active patients but also our older patients that have reduced recuperative abilities. Tissue sparing approaches used with the posterior incision should provide for reduced postoperative pain, accelerated rehabilitation and if-and-when needed conversion to a standard conventional length THA with reduced risk associated with revision THA. The techniques are familiar to most orthopedic surgeons, do not require any special equipment, and should not present a steep learning curve.

Lateral tissue (Soft & Hard) are preserved⇒



Significant tissue sparing compared to HR & conventional THA

"Cutting-Edge Developments on Proximal Modularity in THA"
Mini-Symposium AAHKS, November 7, 2008 Dallas, TX



NOTES

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Introduction:

Polyethylene and metal have been the material of choice since the 1960's. Some consider Polyethylene to be the weakest link in THA prosthetic design.^{1,2}

We are now seeing the next generation of cross-linked polyethylene along with work on alternative hard on hard bearings trying to reduce the generation of wear debris.



Poly Failure Leads to Revision Surgery



Issues have been raised from squeaking to high trace elements, strength characteristics and torsional stability of current materials.^{3,4,5,6,7,8,9}



Two failed CrossLink implants (Longevity™)¹⁴



MOM Bone Necrosis - E. Smit



Cup spin out 7 weeks post-op. Revision made easier by proximal modular neck design.



Thomas 2003



Hypersensitivity to metals

Ideally, the surfaces for articulating bearing surfaces will be made from materials having high strength, high wear, and corrosion resistance, a high resistance to creep, and low frictional moments.

This poster will review characteristics of a novel new approach for a bearing material.



Richard Trehanne, PhD, MBA
Active Implants
Memphis, TN



Timothy McTighe, PhD (hc)
Executive Director
Joint Implant Surgery & Research Foundation
Chagrin Falls, OH



Hugh U. Cameron, M.B., ChB, FRCS
Orthopaedic & Arthritic Institute,
Toronto, Canada



By: Richard Treharne, PhD, MBA*, and Timothy McTighe, PhD (hc)** **Hugh Cameron, M.B. Ch. B.*****

*Active Implants, Memphis, TN., **Joint Implant Surgery & Research Foundation Chagrin Falls, Ohio, ***Orthopaedic & Arthritic Institute, Toronto, Canada

Methods:

A review of past and current materials along with mechanical testing in creating a new approach to the development of a hydrophilic material replacing the polyethylene side of the bearing surface.

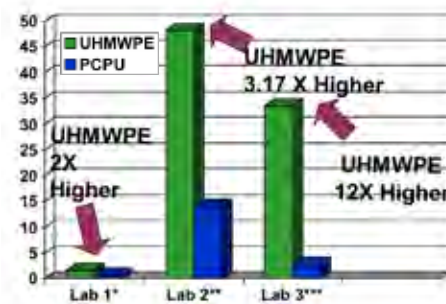
Studies have demonstrated the advantages of the full-fluid film layer of lubrication in-terms of enhanced wear performance.¹⁰

An acetabular "buffer" bearing was developed that features a pliable bearing surface formulated, biocompatible polycarbonate urethane (PCU). A review of design objectives and testing will be highlighted in this poster.

Results:

Wear studies have demonstrated performance up to twelve times better compared to polyethylene.

Fourty-five components have been implanted reaching two years post-op. Two devices have been removed both for non-related implant issues. Retrieval analysis did not show any appreciable wear or damage to the bearing material.



Retrieved Specimen

Did not have any heavy metal elements - was some evidence of abrasion wear on back side (less than mechanical testing).

Note: No evidence of wear on bearing surface. Specimen weight loss measurement demonstrated equal to less mechanical wear testing. Final paper being prepared for publication.

The rough appearance seen on both retrieved specimens was attached protein.



Pt. 001 12 months



"Buffer" after cleaning

Fabrication Parting Line

Conclusions:

To date we are encouraged by the early basic and clinical science, however, only additional research and time will demonstrate the long-term viability of this material.

- Less Wear
- Less Debris
- Hydrophilic
- Shock Absorbing
- Biocompatible
- Less Costly



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Design Considerations and Results for a Modular Neck in Cemented THA



By: Hugh U. Cameron, M.B., C.hB, FRCS; Chris J. Leslie, D.O.; Timothy McTighe, PhD (hc)



Objectives:

Cemented stems are still widely used in THA, however, there remains concerns with hip dislocation and wear debris. Restoring joint mechanics is essential for soft tissue balance and reduction of mechanical impingement. These concerns have lead to the development of a modular neck for cemented THA. This is an update of previous data from ISTA paper presented in 2003.



Materials and Methods:

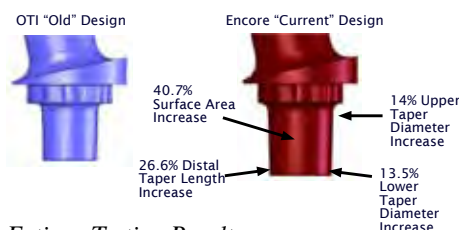
200 R-120™ cemented stems were implanted in 190 patients since 2001. The shape of the stem is trapezoidal with a large collar that provides for impaction and compression of the cement. The stem collar is made with a cavity where a self-locking taper and a positive indexing mechanism provide 12 different positions to ensure proper restoration of joint mechanics.



One to five years follow up with a mean of 2.8 years. Two-thirds were female and one-third male. Age ranged from 39 to 87 with a mean of 73. Majority were treated for OA. A c.c. 28 mm or 32 mm head and poly bearing were used for all patients. Selection of neck position was recorded for all patients.

Results:

63% of all head-neck positions were other than neutral. There were 0 dislocations, no significant leg length discrepancies (± 5 mm), and 0 infections. There was one stem removed due to a post-op peri-prosthetic fracture at 3 years that was treated with a long cementless stem. 1 death due to a PE ten days post-op. 1 intra-operative calcar fracture wired and healed uneventfully. 1 intra-op greater trochanter fracture that was treated with screws. 2 neck fractures revised to cementless stems. Note: Verbal



communication from the Keggi group Waterbury, CT. 150 Old "OTI" style necks in both cemented and cementless stems implanted since 2002 with 10 neck fractures. The Keggi group has discontinued using this device.



Fatigue Testing Results

Fatigue Strength @ 5,000,000 cycles

OTI Design 520-700 lbs.

Encore Medical Design > 1200 lbs.

Conclusions:

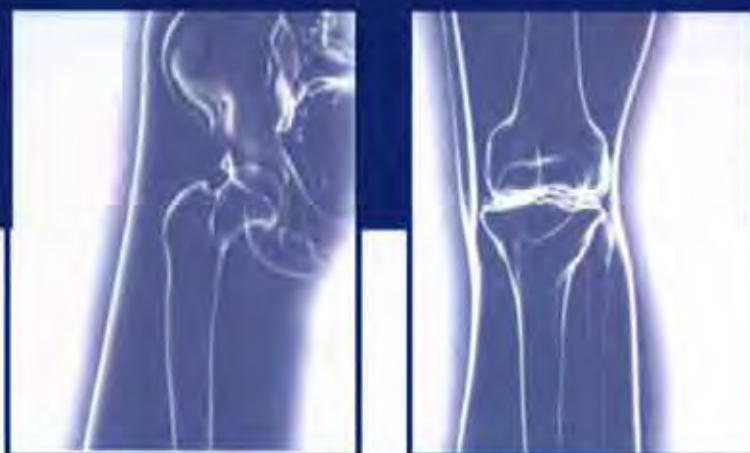
Modular neck design aids in fine tuning joint mechanics after stem insertion, and allows for ease and access in case of revisions. This modular neck design has eliminated (to date) hip dislocations and we remain optimistic about its long-term potential to improve clinical outcomes. Fatigue properties have been significantly improved and no additional neck fractures have occurred.



10th Annual Update in Hip & Knee Arthroplasty and Bearing Surfaces

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Metal-on-Metal Study #1

Title: Wear of metal-on-metal 'off-the-shelf' HA-coated/beaded hip bearings

Authors: Bowsher, J G; Nelson, P; Clarke, I C; McTighe, T; Woodgate, I; Turnbull, A; Keppler L, Donaldson, T K

Introduction

Wear studies of metal-on-metal (MOM) bearings in hip simulators have historically involved 'custom' acetabular cups, i.e. having neither beaded layers nor biological coatings [1]. Such custom designs improve the accuracy of the gravimetric wear assessments. However, it is not always feasible to obtain custom cups for various reasons. Thus, another possibility would be to machine off the implant coatings on 'off-the-shelf' cups [2]. However, this raises questions regarding metallurgical changes or cup deformation [3] and even the possibility of third-body wear damage, all potentially leading to erroneous predictions. Therefore removing these beaded layers may be impractical [3].

To date, no studies have attempted to use the gravimetric method with 'off-the-shelf' beaded and hydroxyapatite (HA) coated MOM cups. Therefore, the aim of this study was to investigate wear using such MOM bearings and evaluate the potential for error in the gravimetric assessment. Primary wear of Co-Cr bearings was estimated from Co and Cr ion concentrations in the serum lubricant [4]. The study hypothesis was that the gravimetric analysis would create unacceptably large errors in predicted MOM wear-rates with beaded cups (> 25%).

Materials and Methods

Six 38mm, high-carbon Co-Cr bearings were supplied with diametral clearances averaging 230 microns (Global Inc, Australia). The cups were received in 'off-the-shelf' condition with a cast Co-Cr beaded/HA-coated backing (Fig.1). The diameter of the cast beads was approximately 1.7mm. To remove the HA-coating, the cups were pre-soaked in lemon juice for 4 days (articular surfaces shielded). The cups were then soaked in bovine calf serum (BCS) until their average weights stabilized within 1mg. All components were cleaned using a standard protocol (ASTM F1714-96). Custom plastic fixtures were machined to fit the beaded contours of the cups (Fig. 1) with a 40° mounting angle in an orbital hip simulator (Shore Western Manufacturing, Monrovia, CA). All metal fixtures were plastic coated to minimize ion contamination. Serum lubricant was a diluted BCS (ISO 14242-1). Four MOM bearings were run to 5Mc using standard Paul load profile, while two MOM were retained as soak-controls. Serum samples were collected at every test interval and stored frozen (-25 °C).

MOM wear was estimated from serum ion concentrations using the following equation: $\text{Wear (mm}^3\text{)} = (C \times V_f) / (m \times \rho)$, where C = combined Co and Cr ion concentration (ppm), V_f = final chamber volume (cm³), m = mass fraction of Co and Cr combined (0.91) and Co-Cr density (8.3 g/cm³). The serum samples were digested in hydrochloric acid and the Co and Cr ion concentrations assessed using an ICP/MS (Wack Laboratories Inc, CA). For gravimetric assessment, all components were cleaned and weighed using standard protocols [1,2]. Persistent biological contaminants were removed with a lint-free cloth. Overall wear rate (OWR) was defined as the total wear at end of test divided by the total number of cycles. Co-Cr surface roughness was assessed by white light interferometry (NewView 600, Zygo).

Results

The majority of the HA-coating was removed from the cups after 4 days of soaking in lemon juice and after 21 days of soaking all cup weights appeared stable (Table 1: within 1mg). Reflected-light microscopy (RLM) showed no discernable signs of HA (Fig.1) and the total weight loss due to HA removal averaged ~400mg.

During the wear study, the two non-wearing beaded cups (soak controls) remained stable in weight (<1mg) to 5Mc duration. There was no visual evidence of deterioration in the wearing cups, i.e. lost or broken beads, elevated wear, 3rd body abrasion etc ($S_a < 30\text{nm}$). The metal ion analyses showed consistent wear trends for all MOM cups. The MOM with the highest wear demonstrated 1.2 mm³/Mc (OWR) at 5Mc (Table 2, Fig.2). In comparison, gravimetric analysis predicted an OWR of 1.3 mm³/Mc for the same MOM, a difference of only 8%. This level of wear was comparable to previous MOM studies.

Discussion and Conclusions

- *Soak conditioning the beaded-HA cups in lemon juice and BCS proved effective in removing the coating. This appeared exactly analogous to soak conditioning UHMWPE liners for their fluid absorption (3 weeks).
- *The beaded cups remained stable in weight during the wear study and caused little discrepancy in gravimetric analysis (8% overshoot).
- *The methods described did not lead to breaking of beads, elevated 3rd-body abrasion, cup damage or distorted wear scar shapes.

*Therefore, our hypothesis that gravimetric analysis would create large errors was negated. Standard gravimetrically techniques can be successfully used on beaded MOM cups of this type when the HA-coating is removed.

Acknowledgements The authors thank JISRF, Global, the Peterson Foundation of Loma Linda University and the Donaldson Arthritis Research Foundation (DARF) for their support.

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Fig.1. Removal of HA-coating from cast Co-Cr beads (RLM images).



Table 1. Average weight loss of cups during pre-test soaking period.

	4 days	16 days	21 days	29 days	36 days
Average Cup Weight Loss (g)	0.3818	0.3861	0.3846	0.3850	0.3839

Table 2. Wear from metal ions compared to gravimetric analysis.

	Total Run-In Wear (mm ³)	Wear Slope (mm ³ /Mc)	Overall Wear Rate (mm ³ /Mc)
Estimated wear from metal ions	5.1	0.16 (r ² =0.95)	1.2
Gravimetric analysis	4.6	0.4 (r ² =0.98)	1.3
Difference (%)	10% decrease	150% increase	8% increase

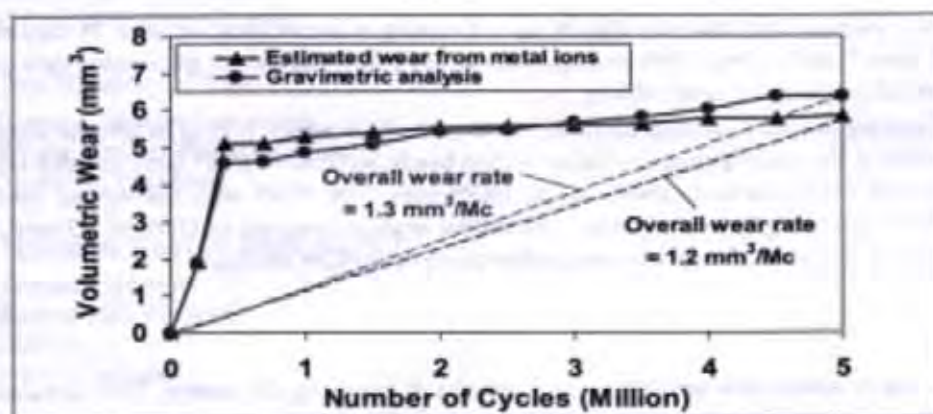


Fig.2. Estimated Co-Cr volumetric wear versus number of cycles for bearing#1 (highest wearing).



“THA-Keep The Neck”

by

***Timothy McTighe PhD (hc);**

*Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio

Ian Woodgate, MD; Allen Turnbull, MD; John Harrison, MD, Declan Brazil, PhD, Sydney, AU.

Kristaps J. Keggi, M.D., John Keggi, MD; Robert Kennon, MD; Middlebury, CT.

Louis Keppler, MD; Cleveland, Ohio & Hugh U. Cameron, MB., CHBS, Toronto, CA

Introduction



Architectural changes occurring in the proximal femur (resorption) after THA (due to stress shielding) continues to be a problem ^{1,2}. Proximal stress shielding occurs regardless of fixation method (cement, cementless). This stress shielding and bone loss can lead to implant loosening and or breakage of the implant. ^{3,4}

In an attempt to reduce these bony changes some surgeon designers (Freeman, Whiteside, Townley and Pipino) have advocated the concept of neck sparing stem designs. ^{5,6,7,8}

Freeman, in describing the biomechanical forces in the reconstructed hip went as far as to say “ the design of all conventional arthroplasty is made worse since the femoral neck is routinely resected. He future stated:

“This is done for reasons that are purely historical. Drs. Moore and Thompson designed stems for the treatment of femoral neck fractures, and for this reason, the femoral neck had to be discarded. In the typical arthritic hip, the neck is intact and therefore it can be retained. There is significant mechanical advantage in retaining the femoral neck, which results in a reduction of torsional forces placed on the implant / bone interface.”

Methods: Review of previous published work was evaluated along with FEA modeling in creating a new approach to neck sparing stems for primary THA.

Examples of short and neck sparing stems



Note: Not all short stems are neck sparing and not all neck sparing have short stems.



To-date most if not all neck-sparing stems have been somewhat disappointed in their long-term ability to stimulate and maintain the medial calcar. Partially for that reason a new design approach was undertaken to improve proximal load transfer and to create a bone or tissue sparing stem that would be simple in design, amenable to reproducible technique and provide for fine tuning joint mechanics while stimulating and maintaining compressive loads to the medial calcar.

In theory neck retaining devices provide for:

- **Bone and/or Tissue conservation**
- **Restoration of joint mechanics**
- **Minimal blood loss**
- **Potential reduction in rehabilitation**
- **Convertible to standard THA in case of revision**
- **Simple reproducible surgical techniques**
- **Opportunity to pick modular options for appropriate bearing surface**
- **Opportunity to select optimum femoral head diameter**
- **The selection of any standard surgical approach to the hip**

There are a number of trends occurring in THA that are worth noting that can be selectively addressed with the MSA™/ NSA™ Neck Sparing Stem System.

- Hip resurfacing is getting more attention with Metal on Metal bearings and the demand from patients requesting a device that allows them an opportunity to get back to their active lifestyles.⁹
- Large head diameters provide a sense of hip stability and appear to be reducing short-term dislocation. There is more awareness to restoring joint mechanics providing for better long-term results.
- There is a movement to bone and tissue sparing approaches.¹⁰



Does hip resurfacing really address these concerns?

- Hip resurfacing requires a larger soft tissue approach vs. small or MIS conventional surgical incisions
 - Most hip resurfacing is done by the posterior approach, which has been shown to significantly affect blood flow to the femoral head
 - Currently only Metal on Metal and Metal on Poly are available for resurfacing and Metal on Ploy in the past has demonstrated drastic clinical results
 - Most surgeons do not recommend Metal on Metal for woman of childbearing age
 - MOM has been shown to be contra-indicated in post-menopausal women
 - Current resurfacing has a high demand learning curve
- Hip resurfacing is not bone conserving on the socket side
- Hip resurfacing does not allow for adjusting or fine tuning femoral offset
- There is concern as to long-term systemic reaction on metal ions



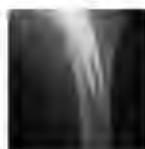


The MSA™ Stem is a combination of a simple curved stem with a unique lateral T-back designed for maximum torsional stability, ease of preparation and insertion. The proximal design has a novel thermal conical shape designed to stimulate and transfer compressive forces to the medial calcar. A modular neck provides for fine-tuning joint mechanics without disruptions of implant bone interface and a distal sagittal slot reduces chances of lateral cortex perforation. In case of stem removal a threaded hole is provided for a solid lock with a slap hammer for retrievability.



Note:

Risk of short stems is varus stem position resulting in perforation of cortex.



Surgical Technique

Pre-operative templating is helpful making sure that x-rays are taken with 20 degrees of internal rotation. This will provide reliable data as to femoral offset and medial neck curve.

Any surgical approach will work with the MSA™ Stem System. The femoral head is cut at the isthmus of the neck, perpendicular to the cervical axis. The distance between the osteotomy and the base of the greater trochanter is approximately 1.5 cm so this conserves the existing femoral neck..



Anterior Approach J. Kegeles



Posterior Approach L. Keppeler

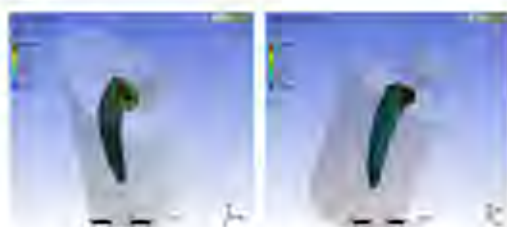


The femoral canal is opened with either a starting awl or curved curette. A flexible reamer may then be used to open the femoral canal or selection of the smallest starting broach. The stem is designed for simplicity in preparation and impaction broaching is used in sequence to the proper fit. The final implant is line-to-line with the broach and the proximal porous coating and later T-back design provide for a tight press fit. The final broach is selected by checking for torsional and axial stability. Trial stems are provided along with modular trial necks and heads ensuring restoration of joint mechanics. Trials can also be done off the definitive implant providing for last minute fine-tuning of joint mechanics.

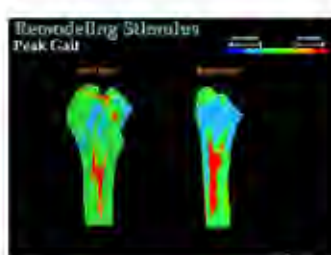
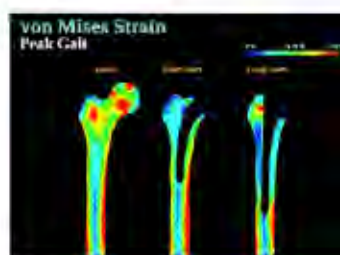
Results

FEA modeling was conducted to look at stress in the modular neck when assembled and subjected to loading prescribed by ISO 7206-6.





Illustrations show a change in stress in the stem with the increased load capacity of the extended taper and changed taper angle from 3.5m to 4° included. Stress is reduced from 662MP_a to 538MP_a.



Strain patterns for the MSA™ stem demonstrated better patterns vs. long stems or the short Biodynamic neck sparing stem.¹¹ We are encouraged with testing to-date. Additional FEA modeling and mechanical testing is underway.

Discussion and Conclusion

In theory neck retaining devices provide for ⁹:

- Bone and/or Tissue conservation ¹⁰
- Restoration of joint mechanics
- Minimal blood loss
- Potential reduction in rehabilitation
- Convertible to standard THA in case of revision
- Simple reproducible surgical techniques
- Opportunity to pick modular options for appropriate bearing surface
- Opportunity to select optimum femoral head diameter
- The selection of any standard surgical approach to the hip

We encourage and believe there are significant advantages in the concept of neck sparing stems. Clinical / surgical evaluation is now underway and will be reported on in the future.

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Note: Presented in part at AAOS, 2008 and the Australian Arthroplasty Society, 2008

10 th Annual Update in Hip & Knee Arthroplasty & Bearing Surfaces, Rancho Mirage, CA Sept. 18, 2008



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This activity jointly sponsored by
Postgraduate Institute for Medicine and Orthopaedic Education, Inc.

Educational grants provided by
DePuy, a Johnson & Johnson Company, EKR Therapeutics, Inc., Genzyme,
Merck & Co., Inc. and Pfizer

THA in 2018: Modular Stems

by

Thomas Tkach, M.D*.; Warren Low, M.D*. & Timothy McTighe, PhD (hc)**

* McBride Clinic, Oklahoma Clinic, OKC, OK., ** Joint Implant Surgery & Research Foundation, Chagrin Falls, OH.

Attempting to predict ten years out what Modular THA will look like we must first review and know the past. There is a strong and long history of modularity in THA. What was once considered novel is now state-of-the-art in design.

Modern day modularity of the femoral component comes from the European experience from the late 1940s' through the 1970s'. Modular heads did not become widely used in the U.S. until the mid 1980s'. Stem modularity made it into prime time with the introduction of the S-Rom® Stem in 1984. With the success of the S-Rom additional modular designs emerged.

Modularity Classification

- Proximal
- Mid-stem
- Distal

Modular heads are now standard on every hip stem system.

Neck Extensions

Trunion sleeve offer increased neck length adjustments, however, tend to reduce range of motion.

Modular Necks

Allow for adjustments of hip mechanics in a mono-block stem.

Anterior / Posterior Pads

Allowed for adjustment in fit & fill in the A/P width of the implant. It was criticized for not having circumferential porous proximal coating and has been discontinued.

Modular Collars have come and gone.

Proximal Shoulders (bodies)

They have the design option of increasing their proximal body height, offset and version angle.

Stem Sleeves

Stem sleeves offer the advantage of fit & fill with adjustment of hip mechanics. Some designs like the S-Rom® require removal of the stem to correct offset or version, while newer designs allow for correction with the stem *insitu*.

Mid-Stem

These designs offer versatility in correction of sizing mismatch between proximal and distal femoral anatomy. The modular junction is located at a high bending moment and fractures have been reported. **Distal Sleeves**

These designs allow for distal stem fit with different distal style options (smooth, fluted, or porous).

Multi-Modularity

The RMS is the best example of excess modular sites for a cementless hip stem and has come and gone.

Summary

These stems represent some of the past and current trends in both design and marketing efforts. This tendency is no doubt due to both the clinical and market success of the S-Rom. Modular designs' goals have changed over the past 24 years. In the early 1980s fit & fill were the principal objectives. Today the reduction of particulate debris and restoration of hip mechanics are the focal point.

Future Predictions

No one would argue that restoration of hip mechanics is critical to long-term successful clinical outcome and modular designs help restore hip mechanics. Today designs exist that allow the correction, or fine-tuning, of the hip mechanics after the stem has been implanted. The future will continue to be focused on modularity. There will however be a new focus with tissue sparing designs that save both hard and soft tissue. Example this neck sparing stem with a modular head and neck. Also, this novel bearing material Polycarbonate-urethane (PCU) The "Buffer" which reduces wear debris. Modularity is here to stay!



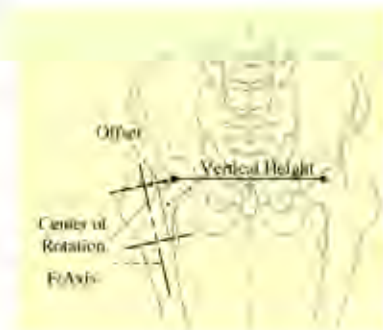
“Restoring Biomechanics in THA; Modularity”

by

Thomas Tkach, M.D*.; Warren Low, M.D*. & Timothy McTighe, PhD (hc)**

* McBride Clinic, Oklahoma Clinic, OKC, OK., ** Joint Implant Surgery & Research Foundation, Chagrin Falls, OH

Restoration of the hip joint mechanics is critical to long-term successful outcome for total hip arthroplasty. Replacement of the normal position of the femoral head is essential for correction of mechanical balance between abductor forces. If vertical height is too short, joint stability is a problem. If too long, patients are very unhappy. Incorrect version angle can result in reduced range of motion and possible toeing in. Short medial offset will cause shorting of the abductor moments resulting in increased resultant force across the hip joint, and increasing the tendency to limp. Offset too great increases torsional and bending forces on the femoral component. In addition, too much offset can result in trochanteric bursitis.



We see a number of trends that indicate hip joint instability a significant concern in THA outcomes: Big heads, increased use of constrained sockets and development of expensive surgical navigation technology.



Proximal modularity allows for fine-tuning joint mechanics without disruption of the implant / bone interface.

Monoblock stem designs limit one's ability to independently adjust for leg length, femoral offset and version angle. There is often the need for a large metaphyseal geometry, and femoral offset with a smaller diaphysis as seen in younger adult males. Trying to get the correct offset with a monoblock often leads to over lengthening the joint and over reaming the distal femoral canal. We also see women that have a large femoral canal (type C-bone) that have a shorter femoral offset making restoration of the biomechanics a challenge with monoblock designs.

› **The following example depicts the benefits of proximal modularity:**
Instability - What should be done? Trial reduction demonstrates joint instability with slight increased leg length.

› **Modular Heads allow length adjustment, unfortunately increase head length increases leg length.**

- › **Big heads! Theoretically, a bigger head is more stable... At the extremes of motion when the neck impinges. In this case, intrinsic stability is unchanged (Head center stays the same).**
- › **Biomechanical Solution Modular Neck! Add offset for joint stability reduce length for proper gait.**

Proximal modularity
Version control



Variable offsets for
every stem



Distal Flutes reduced in length for
ease of insertion.

Distal slotted stem for reduced stem
stiffness.

We have found restoration of normal joint biomechanics on a consistent basis was possible using a proximal modular Dual Press™ femoral stem. Review of monoblock stems vs. proximal modular stems has clearly demonstrated that restoration of the head center was more reproducible with the use of modularity.

Head center data suggest that hip joint reconstruction benefits from the availability of many head centers for every stem size. This unique modular design allows for a large selection of proximal modular bodies to enable restoration of proper soft tissue tension and joint biomechanics.

We are encouraged and remain enthusiastic about the features and benefits of proximal modularity.

“Target Restoration of Biomechanics Following THA”

by

Thomas Tkach, M.D*.; Warren Low, M.D*. & Timothy McTighe, PhD (hc)**

* McBride Clinic, Oklahoma Clinic, OKC, OK., ** Joint Implant Surgery & Research Foundation, Chagrin Falls, OH.



Restoring Hip Mechanics

Restoration of hip joint mechanics is critical to a successful outcome for all total hip reconstruction. Correction of femoral head offset affects the joint reaction and helps restore mechanical balance between abductor forces. If the offset is too short it will result in increased resultant forces across the hip joint, and possibly increase limp and wear. Offset too great will increase torsional and bending forces on the femoral implant possibly increasing aseptic loosening and or femoral component fracture.

Vertical height too short can jeopardize joint stability as a result of soft tissue laxity and if too long can result in nerve palsy and patient complaints. Incorrect version angles can affect range of motion resulting in implant impingement, joint dislocation, and increased generation of particulate debris.

Range of Motion

Three major factors that can affect range of motion are component positioning, component geometry and lack of femoral offset. Head diameter, femoral head center offset, neck shape and skirts on femoral heads can all affect hip range of motion. Although physiological range of motion varies for each patient an average of 114° of flexion is required for sitting. There is no question that certain activities require a greater degree of motion.



Mechanical impingement



Major Problems

Two major problems remain in hip surgery joint stability (correction of leg length & offset) and osteolysis. According to Dr. Hugh U. Cameron, the most significant medical / legal concern in THA is leg length discrepancies. Estimating dislocation rates of both 2% and 10% there would be a corresponding 6 to 30 thousand dislocated hips each year. Subsequently total cost of dislocations in the U.S. would be \$64.5 to \$322.5 million respectively.



Leg length dislocation

Lysis



0° neck version 15° neck version

Proper selection of implants can improve biomechanics and reduce wear debris.

Expanded abstract 2008 Annual Advances in Arthritis, Arthroplasty and Trauma Course Sept.10 - 12, 2008

Improvements in surgical approach, instrumentation and implant designs have improved our ability to restore joint mechanics but lets not forget the preoperative and postoperative process. In order, to target our restoration of hip mechanics we must know where we are starting from. Pre-op x-rays are typically taken with the leg in a neutral or external rotation. This can be misleading on femoral offset by as much as 1 cm. 20° of internal rotation reflects actual offset. If the patient can't internally rotate template of the contra-lateral side.



Normal leg position



20°
Internal
rotation
reflects
actual offset

When in doubt lateralize center of the head, the benefits out weight the risks. Having an implant that allows for fine tuning offset and version is of great value. Intra-operative x-rays also provides significant benefit in determining final implant selection as to size, leg length and femoral offset. Making this part of our overall OR protocol has only added about eight minutes to our surgical time and has reduced complications (implant loosening, malposition and dislocation).

Our clinical / surgical research has clearly demonstrated that a wide variety of offsets and vertical neck lengths are necessary to properly balance the joint soft tissues and restore joint mechanics. In addition, when the data were sorted by distal stem diameter, it was clear that there is little correlation between head center and stem size. A significant number of small stems required large offsets.

The one variable that is outside our ability to control is patient related activities post-operatively. Over the past three decades patients have increased their life style activities. **The effects of this increase activity on wear, frictional torque, counterface roughness, material deformation and particle morphology have not been analysed. Some additional warning to the patient might be of consideration until this area of research has been fully investigated.**

“Femoral Reconstruction with Modular Stems”

by

Thomas Tkach, M.D*.; Warren Low, M.D*. & Timothy McTighe, PhD (hc)**

* McBride Clinic, Oklahoma Clinic, OKC, OK., ** Joint Implant Surgery & Research Foundation, Chagrin Falls, OH.

FEMORAL CONSIDERATION

In comparison to primary THA revisions are associated with a markedly increased technical difficulty, increased complication rate and cost. The primary challenge in revision hip arthroplasty is stable implant fixation in the face of significant bone loss. As this bone loss is most common in the proximal femur, the most widely used implants are those which obtain fixation in the distal diaphyseal bone. Traditionally, the most commonly used revision stems are distally fixed non-modular implants. The ability to adjust version, offset and length is limited once distal fixation is achieved. These constructs have association with markedly higher dislocation rates when compared to indexed THA. Primary rates running from 1.4% to 4.2% with a mean 3.1%. Revision rates range 3.2-10.5% with a mean of 9.4%. Recently there has been an increase in the use of distally fixed proximal modular stems in an attempt to decrease the implant and joint instability and offset problems occurring during revision hip arthroplasty.

The goals of revision surgery remain the same as primary arthroplasty: reduction of pain; equalization of leg length; restoration of movement; creation of joint and implant stability. However, to accomplish the reconstruction successfully, often requires the use of autografts, allografts and modular implants.

The most common cause of proximal bone loss is due to osteolysis and aseptic loosening, resulting in a variety of femoral deficiencies that makes revision surgery more difficult.

The AAOS and a number of authors¹ have defined and classified femoral defects. Some of these classification systems are quite complex and require the need of a reference chart. Mattingly et. al., presented a modified AAOS classification system in a Scientific Exhibit “Revising The Deficient Proximal Femur” at the AAOS 1991 Annual Meeting. This system was helpful but still quite comprehensive. We prefer to use a simpler classification that has proven to be helpful for selection of specific implant design features that was described by Schutte et al. in the JISRF UpDate™ 2005.

Revisions of type 1 defects can be treated with primary stem lengths without much difficulty.

Defects of type 2, 3 & 4 require more planning and surgical options.

The use of autografts, allografts, modular and custom implants place a high demand on both the surgeon and the surgical team. The demands on experienced OR personnel place a higher cost on the procedure, as does the increased surgical time to perform hip replacement surgery.

Modular stems have been helpful in treating these difficult cases. Most companies now offer a modular revision stem system. Often there is proximal and distal mismatch and modularity provides versatility in fit and filling these defects.

Long-term data is available on both the S-Rom®, and Link modular stem systems and clearly demonstrate the viability of modular revision systems. Recent improvements to mechanical properties of the taper along with proven stem design features have allowed a number of newer systems to enter the market.



We have found modular primary stem designs like the Apex to be helpful in simple revision cases requiring standard length stems (in reconstructing the femoral biomechanics of the hip joint) and the Link modular conical stem helpful in the more complex cases.



Predictions and Concerns

- Modularity is continuing to improve in design and materials and is here to stay
- Increased Patient Activity & BMI Influences Outcomes & Device Failure
 1. High Impact Yield Failure
 2. Long Term Fatigue Failure
- Increased Device Malposition due to Limited Exposure
- Increased Medical/Legal Exposure

Final Comments

- All devices are subject to failure.
- Recognize design and material limits and do not over indicate,
- Warn your patients that device failure is directly linked to activity and BMI.
- Recognize required surgical technique for specific modular designs and do not attempted to change surgical technique and device technique at the same time.
- Revisions are always with us – therefore select devices that take retrievability into account.

Arthroplasty Society of Australia

Annual Scientific Meeting

Hyatt Hotel Canberra
30 April – 3 May 2008

PROGRAM & ABSTRACTS



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A NEW APPROACH TO NECK SPARING THA STEM

TIMOTHY MCTIGHE, PhD* (hc).

IAN WOODGATE, M.D.,

ALLEN TURNBULL, M.D.,

JOHN HARRISON, M.D.,

JOHN KEGGI, M.D.,

ROBERT KENNON, M.D.,

LOUIS KEPPLER, M.D.,

DECLAN BRAZIL, PhD.,

HUGH U. CAMERON, M.B., F.R.C.S.

*Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio, USA

INTRODUCTION:

Architectural changes in the proximal femur after THA continue to be a problem. In an attempt to reduce these changes some surgeon designers have advocated the concept of neck sparing stem designs.

To-date neck-sparing stems have been disappointing in their ability to maintain the calcar. A new approach was undertaken to improve load transfer and to create a tissue-sparing stem that would be simple in design, reproducible in technique and provide for fine-tuning joint mechanics while maintaining compressive loads to the calcar.

METHODS:

Review of previous published work was evaluated along with FEA modeling in creating a new approach to neck sparing stems for THA.

The MSA™ Stem is a simple curved stem with a unique lateral T-back designed for torsional stability, ease of preparation and insertion. The proximal design has a novel proximal conical shape designed to transfer compressive forces to the calcar.

A modular neck provides for fine-tuning joint mechanics.

RESULTS:

FEA modeling will be reviewed. Strain patterns for the MSA™ stem demonstrated better patterns vs. long stems or the short Biodynamic stem.

DISCUSSION:

In theory neck retaining devices provide for:
Bone and Tissue sparing
Restoration of joint mechanics
Minimal blood loss
Potential reduction in rehabilitation

Ease of revision
Simple surgical technique
Options for bearing surface
Selection of femoral head diameter
Standard surgical approach to the hip

We are encouraged and believe there are advantages in the concept of neck sparing stems. Clinical / surgical evaluation is now underway and will be reported on in the future.

A NOVEL APPROACH TO REDUCTION OF WEAR IN THA

RICHARD TREHARNE, PhD, MBA,

TIMOTHY MCTIGHE, PhD (hc)*

* Joint Implant Surgery & Research Foundation, Chagrin Falls, Ohio, USA

INTRODUCTION:

Polyethylene and metal has been the material of choice since the 1960's.

We are now seeing the third generation of cross-linked polyethylene along with work on alternative hard on hard bearings trying to reduce the generation of wear debris.

Issues have been raised from squeaking to high trace elements and strength characteristics of current materials.

Ideally, the surfaces for articulating bearing surfaces will be made from materials having high strength, high wear, and corrosion resistance, a high resistance to creep, and low frictional moments.

This paper will review characteristics of a novel new approach for a bearing material.

METHODS:

A review of past and current materials along with mechanical testing in creating a new approach to the development of a hydrophilic material replacing the polyethylene side of the bearing surface.

Studies have demonstrated the advantages of the full-fluid film layer of lubrication in-terms of enhanced wear performance.

An acetabular "buffer" bearing was developed that features a pliable bearing surface formulated, biocompatible polycarbonate urethane (PCU). A review of design objectives and testing will be highlighted in this paper.

RESULTS:

Wear studies have demonstrated performance up to twelve times better compared to polyethylene.

34 components have been implanted reaching two years post-op. Two devices have been removed both for non-related implant issues. Retrieval analysis did not show any appreciable wear or damage to the bearing material.

CONCLUSIONS:

To date we are encouraged by the early basic and clinical science, however, only additional research and time will demonstrate the long-term viability of this material.



“A New Approach To Neck Sparing THA Stem”

Muscle Sparing Approach™ / Neck Sparing Approach™ Total Hip Stem Design Concept

By: Timothy McTighe PhD (hc)^α; Ian Woodgate, MD^β; Allen Turnbull, MD^β; John Keggi, MD^β; Robert Kennon, MD^β; Louis Keppler, MD^Δ; John Harrison, MD^Ω; Declan Brazil, PhD^ς; Wei Wu, MSc^ς; Hugh U. Cameron, MB, ChB., F.R.C.S.^μ



Introduction:



Architectural changes occurring in the proximal femur (resorption) after THA (due to stress shielding) continues to be a problem^{1,2}. Proximal stress shielding occurs regardless of fixation method (cement, cementless). This stress shielding and bone loss can lead to implant loosening and or breakage of the implant.^{3,4}

In an attempted to reduce these boney changes some surgeon designers (Freeman, Whiteside, Townely and Pipino) have advocated the concept of neck sparing stem designs.^{5,6,7,8}



High neck resection

Freeman, in describing the biomechanical forces in the reconstructed hip went as far as to say “the design of all conventional arthroplasty is made worse since the femoral neck is routinely resected.” He further stated “This is done for reasons that are purely historical. Drs. Moore and Thompson designed stems for the treatment of femoral neck fractures, and for this reason, the femoral neck had to be discarded. In the typical arthritic hip, the neck is intact and therefore it can be retained. There is significant mechanical advantage in retaining the femoral neck, which results in a reduction of torsional forces placed on the implant / bone interface.”



Thompson stem-1948

Methods:

Review of previous published work was evaluated along with new FEA modeling in creating a new approach to neck sparing stems for primary THA.

Examples of short and neck sparing stems



Note: Not all short stems are neck sparing and not all neck sparing have short stems.

To-date most if not all neck-sparing stems have been somewhat disappointing in their long-term ability to stimulate and maintain the medial calcar. Partially for that reason a new design approach was undertaken to improve proximal load transfer and to create a bone or tissue sparing stem that would be simple in design, amenable to reproducible technique and provide for fine tuning joint mechanics while stimulating and maintaining compressive loads to the medial calcar.

Is hip resurfacing really a conservative approach?



- Hip resurfacing requires a larger soft tissue approach vs. small or MIS conventional surgical incisions



- Most hip resurfacing is done by the posterior approach, which has been shown to significantly affect blood flow to the femoral head
- Currently only Metal on Metal and Metal on Poly are available for resurfacing and Metal on Ploy in the past has demonstrated poor clinical results
- Most surgeons do not recommend Metal on Metal for woman of childbearing age



- Resurfacing has been shown to be contra-indicated in post-menopausal women
- Resurfacing has a high learning curve
- Hip resurfacing is not bone conserving on the socket side
- Hip resurfacing does not allow for adjusting or fine tuning femoral offset
- There is concern as to long-term systemic reaction on metal ions
- Femoral neck failure is a significant problem

A New Approach



The MSA™ Stem is a combination of a simple curved stem with a unique lateral T-back designed for maximum torsional stability, ease of preparation and insertion. The proximal design has a novel (internal) conical shape designed to stimulate and transfer compressive forces to the medial calcar.

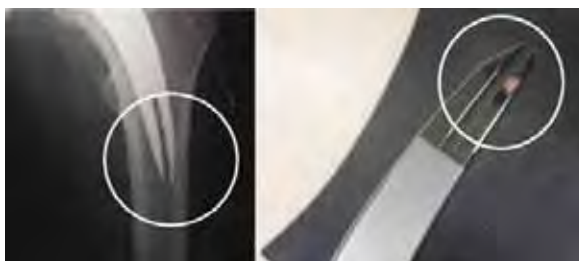


Novel (Internal) Conical Shape

A modular neck provides for fine-tuning joint mechanics without disruptions of implant bone interface and a distal sagittal slot reduces chances of lateral cortex perforation. In case of stem removal a threaded hole is provided for a solid lock with a slap hammer for retrievability.



Note: Risk of short stems is varus stem position resulting in perforation of cortex.



Distal sagittal slot with angled lateral stem reduce risk with varus stem placement.

Surgical Technique



Pre-operative templating is helpful making sure that x-rays are taken with 20 degrees of internal rotation. This will provide reliable data as to femoral offset and medial neck curve.



Neck sparing resection



Typical neck resection.



Head resection



High Neck Resection

Any surgical approach will work with the MSA™ Stem System. The femoral head is cut at the base of the head, perpendicular to the cervical axis. The distance between the osteotomy and the base of the neck is approximately 1.5 cm so this conserves the existing femoral neck.



Anterior Approach "J. Keggi"



Posterior approach "Woodgate"



Shape provides torsional stability

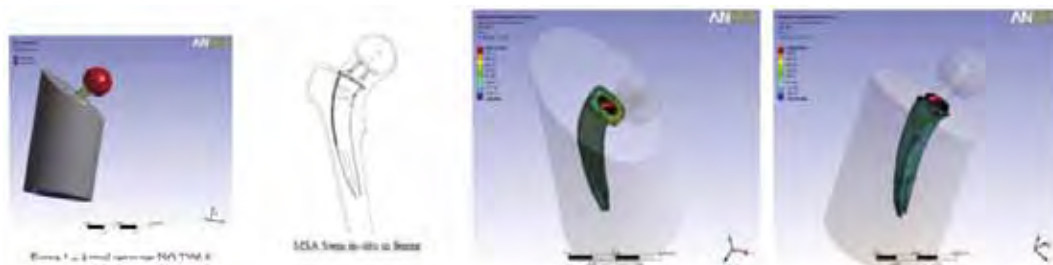
The femoral canal is opened with either a starting awl or curved curette. A flexible reamer may then be used to open the femoral canal or selection of the smallest starting rasp. The stem is designed for simplicity in preparation and rasping is used in sequence to the proper fit. The final implant is line-to-line with the rasp and the proximal porous coating and later T-back design provide for a tight press fit. The final rasp can be used with a trial neck, and head ensuring restoration of joint mechanics. Trials can also be done off the definitive

implant providing for last minute fine- tuning of joint mechanics.

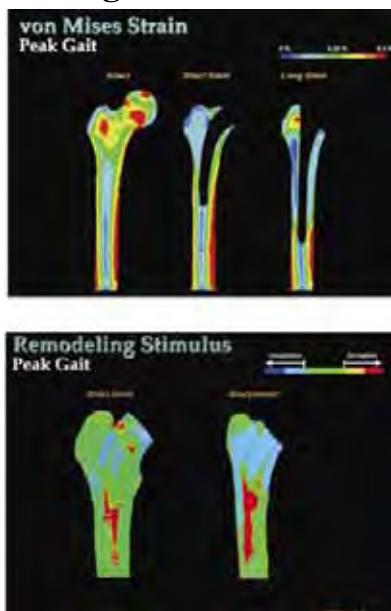


Testing on Modular Neck

FEA modeling was conducted to look at stress in the modular neck when assembled and subjected to loading prescribed by ISO 7206-6.



Testing on Bone



Strain patterns for the MSA™ stem demonstrated better patterns vs. long stems or the short Biodynamic neck sparing stem.¹¹ We are encouraged with testing to-date. Additional FEA modeling and mechanical testing is underway.

Illustrations show a change in stress in the stem with the increased load capacity of the extended taper and changed taper angle from 3.5m to 4° included. Stress is reduced from 662MP_a to 538MP_a.



Discussion and Conclusion

In theory neck retaining devices provide for ⁹:

- Bone and/or Tissue conservation ¹⁰
- Restoration of joint mechanics
- Minimal blood loss
- Potential reduction in rehabilitation
- Ease of revision if necessary
- Simple reproducible surgical techniques
- Modular options for appropriate bearing surface
- Selection of optimum femoral head diameter
- Standard surgical approach to the hip

We are encourage and believe there are significant advantages in the concept of neck sparing stems. Clinical / surgical evaluation are now underway and will be reported on in the future.

Note: This device is currently not available for sale in the U. S. (Patent Pending)

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Target Restoration In THA Are Big Heads Necessary?

By: I. Woodgate; L. Samuels; A. Turnbull; L. Keppler; K. Keggi; J. Keggi; R. Kennon;
H. U. Cameron, M.B., C.hB, FRCS; T. McTighe, PhD (hc)



Objectives:

Dislocation continues to be a significant problem and as a result the use of large M-O-M bearings is increasing. The causes can be multi-factorial, and include: mal-positioned components; component design; head size; component orientation; surgical approach; impingement-on-component or osteophytes; weak abductors; and patient related activities. Are big heads necessary?

Materials and Methods:

Surgeon authors have implanted over 10,000 THA since the 1970's for both primary and revision THA. This paper will highlight experience for 7,000 hips used for primary THA in both cemented and cementless cases as they relate to hip dislocation.

A variety of stems, cups, head diameters, surgical approaches and bearing surfaces have been used over the years. Conventional heads are described as 22mm-32mm in diameter and jumbo head sizes from 38mm-60mm.

22mm heads were used primarily for CDH type indications and were not used for routine cases. A variety of manufactures were used often mixing different stem and cup systems.

A number of variables were encountered during the review that makes any hard impressions just that – impressions.

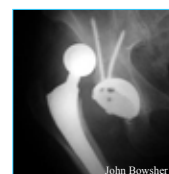
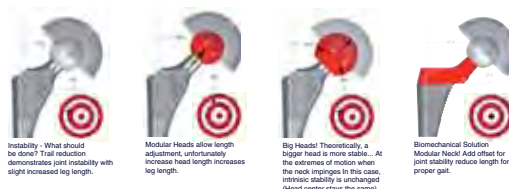
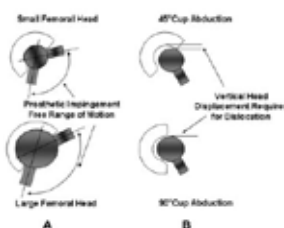
Results:

Half of our surgeon authors have moved on to larger jumbo head sizes while the other half have stayed with conventional head diameters. Conventional head sizes have a dislocation rate of < 1% and the jumbo heads have had one dislocation. Open reduction and replacement of scratched metal head was done, original cup remained in place. There is no statistically significant difference between the groups

The conventional dislocations accrued in the > than 60 year old patients. The use of proximal modularity has virtually eliminated dislocations, as has the use of large jumbo M-O-M heads.

Of the eight-surgeon co-authors, four use large M-O-M, and four still used non-metal on metal conventional heads sizes of 28mm and 32mm. The Keggi group prefer 32mm ceramic on ceramic. The M-O-M users are now also using more proximal modularity.

All of our surgeons have virtually no restrictions on activities after six weeks. Dr. Cameron still recommends to his patients that if you can see the inside of your thigh that is ok but you don't ever want to be looking down at the outside of your thigh.



Conclusions:

All of our surgeon co-authors specialize in total joint surgery. Surgical approach did not appear to influence dislocation rate. Proximal modularity and the use of jumbo head diameters appear to offer an increased safety margin, however, even large heads are dependent on implant position. The only consistent factor with our group is the use of modularity. Potential risk of M-O-M bearings are the real risk of damage to the bearing surface as a result of head dislocation. Systemic risks are a concern and caution is in order with certain profile patients (woman child bearing age, metal sensitivity). We highly recommend that in the rare event of M-O-M dislocation that open reduction and exchange of metal head be done with close examination of metal socket. Large heads are not necessary however due provide and added sense of security to both surgeon and patient.



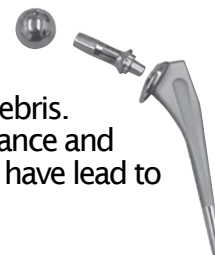
Design Considerations and Results for a Modular Neck in Cemented THA

By: Hugh U. Cameron, M.B., C.hB, FRCS; Chris J. Leslie, D.O.; Timothy McTighe, PhD (hc)

Objectives:



Cemented stems are still widely used in THA, however, there remains concerns with hip dislocation and wear debris. Restoring joint mechanics is essential for soft tissue balance and reduction of mechanical impingement. These concerns have lead to the development of a modular neck for cemented THA.



Materials and Methods:

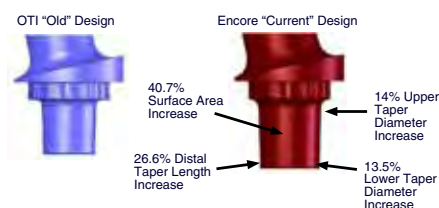
200 R-120™ cemented stems were implanted in 190 patients since 2001. The shape of the stem is trapezoidal with a large collar that provides for impaction and compression of the cement. The stem collar is made with a cavity where a self-locking taper and a positive indexing mechanism provide 12 different positions to ensure proper restoration of joint mechanics.



One to five years follow up with a mean of 2.8 years. Two-thirds were female and one-third male. Age ranged from 39 to 87 with a mean of 73. Majority were treated for OA. A c.c. 28 mm or 32 mm head and poly bearing were used for all patients. Selection of neck position was recorded for all patients.

Results:

63% of all head-neck positions were other than neutral. There were 0 dislocations, no significant leg length discrepancies (± 5 mm), and 0 infections. There was one stem removed due to a post-op peri-prosthetic fracture at 3 years that was treated with a long cementless stem. 1 death due to a PE ten days post-op. 1 intra-operative calcar fracture wired and healed uneventfully. 1 intra-op greater trochanter fracture that was treated with screws. 2 neck fractures revised to cementless stems.



Fatigue Testing Results

Fatigue Strength @ 5,000,000 cycles

OTI Design 520-700 lbs.

Encore Medical Design > 1200 lbs.

Conclusions:

Modular neck design aids in fine tuning joint mechanics after stem insertion, and allows for ease and access in case of revisions. This modular neck design has eliminated (to date) hip dislocations and we remain optimistic about its long-term potential to improve clinical outcomes. Fatigue properties have been significantly improved and no additional neck fractures have occurred.





Restoration of Femoral Offset Using a Modular Dual-Tapered Trapezoid Stem

By: Allen Turnbull, M.D., K. Keggi, J. Keggi, R. Kennon, L. Keppler, M.D., T. McTighe, PhD (hc)

Objectives:

The importance of restoration of femoral offset is well published. However, many stems offer limited offsets. The increased trend of using tapered stem designs places more of a burden on correct restoration of hip mechanics due to the variability of mid-stem contact point during insertion. This poster is a follow-up of previous work intended to review how proximal modularity has been added to a Dual-Tapered Trapezoid Stem design. Dual taper wedge designs have a long



history in Europe with growing use in the U.S. and Australia. However, single offset monoblock designs often prove inadequate in restoration of hip biomechanics.

Unlike traditional dual-tapered stem designs, the K2™ proximal modular stem allows intra-operative versatility with the ability to independently select the correct stem, neck and head configuration based on individual patient anatomy.



Monoblock style Tapered Stem

Materials and Methods:

Head center data for this stem has been reviewed as to previous published works that confirm that a wide variety of offsets and lengths are required to properly balance the soft tissues.

Further, when the data were sorted by distal stem diameter, it was clear that there is little correlation between head center location and stem size. Further, a significant number of small stems required large offsets. Modular stem designs have historically raised concerns about fatigue strength and generation of particulate debris leading to third body wear. High cycle fatigue testing demonstrates this Dual Press™ technology provides similar structural properties to many monoblock designs.



Green previous Apex modular straight stem design
Blue tapered K2 stem design

Testing on abrasion wear generation was less than .004mg after 48.5 million loading cycles. This is in comparison to be 1000x below yearly volumetric wear to published reports on MOM articulations.

Conclusions:

This contemporary modular tapered stem design allows independent selection of stem, neck and head combinations providing last minute fine tuning of joint mechanics without disruption of implant to bone interfaces. The head center data suggest that hip joint reconstruction benefits from the availability of many head centers for every stem size.



The Role of Modularity in Primary THA - Is There One?

By Louis Keppler, M.D. *, Hugh U. Cameron, MB, ChB, FRCS[§], Timothy McTighe, Ph.D. (hc)^Δ



Joint Implant Surgery and Research Foundation
17321 Buckthorne Drive
Chagrin Falls, OH 44023
440-543-0347 • www.jisrf.org

Introduction

Modularity or multi-piece stems are becoming commonplace in hip revision surgery^{6,13,15,17,19,21} with virtually all implant companies offering one version or another. The role of modularity would therefore seem to be firmly established for revision, but what of primary cases?^{8,11}

This study is a follow-up to previous work with a further ten years of cases reviewed. The real question we face does the benefit of modularity pay higher dividends than the potential risk factors. We believe this review will provide guidance for others surgeons to aid in their decision making process.

For almost two decades the two senior authors have been using a proximally modular stem in primary cases. The S-Rom[®] stem has basically not changed since 1986.^{4,12}

The stem design is a monoblock titanium alloy (maximum strength potential). The distal flutes historically were design off the Sampson[™] IM Rod system. The Sharp flutes provide excellent distal torsional stability while reducing chances of distal fixation. It is the design intent of this device to provide proximal fixation and distal torsional stability. An additional feature of the stem is the distal coronal slot. This provides for dual benefits, the first is to reduce hoop tension during stem insertion thus reducing distal fractures of the femur. And second (found out only after the fact during clinical reviews) was the slot reduces distal bending stiffness hence end of stem pain has not been a problem (exception > 15mm dia. stems).⁵

Two Remaining Significant Problems in THA^{10,12,15}

#1 Dislocation

- Reports from 2-8%
- Higher in Posterior Approach?
- Higher in Sm. Dia. Heads
- Higher in Revisions >20%

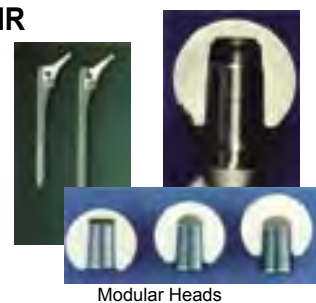


#2 Wear Debris/Lysis



The Role of Modularity in THR

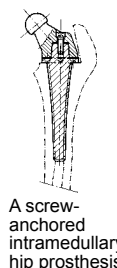
Modular means that the stem has 2 or more parts which can be joined. Does that mean any stem with a modular head is a modular stem? Not in today's definition. This exhibit is limited to the femoral side and includes two or more modular parts.⁷



Modular Heads

Modular Stem History

Modular stems have a long history starting with McBride in 1948 that utilized a threaded femoral component publishing his first account in JBJS in 1952. This was followed in 1978 by Bousquet and Bornand with the development of a proximal modular stem that featured a proximal body that was attached to a stem via a conical mounting post, with 8 perforations that allowed for select angle orientation for biomechanical restoration. Their design also featured a screw-anchored intramedullary stem design that was coated with AL₂O₃. Their initial reports were presented in Basel in June 1982 at symposium on cementless hips and published in Morscher's 1984 book "The Cementless Fixation of Hip Endoprostheses". The BSP Modular stem followed in 1988 and featured a modular collar/neck assembly that was fixed to the stem with a morse taper joint, a swa-tooth macro interlock system (15° rotation per tooth), and a set screw.^{3,18}



A screw-anchored intramedullary hip prosthesis



1988 proximal modular design

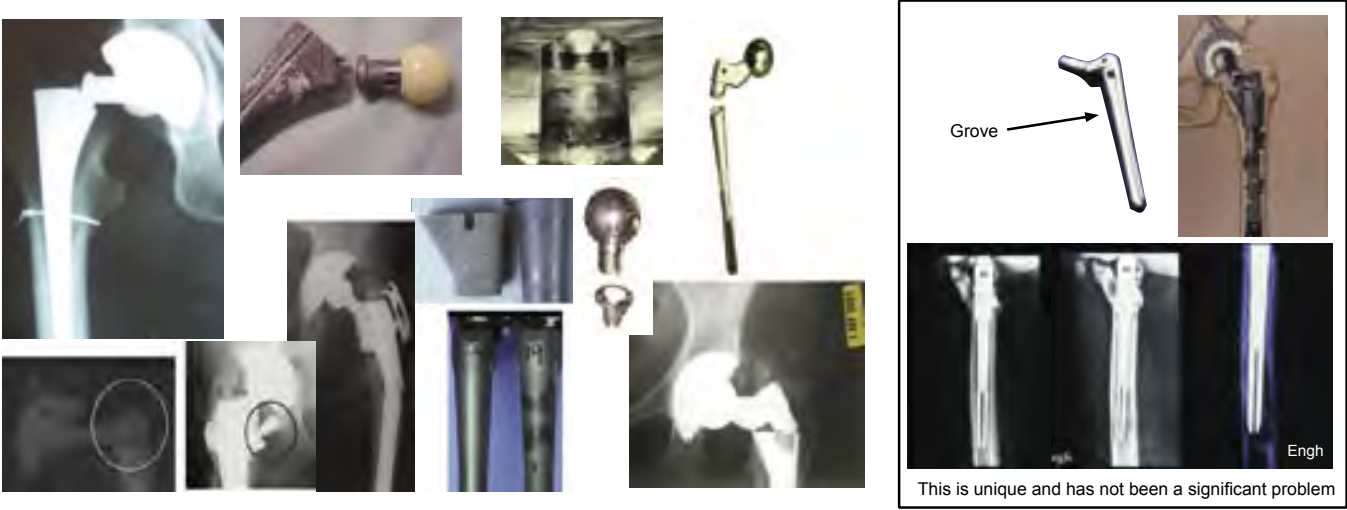
The current S-Rom[®] Stem System represents the fourth generation in the evolution of the Sivash Total Hip Stem since it was introduced in the United States in 1972.^{16,22,23}

Sivash began development of his prosthesis in 1956 at the Central Institute for Orthopaedics and Traumatology, Moscow, Russia. By 1967 Sivash, had selected titanium alloy for the femoral stem and proximal sleeve and chrome cobalt alloy for his socket bearing and femoral head. A major focus was the design of a constrained socket. The Sivash Total Hip System, introduced by the U.S. Surgical Corporation, never received major clinical or market success, partially due to the difficulty of the surgical technique, and positioning of this constrained device.

Modular Designs That Have Come and Gone¹⁴



Modular Failures & Concerns - Increased Risk?



Unsupported Stems Will Fail Regardless of Fixation/Material/Design

(cement/cementless/monoblock/modular)

Bechtol described failure mode in 1970's¹



Material

955 (S-Rom®) primary cases in a combined series performed by two surgeons at separate centers. 2-17 year follow-up (mean 11.5 yrs.)

HC: 517 cases (278 females/239 males) mean age 55; 162 CDH; Mod. Watson-Jones approach; 26 lost to follow-up; 28mm head (1986 stem design)

LK: 438 cases (237 females/201 males) mean age 68; 98 lost to follow-up (older pts./relocation of practice); 32mm head (1986 stem design); Posterior approach

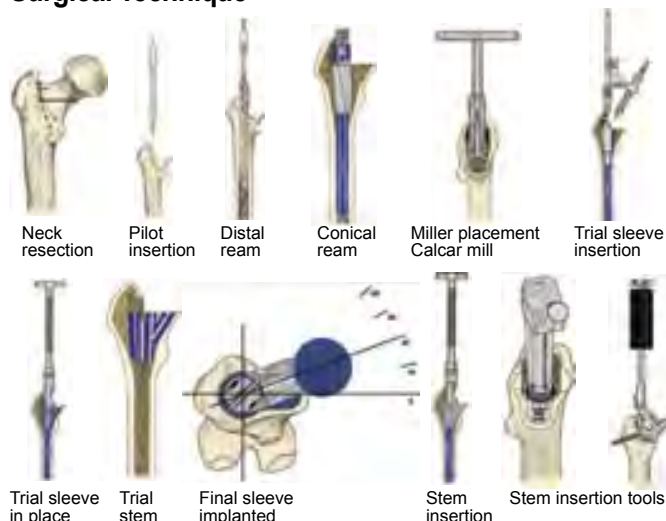
Note: variety of cups used

S-Rom® Evolution



- Monoblock stem
- Stable Geometric Shape (Prox. Cone & medial triangle distal flutes)
- Variety of fit & Fill Sleeves
- Distal coronal slot
- Precise (modular) instrumentation

Surgical Technique



Metal bearing insertion.



Hand ream / better feel.

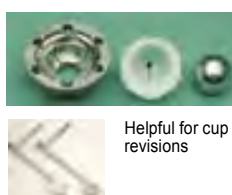


Distal hand reamer preparing medial triangle/ calcar miller not needed.

Examples of problems:

Poly Wear

If delay too long before revision poly wear through & cup damage



Helpful for cup revisions

Constrained liner - 28mm

Skirt on neck made it very vulnerable to mechanical failure.



Fractured greater trochanter through osteolytic cyst

2 hook plate
1 wired
1 compression screws



Failure of bone in-growth so distal stem is part of the effective joint space. Osteolysis developed.



Osteolysis

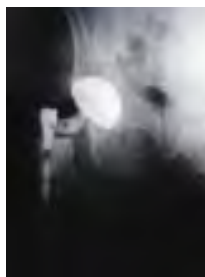
HC: Distal to sleeve - 3; 2 primaries; 1 revision. LK: Distal to the sleeve - 0. Data suggests that the sleeve acts as a seal, reducing poly particles from passing distally. HA Sleeve: 114 currently being reviewed. Will this function as well? Note: the 2 primary cases of lysis one stem exchange with curette through sleeve and one stem/sleeve revision



Sleeve acts as a seal

Dislocations

HC: 6 total; 3 closed reductions; 2 open reductions; 1 stem removed/ new stem inserted into sleeve (30-36mm neck). Note: Extensive trial reductions – does not take routine x-rays.



Trial ROM

Intra-op trial stem

LK: 5 total; 2 closed reductions; 3 open reductions (constrained sockets).

Note: routinely takes intra-operative x-rays/ generally results in fine-tuning of fit.

Stem Revisions

HC: 5 total; 1 for aseptic loosening; 2 late sepsis; 2 early bone fractures.

LK: 4 total; 0 for aseptic loosening; 4 late sepsis.

Note: 5 pts. Required onlay grafting for significant progressive end of stem pain (+15mm dia. stems)



Onlay strut graft



OmniTrack™ table mounted retractor system increases exposure particularly in revisions.

Lessons Learned

HC: Small dia. head greater wear problems; Routine now 32mm c.c. head; Large/active males metal-metal bearings; Neutral liner; Smaller incision; type C bone and elderly (cement stem).



LK: 36mm ceramic head with cross-link poly; + 4mm lateral offset poly (for increased poly thickness & offset); Hand reaming (better feel for bone); Neutral liner; Routine posterior capsule closure (added security); Smaller incision (average 7cm); type C bone (does not use S-Rom, uses a taper cementless stem).



Small posterior incision

Since the advent of the S-Rom® (1984) prosthesis it has been clear that modular (stem/sleeve) approaches can be used to successfully address implant stability especially fit & fill problems.

Final Comments

The long-term results for this series has demonstrated the S-Rom stem to be safe and effective for primary THA. Initial concerns over fretting and fatigue failure of the modular junction have not been observed.

Porous coating separation



Aseptic loose cup.

The lack of aseptic loosening (1 stem) clearly demonstrates this design provides initial stability leading to long term fixation. Stem survivorship is 99.8% at 11.5 years (best case assuming none of the loss to follow-up were revised).

The main problem appears to be cup/liner related and the lack of distal lysis suggests that the stem/sleeve Morse taper interface does not act as a pathway for the migration of debris.



We continue to use and recommend this device.

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Target Restoration of Hip Mechanics in THA

By: Tom Tkach, MD*; Warren Low, MD*; George B. Cipolletti, MS[§]; Timothy McTighe, PhD (hc)^Δ



McBride Clinic
1110 North Lee
Oklahoma City, OK 73101
www.mcbrideclinic.com



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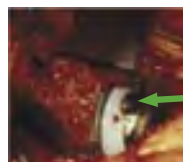
Joint Implant Surgery and
Research Foundation
17321 Buckthorne Drive
Chagrin Falls, OH 44023
440-543-0347 • www.jisrf.org

Introduction

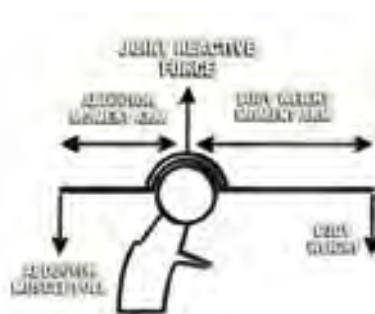
THA continues to improve but complications still occur. Dislocation continues to be a significant problem.^{1,2} The causes for dislocation can be multi-factorial, and include: mal-positioned components, soft tissue laxity, component design, head size, component orientation, surgical approach and impingement of component-on-component or on fixed obstructions such as osteophytes.^{3,4,5,6} Weakness of the abductor muscles due to improper reconstruction can also be a contributing factor.^{7,8} In countering these factors, stability is often achieved at the expense of limb lengthening.

Over lengthening or shortening of the joint center can result in limp, back pain, increased risk of dislocation, revision and legal problems.

We see a number of trends that indicate hip joint instability remains a significant concern in THA outcomes: Big Heads, increased use of constrained sockets and development of expensive surgical navigation technology.



Component-on-component impingement.



Immediate Goals

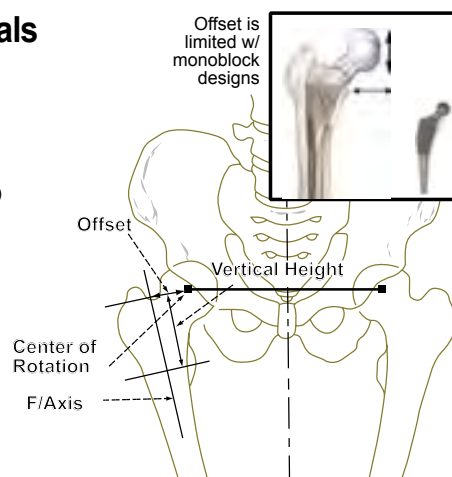
Eliminate Pain

- New hip

Restore Function

- Reproduce hip mechanics

1. Femoral Offset
2. Neck Length
3. Version Angle



Two Remaining Significant Problems in THA



#1 Dislocation



#2 Wear Debris/Lysis



Methods

To study the influence of implant geometry on tissue balancing and joint stability, the authors selected a stem system that permits the independent selection of lateral offset, version and leg length. This study presents the short term results of this experience.

957 THA's were performed using the Apex Modular™ Stem, beginning in May 2001. 842 were primary and 115 were revision cases. All were performed using the posterior approach. Acetabular implants from a variety of manufacturers were employed. All cases were fully cementless. Data on stem, neck and head selection were available for 800 of these cases. Head centers were plotted in bubble chart format.



Instability - What should be done? Trail reduction demonstrates joint instability with slight increased leg length.



Modular Heads allow length adjustment, unfortunately increase head length increases leg length.



Big Heads! Theoretically, a bigger head is more stable... At the extremes of motion when the neck impinges In this case, intrinsic stability is unchanged (Head center stays the same).



Biomechanical Solution Modular Neck! Add offset for joint stability reduce length for proper gait.

Design

Apex Modular™ Stem

- Modular necks for optimized lateral offset, leg length, and anteversion
- Key-hole proximal geometry with steps for good fill and initial stability
- Circumferential plasma sprayed CP titanium coating
- Distal slot(s) for reduced end stem stiffness
- No skirted heads
- Modular design allows for large selection of necks, to achieve proper combination of lateral offset, leg length, and anteversion
- Dual Press™ connection* is simple, robust, and stable
- Indexing permits neutral, and $\pm 13^\circ$ anteversion



Dual Press™

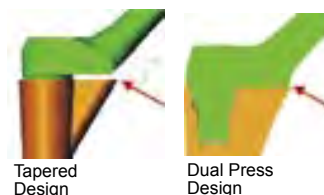
The Dual Press modular junction employs two areas of cylindrical press-fit*.

To create a mechanical lock, the proximal and distal diameters of the peg are slightly larger than the corresponding holes in the stem, creating two bands of interference, or "press-fit".



Dual Press™ vs Taper

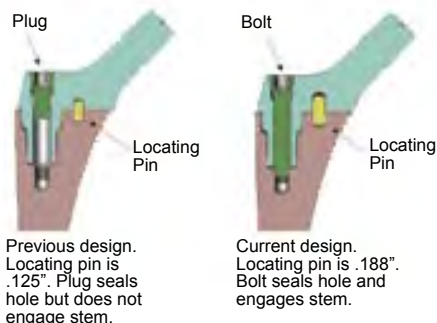
- Taper connection necessitates leaving a gap
- Apex's Dual Press™ connection allows neck to fully seat*
- Stem provides medial support, which increases strength and allows higher lateral offsets



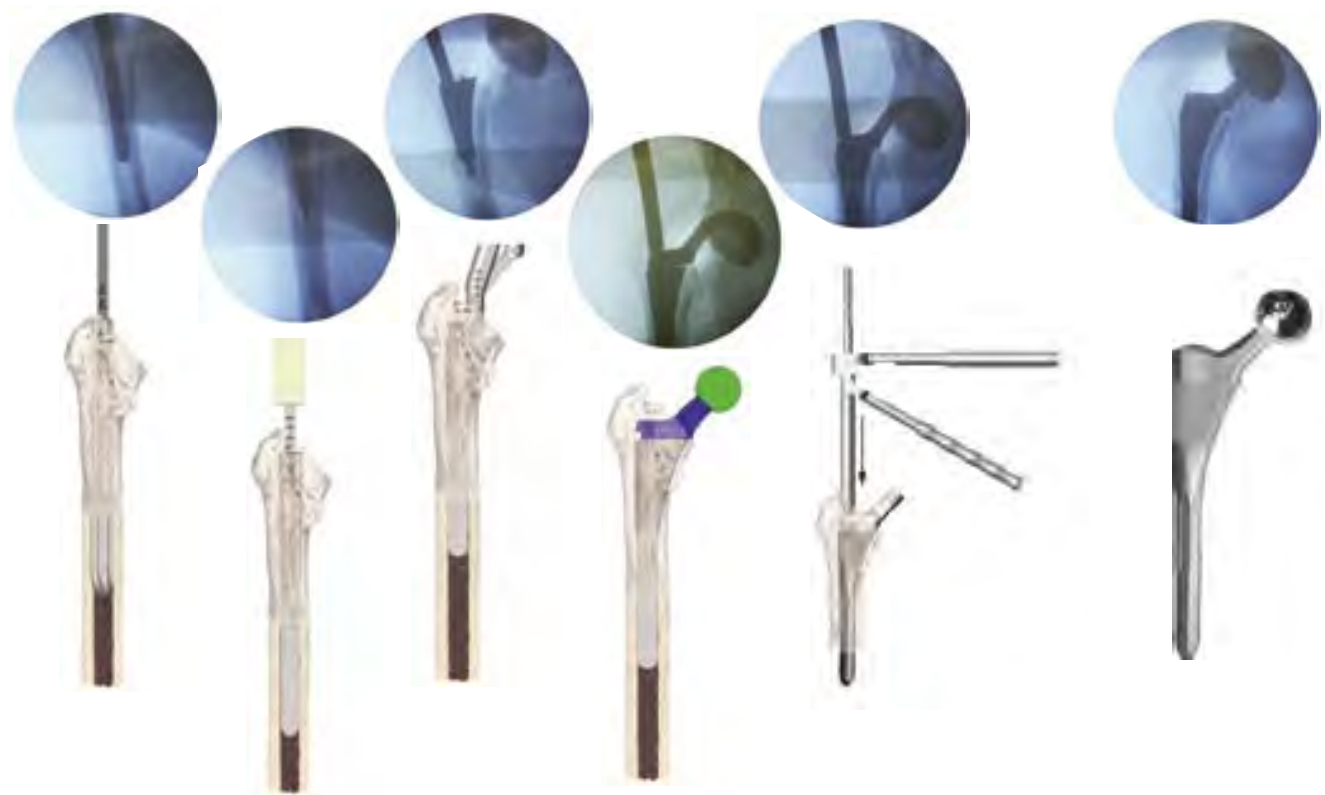
Improvements Made

Pin strength:

Old- 95 ft-lbs New- 210 ft-lbs



Surgical Technique



Typical 15 - 40° more ROM with neck anteverted.



Neutral neck position.



13° anteversion.



13° anteversion



0° neutral



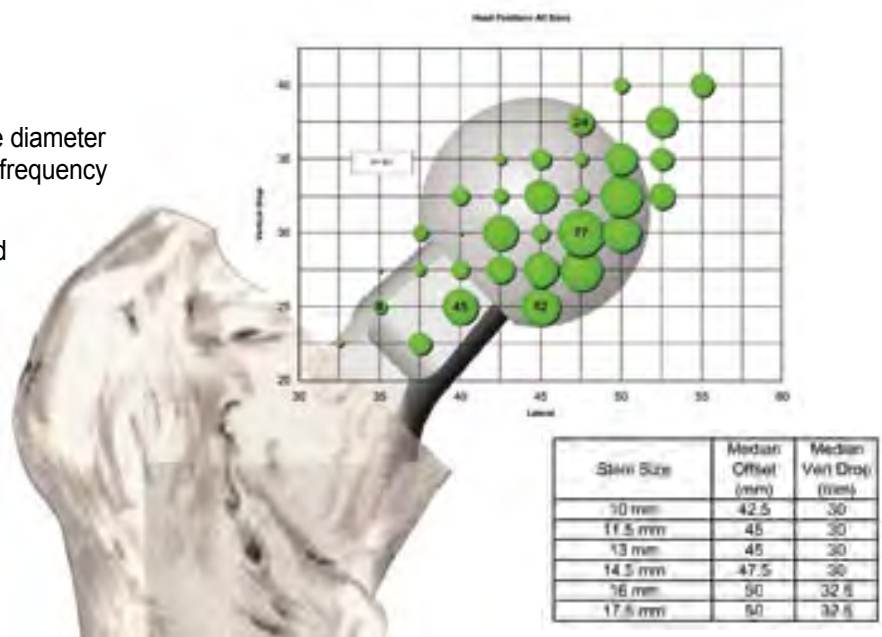
13° retroversion

Anteverted neck used 18 times in the first 200 cases.

Results

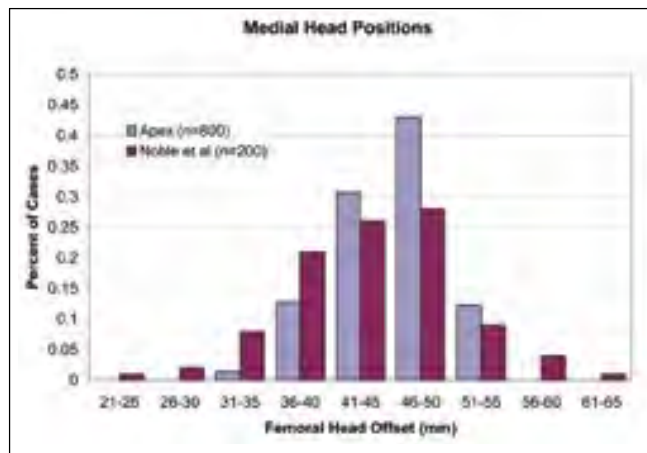
The center of the bubble is head location; the diameter is an indication of frequency. Representative frequency values are given for several locations.

The head center location data clearly showed that a wide variety of offsets and lengths are required to properly balance the soft tissues. Further, when the data were sorted by distal stem diameter, it was clear that there is little correlation between head center location and stem size. Further, a significant number of small (10 mm or 11.5 mm) stems required large (>45 mm) offsets.^{Table 1}



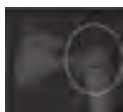
Results (continued)

Lateral offset data are available in the literature for cadaver femora. We plotted our data on the same scale for comparison. The similarity of the lateral offset distribution confirms the appropriateness of the surgeons' head center selections.



1 Noble, Philip C., M.S., Alexander, Jerry W. B.S. et al, "The Anatomic Basis of Femoral Component Design", Clinical Orthopedics and Related Research, Number 235, October, 1988.

- 3 stem's locating pins failed (0.3%)*



- 2 dislocations (0.2%)**



- 0 significant length inequalities (+/- 5mm)

- 14 intra-operative fractures***



- 0 significant thigh pain



- 10% version indexed



13° anteversion

*All three required revision of stems. One replaced with same device, one replaced with cementless monoblock and one replaced at different center.

**One of the dislocations was treated conservatively after closed reduction and went on to an unremarkable course. The second had received a neck in the anteverted position and dislocated anteriorly. The surgeon chose to reoperate, remove the modular neck component and reinsert it in the neutral position, after which the patient rehabilitated normally.

***Intra-op fractures were encountered during first twelve months during instrumentation development (all wired without compromise to recovery).

Discussion

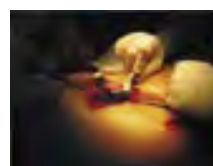
Restoration of normal joint biomechanics on a consistent basis was possible using the Apex Modular™ Stem because of the intra-operative versatility that stem system offers in regards to head center location when compared to monoblock stems. It combines the fit and fill features of today's contemporary cementless stems with updated modular components that provide for independent offset, version and leg length adjustments. This unique modular design allows for a large selection of proximal bodies to enable targeted implant selection for the restoration of proper soft tissue tension and joint biomechanics. Continued long-term follow up will provide additional information to aid in validation of this design concept.

Summary

- Modular neck design aids in fine tuning joint mechanics
- Works with all surgical approaches
- Allows for femoral stem insertion first (aids in reducing blood loss)
- Allows for ease and access in case of revisions
- Reduces chances of mechanical impingement of implants with mini-incision surgical approaches



Anterior-mini incision



Neck placement



Dual Press™ modular stem implanted

Conclusion

The head location data suggest that hip joint reconstruction benefits from the availability of many head centers for every stem size. This may be accomplished with a large inventory of sizes or with a modular device. Review of 957 hips implanted for both primary and revision cementless application leads the authors to conclude that this "Dual Press™" proximal modular stem design is safe, effective and provides for a more accurate approach for reconstructing the biomechanics of the hip.



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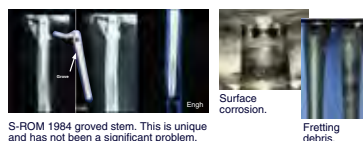
Defining The Role Of Modular Stem Designs In THA

Froehlich, J.A.¹, McTighe, T.², Cameron, H.U.³, Keggi, K.⁴, Keggi, J.⁴, Kennon, R.⁴, Woodgate, I.⁵

Introduction

Modularity or multi-piece stems are becoming commonplace in THA with virtually all implant companies offering one version or another. Therefore the role of modularity would seem to be firmly established, but what if any limits or contraindications should be considered in light of increased patient related activities?

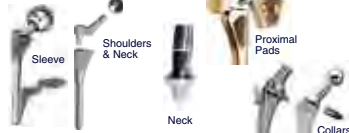
During the 1980's concern was expressed that the use of a modular stem might produce fretting leading to osteolysis and component failure.



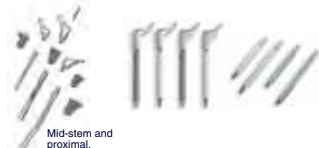
The early nineties saw a number of first and second-generation modular stems come and go. It is important to understand the specific design features and goals of modular total hip stems and not to lump all designs into one simple category "Modular Stems". In fact, modular sites, designs, features, material and quality can be quite different in nature and sophistication.

Modularity Classification

Proximal



Mid-stem



Distal



Multi-Modularity

Some devices have one or more modular junctions. The RMS was one example of Multi-Modularity that provided up to six modular interface sites.

Methods

This paper is a follow-up to previous work by the authors intended to be a concise review of historical perspective, current trends, surgical experience, and results in using a variety (seven) of modular stems.

Surgeon authors have implanted over 3,000 modular stems since 1984 for both primary and revision THA. This paper will highlight experience for 2,248 stems used for primary THA in both cemented and cementless cases as they relate to femoral component failure (fracture).

1. S-Rom (JMPC/DePuy)
1155 stems implanted.
2. Apex Modular (Straight Stem)
500 stems implanted.
3. K2 Apex (taper stem)
109 stems implanted.
4. OTI/Encore R-120 cemented stem
245 stems implanted.
5. OTI/Encore R-120 porous cc cementless stem
82 stems implanted.
6. UniSyn (Hayes Medical)
50 stems implanted.
7. Cremascoli Modular Neck (Wright Medical)
107 stems implanted.

Unsupported Stems Will Fail Regardless of Fixation/Material/Design

(cement/cementless/monoblock/modular)
Bechtol described this failure mode in the 1970's.

Available implant material cannot support high BMI and high patient activity in the absence of bony (structural) support.



Results

12 femoral component failures have occurred

2 in a c.c. proximal modular neck cemented stem (fig. A).



Figure A. Fractured neck.



Figure B. Pin fragment.

10 in a proximal modular titanium shoulder neck cementless stem (fig. B).

Both of these devices were immediately discontinued from clinical use by the authors until redesigned and strength properties significantly improved.

Problems

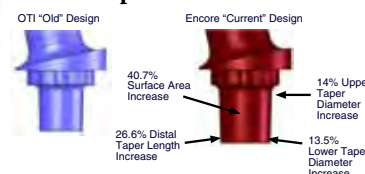
Femoral component fractures historically are a result of fatigue failure as the fractured neck show in Figure A.

However, we are beginning to see high impact static- shear failure of femoral components as shown in Figure B (torsional failure of locating pin).

OTI/Encore Modular Neck



Encore Improvements



Fatigue Testing Results

Fatigue Strength @ 5,000,000 cycles

OTI Design 520-700 lbs.

Encore Medical Design > 1200 lbs.

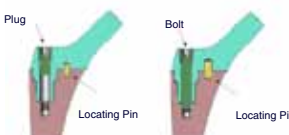
Apex Neck Retrievals

All retrieved stems that we have been examined suggest quasi-static shear failure of the alignment pin – a single high load (high torsion) event.

Apex Improvements

Pin strength:

Old- 95 ft-lbs New- 216 ft-lbs



Pin diameter has been increased from .125" to .188" along with added feature of a bolt that engages the stem. This has resulted in +225% increase in pin shear strength.

Conclusion

Authors remain enthusiastic about the use of modularity and surgeon co-authors continue to use modular stems as part of their routine treatment of THA. It is important to remember all devices are subject to failure. It is also necessary to recognize design and material limits and not to over indicate in high risk patients.

Warn your patients that device failure is directly linked to activity and BMI.

Recognize required technique for specific modular designs and do not attempted to change surgical technique and component selection at the same time.

Revisions are always with us – select devices that take retrievability into account.



¹University Orthopaedics, Inc., Providence, RI



²Joint Implant Surgery and Research Foundation

17321 Buckthorne Drive
Chagrin Falls, OH 44023
440-543-0347
www.jisrf.org



³Orthopaedic & Arthritic Institute, Toronto, CA



⁴Keggi Orthopaedic Foundation, Waterbury, CT



⁵Ian Woodgate
Sydney, AU



"Within Any Important Issue, There Are Always Aspects No One Wishes To Discuss" – Femoral Component Failure

Keggi, K.¹, Keggi, J.¹, Kennon, R.¹, Tkach, T.², Low, W.², Froehlich, J.³, McTighe, T.⁴, Cheal, E.⁵, Cipolletti, G.⁵

Introduction And Aims

Complications still occur in THA. One of these complications continues to be femoral component failure.

This subject needs more open discussion. The literature documents examples that unsupported stems will fail regardless of fixation, material, and design but has not recently addressed the risk due to increased patient activity.

Metal fatigue is caused by repeated cycling of the load. It is a progressive localized damage due to fluctuating stresses and strains on the material.

Metal fatigue cracks initiate and propagate in regions where the strain is most severe.

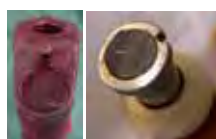
The process of fatigue consists of three stages:

- Initial crack initiation
- Progressive crack growth across the part
- Final sudden fracture of the remaining cross section

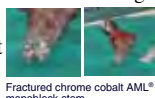
All devices are subject to fatigue failure especially with the increased patient activity we are seeing today. There are reports of device failure regardless of material, and regardless of design style (monoblock, modular). Recent reports of failures of modular revision stems have led to more vigorous testing and the development of implants with stronger modular junctions. In addition stems have been designed with greater ability for bony fixation above the modular junction. It is anticipated that modular stems which allow for fixation above and below the modular junction should be less susceptible to late failure of those junctions. Recognizing design and material limits is part of the surgeon's responsibility in choosing the appropriate implant.



Fatigue failure c.c. modular neck.



Fractured titanium modular neck.



Fractured chrome cobalt AML[®] monoblock stem.



Fractured titanium SROM[®] stem.



Ps. c.c. cemented Ps. Bridge[®] Titanium Cement Ps. c.c. cementless

Reducing Fatigue Failure

The most effective method of reducing fatigue failure is to make improvements in design:

- Eliminate or reduce stress raisers by streamlining the part;
- Avoid sharp surface tears resulting from punching, stamping, shearing, or other processes;
- Prevent the development of surface discontinuities during processing;
- Reduce or eliminate tensile residual stresses caused by manufacturing;
- Improve the details of fabrication and fastening procedures.

There are a number of methods available to a manufacturer to increase fatigue strength and reduce fretting wear. However, no individual design, material, or process offers absolute guarantees with regard to mechanical failure given the increased popularity of high-impact activities in today's lifestyles.

Methods

1,568 cementless stems were implanted since June 2000 for primary THA featuring a proximal modular neck design. All were implanted in six separate centers by eight surgeons. Twenty-two femoral component failures (locking pins) occurred between 13 to 50 months post-operatively. Each center used a different surgical approach (posterior, anterior muscle sparing, modified direct lateral) and a variety of cups and bearing surfaces.

All cases were reviewed as to surgical technique; implant size, patient activity and examination of retrieved device.

Material

Apex Modular[™] Stem Design

- Modular necks for optimized lateral offset, leg length, and anteversion
- Key-hole proximal geometry with steps for good fill and initial stability
- Circumferential plasma sprayed CP titanium coating
- Distal slot(s) for reduced end stem stiffness
- No skirted heads

- Modular design allows for large selection of necks, to achieve proper combination of lateral offset, leg length, and anteversion
- Dual Press[™] connection is simple, robust, and stable
- Indexing pin permits selection of neutral, and 16° anteversion position



Dual Press[™]

The Dual Press modular junction employs two areas of cylindrical press-fit.



To create a mechanical lock, the proximal and distal diameters of the peg are slightly larger than the corresponding holes in the stem, creating two bands of interference, or "press-fit".



Apex's Dual Press[™] connection allows neck to fully seat. Stem provides medial support, which increases strength and allows higher lateral offsets.

Results

Twenty-two locking pins were sheared resulting in torsional instability of the proximal modular junction. Patient's complaint of an initial popping sound associated with a sense of hip instability was consistent in all. Pain was mild to moderate with initial x-ray appearance normal.



Surgical intervention found locking pin to be sheared with rotational instability of the proximal neck and black staining of tissue due to metal debris. Twenty-one stems have been revised with standard length cementless stems of a variety of designs. All have gone on to full recovery. One patient is not a surgical candidate and is not experiencing any significant pain.



No material or fabrication defects were found. No surgical errors were found. Mechanical testing demonstrated safety levels to be beyond published activity loads. The culprit (in most cases) appears to be patient activity.

Stem Removal

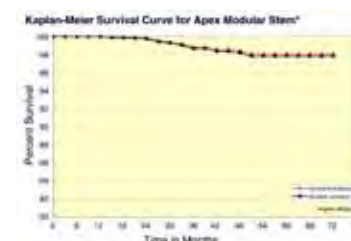
Components are designed with an axial extraction feature that facilitates removal. This allows preservation of proximal bone stock for re-implantation.



Retrieved stem.

Apex Neck Retrievals

All retrieved stems that we have been examined suggest quasi-static shear failure of the alignment pin – a single high load (high torsion) event. There is no evidence of fatigue failure as described earlier.

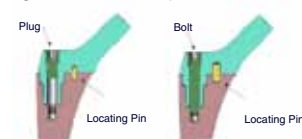


Kaplan-Meier survival analysis indicates a 98% survival at six years, including these mechanical failures.

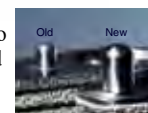
Apex Improvements

Pin strength:

Old- 95 ft-lbs New- 216 ft-lbs



Pin diameter has been increased from .125" to .188" along with added feature of a bolt that engages the stem. This has resulted in +225% increase in torsional strength.



Conclusions

Historical published reports on torsion loading along with BMI have been underestimated. Increased patient activities are subjecting devices to unprecedented load levels.

Current patient activities generate excess of 95 ft pounds of torque. This review should be helpful in stem selection and increased warning guidelines as to patient activities.



⁴Keggi Orthopaedic Foundation, Waterbury, CT



²McBride Clinic, OKC, OK



³University Orthopaedics, Inc., Providence, RI



²Joint Implant Surgery and Research Foundation



⁵Omniflife Science, LLC., Raynham, MA



THE JOURNAL OF BONE AND JOINT SURGERY

VOLUME 88-B 2006

Orthopaedic Proceedings

SUPPLEMENT II

This comparison shows that changes in surgical technique can limit the subsidence seen with tapered stems used in revision total hip replacement. No bone grafts were used in either series, only small changes in bone preparation, and prosthesis selection were used. The outcome as determined by the OHS was similar in both groups.

OGILVIE'S SYNDROME: A RARE AND SEVERE COMPLICATION AFTER TOTAL HIP JOINT REPLACEMENT

A. Vane, T. Lamberton, and A. Heath
Tauranga, New Zealand

We present two cases of Ogilvie's syndrome and to raise awareness of this rare but serious complication.

Methodology: Analysis of two recent cases at our institution. Subsequent 3 year retrospective audit of all joint replacement in Tauranga Hospital and analysis of patient records with a recorded gastrointestinal complication.

We report on two recent cases of Ogilvie's Syndrome (acute colonic pseudo-obstruction) with subsequent caecal perforation after THJ. Case 1: A 49 year old woman underwent THJ for osteoarthritis. Postoperatively developed abdominal pain and distension. Underwent laparotomy for a perforated caecum 10 days following THJ. Died 24 hours later. Case 2: A 73 year old man underwent a revision THJ. Postoperatively developed a distended abdomen. Underwent laparotomy and caecostomy 10 days after THJ. Discharged 29 days after admission. Both cases had GA and spinal anaesthetics with intrathecal Morphine. Both failed to settle with conservative treatment. There was no mechanical obstruction in either case. Audit figures showed 21 other cases of non-mechanical bowel obstruction after hip or knee arthroplasty.

Ogilvie's Syndrome is a rare "malignant" form of postoperative pseudo-obstruction characterised by massive dilatation of the large bowel which, if untreated, results in caecal perforation. It is rare following joint arthroplasty but if occurs has a high morbidity and mortality. Prompt recognition of the presenting features by orthopaedic surgeons with expedient general surgical intervention is necessary to avoid potentially fatal consequences.

EARLY SUBSIDIENCE OF UNCEMENTED ACCOLADE STEM TOTAL HIP JOINT REPLACEMENT

S. Andrews, S. Bentall, and D. Atkinson
Napier, New Zealand

To measure for evidence of early subsidence of Accolade tapered uncemented femoral stems. To quantify any subsidence and to identify factors which may predispose to this.

A retrospective audit of patients who have received Accolade stem total hip joint replacement in Hawkes Bay Hospital from October 2003 to October 2004. Post operative and follow up x rays (within one year of surgery) were reviewed and position of femoral component in the femur was measured and adjusted for magnification and angulation.

Thirty-eight patients were identified. Patients age averaged 66 years old (44 - 82yo). Results show an mean subsidence of 2.8mm with a range of 0 - 13mm.

There is evidence of early subsidence of Accolade femoral stems. In cases of large subsidence under sizing of the femoral component was identified as the most significant contributing factor.

MANAGEMENT OF INFECTED TOTAL HIP ARTHROPLASTY

P. O'Grady, Y. Lodihi, D. Bennett, and P. Keogh
Dublin, Ireland

Total hip arthroplasty has improved the quality of life for many patients with osteoarthritis. Infection is a serious

complication, difficult to treat and often requires removal of the prosthesis to eradicate the infection.

An analysis of the surgical management, risk factors, complications and outcome of infected total hip replacements. Thirty one consecutive patients underwent revision hip arthroplasty for infection between 1997 and 2003. Risk factors, co-morbidity, clinical presentation, biochemical profiles, microbiology, management and radiology were recorded. Outcome and complications following surgery are reviewed. Classification of infection after total hip arthroplasty was based on their clinical presentation—early postoperative, late chronic, or acute haematogenous infection, and positive intraoperative cultures.

All patients underwent resection arthroplasty. 26 had a two-stage revision, 1 had a three stage, 4 did not have a re-implantation. Staph Aureus was the most common organism identified, 16 patients were classified as late chronic infections, 8 early post operative infection, 6 acute haematogenous and 1 occult intraoperative. Average total blood loss was 5 litres, average replacement was 7 units. 1 patient had a persistent infection, 3 underwent further surgery for dislocation, stem perforation or fracture. 5 patients had a persistent limp.

In infected revisions the bone stock is usually adequate, the soft tissues are very poor. Bivalving the femur allows for optimal cement removal. Blood loss can be significant with average replacement of 7 units. Meticulous removal of infected components, cement and tissue is essential for good long-term results.

TARGET RESTORATION OF HIP MECHANICS IN THA

T. McTigue, W. Low, T. Tkach, and G.B. Cipriotti
Chagrin Falls, Ohio, USA

Dislocation continues to be a significant problem in THA. Instability due to improper reconstruction of the abductors can be a contributing factor.

Eight hundred primary THA's were performed over the past four years utilizing a proximal "Dual Press"TM cementless porous coated modular stem. This design allows for a large selection of proximal bodies that enable the restoration of proper soft tissue tension and joint biomechanics after the stem is inserted.

Data on stem, neck, and head centers were available for 600 of these cases. Head center locations were tabulated and compared to data from the literature.

The head center location data clearly showed that a wide variety of offsets and lengths are required to properly balance the soft tissues. Further, when the data were sorted by distal stem diameter, there is little correlation between head center location and stem size. All were performed utilizing the posterior approach and used without bone cement, 3 fractured stems, 2 dislocations, 14 intra-op fractures, no significant leg length inequalities (± 5 mm), and 10% indexed to a position other than neutral.

Restoration of joint mechanics was possible using this proximal modular "Dual Press"TM stem due to the intra-operative versatility offered in regards to head center location when compared to monoblock stems. The data suggest that hip reconstruction benefits from the availability of many head centers for every stem size. The authors conclude that this proximal modular design provides for a more intra-operative accurate approach for reconstructing the biomechanics of the hip.

THE ROLE OF MODULARITY IN PRIMARY THA - IS THERE ONE?

T. McTigue, L. Keppler, and H. Cameron
Chagrin Falls, Ohio, USA

Concern was expressed that the use of a modular stem might produce fretting leading to osteolysis, and component failure. The goal of this study was to document the variability of this design by looking at the long-term i.e. 5-17 year follow-up of the use of a Proximal Modular Stem in primary cases.

A cohort of 955 (S-ROM) primary cases have been followed prospectively and rated clinically using the

Harris Hip Score and radiologically after the fashion of Grison. The mean age was 53. Followup was 5.17 years (mean 8.5).

Aseptic loosening requiring revision occurred in three cases (0.3%). One a non-union of a subtrochanteric osteotomy. Two others, one for fracture at the stem tip and one for fracture of the proximal part of a subtrochanteric osteotomy. Harris rating was 78.2% excellent, 16.4% good, 2.3% fair and 3.1% poor. Gruen rating, no lucency in 98.8%, low grade in 1.1% and high grade in 0.1%. Distal osteolysis occurred in two cases. Six patients had persistent thigh pain (type C bone) that was treated by onlay-strut grafts.

There have been no cases of device failures. Other than in the two loose cases distal osteolysis has not been seen. It would appear therefore that the sleeve does act as an adequate seal. There have been no cases of late aseptic loosening and limited thigh pain in type C bone. The authors concluded that this modular device is safe, effective and continue to recommend its use in primary THA.

MODULAR STEMS FOR REVISION THA

T. McTigue, H. Del Schutte, H.A. Demos, and N.C. Romero
Chagrin Falls, Ohio, USA

Traditionally the most commonly used femoral implants in revision hip arthroplasty are distally fixed monoblock designs. Ability to adjust length version and offset is limited once the stem is inserted. Revision using this type of stem has been associated with high incidence of complications including dislocation. Modular distally fixed femoral implants have been developed in order to decrease the complication rate by restoring normal hip mechanics. The goal of this study is to evaluate the performance of these type stems as it relates to fixation and instability.

Seventy three revisions were done using three modular stem designs. All stems were common in design featuring a proximal cone shape body attached by a taper to a fluted distal stem. Revisions were performed for loosening, periprosthetic fractures and infections. Most revisions were in patients with severe bone loss. Follow-up range from 6 to 72 months with an average of 30 months. Parameters evaluated included fixation and instability.

In this series we obtained excellent bony fixation as well as an acceptable dislocation rate in revision of severely compromised femurs. There were no stem fractures at the modular junction at early follow-up. Dislocation was readily managed by revision of the proximal portion of the stem without compromising distal fixation. This study demonstrates that modular approaches can be used successfully.

ANTERIOR KNEE PAIN ASSOCIATED WITH ARTHROSCOPIC ACL RECONSTRUCTION - A PROSPECTIVE COMPARATIVE STUDY OF TWO METHODS

R. Treggoning
Wellington, New Zealand

The aim was to compare anterior knee pain (AKP) before, and after hamstrings (HS, n = 65) and bone-patellar tendon-bone (B-PT-B, n = 94) ACL reconstructions.

The same questionnaire (modified from Sheffbourne et al 1997) was answered by patients before, and at least 12 months after surgery. Questions covered five main categories of pain i.e. during prolonged sitting, stair climbing, kneeling, sport or vigorous activity, and ADL.

There was no statistical difference in the two groups in overall AKP scores before surgery. After surgery, there were improvements in this overall score in both groups, but the improvement was statistically greater in the HS group (p = 0.02). Analysis of the five different pain categories showed no significant difference in the improvements in sitting, sport or ADL. In both climbing stairs (p = 0.009), and kneeling (p = 0.02) there were significantly greater improvements in the HS group.



171 Ashley Avenue
Charleston, SC 29425
834-792-2300
www.musc.edu



Joint Implant
Surgery and
Research
Foundation

17321 Buckthorne Drive
Chagrin Falls, OH 44023
440-543-0347
www.jisrf.org

Modular Stems for Revision THA

By H. Del Schutte, Jr., M.D., Harry A. Demos, M.D., Neil C. Romero, M.D., Timothy McTighe, Ph.D. (hc)

Introduction

Revision hip arthroplasty has become an increasingly common surgical procedure. Approximately 100,000 joint revisions are done per year in the United States and reports indicate an increase of 11-13% in 2004¹². Recently there has been an increase in the use of distally fixed proximal modular stems in an attempt to decrease the implant and joint instability and offset problems occurring during revision hip arthroplasty.

The most common cause of proximal bone loss is due to osteolysis and aseptic loosening, resulting in a variety of femoral deficiencies that makes revision surgery more difficult^{3,15}. The following assessment system has proven to be helpful for selection of specific implant design features.

Area of Concern - Fatigue Strength

All devices are subject to fatigue failure especially with the increased patient activity we are seeing today. There are reports of device failure regardless of material, and regardless of design style (monoblock, modular). Recent reports of failures of total hip stems have led to more vigorous testing and the development of implants with improved material properties. In addition stems have been designed with greater ability for bony fixation at all levels of the stem. It is anticipated that all stem designs which allow for better fixation have the potential to be less susceptible to late failure. Recognizing design and material limits is part of the surgeon's responsibility in choosing the appropriate implant¹⁶.

The issues of fatigue, fretting and corrosion are areas that we are all

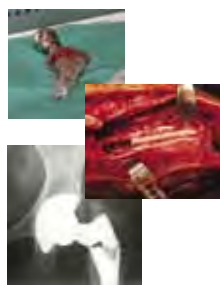


Restoring Hip Mechanics

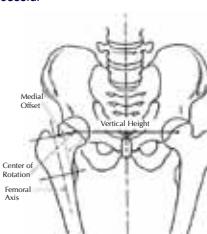
Restoration of hip joint mechanics is critical to a successful outcome for all total hip reconstruction¹⁸.

Correction of femoral head offset affects the joint reaction line and helps restore mechanical balance between adductor forces^{7,12}. If the offset is too short it will result in increased resultant forces across the hip joint, and possibly increase limp⁷. Offset too great will increase torsional and bending forces on the femoral implant.

Vertical height too short can jeopardize joint stability and if too long can result in nerve palsy and patient complaints. Incorrect version angles can impact range of motion resulting in implant impingement, joint dislocation, and increased generation of particulate debris.



Examples of increased patient activity.



Range of Motion

Two factors that can affect range of motion are component positioning and component geometry^{2,15}. Head diameter, neck shape and skirts on femoral heads can all affect hip range of motion¹³. Although physiological range of motion varies for each patient an average of 114° of flexion is required for sitting. There is no question that certain activities require a greater degree of motion.



Major Problems

Two major problems in revision hip surgery are joint stability and correction of leg length. According to Dr. Hugh U. Cameron the most significant medical/legal concern in THA is leg length discrepancies. Estimating dislocation rates of both 2% and 10% there would be a corresponding 6 to 30 thousand dislocated hips each year. Subsequently total cost of dislocations in the U.S. would be \$64.522 to \$322.5 million respectively.



Leg length.

Hip Dislocation.

Implant Selection

The Restoration® Modular Stem system allows for independent selection of proximal bodies and distal stem styles and lengths. The mixing and matching of the modular components provide significant versatility in treating femoral deficiencies. The proximal body is attached by means of a taper lock that has received proprietary processing (shot peening) yielding higher fatigue, fretting and torsion results.

This poster will focus on our experience using the cone-shaped proximal bodies of the R/M Cone, RT3 and Link MP™.

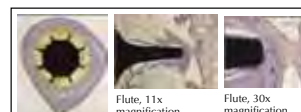
Fifty Restoration® Stems were used for revision of indexed primary stems, secondary revision stems, and infections. A variety of bone deficiencies were encountered from minor bone loss (type 1) to extreme (type 4) requiring both impaction and strut grafts.

Of the fifty, thirty-five stems were the original T3 design, fifteen stems were the new Restoration® Modular cone, and twenty-three Link MP stems.

Distal Stems

Distal stems of the Restoration® Modular are available in three different styles including fluted, plasma coated, and conical straight taper stem. All stems are available in a variety of lengths and styles (straight and bowed). Our experience is with the conical stem.

The fluted distal stem of the Restoration Modular is designed from the successful stem geometry of the Wagner stem that has demonstrated excellent bone adaptation as shown to the right in this retrieved specimen.



Retrieval 5.5 months after implantation, 65 year old, 85kg patient.

R.K. Schenk, U. Wirth, On the reaction of the bone to a cementless, 30 mm revision prosthesis, Orthopaed (1989) 18: 454-462

Results

- 99-02 23 Link MP
 - 1 stem fracture
 - 1 dislocation
 - 0 clinically observable subsidence or aseptic loosening
- 01-Current 50 restorations
 - 01-03 35 RT3
 - 04-Current 15 Restoration Modular
- 2 patients deceased
- 3 patients lost to follow-up
- 0 dislocation
- 0 fractures
- 0 revisions
- No measurable subsidence

Long-term data is necessary to clearly demonstrate the viability of modular revision systems. However, recent improvements to mechanical properties of the taper along with proven stem design features should aid the surgeon in restoring normal mechanics to the reconstructed hip.

Predictions and Concerns

- Modularity is here to stay
- Increased Patient Activity & BMI Influences Outcomes & Device Failure
 1. High Impact Yield Failure
 2. Long Term Fatigue Failure
- Increased Device Malposition due to Limited Exposure
- Increased Medical/Legal Exposure

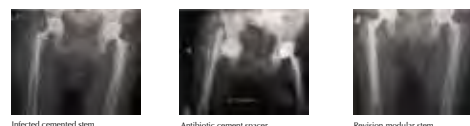
Final Comments

- All devices are subject to failure.
- Recognize design and material limits and do not over indicate.
- Warn your patients that device failure is directly linked to activity and BMI.
- Recognize required technique for specific modular designs and do not attempt to change surgical technique and device technique at the same time.
- Revisions are always with us – therefore select devices that take retrievability into account.



Loose cemented stem.

Revision restoration conical cone one year post-op.



Infected cemented stem.

Antibiotic cement spacer.

Revision modular stem.



Infected hip revision. Antibiotic cement spacer.

Revision modular stem with strut grafts.

Initial post-op.

Two months post-op.



Poster Exhibit
2005



McBride
Clinic

1110 North Lee
Oklahoma City, OK 73101
www.mcbrideclinic.com

(1) Orthopaedic & Arthritis
Center, McBride Clinic, 1110
North Lee, Oklahoma City, OK
73101, (2)



12 Harding St.
Lakeville, MA 02347
www.apexsurgical.com

(2) Managing Director Apex
Surgical, LLC, 12 Harding St.,
Lakeville, MA 02347



Joint Implant
Surgery and
Research
Foundation

17321 Buckthorne Drive
Chagrin Falls, OH 44023
440-543-0347
www.jisrf.org

(3) Executive Director, Joint
Implant Surgery & Research
Foundation, 17321 Buckthorne Dr.,
Chagrin Falls, OH 44023

Target Restoration of Hip Mechanics in THA

By: Tom Tkach, MD¹; Warren Low, MD¹; George B. Cipolletti, MS²; Timothy McTighe, Dr. H.S. (hc)³



Introduction: THA continues to improve but complications still occur. Dislocation continues to be a significant problem. The causes for dislocation can be multi-factorial, and include: mal-positioned components, soft tissue laxity, and impingement of component-on-component or on fixed obstructions such as osteophytes. Weakness of the abductor muscles due to improper reconstruction can also be a contributing factor. In countering these factors, stability is often achieved at the expense of limb lengthening.

To study the influence of implant geometry on tissue balancing and joint stability, the authors selected a stem system that permits the independent selection of lateral offset, version and leg length. This study presents the short term results of this experience.



Instability - What should be done? Trail reduction demonstrates joint instability with slight increased leg length.



Modular Heads allow length adjustment, unfortunately increase head length increases leg length.

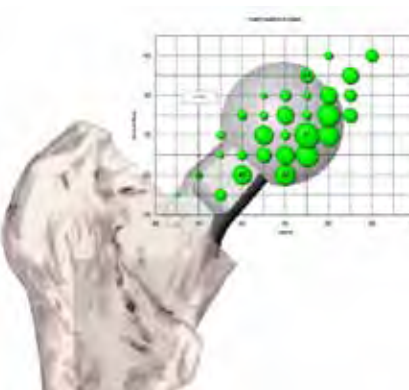


Big Heads! Theoretically, a bigger head is more stable... At the extremes of motion when the neck impinges in this case, intrinsic stability is unchanged (Head center stays the same).

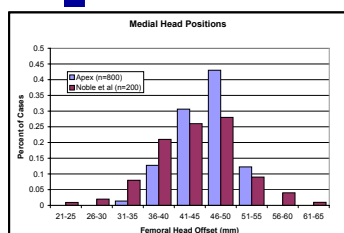


Biomechanical Solution Modular Neck! Add offset for joint stability reduce length for proper gait.

Methods: 957 THA's were performed using the Apex Modular™ Stem, beginning in May 2001. 842 were primary and 115 were revision cases. All were performed using the posterior approach. Acetabular implants from a variety of manufacturers were employed. All cases were fully cementless. Data on stem, neck and head selection were available for 800 of these cases. Head centers were plotted in bubble chart format. The center of the bubble is head location; the diameter is an indication of frequency. Representative frequency values are given for several locations.



Surgical Technique



1 Noble, Philip C., M.S., Alexander, Jerry W. B.S. et al., "The Anatomic Basis of Femoral Component Design", Clinical Orthopaedics and Related Research, Number 235, October, 1988.

Lateral offset data are available in the literature for cadaver femora. We plotted our data on the same scale for comparison. The similarity of the lateral offset distribution confirms the appropriateness of the surgeons' head center selections.

Stem Size	Median Offset (mm)	Median Vert Drop (mm)
10 mm	42.5	30
11.5 mm	45	30
13 mm	45	30
14.5 mm	47.5	30
16 mm	50	32.5
17.5 mm	50	32.5

Table 1

Results: In this clinical series, 3 stem's locating pins failed*, we observed 2 dislocations**, 14 intra-operative fractures***, no significant leg length inequalities (+/- 5mm), and no significant thigh pain. Approximately 10% were indexed to a position other than neutral version. Lateral offset data were tabulated and compared to data from the literature.

The head center location data clearly showed that a wide variety of offsets and lengths are required to properly balance the soft tissues. Further, when the data were sorted by distal stem diameter, it was clear that there is little correlation between head center location and stem size. Further, a significant number of small (10 mm or 11.5 mm) stems required large (>45 mm) offsets. Table 1

*All three required revision of stems. One replaced with same device, one replaced with cementless monoblock and one replaced at different center.

**One of the dislocations was treated conservatively after closed reduction and went on to an unremarkable course. The second had received a neck in the anteverted position and dislocated anteriorly. The surgeon chose to reoperate, remove the modular neck component and reinsert it in the neutral position, after which the patient rehabilitated normally.

***Intra-op fractures were encountered during first twelve months during instrumentation development.

Typical 15 - 40° more ROM with neck anteverted.



Neutral neck position.



15° anteversion.

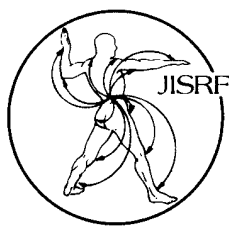
Anteverted neck used 18 times in the first 200 cases.

Discussion: Restoration of normal joint biomechanics on a consistent basis was possible using the Apex Modular™ Stem because of the intra-operative versatility that stem system offers in regards to head center location when compared to monoblock stems. It combines the fit and fill features of today's contemporary cementless stems with updated modular components that provide for independent offset, version and leg length adjustments. This unique modular design allows for a large selection of proximal bodies to enable targeted implant selection for the restoration of proper soft tissue tension and joint biomechanics. Continued long-term follow up will provide additional information to aid in validation of this design concept.

Conclusion: The head location data suggest that hip joint reconstruction benefits from the availability of many head centers for every stem size. This may be accomplished with a large inventory of sizes or with a modular device. Review of 957 hips implanted for both primary and revision cementless application leads the authors to conclude that this "Dual Press™" proximal modular stem design is safe, effective and provides for a more accurate approach for reconstructing the biomechanics of the hip. All current stems feature a larger, stronger locating pin and bolt.



Poster Exhibit
2005



Difficult Hip Revision Surgery, Can It Be Easier?

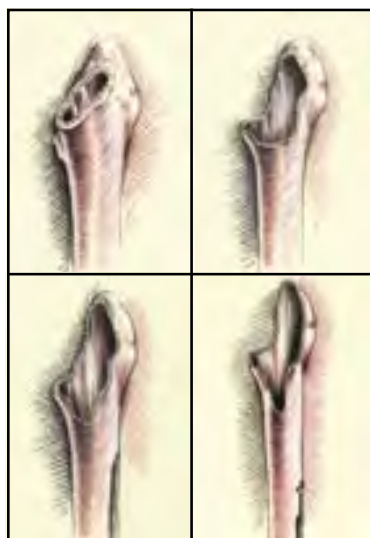
Introduction

By Timothy McTighe, Editor

Since 1971, by the pioneering efforts of its Founder Dr. Charles O. Bechtol, JISRF has brought to the orthopaedic community's attention new techniques, product and research tools in the effort to advance the practice and outcomes of total joint surgery²¹. This edition will highlight three new technologies that we believe can provide the community orthopaedic surgeon new approaches to making difficult hip revision surgery easier, more cost effective and provide for practical clinical outcomes.

Over the past thirty years, total hip revision surgery has become increasingly more sophisticated and demanding as we encounter more difficult and unusual situations^{15,20}. The use of autografts, allografts, modular and custom implants place a high demand on both the surgeon and the surgical team. The demands on experienced OR personnel place a higher cost on the procedure, as does the increased surgical time to perform hip replacement surgery. As a result, the Community Hospital sees no financial reward to offering this treatment modality to its local patients. This is becoming a significant problem to the local community requiring patients to travel greater distance placing more burdens on the family and the family's budget.

Understandably, cases involving difficult hip replacement do not lend themselves to scientific review with statistical analysis. They do, however, give an opportunity to discuss experiences with certain interesting and unusual problems^{6,7,20}.



THA has become increasingly more sophisticated and demanding as we encounter more difficult and unusual situations.

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Joint Implant Surgery and Research Foundation is a non-profit scientific and educational organization founded in 1971 by professor Charles O. Bechtol, M.D.

The foundation over its past 30 years has conducted CME activities for both surgeons and nurses while sponsoring clinical /surgical study groups, including basic science projects that have led to the development and marketing of significant Total Joint Replacement Implants.

Modular Revision Stems

This issue's Feature Article highlights the use of modular multi-component femoral stems in revision hip arthroplasty.

Modularity - does it seem confusing to you?



Modular total hip stems are not new but what is new is the idea of a comprehensive modular stem system that allows the surgeon to select the best possible design features intra-operatively with a simple reproducible instrumentation system. Remember it is important to understand the specific design features and techniques for each modular stem design and not to lump all designs into one simple category "Modular Stems". In fact, modular sites, designs, features, material, fabrication and quality can be quite different in nature and sophistication¹⁶.

There are many competitive revision modular stems currently on the market. Some have proximal modular features, and some mid-stem modularity. Most designs that featured distal modularity have been discontinued due to either poor performance or lack of clinical/ surgical need.



For additional information on cementless modular stems you can review May, 2002 JISRF Update Newsletter.

Also covered in this issue is a new approach to surgical retraction featuring a table-mounted system called Omni-Access™ from Omni-Tract Surgical.



Surgical exposure is always a challenge with revision surgery. This table-mounted device provides excellent exposure with features that place less traction on the skin edges, minimize bleeding and reduce the need for additional surgical assistants.

A new way of generating hard post-operative outcome data in a cost affordable manner is the IDEEA® LifeGait™ System (Intelligent Device for Energy Expenditure & Activity).



FEATURE ARTICLE

Modular Stems for Revision THA

By H. Del Schutte, Jr., M.D., Harry A. Demos, M.D., Neil C. Romero, M.D., Timothy McTighe, Ph.D. (hc)

Introduction

Revision hip arthroplasty has become an increasingly common surgical procedure. Approximately 100,000 joint revisions are done per year in the United States and reports indicate an increase of 11-13% in 2004¹⁰. In comparison to primary THA revisions are associated with a markedly increased technical difficulty, increased complication rate and cost. The primary challenge in revision hip arthroplasty is stable implant fixation in the face of significant bone loss. As this bone loss is most common in the proximal femur, the most widely used implants are those which obtain fixation in the distal diaphyseal bone. Traditionally, the most commonly used revision stems are distally fixed non-modular implants. The ability to adjust version, offset and length is limited once distal fixation is achieved. These constructs have association with markedly higher dislocation rates when compared to indexed THA. Primary rates running from 1.4% to 4.2% with a mean 3.1%. Revision rates range 3.2-10.5% with a mean of 9.4%¹⁴. Recently there has been an increase in the use of distally fixed proximal

modular stems in an attempt to decrease the implant and joint instability and offset problems occurring during revision hip arthroplasty.

The goals of revision surgery remain the same as primary arthroplasty: reduction of pain; equalization of leg length; restoration of movement; creation of joint and implant stability. However, to accomplish the reconstruction successfully, often requires the use of autografts, allografts and modular implants^{8,15}.

The most common cause of proximal bone loss is due to osteolysis and aseptic loosening, resulting in a variety of femoral deficiencies that makes revision surgery more difficult^{3,15}.

The AAOS and a number of authors have defined and classified femoral defects^{1,8}. Some of these classification systems are quite complex and require the need of a reference chart. Mattingly et. al., presented a modified AAOS classification system in a Scientific Exhibit "Revising The Deficient Proximal Femur" at the AAOS 1991 Annual Meeting. This system was helpful but still quite comprehensive. We prefer to use a simpler classification¹¹ that has proven to be helpful for selection of specific implant design features.

Assessment of Bone Loss

Type 1 - Minor Bone Loss

- The metaphysis is slightly expanded, but intact.
- There is minor calcar loss
- There is slight cavitory expansion
- The diaphysis is intact

Type 2 - Significant Bone Loss

- The metaphysis is comprised.
- Calcar is gone
- There is cavitory expansion
- Proximal bone is thin and incapable of structural support
- The diaphysis is intact

Type 3 - Massive Bone Loss

- Proximal cavitory and segmental bone loss extending to the diaphysis.
- Metaphysis and part of the diaphysis are deficient.
- The metaphysis offers no rotational stability.
- There is massive cavitory expansion.
- Implant stability is dependent on distal diaphyseal fixation.

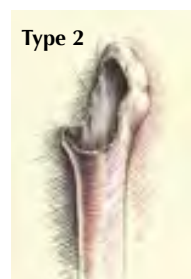
Type 4 - Extreme Bone Loss

- Extensive proximal circumferential segmental bone loss
- Extensive cavitory diaphyseal loss
- Extensive ectasia of the diaphysis.
- Compromised cortical bone requiring strut grafts.
- Segmental defects requiring strut graft and wiring
- Cavitory defects requiring impaction grafts.

Type 1



Type 2



Type 3



Type 4



While revision surgery is technically demanding, this paper will demonstrate that it is possible to achieve short term success in treating revision hip surgery with a new comprehensive modular revision cementless stem system.

Area of Concern

Fatigue Strength

All devices are subject to fatigue failure especially with the increased patient activity we are seeing today. There are reports of device failure regardless of material, and regardless of design style (monoblock, modular). Recent reports of failures of total hip stems have led to more vigorous testing and the development of implants with improved material properties. In addition stems have been designed with greater ability for bony fixation at all levels of the stem. It is anticipated that all stem designs which allow for better fixation have the potential to be less susceptible to late failure. Recognizing design and material limits is part of the surgeon's responsibility in choosing the appropriate implant¹⁶.



Fx. c.c. cemented

Fx. Bridge™ Titanium
Cemented

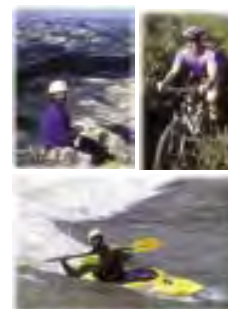
Fx. c.c. cementless

The issues of fatigue, fretting and corrosion are areas that we are all concerned with and need to know how our individual modular devices stack up. It is not possible for community based orthopaedic surgeons to know or be familiar with all the current standards for material testing but we do have a responsibility to demand and review from device manufactures appropriate material test on the devices we are using especially new materials and designs.



Patient activity is placing higher demands than ever before on total joint reconstruction and revision surgery is often the reality especially when one does not understand or appreciate the limits of design and /or material of the device that is selected.

It was not that long ago that we faced problems with modular acetabular cups, concern over corrosion at head/neck tapers and lysis generated by particulate debris due to fretting abrasion wear^{4,5}. Orthopaedic industry has made significant advances in high quality manufacturing and implant design that have resulted in increased product offerings.



Examples of increased patient activity.

There are a number of methods available to a manufacturer to increase fatigue strength and reduce fretting wear. However, no individual design, material, or process offers absolute guarantees with regard to mechanical failure given the increased popularity of high-impact activities in today's lifestyles.

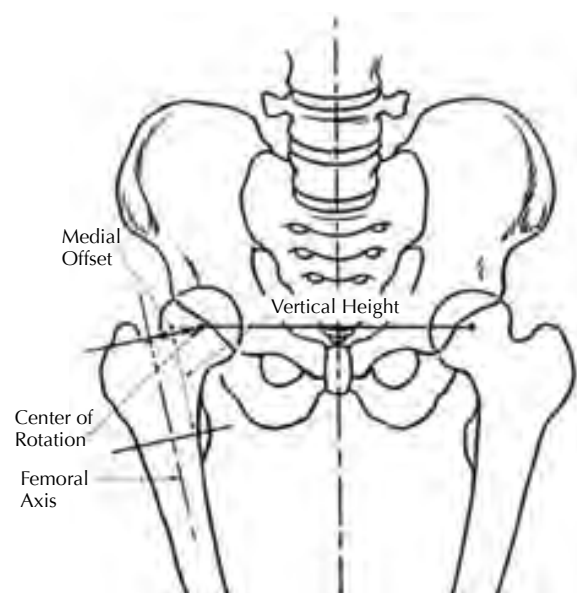
The modular junction of the Restoration® Modular Stem is designed to transfer loads over a large surface. Additionally, the manufacturer utilizes a proprietary shot peening process which enhances the taper junction to improve fatigue and long-term performance.



Restoring Hip Mechanics

Restoration of hip joint mechanics is critical to a successful outcome for all total hip reconstruction¹⁸. Correction of femoral head offset affects the joint reaction line and helps restore mechanical balance between adductor forces^{7,12}. If the offset is too short it will result in increased resultant forces across the hip joint, and possibly increase limp⁷. Offset too great will increase torsional and bending forces on the femoral implant.

Vertical height too short can jeopardize joint stability and if too long can result in nerve palsy and patient complaints. Incorrect version angles can impact range of motion resulting in implant impingement, joint dislocation, and increased generation of particulate debris.



Range of Motion Activities



Two factors that can affect range of motion are component positioning and component geometry^{9,13}. Head diameter, neck shape and skirts on femoral heads can all affect hip range of motion¹³. Although physiological range of motion varies for each patient an average of 114° of flexion is required for sitting. There is no question that certain activities require a greater degree of motion.



Major Problems

Two major problems in revision hip surgery are joint stability and correction of leg length. According to Dr. Hugh U. Cameron the most significant medical/legal concern in THA is leg length discrepancies. Estimating dislocation rates of both 2% and 10% there would be a corresponding 6 to 30 thousand dislocated hips each year. Subsequently total cost of dislocations in the U.S. would be \$64.5²² to \$322.5 million respectively.



Leg length.



Hip Dislocation.

Implant Selection

Immediate implant stability is necessary for cementless revision arthroplasty to work. Often to achieve implant stability the metaphysis must be bypassed and fixation achieved in the diaphysis. It has been previously reported that a constant proportional relationship is not present between the shape and size of the metaphysis and diaphysis. The revision situation results in additional alterations in the normal bony architecture, making fit and fill more difficult to achieve.

The Restoration® Modular Stem system allows for independent selection of proximal bodies and distal stem styles and lengths. The mixing and matching of the modular components provide significant versatility in treating femoral deficiencies. The proximal body is attached by means of a taper lock that has received proprietary processing (shot peening) yielding higher fatigue, fretting and torsion results.

This report will focus on our experience using the cone-shaped proximal bodies of the R/M Cone, RT3 and Link MP™.

Fifty Restoration® Stems were used for revision of indexed primary stems, secondary revision stems, and infections. A variety of bone deficiencies were encountered from minor bone loss (type 1) to extreme (type 4) requiring both impaction and strut grafts.

Of the fifty, thirty-five stems were the original T3 design, fifteen stems were the new Restoration® Modular cone, and twenty-three Link MP stems.



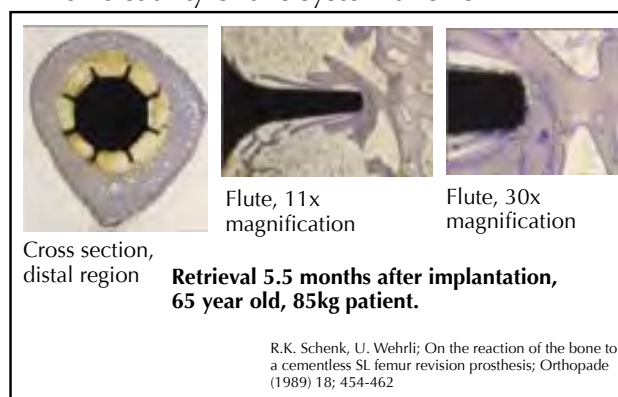
Distal Stems

Distal stems of the Restoration® Modular are available in three different styles including fluted, plasma coated, and conical straight taper stem. All stems are available in a variety of lengths and styles (straight and bowed). Our experience is with the conical stem.



The fluted distal stem of the Restoration Modular is designed from the successful stem geometry of the Wagner stem that has demonstrated excellent bone adaptation as shown to the right in this retrieved specimen.

The versatility of this system allows



interchangeability of the largest proximal body with the smallest stem. Although this is an extreme example this feature provides for dealing with femoral proximal/distal mismatch²⁰.



Examples of Difficult Cases



Infected cemented stem.



Antibiotic cement spacer.



Revision modular stem.



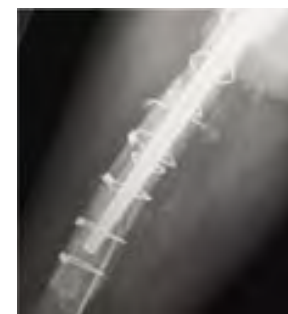
Infected hip revision.
Antibiotic cement spacer.



Revision modular stem with
strut grafts.



Initial post-op.



Two months post-op.



Loose cemented stem.



Revision
restoration
conical cone
one year
post-op.

Impaction
graph three
years post-
op.

Results

- 99-02 23 Link MP
 - 1 stem fracture
 - 1 dislocation
 - 0 clinically observable subsidence or aseptic loosening
- 01-Current 50 restorations
 - 01-03 35 RT3
 - 04-Current 15 Restoration Modular
- 2 patients deceased
- 3 patients lost to follow-up
- 0 dislocation
- 0 fractures
- 0 revisions
- No measurable subsidence

Long-term data is necessary to clearly demonstrate the viability of modular revision systems. However, recent improvements to mechanical properties of the taper along with proven stem design features should aid the surgeon in restoring normal mechanics to the reconstructed hip.

Predictions and Concerns

- Modularity is here to stay
- Increased Patient Activity & BMI Influences Outcomes & Device Failure
 1. High Impact Yield Failure
 2. Long Term Fatigue Failure
- Increased Device Malposition due to Limited Exposure
- Increased Medical/Legal Exposure

Final Comments

- All devices are subject to failure.
- Recognize design and material limits and do not over indicate,
- Warn your patients that device failure is directly linked to activity and BMI.
- Recognize required technique for specific modular designs and do not attempted to change surgical technique and device technique at the same time.
- Revisions are always with us – therefore select devices that take retrievability into account.

Surgeon Highlight



President Australian Orthopaedic Association

Dr. John M. Harrison

B.Sc.(Med) MBBS FRCS FRACS FAOrthoA FAMA FACSP



Medical politics has always been a special interest for Dr Harrison despite a busy orthopaedic practice. Before taking up a years term of office as National President of Australian Orthopaedics in October 2004,

Dr Harrison completed a three months tour as Honorary Manager and Doctor with the Australian Men's Water Polo team attending pre Olympic competitions in The United States and Europe. Being a past National Australian Water Polo goalie selected for the 1968 Mexico Olympics, attending the Athens Olympiad as an honorary official was a challenging experience from a different perspective.

Education

University of Sydney 1961 – 1969

Residency

JRMO Royal North Shore Hospital Sydney 1970
Mona vale District Hospital Sydney 1971
SHO St Bartholomews Hospital London 1972
JSR St Bartholomews Hospital London 1972-73
ASR St Bartholomews Hospital London 1973
OR Royal North Shore Hospital Sydney 1974
OR St George Hospital & R.A.H.C. Sydney 1975
SOR Prince of Wales Hospital Sydney 1976

Hospital appointments

Parramatta Hospital 1976-81
Lottie Stewart Hospital 1977
The Hills Hospital 1978-
Westmead Hospital 1978-84 / 89-94
Auburn Hospital 1981-84/89-93

Other appointments

Honorary Orthopaedic Surgeon:
NSW water polo 1978-83
Cumberland Cricket Association 1983-4
Member Board of Advice Hills Private Hospital 1992-7
Parramatta Rugby Union Club 1986-93
Hills district Rugby League Football Club 1992-5
Australian Women's Water Polo Side 1994-
Kellyville District Rugby League Football Club 1996-9
Austalian Mens Water polo Team (Manager) 2003-

Currently

Member

Co-ordinating Committee WorkCover NSW
Medical Liasion Committee AMA & Law Society NSW

National Chairman Australian Society of Orthopaedic Surgeons
President Australian Orthopaedic Association

Society Memberships:

Australian Orthopaedic Association
Australian Society Orthopaedic Surgeons
Australian Association of Surgeons
Australian Orthopaedic Foot and Ankle Society
Arthroplasty Society of Australia
Royal Australasian College of Surgeons
Australasian College of Sports Physicians
Sports Medicine of Australia
Australian Medical Association
American Academy of Orthopaedic Surgeons
Medico-Legal Society of NSW
Australian Academy of Medicine and Surgery
General Medical Council - London

A Table-Mounted Retraction System is Setting a New Standard For Hip Exposure the OmniAccess™ Hip Retractor System

By Hugh U. Cameron, M.B., C.H.B., Timothy McTighe, Ph.D. (h.c.)

The objective of retraction in surgery is to provide visualization. To do this, the tissues are pulled apart.

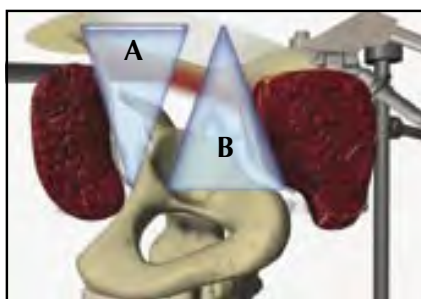
In joint replacement surgery, Homan retractors are commonly used. The point is fixed to a bony prominence and the assistant pulls on the handle. Because they are fixed to bone close to the area to be visualized, e.g. the acetabulum, the hole or viewing port produced is shaped like a truncated wedge.

This results in greater retraction on the skin and superficial tissues than on the deep tissues so that the skin incision is much longer than the inner incision.

Right angle retractors held by the assistant are safer than Homans as they do not have a sharp tip and thus potential damage to nerves and vessels is reduced. They can be angled to produce as much retraction at the object of visualization as they do at the surface and, therefore, they produce a parallel-sided hole. They are, however, very



Traditional handheld retractors (Homans, Right angle, deep blade, bone hook)



A depicts surface retraction of a hand-held instrument (Homan). B shows the toe-in feature for deep retraction of the OmniAccess Hip Retractor System that enables better exposure with less tissue trauma.

tiring to hold. As with all hand-held retractors, movement inevitably occurs as the assistant becomes tired or distracted and the position or visualization

is lost requiring frequent retractor reinsertion.

The advantage of a table-mounted instrument is that both the system and the patient are fixed in place. Once inserted, position loss is largely eliminated and the assistant's hands are free to help with other parts of the operation such as suction, etc.

The OmniAccess Hip Retractor System allows for fixation of traditional Homans, bone hooks and also right-angled retractors.

One significant feature is the ability to toe-in the distal portion of the right angle blade. This produces more exposure at the depth of the wound, thus producing an

inverted truncated cone so that the tension on the skin and superficial structures is lessened and, therefore, the incision does not have to be as large.

This system is of considerable value, especially in hip revision surgery enabling this to be done comfortably and expeditiously with only one assistant. The system works well with all surgical approaches and provides for constant, simple, reproducible exposure and has helped in reducing operating time for complex cases.

We want to acknowledge and thank Drs. Kris and John Keggi who brought this system to our attention and have also had success in using this in their MSA™ (Muscle Sparing Approach) as shown in the following photo.



First assistant is suctioning and there is no need for a second assistant.



Keggi MSA™ anterior surgical approach.

“Mobile Gait Analysis” A New Tool for Post-Op THA Evaluation

By Kevin Lester, M.D., Ming Sun, Ph.D., Timothy McTighe, Ph.D. (hc)

The value of sophisticated, video-based gait analysis is well established.

However, the cost of establishing a gait clinic is very high (+\$250,000). These systems also require highly trained and dedicated personnel. As a result, the routine use of gait analysis in clinical practice has been very limited.

In addition, though in-patient gait labs offer highly sophisticated motion analysis, the lab environment does not mirror the patient's actual living conditions, or motion requirements. It can be difficult to determine the relationship between video kinematic data and the level of a patient's disability in every day living.

The need and potential clinical value of an inexpensive, accurate, easy to use gait analysis system has been repeatedly cited in the medical literature. In particular, the value of an ambulatory system that could acquire gait data from either defined protocols, or actual living conditions, and provide automatic quantitative data analysis.

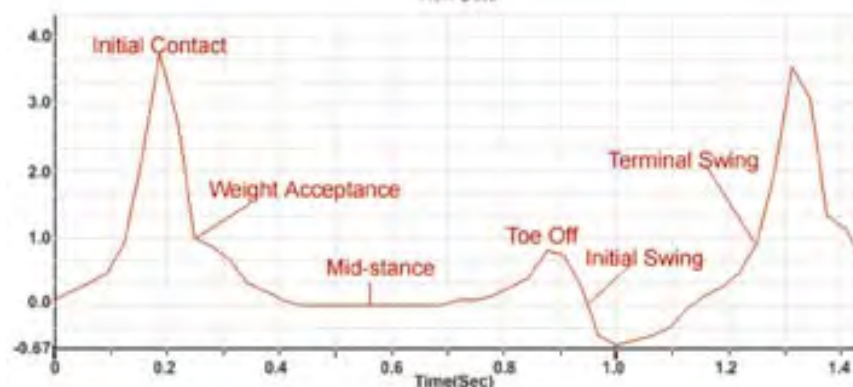


More than 45 types of activity can be measured.



Gait cycle measured by the sensor from right foot.

Raw Data



Years of research have resulted in the development and clinical use of a mobile gait analysis system that can be used in actual living conditions. The IDEEA™ LifeGait System (Intelligent Device for Energy Expenditure & Activity) provides accurate measurement of physical activity, functional capacity and gait analysis.

For any device to be used by patients successfully it must be user friendly. The IDEEA® is a small portable unit the size of an IPOD® and does not hinder any physical lifestyle activity. Once attached to the patient it provides continuous recording from a few minutes to several days. Utilizing pre-determined protocols, gait studies can be performed; in addition, data can be recorded under natural work or living conditions.



Data Reporting

Reports can be generated immediately in the form of tables, charts, animation and histograms.

Validation of accuracy studies has been done by a number of well-known and respected centers:

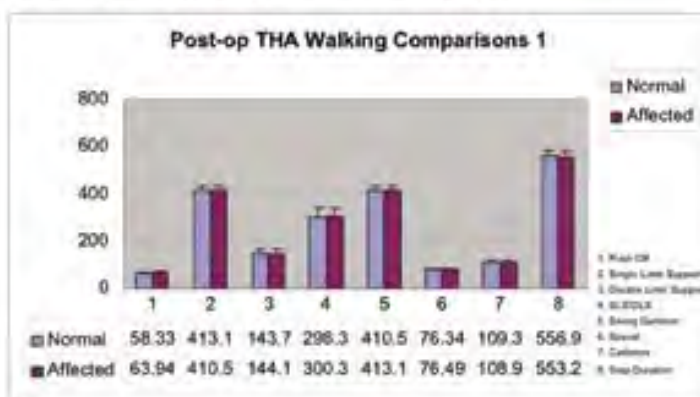
- Locomotion study by Columbia University (99%)
- Energy Expenditure by Columbia University & Vanderbilt University (96%)

The following chart demonstrates examples of our senior authors example of using this device for THA patients. Demonstrating that the posterior approach for THA results in virtually no limp.

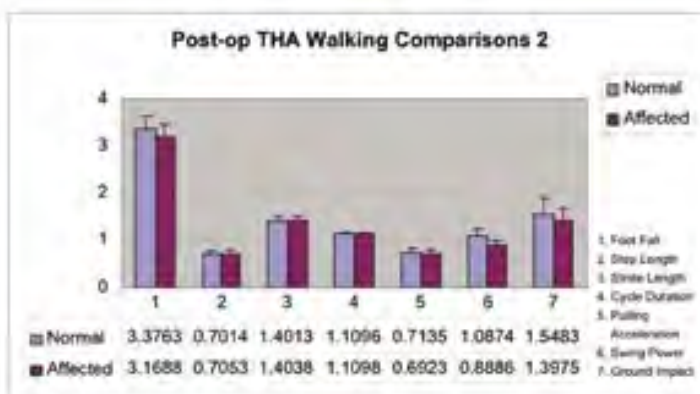


Gait Analysis Using IDEEA System

The following data are group average of 8 patients who had THA surgery.



Gait Analysis Using IDEEA System



In summary we feel the IDEEA LifeGait System provides useful cost effective data for pre and post assessment of total joint patients. In addition other applications aid in the evaluation of workers compensation, balance assessment, and fall risk in patients natural living environment. Measurement of post trauma impairment along with physical therapy monitoring, assessment of orthotic and prosthetic devices and research uses specifically outcome assessment of new surgical procedures or rehabilitation methodologies.

We continue to use the device and recommend that all surgeons interested in objective outcome analysis should consider this technology for use in their own practice.



Kevin Lester, M.D.

Commentary

The article by Schutte and colleagues suggests an approach to the use of modular components for the revision of the femoral component in THA revision. Since the advent of the SROM prosthesis it has been clear that modular approaches can be useful to successfully address implant stability, the restoration of joint kinematics and joint stability in hip arthroplasty. These aspects of arthroplasty are substantially more complex in the Revision situation, and modularity will be an important mechanism to address these same issues in increasingly complex revisions. The authors point out a number of features of modular revision systems that must be addressed by the manufacturer and implanting surgeon, and provide us with their early experience using the restoration modular system and Link MP System. The experience is too early to draw conclusions from, but only to suggest that the features of the systems allowed the surgeons to address the circumstances they faced in an effective manner. Longer term data with cases classified according to the degree of bone loss (using a classification system such as they have suggested) will allow us to draw conclusions as to the long term benefits of this particular system.

The article on the OmniAccess hip retractor provides us with information regarding a useful surgical tool. Retractor systems are now becoming available and necessary in operating environments that require increasing predictability. This system appears worthy of careful evaluation and will likely prove helpful for many surgeons performing hip surgery.

The IDEEA device is a novel device offered to allow the practicing surgeon to perform increasingly sophisticated functional analysis of the patients undergoing joint replacement surgery. Many total joint surgeons believe it is important to document improved performance of their patients, and tools to measure pre and postoperative performance are needed. If this system can continue to demonstrate accuracy of measurement compared to more expensive approaches, it will become a useful tool in the clinical practice of Total Joint Replacement.

Bernard N Stulberg MD

Director: Center for Joint Reconstruction; Cleveland Orthopaedic and Spine Hospital;
Cleveland Clinic Health System
Cleveland Ohio

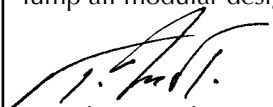
JISRF Position

For over thirty years JISRF has sponsored educational activities, newsletters for surgeons and patients, as well as conducting clinical/surgical study groups. The tradition as established so many years ago, by Professor Charles O. Bechtol, M.D., is not to endorse any one individual product/technology/technique but to expose new methodologies in a fashion that would raise the level of awareness and debate over a particular issue.

Over the past few years we have seen clinical outcomes for most devices demonstrate good to excellent results. It is difficult to say one device is better than another in light of all the considerable variables that must be taken into account. This issue is highlighting three new technologies that we feel have some significant features that might benefit the orthopaedic community. There are sufficient short-term results that warrant exposure in the "UpDate" and we encourage the orthopaedic community to review these devices.

All of the above issues require further investigation and consideration. Additional refinements and modifications will certainly be made, however these technologies represent an exciting direction for the field of reconstructive surgery. JISRF will do its best to keep you informed on the progress and performance of these technologies.

Remember, when it comes to modular implants it is important to understand and appreciate the specific design features and required techniques for that design. Do not lump all modular designs into one simple category "Modular Stems."



Timothy McTighe, Executive Director, JISRF

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Joint Implant Surgery & Research Foundation

17321 Buckthorne Drive
Chagrin Falls, OH 44023

Phone: 440.543.0347

Fax: 440.543.5325

info@jisrf.org • www.jisrf.org

Modular Hips to Restore Proper Mechanics



By:
Timothy McTighe, Executive Director
Joint Implant Surgery & Research Foundation



Introduction:

THA continues to improve but complications still occur. Dislocation and osteolysis continues to be a significant problems. The causes for dislocation can be multi-factorial, and include: mal-positioned components, soft tissue laxity, and impingement of component-on-component or on fixed obstructions such as osteophytes. Weakness of the abductor muscles due to improper reconstruction can also be a contributing factor. In countering these factors, stability is often achieved at the expense of limb lengthening.

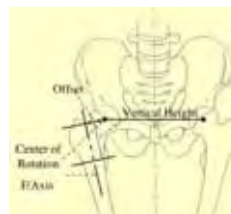
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Restore Function

- Reproduce Hip Mechanics
 1. Femoral Offset
 2. Neck Length
 3. Version Angle



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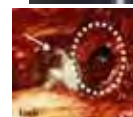
Dislocation

- Reports from 2-8%
- Higher in Posterior Approach
- Higher in Sm. Dia. Heads
- Higher in Revisions >20%



Osteolysis

- Eccentric Poly Wear
- Result Lytic Lesion (4 year post-op)



Discussion:

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Estimating a conservative 2% dislocation rate, there would be a corresponding 6,000 dislocated hips each year.

• **Non-operatively treated** - 4,500 (75%) - **\$6,000**
Cost: relocation, brace, x-rays, rehabilitation

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\$6,000 x 4,500 = \$27 million
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Total cost of dislocations per year in the United States. \$64.5 million

Wright Medical Web Site

Dislocation Treatment Trends



Big Heads



Constrained Sockets



Navigation



Increased Offset Stems

Big heads are helpful for impingement problems, however do not aid in soft tissue laxity. Constrained sockets are indicated for soft tissue laxity but not indicated for mechanical instability. Surgical navigation is promising to reduce implant alignment problems and dual offset stems are helpful for restoring joint mechanics but increase inventory costs.

“Despite a number of improvements in femoral stem neck geometry and increasing femoral head sizes up to 36mm, dislocation continues to be a significant problem after THA”
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R-120™ - Cemented



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IMIN™ Modular Neck Design

3 neck lengths
32, 35, 38 mm



2 neck angles
8° & 12°

Neck Positions for 8°



Version Angle	0°/4°	7°	8°	7°	4°	0°	
Neck Shaft Angle	127°	128°	130°	135°	138°	141°	142°

Surgical Technique:

Technique is the same as any standard fixed neck cement or cementless stem.



Option
Stem First - Then Cup



Posterior Approach



Trial stem
in place.



JEAN-YVES LAZENNEC
MARTIN DIETRICH
Editors

Bioceramics in Joint Arthroplasty



9th BIOLOX® Symposium
Proceedings

STEINKOPFF DARMSTADT



1.1 Ceramic on Ceramic Bearings Used with Proximal Modular Stems in THA

K. J. Keggi, J. M. Keggi, R. E. Kennon and T. McTighe

Abstract

Introduction: Osteolysis generated by wear debris remains a problem in total hip arthroplasty. Alternate bearings surfaces are sought in an attempt to reduce debris particles and prolong prosthetic wear.

Ceramic on ceramic surfaces have a long clinical history but have encountered a number of problems due to design and material properties. Impingement with malposition of the components, ceramic chipping, and ceramic fractures with malposition of the acetabular component have been problems.

Material: This paper will review 185 ceramic on ceramic bearings used with proximal modular stem designs. Two different stem designs and four different cup designs all utilizing ceramic heads and ceramic inserts manufactured by CeramTec were used.

Conclusion: The recent development of proximal femoral modular stem designs provides better surgical exposure and improved orientation of the prosthetic components. This will reduce the complications due to ceramic implants.

Introduction

The senior authors (KJK, JMK) have performed over 800 ceramic on ceramic total hip arthroplasties at our institution since 1983. Demand for durability, better fit, and greater surgical options has led to the use of newer modular designs in recent years, including nearly 200 modular total hip replacements utilizing ceramic on ceramic interfaces. While early ceramic materials with monoblock designs suffered from ceramic chipping, ceramic fractures with malposition of the acetabular components, and impingement with malposition of the components, it has been our experience and impression that newer modular designs have provided better surgical exposure, improved orientation of the components, and greater flexibility in restoration of normal biomechanics. This has in turn reduced the complications due to ceramic implants and obviated the need for extra long skirted ceramic heads.

Materials and Methods

Medical records were retrospectively reviewed for all patients undergoing primary total hip arthroplasty utilizing both modular designs and ceramic on ceramic interfaces. No patients were excluded from this group. All operations were performed using the modified anterior approach developed by the senior surgeon [1]. Specific parameters examined included demographic data, stem type, acetabular type, and nonmedical complications related to the prosthesis or surgical technique, such as dislocation, malposition, subsidence, fracture, or damage to the ceramic component.

Two proximal modular stem designs were utilized in this series. The first is the Apex Modular7m Hip Stem shown in Figure 1 (Apex Surgical, LLC, Lakeville, MA). The second is the PROFEMUR™ Z stem shown in Figure 2 (Wright Medical Technology, Inc., Arlington, TN). Four acetabular components were used: the LINEAGE' acetabular system (Wright Medical Technology), the TRANSCEND' acetabular system (Wright Medical Technology), the BICON-PLUS1 acetabular system (PLUS Orthopedics, Son Diego, CA), and the Cer-Met™ acetabular system (Apex Surgical).



Figure 1: Apex Modular™ Hip Stem
(Apex Surgical, LLC, Lakeville, MA).



Figure 2: PROFEMUR™ Z stem
(Wright Medical Technology, Inc.,
Arlington, TN).

This data is shown in Table 1 and was comprised of 185 total hip replacements.

Femoral Component	Acetabular Component	Total
Apex	Lineage	64
	Transcend	23
	Cer-Met	55
	Bicon	2
ProFemur Z	Lineage	23
	Transcend	5
	Cer-Met	11
	Bicon	2
TOTAL		185

Table 1:

Summary of all modular ceramic on ceramic THA performed.

Results

Five nonmedical complications were noted in this series of 185 total hip replacements, including two hip dislocations, one acetabular component dislocation, one femoral fracture with stem subsidence, and one failed ceramic acetabular liner. The average length of follow-up was approximately two years, but thus for all four complications that have occurred were apparent within six weeks of the initial surgery. The summary of nonmedical complications is presented in Table 2.

Femoral Component	Acetabular Component	Complication
ProFemur Z	Transcend	Ceramic liner fracture at 6 weeks post-op; atraumatic, changed liner/shell/neck/head
ProFemur Z	Cer-Met	Dislocated at 6 weeks post-op and required closed reduction with no further problems
Apex	Bicon	Dislocated with 6 weeks post-op & required open reduction, components retained. [Patient later sustained fractured femur in MVA vs. pedestrian accident and underwent ORIF.]
Apex	Lineage	Acetabular component dislocated at 1 week; underwent acetabular and femoral head replacement at that time. Previous sciatic nerve palsy pre-operatively after acetabular ORIF (MVA) likely contributed. (See Figure 3).
Apex	Cer-Met	Unappreciated femoral fracture discovered at 6 weeks with component subsidence; converted to Echelon cemented stem.

Table 2:
Summary of nonmedical complications.

The first represented the only failure of the ceramic materials in this series. The patient noted the new onset of pain for one week without recalled antecedent trauma approximately six weeks after undergoing primary total hip arthroplasty with a ProFemur Z stem and Transcend cup with ceramic liner. Evaluation revealed him to have a cracked ceramic liner. It is impossible to state the cause of this fracture; it could be due to pure ceramic materials failure or it may have been an undetected malalignment of the component within its titanium shell. The patient underwent exchange of the liner, acetabular shell, neck, and femoral head without further problems. The modular design proved advantageous in this instance, facilitating modular component exchange.

The second complication was a hip dislocation six weeks post-operatively that was associated with noncompliance with total hip precautions. This patient had undergone a primary THA with a ProFemur Z femoral stem and Cer-Met acetabular component. After undergoing a closed reduction under anesthesia, the patient had no further problems after a year of follow-up.

The third complication involved a patient who underwent primary THA with an Apex femoral stem and a Bicon acetabular component. This patient sustained a dislocation six

weeks from the time of surgery after being noncompliant with total hip precautions and required open reduction of the hip with components retained. The patient did well for a limited period of follow-up until suffering extensive trauma as a pedestrian struck by a motor vehicle in which he sustained a periprosthetic femur fracture but no ceramic failure despite his trauma.

The fourth complication was an acetabular dislocation in a patient with a failed traumatic acetabular fracture ORIF (Figure 3a). It occurred one week postoperatively after primary total hip arthroplasty. This patient had an Apex femoral stem and a Lineage acetabular component. Contributing factors were preexisting sciatic nerve palsy with foot drop, her post-traumatic acetabular bone deficiency, obesity, and active hyperextension of the hip. The revision was relatively easy since it was possible to remove the proximal (modular) neck component and achieve acetabular exposure without removal of the entire femoral prosthesis (Figure 3b). The patient's THA subsequently has remained **stable**.



Figure 3a:
Acetabular component dislocation.



Table 1:
Post-operative film after acetabular and femoral head replacements.

The fifth complication occurred with an Apex stem and Cer-Met acetabular component in which a peri-operative femur fracture was unappreciated at the time of surgery. This was subsequently noted six weeks post-operatively with subsidence of the femoral component that necessitated its revision to a cemented Smith-Nephew-Richards (Memphis, TN) Echelon™ femoral stem.

Discussion

Since Pierre Boutin attempted the first ceramic total hip arthroplasty in 1970, there has been interest in ceramic bearing surfaces to improve implant longevity and decrease wear [2]. However, early experience with ceramics indicated high failure rates due to component loosening and early need for revision, with failure rates approaching 27% - 35% in some

studies [3,4,5]. Our own early results using the noncemented Autophor were satisfactory and matched the success of Mittelmeier, and we have had some extremely good long term successes with the device in some young and very active patients [6,7,8]. We have not seen any osteolysis on long term follow-up, but the overall failure rate has been unsatisfactory because of inadequate acetabular fixation, acetabular migration, fractures of the thinner acetabulums, and inadequate osteointegration of the femoral component [9].

Although many investigators concluded that much of the fault with these prostheses lay with design and technique in greater part than the ceramic material, ceramic on ceramic joints were abandoned in the United States for over a decade. Ceramic heads in polyethylene acetabular components continued to be used in the United States while the ceramic itself was improved (BioloX-Forte) and its fixation to bone modified in Europe. While first generation ceramics before 1985 had fracture rates as high as 10% in some reports [10], contemporary third generation alumina ceramics have smaller grain size, fewer impurities, and a more stable crystalline structure with fracture rates as low as 4 in 100,000 [11].

Prosthetic designs have also improved with enhancements such as highly polished articular surfaces, optimized clearance between the head and liner to provide a fluid boundary, improved sphericity, tightened tolerances for tapers, and elimination of skirts on ceramic heads. The advent of modular femoral components has also facilitated the insertion and positioning of the ceramic joint itself. A decrease in malaligned acetabulums and femoral necks should optimize long term wear of the ceramics.

The marriage of contemporary ceramic articulating surfaces and proximal modular design affords several benefits. Modular designs allow better surgical exposure, and modularity allows multiple sizing and positioning options to improve orientation of the implants and, ultimately, the stability and biomechanical restoration of the hip replacement. Current designs also do not require the extra long skirted ceramic heads which have historically been more likely to impinge and break.

Our current series of modular ceramic on ceramic hip replacements has shown promising results after an average of one year of follow-up. While this is still an early period of observation, it is our impression that these hip replacement systems perform well and offer a significant addition to the surgeon's armamentarium.

Conclusion

While ceramic on ceramic surfaces have a long clinical history with progressive improvement in materials science, a relatively new approach has been the implantation of ceramic on ceramic surfaces with proximal modular total hip designs. In reviewing all of our modular ceramic on ceramic total hip replacements, we have found them to have excellent performance with few problems in the short term. In particular, there was only a single failure due to chipping or fracture of the ceramic materials - one acetabular liner - and no failures of the ceramic femoral heads. It is our impression that newer modular total hip designs utilizing ceramic interfaces have reduced the complications which were present in earlier monoblock femoral prostheses utilized 15 to 20 years ago. Modular femoral components also allow better surgical exposure, improved component orientation,

and reproduction of the proximal femoral anatomical variations such as varus, valgus, or anteversion.

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Design Considerations for a Modular Neck in Total Hip Arthroplasty



By:

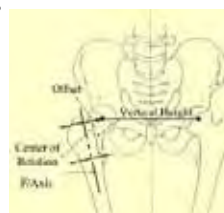
Timothy McTighe¹, Kristaps J. Keggi, M.D.², H. M. Reynolds, M.D.³, Milton Smit, M.D.⁴,
John Keggi, M.D.², Hugh U. Cameron, M.B., Ch. B.⁵, Bernard Stulberg, M.D.⁶

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Stem Designs



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Alfa II™ - Cementless

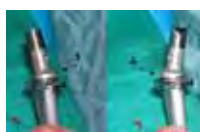
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3 neck lengths
32, 35, 38 mm



12 Settings



2 neck angles
8° & 12°

Neck Positions for 8°



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0°	4°	7°	8°	7°	4°	0°
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Surgical Technique:

Technique is the same as any standard fixed neck cement or cementless stem.



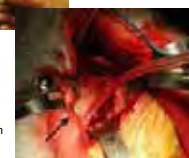
Option
Stem First - Then Cup
Benefit: blood loss reduction



Posterior Approach



Trial stem in place.



Surgical Technique: *continued*

Anterior Mini-Dual Incision

Implant orientation is a significant part of surgical technique. The mini-incision places a higher demand on implant positions. Proximal modular stems provide adjustments reducing the risk of implant discrepancy, and soft tissue laxity.



Fine Tuning Joint Mechanics



The Advantage of Proximal Modular Necks: With the trials in place the surgeon can verify joint stability and range of motion without disrupting the implant/bone interface. If necessary, the surgeon can also *fine tune the joint mechanics* by adjusting the modular neck.

Variable Femoral Offset



Valgus Neck Shaft Angle
147° (position 6)

Varus Neck Shaft Angle
123° (position 0)

(Same pt., same implants,
different neck positions)

Femoral Stem & Cup in Place w/o Neck



Insertion of Neck & Head

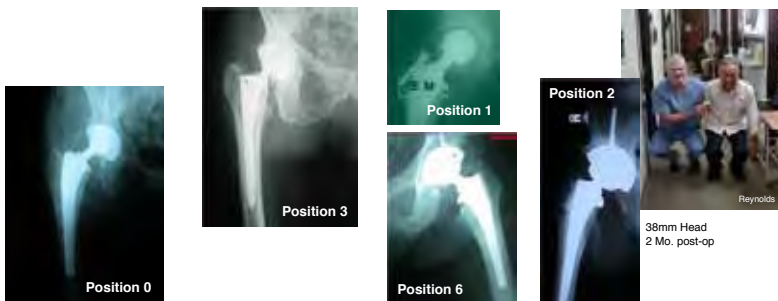
Head neck insertion can be done by assembling head onto neck and inserting as a single unit.



Another approach is to insert the modular neck first then assemble the head onto the neck then impacting both together.



Post-op X-Rays



Ways to Reduce Dislocation

- Restore Hip Mechanics
- Modular Necks Aid in Restoration
- Anterior or Direct Lateral Approach
- 32 mm Dia. Head or Larger
- Do not use skirted necks or modular trunnion necks
- Constrained sockets (not indicated for impingement problems)
- Reduce Use of Angled Poly Inserts
- Navigation System (Digital \$60,000 / Image 250,000)



Summary

- This modular neck design aids in fine tuning joint mechanics
- Works with all surgical approaches
- Allows for femoral stem insertion first (aids in reducing blood loss)
- Allows for ease and access in case of revisions
- Allows for replacement of ceramic heads by replacement of modular neck
- Reduces chances of mechanical impingement of implants especially with mini-incision surgical approaches

Clinical Summary

Primary Total Hips

270 stems implanted since 1/02

- (136 cementless / 134 cemented)

3 Revisions

- 1 traumatic fx. Greater Trochanter
- 1 cup revision (mod. neck removed for access)
- 1 dislocation (mod. neck revised and indexed)

0 Stem Revisions

0 intra-op fractures

2 GI Bleeds

0 infections

No significant leg length inequalities (+/- 5mm)

+50% indexed to positions other than 0

Early Clinical/Surgical Impressions

No long term data available at this point, however, we are extremely encouraged that this device will aid in reducing post-op dislocations and help restore joint mechanics.

**Poster Exhibit
October 2003
Berlin, Germany**



Osteoarthritis Research Society International
17000 Commerce Parkway, Suite C
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Falls, OH 44023

(3) Jackson Arthritis Center
3300 Webster Street
Suite 1202
Oakland, CA 94609

(5) 43 Wellesley St. East
#318, Toronto, Ontario,
Canada M4Y 1H1

(2) Department of Orthopaedics &
Rehabilitation, Yale University School of
Medicine, Keegi Orthopaedic Foundation,
1201 West Main St., Waterbury, CT 06708

(4) Orthopedic Associates of Kankakee
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Suite 100
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Keggi
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1201 West Main Street
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203-757-9855
www.keggiorthofoundation.org

(1) Department of Orthopaedics &
Rehabilitation, Yale University School
of Medicine, Keggi Orthopaedic
Foundation, 1201 West Main St.,
Waterbury, CT 06708



820 Flynn Road,
Cambridge, CA 95012
www.kinamed.com

(2) R&D Director, Kinamed Inc, 820
Flynn Road, Cambridge, CA 95012



12 Harding St.
Lakeville, MA 02347
www.apexsurgical.com

(3) Managing Director Apex
Surgical, LLC, 12 Harding St.,
Lakeville, MA 02347



Joint Implant
Surgery and
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17321 Buckthorne Drive
Chagrin Falls, OH 44023
440-543-0347
www.jisrf.org

(4) Executive Director, Joint
Implant Surgery & Research
Foundation, 17321 Buckthorne Dr.,
Chagrin Falls, OH 44023

Poster Exhibit
September 2003



The Union of Emerging Techniques and Technologies in THA

By: John J. Keggi, MD¹; Kristaps J. Keggi, MD¹; Vineet K Sarin, PhD²; Edward J. Cheal, PhD³; Timothy McTighe⁴

Introduction: Reduction of pain, restoration of joint mechanics and reduction of post-operative rehab are the primary goals of THA. Current trend of mini-surgical incisions offers some opportunities for reduced rehab time and cost, however, may increase risk as to implant malposition and possible dislocation. New emerging technologies of surgical navigation and proximal modular stem may demonstrate reliable and reproducible implant positioning with mini-surgical incisions.



Anterior Mini-Incision

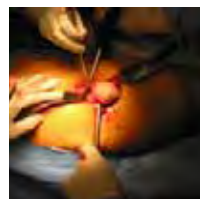


Apex™ Modular
Cementless Stem



NaviPro™ Surgical
Navigation System

Techniques & Technologies

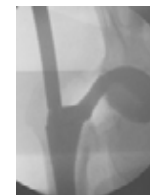


Discussion: Implant orientation is a significant part of total hip surgical technique. The mini-incision places a higher demand on awareness of implant positions. Proximal modular stems and surgical navigation provide for fine-tuning adjustments thus reducing the risk of implant impingement, leg length discrepancy and soft tissue laxity. The uniting of these technologies and designs aid the surgeon who is not familiar with the anterior mini-incision to be confident in their ability to routinely implant components in their proper biomechanical orientation.

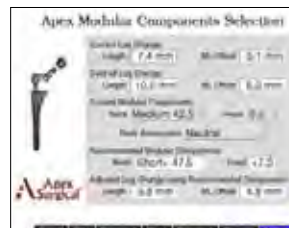
Proximal modular hip stem design aids in minimizing soft tissue trauma, obviating the need for posterior capsular and deep posterior blood vessel release, resulting in decreased blood loss.



Modular Neck = Reduced
Profile = Smaller Incision



NaviPro™ is a image-free surgical navigation system that has been programmed with the Apex Modular Cementless total hip system. Optical tracking devices are fixed to the pelvis and the femur prior to hip dislocation and data registered. Based on the surgeon's objectives for length and offset, the system is used to calculate the change in length and offset changes after trial reduction; compare these changes to the pre-operative objectives and recommend a different choice of modular components in order to best achieve the reconstructive objectives.



Conclusion: Surgical navigation and modular stems are not necessary to successfully perform THA using the anterior mini-incision approach. However, uniting these designs and technologies can provide for a more reproducible teaching system that increases the confidence of surgeons while they gain experience with this surgical approach. Furthermore, surgical navigation systems that are programmed with modular component sizing and availability can enhance and expedite the intra-operative decision-making process. By integrating these emerging technologies, the surgeon can efficiently evaluate the effect of component variability and choose the modular components that best achieve the reconstructive objectives.



McBride
Clinic

1110 North Lee
Oklahoma City, OK 73101
www.mcbrideclinic.com
(1) Orthopaedic & Arthritis
Center, McBride Clinic, 1110
North Lee, Oklahoma City, OK
73101, (2)



12 Harding St.
Lakeville, MA 02347
www.apexsurgical.com

(2) Managing Director Apex
Surgical, LLC, 12 Harding St.,
Lakeville, MA 02347



Joint Implant
Surgery and
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17321 Buckhorn Drive
Chagrin Falls, OH 44023
440-545-0347
www.jisrf.org

(3) Executive Director, Joint
Implant Surgery & Research
Foundation, 17321 Buckhorn Dr.,
Chagrin Falls, OH 44023

Poster Exhibit
September 2003



Target Restoration of Hip Mechanics in THA

By: Tom Tkach, MD¹; Warren Low, MD¹; George B. Cipolletti, MS²; Timothy McTighe³



Introduction: THA continues to improve but complications still occur. Dislocation continues to be a significant problem. The causes for dislocation can be multi-factorial, and include: mal-positioned components, soft tissue laxity, and impingement of component-on-component or on fixed obstructions such as osteophytes. Weakness of the abductor muscles due to improper reconstruction can also be a contributing factor. In countering these factors, stability is often achieved at the expense of limb lengthening.

To study the influence of implant geometry on tissue balancing and joint stability, the authors selected a stem system that permits the independent selection of lateral offset, version and leg length. This study presents the short term results of this experience.



Instability - What should be done? Trail reduction demonstrates joint instability with slight increased leg length.



Modular Heads allow length adjustment, unfortunately increase head length increases leg length.

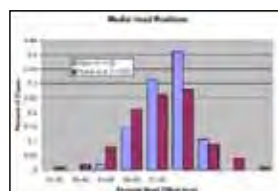
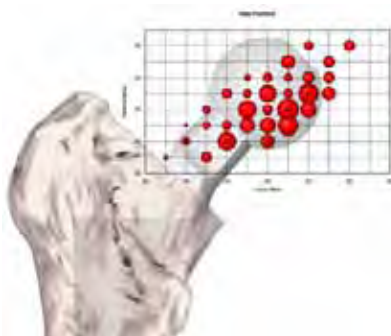


Big Heads! Theoretically, a bigger head is more stable... At the extremes of motion when the neck impinges in this case, intrinsic stability is unchanged (Head center stays the same).



Biomechanical Solution
Modular Neck! Add offset for joint stability reduce length for proper gait.

Methods: 525 THA's were performed using the Apex Modular™ Stem, beginning in May 2001. 494 were primary and 31 were revision cases. All were performed using the posterior approach. Acetabular implants from a variety of manufacturers were employed. All cases were fully cementless. Data on stem, neck and head selection were available for 472 of these cases. Head centers were plotted in bubble chart format. The center of the bubble is head location; the diameter is an indication of frequency. Representative frequency values are given for several locations.



1 Noble, Philip C., M.S., Alexander, Jerry W. B.S. et al. "The Anterior Basin of Femoral Component Design", Clinical Orthopedics and Related Research, Number 235, October, 1988.

Lateral offset data are available in the literature for cadaver femora. We plotted our data on the same scale for comparison. The similarity of the lateral offset distribution confirms the appropriateness of the surgeons' head center selections.

Stem size	Median Offset (mm)	Median Vert Drop (mm)
10 mm	40	25
11.5 mm	45	30
13 mm	45	30
14.5 mm	47.5	30
16 mm	47.5	32.5

Table 1

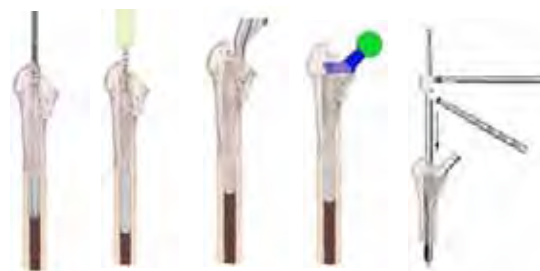
Results: In this clinical series, we observed 2 dislocations*, 14 intra-operative fractures**, no significant leg length inequalities (± 5 mm), and no significant thigh pain. Approximately 10% were indexed to a position other than neutral version. Lateral offset data were tabulated and compared to data from the literature.

The head center location data clearly showed that a wide variety of offsets and lengths are required to properly balance the soft tissues. Further, when the data were sorted by distal stem diameter, it was clear that there is little correlation between head center location and stem size. Further, a significant number of small (10 mm or 11.5 mm) stems required large (>45 mm) offsets.¹

*One of the dislocations was treated conservatively after closed reduction and went on to an unremarkable course. The second had received a neck in the anteverted position and dislocated anteriorly. The surgeon chose to reoperate, remove the modular neck component and reinsert it in the neutral position, after which the patient rehabilitated normally.

** Intra-op fractures were encountered during first twelve months during instrumentation development.

Surgical Technique



Typical 15 - 40° more ROM with neck anteverted.



Neutral neck position.



15° anteversion.

Anteverted neck used 18 times in the first 200 cases.

Discussion: Restoration of normal joint biomechanics on a consistent basis was possible using the Apex Modular™ Stem because of the intra-operative versatility that stem system offers in regards to head center location when compared to monoblock stems. It combines the fit and fill features of today's contemporary cementless stems with updated modular components that provide for independent offset, version and leg length adjustments. This unique modular design allows for a large selection of proximal bodies to enable targeted implant selection for the restoration of proper soft tissue tension and joint biomechanics. Continued long-term follow up will provide additional information to aid in validation of this design concept.

Conclusion: The head location data suggest that hip joint reconstruction benefits from the availability of many head centers for every stem size. This may be accomplished with a large inventory of sizes or with a modular device. Review of 525 hips implanted for both primary and revision cementless application leads the authors to conclude that this "Dual Press™" proximal modular stem design is safe, effective and provides for a more accurate approach for reconstructing the biomechanics of the hip.



Joint Implant Surgery
& Research Foundation
DECEMBER, 2002

JISRF Update

New Era of Minimally Invasive Surgical Approaches for THA

Timothy McTighe, Editor
Executive Director, JISRF

Introduction

What's old is new again! Over the past year there has been considerable interest, debate and controversy over the role of minimally invasive surgical approaches for both total hip uni-compartmental knee replacements. This edition of JISRF *Update* will review both current trends and reflect on the historical evolution of these techniques for THA.

In discussing the current trends on mini-surgical approaches it is important to understand specific terminology and surgical approach and not to lump all small incisions into one simple category – "mini-incisions." There are single, dual, even three mini-incision techniques utilizing the anterior or posterior approach.

What are the indications, contraindications, advantages, disadvantages, and more importantly, the outcomes for these surgical approaches? Recent reports from a study on the feasibility and potential benefits of Zimmer's 2-incision* total hip replacement found that in the first 10 consecutive cases mean operative time averaged 100 minutes with no intraoperative complications. No patient died in the hospital more than 23 days and 75% went home the day of surgery. (*Zimmer Holdings, Inc. 7/23/02)

Is outpatient total joint surgery the future or a passing fad? Let's remember the principal necessity for surgery is to fix or correct a problem. The incision provides both access and exposure necessary to enable correction of the problem. In my opinion most



Incision needs to be just large enough to insert the cup. Keggi

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Incision Technique
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documentation
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Joint Implant Surgery and Research Foundation

is a non-profit scientific and educational organization founded in 1971 by professor Charles O. Bechtol, M.D.

The foundation over its past 30 years has conducted CME activities for both surgeons and nurses while sponsoring clinical / surgical study groups, including basic science projects that have led to the development and marketing of significant Total Joint Replacement Implants.



Joint Implant Surgery & Research Foundation

17321 Buckthorne Drive
Chagrin Falls, OH 44023
Phone: (440) 543-0347

Current THA Trends:

Mini-Incisions
 Hard-On-Hard Bearings
 Large Diameter Heads
 Surgical Navigation Systems
 Increased Femoral Offset
 Increased Use of Constrained Sockets
 Reduced Hospital Stay

Trends often appear to provide short-term gains while setting up long-term disadvantages. Hopefully our contributing articles will address some or all of the following questions and concerns:

1. Can you see what you are doing?
2. Do you require additional or modified instruments?
3. Do you need surgical navigation tools?
4. Do you increase chances for component malposition?
5. If so, do you increase chances for dislocation?
6. Do you increase chances for fracture and/or neurovascular injury?
7. Does ultra-early discharge put the patient at increased risk for bleeding and/or DVT?
8. Does the procedure provide for reproducible good results?
9. What skills and/or implant designs aid in reproducible good results?
10. Will this surgical approach provide an improvement in long-term results for THA?

F E A T U R E A R T I C L E

Anterior Approach THA Via Mini-Incision Technique

by Kristaps J. Keggi, M.D.

In recent years there has been increased interest in minimally invasive total hip arthroplasty. A number of different techniques have been described with the goal of minimizing soft tissue dissection, decreasing perioperative complications and accelerating soft tissue rehabilitation. This article reports on the one, two or three mini-incision technique through an anterior approach.

This anterior approach has been employed by us over the past thirty years with excellent results in over 6,000 cases including both cemented and cementless prostheses as well as both primary and revision THA. Experience to date has demonstrated short operative times, small blood loss and few complications both in the perioperative period and over a long period of follow-up. While this approach is technically more demanding than the standard operations with wide exposure, the results have been quite satisfactory.

As with all surgical experience my technique has evolved using a modified anterior approach with one, two or three mini-incisions, whichever best fits the surgical profile of that patient.

Single Small Incision

The incision is made from a point just distal to the anterior superior iliac spine to the anterior border of the greater trochanter. The incision is curved with its convexity in a lateral direction. The average incision in a thin patient is approximately 5 to 8 cm.

The subcutaneous tissues are transected in line with the skin incision and the medial skin is undermined to the anterior (medial) border of the tensor fascia lata muscle.

margin. A strip of muscle is left medially to protect the lateral femoral cutaneous nerve and to facilitate closure.

The anterior capsule of the hip is identified by blunt dissection.

Cobra retractors are placed on the superior and inferior aspects of the capsule. They retract tensor fascia lata with the abductor muscles laterally and rectus femoris with the sartorius medially.

An anterior capsulectomy is then performed. If possible the lateral femoral circumflex artery and vein are preserved. They lie in loose connective tissue at the base of the femoral neck and are easily identified. If these vessels are transected to achieve better exposure they are controlled with suture ligatures or electrocoagulation.

After the anterior capsulectomy the femoral neck is visualized. The Cobra retractors are placed within the hip capsule on the superior and inferior borders of the femoral neck. The placement of these Cobra retractors is important. They expose the femoral neck once the capsulectomy has been completed. The lesser trochanter and the trochanteric fossa are palpated to facilitate orientation. The excision of the anterior capsule, especially if it was contracted, now



Anterior small single incision approach (Keggi)

e femoral neck is cut with an oscillating saw. The placement of the cut has been predetermined by preoperative templating of the patient's x-rays and is easily determined once the base of the neck is fully visualized. Restoration of the patient's normal neck shaft angle and neutral seating of the prosthesis within the femoral shaft are the two major concerns with the templating and the femoral cut.

Efficient removal of the femoral neck makes it difficult to align the femoral shaft and can lead to varus placement of the component within the proximal femur. This does not mean the femoral neck is removed down to the lesser trochanter. The femoral cuts can be at different levels based on the patient's neck anatomy. The base of the calcar must be preserved since this is a solid bony structure and contributes to the stability of the components be they cemented or uncemented.

After the osteotomy of the femoral neck has been completed the femoral head is removed. In most instances the head can be removed with a standard hip skid with or without the assistance of a "link screw" extractor. Occasionally the head can be fragmented and removed in piecemeal fashion. In cases of severe osteolysis or fusion the femoral head may have to be drilled or reamed out of the acetabulum. After removal of the femoral head, the acetabulum is fully exposed. This is one of the advantages of the anterior approach since the acetabular exposure is excellent, the palpation of the pelvis can be palpated on the table and palpation by direct visualization is simple. If the surgeon is uncertain about the exact position of the acetabulum, the procedure can be done on a radiolucent table and the position of the acetabulum can be checked fluoroscopically. In our own experience this has never been necessary and we have used fluoroscopy only for educational and training purposes.



Head removal.

The acetabular exposure is best achieved by the insertion of a sharp tipped Cobra retractor under the bony rim of the anteromedial acetabulum. This solid fixed Cobra allows retraction of the anteromedial tissues (rectus, sartorius, fat, etc.). A second Cobra placed on the lateral ilium just proximal to the acetabulum retracts the tensor fascia lata. If necessary, a third retractor (usually a Homan) can be placed carefully over the rim of the pelvis anteriorly for further soft tissue retraction and exposure of the anterior

acetabular reamers. Significant amount of variation in acetabulums exist. There are the obvious congenital dysplasias, but some acetabulums have been grossly deformed by the degenerative process. The reaming must be performed in such a manner as to preserve as much of the acetabular walls as possible. Thus, for example, if the anterior wall of the acetabulum is defective, the centralization of the reamers should be more posterior. It is our preference to medialize the acetabulums as much as possible.

We expose the true medial wall by curettes and small sized reamers. After we have established this point of reference we then centralize our final reamers in such a manner as to preserve both the anterior and posterior walls of the acetabulum. Our goal in acetabular placement has been to recreate as much as possible the patient's own normal anatomical center of rotation. We remove as much bone as necessary to do this but do not feel it is necessary to have the entire acetabulum down to soft bleeding cancellous bone.



Floro image reaming socket.

Over the years both cemented and cementless acetabular components have been used. The supine position and the ability to palpate the axis of the pelvis facilitate visualization of the acetabular angles. We have always thought in terms of a 45 degree varus/valgus angle but have tended to err on a more horizontal (or valgus) side. Thus, our average acetabular angle is closer to 40 degrees than 45 degrees. In the valgus position the implant is more horizontal and more stable within the bony acetabulum. This gives better coverage to the femoral head, transmits forces to the acetabular prosthesis and the pelvis in a more even manner, and makes dislocation less likely. In this anterior position it is also easy to establish the exact anteversion (approximately 15 to 20 degrees) which corresponds to the normal anatomy. Once the acetabulum is in place, peripheral osteophytes, if they are present, are removed with special attention paid to the anterior osteophytes. They, more than any others, would act as fulcrums for dislocations. Large lateral medial and posterior osteophytes are also removed.

Attention is now directed to the femur. Sponges are placed within the acetabulum to protect it from injury during the manipulation, rasping and positioning of the femur. The patient's leg is placed in maximum external rotation and the osteotomy of the base of the femoral neck is visualized. This visualization is facilitated by the use of a bone hook placed around the femur at the level of the lesser trochanter. Traction on this bone hook frequently is sufficient to deliver the proximal femur into the operative site. A curved pointed

used only on rare occasions. Exposure of the proximal femur is extremely important since inadequate mobilization of the femur is likely to lead complications in the course of femoral shaft preparation and prosthesis insertion (perforations, fractures, etc.). If necessary to achieve this we perform a posterior capsulectomy and release the short external rotators and piriformis near their insertion along the posterior greater trochanter. We have never re-attached them at the end of the procedure.



Dual incision cup and stem in place without neck.

After adequate mobilization and exposure of the proximal femur has been achieved, the rasping of the femoral shaft is started. The first step is curettage of the neck osteotomy along its lateral aspect in order to allow insertion of the rasps in the long axis of the medullary canal. Modified angled rasps have been used for this purpose although a straight

rasp can also be inserted if the femur has been well mobilized. A straight rasp can also be inserted through a stab wound or "second" incision in the region just proximal to the greater trochanter. A short starter rasp is used at first and gradually the size and length of the rasp is increased until the largest possible rasp has been inserted into the femoral shaft in a position of anteversion.

After the femoral shaft has been rasped, trial prostheses are inserted in the femur and reduced into the acetabular component. The neck selection is based on the appearance of the patient's proximal femur. If the patient has a high offset varus type neck, a high offset varus type neck is selected if such is available in the system used. The most



Apex Modular™ Cementless Stem



R-120™ Cemented Stem featuring IMIN™ Neck

important factor is a stable hip. In our own experience we have estimated approximately 4 percent of our hips to be slightly longer (usually 1/4 to 1/2 an inch) because leg length has been sacrificed for hip stability. After the proper neck length, head size and stem size have been determined by means of the trial prostheses, a permanent prosthesis of the selected size is inserted into the femur. Either a cemented or a cementless device is chosen depending on patient's age, bone quality, and activity level. Between 1950 and 1985 we have had experience with a variety of cementing techniques, bone plugs, chrome cobalt plugs, silicon plugs, pressurized cement, low viscosity cement, refrigerated cement, centrifuged cement and syringe injected cement. In 1985, however, we returned to a finger packing method with a catheter in the femoral shaft and Palacos cement. This has produced excellent results since the dou

Floro Images



Screw insertion.



Femoral broach.



Trial modular stem w/o neck.



mass of Palacos is sucked into the femoral canal (as if cted) and its distal portion acts as a plug due to its ghy characteristics. In the proximal portion of the femur cement can be pressurized into cancellous bone by direct er pressure.

is of note that recently we have used a variety of newer lular femoral devices (Apex Modular™ Cementless n and OTI R-120™ Cemented Modular Neck) which allow for more accurate reproduction of the mechanics of the hip and minimize the need for the erior capsular and external rotator releases.

al Mini-Incision Technique

or close to twenty years I have also been using a dual sion approach which originated in response to the need more precise preparation of the femoral canal in non-ented total hip devices. By using a stab wound or a short nd incision just proximal to the greater trochanter, it has 1 possible to insert cylindrical reamers and rasps of all s to prepare the femoral canal. We have also inserted the al prosthesis through the second incision but in most ances with the standard (non-modular) prosthesis we still er to insert the prosthesis through the main anterior sion after the appropriate mobilization and delivery of proximal femur into the wound. As stated in the previous igraps, in order to achieve this we have done posterior sulectomies, released the short external rotators and ñormis and, if necessary, the anterior origin of the tensor ia lata from the iliac crest.

he second incision has allowed us to do non-cemented ices with shorter skin incisions and it is also of note that ave not used any special retractors or instruments other our Cobras and Homans.

ve have, however, modified the rasp handles on the sthesis we have used. In some systems we have bent the s and have been able to insert the prosthesis without a nd stab wound. In other systems we have had nothing straight rasps inserted though the stab wound eymuller and more recently Spectron, SNR) ve have not used surgical navigation techniques nor roscopy to insert our rasps. The pictures in this article e taken on a radiolucent operating table for teaching oses. If there is any doubt in the surgeon's mind about rasp and prosthetic placement, fluoroscopy techniques be easily applied to the process.

ree Mini-Surgical Incision Approach

he third mini-incision is basically a stab wound distal to main anterior incision. Through this stab wound abular reamers and acetabular inserters can be ograded to allow reaming and prosthetic placement ough the short anterior incision; the acetabulum exposed



Inferior stab wound aids in placement of the acetabular reamer.



Inferior stab wound serves for placement of suction drain.



Superior stab wound aids in placement of femoral instruments.

procedure this third incision or stab wound is used for suction drains.

By using three short incisions we have been able to do both cemented, non-cemented, and hybrid procedures in the obese and/or very muscular patients without making long skin incisions, undermining thick layers of fat and cutting muscles unnecessarily (heaviest patient 450 lbs.).

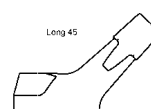
Our outcomes in this subset of large patients have also been good and we do not hesitate to perform total hip arthroplasties in these weight challenged patients.

Clinical/Surgical Impression of Newer Proximal Modular Designs

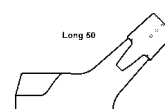
Implant orientation is always a significant part of any total hip technique. The mini-incision approach places a higher demand on awareness of implant positions due to the limitations of exposure and the increased risk of hip dislocation. Proximal modular stems provide for final mechanical adjustments thus reducing the risk of implant impingement, leg length discrepancy, and soft tissue laxity. These newer designs should aid surgeons who are not familiar with the anterior mini-incision approach to be confident in their ability to routinely implant components in their proper biomechanical orientation.



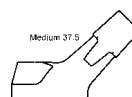
Proximal Modular Cementless



Long 45



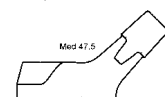
Long 50



Medium 37.5



Med 42.5



Med 47.5

Minimal Invasion Incision Using the Posterior Approach

By Lawrence D. Dorr, M.D.

The MIS posterior hip incision can be performed in a majority of THR patients with a length of 5-10 cm placed along the posterior border of the greater trochanter from the level of the tip of the trochanter to that of the vastus tubercle (Figure 1). This incision can be used in patients who have a body mass index (BMI) that is between 26.0 and 50.0. With a BMI above 30 the incision for us averages 13 cm. The patients for whom an MIS incision is most difficult are those who have a very thick gluteus maximus muscle and these are

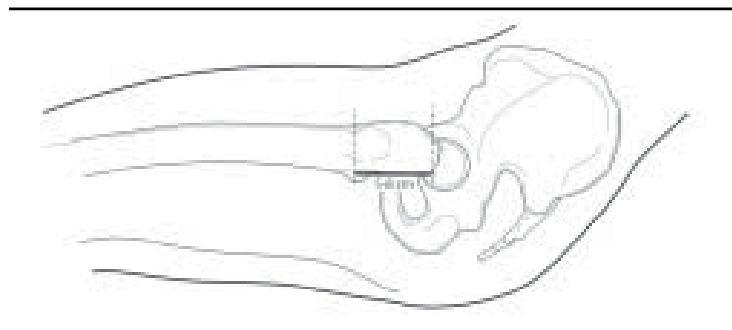
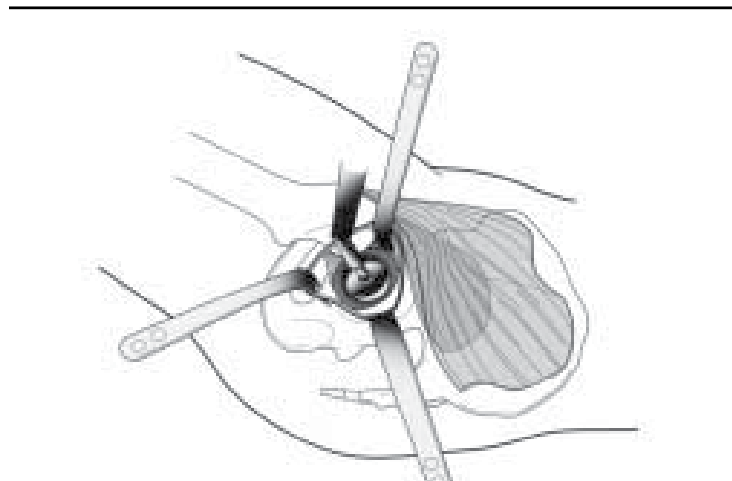


Figure 1: Incision.

big men. The learning curve to become proficient with a 5-10 cm incision, so that it can be predictably and reproducibly employed, will be 40 hip replacements with appropriate instrumentation. With the appropriate instrumentation the components can be implanted in 30-40 minutes and the closure, which includes the capsule and use of a subcuticular suture for skin, will take approximately 20 minutes.

Our data with 76 consecutive hips is that 60 (80%) could be done with a 10 cm or less incision (16 others averaged 13 cm). These operations were done with specifically designed instruments including a curved reamer (Figure 2). Our data



showed discharge was 1.5 days quicker with only two patients having to go to rehabilitation (previously 33% did so). Complications included one infection, one transient sciatic palsy which resolved within one month, and no dislocations. Pain scores (1-10 with 10 being worst) were 3 on the three postoperative days in the hospital, and 3-4 pain tablets being used per day. No narcotics are used by Ropivacaine is used in the epidural for an average of 20 hours and Toradol is given intravenously for two days. One third of patients go home on a cane and by six weeks 80% are on no assistive device (we use non-cemented implant). Gait analysis shows cadence, stride length, and gait velocity

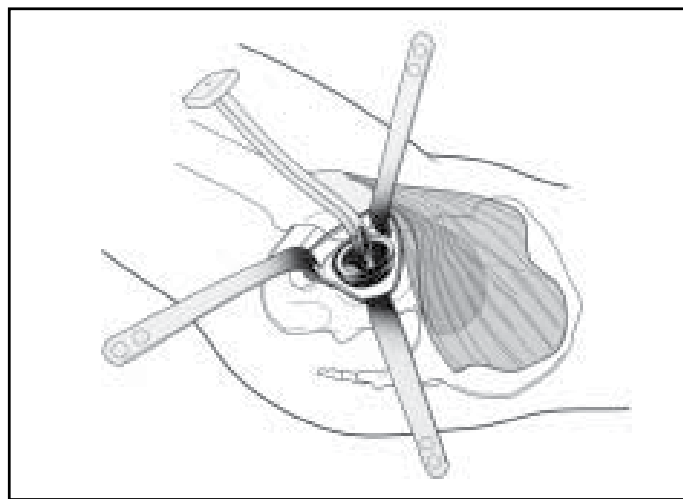


Figure 3: Cup insertion.

all are 80-90% within normal by six weeks. Stride length is only 60-70% of normal at six weeks because extension of the hip is limited by still abnormally firing flexor muscle. All other hip muscle studies are essentially normal for phasic function by 6-12 weeks.

MIS hip surgery has tremendous mental benefits for patients. They feel their body is less violated and less injured. This positive mental attitude accelerates recovery, decreases pain medicine use, and decreases postoperative depression. Providing this mental comfort for the patient is as much a responsibility of the surgeon as the physical care as long as the operation can be predictably and reproducibly performed by the surgeon with the small incisions of 5-10 cm. It remains the responsibility of the surgeon to perform a predictable and reproducible operation as this is a more important responsibility of the surgeon to the patient than the length of the incision. However, if the experience and skill of the surgeon allows the small incision to be used

Surgical Navigation the Answer and Is Real Time Intra-operative Documentation Needed?

I.M. Reynolds, M.D. and Timothy McTighe



There has been growing interest in surgical navigation in part due to continued problems with dislocation. Dislocation have been reported in primary surgeries from 1-10% and as high as 29% in revisions. This senior author has revised over a hundred loose cementless cups just in the past year due to a well known recall of hip implants with fabrication problems. These have increased our dislocation rate from 2% to over 20%. Many of these revised cups present significant problems in determining proper cup orientation, cup stability, and added problems to joint stability due to compromised soft tissue integrity.

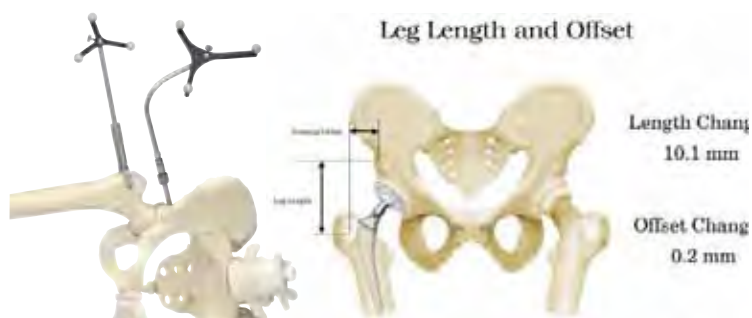
Intense and excess rehab, along with reduced levels of activity, post-op bracing modification of life styles have allowed some patients to back into reduced normal physical routines. Limb alignment, implant position and soft tissue balance have become significant problems. There is no easy and accurate way to track the relationship between pelvis and the femur during surgery. Certainly patient position and manipulations of conventional instruments can affect cup positioning. Drapes obscure the patient and make leg alignment for orientation difficult. In addition we are often dealing with significant loss of bone and orientation landmarks.

Leg length measurement is difficult at best. Pelvic tilt can be found intra-op leg length checks. One solution would be to use trackers fixed to the pelvis and femur that can record the relationship to dislocation to ensure the desired leg length and femoral offset is achieved.

This intra-operative documentation system will provide real time feed back that will aid the surgeon in knowing where he is and where he needs to go to correct the mechanical aspects of his hip reconstruction. Possible additional benefits of such a system would be to document surgical results such as cup position (abduction=45°), femoral offset 45 mm, leg length +2mm femoral version angle 15°.

Printouts for posting in the patient's chart should immediately be made available, reducing the chance of error in transcription.

A simple reproducible system of documenting limb alignment and implant orientation that does not require special operators or extensive preoperative preparation and



One such system is the NaviPro™ System from Kinamed. This system is based on digital technology. It allows for checking relationship between femur and pelvis before and after implantation without imaging technologies. Basic components include a mobile trolley cart that holds a stereo camera, low-profile computer, flat-panel display, foot controls and a mini-printer.

Surgical instruments include passive trackers for the pelvis, femur and a calibrated probe. The technique requires location and marking pelvic landmarks, both ASIS joints, and the Mid-Pubis. Draping, soft-tissue or the patient holder may obscure landmarks. A calibrated patient holder is helpful for the posterior approach. Recording the native pelvis-femur relationship prior to dislocation can be done with manual manipulation of the leg.

At this point standard surgical technique for acetabulum preparation is carried out. During insertion of the trial cup, a tracking probe can be attached to the shaft of the cup impactor and cup position can be registered by engaging a foot pedal. The LED screen provides real-time feedback on cup position (abduction & anteversion).

A tracking device is attached to the greater trochanter for referencing leg length and femoral offset. Standard femoral preparation of the femur is carried out and with femoral trials in place, the reduced hip measurement is carried out by a click of the foot pedal. The NaviPro™ software computes the new pelvic-femur relationship, registering leg length and offset.

A simple printout summarizes results of the surgical case accurately, documenting implant orientation and biomechanical restoration. We are excited about the prospects of this technology and will report our particular experience with it in the future.



Prof. Kristaps J. Keggi, M.D.

Yale University School of Medicine
New Haven, Connecticut

Education:

Yale University, 1955 B.A.
Yale University School of Medicine,
1959, M.D.
American Board of Orthopaedic
Surgery, 1968

Residency:

Intern & Assistant Resident Surgery
The Roosevelt Hospital, New York,
NY 1959-1961
Assistant Resident & Resident in
Orthopaedic Surgery
Yale University 1961-1964



Captain, MC, USAR

Orthopaedic Staff, William Beaumont General Hospital, 1964-1965
Chief, Orthopaedic Surgery, Third Surgical Hospital, Vietnam, 1965-1966
Director, Orthopaedic Center for Joint Reconstruction, Waterbury Hospital
Clinical Professor of Orthopaedics and Rehabilitation

Academic Awards and Honors:

Yale Orthopaedic Teaching Award, 1969, 1976, 1984, 1985, 1993, 1999
Honorary Doctorate, Latvian Medical Academy (Medicinae Doncotrem
Honoris Cause), 1997
Honorary Doctor of Humane Letter Degree, Quinnipiac College, 2000
Orthopedist of the Year 2001, Connecticut Orthopedic Society
Latvian Academy of Science, June 1990, Honorary Member
Russian Academy of Medical Science, 1993
Latvian Order of the Tree Stars, 1995
V Class Order of the Estonian Red Cross, 1999

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American Association of Hip and Knee Surgeons
Society for Arthritic Join Surgery



Joint Implant Surgery & Research Foundation

321 Buckthorne Drive • Chagrin Falls, OH 44023
Phone: (440) 543-0347 • FAX: (440) 543-5325
info@jisrf.org • www.jisrf.org

This edition of JISRF Update provides stimulating material for consideration of two “hot” topics in reconstructive surgery. Both the less invasive hip replacement surgery and navigation systems have gained greater interest and consideration by reconstructive surgeons.

Just as arthroscopic assisted surgeries have revolutionized many knee and shoulder reconstruction less invasive exposure, perhaps in conjunction with navigation or other imaging techniques, hold promise for diminished patient pain, quicker rehabilitation and more accurate placement of components. This should result in better clinical outcomes and improved long term implant durability.

From the outset it is important to realize, and accurately convey to our patients, that hip replacement still remains an invasive procedure with inherent risk regardless of approach. Early reports come from very experienced hip surgeons with a wealth of experience and expertise. These reports suggest benefits including diminished blood loss, decreased length of stay and earlier return to more normal gait. However, minimal invasive approaches should not be pursued at the expense of inadequate visualization or sub optimal component positioning and stability. The advent of modular femoral components should facilitate less extensive exposure as well. Modularity also allows adjustment of leg length, offset, anteversion and most importantly improved hip stability.

The second hot topic concerns the utility of navigation systems. Current interest in these systems would seem to stem from two concerns, dislocation and leg length discrepancy. Although several large studies suggest that a posterior approach is not associated with a statistically higher incidence of dislocation, many surgeons have abandoned this approach despite its ease. Navigation clearly should optimize acetabular cup position, which is the most common cause of hip instability regardless of approach. Leg length discrepancy remains the number one basis for legal action. Again, navigation systems are capable of accurately determining and documenting changes which occur during arthroplasty. When used in conjunction with a modular system, the surgeon can manipulate leg length, offset and resultant hip stability.

All of the above issues require further investigation and consideration. Further refinements certainly will be made. This clearly represents an exciting direction in reconstructive surgery.



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NOVEMBER 8, 2002

Yale Grand Rounds

Sponsored by an educational grant from JISRF
and Keggi Orthopaedic Foundation

Why Use a Modular Neck Design for Cemented THA?

by

Hugh U. Cameron, M.B., Ch.B.

Timothy McTighe, Ph.D. (hc)

Bernard Stulberg, M.D.

Kristaps J. Keggi, M.D.

What are the immediate goals of THA?

Eliminate Pain:

- New Hip

Restore Function:

- Reproducing Hip Mechanics
- 1. Femoral Offset
- 2. Neck Length
- 3. Version Angle



What are the immediate goals of THA? (cont.)

Eliminate Pain:

- New Hip

Restore Function:

Reproduce Hip Mechanics:

1. Femoral Offset
2. Neck Length
3. Version Angle



Two Remaining Significant Problems in THA

- Dislocation



Dislocation

- Reports from 2-8%
- Higher in Posterior Approach
- Higher in Sm. Dia. Heads
- Higher in Revisions >20%



Two Remaining Significant Problems in THA (cont.)

- Instability



Keys to Success in THA

- Technique, Technique, Technique

Limb Alignment
Implant Position
Soft Tissue Balance

- Patient Selection
- Implant Design
- Implant Materials

Current Trends

- Surgical Navigation Systems
- Mini-Incisions
- Hard on Hard Bearings
- Large Femoral Heads
- Increased use of Lateral Femoral Offsets
- Increased use of Constrained Sockets

Current Trends Surgical Navigational Systems

- **Challenges in THA**
 - Optimum cup alignment
 - Desired leg length
 - Optimum femoral offset



Challenges in THA

Cup Alignment
>30% Malpositioning

Optimum

45° Abduction

20° Anteversion



Single biggest medical / legal problem in THA

- **Desired Leg Length**



Modular Neck

Benefits

- Adjustment of Hip Mechanics
- Less chances of implant impingement
- Option of Stem Insertion Prior to Cup
- Reduced Operative Bleeding
- Modular Site Outside of Bone Interface
- Accessibility to Cup in case of Revision
- Replacement of Ceramic Head if Necessary (new neck taper)

R-120™ Cemented Stem Collared Design

- Intrinsic Modular Indexable Neck
- C.C. Conventional Styled Stem
- Full Collar
- A/P Teardrop Cement Groove
- Proximal Male Finish
- Distal tip Polished
- Currently 6 sizes



IMIN™ Features

- **Version Adjustment**
(8°, 12°, 15°)
- Neck Shaft Angle Adjustment
- Stem Insertion / Acetabular Exposure



IMIN™ Features (cont.)

- Version Adjustment
- Neck Shaft Angle Adjustment
- Stem Insertion / Acetabular Exposure



R-120™ Modular Neck Features (cont.)

- Version Adjustment
- Neck Shaft Angle Adjustment
- Stem Insertion / Acetabular Exposure



Surgical Approaches

- **Anterior**
 - Mini-Dual
 - Mini-Tri
- **Direct Lateral**
- **Posterior**
 - Mini-Dual

Surgical Approaches

- **Anterior/Lateral (Modified Watson-Jones)**
Dr. Hugh Cameron, Toronto, Canada



Stem Driver



Trials at position #3

(Cameron)



Stem w/o Neck

(Cameron)



Cup & Stem w/o Neck in Place

(Cameron)



Pre & Post-Opt X-ray

(Cameron)



Posterior Approach

Dr. Bernard Stulberg, Cleveland, Ohio



Posterior Approach

- R-120™ stem w/o neck in place

(B. Stulberg)



Posterior Approach

- R-120™ post-op x-ray

(B. Stulberg)



Surgical Approaches cont.

- Anterior mini-dual approach

Dr. Kristaps J. Keggi, Waterbury, CT



Surgical Approach

- Anterior *non*

Small Single

Dual Mini-Incision



Surgical Approach

- Anterior (Keggi)

Tri Mini-Incision used for these pts. (450lbs.)

Closed Tri Mini
Inferior stab would
used for drain



Incision needs to be large enough to insert cup

(Keggi)



Cup In Place Screw Insertion

Keggi



Canal Reaming



Long Straight Femoral Broach



Femoral Trial Insertion



Optimum Femoral Offset

Valgus Neck Shaft Angle
147° (position B)

Varus Neck Shaft Angle
123° (position B)

(Same pt., same implants,
different neck positions)



Femoral Stem & Cup in Place w/o Neck



Post-op X-Ray



Ways to Reduce Dislocation

- Anterior or Direct Lateral Approach
- **Restore Hip Mechanics**
- **Modular Neck to Aid in Restoration**
- 32 mm Dia. Head or Larger
- Do not use skirted necks or modular truion necks
- Constrained sockets (not indicated for impingement problems)
- Reduce Use of Angled Poly Inserts
- Navigation System (\$50,000-250,000)

Summary

- **Modular neck design aids in fine tuning joint mechanics**
- Works with all surgical approaches
- Allows for femoral stem insertion first (aids in reducing blood loss)
- Allows for ease and access in case of revisions
- Reduces chances of mechanical impingement of implants with mini-incision surgical approaches



Clinical Summary to Date

50 implanted since 1/02 by authors

250 implanted in last 12 months by study group members*

0 dislocations

0 intra-op fractures

No significant leg length inequalities

70% indexed to positions other than 0

IMIN™ Study Group Members*

Design: R-120™

Hugh U. Cameron, M.B., Ch.B.

Timothy McTighe, Ph.D.

Ian Murray, M.E.

Clinical/Surgical

Milt Smit, M.D.

Bernard Stulber, M.D.

John Froehlich, M.D.

Peter Buchert, M.D.

Kristaps Keggi, M.D.

John Keggi, M.D.

Dave Halley, M.D.



**Joint Implant Surgery
& Research Foundation**

17321 Buckthorne Drive • Chagrin Falls, OH 44023

Phone: (440) 543-0347 • FAX: (440) 543-5325

info@jisrf.org • www.jisrf.org



Cementless Modular Stems

Timothy McTighe, Editor

Introduction

In our past November 2001 feature article reviewed and highlighted a specific modular design for use in a cemented total hip stem. This article will look at modular cementless stems. Both of these publications are dealing with the restoration of the joint mechanics. The goal of biomechanical restoration of the hip is the same regardless of the type of stem design used. However, due to the inherent properties of materials, limitations can and do exist for specific design features. Example: specific designs that are acceptable and reliable for cobalt chrome alloy might be unacceptable for titanium alloy designs. In the early nineties saw a number of first and second-generation modular stems come and go. It is important to understand the specific design features and goals of Modular Total Hip Stems and not to lump all designs into one simple category "Modular Stems". In fact, modular sites, designs, features, material and quality can be quite different in nature and classification.

Modularity Classification

- Proximal
- Mid-stem
- Distal

Product Review

Proximal

Head/Neck

ML[®] is now considered both state-of-the-art in head/neck design and gold standard as cementless stem.



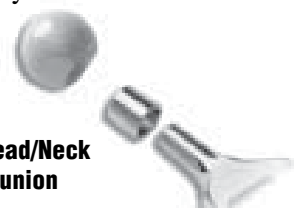
Retrieved
ingrowth
sample (Collier)



Example head/neck
design

Neck Extensions

Trunion sleeves offer increased neck length adjustments, however, tend to reduce range of motion. Many designs have discontinued offering this feature.



Head/Neck
Trunion

In This Issue:

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- 1 Introduction
- 1 Product Review
- 6 Modular "Dual Press™" Stem Design
- 10 Modular Neck Design
- 11 Commentary

Joint Implant Surgery and Research Foundation

is a non-profit scientific and educational organization founded in 1971 by professor Charles O. Bechtol, M.D.

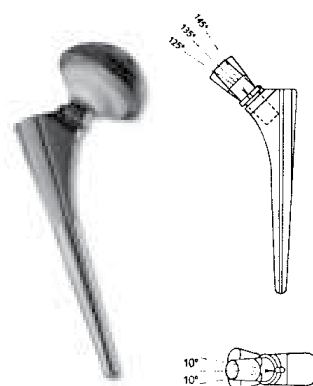
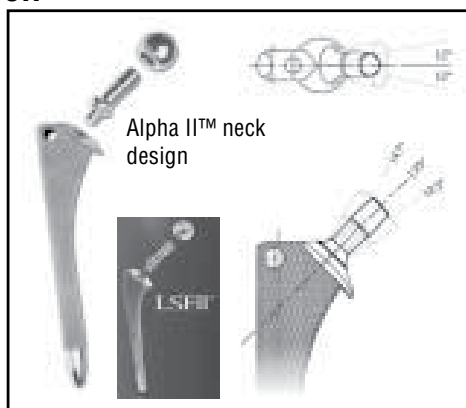
The foundation over its past 30 years has conducted CME activities for both surgeons and nurses while sponsoring clinical / surgical study groups, including basic science projects that have led to the development and marketing of significant Total Joint Replacement Implants.

Product Review *(continued)*

Modular Necks

These designs allow for adjustment of hip mechanics in a mono-block stem. In addition, they provide the option for stem insertion prior to cup preparation, thus reducing operative blood loss. The OTI design is the only c.c. modular neck design of which we are aware.

OTI



Lima F2L™ Multineck des

Anterior / Posterior Pads

This design allowed for adjustment of fit & fill in the A-P width of the implant. It was criticized for not having circumferential porous proximal coating. While the design allowed for adjustment or fine tuning of joint mechanics, it was discontinued.

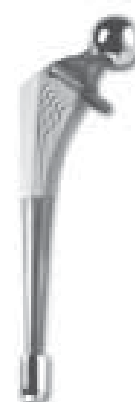
Richards Modular Stem



Modular Collars

These designs increase collar/calcar contact. Omni-Flex porous was criticized like the RMS for not having circumferential coating and was discontinued, however the HA version is still in limited use. There have been no reported fractures of their collars.

Link®



OmniFlex™



Proximal Shoulders (bodies)

This area of modularity encounters the largest differential in design styles. Some devices like Apex and Margron are more than just a neck, but less than a metaphyseal body. They have the design option of increasing their proximal body height to compensate for bone loss. Some of these designs, like Apex and Margron, also allow for variable anteversion.

These designs all feature different locking mechanisms for the modular components.



duct Review (continued)

n Sleeves

stem sleeves offer the advantage of fit & fill with restoration of hip mechanics. Some designs like the S-Rom™ require removal of the stem to correct offset or alignment, while newer designs allow for correction with the *insitu*. All of these designs feature a modular site embedded within the femoral bony cavity. This has a higher potential of fretting wear debris being delivered directly to the implant/bone interface versus designs with modular sites embedded out of the femoral cavity.

The Sivash is credited with creating the first stem/sleeve cementless total hip stem introduced in the United States by J.S. Surgical Corporation.

The Sivash total hip system never received major clinical market success, partially due to the difficulty of the surgical technique, and the positioning of this constrained design. We must, however, not overlook its major areas of contribution.

Titanium alloy for femoral stem and chrome cobalt for head articulation

Cementless (threaded) petalled acetabular component

Titanium alloy proximal sleeves for enhanced collar/bone contact

Constrained articulation (metal on metal)

1975 Noiles and Russin redesigned the Sivash stem to improve its function in cementless THA. Adding

longitudinal flutes similar to that of the femoral intramedullary rod reduced torsional stresses on the implant interface.

The Hugh Cameron started his clinical use of cemented sleeves and the S-Rom stem in July,

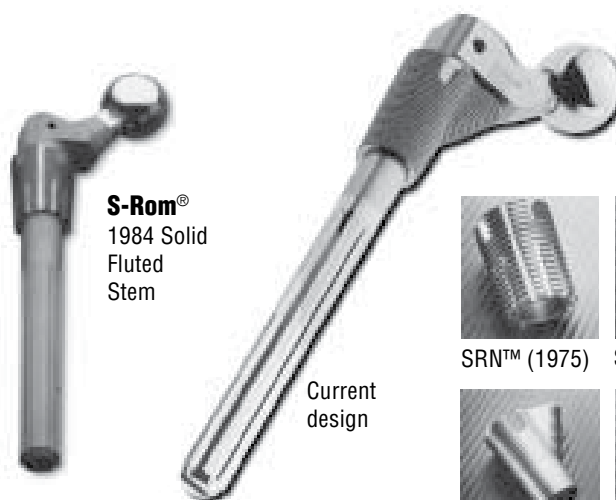
1975. Due to demanding surgical technique, an alternative of press-fit taper-lock sleeves was developed. This evolved into the current stem/sleeve combination and is now considered the standard for modular cementless stems.



Sivash



SRN™



S-Rom®
1984 Solid
Fluted
Stem

Current
design



SRN™ (1975)



S-Rom (1983)



SPT™ (1984)



SPA™ (1984)

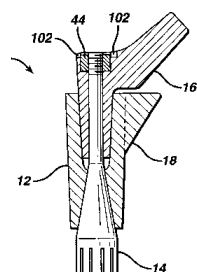


AcuMatch™

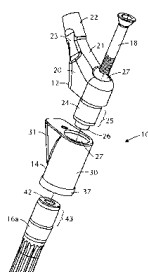


UniSyn™

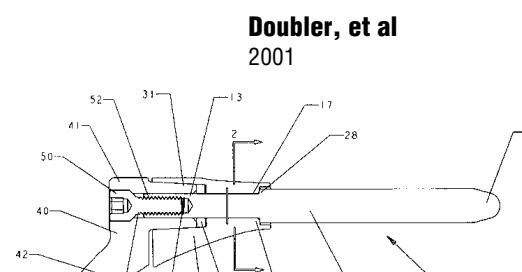
Recently Issued Stem Sleeve Patents



Noiles, et al
2001



Fernandez, et al
2001

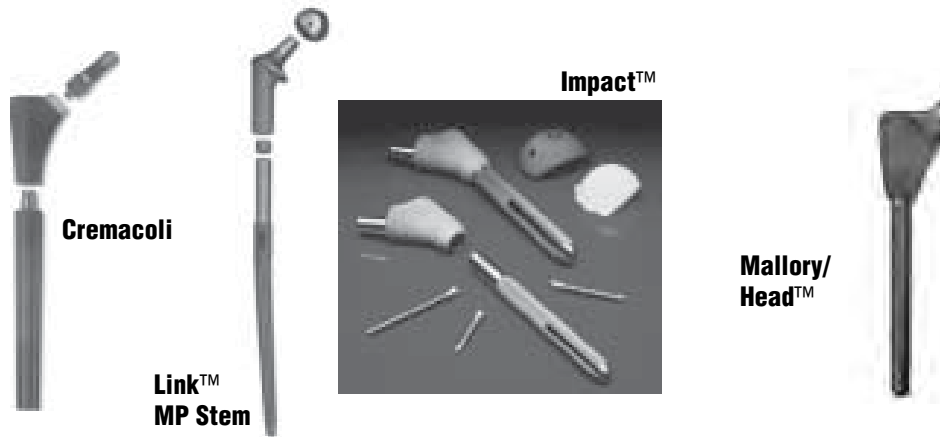


Doubler, et al
2001

Product Review (continued)

Mid-Stem

These designs offer versatility in correction of sizing mismatch between proximal and distal femoral anatomy. This feature has been very helpful in complex revision cases.

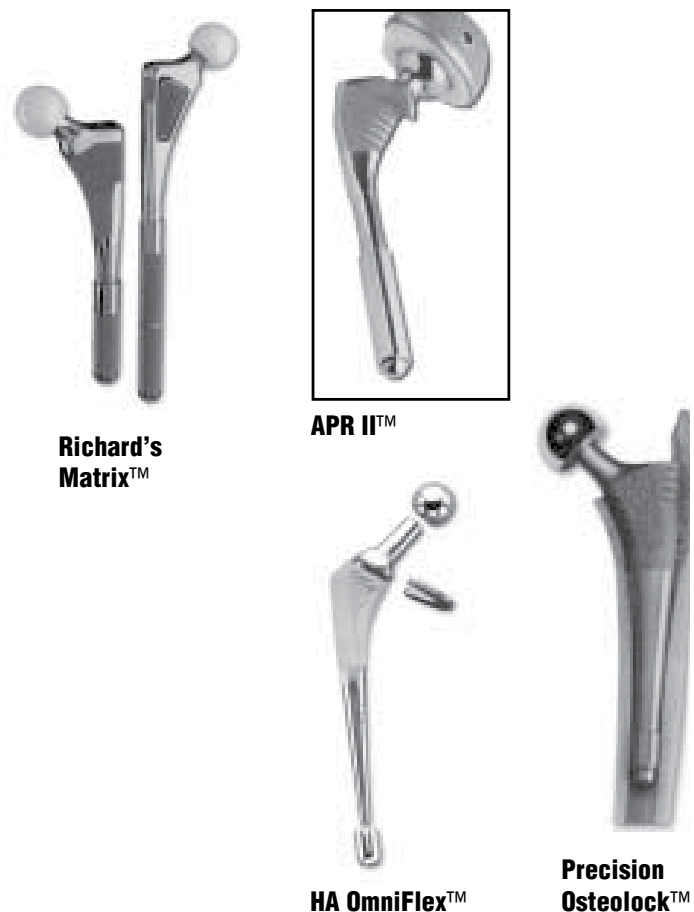


Distal Sleeves

These designs allow for distal stem fit with different distal style options (smooth, fluted, or porous). One of the more interesting concepts is the Omniflex™ stem from Osteonics. This stem features a polished distal stem tip. The design goal was to improve load transfer and minimize the thigh pain associated with a poor fitting or toggling distal stem.

Devices like the APR II and RMS had other under-designed features including the lack of circumferential coatings, poor locking designs on modular cups, and, in the case of the APR II titanium femoral heads, significant bone lysis. The combination of problems certainly affected the acceptance of distal sleeve designs. Possibly, with current technology, distal sleeves could be designed with minimal abrasion wear problems. However, I believe distal sleeves would have great difficulty gaining acceptance in the marketplace.

Of these devices, I believe only the Omniflex HA stem is still available.



Multi-Modularity

The RMS is the best example of excess modular sites for a cementless hip stem.

In addition to the modular sites for its cementless porous cup and optional screws, you could end up with over six interface sites. From a fit & fill point of view this system was a very novel approach that offered significant versatility in addressing surgical and anatomical situations. However, it faced too many problems in the market and has been



Summary

These stems represent some of the current trends in both design and marketing efforts. This tendency is no doubt due to the clinical and market success of the S-Rom and the competition attempting to improve upon the S-Rom stem by adding different design features. These designs attempt to add features for fit & fill of the implant to the bone and adjustment of joint mechanics.

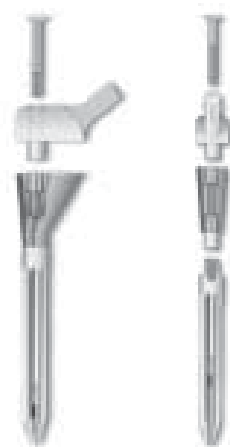
But certain modular designs' goals have changed over the past 17 years. In the early 1980s fit & fill were the principal objectives. Today aseptic loosening does not have the same concern. The reduction of particulate debris and restoration of joint mechanics are the focal point.

The AML certainly has become the gold standard for cementless monoblock stems and the S-Rom stem is considered the gold standard for modular cementless stems. With all advancements in design and technology, designs that work well today would not necessarily be needed as is with our current knowledge base.

In 1995, along with coauthors Trick and Koenig, we wrote a chapter in the Encyclopedic Handbook of Materials and Bioengineering, "Design Considerations for Cementless THA". In that chapter we reviewed the use

of modularity and made some predictions as to product design features in the near future. The main focus of our design direction was for the stem to incorporate a proximal modular body that would allow for correction of version, offset and vertical height without disruption of the stem body from its bone interface. Proximal bodies of different sizes and shapes would be available that provide for versatility and retrievability with little or no bone destruction.

No one would argue that restoration of hip mechanics is critical to a long-term successful clinical outcome. Today designs exist that allow the correction, or fine-tuning, of the hip mechanics after the stem has been implanted. This issue will feature one specific design (Apex Modular Stem).



McTighe, et al
"Intrinsic" Design

Surgeon Highlight



Dr. Tom Tkach Oklahoma City, Oklahoma

Education:

Premedical B.S., Zoology, University of Oklahoma - 1985
M.D., University of Oklahoma - 1989
Intern General Surgery, University of Oklahoma - 1989 to 1990
Residency Orthopaedic Surgery and Rehabilitation, University of Oklahoma Health Sciences Center - 1990 to 1994
Fellowship Total Joint Fellowship, University of Utah - 1994 to 1995

Honors & Awards:

The University of Oklahoma College of Medicine
Admissions Committee - 1989
The University of Oklahoma Dean's List, Fall - 1983

Professional Organizations:

Oklahoma Medical Student Association
Oklahoma State Medical Association
Oklahoma County Medical Society
Oklahoma State Orthopaedic Society
American Academy of Orthopaedic Surgeons
American Medical Association
American Association of Hip and Knee Surgeons
Mid-America Orthopaedic Association

New Proximal “Dual Press™” Modular Stem Design

By *JISRF/Apex Study Group Members

The clinical success of the S-ROM cementless stem not only comes from its modular feature improving fit & fill but primarily from its stable intrinsic design features: proximal cone; medial triangle; distal straight stem with torsional flutes and a coronal slot.

Today there are a number of cementless stems, both monoblock and modular, that incorporate these same features. However, a number of concerns still remain: imitations for correction of joint mechanics (particularly after stem implantation); generation of particulate debris; fatigue strength and retrievability.

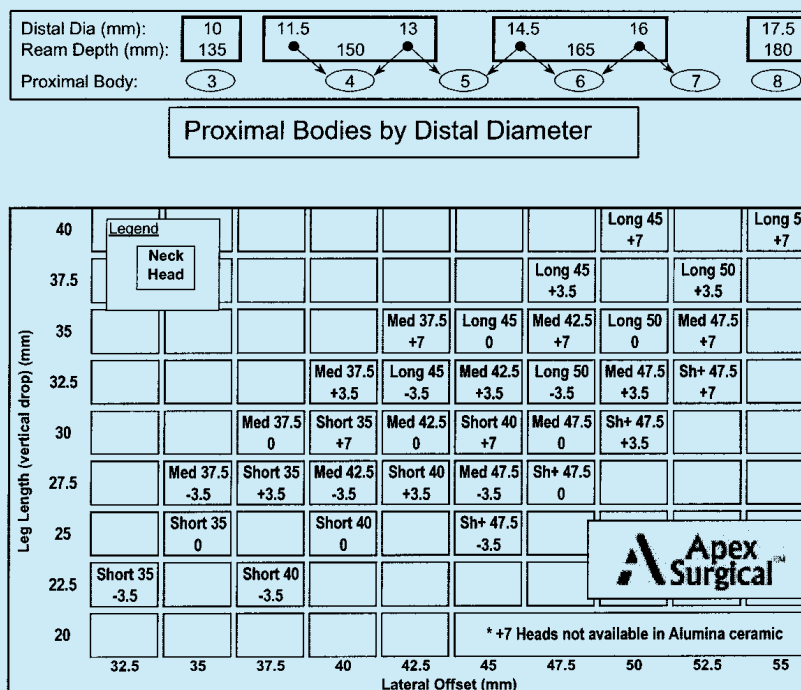
With these concerns in mind a design goal was established to provide for a new proximal modular cementless stem (Fig. 1) that would address the proven fit & fill features of today's contemporary cementless stems with updated modular features that provide for more intra-operative options (Fig. 2).

The Apex Modular hip stem employs a modular junction between the titanium alloy stem and neck that is simple,



Apex Modular femoral components

Figure 2



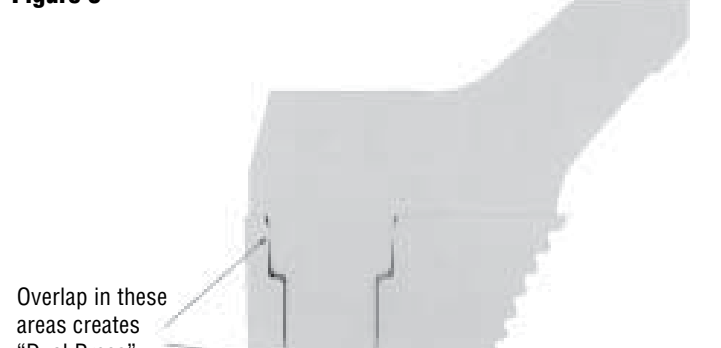
Modular Neck/Head Selection Chart

robust, and very stable. This patent pending modular design allows for a large selection of necks to enable the proper combination of anteversion angle, lateral offset, and neck length/leg length, for the restoration of proper soft tissue tension and joint biomechanics.

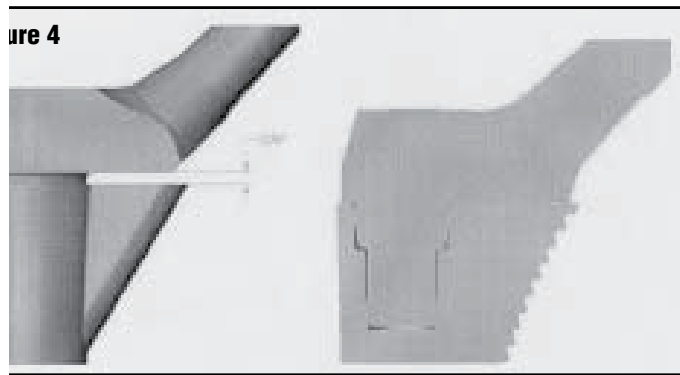
The neck is connected to the stem with a Dual Press junction (Fig. 3). This modular attachment mechanism is new to orthopaedic implants, but the concept was derived from conventional mechanical tool design. The main distinguishing feature is that the hole in the stem and the mating peg on the neck are cylindrical rather than conical tapered. To create a mechanical lock, the proximal and distal diameters of the peg are slightly larger than the corresponding holes in the stem, creating two bands of interference, or “press fit”.

This design eliminates the need for locking tapers, which can be difficult to manufacture and prone to disassociation and avoids the use of screws, which can loosen and disassemble. For all practical purposes, the stem performs as a one-piece stem (with a conventional modular head) after

Figure 3



Overlap in these areas creates “Dual Press”



Schematic of S-ROM® (taper-fit)

Schematic of Apex (Dual Press)

ilar neck. Each neck has three holes, corresponding to plus 15, and minus 15 degrees of version. This ability just neck orientation eliminates the need for separate and right stems, thus reducing inventory requirements, enabling better restoration of joint biomechanics. The and hole also provide additional torsional stability, as as control of the version angle.

e problem with a taper connection is that the axial ion of the two parts after assembly cannot be controlled ly, due to the required manufacturing dimensional nces. For example, notice the large axial gap (tional) between the taper-fit S-ROM® stem and sleeve 4). In such a design, all of the load applied to the ral head must pass through the tapered portion, and will always be variability (due to manufacturing nces and force of assembly) of the final axial position eg length).

contrast, the advantage of a press-fit connection (used stem-neck junction of the Apex Modular hip) is that vo parts can be designed and manufactured to fully seat assembly.

at does this mean for the Apex Modular stem? This -fit design provides two important advantages (see es 3 and 4):

- the neck can be fully seated against the top surface of em, so leg length is predictable; and,
- the neck strength is increased by the direct support of em (versus having all of the load transmitted through eg), so offsets can be greater.

Relative Summary of Testing To Date†

e Apex Modular™ Hip Stem includes two modular ections: the industry standard taper connection between odular head and the modular neck, and the Dual ™ connection between the modular neck and the ilar stem. Testing of these modular components ded: forces required for assembly of the neck onto the

three of the modular femoral stems and necks were assembled using an instrumented mallet to measure the required assembly forces, at the Orthopaedic Bioengineering Laboratory, UCSF. For each impact applied to the neck, the force profile and instantaneous peak force were recorded. The maximum peak force required for assembly of these components ranged from 801 to 944 lbf.

Tests of fatigue strength, disassembly strength, and fretting of the Apex Modular femoral stem were performed by Paul Postak at the Orthopaedic Research Laboratories (under the direction of A. Seth Greenwald, D. Phil. (Oxon)). The smallest stem (size 2, 9 mm distal diameter) was tested with a medium 42.5 neck and a 28 mm head with a +7 mm offset. This combination results in a total lateral offset of 47.5 mm. The fatigue tests were performed with the load configuration as per ISO 7206-4 and load magnitude as per ISO 7206-8. In this configuration, the stem is tilted 9 degrees out-of-plane (in the anterior-posterior direction), which results in torsional loading of the stem and the neck-stem modular connection (Fig 5). Six devices reached 5×10^6 cycles without failure, as required by ISO 7206-8 and the FDA guidance document for femoral stem prostheses.

The same six components were tested for static assembly strength (after fatigue). Each of the stem-neck assemblies was sequentially loaded to 60 ft-lbf of torsion, and then tension up to disassembly (or 1000 lbf, whichever came first). No disassemblies occurred during the torsional loading, with all stem-neck assemblies reaching the torque limit. The minimum tensile load required to disassemble the neck from the stem (after the fatigue and torsional loading) was 593 lbf (3 of the 6 stems reached the 1000 lbf limit).

Finally, the three disassembled components were examined under a stereomicroscope for evidence of fretting and corrosion between the mating parts. Fortunately, the worst damage (type “C”) on the fatigue-tested Apex Modular femoral stems was found on a location that is unlikely to fracture. The location and pattern of this damage corresponded to the outer edge of the proximal stem surface, where the neck was overhanging the stem. This overhang was relatively extreme in the tested components due to the combination of the smallest stem with a relatively high offset neck. There was no severe (type “C”) damage at the critical neck-peg modular junction; the large majority of the damage at the press-fit surfaces was classified as slight (type “A”), with the remainder classified as mild (type “B”).

In summary, the size 2, 9 mm stem with the medium 42.5 neck and +7 mm offset head (total lateral offset of 47.5 mm) successfully passed fatigue testing as per the relevant ISO standards and FDA guidance document. In addition, based on supplemental finite element studies (Fig. 6), the only stem-neck combinations that are worse case than the fatigue-tested combination are the size 2, 9 mm stem with the

in the fluted region of an additional stem in the fatigue study, this fracture resulted from a failure of the embedding protocol, and the strength in the fluted region is equivalent to the strength of the fluted region of a similarly sized S-ROM stem.

Device Fatigue Testing

The fatigue tests were performed with the load configuration as per ISO 7206-4 and load magnitude as per ISO 7206-8. In this configuration, the stem is tilted 9 degrees out-of-plane (in the anterior-posterior direction), which results in torsional loading of the stem and the neck-stem modular connection (Fig. 5). The load was cycled at 10 Hz, sinusoidal loading, with minimum and maximum peaks of 300 N and 2300 N (compression), respectively. Six devices reached 5×10^6 cycles without failure, as required by ISO 7206-8 and the FDA guidance document for femoral stem prostheses.

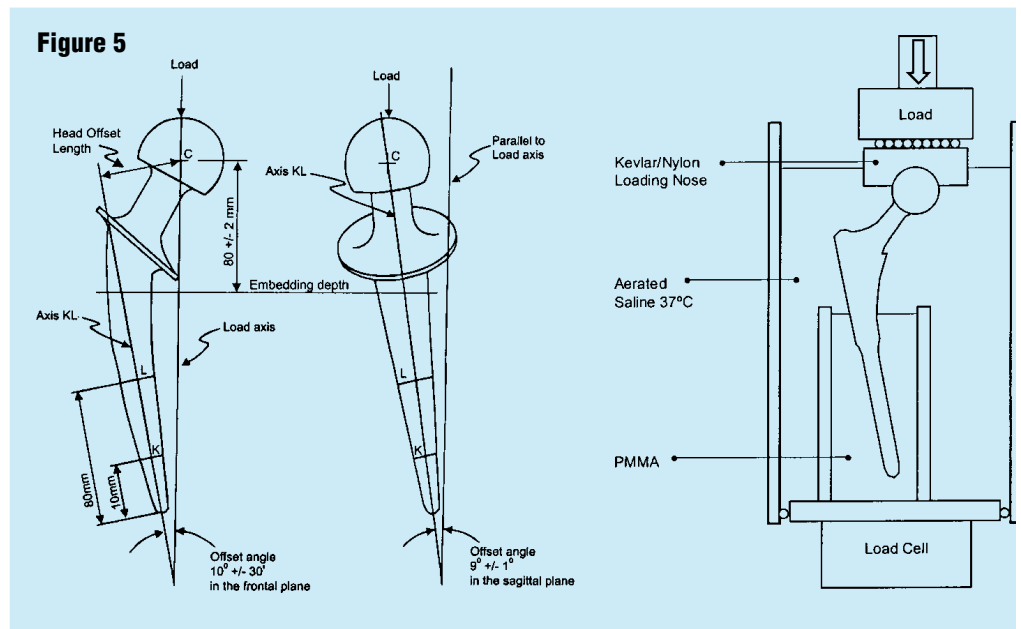
Strength of Other Stem-Neck Combinations

A design analysis using finite element methods was performed to evaluate the strength of other stem and neck combinations relative to the combination that was fatigue tested (Fig. 6).

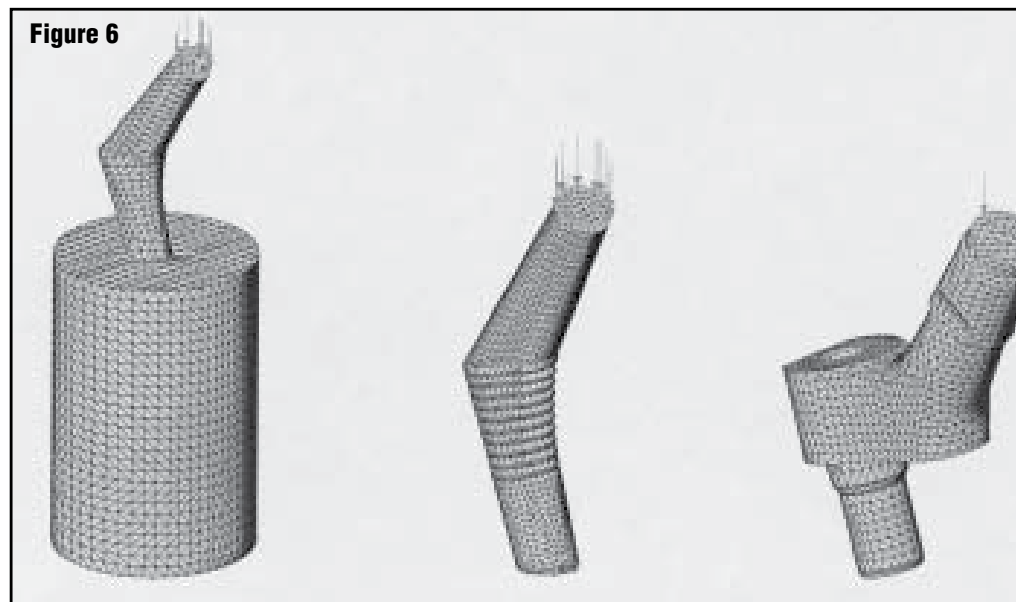
The highest tensile stress, and thus the area at greatest risk of fracture initiation, was predicted to occur on the lateral surface of the stem. The maximum tensile and effective stresses in the neck were less than the maximum stresses in the stem, and thus the models predict that the neck is less likely to fracture than the stem.

High Cycle Fatigue Testing of the Apex Modular™ Hip

In addition to the previous study, size 6, 14.5 mm stem, and neck-head combination with 52.5 mm of lateral offset, survived 48.5 million cycles of fatigue loading with no failure. The increasing cyclic loads reached a maximum peak value of 6 times body weight for a 180 lb individual. The test was terminated at 48.5 million cycles due to failure



Specimen orientation and test schematic 3 as per ISO 7206-4.



Example finite element meshes used to predict fatigue for the various stem-neck combinations.

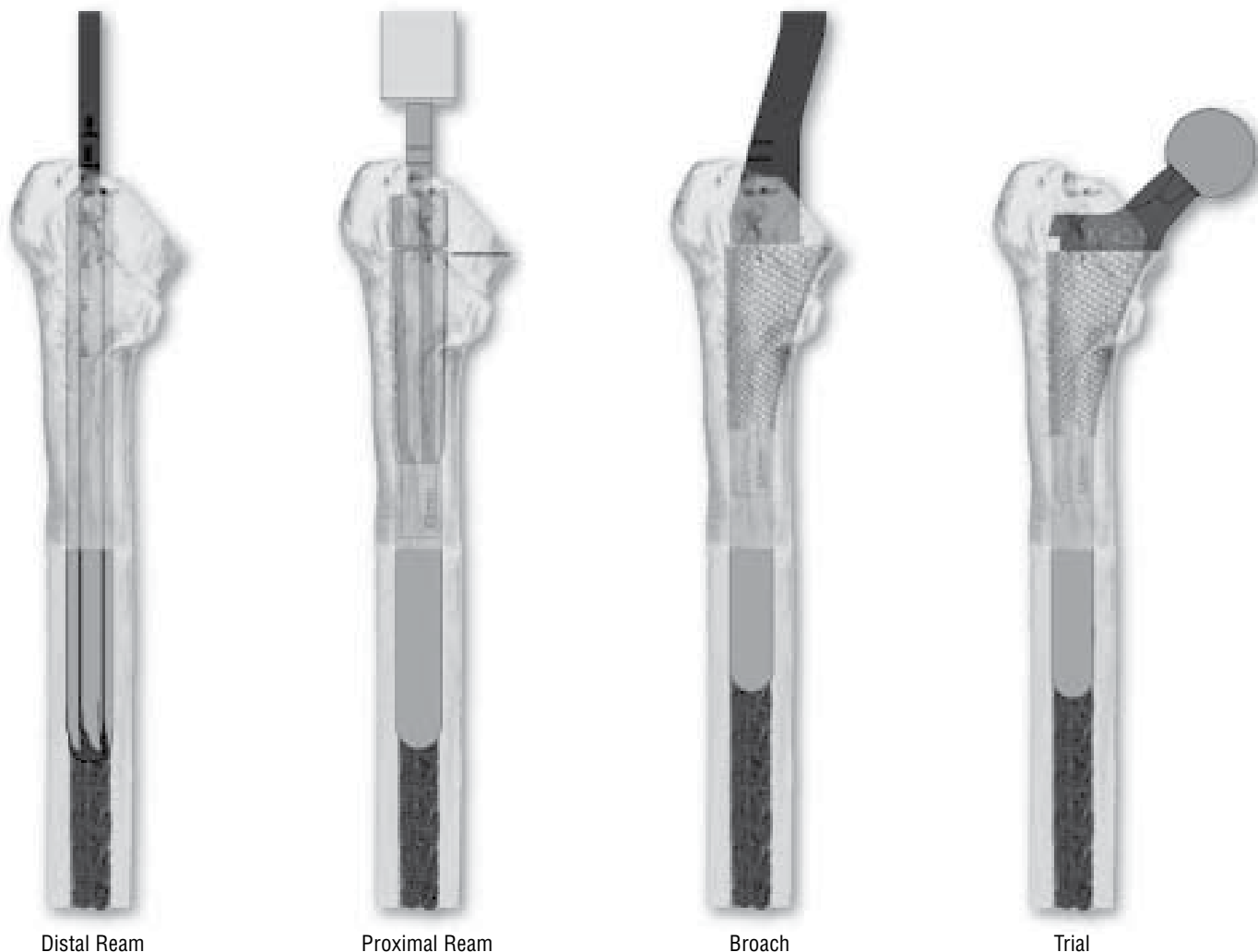
to the horizontal interface. The average amount of titanium debris generated over a 1 million cycle period, measure a 10, 15 and 20 million cycles, was less than 0.004 mg. This equates to a volume of less than 0.001 mm^3 per 10^8 cycle. As a point of comparison, the reported volumetric wear of metal-on-metal total hip replacements is on the order of 1 mm^3 per year, or more than 1000 times higher than the titanium debris measured for the Apex Modular stem in the present study.

Surgical Procedure

1. Femoral osteotomy
2. Open the medullary canal with an osteotome or reamer
3. Straight ream to correct size and depth

4. Conical ream to correct size and depth
5. Broach (medial calcar only)
6. Trial neck and head with broach
7. Assemble and implant stem and neck

Intraoperative Instrumentation



Clinical Summary to Date

380 total implanted (as of 1-Mar-02)

25 different surgeons

2 dislocation*

No infections

No revisions

No significant leg length inequalities

Approx. 10% anteverted

No significant pain at 3 months

The first patient had postop dislocation occurred while getting from a low seated position (lawn chair), closed reduction treated with a brace, no further incidence. The second patient encountered two dislocations due to malpositioning of acetabular component not recognized at

Early impressions as a group

We are better able to address restoration of hip mechanics with this device as compared to prior experience with other cementless implants. However, only long-term outcome data will provide and demonstrate whether this device will improve clinical scores and survivorship. We are extremely encouraged at this point.

*Members

Warren Low, M.D., Oklahoma City, OK
Tom Tkack, M.D., Oklahoma City, OK
Joseph Cheng, M.D., Nashville, TN

Dave LaSalle, M.B.A., Lakeville, MA
Jim Henry, B.A., Oklahoma City, OK
John Froehlich, M.D., Providence, RI

Early Impressions of a Modular Neck Cementless Total Hip Stem

By Milton John Smit, M.D., F.A.C.S.

For many years I have been satisfied with the solid fixation of the AML-type, fully porous-coated mono lock stem. But I, as other clinicians, have noticed there is need for some proximal variability in design to help accommodate the various clinical conditions. Modular femoral stems have been designed to accommodate changes, such as difference in size between the stem and the hip as well as changes in rotation and neck shaft angle. I have recently come into contact with a new design modular neck (ALFA II hip). I have been using the fully porous-coated stem, the ALFA I, since 1996 and have implanted over 314 stems with no revisions. However, I did feel the need on several occasions to be able to adjust the neck for both varus hips and hips where the size of the femoral canal is disproportionate to the size of the hip joint. The ALFA II is designed to accommodate modularity specifically by being able to change the neck. It has the standard proximal Morse taper for articulation with the head but has a unique, distal double Morse taper at the distal end of the neck at the junction with the stem. This has mechanical indexing to allow for changing the rotation of the neck as well as the length of the neck separate from the stem. This has several theoretical advantages.

Since the design is a dual Morse taper, there is minimal risk for micro-motion or fretting.

Because a modular site is at the neck, it is easily accessible at the time of surgery being outside the bone. Since the neck is outside the bone, this can be modulated after fitting the femoral stem, which has two advantages, that is, the trial can be done after full stem implantation as a separate part of the procedure, and also allows for insertion of the stem prior to doing the acetabular component. This may, in theory, decrease blood loss at the time of surgery.

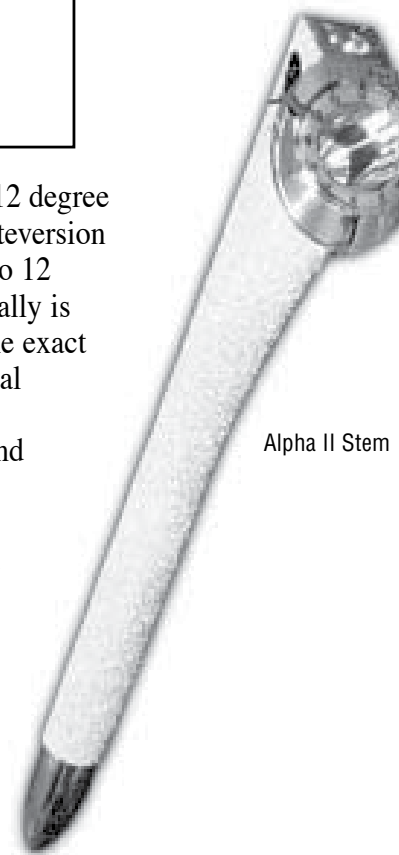
The mechanical indexing available at the distal double



Dr. Milton Smit

with the 8 degree and 12 degree available necks, the anteversion can be rotated from 0 to 12 degrees. This theoretically is helpful in correcting the exact anatomy of the proximal femur and aligning the direction of the head and neck directly into the acetabulum as desired. Clinically, of course, it would help correct lateral offset of the proximal femur to allow for adequate balancing the muscles without excessively lengthening the leg.

In addition, the modular necks are available in three different lengths so whereas they can be indexed in different positions, they can also be chosen independently of the size and length of the stem. This theoretical advantage can be useful in adjusting difference

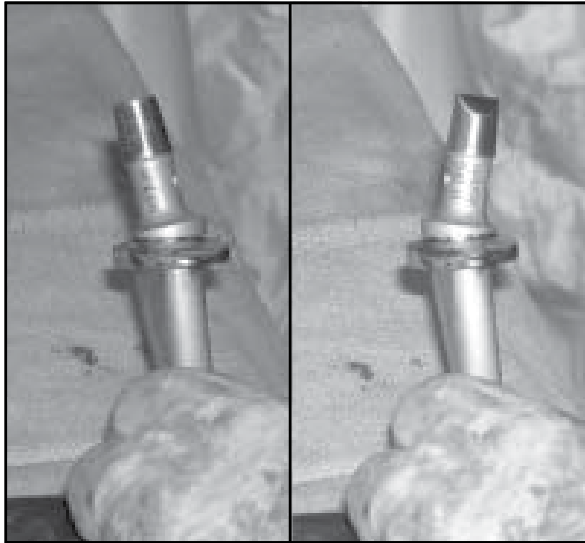


Alpha II Stem

t neck at an appropriate angle and rotation to correct the omy. Whereas, a large man who might have a very small d due to strong cortical bone might use a smaller stem and still require a longer neck, which can accommodate patient's anatomy without using a head segment that ; not have a collar. This might help correct the anatomy out adding impingement. In summary, being able to ige all of these factors - rotation, neck shaft angle and th - the anatomy can be accommodated precisely to v for excellent lateral offsets as well as correct leg ths and version angles. Better control of these factors is ssary not only to prevent dislocations but, theoretically, duce polyethylene wear.

nally, if a hip of this type were to show polyethylene r, acetabular revision surgery would simplified since the femoral head and neck can be completely removed. e stem is stable, correction of neck shaft angle, version leg length are relatively simple.

rly impressions to date are that this modular indexable : design is no more difficult to use than the standard oblock stem which is available in standard size necks at f anteversion and 135° neck shaft angle. Although my of this design is limited (16 cases to date), as with the er modular heads the more experience one gets the more



Version Angles

atility one sees in this new modular junction. nly long-term follow up will clearly demonstrate the ility of this design, but it appears to be a promising new native for restoration of joint mechanics for Total Hip placement. I would also note that additional studies are ing in other medical centers regarding the use of this e modular neck design in the cemented R-120™ Stem.

Commentary

In our feature article, laboratory testing has demonstrated improvements in the mechanical modular interface “Dual Press” while providing benefits to fatigue strength levels of the constructed stem. The sizing matrix offers an impressive array of options in adjustment of offset and leg lengths.

The system appears at this stage of development to have some limitations by design in the ability of positioning version angles. This should not and has not been a problem in treating primary or stage I revisions. However, it might be limited in this feature in treating complex revision cases. I am sure this will be addressed as the system grows to its next developmental stage.

The Alpha II modular neck stem offers a c.c. fully porous coated design similar to the market leader “AML™”. This design offers the surgeon the opportunity for last minute adjustments or fine-tuning the joint mechanics without removing the femoral stem. A mono-block stem design does not offer the versatility of other modular stems for fit & fill features but has an advantage that the modular site is outside the bony cavity.

In addition, with the current trend of small “mini” incisions, proximal modular stem designs that allow for stem insertion and in-situ assembly provide a more reproducible technique and opportunity for last minute correction of joint mechanics. These examples of current stem designs demonstrate that the market place is offering various designs and features to better aid the operating surgeon to provide the best device indicated for his patient.

Remember, it is important to understand and appreciate the specific design features and required techniques for that design and not to lump all modular designs into one simple category of “Modular Stems.”



INTRODUCTION

Timothy McTighe, Editor

Joint fixation has stood the test of time. Lately, due to increased medical advances, there has been a strong movement away from the use of cement as a means of fixation for primary THA. Many companies have been influenced to design newer systems that incorporate a common set of instruments for both cemented and cementless stems. Caution is required in making quick decisions concerning changing to these newer systems.

Over the years the mechanical properties of PMMA, implant design and surgical technique have been refined and improved. As a result, aseptic loosening and product failure have not been a problem with regards to primary THA. However, design differences are different for cemented and cementless stems. By trying to standardize upon a set of common

instruments for a cement and cementless system it is very probable that one design might be compromised.

Several variables can affect the basic outcome of cemented THA:

- Stem Geometry and Material
- Cement Mantle Thickness
- Component Position
- Surgical Technique

The two persistent problems that remain a concern with both cemented and cementless THA are dislocation and osteolysis.

Several factors can contribute to dislocation:

- Anatomical
- Technical
- Mechanical

This volume is dedicated to reviewing these factors and some of the newer approaches addressing these concerns.

In This Issue:

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- 1 Introduction
- 1 Feature Article: Femoral Design Concept that Aids in Fine Tuning the Restoration of Joint Mechanics in THA
- 4 New Approach for Preparation of Bony Surfaces for Cemented Total Joint Arthroplasty
- 5 Commentary

Joint Implant Surgery and Research

Foundation is a non-profit scientific and educational organization founded in 1971 by professor Charles O. Bechtol, M.D.

The foundation over its past 30 years has conducted CME activities for both surgeons and nurses while sponsoring clinical /surgical study groups, including basic science projects that have led to the development and marketing of significant Total Joint Replacement Implants.

FEATURE ARTICLE

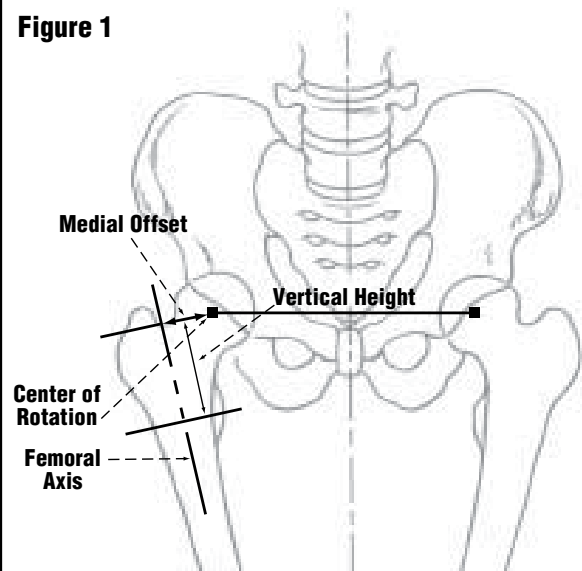
Hugh U. Cameron, M.B. & Timothy McTighe

Femoral Design Concept that Aids in Fine Tuning the Restoration of Joint Mechanics in THA

Restoration of the hip joint mechanics is critical to a long-term successful outcome for total hip arthroplasty.¹ Two important angles need to be considered: the neck shaft angle and the angle of anteversion. In addition to these two angles, femoral head offset affects the joint reaction force.² The placement of the normal position

height is too short, joint stability is a problem. If too long, patients are very unhappy. Incorrect version angle can result in reduced range of motion and possible toeing in. Short medial offset will cause shortening of the abductor moments resulting in increased resultant force across the hip joint, and increasing the tendency to limp. Offset too great

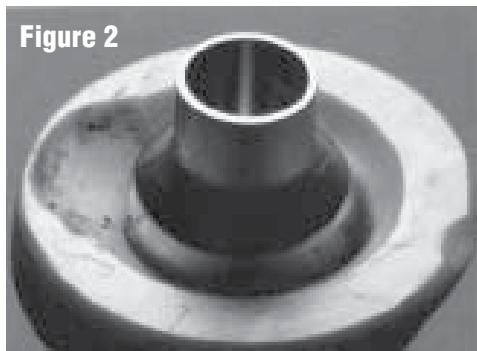
Figure 1



“Technique, technique, technique” as quoted by David Hungerford, M.D. is more important than design or material. With that said, we feel design features can aid in correcting technique related problems.

Surgical approach and technique not only affects soft tissue laxity but also can have a significant influence on component position. The most common surgical errors relate to malpositioning the acetabular component,

Figure 2



however, malposition of the femoral component can contribute to increase component impingement and dislocation (Fig. 2).^{4,5}

Malpositioning of a cemented stem not only can result in impingement, compromise of cement mantle thickness and dislocation but can significantly impact bone loss by requiring revision of the femoral stem. In addition, malposition can contribute to bone lysis by the increase of articulation wear debris.⁶

Two factors that can affect range of motion are component positioning and component geometry.⁴ Although physiological range of motion vary for each patient an average of 114° of flexion is required for sitting. There is no question that increased range of motion results in better clinical results.

Head diameter, neck shape and skirts on femoral heads can all affect hip range of motion (Fig. 3)¹

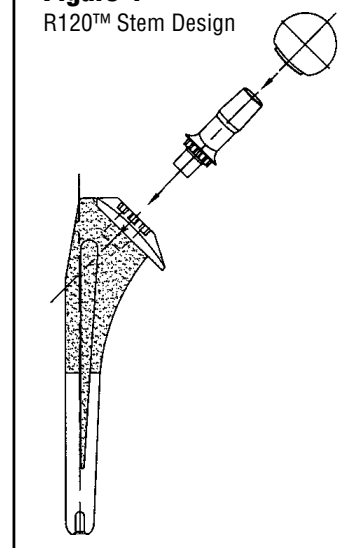
The following stem design approach is recommended in an attempt to aid in restoration of joint mechanics and to allow the surgeon a final opportunity to correct for malpositioning of implants due to technique, and /or bony deformity.

R120™ Modular Indexable Neck Cemented Stem

The stem is designed to use standard conventional cementing techniques. The shape of the stem is trapezoidal

posterior portion of the implant increases the cement to prosthesis interface therefore increasing resistances to axial and torsional forces (Fig. 4)

Figure 4
R120™ Stem Design



The proximal stem features a matte surface, which enhances fixation of the implant to the PMMA cement, while the distal portion is polished allowing for ease of retrieval if necessary.

An optional distal PMMA stem centralizer is available depending on each individual's philosophy.

Proximally, R120 stems are designed in five (5) sections with three (3) interchangeable modular neck lengths of 32mm, 35mm, and 38mm and two

angle variations of 8° and 12°. The proximal stem collar is made with a cavity where a self-locking taper and a positive indexing mechanism are employed to ensure the proper head, length, version and offsets are obtained. (Fig. 5)

This unique design features twelve (12) self-locking positions providing several combinations of neck length version and offset for closer match to restoring hip joint mechanics.

This innovative approach provides the surgeon with the opportunity to intervene at the last possible surgical moment and fine tune the hip joint mechanics without disruption of the implant-cement-bone interface. In addition it should provide for increased opportunity to surgically intervene for certain post-op complications, like component malposition, leg length discrepancy, dislocations and replacement of bearing surfaces, with minimal disruption of bony interfaces.

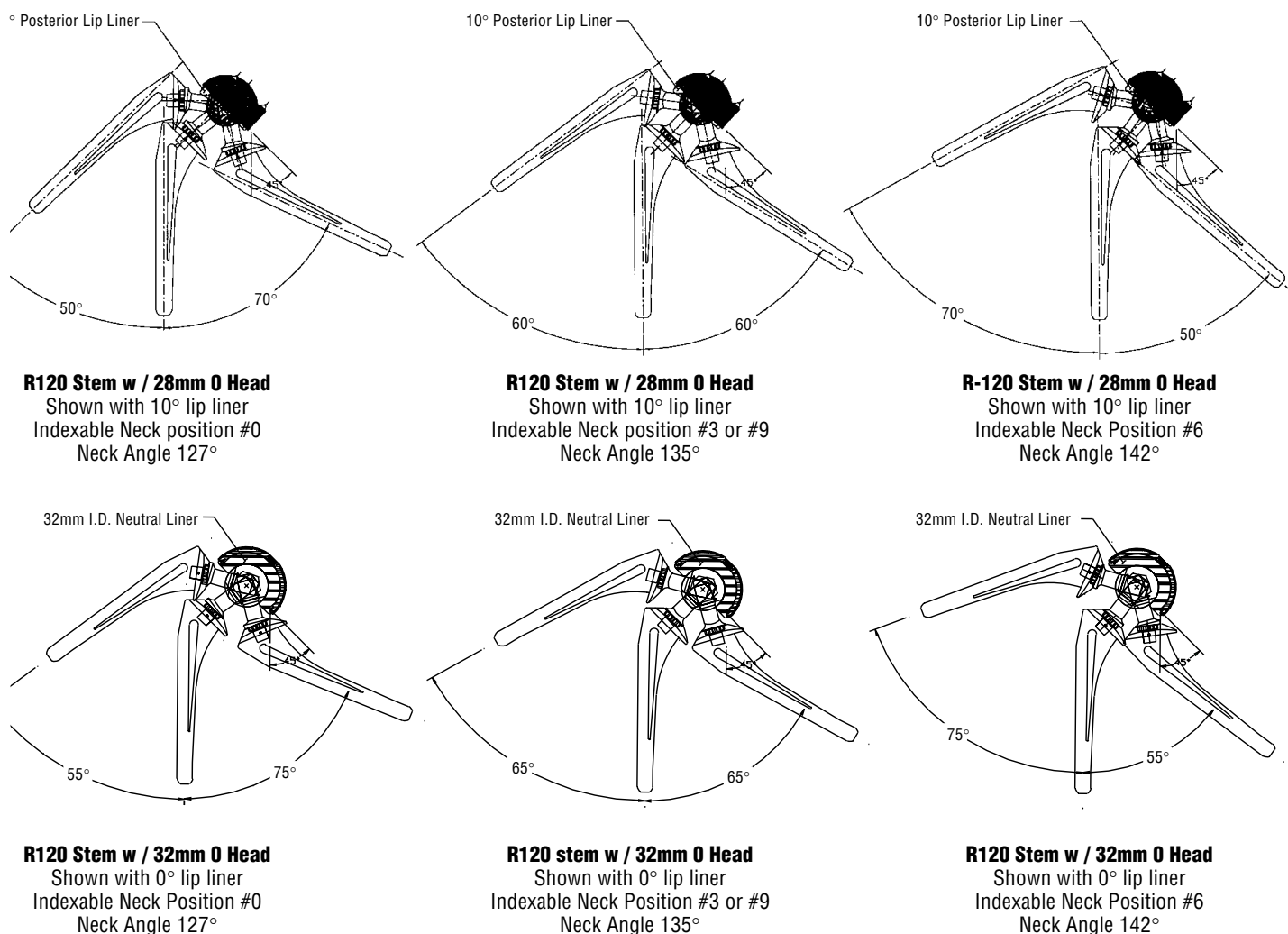
These are just some examples of the flexibility of using this unique Modular Indexable R120™ Neck System (Fig. 6).

The references for the pro and con use of modular couplings have been well documented and are too many to list here. We suggest the basic decision-making be left to

Figure 5

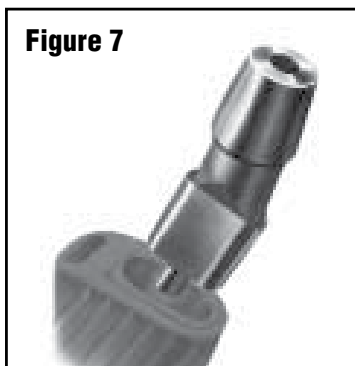


Figure 6



modular necks have been used in titanium cementless stems in Europe successfully for years (Fig. 7). Both mechanical and clinical results have demonstrated the design approach to be safe and effective.^{7,8,9} However, the authors feel, for cemented application, cobalt chrome or bismuth alloy is preferable both for interfacing with cement and for providing less risk of fretting and/or corrosion at the modular stem neck junction.^{10,11} The ability of modular necks and heads allow for unprecedented flexibility in designing hip joint mechanics. Ideally long-term outcome will clearly demonstrate the reliability of this modular design, however, basic mechanical principals and attention to the design details presented should help the surgeon in fine-

Figure 7



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New Approach for Preparation of Bony Surfaces for Cemented Total Joint Arthroplasty

By H.M. Reynolds, M.D., Richard "Dickey" Jones, M.D. and Timothy McTighe

There is a strong movement back to using bone cement in total joint arthroplasty as a primary fixation method. However, it is important to recognize its inherent biological and mechanical limitations. Bone cement is a grouting agent and does not possess adhesive properties. Successful fixation is dependent upon the mechanical interface between cement, bone and implant.

Poor cement coverage and inadequate intrusion into trabecular bone are associated with stem loosening, while deep and uniform penetration is important to the success of THA.¹

Clinical symptoms resulting from loose implants continues to be a significant problem and expose the patient to serious medical risks associated with revision surgery.

Current surgical technique for implantation of cemented implants consists of shaping the bony cavity with hand and power tools, followed by brushing and saline lavage. Surgical sponges or tampons are inserted into the cavity to dry the bone surface. The canal is then plugged and cement injected under pressures to assure interdigitation of cement into the prepared cancellous bony bed.

Cardiopulmonary dysfunction has been reported as a risk factor associated with the use of cemented arthroplasty. The principle factor is attributed to particulate fat and marrow emboli.²⁻¹⁰ Thorough cleaning of fat tissue and debris helps reduce the incidences of emboli complications.

The carbojet device was created for the use of using pressurized dry carbon dioxide gas to be used as a lavage to the bony surface, to clean and dry the area prior to cement implantation (Fig. 1).

Mechanical and clinical investigations of this device has

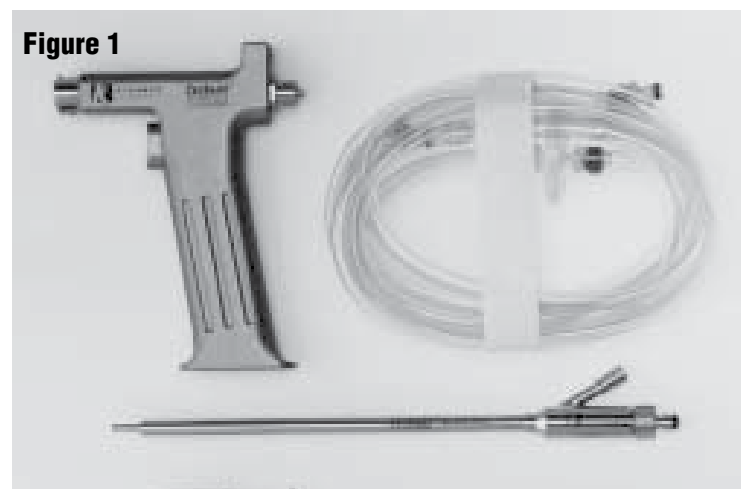


Figure 1

proven this device to be safe and effective.

The carbojet device is used as the final step in bone preparation, employed immediately prior to cement introduction. The flow of gas aids in removing fat and debris from the bone surface reducing interposed fluid between cement and bone.

The carbojet device consists of a reusable hand piece and a variety of nozzles, along with a pressure regulator needed for use with standard CO₂ tanks (Fig. 2, 3). The sterile CO₂ tube set features an appropriate quick disconnect fitting and an in-line microbial filter for filtration purposes.

Figure 2



Femoral canal preparation.

Invitro testing has been conducted on human cadaver bone to determine impact force as well as the cleaning effectiveness as compared to standard pulse saline lavage devices. Results of the laboratory testing demonstrate a significant

capability of cleaning and debris removal. In addition, testing demonstrated that a moderate gas flow rate is sufficient to clean and dry the bone. High flow rates have the potential for damaging soft tissue and fragile bony areas. The flowing gas of the Carbojet™, however, can be directed at the skin without discomfort or damage to soft tissue. An

Figure 3



is recommended, the regulator delivery pressure is set to 65 psi as an absolute maximum. The resulting gas rate is approximately 25 lpm.

Clinical surgical evaluations demonstrated intraoperative clotting to be uneventful. One year follow-up monitoring was also uneventful. Throughout the clinical use no complications have been encountered in using a Carbojet™ device.

Since 1993 and thousands of total joint surgeries surgical video impressions are the Carbojet™ device demonstrated provided or equivalent results as compared to pulsating lavage and cleaning cancellous bone prior to cement implantation.

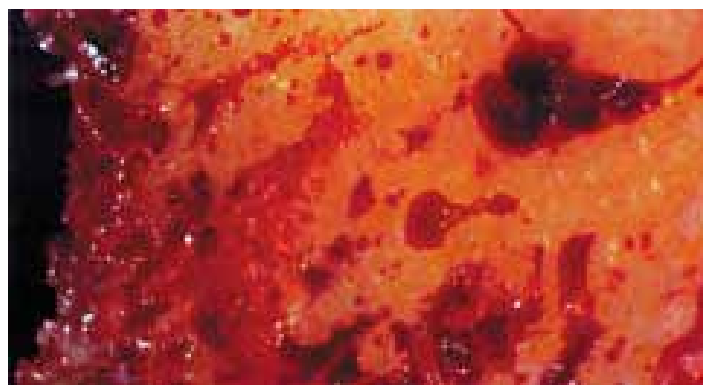
Compressed CO₂ gas has been employed as an inflation medium in laparoscopic procedures for many years and is readily available at all hospitals.

Long-term fixation of cemented implants relies upon basic mechanical principles of inter-locking. Thorough intraoperative cleaning of fat, tissue and debris will help ensure long-term fixation while reducing the risk of emboli. Mechanical and clinical testing to date has demonstrated that the use of dry carbon dioxide gas is a safe, effective way of preparing the bone prior to cement implantation and only additional clinical testing and long-term follow-up will determine if this device can improve long-term clinical outcome results.¹

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In vivo preparation for a Total Knee Cemented Device demonstrating the effectiveness of using CO₂ to clean and remove fat and debris, prior to cementing.



Tibial plateau after resection (shows blood, fat, and debris).



Same area after pulsatile saline lavage (shows fat and fluids remain).



Commentary

By Timothy McTighe

The tragedy of September 11, 2001 brings our emotions right to the surface. Watching the significant loss of life and the effect it is having on loved ones is heartbreaking. Times of this nature make one reflect on the important relationships in your life, current and past. It also places the importance of relationships first and foremost in your mind.

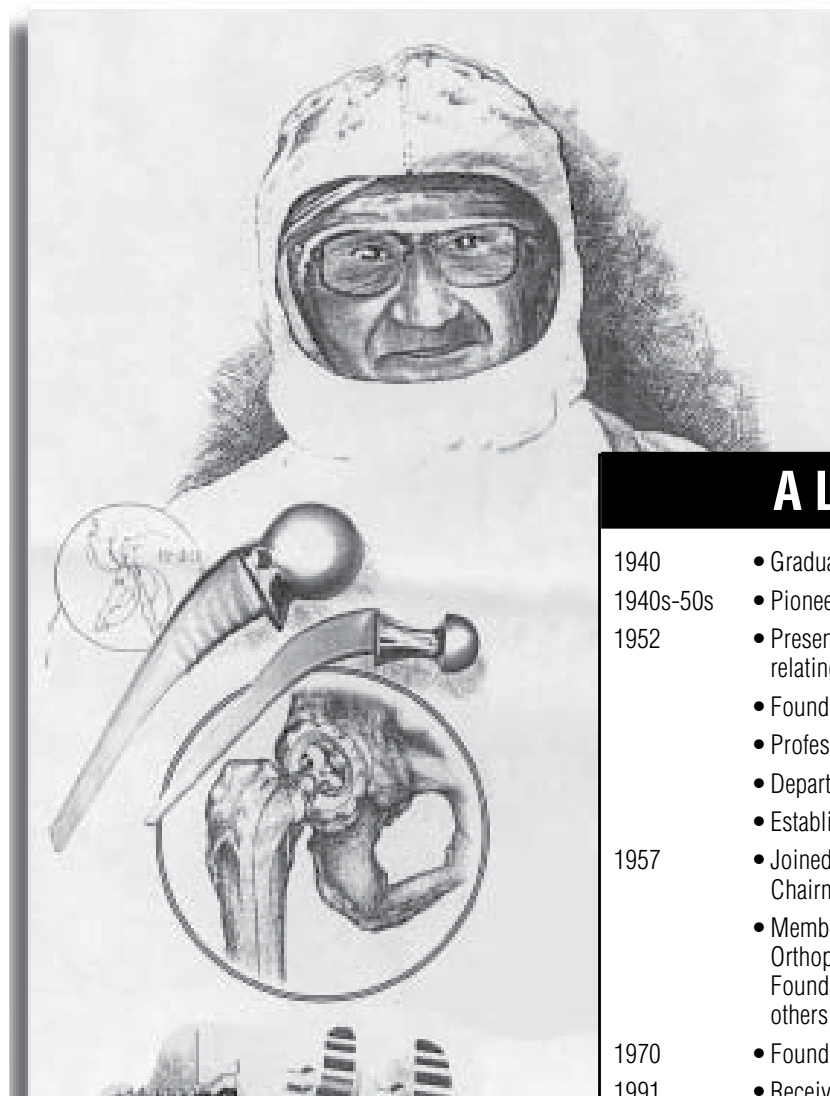
Significant relationships have been brought back to mind and I feel compelled to mention them here in an attempt to pay respect to all those that have suffered due to the tragic events of this September and to challenge every one not to take for granted the people that directly and indirectly effect their lives.

Charles O. Bechtol, M.D.

August 23, 1911 - July 16, 1998

Most people in the industry who know me understand the influence the Professor had on both my professional and personal life. He was a very special part of my life from 1974 till his passing in 1998. This is a time to reflect on his memory.

Charles and his lovely wife Louise shared many times with my wife Cathy and I, all over the world. We were honored to be part of the Memorial



A Lifetime Of Achievement

- | | |
|-----------|--|
| 1940 | • Graduate of Stanford Medical School |
| 1940s-50s | • Pioneered the development of improved artificial limbs |
| 1952 | • Presented the first lecture to the American Academy of Orthopedic Surgeons relating engineering principles to orthopedic surgery |
| | • Founding member of the F4 Committee (biomaterials) of the ASTM |
| | • Professor and chairman of the Yale Medical School |
| | • Department of Surgery (orthopedics) |
| | • Established Yale Biomechanics Laboratory |
| 1957 | • Joined UCLA Medical School where he would serve as professor and Chairman of the Department of Orthopedic Surgery |
| | • Member and chairman of research committees for the American Academy of Orthopedic Surgeons, the Orthopedic Research Society, the National Science Foundation, the Los Angeles County and California Medical Associations, and others |
| 1970 | • Founded and chaired the joint Implant Surgery & Research Foundation. |
| 1991 | • Received the Academy of Surgical Research's Markowitz Award for a lifetime |

ices for Charles, and he still remains close in our hearts. His genius will continue to be felt in the countless steps that might never have been taken or in the rational act of holding a child or picking a flower. In these ordinary ways the world will silently remember this extraordinary healer.

Joseph R. Shurmur, M.D.

August 2, 1941 - July 16, 1996

started my career in orthopaedics as a Army Corpsman during the Vietnam conflict and spent 34 years (69-73) learning the basics of orthopaedic treatment, surgery, traction, casting and had some interesting times with the Marine Corps specializing in field orthopaedic treatment. I was a Lt. Colonel in the



Commander in the Army Reserve who had been called up for his two-year active commitment. He had just finished his orthopaedic residency training and was coming on board as my immediate commanding officer. I had the pleasure of serving with him and working for Joe for almost two years prior to my being transferred to field duty with the Marine Corps. He was not only instrumental in my professional life but the strength of character provided me with the subtle traits of a role model for my personal life. I was honored to have been one of Joe's pallbearers and remain close to his family today. The following prayer was Joe's favorite and I believe it conveys a significant message for today.

Life is to live and life is to give and talents are to use for good if you choose. Do not pray for easy lives. Pray to be stronger. Do not pray for tasks equal to your powers. Pray for powers equal to your tasks - then the doing of your work shall be no miracle but you shall be a miracle. Every day you shall wonder at yourself... at the richness of life which has come to you by the grace of God. But everyone needs someone - knowing that somewhere someone is

I would like to end this commentary by quoting a poem that illustrates what is becoming one of my most cherished traditions. I say this in honor for all the fathers that will not have a chance to create a special tradition for their sons and daughters' weddings.

As a father of six I have had the pleasure of sharing the wedding day of two of our children. Our oldest son Jason was married in 1997 to Michelle. Two and a half years ago they brought Cathy and I our first grandson, Jack. This past June I had the pleasure of escorting my youngest daughter Katie down the aisle to David.

My toast to both couples could be called a prayer, a wish, a desire. I refer to it as:

A Fathers Thought

*May there be light on every path you follow.
Wisdom to guide your every step.
Peace to confirm your every decision.*

*May you watch your thoughts; for they
become words.
Watch your words; they become actions.
Watch your actions; they become habits.
Watch your habits; they become your
character.
Watch your character; it becomes your
destiny.*

*And know I will always be there.
May God bless you*

NEXT ISSUE

Featuring Cementless
Modular Stems



Design Considerations for Cementless Total Hip Arthroplasty

By: Timothy McTighe, Executive Director, JISRF
Terrigal, Australia, 11/99



Notes

Introduction

“Technique, technique, technique” is a quote from David Hungerford, M.D. Technique is more important than design or material. In order for a surgical procedure to be considered a success, it must provide reproducible, satisfactory clinical results, reproducibility being the key word. The best implant put in poorly is not as good as the worst implant put in well.

There is no question that bone cement has made and continues to make a significant contribution to the success of total hip replacements. However, it is important to recognize its inherent biological and mechanical limitations (low modulus, low fatigue strength, potential toxicity, and propensity for late hematogenous infection). At this time, there continues to be a significant controversy about cement versus cementless fixation.

Acetabular Consideration

The hip joint is not a perfect ball-and-socket joint; the femoral head is oval in shape and the articular surface of the acetabulum is horseshoe shaped. The dome of the acetabulum, which has been considered a weight-bearing area, is in fact flexible. The horns of the acetabulum can thus close up and contact the femoral head when the joint is loaded [33,70]. The degree of this movement is dependent upon age, load, and femoral anteversion. This mobility of the acetabular horns could explain biomechanically the development of aseptic loosening that occurs around acetabular components.

The acetabulum is generally spherical in shape and its opening is oriented closer to 55° than 45°, downward in the coronal and sagittal plane, and anteverted approximately 15° to 20° in the midsagittal plane.

Initial acetabular component stability is affected by the cup's ability to engage with the host bone. This is a function of cup design, size, and surgical technique. Cups of a true hemispherical design are more stable than low-profile designs [1]. Adjunct screw fixation can enhance initial stability but may contribute to osteolysis in the long term. Care should be taken to not penetrate intrapelvic structures by screws or drill bits. A study by Perona et al. demonstrated that the ilium provides the least amount of intrinsic support to cup fixation, while the anterior and posterior columns provide more stability [60]. Current technique attempts to press fit 1-2 mm of a hemispherical design and only use adjunct screw fixation when necessary. If a modular design is used with dome screw fixation, the anterior superior quadrant of the acetabulum should be avoided because it is the highest-risk area due to the medial intrapelvic vascular structures [73,40]. When possible, peripheral screws should be used over dome screws due to their greater ability to restrict micromotion of the anterior and posterior columns in addition to being placed in a more appropriate safe zone away from intrapelvic vascular structures.

A. Acetabular Components

Cementless acetabular components are gaining popularity in the United States and in the rest of the world. These implants are indicated for both primary and revision surgery. It appears the bony matrix of the acetabulum is well suited for cementless fixation. Cementless fixation is best accomplished in the well-formed acetabulum where the shape is hemispheric and the implant can be placed in close apposition with the trabecular bone.

Threaded acetabular components, as compared to porous press-fit designs, have had the longer history of cementless application in total hip arthroplasty. The Europeans have pioneered and championed this concept in both primary and revision surgery.

Lord [46] and Mittelmeier [56,57,58] have both reported comparable results, with approximately 90% good to excellent results for primaries and 75% good to excellent results for revisions. Mittelmeier continues to use his ceramic threaded device today. The success of the Europeans spurred enthusiasm in usage in the United States and by 1986 threaded designs were being promoted by most implant companies.

Bierbaum, Capello, Engh, Mallory, Miller, and Murray are a few of the pioneers of clinical usage of threaded devices in the United States [51]. Each has encountered different degrees of success with various designs.

The lack of a full understanding of the design features and the required surgical technique, along with proper indications and contraindications, predisposed some of these devices to failure. First and foremost in the successful implantation of a cementless device, and particularly a threaded device, are exposure and surgical technique. Acetabular exposure must be greater for these devices than for conventional cemented cups. Threaded components have a major, or outside, diameter larger than that of the prepared dimensions of the acetabulum. It is therefore necessary to directly face the acetabulum for insertion of these threaded devices.

There are four basic classifications of threaded cup designs. It is crucial to understand the differences in these designs and most of all to understand the particular design chosen for implantation. A complete understanding of the design will enable the surgeon to maximize surgical techniques to achieve a good result.

B. Threaded Cups

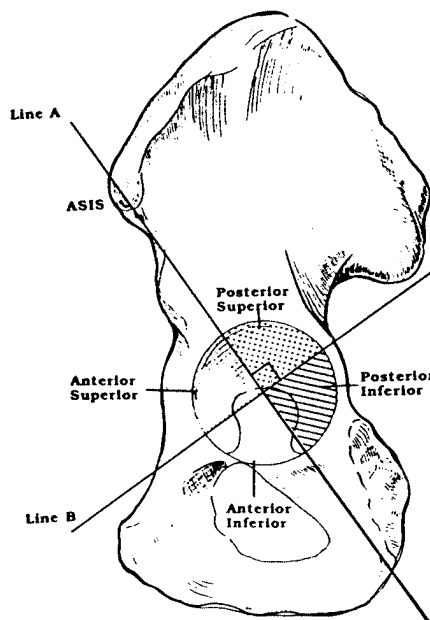
Classification of Threaded Cups

This section discusses four classifications of threaded cups:

- Truncated cone
- Hemispherical ring
- Hemispherical shell with conical threads
- Hemispherical shell with spherical threads

C. Modular Acetabular Components

Two-piece, modular porous acetabular components have gained major market acceptance in total hip arthroplasty. The main advantage over threaded devices is ease of insertion. Adjunct fixation can be enhanced by bone screw fixation. Polyethylene liners come in a variety of head diameters as well as offering different offset angles to enhance head coverage. However, as



Acetabulum quadrants.



Notes

pointed out by Krushell et al., elevated polyethylene liners are not without problems [42]. Elevated rim liners increase range of motion in some directions and decrease range of motion in other directions. They do not in any global sense provide greater range of motion than a neutral liner. Therefore, routine use of an elevated rim liner is not recommended. If a cup is malpositioned, a liner might offer some immediate implant stability; however, polyethylene is not a good material for structural support, and cold flow, deformation, disassociation, and late joint dislocation are real probabilities. It is preferable to reposition the metal cup rather than relying on polyethylene to function under high loads.

However, these modular designs are not without problems. Since their introduction, osteolysis due to particulate debris has increased in cementless total hip arthroplasty.

The most common cause of proximal, femoral bone loss is due to osteolysis [52,9]. Although the specific cause of lysis is not known, it has been attributed to a variety of factors such as motion of the implant. Foreign-body reaction to particulate debris, in particular to polymeric debris, probably plays the greatest role. It has been almost two decades since Willert et al. first described the problem of polyethylene wear leading to periprosthetic inflammation, granuloma, bone resorption, and implant loosening [75]. Since then, many studies have documented the finding of particulate bone cement and polyethylene in periprosthetic tissue [36,66].

Variations of polyethylene wear rates probably relate to acetabular implant design, femoral head size, femoral head material, and at least in part to the quality of the polyethylene used [44,2]. Wide variations are known to exist between batches of polyethylene and between different polyethylene suppliers [76].

Metal particulate debris generated from the stem or cup in sufficient quantities could activate macrophage-mediated osteolysis. More likely the cause is the migration of metallic debris into the articulation, resulting in increased third-body wear of polyethylene. Additional poly debris can be generated by poor modular designs, incomplete conformity of the liner within the metal cup, thin polyethylene resulting in cold flow, and wear through and abrasion of screw heads against the convex polyethylene surface.

Problems with excessive wear due to titanium bearing surfaces have been reported. In addition, clinical evidence indicates higher volumetric wear with 32 mm heads.

Ideally, the bearing surface for most sliding, rotating, or articulating bearing surfaces will be made from material having relatively high strength, high wear, and corrosion resistance; a high resistance to creep; and low frictional movements. In reality no one material presently exhibits all of these characteristics. Therefore, with present bearing systems compromises are typically made between these various characteristics. There are, however, some immediate steps that can be taken to reduce the generation of particulate debris.

1. Use ultra-high molecular weight polyethylene with high ratings in key mechanical and physical properties.
2. Use non-modular, molded acetabular components.
3. Use modular components with:
 - High conformity and support.
 - Polished interface.
 - Secure locking mechanism.
 - Minimum polyethylene thickness 6-8 mm.
4. Use a 28 mm or smaller head diameter.
5. Do not use titanium alloy as a bearing surface.
6. Minimize modular sites on femoral side to reduce chances of third-particle wear debris.

Femoral Consideration

The femoral head is slightly larger than one half of a sphere, and the shape is more oval than spherical. The stresses on the femoral head usually act on the anterior superior quadrant, and surface motion can be considered as sliding on the acetabulum. Two important angles need to



Notes

be considered: the neck shaft angle and the angle of anteversion. In addition to these two angles, the joint reaction force is affected by femoral head offset [28,65,37]. It is also important to remember that while static force is considerably greater than body weight, even greater force is generated posteriorly in dynamic situations such as acceleration and deceleration: manifest in negotiating stairs or inclines, in changing from a sitting to a standing position or vice versa, and in other routine activities of daily living that load the hip in flexion.

The biological response of bone to stress greatly affects the outcome of cementless total hip arthroplasty. The adaptive bone remodeling process, “Wolff’s law”, must be taken into consideration in deciding on material, geometry, and size selection for cementless femoral components. Many clinical and radiological studies have demonstrated the sensitivity of this adaptive remodeling process [31].

Cancellous bone is a poor material for structural support of a prosthesis. Cancellous bone is a biological engineered material, and its strength depends on its having the entire bulk of the structure intact. The creation of an interface with areas of cancellous bone disproportionately weakens the structure. In addition, interfacing an implant with cancellous bone merely serves to increase the stress at the interface to a level that causes fatigue failure of the bone [62].

Through proper design and surgical technique, one can achieve significant enhancement of the mechanical properties of the procedure consistent with basic biomechanical principles. It is recommended that most, if not all, of the cancellous bone be removed. Structuring the surface of an implant will minimize the surface shear stresses. In addition, structuring will transfer hoop stresses into compression stresses within the femur. For an uncemented femoral component to be successful it is universally agreed that initial stability is essential. In addition, there must be a mechanism to ensure longterm bony fixation.

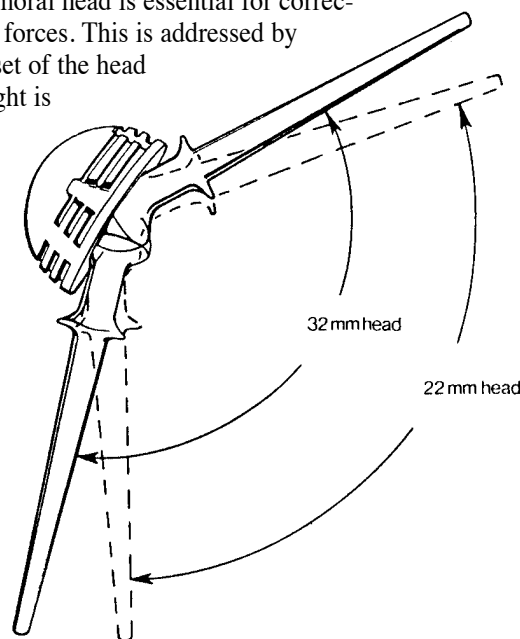
Replacement of the normal position of the femoral head is essential for correction of mechanical balance between abductor forces. This is addressed by vertical height, version angle, and medial offset of the head relative to the axis of the stem. If vertical height is

too short, joint stability is a problem. If too long, patient complaints result and nerve palsy is possible. Incorrect version angle can result in reduced range of motion and possible hip dislocations. Medial offset that is too short will cause shortening of the abductor moments, and there will be greater resultant force across the hip joint. If offset is too great, increased torsional forces will be placed on the femoral implant. For a femoral component to be successful it must have initial torsional stability with or without cement.

Normally the femur is loaded from the outside cortex, and stresses are transferred internally. However, in a stemmed reconstruction the biomechanical loading has been changed to an internal loading mechanism. Intramedullary stems place an unnatural hoop stress on the bone. This hoop stress must be transferred into compressive loads to the proximal femur. One way to help accomplish this is to design proximal steps into the femoral component. Early endoprosthesis stems were developed by Bechtol in 1954, the “Stepped Prosthesis”, and a later one by Townley also featured this stepped-design concept. However, the idea was not revisited until Pughs’ work in 1981 led to the OmniFit™ design and his additional work that led to the 1984 S-ROM proximal sleeve design [62,63].



Notes



Range of motion.



Notes

A. Femoral Components

The objective for cementless total hip stems of long-term pain-free stability is dependent on both primary and secondary fixation of the implant to the bone. An effective cementless stem should resist subsidence, tilting and torsional forces.

Primary mechanical stability is, therefore, a prerequisite for long-term success. Torsional fixation of the femoral component is considered the most important criteria for long-term success [48]. It is only logical that design features that improve fixation are likely to improve clinical results.

Although there may be advantages in bone remodeling by initial stability by proximal fixation, irregularity in shape and structure of the bone in the metaphyseal area can compromise stability. It has been previously reported that a constant proportional relationship is not present between the shape and size of the metaphysis and diaphysis. In addition the revision situation results in alterations in the normal bony architecture, making fit and fill more difficult to achieve [47,67]. Distal stem stability enhances overall initial stability of the implant in both primary and revision total hip arthroplasty.

With cavitary and segmental bone damage it is difficult to achieve stability of the implant. In this situation some authors have previously recommended distal fixation. It is our opinion that distal stability is preferable over distal fixation. This can be achieved by fluting the distal end of the stem. Whiteside [48] and Koeneman [45] have shown that fluting offers more initial stability in torsion as compared to a fully porous coated stem.

It is generally agreed that the better the fit and fill ratio of the femoral component, the better the initial stability and potential for long-term fixation. Over the past 10 years fit and fill has taken several approaches: (1) a large quantity of sizes (unibody); (2) modularity; and (3) custom (intraoperative or preoperative).

B. Unibody Stems

Due to concerns that modular sites generate particulate debris along with social economical pressures, there is a strong movement back to one-piece stem designs, especially for routine primary hip reconstruction. The challenge for unibody designs as with all designs is to optimize fit and fill, to ensure optimal loading of stress to the proximal femur, to avoid the problems of torsional and axial instability while providing for reproducible surgical technique.

Currently there is considerable controversy as to straight vs. anatomical and collar vs. collarless stem designs. In an attempt to appeal to both mentalities, newer geometric designs are emerging. These designs feature straight stems with anterior flares and anteverted necks.

C. Modular Stems

The concept of modularity is to provide for intraoperative customizing of fit and fill with each individual femur. There are a variety of modular designs available, from modular necks, proximal and distal sleeves, and mid-stem tapers. Each design has specific features and benefits and requires complete knowledge of each individual design and surgical technique.

While modular designs represent an advance in the ability to precisely fit the implant to the bone, the mechanical integrity of the assembled component must be fully tested prior to clinical usage. Machining methods, tolerances, surface characteristics, materials, electrochemical environment and mechanical environment are all critical factors that need careful consideration in evaluating the long-term performance of modular interfaces [69].

D. Custom Stems

Customs offer great versatility; however, intraoperative customs reduce surface treatments such as hydroxyapatite (HA) or porous surfaces. In addition, there is the concern of increased operating room time and the difficulty in achieving reproducible, clinical and surgical results [30]. As for preoperative customs, again, in routine cases there are no outcome data to support

this approach over standard off-the-shelf designs, which generally speaking are less costly. It will take another 10 years of clinical comparison to judge whether customs have an advantage over standard off-the-shelf cementless devices. This is one problem in total joint surgery that does not seem to exist in other medical disciplines. In the meantime, it follows that advances must be made based mainly on theoretical grounds, good solid, basic science, and animal experimentation rather than on short-term clinical evaluations by the implant-developing surgeon in a small number of patients.

Obviously there is a need for all three types of implant modalities: unibody, modular, and customs (although these are not necessary with adequate modularity).

However, the surgeon must be aware of all the design features and pick and choose the appropriate design indicated for individual patients. No one design is going to fill all the needs that are found in total hip replacement surgery today. The future challenge will be to address growing indications in a restricted health care financial market.

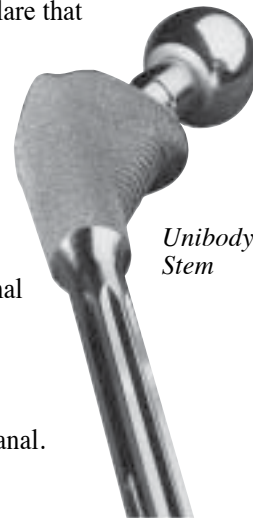
Recommended Design Concept

A. Unibody Stem

This stem is a geometric design that features a proximal anterior flare that works in tandem with a 30° proximal conical flare collar. These two specific features aid in axial and torsional stability while providing increased surface geometry, resulting in increased compressive stress to the proximal femur. The neck shaft angle is 135° with 10° of anteversion. Lateral displacement of the femoral head is 40 mm.

The proximal conical collar allows for settling of the implant resulting in increased surface contact throughout the entire proximal stem geometry. In addition, the conical shape acts as a step in transferring hoop stress into compressive loads.

While providing improved fit and fill, the proximal conical shape provides a seal occluding wear debris from entering the femoral canal.

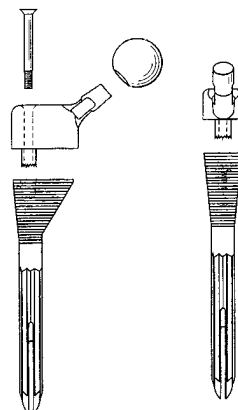


Unibody Stem

B. Bibody Modular Stem

This stem's design incorporates a proximal, modular body that allows for correction of version, offset, and vertical height without disruption of the stem body. The two modular parts feature a double locking mechanism. The first is a trunion that engages in the stem body by means of ratchet teeth. The specific design of these ratchet teeth allow for version adjustment in increments of 10°. The second locking feature is a set screw, which protects from disassembly.

The unique features of this design traps any debris that might be generated by the modularity and restricts this debris from interfacing with the host bone. In addition, once the bone has grown into the proximal porous area, polyethylene debris generated from normal wear is restricted from the distal stem area. Proximal bodies of different offsets, and vertical heights will allow for fine tuning hip joint biomechanics without removal of the stem.



Bibody Modular Stem

Stem Design Features

A. Material

This stem will utilize high-strength titanium alloy. Manufacture will utilize forgings.



Notes

B. Taper Head Neck

The neck will accept a chrome-cobalt or ceramic articulation. The neck diameter has been designed to maximize range of motion as compared to other designs.

C. Offset

In order to improve biomechanical function, the proximal design features interchangeable modular necks. This feature allows for intraoperative adjustment of offset, leg length and version angle. This design could have a significant impact on reducing postoperative dislocations.

D. Surface Preparation

The stem is proximally porous coated utilizing a single, beaded porous coating of commercially pure titanium. This is sintered over a macrotextured design of horizontal steps, which helps to protect the beaded interface from shear forces and also helps in transferring hoop stresses to compression forces. An additional option is a coating of HA which is plasma sprayed over the single, beaded porous surface. This single, beaded porous surface protects the HA in shear while also providing a backup for bony remodeling in case the HA is biochemically mobilized. Also, the nonporous surface has been treated with a proprietary microclean process that leaves a clean yet microrough surface [55].



E. Distal Bending Stiffness

The distal one third of the stem has been slotted in both the coronal and sagittal planes. These slots serve to reduce distal stem stiffness, allowing the stem to flex with the femur during normal daily activity. This feature has historically demonstrated reduced thigh pain [13]. In addition, it helps to reduce chances of intraoperative femoral fractures during stem insertion.

F. Distal Stability

To increase stem rotational stability, distal flutes have been incorporated into the stem design. Rotational stability remains the primary concern of any femoral component.

G. Stem Tip

Bulleted geometry helps reduce distal point loading while creating a smooth transition zone for load transfer.



Summary

In view of the hundreds of thousands of total hip surgeries that have been performed since the surgery was introduced by Sir John Charnley over two decades ago, the small number of reported failures are not wholly unexpected. There is currently a great deal of debate over cement versus cementless indications. Initial concerns about wear rates of polyethylene have risen again due to the increased incidence of osteolysis induced by particulate debris.

Current methods of achieving implant fixation vary in concepts and

techniques. Each method presents problems which must be addressed if cementless fixation is to survive long term. The justification for the continued use of cementless implants should be based on well-developed clinical and radiographic evidence.

Everything possible should be done to reduce the generation of particulate debris. Continued research in surgical methodology, materials, and component design of total hip replacement can help to increase the longevity of implants and increase indications to a broader range of patients.



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Notes

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Design Considerations for Cementless Total Hip Arthroplasty

Timothy McTighe

Joint Implant Surgery and Research Foundation, Chagrin Falls, Ohio

Lorence W. Trick

University of Texas Health Science Center, San Antonio, Texas

James B. Koeneman

Orthologic, Phoenix, Arizona

I. INTRODUCTION

“Technique, technique, technique” is a quote from David Hungerford, M.D. Technique is more important than design or material. In order for a surgical procedure to be considered a success, it must provide reproducible, satisfactory clinical results, reproducibility being the key word. The best implant put in poorly is not as good as the worst implant put in well.

Many varieties of designs for cementless total hip replacement are currently available and provide good to excellent results in the hands of their developers (Fig. 1). However, the challenge comes when these individual designs and techniques expand into the general marketplace. Too often general orthopedists do not appreciate the required technique for a given design. In addition, they often have less experience, and tend to overextend indications. Certainly clinical results have been less satisfactory in the young, active patient population [16,15,29].

There is no question that bone cement has made and continues to make a significant contribution to the success of total hip replacements. However, it is important to recognize its inherent biological and mechanical limitations (low modulus, low fatigue strength, potential toxicity, and propensity for late hematogenous infection). At this time, there continues to be a significant controversy about cement versus cementless fixation. This chapter reviews only cementless considerations.

This review covers anatomy, materials, testing, history, surgical technique, and a look into the immediate future for cementless total hip implants. It is our hope that this text will offer guidelines to students, residents, implant developers, and surgeons, as well as the orthopedic hip specialist.



Figure 1 Varieties of cementless stems.

II. ACETABULAR CONSIDERATION

The hip joint is not a perfect ball-and-socket joint; the femoral head is oval in shape and the articular surface of the acetabulum is horseshoe shaped. The dome of the acetabulum, which has been considered a weight-bearing area, is in fact flexible (Fig. 2). The horns of the acetabulum can thus close up and contact the femoral head when the joint is loaded



Figure 2 Radiolucent triangle.

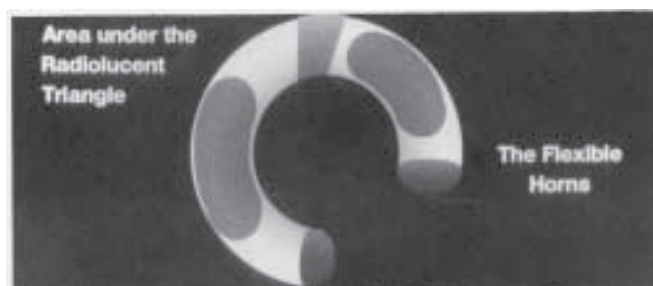


Figure 3 Principal weight bearing areas of the acetabulum.

[33,70]. The degree of this movement is dependent upon age, load, and femoral anteversion. This mobility of the acetabular horns could explain biomechanically the development of aseptic loosening that occurs around acetabular components.

Pauwels describes a radiolucent triangular space above the dome of the acetabulum. [59] (Fig. 3). The shape of this triangle is subject to modifications that are dependent upon femoral loading orientation. In advanced osteoarthritis of the hip the surface area of this triangle decreases and vanishes. It is interesting to note that with age, the hip becomes more congruent and the radiolucent triangle disappears while a trabecular pattern becomes apparent.

Apart from the initial stability at the acetabular implant bone interface, some time after initial implantation is needed for the acetabular horns to become mobile again. This corresponds to radiographic evidence of radiolucent lines in zones I and 3 [8,27] (Fig. 4). In fact, clinical analysis of cemented devices demonstrates considerable progression of acetabular component loosening beyond the 12th year and even earlier in young, active patients [2,17,15,20,26]. This mobility might further explain finding little or no bone ingrowth on retrieved cementless implants [19,61,21,22,23]. Mobility of the acetabular horns must be considered in design parameters if long-term fixation is to be

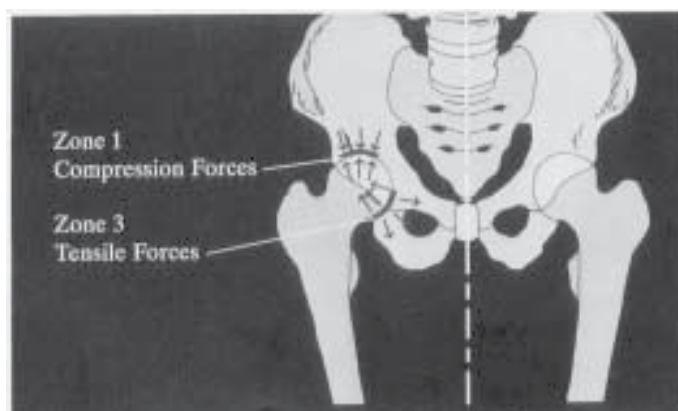


Figure 4 Compressive and tensile forces acting on acetabular components.

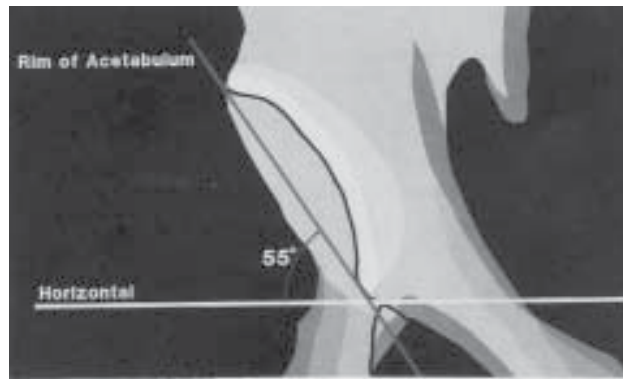


Figure 5 Orientation of acetabulum.

achieved. Fixation is enhanced if the prosthesis is set in a position of less than 45° abduction to promote compression and eliminate tension at the interfaces.

The acetabulum is generally spherical in shape (Fig. 5) and its opening is oriented closer to 55° than 45°, downward in the coronal and sagittal plane, and anteverted approximately 15° to 20° in the midsagittal plane.

Initial acetabular component stability is affected by the cup's ability to engage with the host bone. This is a function of cup design, size, and surgical technique. Cups of a true hemispherical design are more stable than low-profile designs [1]. Adjunct screw fixation can enhance initial stability but may contribute to osteolysis in the long term. Care should be taken to not penetrate intrapelvic structures by screws or drill bits. A study by Perona *et al.* demonstrated that the ilium provides the least amount of intrinsic support to cup fixation, while the anterior and posterior columns provide more stability [60]. Current technique attempts to press fit 1-2 min of a hemispherical design and only use adjunct screw fixation when necessary. If a modular design is used with dome screw fixation, the anterior superior quadrant of the acetabulum should be avoided because it is the highest-risk area due to the medial intrapelvic vascular structures [73,401 (Fig. 6). When possible, peripheral screws should be used over dome screws due to their greater ability to restrict micromotion of the anterior and posterior columns in addition to being placed in a more appropriate safe zone away from intrapelvic vascular structures.

A. Acetabular Components

Cementless acetabular components are gaining popularity in the United States and in the rest of the world. These implants are indicated for both primary and revision surgery. It appears the bony matrix of the acetabulum is well suited for cementless fixation. Cementless fixation is best accomplished in the well-formed acetabulum where the shape is hemispheric and the implant can be placed in close apposition with the trabecular bone.

Historically, Phillippe Wiles is credited with implanting the first total hip replacement in 1938 [74]. The surgery was performed in London, England, and the implant consisted of two steel components. It was McKee, however, who began to popularize this procedure, beginning his development work in 1940 [49,50]. By 1951 only a limited clinical experience existed. His design consisted of a metal acetabular component that was se-

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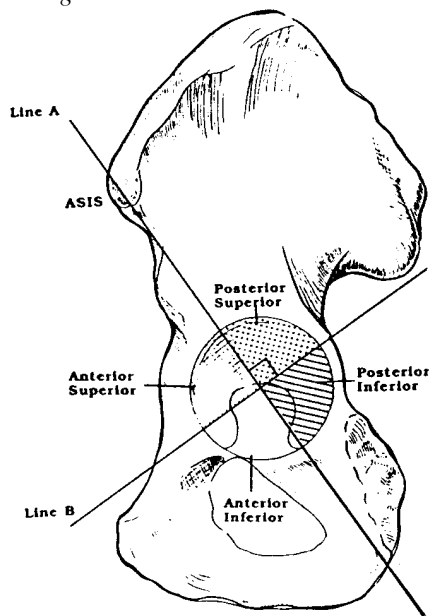


Figure 6 Acetabulum quadrants.

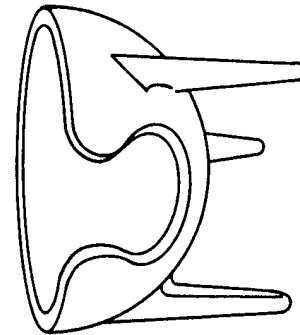


Figure 7 Urist cup.

cured by screw fixation. During this time, McKee helped to identify one of the key problems in total joint fixation, namely, the distribution of forces at the interface between prosthesis and bone.

In 1957 Urist [72] evolved an acetabular cup endoprosthesis similar to the earlier Smith-Peterson cup (Fig. 7). His clinical results, however, were not encouraging since most patients required revision after 2-3 years.

In 1956 Sivash [38], of the Soviet Union, began work on an all-metal total hip design. By 1957 his acetabular model provided a helical thread on its outer surface with a 7 turn pitch and a 110 mm depth. This design proved to be difficult to insert and evolved into a 1962 modification. The 1962 design included four rows of circumferential blades (Fig. 8). Surgical technique required reaming the acetabular rim 3 mm smaller than the diameter of the prosthesis, which allowed the sharp edges to be impacted and rotated into the bony rim. Additional fixation was achieved by the use of screws placed through the rim of the prosthesis [68].

In 1969 Boutin, of France, introduced the use of porous ceramics as a means of attachment [10,11]. At about the same time, the Judet brothers began an acetabular design that achieved fixation through a series of bone screws but rapidly failed because of the acrylic head [39].

These developments created the initial interest in the search to find a satisfactory and enduring method of skeletal attachment for acetabular components. However, the introduction of acrylic bone cement for fixation by Chamley soon led to its widespread use and the abandonment of attempts to develop cementless designs [18]. As clinical reports of long-term cemented hip replacements began to emerge, concerns were raised about the mechanical longevity and the osteolytic potential of fragmented bone cement [75,36]. In an attempt to overcome some of these problems, Harris began a clinical series in the early 1970s utilizing a metal-backed component to be used with acrylic bone cement (Fig. 9). The metal-backed design sought to reduce peak stresses at the bone-cement

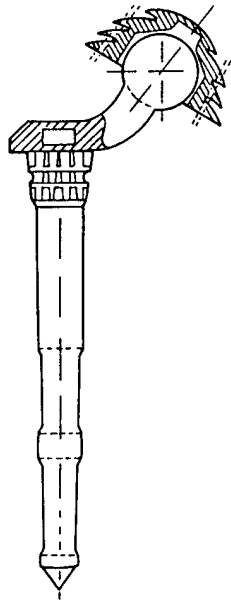


Figure 8 Sivash 1962 design.

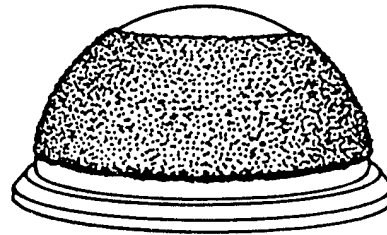


Figure 9 Harris cup.

interface, to contain and support the poly insert, and to reduce cold flow with the option of insert replacement due to wear [34].

In 1982 Noiles introduced the S-ROM™ threaded design that was evolved from the earlier Sivash design (Fig. 10). The design featured a low-profile, self-cutting cup that was inserted through impaction and torque. This was the first acetabular component that offered optional angled poly inserts to enhance joint stability.

Mallory, McTighe, and Noiles [51] further collaborated on the S-ROM by adding regionally placed porous coatings (Fig. 11). This design, called the Super Cup™, offers immediate mechanical skeletal fixation by the feature of threads and also allows for the potential of long-term bone ingrowth into the porous beads. This design continues to be used in the United States.

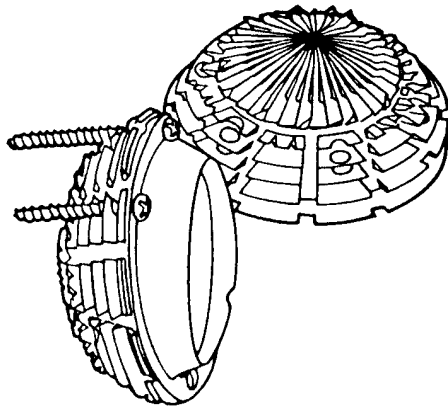


Figure 10 1982 S-ROM design.

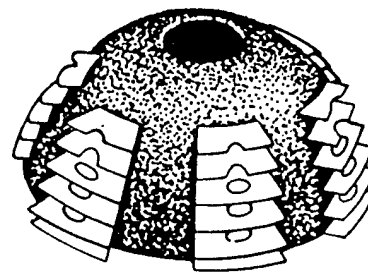


Figure 11 Super Cup design.



Figure 12 Mittelmeier ceramic cup and press fit stem.

Threaded acetabular components, as compared to porous press-fit designs, have had the longer history of cementless application in total hip arthroplasty. The Europeans have pioneered and championed this concept in both primary and revision surgery.

Lord [46] and Mittelmeier [56,57,58] have both reported comparable results, with approximately 90% good to excellent results for primaries and 75% good to excellent results for revisions. Mittelmeier continues to use his ceramic threaded device today (Fig. 12). The success of the Europeans spurred enthusiasm in usage in the United States and by 1986 threaded designs were being promoted by most implant companies.

Bierbaum, Capello, Engh, Mallory, Miller, and Murray are a few of the pioneers of clinical usage of threaded devices in the United States [5 11]. Each has encountered different degrees of success with various designs. As of this writing, none of these surgeons are currently using threaded devices for primary or revision surgery.

The lack of a full understanding of the design features and the required surgical technique, along with proper indications and contraindications, predisposed some of these devices to failure. First and foremost in the successful implantation of a cementless device, and particularly a threaded device, are exposure and surgical technique. Acetabular exposure must be greater for these devices than for conventional cemented cups. Threaded components have a major, or outside, diameter larger than that of the prepared dimensions of the acetabulum. It is therefore necessary to directly face the acetabulum for insertion of these threaded devices.

There are four basic classifications of threaded cup designs. It is crucial to understand the differences in these designs and most of all to understand the particular design chosen for implantation. A complete understanding of the design will enable the surgeon to maximize surgical techniques to achieve a good result.

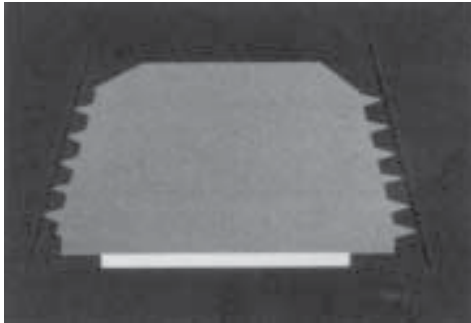


Figure 13 Truncated cone.

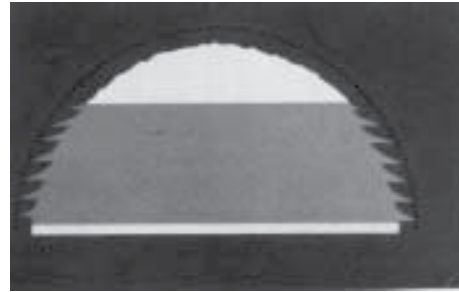


Figure 14 Hemispherical ring.

B. Threaded Cups

Classification of Threaded Cups

This section discusses four classifications of threaded cups:

- Truncated cone (Fig. 13)
- Hemispherical ring (Fig. 14)
- Hemispherical shell with conical threads (Fig. 15)
- Hemispherical shell with spherical threads (Fig. 16)



Figure 15 Hemispherical shell with conical threads.

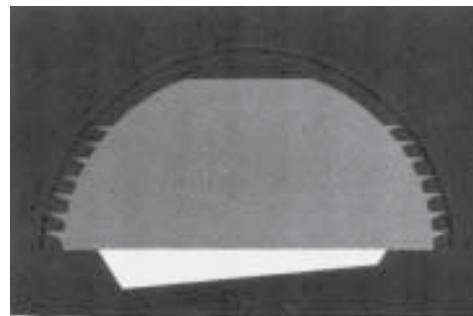


Figure 16 Hemispherical shell with spherical threads.



Figure 17 Hemispherical reaming.



Figure 18 Hemispherical reaming with truncated cup.

1. Truncated Cone

The truncated cone is the design of most European systems, including both Lord and Mittelmeier devices. Whether the truncated cone design is a cup or a ring, the geometry of a truncated cone makes the design inherently very stable. However, it does require more bone removal than a hemispherical design (Fig. 17).

Although very successful in Europe, these designs have not met with great acceptance in North America. The surgical technique required to ensure proper seating for a truncated cone is quite demanding. If reamed spherically, the threads engage very little bone (Fig. 18). If deepened with the reamer, contact between implant and bone is increased. However, bone stock is sacrificed. It appears the device must penetrate subchondral bone in the medial wall to ensure maximum purchase (Fig. 19).



Figure 19 Proper position for truncated cone cup.

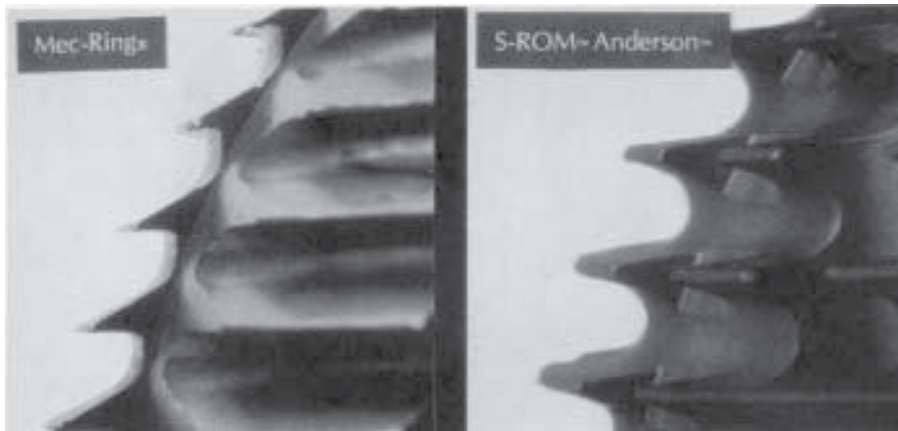


Figure 20 Thread profiles.

2. Hemispherical Ring

The Mec-ring[®] from Germany appears to be the most popular ring design. It is a threaded ring, spherical in shape, with a large apical hole. This apical hole allows the poly insert to protrude through the ring, thus interfacing with the prepared acetabular bony bed.

A close look at this design raises some questions and concerns. The thread buttress angle provides for maximum pull-out resistance. However, this is not the mode of loading for threaded cups. Since the majority of the loads placed on the acetabular component are in compression, a horizontal thread profile would be more appropriate for proper load transfer (Fig. 20). An extremely large apical hole allows for more load transfer to the thin fossa as compared to designs that have either a small hole or an enclosed dome (Fig. 21).

The designs with a smaller hole do not allow the poly inserts to protrude through the hole. These are classified as cups, not rings.

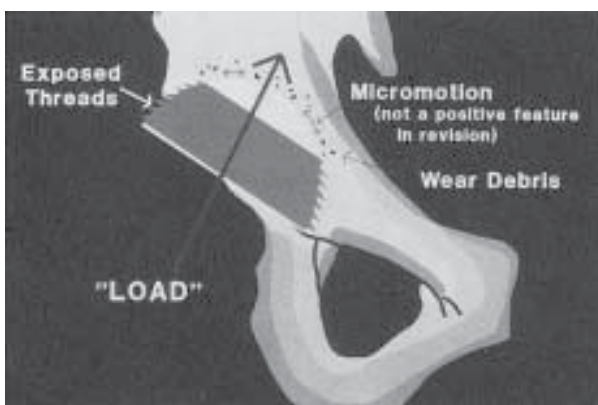


Figure 21 Threaded ring.

In revision situations where the subchondral bone is diminished or lost, loading should be transferred to the periphery to protect or shield this area.

Earlier designs had only neutral-angle poly inserts requiring a more horizontal orientation of the cup to ensure joint stability. This type of positioning can compromise bony coverage of the implant, resulting in less implant fixation. In addition, if any micromotion occurs between poly insert and bone, the possibility of wear debris exists [71,43].

3. Hemispherical Shell with Conical Threads

This is the design of most U.S. manufacturers. The hemispherical shell has an advantage over a truncated cone because it allows preservation of the subchondral bone by reaming hemispherically. The conical threads are much easier to design and manufacture as compared to spherical threads. However, the conical thread does compromise maximum potential for seating the entire thread into a hemispherically reamed acetabulum.

4. Hemispherical Shell with Spherical Threads

The S-ROM Anderson TM Cup was the first hemispherically domed shell with spherical threads. Note that the thread buttress angle provides maximum resistance to the compression loads going into the acetabulum. The apical hole is small enough to reduce

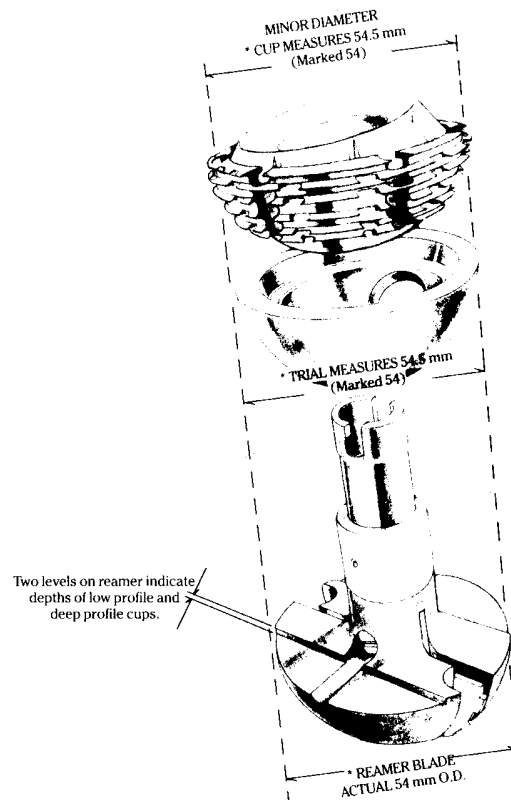


Figure 22 Reamer versus threaded cup diameter.

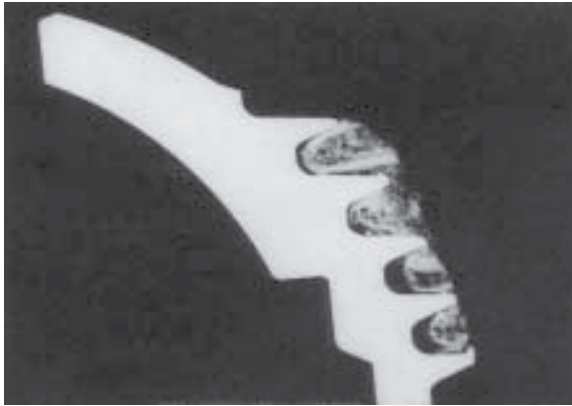


Figure 23 Cross section of retrieved threaded cup.

loads that are transferred through the apex; however, the hole is still large enough for visualization and access for bone graft material.

The major diameter of the thread is 5 mm greater than the diameter of the trial. Therefore, the penetration of each thread is 2.5 mm relative to the dome and flute spherical surface. The actual thread minor diameter, or root diameter, is such that the root of each thread lies 0.5 mm below the dome and cutting flute's spherical surface, thus allowing 0.5 mm space for bone chips from thread cutting to accumulate (Fig. 22).

By 1990 most threaded devices, with the exception of the S-ROM Super Cup, had been discontinued from routine use in both primary and revision surgery (Fig. 23).

It is important to note that threaded acetabular components are not all the same, just as porous and cemented designs are not all the same. Only full understanding of the chosen design and the required technique for that design will ensure a good, long-lasting result.

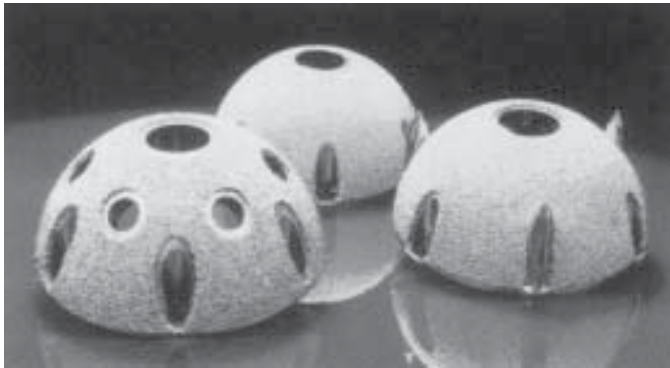


Figure 24 Porous cups.

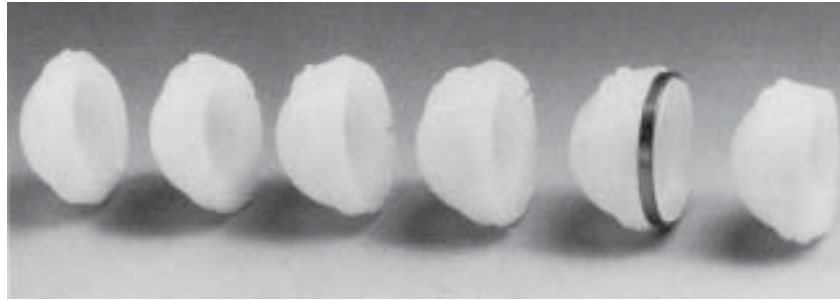


Figure 25 Polyethylene lines available in different angles.

C. Modular Acetabular Components

Two-piece, modular porous acetabular components have gained major market acceptance in total hip arthroplasty (Fig. 24). The main advantage over threaded devices is ease of insertion. Adjunct fixation can be enhanced by bone screw fixation. Polyethylene liners come in a variety of head diameters as well as offering different offset angles to enhance head coverage (Fig. 25). However, as pointed out by Krushell et al., elevated polyethylene liners are not without problems [421]. Elevated rim liners increase range of motion in some directions and decrease range of motion in other directions. They do not in any global sense provide greater range of motion than a neutral liner. Therefore, routine use of an elevated rim liner is not recommended. If a cup is malpositioned, a liner might offer some immediate implant stability; however, polyethylene is not a good material for structural support, and cold flow, deformation, disassociation, and late joint dislocation are real probabilities. It is preferable to reposition the metal cup rather than relying on polyethylene to function under high loads.

However, these modular designs are not without problems. Since their introduction, osteolysis due to particulate debris has increased in cementless total hip arthroplasty.

The most common cause of proximal, femoral bone loss is due to osteolysis [52,9] (Fig. 26). Although the specific cause of lysis is not known, it has been attributed to a variety of factors such as motion of the implant. Foreign-body reaction to particulate debris, in particular to polymeric debris, probably plays the greatest role. It has been almost two decades since Willert et al. first described the problem of polyethylene wear

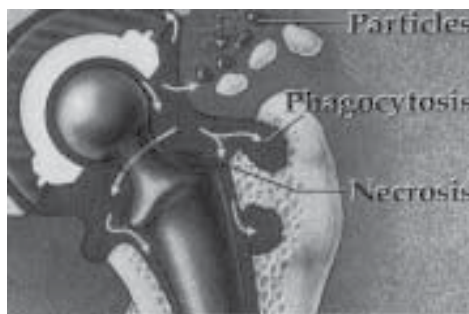


Figure 26 Osteolysis.



Figure 27 Bone loss due to particulate debris generated osteolysis.

leading to periprosthetic inflammation, granuloma, bone resorption, and implant loosening [75]. Since then, many studies have documented the finding of particulate bone cement and polyethylene in periprosthetic tissue [36,661.

In normal-wearing artificial joints, linear wear rates of 0.05-0.2 mm per year result in the generation of about 25-100 mm³ (25-100 mg) of polyethylene debris annually. On a basis of known dimensions of polyethylene particles found in tissue around the hip prosthesis, this equates to the annual production of tens to hundreds of billions of particles [9].

Variations of polyethylene wear rates probably relate to acetabular implant design, femoral head size, femoral head material, and at least in part to the quality of the polyethylene used [44,2]. Wide variations are known to exist between batches of polyethylene and between different polyethylene suppliers [761.

Metal particulate debris generated from the stem or cup in sufficient quantities could activate macrophage-mediated osteolysis. More likely the cause is the migration of metallic debris into the articulation, resulting in increased third-body wear of polyethylene (Fig. 27). Additional poly debris can be generated by poor modular designs, incomplete conformity of the liner within the metal cup, thin polyethylene resulting in cold flow, and wear through and abrasion of screw heads against the convex polyethylene surface (Fig. 28).

Problems with excessive wear due to titanium bearing surfaces have been reported (Fig. 29). In addition, clinical evidence indicates higher volumetric wear with 32 mm heads.

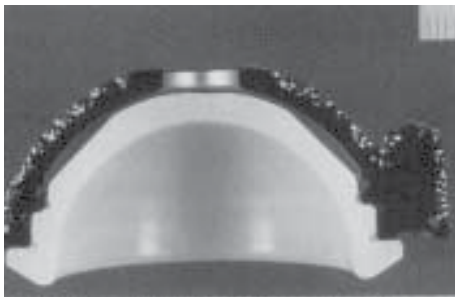


Figure 28 Incomplete conformity of cup and poly insert.

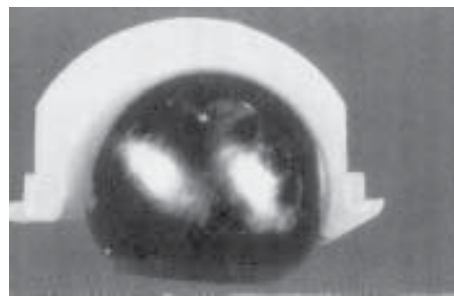


Figure 29 Excess wear due to titanium head.

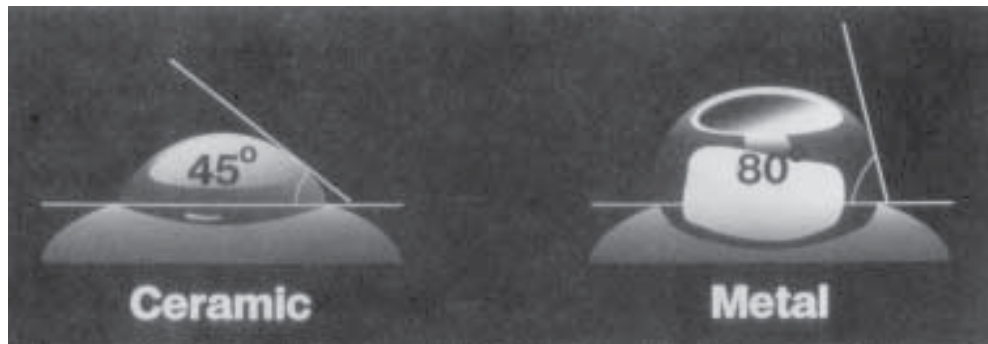


Figure 30 Wettability of ceramic versus metal.

Ideally, the bearing surface for most sliding (Fig. 30), rotating, or articulating bearing surfaces will be made from material having relatively high strength, high wear, and corrosion resistance; a high resistance to creep; and low frictional movements. In reality no one material presently exhibits all of these characteristics. Therefore, with present bearing systems compromises are typically made between these various characteristics. There are, however, some immediate steps that can be taken to reduce the generation of particulate debris.

1. Use ultra-high molecular weight polyethylene with high ratings in key mechanical and physical properties.
2. Use non-modular, molded acetabular components.
3. Use modular components with:
 - High conformity and support.
 - Secure locking mechanism.
 - Minimum polyethylene thickness 6-8 mm.
4. Use a 28 mm or smaller head diameter.
5. Do not use titanium alloy as a bearing surface.
6. Minimize modular sites on femoral side to reduce chances of third-particle wear debris.

III. FEMORAL CONSIDERATION

The femoral head is slightly larger than one half of a sphere, and the shape is more oval than spherical. The stresses on the femoral head usually act on the anterior superior quadrant, and surface motion can be considered as sliding on the acetabulum. Two important angles need to be considered: the neck shaft angle and the angle of anteversion. In addition to these two angles, the joint reaction force is affected by femoral head offset [28,65,37]. It is also important to remember that while static force is considerably greater than body weight, even greater force is generated posteriorly in dynamic situations such as acceleration and deceleration: manifest in negotiating stairs or inclines, in changing from a sitting to a standing position or vice versa, and in other routine activities of daily living that load the hip in flexion.

The biological response of bone to stress greatly affects the outcome of cementless total hip arthroplasty. The adaptive bone remodeling process, “Wolff’s law”, must be taken into consideration in deciding on material, geometry, and size selection for cementless femoral components. Many clinical and radiological studies have demonstrated the sensitivity of this adaptive remodeling process [3 11 (Fig. 3 1).

It has been shown that trabecular microfracture and remodeling is a major mode of accelerated remodeling in response to changes in mechanical demands on the bone [321. Trabeculae that fail, either by fatigue mode or by overloading, will disappear if the ends do not contact each other and if the resulting trabecula bears no load (disuse atrophy). However, if the fractured trabecula realigns itself and the fracture site still maintains control such that the structure is able to transmit load, the trabecula will remodel in the new direction much more quickly than through the mechanism of ordered resorption and apposition. Interfaces created surgically within the structure and subsequently loaded by mechanical means result in severe overloading of the remaining cancellous structure.

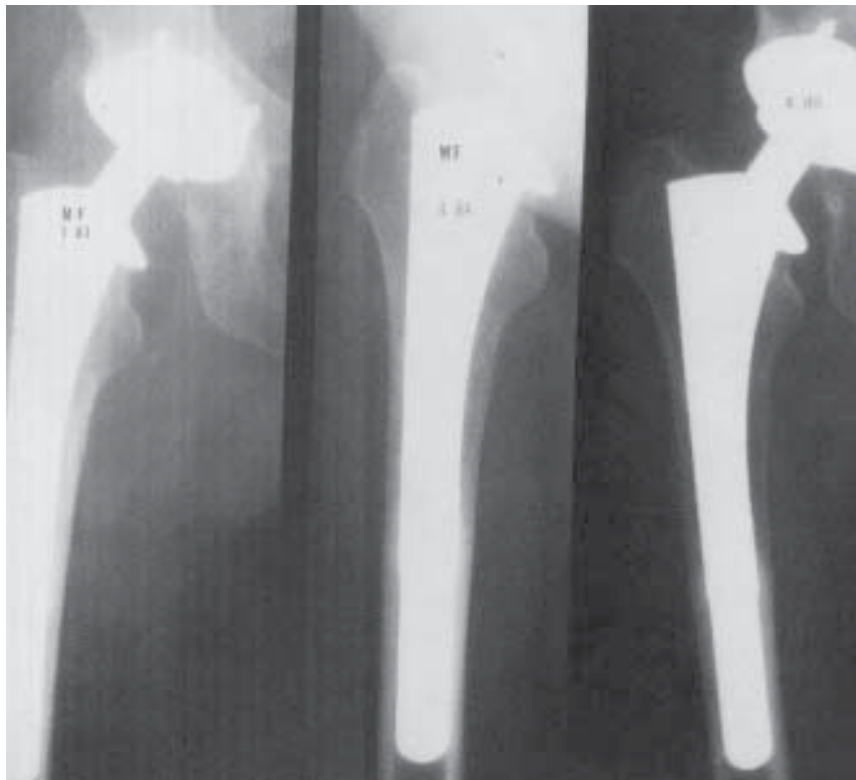


Figure 31 Bone remodeling in a porous coated AMLI stem.

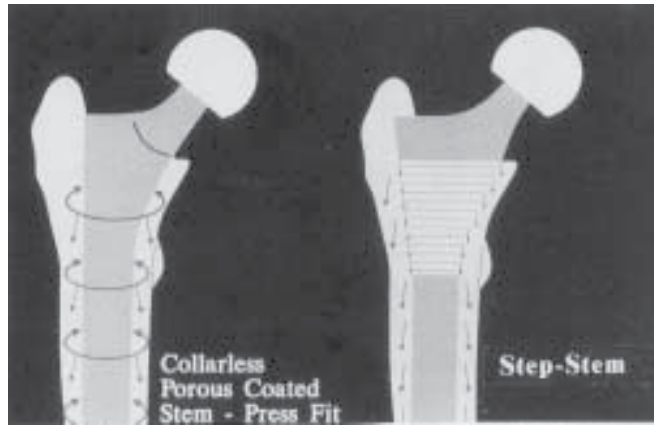


Figure 32 Hoop stresses versus compressive stresses.

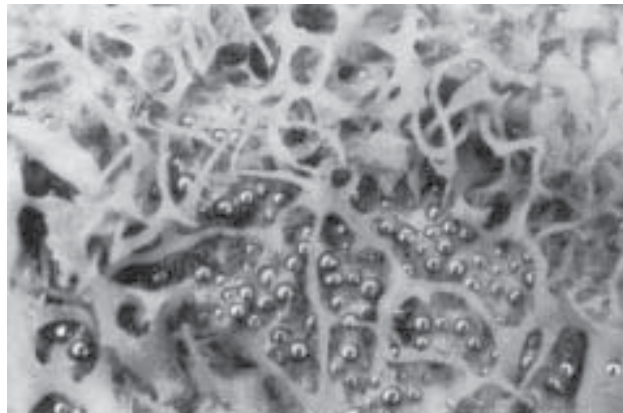


Figure 33 Bone ingrowth into a porous surface.

Cancellous bone is a poor material for structural support of a prosthesis. Cancellous bone is a biological engineered material, and its strength depends on its having the entire bulk of the structure intact. The creation of an interface with areas of cancellous bone disproportionately weakens the structure. In addition, interfacing an implant with cancellous bone merely serves to increase the stress at the interface to a level that causes fatigue failure of the bone [62].

Through proper design and surgical technique, one can achieve significant enhancement of the mechanical properties of the procedure consistent with basic biomechanical principles. It is recommended that most, if not all, of the cancellous bone be removed. Structuring the surface of an implant will minimize the surface shear stresses. In addition, structuring will transfer hoop stresses into compression stresses within the femur (Fig. 32). For an uncemented femoral component to be successful it is universally agreed that initial stability is essential. In addition, there must be a mechanism to ensure longterm bony fixation (Fig. 33).

During the past three decades, techniques, materials, and prosthetic designs for cementless total hip arthroplasty have been improved significantly. During the last 15 years in particular, there has been a growing movement into more complex cementless designs, particularly in the area of modularity. (Fig. 34). Not all cementless designs are equal, and it is important to understand certain design features that segregate individual implants into specific categories within the cementless group. Some appear to be successful whereas others have failed rapidly. To date, all current cementless designs have one feature in common - a modular head. So the simplest of designs features a unibody stem with a modular head that takes either a metal or ceramic articulation (Fig. 35). However, there is a fast-growing trend to add additional modular features to aid in achieving initial implant-to-bone stability by better fit and fill criteria, that is, maximization of endosteal contact.

Replacement of the normal position of the femoral head is essential for correction of mechanical balance between abductor forces. This is addressed by vertical height, version angle, and medial offset of the head relative to the axis of the stem (Fig. 36). If vertical height is too short, joint stability is a problem. If too long, patient complaints result and nerve palsy is possible. Incorrect version angle can result in reduced range of



Figure 34 Multimodular design.

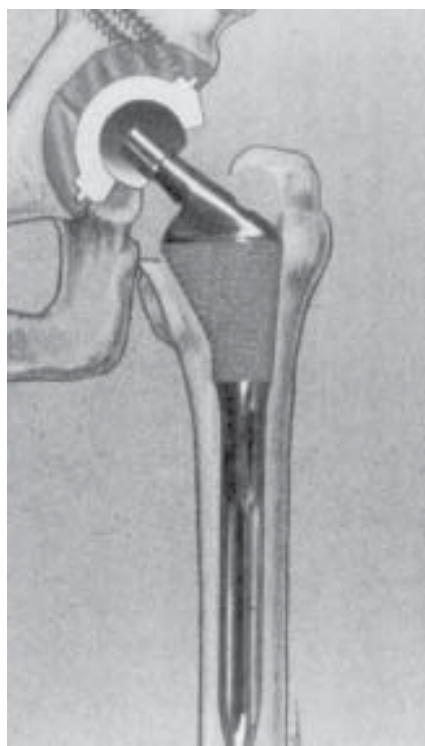


Figure 35 Unibody stem design with modular head.

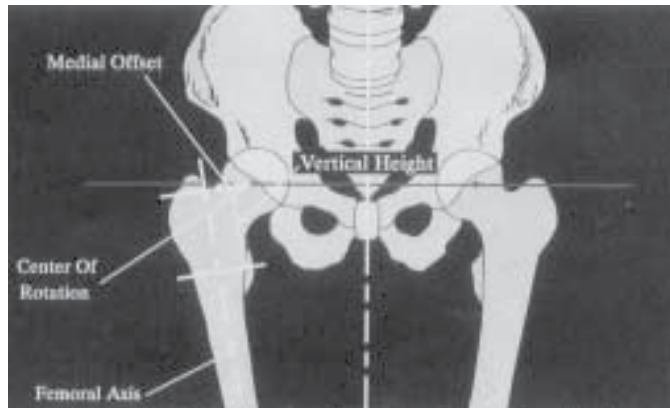


Figure 36 Biomechanical function.

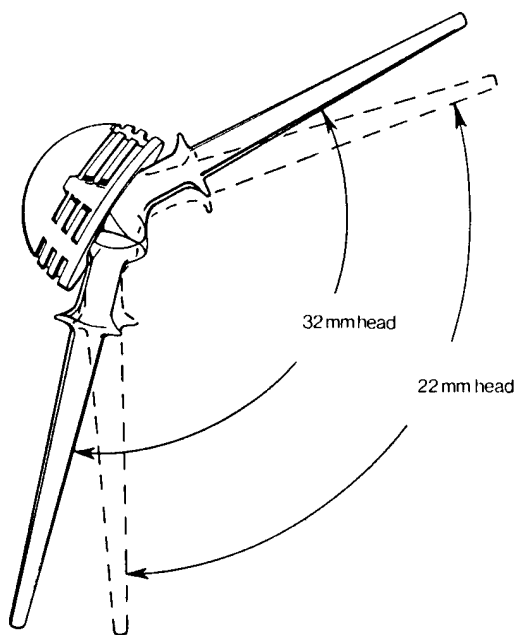


Figure 37 Range of motion.

motion and possible hip dislocations. Medial offset that is too short will cause shortening of the abductor moments, and there will be greater resultant force across the hip joint. If offset is too great, increased torsional forces will be placed on the femoral implant. For a femoral component to be successful it must have initial torsional stability with or without cement.

Modular head diameters are available from 22 to 32 mm. Charnley strongly advocated a 22 mm head due to its lower frictional properties [171]. However, joint stability is not as good as in a larger-diameter head (Fig. 37). Most designers and surgeons now compromise on a 26 or 28 mm diameter, which provides adequate polyethylene thick-



Figure 38 Betchel stepped stem.

ness on the acetabular bearing side, as, well as improved range of motion and stability compared with a 22 mm diameter [44].

Normally the femur is loaded from the outside cortex, and stresses are transferred internally. However, in a stemmed reconstruction the biomechanical loading has been changed to an internal loading mechanism. Intramedullary stems place an unnatural hoop stress on the bone. This hoop stress must be transferred into compressive loads to the

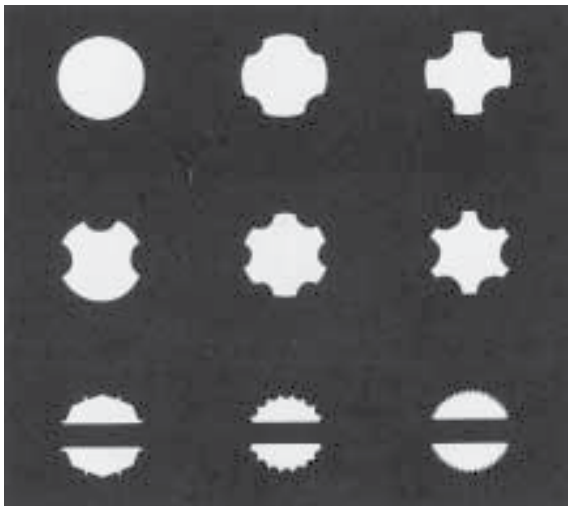


Figure 39 Distal Cross-Sectional Geometry.



Figure 40 Femoral cavity and segmental defect.

proximal femur. One way to help accomplish this is to design proximal steps into the femoral component. Early endoprosthetic stems were developed by Bechtol in 1954, the “Stepped Prosthesis”, and a later one by Townley also featured this stepped-design concept (Fig. 38). However, the idea was not revisited until Pughs’ work in 1981 led to the OmniFifl design and his additional work that led to the 1984 S-ROM proximal sleeve design [62,63].

A. Femoral Components

The objective for cementless total hip stems of long-term pain-free stability is dependent on both primary and secondary fixation of the implant to the bone. An effective cementless stem should resist subsidence, tilting and torsional forces.

Primary mechanical stability is, therefore, a prerequisite for long-term success. Torsional fixation of the femoral component is considered the most important criteria for long-term success [48]. It is only logical that design features that improve fixation are likely to improve clinical results.

Although there may be advantages in bone remodeling by initial stability by proximal fixation, irregularity in shape and structure of the bone in the metaphyseal area can compromise stability. It has been previously reported that a constant proportional relationship is not present between the shape and size of the metaphysis and diaphysis. In addition the revision situation results in alterations in the normal bony architecture, making fit and fill more difficult to achieve [47,67]. Distal stem stability enhances overall initial stability of the implant in both primary and revision total hip arthroplasty. (Fig. 39).

With cavity and segmental bone damage it is difficult to achieve stability of the implant (Fig. 40). In this situation some authors have previously recommended distal fixation. It is our opinion that distal stability is preferable over distal fixation. This can be

achieved by fluting the distal end of the stem. Whiteside [48] and Koeneman [45] have shown that fluting offers more initial stability in torsion as compared to a fully porous coated stem.

It is generally agreed that the better the fit and fill ratio of the femoral component, the better the initial stability and potential for long-term fixation. Over the past 10 years fit and fill has taken several approaches: (1) a large quantity of sizes (unibody); (2) modularity; and (3) custom (intraoperative or preoperative).

B. Unibody Stems

Due to concerns that modular sites generate particulate debris along with socioeconomic pressures, there is a strong movement back to one-piece stem designs, especially for routine primary hip reconstruction. The challenge for unibody designs as with all designs is to optimize fit and fill, to ensure optimal loading of stress to the proximal femur, to avoid the problems of torsional and axial instability while providing for reproducible surgical technique.

Currently there is considerable controversy as to straight (Fig. 41) vs. anatomical (Fig. 42) and collar vs. collarless stem designs. In an attempt to appeal to both mentalities, newer geometric designs (Fig. 43) are emerging. These designs feature straight stems with anterior flares and anteverted necks.

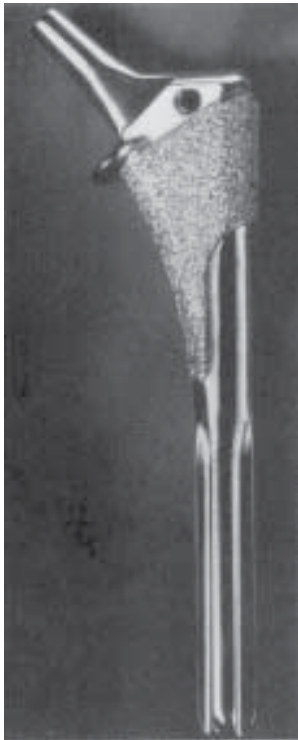


Figure 41 Multilock™ straight stem.

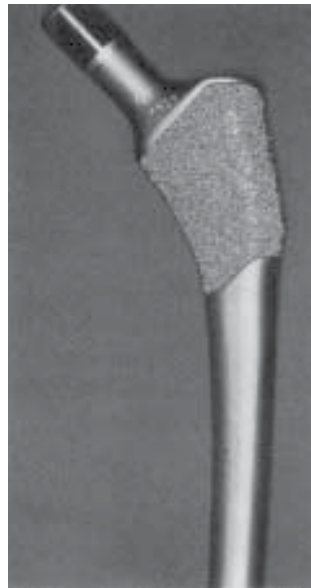


Figure 42 PCA™ Anatomic stem.



Figure 43 Replica™ geometric stem.

C. Modular Stems

The concept of modularity is to provide for intraoperative customization of fit and fill with each individual femur. There are a variety of modular designs available, from modular necks (Fig. 44), proximal (Fig. 45) and distal sleeves (Fig. 46), and mid-stem tapers (Fig. 47). Each design has specific features and benefits and requires complete knowledge of each individual design and surgical technique.

While modular designs represent an advance in the ability to precisely fit the implant to the bone, the mechanical integrity of the assembled component must be fully tested prior to clinical usage. Machining methods, tolerances, surface characteristics, materials, electrochemical environment and mechanical environment are all critical factors that



Figure 44 Modular neck.

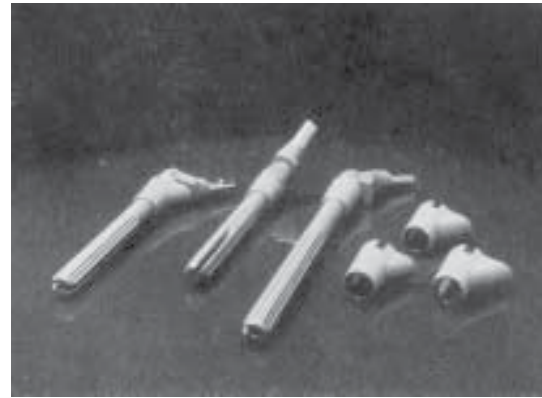


Figure 45 S-ROM stem.



Figure 46 Example modular distal sleeves.



Figure 47 Mid-stem taper design.

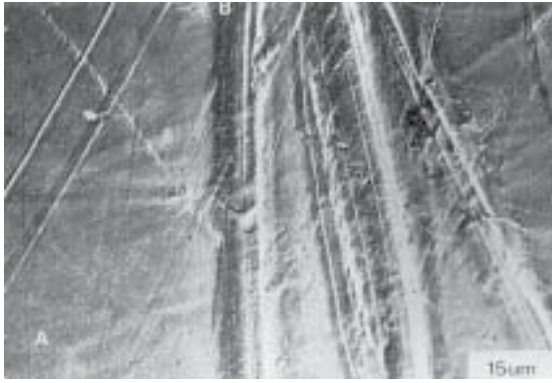


Figure 48 Example of increased wear of bearing surface.

need careful consideration in evaluating the long-term performance of modular interfaces [69].

In evaluating the mechanical performance of cementless femoral stems, there is no single test that can adequately represent the various bony conditions that a hip stem may be subjected to *in vivo*. This in part explains the wide variance in testing methods found today.

Recently, concern about particulate debris generated by modular interfaces has been raised. In fact, we are now beginning to see published reports concerning *in-vitro* testing of modular designs [41,24]. One major concern of metal particulate debris, is the possibility of increasing the rate bearing surfaces wear (Fig. 48).

Modularity has been shown to be cost-effective and offers many intraoperative custom capabilities [47,67]. Short-term results are very encouraging and have high appeal

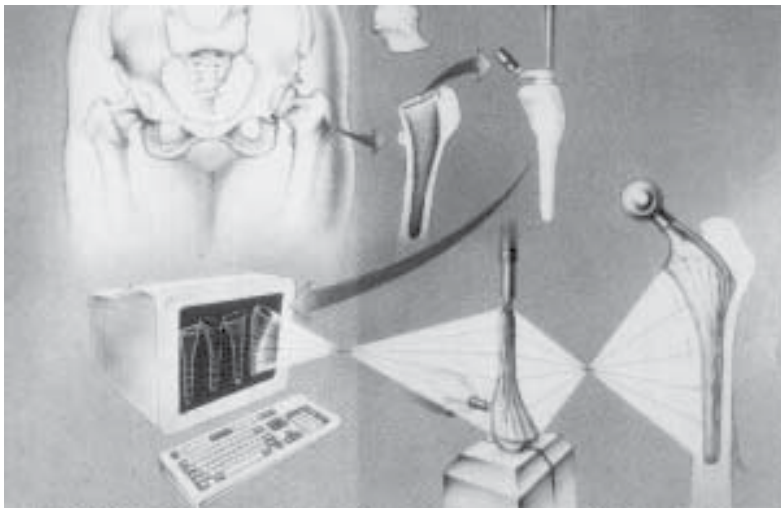


Figure 49 Intraoperative custom.

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for revisions and difficult primaries such as congenital dysplasia [14]. However, modularity has made surgical technique more demanding.

D. Custom Stems

Customs offer great versatility; however, intraoperative customs reduce surface treatments such as hydroxyapatite (HA) or porous surfaces (Fig. 49). In addition, there is the concern of increased operating room time and the difficulty in achieving reproducible, clinical and surgical results [30]. As for preoperative customs, again, in routine cases there are no outcome data to support this approach over standard off-the-shelf designs, which generally speaking are less costly. It will take another 10 years of clinical comparison to judge whether customs have an advantage over standard off-the-shelf cementless devices. This is one problem in total joint surgery that does not seem to exist in other medical disciplines. In the meantime, it follows that advances must be made based mainly on theoretical grounds, good solid, basic science, and animal experimentation rather than on short-term clinical evaluations by the implant-developing surgeon in a small number of patients.

Obviously there is a need for all three types of implant modalities: unibody, modular, and customs (although these are not necessary with adequate modularity).

However, the surgeon must be aware of all the design features and pick and choose the appropriate design indicated for individual patients. No one design is going to fill all the needs that are found in total hip replacement surgery today. The future challenge will be to address growing indications in a restricted health care financial market.

IV. MATERIAL CONSIDERATION

Biomedical materials are synthetic polymers, biopolymers, natural macromolecules, metals, ceramics, and inorganics such as hydroxyapatite. For materials to be used successfully in the body, they must have minimal degradation in the body, they must be compatible with the biological environment, and they must be strong enough to perform their intended purpose.

Stainless steel, especially 316L, has been used for many years as an implant material [3,51]. Early total joint replacements and current internal fracture fixation devices utilize stainless steel. In some designs this material has shown crevice corrosion. Cobalt-chrome alloys have been popular as implant materials because of their corrosion resistance and good wear properties. CoCrMo alloy is typically used in devices that are cast.

Forged parts are made from CoNiCrMo alloy. These alloys have relatively high elastic moduli. A desire for a lower modulus material led to the use of titanium and its alloys. Commercially pure titanium is used because of its corrosion resistance, but it is not used in applications that require high structural strength. The titanium alloy that has been most widely used in orthopedic applications is the Ti6Al4V alloy. This material has good fatigue properties but is softer and has lower resistance to wear, especially when extraneous materials are introduced [2,6]. Surface treatments of these alloys have shown improved wear resistance. Titanium alloys with moduli even lower than the Ti6Al4V alloy are beginning to be used. Specialty applications that utilize a change in part shape after implantation use an alloy that is approximately one half nickel and one half titanium, which returns to an original shape under body temperature. These materials are tolerated well by body tissues. Tantalum has excellent biocompatibility and is used for

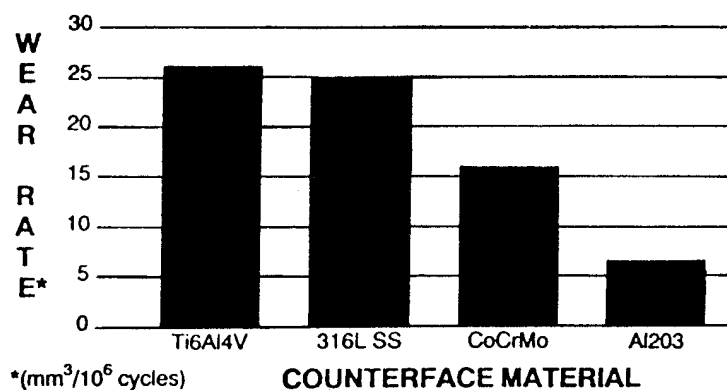


Figure 50 Wear rates.

markers because of its high radiodensity. With all metals there has been a concern for long-term protein-metal interactions and hypersensitivity of individuals to some of the metal ions that diffuse into body tissues.

Aluminum oxide ceramics have been used extensively as bearing surfaces in artificial joints because of its excellent wear properties [25,57,64] (Fig. 50). It has not been used extensively for other structural applications because of its high elastic modulus and brittleness. Zirconia has been introduced recently as an alternative to aluminum oxide.

Polymeric composite materials have been investigated as implant materials. Carbon, glass, quartz, and polymeric fibers have been used for the reinforcing phase, and carbon (carbon-carbon composites), epoxy, polyetheretherketone (PEEK), polybutadiene, and polysulfone have been used as matrices.

Initial testing of artificial implants was prompted by a fatigue fracture rate of about 3 % in early (1970s) femoral stems of artificial hip implants [61] (Fig. 51). The test methods that were developed simulated the failure mode of these early implants. Both the American Society for Testing and Materials (ASTM) and the International Standardiza-



Figure 51 Fractured cemented stem.

tion Organization (ISO) have test methods for femoral stems that support the distal stem and leave the proximal stem unsupported. Although noncemented stems rarely have this type of failure mode, these stems are often tested with this test method. The disadvantage of the method is that if the stem is designed to pass the test, it encourages a bulky and stiff design. This is the opposite of what is needed for maintenance of bone strain and what is desired to combat bone resorption due to stress shielding. An alternative test method that has been reported utilizes proximal fixation with a free distal stem except for a point load on the lateral stem. Both ASTM and ISO are developing test methods to be used with low-stiffness stems. Similar fatigue tests have been developed for other joints such as the knee. Loading typically is at high frequency and at loads higher than expected in service. Ten million cycles has been chosen as representing a run-out; that is, the load is probably below the endurance limit.

V. SOCIAL-ECONOMIC CONSIDERATION

There is no debate on the fact that cost is becoming more and more an influence on the decision process for medical treatments and on product development programs.

A. The Current Health Care Environment

The health care environment includes the following important characteristics:

- Enormous duplication of services Competition among providers
- Technology that changes faster than clinical practice
- Pressure from payers for less costly service
- Pressure on providers to deliver care in a capitated environment
- Vertical Integration and consolidation
- Pressure for information on the value of new approaches

B. Factors Influencing Adoption of New Technology

Several factors are involved in adoption of new technology:

- Method of financing the initial cost
- Method of recovering operating costs Level of regulation
- Degree of competition Institutional capacity for technology assessment
- Organizational relationships: shared risk means slower adoption

C. Implications for Developers

Developers need to consider the following:

- Move from better medicine to better medical economics
- New is not synonymous with improved
- Expect a bumpy ride in an increasingly volatile market
- Focus product development
- "In God We Trust. All others bring data."

VI. IMMEDIATE FUTURE TRENDS AND PRODUCTS

Use of modularity in the acetabulum has contributed to significant debris generation problems (Fig. 52) [4,9]. This trend is slowly reversing and it is predicted that developers will go back to preassembled, metal-backed, porous-coated devices with molded polyethylene inserts rather than machined. One such ideal design would have the following characteristics:

- Hemispherical shape
- Sintered, porous beads for ingrowth
- Polyethylene, compression molded directly to metal shell
- Peripheral screw holes for adjunct fixation with no dome screw holes and/or a capping mechanism to seal the holes
- Neutral poly liner (no offsets)

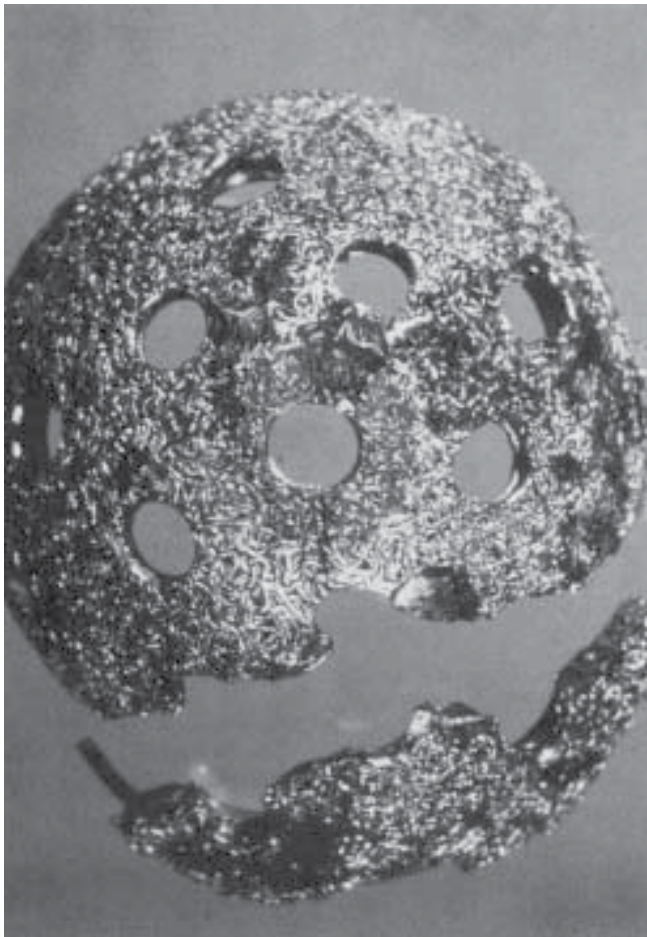


Figure 52 Failed porous mesh cementless cup.

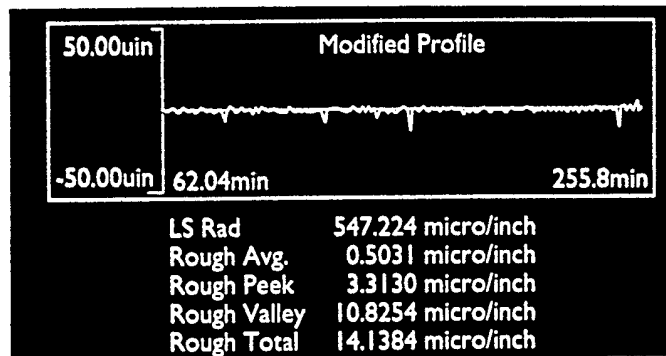


Figure 53 Surface finish for ceramic femoral head.

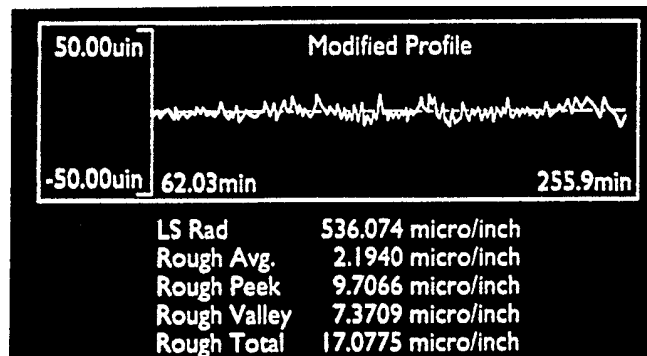


Figure 54 Surface finish for CoCr femoral head.

VII. NEAR FUTURE PRODUCTS

Ceramics have characteristics that are very desirable for use in sliding, rotating, and articulating bearing surfaces (Figs. 53 and 54). In addition to high compressive strength, they exhibit high wear and corrosion resistance with relatively low frictional movements. However, use of such ceramic materials in bearing systems has been inhibited because such materials are susceptible to fracture due to their relatively low tensile and shear strengths. This weakness is one reason why metal and/or polymeric materials have been used for many bearing surfaces. Compared to bearing ceramics, bearing metals and polymers typically have lower wear and corrosion resistance and higher frictional movements.

In bearing systems where ceramics have been used, their low tensile and shear strengths often force the adoption of costly design compromises. Thus, one design compromise has been to make the entire bearing component, rather than just a portion thereof, out of solid ceramic, effectively increasing the structural strength of the bearing surface. Such a solid ceramic bearing component can be larger and bulkier than its metal and/or polymeric counterpart.

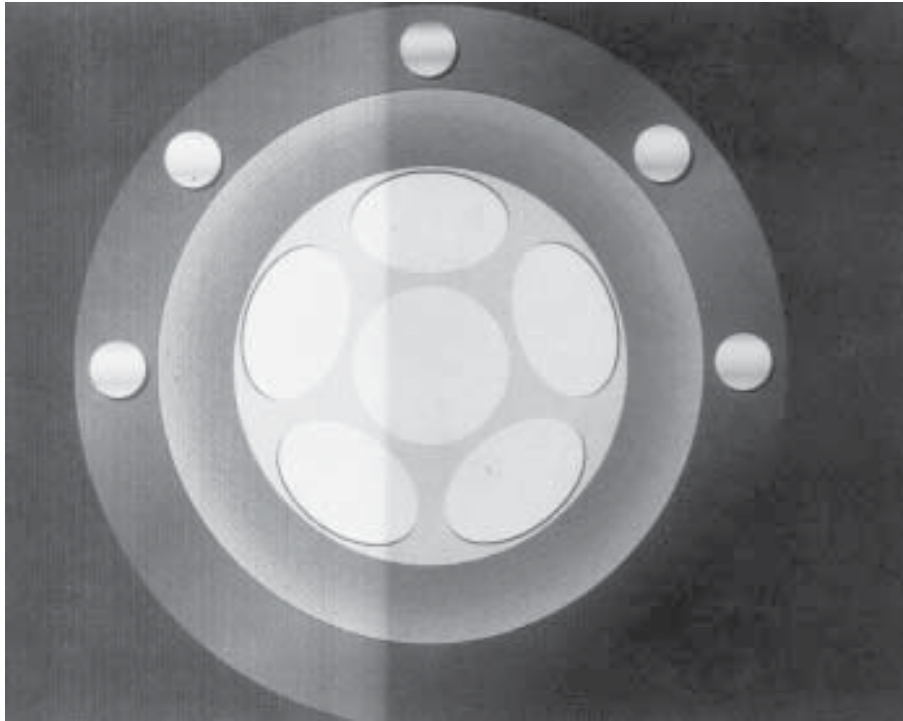


Figure 55 Segmented ceramic cup.

Making an entire bearing component such as the acetabular cup out of solid ceramic helps to compensate for the relatively poor tensile and shear strength typically found with ceramics. Also, because bearing ceramics are typically inflexible, additional manufacturing quality control of the geometry of both articular surfaces must be maintained in order to maximize the contact area between the two surfaces. If tight control is not maintained, point contact may develop between the bearing surfaces. As the contact area between two bearing surfaces decreases, the stress that is transmitted between the surfaces increases. This can result in greater wear and can increase the possibility of fracture of one or both surfaces [35,64].

In an attempt to address these problems, a segmented, ceramic bearing system has been developed [53] (Fig. 55). The segmented bearing system provides ceramic surfaces for mechanical bearings that would apply loads over a greater bearing area, resulting in reduced bearing stresses and would, in turn, reduce creep, wear, and the likelihood of fracture of the bearing surfaces.

The acetabular component is designed with ceramic articular segments that are backed and held in a predetermined pattern and configuration by either polyetheretherketone or polyethylene. Both of these materials have a lower elastic modulus than the segmented ceramic material. In addition, the polymeric material is reduced in height so that only the segmented ceramic material articulates with a ceramic femoral head.

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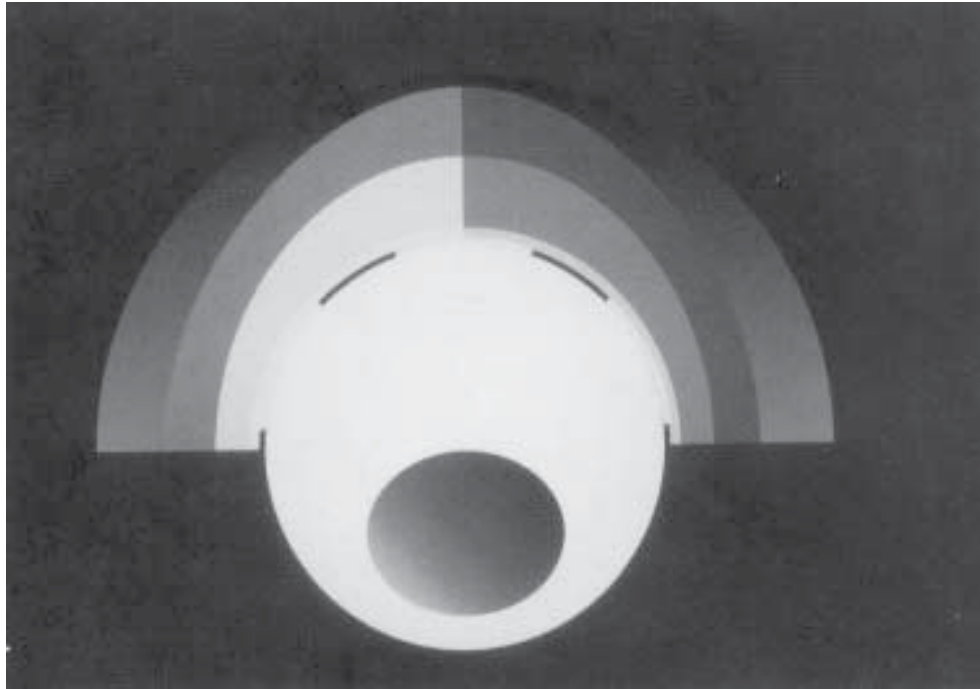


Figure 56 Lubrication channels in segmented cup.

Because of its resilience and lower elastic modulus, the polymeric material flexes as loads are transmitted between bearing surfaces while the shape of the surfaces of the segments remain relatively unchanged. This freedom of movement of the segments, under an applied load, allows for greater contact area between bearing surfaces because the segments as a group are able to conform to the geometry of the opposing bearing surface. Thus, rather than having the highly localized stress concentrations typically occurring in bearing systems, any applied load is shared by a number of segments, which results in lower stress being applied to the bearing surface and each segment.

An additional feature of this design is the formation of channels generated by locating the polymeric material slightly below the surface of the ceramic segments for lubrication and for allowing debris that finds its way into the bearing to either pass between the segments or be trapped into the polymeric material (Fig. 56).

This design allows for the segmented composite insert to be used with cemented hemispherical designs or cementless acetabular components. This highly innovative design provides for an alternative bearing surface that is cost-effective while it reduces or eliminates the generation of articulated polymeric or metallic debris. This design should have a tremendous positive effect on the overall reduction of particulate debris, resulting in increased longevity of total hip arthroplasty.

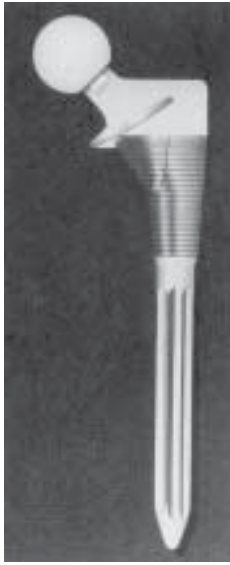


Figure 57 Unibody stem.

VIII. NEW DESIGN CONCEPT

In light of all that has been discussed, this section provides a review and current description of a new cementless total hip system. This system is a comprehensive system designed for primary and revision total hip replacement arthroplasty.

Patients face a variety of problems and solutions must be tailored to their individual needs.

A. Unibody Stem

This stem is a geometric design that features a proximal anterior flare that works in tandem with a 30° proximal conical flare collar. These two specific features aid in axial and torsional stability while providing increased surface geometry, resulting in increased compressive stress to the proximal femur. The neck shaft angle is 135° with 10° of anteversion. Lateral displacement of the femoral head is 40 mm.

The proximal conical collar allows for settling of the implant resulting in increased surface contact throughout the entire proximal stem geometry. In addition, the conical shape acts as a step in transferring hoop stress into compressive loads.

While providing improved fit and fill, the proximal conical shape provides a seal occluding wear debris from entering the femoral canal (Fig. 57).

B. Bibody Modular Stem

This stem's design incorporates a proximal, modular body that allows for correction of version, offset, and vertical height without disruption of the stem body. The two modular parts feature a double locking mechanism. The first is a trunion that engages in the stem

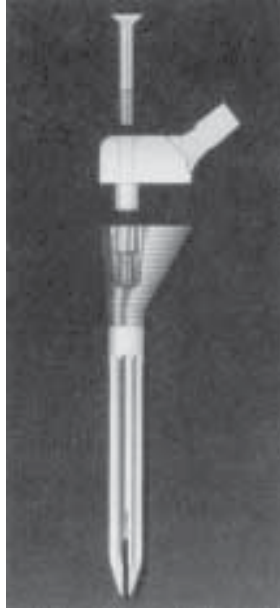


Figure 58 Bibody stem.

body by means of ratchet teeth. The specific design of these ratchet teeth allow for version adjustment in increments of 10°. The second locking feature is a set screw, which protects from disassembly.

The unique features of this design traps any debris that might be generated by the modularity and restricts this debris from interfacing with the host bone. In addition, once the bone has grown into the proximal porous area, polyethylene debris generated from normal wear is restricted from the distal stem area. Proximal bodies of different offsets, and vertical heights (Fig. 58) will allow for fine tuning hip joint biomechanics without removal of the stem.

IX STEM DESIGN FEATURES

A. Material

This stem will utilize high-strength titanium alloy. Manufacture will utilize forgings.

B. Taper Head Neck

The neck will accept a chrome-cobalt or ceramic articulation. The neck diameter has been designed to maximize range of motion as compared to other designs.

C. Offset

In order to improve biomechanical function, offset has been increased in comparison to competitive stems.

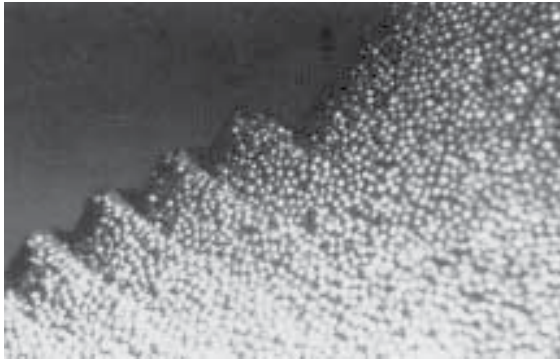


Figure 59 Stepped geometry with porous coating.

D. Surface Preparation

The stem is proximally porous coated utilizing a single, beaded porous coating of commercially pure titanium. This is sintered over a macrot textured design of horizontal steps, which helps to protect the beaded interface from shear forces and also helps in transferring hoop stresses to compression forces (Fig. 59). An additional option is a coating of HA which is plasma sprayed over the single, beaded porous surface. This single, beaded porous surface protects the HA in shear while also providing a backup for bony remodeling in case the HA is biochemically mobilized. Also, the nonporous surface has been treated with a proprietary microclean process that leaves a clean yet microrough surface [551].

E. Distal Bending Stiffness

The distal one third of the stem has been slotted in both the coronal and sagittal planes. These slots serve to reduce distal stem stiffness, allowing the stem to flex with the femur during normal daily activity. This feature has historically demonstrated reduced thigh pain (Fig. 60) [13]. In addition, it helps to reduce chances of intraoperative femoral fractures during stem insertion.

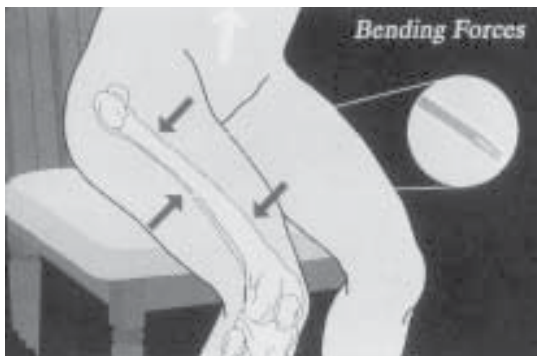


Figure 60 Bending forces.

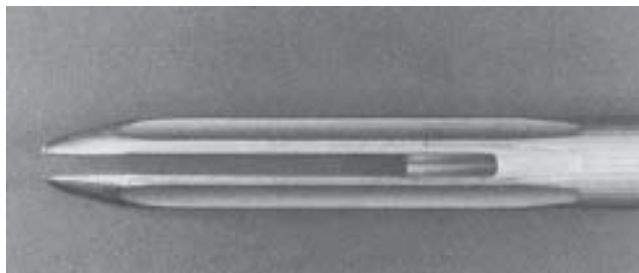


Figure 61 Distal slot design with flutes.

F. Distal Stability

To increase stem rotational stability, distal flutes have been incorporated into the stem design (Fig. 61). Rotational stability remains the primary concern of any femoral component.

G. Stem Tip

Bulleted geometry helps reduce distal point loading while creating a smooth transition zone for load transfer.

H. Instruments

Both stems - unibody and bibody - utilize the same instruments. Thus cost is reduced and there is also surgical ease in going from one stem to the next.

I. Acetabular Components

Two acetabular designs are offered in the system. The first is a standard ultra-high molecular weight (UHMWP) articulation that is compression molded to a hemispherical titanium alloy shell with CPT porous coating. This design will feature reduction in modularity with no angled offsets, which can result in decreased range of motion and can also result in increased chances of generation of particulate debris. The metal shell will feature peripheral screws for additional adjunct bony fixation, if indicated. This device will be indicated for, but not limited to the patient with a life expectancy of less than 15 years. It will also have significant cost savings over traditional systems.

The second design will have the same features; however, it will provide a ceramic articulation and will be indicated for, but not limited to the patient who has a life expectancy of more than 15 years.

X. SUMMARY

In view of the hundreds of thousands of total hip surgeries that have been performed since the surgery was introduced by Sir John Charnley over two decades ago, the small number of reported failures are not wholly unexpected. There is currently a great deal of debate over cement versus cementless indications. Initial concerns about wear rates of polyethylene have risen again due to the increased incidence of osteolysis induced by particulate debris.

Current methods of achieving implant fixation vary in concepts and techniques. Each method presents problems which must be addressed if cementless fixation is to survive long term. The justification for the continued use of cementless implants should be based on well-developed clinical and radiographic evidence.

In our opinion, everything possible should be done to reduce the generation of particulate debris. Continued research in surgical methodology, materials, and component design of total hip replacement can help to increase the longevity of implants and increase indications to a broader range of patients.

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An Excerpt From:

8th ANNUAL INTERNATIONAL
SYMPOSIUM ON TECHNOLOGY
IN ARTHROPLASTY (ISTA)
(FORMERLY ISSCP)
FINAL PROGRAM

SAN JUAN - PUERTO RICO
CERROMAR BEACH RESORT

WED. SEPTEMBER 27th - SUN. OCTOBER 1st 1995

SPONSORED BY THE DIVISION OF ORTHOPAEDIC SURGERY
UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE

THE USE OF CARBON DIOXIDE GAS FOR PREPARATION OF BONY SURFACES IN CEMENTED TOTAL JOINT ARTHROPLASTY

By

Timothy McTighe, Joint Implant Surgery Research Foundation, Chagrin Falls, Ohio
H. M. Reynolds, F.A. Matsen, William R. Murray, Harry B. Skinner, Jason Guevara, and Karen Roche.

Introduction:

There is a strong movement back to using bone cement as the primary fixation method in total joint arthroplasty. However, it is important to recognize its inherent biological and mechanical limitations. Because bone cement is a grouting agent and does not possess adhesive qualities, successful fixation is dependent upon the mechanical interface between cement, bone and implant.

Mechanical loosening is reported in approximately 70% of all hip replacement failures. Five to ten year results demonstrate a loosening rate as high as 25%. Clinical loosening of implants represents a significant problem and exposes the patient to the medical risks associated with revision surgery.

Current surgical techniques for implantation of cemented implants consist of shaping the bony cavity with hand and powered tools, followed by brushing and saline lavage. Suction and surgical sponges inserted into the cavity are utilized to dry the bone surface. Cement is then injected, under pressure, to assure interdigitation of cement into the prepared cancellous bone bed. In hip arthroplasty, a femoral plug is generally placed prior to cement introduction.

Cardiopulmonary dysfunction is a recognized risk factor associated with cemented arthroplasty procedures. This physiologic dysfunction is generally attributed to particulate, fat and marrow embolism. Thorough cleaning of fat, tissue and debris can help to reduce the incidence of embolic complications.

Purpose:

The CarboJet™ device delivers a pressurized flow of dry carbon dioxide gas to the bone surface, to clean and dry the area prior to cement implantation. This paper reviews the design concept and application, and reports results from clinical and laboratory testing of the CarboJet™ device, undertaken to evaluate its safety and effectiveness.

Methods:

The CarboJet™ device is used as a final step in bone preparation, employed immediately prior to cement introduction. The focused flow of gas aids in removing fat, liquids, and particulate debris from the bone, helping to improve mechanical interdigitation by reducing the volume of these materials which are otherwise interposed between cement and bone.

The CarboJet™ device consists of a reusable hand-piece and a variety of nozzles, along with a pre-set pressure regulator for use with standard CO₂ tanks.

The sterile CO₂ delivery tube set features quick-

disconnect fittings and an in-line microbial filter to assure sterility of the CO₂.

In vitro testing was conducted on human cadaver bone to compare cleaning effectiveness of gas lavage to conventional pulsatile saline lavage preparation.

A prospective randomized clinical investigation was also conducted, comprising a total of 74 procedures done in 70 patients. Procedures performed included total shoulders, knees, hips, and elbows, and included both primary and revision surgery.

The investigational protocol included intra-operative monitoring of blood pressure, heart rate and end-tidal CO₂.

Results:

Laboratory testing demonstrated significant cleaning and debris removal, with an improved penetration of cement into available intertrabecular spaces. Testing demonstrated that a moderate gas flow rate is sufficient to clean and dry the bone, with impact forces less than those delivered to tissue by pulsed saline. The CarboJet™ regulator delivers 50 psi of line pressure, with a resulting gas flow rate of approximately 25 LPM.

Clinical evaluations demonstrated a visible improvement in bone bed cleaning. Intra-operative monitoring was uneventful. Throughout the clinical experience, no complications relating to CarboJet™ use have been encountered.

Conclusions:

Subjective surgical impressions are that the CarboJet™ delivers improved or equivalent results in cleaning and local drying as compared to conventional techniques.

Successful long-term implant fixation relies upon solid mechanical interlocking between cement and bone. Thorough intra-operative cleaning and removal of fat, liquids and particulate debris prior to cement introduction helps to provide for intimate mechanical contact and may help to reduce the incidence of embolic complications arising from debris in the canal.

Mechanical and clinical testing has demonstrated that dry carbon dioxide gas lavage is a safe and effective method for bone bed preparation prior to cemented implantation of arthroplasty devices. Only additional testing and long-term clinical follow-up will demonstrate the CarboJet™'s potential contributions to clinical outcome.

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DESIGN FEATURES THAT REDUCE THE GENERATION OF PARTICULATE DEBRIS FOR CEMENTLESS THA

By

Timothy McTighe, Joint Implant Surgery Research Foundation, Chagrin Falls, Ohio

Purpose:

To reduce the generation of foreign particulate debris.

Conclusion:

Specific design parameters can reduce or eliminate the generation of particulate debris.

Significance:

The reduction of particulate debris volume can reduce the chances of osteolysis.

Summary of Methods and Results:

There is major concern over osteolysis and its effect on survivalship of total hip implants. Past research has shown a direct relationship between foreign particulate debris and its association with osteolysis and implant loosening.

This paper will review design features that reduce the chances of generating particulate debris. The following areas will be highlighted in this paper:

- Wear Related to Polyethylene
- Wear Related to Acetabular Implants
- Wear Related to Femoral Head Size
- Wear Related to Femoral Head Material
- Wear Related to Modular Parts
- Wear Related to Implant Bone Abrasion
- Wear Related to Third-Body Abrasion

Particular debris and osteolysis are of major concern, and every attempt to reduce the generation of debris should be done. This paper clearly demonstrates specific design features that can have a positive effect in that area.

An Excerpt From:

The 15th Annual Verne T. Inman Lectureship

and

The 29th Annual Scientific Program and
39th Annual Visiting Professorship

of the

LeRoy C. Abbott Orthopaedic Society

May 4-6, 1994

University of California, San Francisco, CA

A NEW APPROACH TO BEARING SURFACES FOR TOTAL HIP ARTHROPLASTY

TimothyMcTigbe, Ph.D. (hc), John W Grabam, and H.M. Reynolds, M.D.

The most common cause of proximal femoral bone loss is due to osteolysis. Although the specific cause of lysis is not known, it has been attributed to a variety of factors, including motion of the implant and foreign body reaction to particulate debris, in particular to polymeric debris. It has been almost two decades since Willett first described the problem of polyethylene wear leading to peri-prosthetic inflammation, granuloma, bone resorption, and implant loosening. Since then, many studies have documented the finding of particulate bone cement and polyethylene in peri-prosthetic tissues.

In normal wearing artificial joints, linear wear rates of 0.05-0.2 mm per year results in the generation of about 25-100 μ m (25 to 100 mg) of polyethylene debris annually. On a basis of known dimensions of polyethylene particles found in tissues around hip prostheses, this equated to the annual production of tens to hundreds of billions of particles.

Variations of polyethylene wear rates probably relate to acetabular implant design, femoral head size, femoral head material, and at least in part to the quality of the polyethylene used. Wide variations are known to exist between batches of polyethylene and between different polyethylene suppliers.

Based on favorable clinical trials in Europe during the past decade, improved ceramic on ceramic and metal on metal bearing combinations have been renewed as possible solutions to the problem of polyethylene wear. This paper will review one such concept of ceramic on ceramic articular for use in total hip arthroplasty.

Ideally, the bearing surfaces for most sliding, rotating, or articulating bearing surfaces systems will be made from material having relatively high strength, high wear, and corrosion resistance, a high resistance to creep, and low frictional moments. However, in reality no one material presently exhibits all of these characteristics. Therefore, with present bearing systems compromises are typically made between these various characteristics.

Ceramics have characteristics which are very desirable for use in sliding, rotating, and articulating bearing systems. In addition to

high compressive strength, they exhibit high wear and corrosion resistance with relatively low frictional moments. However, use of such ceramic materials in bearing systems has been inhibited because such materials are susceptible to fracture due to their relatively low tensile and shear strengths. This weakness of ceramic materials is one reason why metal and/or polymeric materials have been used for many bearing surfaces. Compared to bearing ceramics, bearing metals and polymers typically have lower wear and corrosion resistance or resistance to creep and higher frictional moments.

In bearing systems where ceramics have been used, their low tensile and shear strengths often force the adoption of costly design compromises. Thus, one design compromise has been to make the entire bearing component rather than just a portion thereof out of solid ceramic, thereby increasing the amount of ceramic used and, therefore, effectively increasing the structural strength of the bearing surface. Such a solid ceramic bearing component can be larger and bulkier than its metal and/or polymeric counterpart.

Making an entire bearing component, like the acetabular cup, out of solid ceramic helps to compensate for the relatively poor tensile in shear strength typically found with ceramics. Also, because bearing ceramics are typically inflexible, additional manufacturing quality control of the geometry of both articular surfaces must be maintained in order to maximize the contact area between the two surfaces. If tight control is not maintained, point contacts may develop between the bearing surfaces. As the contact area between two bearing surfaces decreases, the stress that is transmitted between the surfaces increases. This can result in greater wear and increased possibility of fracture of one or both surfaces.

In the past one solution with this problem has been to manufacture prostheses with matching pairs of heads and cups. However, this solution is not only costly due to maintaining the quality levels required, but are additional inventory costs while making surgical intervention more difficult.

In an attempt to address these real life problems, a segmented ceramic bearing system has been developed. This segmented bearing system provides ceramic surfaces for mechanical bearings that would apply loads over a greater bearing surface area, resulting in reduced bearing stresses and, in turn, reduces creep, wear, and likelihood of fracture of the bearing surfaces.

The acetabular component is designed with several ceramic articular segments that are backed and held in a pre-determined pat-

tern and configuration by either Polyetheretherketone or Polyethylene. Both of these materials have a lower elastic modulus than the segmented ceramic material. In addition, the polymeric material is reduced in height so that only the segmented ceramic material articulates with a ceramic femoral head.

Because of its resilience and lower elastic modulus, the polymeric material flexes as loads are transmitted between bearing surfaces while the shape of the surfaces of the segments remain relatively unchanged. This freedom of movement of the segments, under an applied load, allows for greater contact areas between bearing surfaces because the segments as a group are able to conform to the geometry of the opposing bearing surface. Thus, rather than having highly localized stress concentrations typically occurring in bearing systems any applied load is shared by a number of segments which result in lower stress being applied to the bearing surfaces and each segment.

An additional feature of this design is the formation of channels generated by locating the polymeric material slightly below the surface of the ceramic segments for lubrication and for allowing debris that finds its way into the bearing to either pass between the segments or be trapped in the polymeric material.

This design allows for the segmented composite insert to be used with hemispherical design cemented or cementless acetabular components. This highly innovative design provides for an alternative bearing surface that is cost effective while it reduces or eliminates the generation of articular polymeric or metallic debris which should have a tremendous positive effect on overall reduction of particulate debris resulting in increased longevity of our total hip reconstruction. A review of fatigue and wear data will be presented; however, to date no in vivo testing has been done and only long-term clinical data will prove the viability of this design approach.

A NEW APPROACH TO BEARING SURFACES FOR TOTAL HIP ARTHROPLASTY

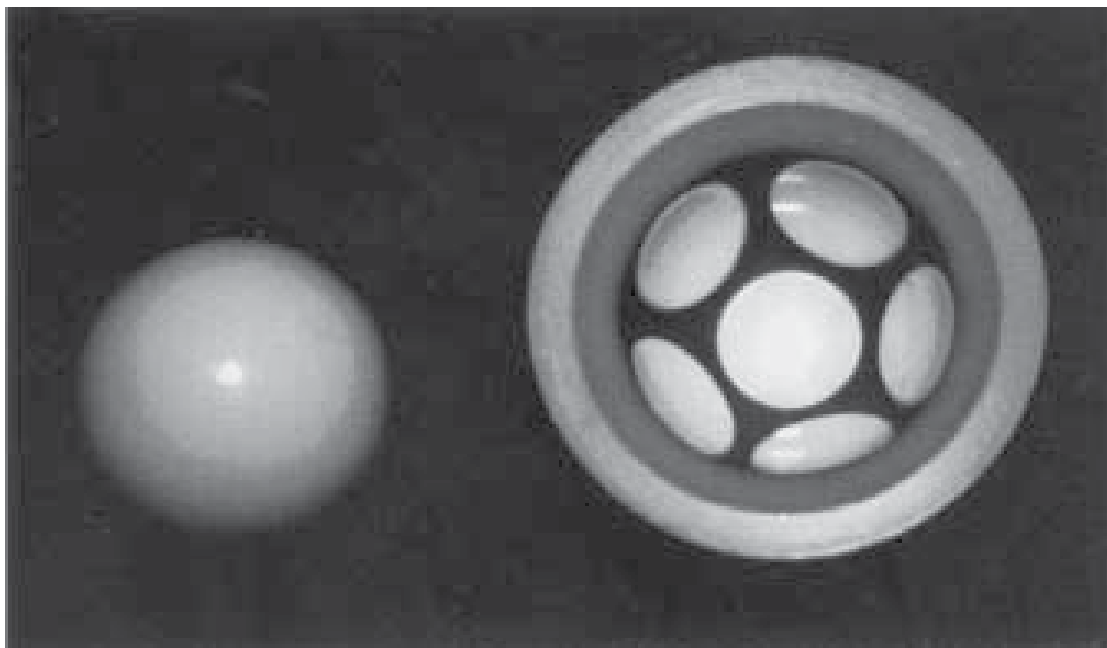
by

Timothy McTighe, Exec. Dir., JISRF, Chagrin Falls, Ohio

Ying Ko, Ph.D., Cincinnati, Ohio

Russell B. Bennett, Ph.D., Cincinnati, Ohio

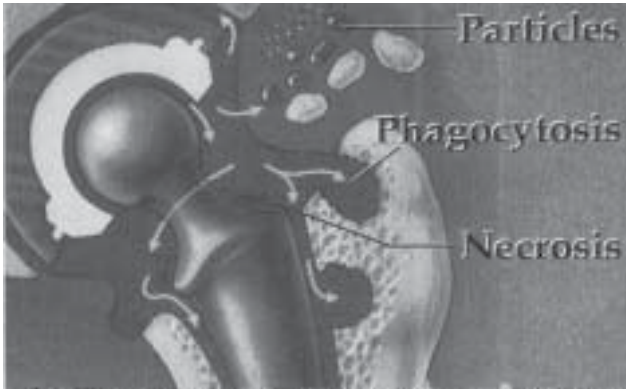
James Adams, P.E., Cincinnati, Ohio



A POSTER EXHIBIT AT THE 1994 AAOS MEETING

INTRODUCTION

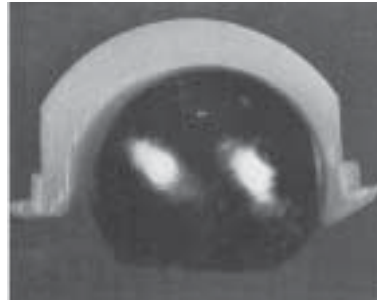
The most common cause of proximal femoral bone loss is due to osteolysis.¹ Although the specific cause of lysis in THA is not known, it has been attributed to a variety of factors, including motion of the implant and foreign body reaction to particulate debris, in particular to polymeric debris. It has been almost two decades since Willert first described the problem of polyethylene wear leading to



Osteolysis

periprosthetic inflammation, granuloma, bone resorption, and implant loosening.¹ Since then, many studies have documented the finding of particulate bone cement and polyethylene in periprosthetic tissues.^{3,4}

In normal wearing artificial joints, linear wear rates of 0.05-0.2mm per year result in the generation of about 25-100 mm³ (25 to 100 mg) of polyethylene debris annually.^{5,1} On a basis of known dimensions of polyethylene



Excessive Wear

particles found in tissues around hip prostheses, this equated to the annual production of tens to hundreds of billions of particles.

Variations of polyethylene wear rates probably relate to acetabular implant design,⁶ femoral head size,⁸ femoral head material,⁹ and at least in part to the quality of the polyethylene used.¹⁰ Wide variations are known to exist between i batches of polyethylene and between different polyethylene suppliers.

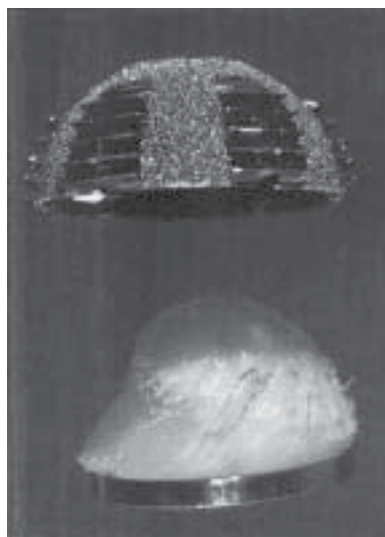
Examples of Design Flaws



Examples of Poor Contact of Liner With Metal Cups



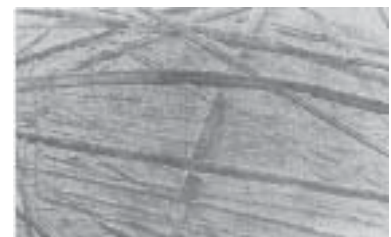
Examples of Failures



Constrained Socket



Fiber Mesh Cup



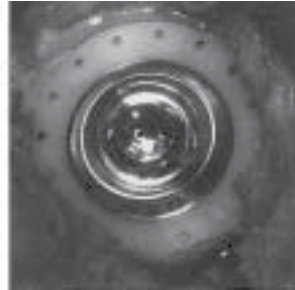
Increased Wear of Poly Cups

REVIEW

Based on favorable clinical trails in Europe during the past decade, improved ceramic-on-ceramic and metal-on-metal bearing



*Ceramic Articulation
Mittellemeier Design*



*Metal Articulation Cup
Design*

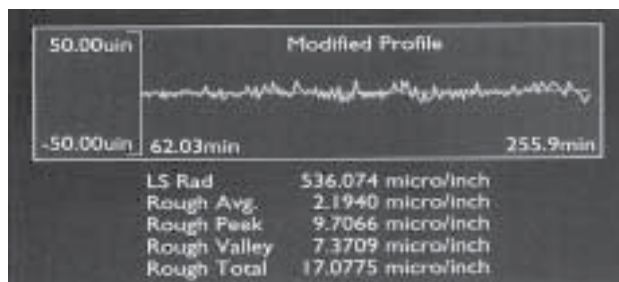
combinations have been renewed as possible solutions to the problem of polyethylene wear.

Ideally, the bearing surfaces for most sliding, rotating, or articulating bearing surfaces systems will be made from material having relatively high strength, high wear, and corrosion resistance, a high resistance to creep, and low frictional

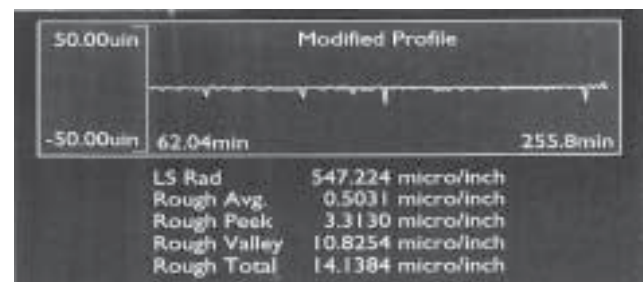
moments. However, in reality no one material presently exhibits all of these characteristics.

Ceramics have characteristics which are very desirable for use in sliding, rotating, and articulating bearing systems.”,” In addition to high compressive strength, they exhibit high wear and corrosion resistance with relatively low frictional moments. However, use of such ceramic materials in bearing systems has been inhibited because such materials are susceptible to fracture due to their relatively low tensile and shear strengths. This weakness of ceramic materials is one reason Why metal and/or polymeric materials have been used for many bearing surfaces.

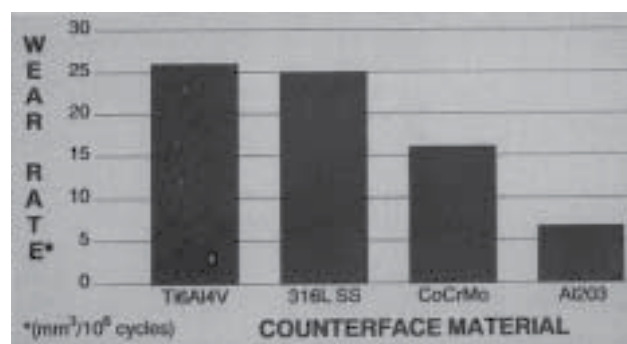
Compared to bearing ceramics, bearing metals and polymers typically have lower wear and corrosion resistance or resistance to creep and higher frictional moments. In bearing -systems where ceramics have been used, their low tensile and shear strengths often force the adoption of costly design compromises. Thus, one design compromise has been to make the entire bearing component rather than just a portion thereof out of solid ceramic, thereby



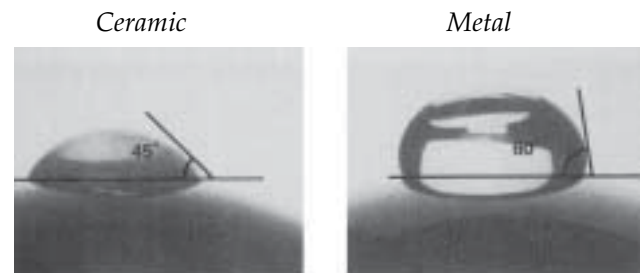
Surface Roughness: CoCr



Surface Roughness: Ceramic



Wear Rates



Surface Wettability

increasing the amount of ceramic used and, therefore, effectively increasing the structural strength of the bearing surface .12 Such a solid ceramic bearing component can be larger and bulkier than its metal and/or polymeric counterpart.



Ceramic Truncated Cone Design

Making an entire bearing component, like the acetabular cup, out of solid ceramic helps to compensate for the relatively poor tensile and shear strength typically found with ceramics. Also, because bearing ceramics are typically inflexible, additional manufacturing quality control of the geometry of both articular surfaces must be maintained in order to maximize the contact area between the two surfaces. If tight control is not maintained, point contacts may develop between the bearing surfaces. As the contact area between two bearing surfaces decreases, the stress that is transmitted between the surfaces increases. This can result in greater wear and increased possibility of fracture of one or both surfaces.

In the past one solution to this problem has been to manufacture prosthesis with matching pairs of heads and cups. However, this solution is not only costly due to maintaining the quality levels required, but are additional inventory costs while making surgical intervention more difficult.

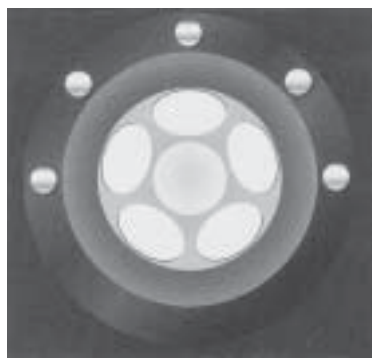
INTRINSIC™ SEGMENTED CERAMIC CUP DESIGN

This paper will review one such concept of ceramic-on-ceramic articulation for use in total hip arthroplasty

In an attempt to address these real life problems, a segmented ceramic bearing system has been developed. This segmented bearing system provides ceramic surfaces for mechanical bearings that would apply loads over a greater bearing surface area, resulting in i reduced bearing stresses and, in turn, reduce creep, wear, and likelihood of fracture of the bearing surfaces.

The acetabular component is designed with several ceramic articular segments that are backed and held in a pre-determined pattern and configuration by either polyetheretherketone or polyethylene. Both of these materials, have a lower elastic modulus than the segmented ceramic material. In addition, the polymeric

material is reduced in height so that only the segmented ceramic material articulates with a ceramic femoral head.



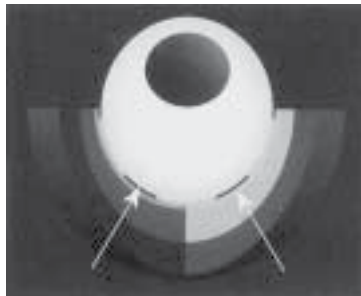
Intrinsic™ Segmented Ceramic Cup

Because of its resilience and lower elastic

modulus, the polymeric material flexes as loads are transmitted between bearing surfaces while the shape of the surfaces of the segments remain relatively unchanged. This freedom of movement of the segments, under an applied load, allows for greater contact area between bearing surfaces because the segments as a group are able to conform to the geometry of the opposing bearing surface. Thus, rather than having highly localized stress concentrations

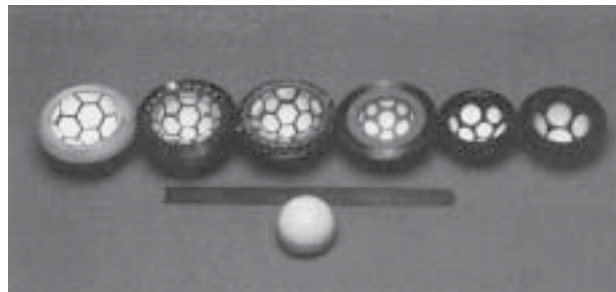
typically occurring in bearing systems, any applied load is shared by a number of segments which result in lower stress being applied to the bearing surfaces and each segment.

An additional feature of this design is the formation of channels generated by locating the polymeric material slightly below the surface of the ceramic segments for lubrication and for allowing debris that finds its way into the



Lubrication Channels

bearing to either pass between the segments or be trapped in the polymeric material.

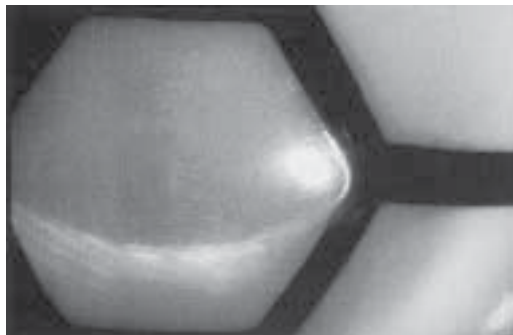


Segmented Evolution

This concept has evolved over the past five years from the ceramic in a hex shape imbedded in polysulfone to a current design that is circular imbedded in either polyetheretherketone or polyethylene."

TESTING

Post-fatigue testing (10 million cycles) has demonstrated no significant mechanical failures of the grout material (polysulfone) or of the ceramic bearing. SEM evaluations did demonstrate a small micro fracture within the grout and a polishing effect on the ceramic bearing surface.



Hex Design Pre-Test



Hex Design Post-Test



500X Pre-Test



500X Post-Test

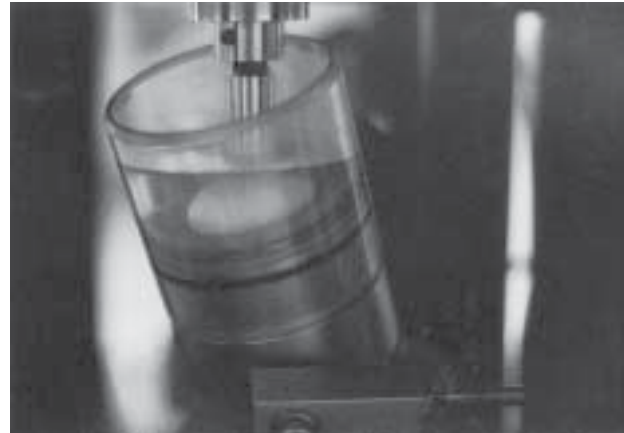
This test suggests that the bearing surface might benefit from pre-cycling to reduce initial ceramic debris.

Ongoing wear testing comparing different grout materials (peek and poly) on a P.M. state-of-the-art wear tester in conjunction with contact area and finite element analysis studies will help to determine the value of this design.

To date we are optimistically encouraged by the preliminary work concerning this unique approach. However, only additional solid basic science results can justify in-vivo clinical evaluation.



P.M. Wear Tester



Cup Being Tested

SUMMARY

Intrinsic™ Segmental Ceramic Bearing Surface

**Hemispherical Design
High Wear Resistance
Low Friction
High Compression Strength
Greater Bearing Surface Area
Self-Adjusting Design (Lower Surface Stress)
Lubrication Channels
Cost Effective**

Note: This device is not available for commercial use.

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Reprint request to:

T. McTighe, 8183 Stoneybrook Drive, Chagrin Falls, Ohio 44023

An Excerpt from:

10th Annual State-Of-The-Art In Total Joint Replacement

An International Symposium

November 21-24, 1993
Scottsdale, Arizona

A NEW APPROACH TO BEARING SURFACES FOR TOTAL HIP ARTHROPLASTY

By: Timothy McTighe, John W. Graham

Timothy McTighe, Exec. Dir., JISRF, Chagrin Falls, Ohio
John W. Graham, Cincinnati, Ohio

The most common cause of proximal femoral bone loss is due to osteolysis.¹ Although the specific cause of lysis is not known, it has been attributed to a variety of factors, including motion of the implant and foreign body reaction to particulate debris in particular to polymeric debris. It has been almost two decades since Willert first described the problem of polyethylene wear leading to periprosthetic inflammation, granuloma, bone resorption, and implant loosening.² Since then, many studies have documented the finding of particulate bone cement and polyethylene in periprosthetic tissues.^{3,4}

In normal wearing artificial joints, linear wear rates of 0.05 - 0.2 mm per year result in the generation of about 25 - 100 mm of polyethylene debris annually.^{5,6} On a basis of known dimensions of polyethylene particles found in tissues around hip prostheses, this equated to the annual production of tens to hundreds of billions of particles.

Variations of polyethylene wear rates probably relate to acetabular implant design⁷ femoral head size,⁸ femoral head material,⁹ and at least in part to the quality of the polyethylene used. Wide variations are known to exist between batches of polyethylene and between different polyethylene suppliers.

Based on favorable clinical trials in Europe during the past decade, improved ceramic on ceramic and metal on metal bearing combinations have been renewed as possible solutions to the problem of polyethylene wear. This paper will review a new concept of ceramic on ceramic articulation for use in total hip arthroplasty.

Ideally, the bearing surfaces for most sliding, rotating, or articulating bearing surfaces systems will be made from material having relatively high strength, high wear, and corrosion resistance, a high resistance to creep, and low frictional moments. However, in reality no one material presently exhibits all of these charac-

teristics. Therefore, with present bearing systems compromises are typically made between these various characteristics.

Ceramics have characteristics which are very desirable for use in sliding, rotating, and articulating bearing systems.^{10,11} In addition to high compressive strength, they exhibit high wear and corrosion resistance with relatively low frictional moments. However, use of such ceramic materials in bearing systems have been inhibited because such materials are susceptible to fracture due to their relatively low tensile and shear strengths. This weakness of ceramic materials is one reason why metal and/or polymeric materials have been used for many bearing surfaces. Compared to bearing ceramics, bearing metals and polymers typically have lower wear and corrosion resistance or resistance to creep and higher frictional moments.

In bearing systems where ceramics have been used, their low tensile and shear strengths often force the adoption of costly design compromises. Thus, one design compromise has been to make the entire bearing component rather than just a portion thereof out of solid ceramic, thereby increasing the amount of ceramic used and, therefore, effectively increasing the structural strength of the bearing surface.¹⁰ Such a solid ceramic bearing component can be larger and bulkier than its metal and/or polymeric counterpart.

Making an entire bearing component, like the acetabular cup, out of solid ceramic helps to compensate for the relatively poor tensile in shear strength typically found with ceramics. Also, because bearing ceramics are typically inflexible, additional manufacturing quality control of the geometry of both articular surfaces must be maintained in order to maximize the contact area between the two surfaces. If



fight control is not maintained, point contacts may develop between the bearing surfaces. As the contact area between two bearing surfaces decreases, the stress that is transmitted between the surfaces increases. This can result in greater wear and increased possibility of fracture of one or both surfaces.

In the past one solution with this problem has been to manufacture prosthesis with matching pairs of heads and cups. However, this solution is not only costly due to maintaining the quality levels required, but are additional inventory costs while making surgical intervention more difficult.

In an attempt to address these real life problems, segmented ceramic bearing system has been developed. This segmented bearing system provides ceramic surfaces for mechanical bearings that would apply loads over a greater bearing surface area, resulting in reduced bearing stresses and, in turn, reduce creep, wear, and likelihood of fracture of the bearing surfaces.

The acetabular component is designed with several ceramic articular segments that are backed and held in a pre-determined pattern and configuration by either Polyetheretherketone or Polyethylene. Both of these materials have a lower elastic modulus than the segmented ceramic material. In addition, the polymeric material is reduced in height so that only the segmented ceramic material articulates with a ceramic femoral head.

Because of its resilience and lower elastic modulus, the polymeric material flexes as loads are transmitted between bearing surfaces while the shape of the surfaces of the segments remain relatively unchanged. This freedom of movement of the segments, under an applied load, allows for greater contact area between bearing surfaces because the segments as a group are able to conform to the geometry of the opposing bearing surface. Thus, rather than having highly localized stress concentrations typically occurring in bearing systems any applied load is shared by a number of segments which result in lower stress being applied to the bearing surfaces and each segment.

An additional feature of this design is the formation of channels generated by locating the polymeric material slightly below the surface of the ceramic segments for lubrication and for allowing debris that finds its way into the bear-

ing to either pass between the segments or be trapped in the polymeric material.

This design allows for the segmented composite insert to be used with hemispherical design cemented or cementless acetabular components. This highly innovative design provides for an alternative bearing surface that is cost effective while it reduces or eliminates the generation of articulated polymeric or metallic debris which should have a tremendous positive effect on overall reduction of particulate debris resulting in increased longevity of our total hip reconstruction. A review of fatigue and wear data will be presented, however, to date no in vivo testing has been done and only long-term clinical data will prove the viability of this design approach.

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Harrington Arthritis Research Center
1800 East Van Buren Street, Phoenix, Arizona 85006

Update



N • E • W • S

April 1993

INTRODUCTION

by Timothy McTighe, Editor

This is the second edition of JISRF's Update News and we will highlight the recent Fifth Annual International Symposium on Custom Made Prostheses held in Windsor, England, October 1-3, 1992. Program Chairman was Professor Peter S. Walker from the Department of BioMechanical Engineering Institute of Orthopedics, Stanmore, England. The sponsoring body for this symposium is the International Society for the Study of Custom Made Prostheses.

This Society, (ISSCP) was created for formalizing the interaction of surgeons, design engineers, scientists, researchers, and manufacturers from around the world.

I have attended three (3) of the past five (5) symposia and have found this meeting to be highly informative with major emphasis on new developing technologies in imaging, fabrication, design shapes, radiographic analysis and robotics. Also how these technologies have become applicable to primary and revision arthroplasty of the hip, knee and other musculoskeletal deficiencies. This is an exciting new Society that has a bright future and is actively soliciting interested surgeons, engineers, manufacturers and researchers to apply for membership. You will find a membership form enclosed in this edition.

Also please note, next year's meeting is being held at Amelia Island, Florida, September 30 - October 2, 1993. Program Co-Chairmen are Louis P. Brady, M.D. of Orlando, Florida and Bernard N. Stulberg, M.D., Cleveland, Ohio. You will find a course registration enclosed for the Sixth Annual International Symposium on Custom Made Prostheses.

Our feature article is on HA-Coatings. As you are probably aware, this has been a hot topic for the past couple of years. Some surgeons and researchers have even gone as far as saying HA is the "white knight" for biological fixation. JISRF feels cautiously optimistic concerning

this material for use with cementless implants. We also feel HA should be looked upon as an enhancement to fixation. It is not intended to be the principal mode of stability, that role is reserved for the intrinsic design of the implant. HA will not solve the problems presented by a poorly designed implant.

Dr. John Kay, author of our feature article, is considered one of the leading researchers in this area. However, a balanced review of material is important and since Dr. Kay has a long term bias interest (President, Bio-Interfaces, Inc.), we have asked Dick Tarr, Vice President of R&D for DePuy, to critique our feature article.

Please note Dr. Kay will have an opportunity to respond to the critique in our next newsletter.

FEATURE ARTICLE

HA-COATINGS FOR NON- PRECISION IMPLANT PLACEMENTS

John F. Kay, Ph.D.

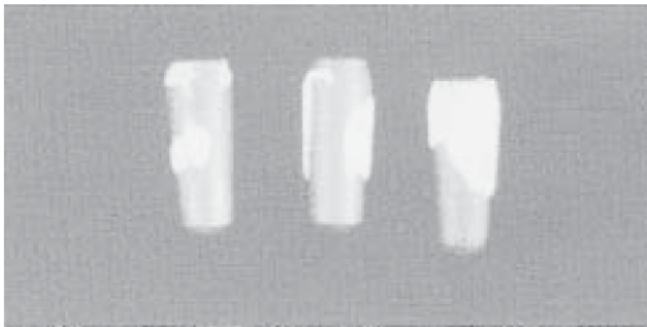
Bio-Interfaces, Inc., San Diego, California, U.S.A.

Introduction

Pre-clinical (in-vivo) efficacy studies show that high quality ceramic hydroxylapatite (HA) coating results in faster bony adaptation, and firmer implant-bone attachment. Properly placed in a precision fashion, dental and orthopaedic joint replacement devices coated with a high quality HA have demonstrated a clinically acceptable rate of short term success, when compared with other clinical treatment modalities. The coating of such implants with calcium phosphate materials such as hydroxylapatite can be seen as a "belt-and-suspenders" approach towards gaining an advantage of biological

fixation that can only be proven unequivocally through long-term clinical experience. Perhaps the most compelling usage of such calcium phosphate coatings today is for the placement of implants in non-precision sites where ideal bone contact and implant placement upon revision is not attained.

In oral implantology, placement of dental implants in fresh tooth extraction sites is difficult since a void of non-intimate bone contact is generally created in the superior aspect of the implanted ridge, while the apical portion of the implant may be firmly seated. Dental implants placed in the maxilla also suffer from a lack of total bone contact over the entire implant length and are generally perceived to be more difficult to place than implants in the maxilla, with historically lower percentages of overall implant success. Dental implants placed concurrently with bone grafting material, either autogenous or allografts, are also not in total direct contact with an appropriate bone receptor site and, therefore, represent a non-precision placement; the benefits of a bone conductive surface on an implant may be a benefit.



(Failed Dental Implant)

In orthopaedics, osteoporotic (type C bone) patients may not have total bony support for much of the proximal area of the implant as normally desired. Non-intimate bone contact may exist along much of the attachment area of a revision total joint component and sometimes the bone conditions available due to the localized bone pathology, compromises implant placement in primary cases. Certainly, implants placed concurrent with bone grafts, whether primary or revision in nature, represent a more challenging joint replacement procedure and again represent situations where the surface of the device designed for biological attachment or adaptation is not in direct contact with vital bleeding bone.

The in-vitro characterization of a calcium phosphate coating is very important but this characterization cannot stand alone as a predictor of in-vivo performance. In-vivo pre-clinical efficacy studies must be conducted. A high quality plasma sprayed HA-coating* was applied to smooth, grooved, and porous transcortical canine implants, smooth surface canine hip implants with a circular cross-section, and porous intermedullary implants; uncoated controls were used for all specimens. HA thickness for smooth and grooved implants were approximately 60 microns thick and 30 microns for porous implants. In all cases, the devices to be HA-coated

were undersized to account for the application of a coating, except for the porous materials where the HA-coating was thin enough and the reality of changing bead sizes to accommodate such a thin coating (approximately 30 microns) prohibited that dimensional normalization. The implants were placed using conventional and accepted techniques ensuring a snug interference-fit. Precision interference-fit placements were obtained for transcortical implants where the model allows for direct, accurate bicortical placement; usually, an interference-fit of 0.05mm is obtained.

In-vivo evaluations, using the canine transcortical model, demonstrate the following:

TABLE I-Bone Implant Attachment (MPa)

	3 WK	6 WK	12 WK	26 WK	52WK
HA/Ti	6.04 (3.00)	8.75 (1.99)	8.17 (1.09)	n/a	11.06 (2.22)
Grit Blast Ti	1.31 (0.70)	2.89 (1.16)	2.74 (0.145)	n/a	5.51 (1.65)
Grooved HA/Ti	9.37 (1.67)	11.80 (2.31)	13.61 (2.86)	18.09 (3.35)	19.10 (3.77)
	4WK	6WK	8WK	26WK	52WK
Porous CoCr	6.7 (2.17)	10.5 (2.68)	10.5 (2.26)	22.0 (3M)	18.71 (3.74)
HA/CoCr	10.1 (4.20)	12.8 (2.30)	12.8 (2.72)	27.1 (2.36)	21.21 (3.80)

Standard deviation in () under mean value,

In an intermedullary model employing interface gaps of up to 2mm tested at times up to one-year, this HA-coating provided the following enhancements in bone deposition and attachment strengths:

*the Bio-Interface [R] brand of HA-coating

TABLE 4 - Interface Shear Attachment Strength. MPa

Values shown are mean standard deviation in below

Implant	6mm	8mm	9mm	10mm
Diameter	(2mm gap)	(1mm gap)	(0.5mm gap)	(no gap)
4 WK				
HA	0.257 (0.411)	0.373 (0.112)	0.632 (0.556)	1.831 (0.981)
UNCOATED	0.095 (0.034)	0.112 (0.067)	0.187 (0.143)	0.460 (0.408)
8 WK				
HA	0.373 (0.309)	1.388 (0.822)	2.061 (1.199)	5.738 (1.532)
UNCOATED	0.112 (0.067)	0.339 (0.328)	0.816 (0.802)	2.759 (1.795)

12 WK				
HA	0.780 (0.811)	1.777 (1.557)	4.512 (6.635)	9.106 (5.432)
UNCOATED	0.248 (0.179)	0.748 (0.584)	1.226 (0.800)	3.701 (1.958)
24 WK				
HA	1.016 (1.682)	2.072 (1.520)	4.038 (2.950)	9.249 (5.350)
UNCOATED	0.378 (0.382)	1.543 (1.420)	2.296 (2.406)	5.896 (3.377)
52 WK				
HA	0.687 (0.517)	2.567 (2.529)	4.225 (1.776)	11.442 (5.819)
UNCOATED	0.355 (0.253)	0.667 (0.533)	1.926 (2.013)	4.706 (2.677)

The results indicate that HA-coatings were effective in providing enhanced bone apposition and attachment strength for gaps of 1mm and less, providing the implants were initially stable. Positive attachment effects observed for HA were seen but delayed because of the gap indicating that the presence of any space, or nonprecision placement, will require additional time to resolve the intermediate defect before bony fixation can be obtained. The presence of HA, however, minimizes or eliminates the presence of any fibrous tissue seam associated with either the material placed or the presence of a gap that retards the direct adaptation of bone, to a limitation of less than 1 mm. This data has been presented in *Seminars in Arthroplasty* Vol; 268-279, 1991.

Clinical Applications

In fresh tooth extraction sites, bone has been observed to adapt to the HA-coated implant surface and is not as compromised by downgrowth of epithelial tissue. Implants must be initially stable, however, and with sufficient proportion of the apical implant body length secured in a precision-drilled site. Clinical results show that bone then will cover the implant surface, resolve the superior defect and provide biointegration of the dental implant.

For revision total joint arthroplasty, HA-coated experience with custom-coated implants generated by CAD/CAM programming-model generation have been designed with a grooved macrotextured surface, consistent with data obtained in animal pushout experiments presented by David Stulberg, M.D. at the 1991 ISSCP meeting in San Francisco. The preliminary clinical results over two years show higher hip scores and a decreased tendency for radiolucencies at the two-year time period. HA-coated macrotextured grooves and porous ingrowth devices provide for bone adaptation by mechanical and chemical means.

Conclusions

Based on in-vivo data from pre-clinical efficacy studies and limited, primarily anecdotal clinical experience, the presence of an HA-coating on metallic implant devices provides an enhancement of bony response over uncoated metallic components. A limited amount of controlled clinical data exists and a prospectively defined randomized clinical evaluation would be very difficult for indications involving non-precision sites. As of this writing, however, this characteristic of providing a mechanism to overcome non-precision placement is a viable approach for HA-coated metal implants. If used for such nonprecision placement, the stability of the coating must be demonstrated, as its early loss would preclude the desired bone adaptation.

Only long term clinical data will show whether the positive characteristics demonstrated in animal studies will be eventually manifested in the human clinical setting.

FEATURE ARTICLE CRITIQUE

by Dick Tarr, V.P. DePuy

Osteoconductive bioceramic materials such as hydroxyapatite and tricalcium phosphate have been investigated for over two decades as potential treatment enhancements in both dentistry and orthopaedics. It was hoped that these bioceramics would become an attractive adjunct to deal with bony loss or to improve implant fixation. However, most studies have identified device design and geometry (when these materials are coupled with implants) as a key factor in the success of this adjunctive therapy. In my opinion, I remain cautiously optimistic about the use of these bioceramic compounds as improvements to implant fixation issues. Implant design is still the most important criteria for success.

In the feature article entitled, "HA-Coatings for Nonprecision Implant Placements" by John F. Kay, Ph.D., the author summarizes work he and his co-workers have performed and published in the following articles: S.D. Cook, et. al., "Enhanced Bone Ingrowth and Fixations Strength with Hydroxyapatite-Coated Porous Implants," *Seminars in Arthroplasty* 2(4): 268-279, 1991; and S.D. Cook, et. al., "Hydroxyapatite Coating of Porous Implants Improves Bone Ingrowth and Interface Attachment Strength," *Journal of Biomedical Materials Research*, 26:989-1001, 1992. Through the experimental models presented in this feature article, Dr. Kay attempts to present evidence that HA coating on implants was effective in providing enhanced bone apposition and increased attachment strengths for gaps between the bone implant interface of 1 mm or less. He also points out that the implants must remain stable for this fixation to occur. In general, I would agree that these osteoconductive material coatings have been shown to bond directly to bone if the implants remain stable.

However, data presented in this paper are not conclusive and only indicate a potential trend for short-term fixation enhancements with HA coated implants. Issues of the integrity of the HA substrate (implant) bond strength and relatively slow resorption rates of HA are also concerns in long-term orthopaedic applications.

In the femoral transcortical implant model, it appears only one dog was evaluated per time point. This is a major weakness of this study. Each dog had five transcortical implants spaced approximately 1.5cm apart in the mid-diaphyseal region of both femora. The text describes the precision with which implants were coated and the tight interference fit achieved in the drill holes. I would question the ability to maintain a tolerance of .002" - .003" on coating dimensions over a porous surface during manufacture of these components. Most orthopaedic manufacturers find it difficult using computer-aided, numerical-controlled turning and milling centers to achieve consistent and reproducible quality to these standards on metallic devices. I also find it hard to imagine that a hand-drilled hole can be reproducibly held to a tolerance of .002".

I would agree; however, that even with only one dog utilized per time point, the data are consistent with previous studies indicating that HA coatings of smooth devices in a non-loaded "relatively" tight, stable implant model will yield improvements in bone attachment and fixation strengths over smooth devices devoid of HA. However, the data also suggest the possibility that in the long-term, the bond strength achieved between the implant and the coating may be deteriorating. There appears to be a trend in the data suggesting that between week 26 and week 52, the push-out strengths are beginning to decrease. It should also be noted that previous studies have not shown a difference in the mechanical stability of either textured or porous surfaces whether they were HA coated or uncoated. The data presented in Table 1 suggest a similar finding with the only true differences noted in the uncoated smooth, grit-blasted titanium surface versus all other component surface designs.

In the second model presented, namely that of an intramedullary rod placed bilaterally in the femora of five animals per time point, the interfacial shear strength was measured for HA coated versus uncoated rods for gaps of 2mm, 1 mm, 1/2mm. and no gap. It should first be noted that the data presented in Table 4 in parentheses should indicate standard errors and not standard deviations (standard error equals standard deviation divided by the square root of the sample size). Also of note are the large standard error variations for all measurement results compared to the average values.

Previous work has shown that bone will grow across and onto an HA coated rod in the presence of a gap. However, the attachment sites are far from completely gap filling. In these studies, bone bridged the gap with a spot attachment and then grew up along the HA coating forming a "neo-cortex." This may explain the trend in the

data for the non-loaded intramedullary rods in which the shear strength increases for decreasing gap dimensions. Whether these data support the conclusion that gaps of 1mm or less show sufficient interfacial shear strength is a matter of opinion.

The most substantial finding from this research indicates material coating should not be a substitute for 1) appropriate pre-operative planning; 2) proper implant design; and 3) precise surgical technique. Recent clinical results presented at major orthopaedic meetings indicate the variability of resorption rates with HA coated devices, and potential beneficial effects of these bioceramic coatings in the orthopaedic arena. Appropriate selection and use of hydroxyapatite coating, which resorbs slowly, should be reserved for those applications in which the geometry of the implant would remain stable regardless of the coating technology. For porous coated products, a more rapidly resorbing, osteoconductive material such as tricalcium phosphate may be superior to HA. With tricalcium phosphate, bone would be conducted into the pores or irregular features of the implant design, and with living bone quickly replacing the tricalcium phosphate, ensure long-term stability. Many of the clinical studies under current IDE investigation will elucidate these potential beneficial effects. Until these results are in, we should carefully examine the applications and early clinical results for these osteoconductive compounds.

THE EFFECT OF FEMORAL STEM LENGTH, SHAPE AND MATERIAL PROPERTIES IN MINIMIZING PROXIMAL FEMORAL STRESS-SHIELDING

by JH FU

Stress-shielding in the proximal femur arises because the rigidity of the total hip femoral prosthesis is markedly greater than that of the cortical bone. Therefore, the possibility arises that by reducing the stem rigidity in relationship to the surrounding cortical bone, the effects of stress-shielding can be minimized.

The analysis showed that reducing the length of the femoral stem reduces the stress concentration in the femur at the stem tip, but does not alter the proximal femoral stress distribution. Unfortunately, as the femoral stem is shortened, the axial and rotational stability of the prosthesis is decreased limiting the usefulness of this design modification.

THE EFFECT OF STEM LENGTH ON TORSIONAL STABILITY OF CUSTOM PROXIMAL FEMORAL COMPONENTS

By DD Robertson, B Chan, Jr Essinger, MJ Curtis, RH Jinnah, AJ Zarnowski

Introduction

A major concern in replacement arthroplasty is the initial fixation of the implant to the bone. Motion at the implant at the interface can decrease or impede bone ingrowth, produce resorption, lead to subsidence or tilt, cause pain, and ultimately lead to revision. Recent work by Hayes et al (ISSCP '90) has shown increased fit and fill in the proximal femur to be correlated with decreased micromotion. We examined short and standard length symbios custom hip stems to see if there was a difference in the proximal fit and fill and in proximal torsional stability.

Results

There was no statistical difference between the proximal fit and fill of the short and standard length custom stems (paired t-test). Torsional micromotion was less than 60 microns (< 30 microns for many of the bones) during the applied torques from 3-18 N-m. Micromotion increased as the applied torques increased. There was no statistical difference in the micromotion between the short or standard length custom stems (paired t-test).



DESIGN RATIONALE FOR THE STABILITY™ CEMENTLESS TOTAL HIP SYSTEM

By T McTighe, GT Vise, S Murphy, BK Vaughn, B Shephard

Optimization of fit and fill has taken several approaches: off the shelf one piece; off the shelf modular pieces; preoperative customs, intra-op customs. The growing concern of osteolysis has led to the development of the Stability™ hip system. This system offers the versatility of modular components, however, it reduces the potential sites that can generate particulate debris.

The short term clinical results of the intra-operative custom technique of Identifit™ has had mixed results in the United States. However, the learning experience has demonstrated a number of factors. Initial focus was on fit and fill. Then the importance of shape was introduced, and recently the advent of macrotexturing and flutes.

Fit and fill, shape, and surface geometry are all important ingredients to achieve axial and torsional stability. However, fit and fill is difficult to achieve due to the varying geometry of the proximal femur. The question is: How can we improve our ability to fit and fill varying geometries? One answer is to have a large quantity of sizes, the second is customs, and the third is modular designs. All three of these answers must address the geometry considerations of proximal size and shape, distal size and shape, and stem length.

Although the cost of customs has been coming down, it still is not equivalent to standard cementless, off the shelf devices. In addition, pre-operative customs limit the intra-operative options that one is faced with and requires considerable pre-operative, precision in working with the device manufacturer.

On the other hand, in the past, a large quantity of sizes has been prohibitive because of cost involvement in standard manufacturing procedures. However, Orthogenesis technology of surface milling now makes this option cost effective. A large quantity of sizes offers many intra-operative options and reduces pre-operative precision planning. However, it still requires understanding all options (sizes) and requirements for surgical technique.

Modularity has been cost effective, offers many intra-operative options, generally has high demanding surgical technique, a high learning curve in understanding of intra-operative options and has been shown to be a site for generation of particulate debris, which can lead to osteolysis.

1. Overview - Stability™ Components

- Initial sizes 4 diameters straight stems (12, 14, 16, 18mm)
- Standard Stem Length (150, 155, 160, 165mm)
- The tapered neck permits the use of a variety of head diameters and neck length in either the c.c. or ceramic.
- Graduated Proximal Design
There are two cone bodies for each dia. stem. Also two triangle sizes for each cone size. A total of four different proximal sizes are available for each stem dia. A third proximal triangle is being added to the large cone by mid 1993.

II. Design Features Stem

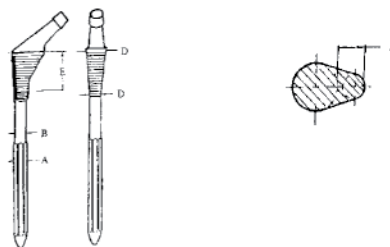
Material: Titanium Alloy

1. Taper Neck - allows for modular heads.
2. Conical Proximal body with Medial Triangle - allows for better fit and fill.
3. A Circular Distal Dia. Stem - allows for easy, precise preparation by reaming.
4. Longitudinal Flutes on Distal Stem - increases torsional resistance.
5. Non-Bead Blasting Surface - reduces surface particulate debris.
6. Forged Titanium Alloy - excellent fatigue strength, low bending modulus.
7. HA Coated - or Porous coating available.
8. Proximal Body - approximates the shape of the prepared endosteal cortex.
9. Proximal Body - 5' taper prox. to distal.
10. Proximal Steps - transfers hoop tension into compression. Helps reduce subsidence.
11. Two Triangle Sizes Per Cone - allows for better fit and fill.
12. Distal conical slot reduces distal bending modulus and reduces distal hoop stresses resulting in a more even stress transfer while facilitating ease of insertion.
13. Offers versatility of modular design for routine primary indications while reducing the need for modular sites that are known to produce particulate debris.

Summary

The fabrication process of surface milling now allows for increasing off the shelf size offerings reducing the need for modularity and customization; and, more importantly, lends itself to design evolution in a cost effective manner.

	Distal Maj. Dia.	Stem Size Prox. Dia.	Triangle	Stem Dia. mm (Minor)	Distal Reamer Dia. mm	Proximal Reamer	Proximal Triangle
1	12	20	Sm	11	11.5	20	Sm (12)
2	12	20	Med	11	11.5	20	Med (16)
3	12	22	Sm	11	11.5	22	Sm (12)
4	12	22	Med	11	11.5	22	Med (16)
5	12	22	Lg	11	11.5	22	Lg (20)
6	14	22	Sm	13	13.5	22	Sm (12)
7	14	22	Med	13	13.5	22	Med (16)
8	14	24	Sm	13	13.5	24	Sm (12)
9	14	24	Med	13	13.5	24	Med (16)
10	14	24	Lg	13	13.5	24	Lg (20)
11	16	24	Sm	15	15.5	24	Sm (12)
12	16	24	Med	15	15.5	24	Med (16)
13	16	26	Sm	15	15.5	26	Sm (12)
14	16	26	Med	15	15.5	26	Med (16)
15	16	26	Lg	15	15.5	26	Lg (20)
16	18	26	Med	17	17.5	26	Sm (12)
17	18	26	Med	17	17.5	26	Med (16)
18	18	28	Sm	17	17.5	28	Sm (12)
19	18	28	Med	17	17.5	28	Med (16)
20	18	28	Lg	17	17.5	28	Lg (20)



Material: Ti-6Al-4V
Taper: Articul-eze
Head Diameter Available: 26, 28 & 32
Anteverson: no

Neck Shaft Angle: 130 degrees

Base Offset: 37.20 mm

Broach match: Broach diameter is the same as the minor diameter of the stem

Neck Lengths:

26 mm:	Metal	+4,+7,+10
	Ceramic	none
28 mm:	Metal	+1.5,+5,+8.5,+12
	Ceramic	+1.5,+5
32 mm:	Metal	+1,+5,+9,+13,+17
	Ceramic	+1,+5,+9

THE FIT AND FILL OF A PROSTHESIS CUSTOMIZED VIA INTRA-OPERATIVE MOULDING - A CT AND BONE SECTION ANALYSIS

By R Grelsamer, R Iorio, J Collier, N Haramati, O Nercessian, N Eftekhari

Significance

The ability to evaluate the fit and fill of cementless prostheses is critical: Implants featuring different designs can be objectively compared, and clinical correlation may eventually provide us with thresholds of acceptable fit and fill.

Purpose

To demonstrate that CT scan technology can be modified to evaluate the fit and fill of the femoral canal by a metallic prosthesis.

Methods

Matched pairs of cadaver femora were analyzed both with CT scans and sectioning methods after implantation of a prosthesis. The images of 10 cross sections of

the femur and the corresponding CT cuts were analyzed through an image program and compared for accuracy. The matched pairs were controlled for surgeon, technique, and type of prosthesis. Four different surgeons participated in canal preparation and prosthesis insertion. The fit and fill of the Identifit™ prosthesis was then compared with other off-the-shelf, uncemented prostheses for fit and fill. Specifically, the Identifit™ was compared with anatomic and straight stem models. Cobalt chromium prostheses were compared with the titanium Identifit™ to validate the CT scan technique with other metals.

Results

CT scanning of the femur accurately describes the fit of an uncemented femoral prosthesis with an accuracy of 97.2% when compared with cadaveric cross sections.

Conclusion

CT scan technology can be modified to evaluate 'fit and fill' with a high degree of accuracy.

SHAPE OPTIMIZATION OF INTRA-OPERATIVELY MANUFACTURED CUSTOM PROSTHESES

By V Salvi

The aim of the majority of cementless prostheses is to optimize fit and fill against good quality bone with the femoral canal.

That this aim is problematical for a range of off-the-shelf prostheses may be demonstrated by the existence of 47 recognized morphotypes.

Using custom prostheses, good cortical contact can usually be obtained along the full length of a prosthesis medially; however, laterally this may only be achieved in the distal half of the stem. Anatomical considerations mean that the proximo-lateral portion of the stem can only contact with cancellous bone. There is, however, the possibility of good cortical contact in the mid-lateral portion of the stem and also useful contact with good quality cancellous bone proximo-laterally. The risk the designer must take in optimizing this lateral support is in impinging on the greater trochanter at insertion.

When the prosthesis is manufactured intraoperatively using the Identifit™ system, the surgeon becomes the designer, and can work to optimize the cavity. The Identifit™ software can complement the work of the surgeon by designing a prosthesis for the cavity which can still be inserted.

The prostheses manufactured in Torino using the Identifit™ System have passed through three distinct design phases resulting in three different proximal

shapes, each trying to enhance the level of lateral support.

The final design phase has placed a greater emphasis on lateral geometry which, from a biomechanical point of view, gives the stem an improved resistance to the torsional and vertical components of the joint reaction force.

Moreover, this appears to give improved clinical results together with a very satisfactory radiological appearance.

A PROSPECTIVE COMPARISON OF TITANIUM VS CHROME COBALT FEMORAL HEADS IN CEMENTLESS TOTAL HIP ARTHROPLASTY

By TP Gross, WJ Murzic, JK Taylor, WL Baryar

This is the first clinical series comparing chrome cobalt to titanium bearing surfaces using the same femoral component design. Titanium and its alloys have been implicated in several reports on metallic-wear debris. Polymethylmethacrylate (PMMA) cement, ultra high molecular weight polyethylene (UHMWPE), and metal debris have been shown to be associated with osteolytic lesions and inflammatory membranes around both stable and loose prostheses. The in vitro wear characteristics of titanium alloy against UHMWPE are inferior to cobalt-chrome or ceramic combinations against UHMWPE.

Forty-two patients had 51 primary uncemented total hip arthroplasties. One was lost to follow-up. All patients had a titanium alloy custom stem (Techmedica) and a Harris-Galante (Zimmer) acetabular component. The first 25 patients had a femoral head made of titanium alloy (Ti-6Al-4V), the next 25 had chrome-cobalt femoral heads. The titanium head group had an average age of 43 and weight of 150, while the chrome-cobalt head group had an average age of 50 and weight of 174.

At 4 year follow-up there were 4 cases with femoral osteolysis in the titanium head group (16%) and none in the chrome-cobalt head group. The follow-up in the titanium head group is approximately 1 year longer than in the cobalt-chrome head group. There have been 3 additional cases of osteolysis in the titanium head group at 5 years of follow-up for a total incidence of 28%. There were 4 loose prostheses in the titanium head-group, 2 were due to pad separation from the stem. In the cobalt chrome head group there was 1 loose prosthesis due to pad separation.

There were a total of 10 re-operations, 5 head and liner exchanges for osteolysis with well fixed components, and 5 femoral revisions for loosening (3 with pad separation and 2 for failure of ingrowth). In all re-operated cases where titanium heads were present (9 cases), the

prosthetic head appeared burnished; in all but one the articular pseudocapsule was stained gray to black. In the one case where a cobalt chrome head was encountered, these findings were absent. The femoral membranes of those cases where the stem was revised (5 cases), also were stained darkly. In every re-operation, the acetabular component was found to be well-fixed. There was no evidence of wear of any of the acetabular liners.

The joint capsule was examined using H&E stains to look for metallic particles, and polarized light microscopy to look for polyethylene. In the cases with titanium heads (9 cases) metallic intracellular articular debris, but no polyethylene debris was found.

A CLINICAL AND RADIOGRAPHIC EVALUATION OF 337 CUSTOM MADE PROSTHESES: A ONE TO SIX YEAR FOLLOW-UP STUDY

by JJ Bougault, JN Argenson, M Pizzetta, JM Aubaniac

We evaluated by clinical and radiographic assessment a group of 337 consecutive custom made total hip arthroplasties performed in our orthopaedic department.

Material and Method

On a total of 468 cases of custom replacement we selected 337 cases, excluding the patients who lacked one year follow-up. This study evaluated three designs; Egoform, Medinov and Symbios. Egoform I is designed with morphological data provided by two radiographs, 126 cases have been realized. Medinov used CT-Scan views to draw the prostheses, and 6 cases were performed. Since 1990 we are using the Symbios procedure whose design is based on the numerical CT-Scan data, 205 prostheses have been implanted.

Results

The mean follow-up is 30 months with a minimum of 1 year and maximum of 6 years. The clinical evaluation is realized according to the Harris hip score, adding the assessment of thigh pain.

The radiographic analysis studies prosthesis stability by: stem positioning and migration. The bone-prosthesis fixation is evaluated by dividing the femur in 16 areas, for each area is recorded: endosteal new bone, lucencies, cortical hypertrophy, osteolysis. The total amount of stress shielding is evaluated according to the C. Engh classification. Ectopic ossification is also recorded with Brooker criteria.

Eleven complications requiring revision occurred: two for trochanter non union, two for loosening, five dislocations, and two infections.

Discussion

The proximal fill provided by custom implants may increase the recovering of the function.

PROBLEMS AND CONSEQUENCES FOLLOWING PELVIC TUMOR PROSTHESES

by R Gradinger, H Rechl, R Ascherl, A Kolling

Introduction

Anatomical reconstruction following pelvic tumor resections, especially of the IIa and IIc type, is a surgically high demanding procedure. CAD/CAM techniques, allowing 3-D-Imaging of anatomical structures based on CT scans has been used through the last couple of years to improve planning and reconstruction, as well as the prosthetic design.

Material and Method

From 1977-1992 24 tumor prostheses have been implanted for primary and secondary malignant tumors of the pelvis, mostly following type IIc resections. Diagnoses was Chondrosarcoma in 6, Ewingsarcoma in 4, Osteosarcoma in 4, Reticulumcellsarcoma in 1, malignant fibrous Histiocytoma in 1, metastasizing hypernephroma in 3, -thyroid-ca in 3, and, -breast-ca in 2 patients. In 19 of those 24 patients we used an intraoperative adaptable implant system which was described by us in 1986. In 12 of those 19 patients our 3 dimensional planning strategy has been applied using a original sized model of the patient's pelvis.

Results

It is well documented, that internal hemipelvectomy, especially if reconstructed with pelvic mega prostheses, has a high complication rate. In our experience there were problems with postop dislocations, disconnection of the conus between fixation device and acetabulum, one prosthesis fracture following trauma and skin perforation due to prominent fixation screws and the prosthesis. There were also problems with external rotation contractures, due to extensive muscle resections and hence alteration of the muscle balance at the hip joint.

Discussion and Conclusion

The postop joint stability was improved by the 3-1) planning procedure and the use of overlapping PE-Kuroki-Inlays and anti-dislocation sockets. The conus can be secured with a splint and a roughened surface, and a fixation device has been changed to a stronger design with fixation screws in the direction of the biomechanical stress lines. We avoid designs with prominent edges, and use tissue transfer if the soft tissue coverage is insufficient. In 2 patients with external rotation contractures and subluxation of the hip a secondary partial release of scar and muscle tissue at

the greater trochanter and the pseudocapsule improved malposition of the extremity function.

Just recently, as a result of our experience with pelvic endoprosthetic reconstructions, we have been able to replace a hemipelvis in combination with a total femur in a patient with metastasizing breast cancer.

COMMENTARY

By Earnest A. Eggars, M.D.

Future of Custom Hip Prosthetics

For over a decade there has been a shift from conventional cemented systems to alternatives without cement. Although experience with methylmethacrylate was excellent, progression of time brought an increased incidence of aseptic loosening and varying degrees of bone destruction.

Orthopaedists responded with improved cement technique and conventional cementless prosthetics. The plethora of systems have developed with different shape, length, modulus, and surface treatment. Certainly clinical and laboratory studies have shown that the quality of initial fixation is closely associated with accuracy of fit and patient performance. Questions remain about the relationship between bone prosthetic fit and asymptomatic. We have established that there must be some degree of contact between stem and endosteal surface, along with maximum proximal and distal fit, and rotational stability.

Complications of aseptic loosening, stress shielding, and thigh pain are well documented. Biologic ingrowth fixation has not become a "given", and continued pain from any of the foregoing complications does result in revision surgery.

Custom prosthetics have been in the surgical arena for over a decade. Early use may have centered around treatment of tumor and serious bone loss. Since the mid-80s various primary and revision custom implants have developed as a result of radiographic measurement, CAT-SCANS, and inter-operative mold (Prof. Mulier). Thusly, the role in requirements of custom prosthetics is changing, and the production of quality in a shorter time has pushed technology to new limits. A closer relationship between the physician and the engineer has developed and consistency of excellent results beyond the early "learning curves" have become a reality.

Studies reported at the International Symposium of Custom Made Prostheses have suggested that more secure initial fixation and proximal fit do tend to improve proximal load transfer. The Identifit™, or molded hip, has been shown to have rotational stability equal to that of cemented prostheses. The proximal geometry of the femoral prosthesis and a stable distal fit appear to be key

elements to clinical success. Further studies with variations in surface geometry are under way, including transverse ridges, step-off, and porous coatings. Distal stem treatment with fluting may also add to proximal stability.

While custom implants have better overall fit characteristics compared to off the shelf prostheses, there still remains the proof over time of clinical superiority. The incidence of proximal atrophy, subsidence, loosening, and transmission of particulate debris into the isthmus will be watched closely.

Customization in hip surgery is rapidly gaining momentum both in the U.S. and Europe. Engineering interest and input has been remarkable. As series of cases increase, costs are dramatically falling. The introduction of technology, engineering principles, and many pioneering surgeons will change the geometry, the preferential fit, and even the surface treatment of femoral implants in the future.

I am currently doing all my primary cementless hips using the custom XPress™ services from DePuy. My early clinical impressions are very good as compared to my previous cementless experience and are in the process of being worked up for publication.



(Ex-Press™ Stem)



Joint Implant Surgery and Research Foundation

17321 Buckthorne Drive
Chagrin Falls, OH 44023
Phone: 440-543-0347
FAX: 440-543-5325
www.jisrf.org



PARTICULATE DEBRIS IN TOTAL HIP ARTHROPLASTY: PROBLEMS AND SOLUTIONS



J.D. Bobyn, Ph.D., Montreal General Hospital, Quebec
J.P. Collier, D.E., Hanover, New Hampshire
M.B. Mayor, M.D., Hanover, New Hampshire
T. McTighe, Chagrin Falls, Ohio
M. Tanzer, M.D., Montreal, Quebec
BK Vaughn, M.D., Raleigh, North Carolina

**A SCIENTIFIC EXHIBIT AT THE 1993 AAOS MEETING
SAN FRANCISCO, CALIFORNIA**

INTRODUCTION

There is acute concern, particularly with noncemented implants, about polymeric and metallic debris generation and accumulation in total hip arthroplasty and its association with osteolysis and implant loosening. The purpose of this paper is to describe the problems associated with particulate debris, the sources of particulate debris in THA, and potential solutions or approaches to minimize particle formation.

BASIC PROBLEMS

Polymeric Debris

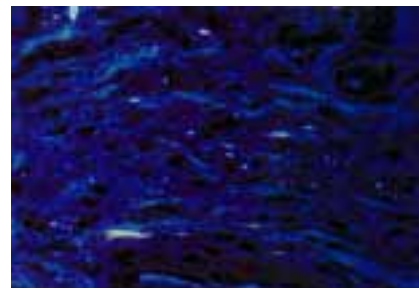
It has been almost two decades since Willert first described the problem of polyethylene wear leading to peri-prosthetic inflammation, granuloma, bone resorption, and implant loosening.¹ Since then, many studies have documented the finding of particulate bone cement and polyethylene in peri-prosthetic tissues.²⁻⁴ The underlying biologic mechanism is thought to be mediated by the activity of macrophages which, upon ingestion of foreign material, release a number of factors (prostaglandins, interleukins) that stimulate osteoclastic activity.⁵⁻⁷ Particles less than about 10 microns are more important in this mechanism because they are most easily phagocytosed by macrophages.^{8,9} Histologic study of synovium and granuloma biopsies from THA has shown intracellular polyethylene particles in the sub-micron size range.¹⁰⁻¹²



Eccentric cup wear with acetabular and proximal femoral osteolysis 8 yrs; postop



Proximal femoral cavity from polyethylene granuloma 4 yrs postop



Polarized light micrograph showing intracellular and extracellular PE debris

Metallic Debris

Metallic particles in sufficient quantities could potentially activate macrophage-mediated osteolysis. Metal debris could also migrate into the articulation, scratch the femoral head, and cause increased third-body wear of polyethylene.



Intracellular and extracellular metal debris in capsule 6 yrs postop



Scratches in polyethylene liner from abrasive third-body wear

PROBLEM: Wear Related to Polyethylene Quality

In normally wearing artificial joints, linear wear rates of 0.05 to 0.2 mm per year result in the generation of about 25 to 100 mm³ (25 to 100 mg) of polyethylene debris annually.¹³⁻¹⁵ On the basis of known dimensions of polyethylene particles found in tissues around hip prostheses, this equates to the annual production of tens to hundreds of billions of particles.

Variations in polyethylene wear rates probably relate, at least in part, to the quality of the polyethylene used.¹⁵ Wide variations are known to exist between batches of polyethylene and between different polyethylene suppliers.

SOLUTION:

Use ultra high molecular weight polyethylene (UHMWPE) with high ratings in key mechanical and physical properties (Table 1). Use UHMWPE with a consistently high level of quality control over parameters such as starting powder composition, extrusion processing (extruded rod generally results in better consolidation and improved properties compared with compression molded UHMWPE sheets), post-extrusion annealing (to increase crystallinity and dimensional stability), ultrasound inspection for voids and inclusions, oxidation, and mechanical properties. In general, polyethylene that exceeds minimum ASTM standards is available from several implant manufacturers (Table 1).

Table 1. Properties of UHMWPE

	ASTM Standard	Commercially Available PE ¹⁶	Commercially Available PE ¹⁷
Molecular Weight	3 x 10 ⁶	5 x 10 ⁶	—
Ultimate Tensile Strength	4000 PSI	6700 PSI	6000 PSI
Tensile Yield	2800 PSI	3300 PSI	4100 PSI
Izod Impact	20 FT-LB	No Break	No Break
Hardness	60 Shore D	69 Shore D	65 Shore D
Elongation to Failure	200%	350%	330%

PROBLEM: Polyethylene Wear Related to Modular Acetabular Implants

Additional sources of polyethylene wear can result from the use of modular (2-piece) acetabular implants.”-” These include:

Polyethylene liner/metal back motion - related to mechanical integrity of the locking mechanism



Incomplete conformity of liner with metal back can result in cold flow, plastic deformation, increased stress, increased wear



Thin polyethylene resulting from modular design can cause higher stress, increased wear, liner fracture



Liner fracture 4 yrs postop, head wear of cup metal backing, tissue metallosis

Abrasion of screw heads against the convex polyethylene surface



SOLUTIONS:

- Use non-modular acetabular components
- Use modular acetabular components with:
 - high degree of liner/metal back conformity and support (with smooth concave metal surface to minimize abrasive wear)
 - highly secure liner/metal back locking mechanism
 - minimum polyethylene thickness of 6 to 8 MM^{22,23}



PROBLEM: Polyethylene Wear Related to Femoral Head Size

Clinical evidence indicates that the use of 32 mm heads in THA increases the volumetric wear. This problem is accentuated with cups possessing relatively thin polyethylene, as occurs with smaller size modular prostheses.

SOLUTION:

A recent clinical study by Livermore et al indicated that a 28 mm head size was preferred for optimization of both linear and volumetric wear.²⁴ Choosing head size to maximize polyethylene thickness is a priority. The recommendation is to use 26 mm or 28 mm heads more often, although 32 mm heads are still appropriate with larger cups having thick polyethylene.



PROBLEM: Polyethylene Wear Related To Femoral Head Material

Polyethylene wear is generally increased with the use of femoral heads made of titanium alloy because of its lower hardness and abrasion resistance. Problems with osteolysis due to excessive head and cup wear have been reported with titanium bearing surfaces.²⁵⁻²⁷

SOLUTIONS:

- Do not use titanium alloy femoral heads
- Use titanium alloy femoral heads with improved wear characteristics. This can be accomplished by shallow implantation of nitrogen or oxygen into the surface or chemical deposition of a harder bearing surface such as titanium nitride.
- A preferred option is to use femoral heads made of cobalt-chrome because of its superior wear characteristics.
- Laboratory evidence supports the use of femoral heads made from ceramic materials, alumina or zirconia oxide, for reduced polyethylene wear. Preliminary clinical evidence from Europe and Japan suggests a reduced wear rate in patients but the data are not yet definitive.³⁰⁻³³ At the very least, ceramic bearing materials are more resistant to scratching from third bodies such as PMMA or metallic debris from fretting, corrosion, or loosened fragments of porous coating.
- Based on favorable clinical trials in Europe during the past decade, improved ceramic-on-ceramic and metal-on-metal bearing combinations have been renewed as possible solutions to the problem of polyethylene wear.³⁴ Further research and development in this area will be required to establish reliability and efficacy.

SOURCES OF METALLIC DEBRIS

PROBLEM: Fretting Wear of Metallic Implant Components

Fretting wear of mechanically joined metallic implant components is inevitable given sufficient load and number of load cycles.³⁵⁻³⁸ Thus, all modular implant junctions are prone to fretting and the generation of metallic debris. This includes:

- Junctions between screws and metal backing of modular cups
- Head/neck taper junctions
- Other stem modular junctions utilizing locking mechanisms such as tapers or dovetails to connect sleeves, pads, or stem segments.

SOLUTIONS

- Minimize the number of modular junctions (e.g., use cups without screw holes or reduce use of screws for acetabular cup fixation)
- Use modular junctions with secure locking mechanisms, high quality fabrication tolerances, surface finishes that reduce debris generation, and proven mechanical safety in laboratory testing.



Fretting marks on Ti-6Al-4V taper 4 yrs postop



Scanning electron micrograph of fretting marks on Ti-6Al-4V taper



Small areas of fretting on modular stem taper 6 yrs postop



Scanning electron micrograph of fretting scars on modular stem taper

PROBLEM: Corrosion at Head/Neck Taper Junctions

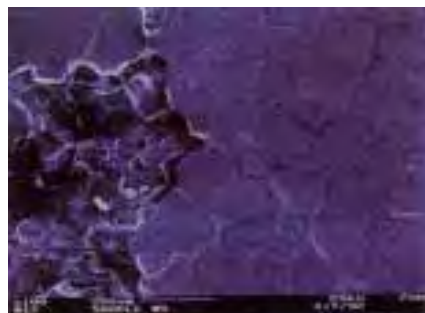
Recent analysis of retrieved femoral implants used in THA has revealed that corrosion sometimes occurs at the modular head/neck junction.³⁹⁻⁴¹ Corrosion in varying degrees has been reported both with dissimilar (Co-Cr head/Ti alloy neck) and similar (Co-Cr head/Co-Cr neck) metal combinations. The corrosion problem has not been the cause of clinical failure except in a few rare cases with Co-Cr/Co-Cr tapers that have fractured. Galvanic corrosion, crevice corrosion, and fretting corrosion have all been suggested as mechanisms that are responsible for this problem.³⁹⁻⁴³



Corrosion on mixed-metal taper 22 months postop



Corrosion on Co-Cr/Co-Cr taper 10 yrs postop



SEM showing intergranular corrosion and grain loss with a Co-Cr taper 10 yrs postop

SOLUTIONS:

For head/neck tapers with dissimilar metals, the risk of corrosion can be reduced by using tapers with tight manufacturing tolerances. This reduces fluid ingress and the extent of fretting which could trigger corrosion by depassivating the protective metallic oxide layers and setting up a crevice corrosion cell.^{37,42,43} In response to the corrosion problem, the orthopaedic implant industry is improving the tolerances and quality control of head/neck tapers.

- For all modular tapers, lock the femoral head onto the neck with adequate force. It is helpful to initially twist the femoral head into position and then apply 3 or 4 seating taps. Ensure that both male and female surfaces are clean and dry prior to assembly.
- For tapers on Co-Cr stems, in addition to high quality manufacturing, ensure that heat treatments used to apply porous coatings do not create intergranular zones that are prone to corrosive attack and eventual mechanical failure.⁴⁴



Metal-stained acetabulum after removal of loose Ti-6Al-4V cup

PROBLEM: Particulate Release Through Implant Bone-Abrasion

Noncemented implants which move relative to the implant site can release particulate debris through simple abrasion mechanisms. This problem is worse with Ti-based implants because of lower hardness and abrasion resistance.⁴⁵ Furthermore, cosmetic implant preparation techniques such as bead blasting tend to leave residual contaminants (silica or alumina) and create tenuous surface irregularities -these are prone to being dislodged by abrasion against bone.

SOLUTIONS:

- Increase the surface hardness and abrasion resistance of Ti-based implants through creation of a surface-rich zone of nitrogen or oxygen.
- Increase the cleanliness and smoothness of implant surfaces by avoiding grit-blasting or sand-blasting. Instead, leave the implant surface simply polished or cleaned and micro-etched with chemical-milling techniques.⁴⁵⁻⁴⁸
- Use noncemented implants with design features that maximize the opportunities for stability, thereby minimizing the risk of interface micromotion and abrasion.



Scanning electron micrograph of bead blasted Ti-6Al-4V implant



Reduced wear of nitrided Ti alloy abraded against PMMA & cortical bone (pin on disk)



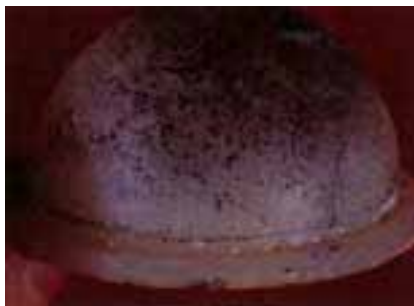
SEM of polished and nitrided Ti alloy to reduce metallic particulate debris

PROBLEM: Third-Body Wear From Debonded Porous Coating

There are numerous reports of loosened fragments of porous coating migrating into the joint space and causing third-body wear of the bearing surfaces.⁴⁹⁻⁵¹ This problem has also been reported with loosened fragments of hydroxyapatite coating.^{52,53} Excessive polyethylene wear can result in particulate debris-induced granuloma, bone loss, implant loosening, and revision.



Loose stem, debonded porous coating, 3-body cup wear, marked polyethylene granuloma



Debonded porous coating fragments embedded in PE liner - fragments migrated through screw holes of metal backing

SOLUTIONS:

- Use noncemented implants with well-bonded porous coatings and a proven history of use without this problem. In general, metallic porous coatings with metallurgical bonds (e.g., diffusion bonded or sintered) are more mechanically resistant than metallic or calcium phosphate coatings applied with plasma spray techniques.
- Use noncemented implants with design features that increase the likelihood of secure fixation. Coatings debond more easily in the presence of motion.

MIGRATION OF PARTICULATE DEBRIS

PROBLEM:

Regardless of origin, through the cyclic pumping action of joint pressure, polymeric or metallic debris can migrate throughout the effective joint space, accessing bone-implant interfaces and articulating surfaces.^{4,54} Particle migration has been documented with both cemented and noncemented implants.



Canine knee implant model with chronic PE injections. Result: fibrous membrane around the smooth implant half only⁵⁷

SOLUTIONS:

- For noncemented hip prostheses, it has been suggested that circumferential porous coating will allow more complete tissue ingrowth and help restrict the access of particulate material along bone-implant interfaces.^{6,55} There is experimental evidence to support the theory that smooth implant interfaces allow greater access of polyethylene debris.^{56,57}
- Press-fitting of noncemented acetabular implants results in a tight peripheral fit which may impede access of particulate debris to the bone prosthesis interface.⁵⁸
- Minimize the overall generation of particulate debris through all of the above recommendations.



Canine knee implant model.⁵⁷ PE particles within fibrous membrane on smooth implant half only (polarized light)

Acknowledgements:

Technical assistance provided by Jan Krygier. Assistance with photographic material provided by Dr. Emerson Brooks, Dr. Jack Parr, Dr. John Moreland, Dr. Gerard Engh, Dr. Charles Engh, Dr. Isaac Graham, Jeff Schryver and Victor Surprenant. Prepared in association with the Joint Implant Surgery and Research Foundation, a non-profit scientific and education organization. Reprint requests to: J.D. Bobyn, Montreal General Hospital, 1650 Cedar Avenue, Montreal, Quebec, CANADA, H3G 1 A4.

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By: ERNEST A. EGGERS, M. D. and TIMOTHY McTIGHE
Poster Exhibit AAOS 1993, San Francisco, CA

INTRODUCTION

Accurate data of the dimensions of the proximal femur are available from x-rays when specific techniques are followed. Three calibrated x-rays are required: a full pelvis view which includes both hips and anterior-posterior view of the proximal two-thirds of the affected femur and a direct lateral view of the end of the proximal two-thirds of the affected hip.

Each view requires a specific magnification marker positioned at the level of the bone near the greater trochanter.

METHOD

This particular x-ray technique has been developed to facilitate custom fabrication through the X-Press™ process provided by Orthogenesis. The reproducibility of this technique cannot be attested to utilizing other fabrication processes.

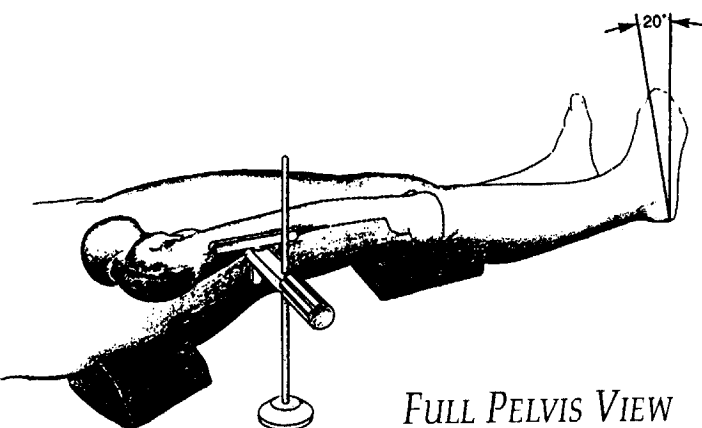
56 Custom X-Press™ titanium stems have been fabricated and implanted based on the x-ray techniques described here. Ten stems have had a HA proximal surface, 40 stems a beaded, commercially pure titanium surface, and six stems with surface geometry consisting of proximal steps with HA and distal flutes.

TECHNIQUE

Calibrated x-ray views are required for this procedure. Marking the patient's skin at the level of the greater trochanter prior to making the first x-ray simplifies location for additional needed x-rays.

FULL PELVIS VIEW

Patient Position: patient lies supine with both legs extended and the pelvis near level both with the plane of the film and in the patient's transverse plane. In most cases, patients feet are pointed internally by approximately 15-20° (less if the patient is unable to internally rotate without excessive pain) to orient the femoral neck parallel to the film plane. The entire length of the femur must also be approximately parallel with the film plane. Wedges of foam blocks may be used under the knee to maintain the parallel orientation between the length of the femur and the plane of the film. Place the magnification marker at the level of the femur between the patient's legs as proximally as possible, insuring that it appears in the imaging area.



FULL PELVIS VIEW

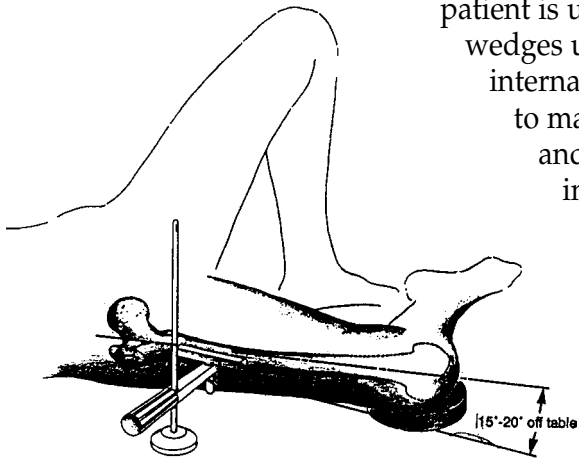
X-RAY CRITERIA

The entire width of the pelvis, both acetabula and both proximal femora should appear in the x-ray image. The femora should be approximately parallel to each other, and at 90° to a line connecting the two acetabula. The lesser trochanter should be invisible or nearly invisible (with less than 5 mm of exposure), as it is posterior to the femur when the femur is rotated properly. The three balls of the magnification marker should be clearly visible.

PROXIMAL FEMUR VIEW

Patient Position: Place the patient exactly as he or she was positioned for the full pelvis view. Correct internal rotation of the affected femur is critical in this view. If the

patient is unable to internally rotate without excessive pain, place foam wedges under the affected hip, raising that side of the body until 20° of internal rotation is realized. Place foam blocks or wedges under the knee to maintain the parallel orientation between the length of the femur and the table. Reposition x-ray equipment to extend the view to include the proximal two-thirds of the femur rather than the full width of the pelvis.



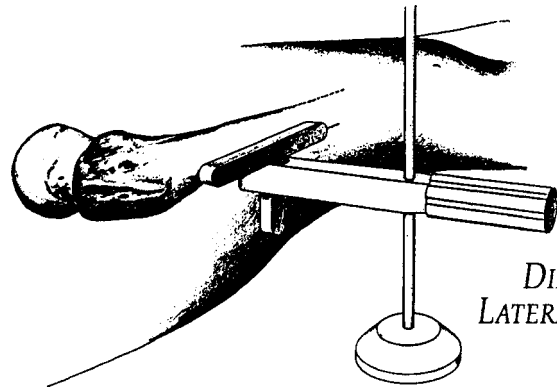
PROXIMAL FEMUR VIEW

X-RAY CRITERIA

The view should include the entire affected acetabulum and the proximal two-thirds of the femur. The lesser trochanter must be invisible or nearly invisible (with less than 5 mm of exposure), as it is hidden by the internal rotated femur. The three balls of the magnification marker should be clearly visible.

DIRECT LATERAL VIEW

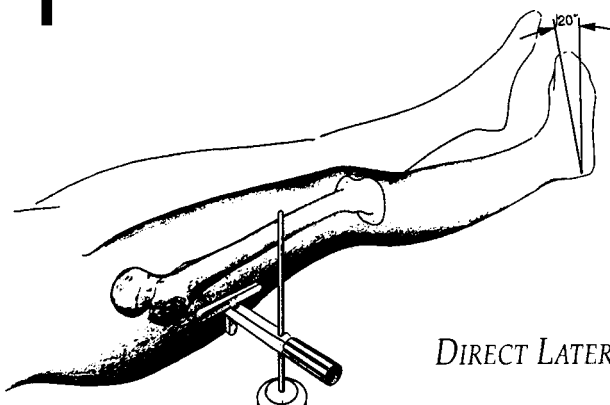
Patient Position: Patient lies supine. The patient's unaffected leg is flexed and the foot is placed flat on the x-ray table. The affected leg is flexed and externally rotated so that the ankle touches the surface of the table. Place foam blocks under the knee to maintain an angle of 20° between the length of the femur and the table. If the patient is unable to flex and externally rotate without pain, place foam wedges or blocks under the unaffected hip, rotating the entire pelvis until the knee is lowered into position. A sandbag may be used to steady the knee against the foam. Place the magnification marker at the level of the femur against the rotated anterior surface of the patient's leg. Orient the x-ray equipment to include the acetabulum and the proximal two-thirds of the femur.



DIRECT LATERAL VIEW

X-RAY CRITERIA

The view should again include the entire acetabulum and the proximal two-thirds of the femur on the affected side. The lesser trochanter should be clearly visible protruding from the posterior side of the rotated femur. The three balls of the magnification marker should be clearly visible.



DIRECT LATERAL VIEW

INDICATIONS: Routine cementless primary and many non-complicated revision cases.

POSSIBLE CONTRA INDICATIONS

Extreme bony defects and abnormalities might require more detailed imaging of the hip, i.e. MR1.

SURGICAL TECHNIQUE

With the patient placed in a true lateral position, a standard posteriolateral incision is made. Routing soft tissue dissection is carried out. A subcapital osteotomy is made corresponding to preoperative templating. The cut through the femoral neck is an oblique angle to match the implant neck-stem transition geometry. The trochanteric fossa is identified and perforated with a punch or intramedullary initiator. To open up the proximal femur that will allow the initial cylindrical reamers to pass directly down into the isthmus of femoral canal in a neutral orientation.

Distal reaming is carried out in half millimeter increments and when the appropriate cortical chatter is encountered, and intraoperative cortical chatter is encountered, an intraoperative x-ray is taken with the distal reamer in place. This is done to ensure that we are indeed in a neutral position and we have achieved proximal canal filling. (Note: it is better to take in intraoperative x-ray while it is still possible to correct for malalignment and/or undersizing as opposed to waiting for a postoperative view.

The initial custom broach, designed for this implant only is introduced pushing its lateral border in the direction of the greater trochanter. The initial broach is removed, and the final broach is introduced in the same manner.

Final broach designed specifically for this implant only prepares the canal to accept the implant and is intended for use during the trial reduction. Often an AP x-ray is taken to assess the position of the broach.

Upon complete insertion of the broach, there should be no rotary instability, A trial reduction is carried out to determine proper neck length and joint stability.

After removal of the trial broach, lavage is carried out on the proximal femur with antibiotic solution and final insertion of the custom implant.

Postoperative x-rays will demonstrate some areas of cancellous bone between cortex and prosthesis. A six-week postoperative x-ray should be taken in the same position as the original preop to assess fit and fill measurements of the device. (Note: initial post op done in recovery room will have the patient in a slightly different position as compared to the preoperative x-rays taken. This can result in some differences in calculations of fit and fill measurements.

POSTOPERATIVE RESULTS

56 stems have been done to date with follow up between three months and one year average being six months. Ten stems have had a HA coating, 40 stems a porous beaded coating, and six stems a surface geometry consisting of proximal steps with HA and distal flutes. Short term comparison reveals no difference between x-ray image and/or clinical results. There has been no anterior thigh pain and no subsidence seen to date.

One stem was not used due to an intraoperative decision which evaluated the bone quality to be too osteoporotic and a standard cemented stem was used in its place.

Certainly long term clinical follow up is necessary to make any definitive statements. However, early clinical comparison to other cementless devices used by this surgeon have found the X-Press™ Custom technique to offer improved pain relief with no revision to date and no ending revisions anticipated in the near future. Long term follow up will demonstrate if there is any clinical difference between different surface coatings. At this point all three surface geometries appear to be equal.

An Excerpt from:

International Society for the Study of Custom-made Prostheses

ABSTRACTS

5th Annual International Symposium on Custom-made Prostheses

1-3 October, 1992
Castle Hotel, Windsor, England, UK

Department of Biomedical Engineering
Royal National Orthopaedic Hospital Trust, Stanmore,
Middlesex, England.

TITLE
DESIGN RATIONALE FOR THE STABILITY™ CEMENTLESS TOTAL HIP SYSTEM

AUTHORS
T McTIGHE, GT VISE, AA LOMARDI, BK VAUGHN, J McCARTHY, DR MAUERHAN

INSTITUTION
JOINT IMPLANT SURGERY AND RESEARCH FOUNDATION, CHAGRIN FALLS, OHIO
AND JACKSON, MISSISSIPPI JOINT IMPLANT SURGEONS, COLUMBUS, OHIO.
RAELIEGH, ORTHOPEDIC CLINIC. BOSTON, MASSACHUSETTS.
MILLER CLINIC, CARLOT, NORTH CAROLINA

Optimization of fit and fill has taken several approaches: off the shelf one piece; off the shelf modular pieces; pre-operative customs; intra-op customs. The growing concern of osteolysis has led to the development of the Stability hip system- This system offers the versatility of modular components, however, it reduces the potential sites that can generate particulate debris.

There are many design features available on cementless total hips today- However, we are still very limited in our selection of materials. We now know modularity is a site for generation of particulate debris. We must be careful in our selection of modularity to insure that we do not extend the risk benefit ratio beyond reasonable approaches. In a revision situation it is desirable to have many intra-operative options. However, routine primary surgery particularly in a patient with a life expectancy over 20 years may be a different situation. Do we really need to consider using excessive modular sites that can generate increased particulate debris for these routine cases, or can we accomplish the reconstruction with a more conventional one-piece stem?

Utilization of proven design concepts and proven fabrication techniques have now made it possible to generate

increased sizes for an off the shelf one-piece, cementless primary total hip stem.

The short term clinical results of the intra-operative custom technique of Identifit™ has had-mixed results in the United States. However, the learning experience has demonstrated a number of factors. Initial focus was on fit and fill. Then the importance of shape was introduced, and recently the advent of macrotexturing and flutes.

Fit and fill, shape, and surface geometry are all important ingredients to achieve axial and torsional stability. However, fit and fill is difficult to achieve due to the varying geometry of the proximal femur. A question is how can we improve our ability to fit and fill varying geometries. One answer is to have a large quantity of sizes, the second is- customs, and the third is modular designs. All three of these answers must address the geometry considerations of proximal size and shape, distal size and shape, and stem length.

Although the cost of customs has been coming down, it still is not equivalent to standard cementless, off the shelf devices. In addition, pre-operative customs limit the intra-operative options that one is faced with and requires

considerable pre-operative precision in working with the device manufacturer.

On the other hand, in the past, a large quantity of sizes has been prohibitive because of cost involvement in standard manufacturing procedures. However, Orthogenesis technology of surface milling now makes this option cost effective. A large quantity of sizes offers many intraoperative options and reduces pre-operative precision planning.

However, it still requires understanding all options (sizes) and requirements for surgical technique.

Modularity has been cost effective, offers many intra-operative options, generally has a high demanding surgical technique, also a high learning curve in understanding of intraoperative options and has been shown to be a site for generation of particulate debris, which can lead to osteolysis.

Overview - Stability Components

- A. Initial sizes, four diameters (12, 14, 16, 18 mm)
Standard Stem Length (150, 155, 160, 165 mm)
The tapered neck permits the use of a variety of head diameters, neck lengths, and C.C. or ceramic material.
- B. Graduated Proximal Design
There are two cone bodies for each diameter stem. Also, two triangle sizes for each cone size. A total of four different proximal sizes are available for each stem diameter.
- C. Design Features Stem
A material: titanium alloy.
 - 1. Taper neck - allows for modular heads.
 - 2. Conical proximal body with

medial triangles - allows for better fit and fill.

- 3. A circular, distal diameter stem - allows for easy, precise preparation by reaming.
- 4. Longitudinal flutes on distal stem - increased torsional resistance.
- 5. Non-bead blasted surface (chem-mill) - reduces surface particulate debris.
- 6. Forged titanium alloy - excellent fatigue strength, low bending modulus.
- 7. HA coated - increased bony response.
- 8. Proximal body - approximates the shape of the prepared endosteal cortex.
- 9. Proximal body - five degree taper proximal to distal.
- 10. Proximal steps - transfer hoop tension into compression. Helps reduce subsidence. Also helps to increase shear resistance of proximal coatings.
- 11. Two triangle sizes per cone - allows for better fit and fill.
- 12. Distal coronal slot - reduces distal bending stiffness.
- 13. Offers versatility of many sizes for routine primary indication while reducing the need for modular sites now known to produce particulate debris.

Summary

The fabrication process of surface milling now allows for increasing off the shelf size offerings reducing the need for modularity and customization; and, more importantly, lends itself to design evolution in a cost effective manner.

Update



N • E • W • S

April 1992

INTRODUCTION

*By Timothy McTighe
Editor*

Recently there has been considerable discussion, debate, and controversy concerning the term fretting. What is fretting and what clinical/ surgical concern should there be as a result of fretting? Fretting is particulate debris generated by abrasion of two surfaces. However, is fretting the real issue of concern or is it osteolysis?

The most common cause of proximal, femoral bone loss is due to osteolysis. Although the specific cause of lysis is not known, it has been attributed to a variety of factors, including motion of the implant, foreign body reaction to particulate debris and hypersensitivity to metal. Femoral osteolysis is well documented with many loose and some well fixed cemented total hip arthroplasties. Particulate debris of polyethylene and/or polymethylmethacrylate seem to be responsible for causing this phenomenon. Osteolysis is now recognized to occur with cementless femoral components. It has occurred around loose as well as rigidly fixed femoral implants. Osteolysis is a potential problem common to all femoral components, independent of their metallurgy, design, or means of fixation whether cemented or cementless. The common underlying pathology in all cases is the host's response to the presence of particulate debris. Particulate prosthetic debris and its potential biological

response is of growing interest to all total joint surgeons. In light of this concern, JISRF is publishing this report in an attempt to help clarify and understand this perplexing problem.

We look forward to your questions and concerns regarding this issue and will make every attempt possible to respond to your needs.

TORSIONAL RESISTANCE AND WEAR OF A MODULAR SLEEVE / STEM HIP SYSTEM

*Stephen D. Cook, Ph.D.
Tulane University School of Medicine
New Orleans, LA*

Maximum metaphyseal fill with good contact of dense bone enhances mechanical fixation and bone ingrowth in porous coated hip replacement. In order to improve initial fit and fill, the S-ROM™ Total Hip System (Joint Medical Products Corporation, Stamford, CT) was developed with modular proximal sleeves and stems to allow the surgeon to "customize" the implant to the individual patient. However, concerns have arisen as to the torsional resistance of the sleeve/stem assembly and the potential for significant wear debris generation at this interface.

In total hip replacement considerable torque is generated against the femoral component in daily activities. Recently, using a

telemeterized femoral prosthesis implanted into an elderly 275 Kg (125 lb.) woman, in vivo torques were reported as high as 22 Nm (194.7 in-lb.) during activities such as stair climbing. In addition to having to withstand considerable torque, modular proximal sleeves and stem components introduce a metal/metal interface to the biological environment and the possibility of wear debris generation.

Fretting is the mechanical process whereby high contact stresses between two surfaces together with relative tangential, cyclic micromovements cause local removal of one or both surfaces. The fretting debris is usually trapped first, causing further surface destruction and particulate generation. For implant metals the passive oxide surface layer which protects subsurface metal is removed and corrosion in body fluids is greatly enhanced.

Implant wear debris can stimulate cells to elaborate agents capable of causing resorption of osseous tissue at the bone/implant interface. Investigations indicate that all of the orthopaedic biomaterials (metals, polymers and ceramics), when present in particulate size range small enough to be phagocytosed (less than about 10 microns), can elicit this biological response. Modular hip proximal sleeves and stems may result in the generation of interface metallic wear debris.

We have studied the torsional resistance of the bone/sleeve and sleeve/stem interfaces of the S-ROM™ Total Hip System and quantified the number and particle size distribution of wear debris generated during cyclic loading and physiological levels. The results indicate that the sleeve/stem interface of the S-ROM™ system is capable of withstanding a physiologic torque of 18-28 Nm under ideal conditions. Several samples underwent repeated disengagement and reimpaction of the stem into the sleeve as described in the surgical guide using appropriate instrumentation. This resulted in a decrease in maximum torque to interface slippage to 15-18 Nm. Contamination of the sleeve/stem interface with blood and fatty elements also resulted in a significant decline in the resis-

tance to torsional slippage.

Axial and torsional cyclic wet testing of the S-ROM™ sleeve/stem system resulted in the generation of significant wear debris. The wear debris generated during axial fatigue testing within the saline solution was relatively uniform in size with 99.8% of the particles in the range 0.255-1.915 microns. The wear debris adherent to the sleeve and stem interface surfaces was slightly less uniform in size with 99.8% of the particles in the range 0.098-4.012 microns. Approximately 8.32×10^1 wear particles were generated and collected in the axial fatigue test specimen.

A significant amount of wear debris was also generated during torsional fatigue testing of the sleeve/stem system. Again, the wear debris was uniform in size with 99.0% of the particles in the range 0.6902-3.06 microns. The wear debris adherent to the sleeve and stem interfaces was slightly less uniform in size with 99.0% of the particles within the range 0.669-4.282 microns. There were fewer total wear particles generated during the torsional testing (3.5×10^6) which is most likely the result of significantly milder loading conditions.

Scanning electron and optical microscopy revealed significant wear and abrasion of the stem and sleeve surfaces. Wear and abrasion was observed primarily at the proximal and distal regions of sleeve/stem contact, and in areas of contact of the sleeve/stem components. Surface analysis also indicated minimal surface contact of the surfaces which may be the result of poor machining tolerances or distortion of the sleeve component due to the high temperature sintering processes used to apply the porous coating to the sleeve.

Our findings indicate that implants having modular proximal sleeves may be prone to slippage under physiologic loading conditions. Slippage of the sleeve/stem interface of the S-ROM™ system occurred in one half of our specimens under ideal conditions below torques reported for an elderly woman. Larger patients would most likely subject the

interface to higher torques because of both greater body weight and larger stem head offsets. The recommended feature of readjusting stem anteversion by repeated disengagement and impaction of the sleeve/stem interface should be discouraged because of the significant reduction in torsional resistance. Clinically, before assembly the stem/sleeve interface should be free of surface contaminants to provide maximum torsional resistance.

Our results also indicate that substantial wear debris are generated during both axial and torsional cyclic loading of the sleeve/stem interface. The majority of particles produced by the testing were much below 5 microns in diameter. Particles below this size are more likely to be ingested by macrophages and have been associated with osteolysis, joint pain, and implant loosening. Based upon the findings of our studies, the implantation of any type modular system must be carefully considered.

STRENGTH, STABILITY AND WEAR ANALYSIS OF A MODULAR TITANIUM FEMORAL HIP PROSTHESIS TESTED IN FATIGUE

*By
J.D. Bobyn, Ph.D.
Montreal, Canada*

Materials and Methods The modular implant (S-ROM™, Joint Medical Products Corp., Stamford, Ct.) was fabricated from Ti-6Al-4V alloy and consisted of a sintered proximal sleeve that connected with a grit-blasted stem via a Morse taper. The in vitro experiments were performed with 30 implants under both dry and wet environments using a test setup that was designed to simulate proximal fixation of the device at the sleeve-bone interface only, with distal support against the lateral endosteal cortex. A porous coated sleeve was combined with an 11 mm stem size (36 mm neck length and a 150 mm body length) in all tests. To establish baseline mechanical properties two series of

tests were performed in air at room temperature: one with direct vertical loading and one with a compound loading angle directed at 15 degrees out of plane (to simulate torsional physiological loads). Head loads ranging from 800 to 1400 lbs were delivered at 10 Hertz by an Instron apparatus to establish the stem endurance limit. The wet tests were conducted in a saline chamber with physiologic loading of 400 lbs applied 20 degrees out of plane for 20 million cycles. After each test, the sleeve was carefully sectioned and removed from the stem to allow examination of contact areas by optical stereomicroscopy and scanning electron microscopy (SEM). The same examination protocol was used with 5 stems retrieved from patients after 1 to 6 years of implantation. Saline samples obtained from the wet chambers were analyzed using a sophisticated particle counting technique based on impedance discharge technology (electrozone method). Rotational stability of the stem with respect to the sleeve was constantly monitored during testing with a linear voltage displacement transducer (LVDT).

Results In the dry fatigue tests, the stem endurance limit (load at 100 million cycles with fracture) was between 1000 and 1100 lbs for both load angles. Using high sensitivity displacement monitoring (detection limit = 100 µm), no relative motion was detected between the stem and sleeve for any tests. Upon inspection of the Morse taper surfaces, it was generally observed that contact areas between sleeve and stem were quite random and much less uniform than expected. The areas of high pressure contact between sleeve and stem were most evident at the proximal medial and distal lateral aspect of the sleeve.

Examination of the contact areas under SEM revealed surface modification (burnishing of the grit-blasted surface and oxidation) with occasional evidence of loose wear debris. The saline environment tests at 400 lbs also revealed random and surprisingly low contact areas between stem and sleeve. Retrieved human implants (up to 6 years after surgery) showed minimal stem and sleeve surface modification that was uniformly less

than observed in vitro. The particle analysis of the wet environment tests yielded particle counts in the saline chamber up to twenty million, but the technique was unable to discriminate between metal and non-metal particles (arising from background contamination).

Total particle volume was only on the order of $5 \times 10^{-3} \text{ mm}^3$, because of the small average particle size of about $1 \text{ }\mu\text{m}$. Assuming all the particles were titanium alloy (a worst case assumption since the background particle count for plain saline alone was several hundred thousand and contamination from the test setup was inevitable), an upper bound on the particles generated during the 20 million cycle fatigue tests was calculated to be $50\text{--}100 \text{ g} \times 10^{-6}$.

Discussion and Conclusions

- The S-ROM modular hip implant shows adequate fatigue strength and secure locking of stem and sleeve components.
 - Fretting (defined as $\leq 25 \text{ }\mu\text{m}$ of cyclic relative motion) scars develop at the small contact areas of the stem-sleeve interface in the presence of gross component stability.
 - This results in surface modification and the generation of particulate debris. In vitro surface modification was greater than that observed with human retrievals.
 - Particulate debris would probably be reduced by improving component surface finish and quality of fit.
 - The particle levels generated in the wet tests are substantially less than the levels of polyethylene particles generated in the hip due to acetabular cup wear (based on a linear wear rate of 0.2 mm/yr and particle size range of 0.2 to $20 \text{ }\mu\text{m}$).
 - Fretting and debris formation are inevitable at the hip prostheses modular junction.
- *There is a general lack of understanding about the level of metallic particulate debris that may be biologically active or inactive.

ISSUES IN COMMERCIALLY AVAILABLE UHMWPE

*Stephen Li, Ph.D.
Biomaterials Program Manager
Du Pont Polymers Experimental Station
Research & Development Division
Wilmington, Delaware*

Ultra high molecular weight polyethylene (UHMWPE) has been the orthopaedic bearing material of choice for over 15 years. However, as it has become evident that debris from UHMWPE can lead to implant loosening, more attention has been paid to the mechanisms that lead to polymer damage in both acetabular and tibial components. There are ASTM guidelines for medical grade UHMWPE for use in implants but they only provide minimum values and do not address some properties important to observed damage mechanisms. It is worth noting that the guidelines for medical grade UHMWPE are not directly performance related. Important design material properties such as yield strength and modulus are not guidelines. It is probable that a portion of the differences seen in in vitro wear tests and in retrieval analysis are due to these material property and processing differences. With few exceptions^{2,3} little attention has been paid to the nature of medical grade UHMWPE and the possible variations in material properties and quality that can occur in commercially available materials. This work addresses methods of characterizing UHMWPE and compares several commercial sources of material. These variations have direct implications on the performance of the polymer in total joint replacement applications.

Variations in Commercially Available UHMWPE

Several graded and lots of commercially available medical grade (implant quality) UHMWPE were obtained for testing along with the appropriate certifications from the suppliers. The materials included 415 GUR, 412 GUR (Hoechst/ Celanese), 1900cm (Himont) and Hylamer® (Du Pont)

Orthopaedic Bearing Polymer. The materials were characterized chemically (density, melting point, crystallinity, impurities) and physically (tensile modulus, yield strength, ultimate tensile strength, elongation to break and creep at 1000 psi) and then compared to certification values when possible. Further, optical evaluations were done to assess the quality of these materials. Materials were received in the form of 3" diameter cylindrical rods obtained from Poly He, Westlake Plastics and Du Pont. All materials were received with certification of physical and chemical properties. Tensile and flexural related tests were done in accordance with ASTM D638 guidelines with Type I tensile bars. Creep measurements were done in accordance with ASTM D621. Density measurements were conducted as described in ASTM D 1505. Sectioned slices for visual inspection were obtained using a Reichert-Jung 2040 microtome.

We found that there is a wide range of properties and quality of medical grade UHMWPe that can be obtained. There are extremely large physical property differences between the various grades of UHMWPe. The variations within a grade can also be significantly large. The magnitudes of the variations in important criteria such as the yield strength and creep of the materials are large enough to potentially influence the performance of the material in a joint replacement. In average overall types of conventional medical grade UHMWPe, yield strength varies 25%, modulus varies from 170 - 230 kpsi (35%) and creep varies over > 100%. We have also found that sheet stock material can be different from rod stock. These material variables have not been included in assessing the damage mechanisms of UHMWPe.

Optical examination of cross sections of materials shows there is often unconsolidated UHMWPe particles in the stock shape. These unconsolidated particles may lead to pitting, fracture or other observed types of damage.

To date, most of the attention has been focused on the physical properties of the material and little attention has been paid to

the chemical degradation, in the form of oxidation, that is also occurring during use. Chemical degradation of UHMWPe may be an important factor in the damage rate of implants, especially at long implant times.⁴ Earlier, we reported a Fourier Transform Infrared Microspectrometric (FT-IRM) Technique for assessing the level of type of oxidation found in UHMWPe.^{3,6}

We report here detailed analysis of the oxidation state of commercial implants prior to implantation and analysis of retrieved knee and hip components at different implant durations. We also compare the relative chemical resistance of two UHMWPe samples of different crystallinity. The FT-IRM method allows us to assess the levels and locations of oxidation in both retrieved acetabular and tibial components. In general, we find that high levels of oxidation are almost always associated with high levels of damage in both acetabular and tibial components. The extent of oxidation also appears to increase with both increased stress and increased implant duration.

All microspectrometric measurements were obtained using a Digilab 60A FT-IR spectrometer with a UMA 300 IR microscope (Cambridge, MA). Spectra were obtained at a resolution of 4 cm^{-1} , for 100 scans with a narrow range MCT detector. The microscope was equipped with a 4 x 4 motorized stage, capable of accurately moving 10 micron steps. The adjustable aperture, was set to 50 μm x 200 μm . A Reichert-Jung 2040 microtome was used to make 250 μm cross-sectional slices of the samples. Spectra were obtained at depths from 0 μm to 2000 μm below the surface.

Studies on the degree of oxidation are done by examining the carbonyl bands between 1700 cm^{-1} and 1750 cm^{-1}) and the ester, ketone and acid bands occurring at 1738 cm^{-1} , 1720 cm^{-1} and 1697 cm^{-1} respectively. The overall peak area of the entire carbonyl band is determined between 1800 cm^{-1} and 1660 cm^{-1} . The data is normalized for sample thickness. This area is a measure of the extent of oxidation.

We find in studying commercially available implants prior to implantation, that the level of oxidation in some components is very high prior to use. This may be due to the type or quality of UHMWPe used, the sterilization methods and the thickness of the component.

We find the level of oxidation in retrieved acetabular and knee components is significantly higher than a corresponding new component. The extent of oxidation generally follows the extent of damage. The more severely damaged the component, the higher the level of oxidation. In acetabular components we find that the inside (articulating) surface is much more oxidized than the outside surface. In tibial components we find that the level of oxidation increases with time and is highest in areas of higher stress. Interestingly, we also find that the maximum level of oxidation in tibial components is found 1-2 mm below the surface the same area as predicted to have maximum stress.

It is expected that increasing the crystallinity of UHMWPe will improve the resistance to degradation. This has been demonstrated by exposing two samples of UHMWPe with different crystallinity and morphology to a strong oxidizing acid, chlorosulfonic acid. This acid turns UHMWPe black as it oxidizes. By measuring the depth of acid penetration with time, an oxidation rate can be obtained. UHMWPe of 50% crystallinity was 415 GUR. The 75% crystalline material was enhanced UHMWPe, Hylamer® Orthopaedic Bearing Polymer. The acid oxidized the more crystalline material at a slower rate.

Oxidation is a phenomenon that is strongly associated with the damage of UHMWPe. Oxidation of UHMWPe changes the chemistry of UHMWPe which may make it more susceptible to further damage. The rate and extent of oxidation may also be increased with increased stress. Oxidation may be a strong influence on the damage mechanisms of UHMWPe components, especially at long implant times.

It is evident from our studies that ASTM certified conventional UHMWPe can be highly

variable in properties and quality. These variations are of a magnitude that may significantly influence the generation of polyethylene debris. Further, the oxidative state of UHMWPe in devices prior to implantation are also highly variable and may contribute to accelerated polyethylene damage.

In order to improve upon the conventional UHMWPe currently being used, a new material should provide improvements in creep resistance, chemical stability, quality, and strength without sacrificing other material properties. An offering that fits the criteria is Hylamer® Orthopaedic Bearing Polymer made by DePuy - Du Pont Orthopaedics® which has been introduced into the marketplace as a bearing surface for acetabular liners. Hylamer® has improved creep resistance (50% improvement at 1000 psi load), increased yield strength (30%), increased tensile and flex modulus (ca 100%) over that of conventional UHMWPe. Further, its increased crystallinity has been shown to provide greater resistance to very strong oxidizing reagents and high doses of gamma irradiation. Hylamer® also has the highest known quality control standards of an orthopaedic bearing material.

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THE EFFECTS OF IMPLANT WEAR DEBRIS AND HUMAN BONE CELL PROLIFERATION: IN VITRO ANALYSIS

*By William L. Lanzer, M.D.,
Guy A. Howard, Ph.D., Scott F.M. Duncan
Seattle, Washington*

Purpose This is the first study to use human bone cell cultures to investigate the biocompatibility of clinically relevant wear particulates, i.e., in terms of particle size and shape as demonstrated in vivo. Several investigators have reported significant levels of implant wear debris at revision surgery

implicating wear in osteolysis and loosening.

Methods

We used normal primary human bone cell cultures to characterize the metabolic response to various implant materials in particulate form. We feel the inhibition of cell growth as measured by [³H] TdR incorporation during DNA synthesis, is a sensitive and valid way of determining the relative effects of implant materials on cell proliferation. In vitro models focus on the simulation of the in vivo environment. Since frictional heating during artificial hip joint articulation, as shown by Bergman, may potentially effect the response of the host-to-wear particulates, temperature was an additional variable.

Results

There was a definite inhibitory effect on the rate of bone cell proliferation with all the particles tested and with temperature elevations. Total cell counts reflected a 40% decrease in cell proliferation as compared to 37°C. This inhibitory effect was dose dependent and statistically significant when tested at specific concentrations. Elevated temperature appears to potentiate the metabolic response of bone cells to wear debris. Ti-6Al-4V particulates demonstrated the least inhibitory and the stainless steel particulates the most inhibitory effect. Inhibition was detected only with physical contact between cell and particulate. Conditioned media (pre-incubated with particulates) also did not affect proliferation. Although there was a reduction in the proliferation of cells as determined by DNA synthesis, the cells did not appear to be dying as judged both by microscopic examination and alkaline phosphatase level per cell. A decrease in enzyme activity with the addition of the particles was about the same ratio as with the decrease seen in DNA synthesis.

Discussion

Since both cells are known to produce autocrine and/or paracrine growth factors in vitro (e.g. TGF β , IGF-I and -II) cell proliferation inhibition could be due to adsorption of these factors by particulates. Since physical contact was necessary for inhibition in our

assay, adsorption did not appear to be the mechanism of inhibition. While the size of particulates has been shown to be in the range of 2-10 μ m in vivo, the concentration at interfaces between bone and fibrous tissues, and fibrous tissues and implant is unknown. The cells in our assays appear to respond in a dose dependent manner, thus in vivo concentration becomes important. The fibrous membrane around prostheses in vivo may act as a physical barrier to mitigate the effects of particulates. The fact that hydroxyapatite significantly inhibited bone cell proliferation is not surprising since hydroxyapatite crystals in synovial joints induce intense inflammatory reaction (as in the Milwaukee Shoulder).

Conclusion

It is concluded that some characteristic unique to each biomaterial particulate has an inhibitory effect on bone cells. We are actively investigating the interesting effects of both temperature elevation and particulate characteristics focusing on the mechanisms of cellular inhibition.

CERAMIC IMPLANTS - BELATED ANSWER TO OSTEOLYSIS CONCERNS

*Ian C. Clarke, Ph.D.
Kinamed, Inc.*

Why should we consider the more expensive ceramic femoral ball for total hips? Isn't there a real risk of catastrophic fracture, and is the added expense justified?

Some of this ceramic risk/benefit rationale ties into reduce polyethylene wear with associated osteolytic potential, and to the newly identified risk of metallic debris from the use of modular titanium and cobalt alloy femoral balls. There is a renewed awareness of the peri-implant destruction caused by debris-mediated osteolysis (Clarke and Campbell, 1989). With the advent of porous-coated titanium implants, the propensity for shedding of metallic debris with

3-body abrasive wear of both Ti-6Al-4V balls and accelerated UHMWPE wear has caused many concerns (Agins et al, 1988; Anthony et al, 1990; Nasser et al, 1990; Dorr et al, 1991). As an obvious knee-jerk reaction, it has now become popular to advocate "improved coatings" for metallic balls (anodizing, ion-bombarding, nitriding, etc.).

However, in a further escalation of concerns over metallic debris, European authors have now described crevice corrosion with modular CoCr balls mounted on CoCr stems, with release of metal particulates into the joint space (Mathieson et al, 1991). In the USA, several centers are now describing galvanic corrosion with the combination of Ti-6Al-4V stem and modular CoCr ball (McKellop et al, 1991; Collier et al, 1991). Concerns here relate to the two findings a) that it has 100% occurrence in implants with over 2 years implantation, and b) the corrosion phenomenon is progressive!

The first recorded use of the ceramic ball was in France as a non-modular stem design by P. Boutin in 1970. However, the modern history evolves from the modular, morse-taper designs popularized by Drs. P. Griss and H. Mittlemeier in Germany, circa 1973. These innovators visualize the alumina ceramic as a very inert, corrosion-free material with virtually a diamond-hard surface for good biocompatibility, low-friction and exceptional wear resistance. Early experiences combined with the use of ceramic acetabular cups (threaded-cup designs) were mixed, with some cases featuring component fractures and accelerated ceramic wear (Walter and Plitz, 1985; Cameron, 1991). However, modern designs of alumina ceramic ball combined with UHMWPE bearings have shown clinically 2-4 times Pe-wear reduction compared to metal balls (Clarke and Kabo, 1991). In addition, there has been zero recorded incidence of corrosion problems at the morse-taper interfaces (L. Sedel, 1991; P. Bosch, 1991 - personal communications). Thus the ceramic ball appears to confer a clinically significant, increased protection from Pe-debris and eliminated the release of metallic corrosion products as demonstrated over an 18-year history.

Given the above comparisons between modular ceramic and CoCr balls, the surgeon may wonder why then has the ceramic ball not been more popular in North America? The answer predominantly lies in the fact that the FDA did not reclassify the alumina ceramic: UHMWPE total hip until January of 1989, and thus the approval processes occurred after this period. The alumina ceramic approvals were followed in 1990 by approval of zirconia ceramic balls.

Are the ceramic balls safe to use? The initial testing regime used in various 51 OK applications to the FDA was to subject the ceramic balls to a high level of cyclic loading for 10 million cycles. Fatigue loads of over 40kN (almost 9,000 lbs.) were used initially as a stringent criterion, with the balls expected to pass 10 million cycles without failure. The represented a safety margin of over 50 times (patient weight = 180 lbs. avg.). Despite this, at least three ceramic ball fractures have occurred in North America, one a sterilization mishap, one a traffic accident, and one unexplained (Cameron et al, 1991). Now that the ceramic 51 OK applications can get FDA approval with fatigue loads as low as the 3.5kN range (900 lbs.), there may well be an increased risk of fracture with certain designs in the future. The alumina ceramic ball has certainly fulfilled expectations with over 18 years of clinical history. However, the introduction of the new ceramic zirconia comes with very little history. Thus, with various claims that it has improved wear resistance, the surgeon needs to be fully aware the zirconia has little or no clinical history and also that it is labelled as "partially-stabilized zirconia," meaning that there has been concern that the material could degrade (Christel et al, 1990).

From the surgeon's point of view, there must also be total awareness of the uniqueness of ceramic design features. Given the specific features of taper-cone diameter, taper angle, specific contact-zones and tolerances, it is not possible to mix-n-match from one manufacturer's design to another. Even if the ceramic ball from one brand appears to fit nicely onto the femoral stem of another brand, do not take this risk.

So overall, it would appear that the approval and use of ceramic balls comes fortuitously at a time when the modular Ti-6Al-4V and CoCr balls have become increasingly suspect as one of the sources of the metallic debris implicated in the accelerated wear (3body abrasion) of the UHMWPE bearings. In addition, the ceramic balls have lower friction and much reduced Pe-wear which offers significant reduction of Pe-driven osteolysis. However, this technology comes at a price (\$300-700 over CoCr ball price) and potentially could result in a small incidence of ceramic fractures. Thus the test standards must be maintained at a high level and the surgeons must respect the labelling requirements and resist the temptation to mix-n-match between brand names. Given these caveats, it would appear that the replacement of a metal femoral ball with ceramic will confer clinically significant improvements to the longevity of the total joint replacement.

SUMMARY

*By
Guy T. Vise, M.D.
Jackson, Mississippi*

The incidents of cementless osteolysis appears to be more than anticipated versus cemented stems compared to the same clinical time period. This perplexing problem must be addressed if we are to achieve 20 year plus survivorship of cementless implants.

There are many design features available on cementless total hips today however, we are still very limited in our selection of materials. We now know modularity is a site for generation of particulate debris. We must be careful in our selection of modularity to insure that we do not extend the risk benefit ratio beyond reasonable approaches. In a revision situation it is desirable to have many intra-operative options. However, routine primary surgery particularly in a patient with a life expectancy over 20 years may be a different

situation. Do we really need to consider using excessive modular sites that can generate increased particulate debris for these routine cases or can we accomplish the reconstruction with a more conventional one piece stem? Can we modify, improve or strengthen all modular connections such that wear debris will not present itself as a clinical problem? Answers are not yet in.

It is becoming more and more obvious to many that we should do more to reduce the generation of particulate debris. This can be accomplished by the following actions:

- Use modularity only when needed.
- Do not use titanium as a bearing surface.
- C.C. or ceramic should be used. Consider ceramic in younger patients.
- Careful consideration on acetabular component design.
- Quality UHMWPE in all patients.
- Thick poly in younger patients.

These are actions that we, as surgeons, can initiate now. We also need to continue to encourage orthopaedic industry to spend money in research and development to design and develop new and improved materials.

Some have called the 90's the decade of poly wear or particulate debris. How fast can we alter that picture and prevent unexpected surprises? Remember, for our patients the best surprise is no surprise at all!

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TORSIONAL STABILITY OF UNCEMENTED REVISION HIP STEMS

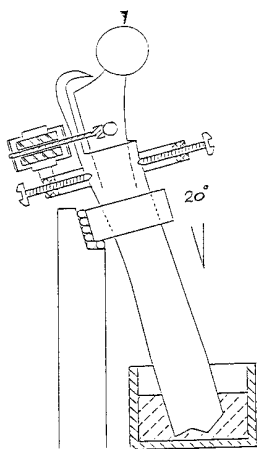
J.A. Longo*, T. McTighe, J.B. Koeneman*, R.L. Gealer*

*Harrington Arthritis Research Center

*Joint Medical Products Corporation, Stamford, CT

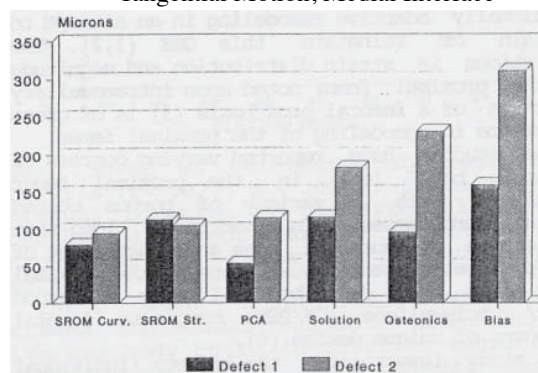
INTRODUCTION - Excessive interfacial motion can be detrimental to the functioning of non-cemented joint replacements. Significant torsional moments are applied to the proximal femur at the extremes of flexion and extension during gait, rising from a chair, and in stair climbing [1]. Revisions of loose femoral stems often leaves a femur with proximal bone loss, segmental and often cavitory in form, thus reducing the inherent implant rotational stability provided by normal proximal femur geometry. Previous studies have examined the effect of stem length and curvature on torsional stability [2]. The purpose of this study is to investigate the torsional stability of different revision stem designs in a segmental proximal deficient femur and a segmental cavitory proximal deficient femur with a bent-hip load.

METHODS - Six prostheses were tested in identical adult size left synthetic composite bone (Pacific Research Labs). The bones have approximately the same bending stiffness as human bones [3]. The prostheses tested were the long stem PCA (size 6, 250 mm. long), a long stem Osteonics (size 10, 250 m long), a Solution (15 mm, 10 inches long), a BIAS (16mm, 232 m long), a straight stem SROM (20 X 15, 225 mm. long), and a curved stem SROM (20 X 15, 225 mm. long). A segmental defect was prepared in the proximal femur to the lesser trochanter and the implants were implanted according to manufacturer's instructions. The centers of all femoral heads were sized to match the center of the natural head, and the femurs were potted distally. Each femur was placed in 20 degrees of flexion as shown in Figure 1. A circular collar was fixed to the proximal femur. This collar was supported by a circular bushing support which allowed rotation of the femur but prevented bending. Loading was applied as shown in Figure 1 at a rate of 50 Newtons per second up to a maximum load of 2500 Newtons. Relative motion was measured by two LVDTs (050HR, Schaevitz) that were attached to the proximal femur. Pins were bonded into the lateral and medial surface of each implant these moved the cores of the LVDTs. Tangential motion at the prosthesis-bone interface was calculated. At least three runs were made for each prosthesis and then the LVDT frame was dismantled and reassembled and the tests repeated. A total of three setups with three runs per setup were conducted for each prosthesis. A/P and lateral radiographs were taken of each implant and the respective fit and fill recorded using the method of Gruen [4]. After completion of the test-



ing for the segmental defects, *the implants* were atraumatically removed, and the metaphyseal bone removed from the proximal femur to simulate a segmental cavitory type defect. The prostheses were reimplanted, tested as before and then cycled one hundred loads and retested.

Tangential Motion, Medial Interface



RESULTS - All implants had excellent fit and fill (> 94%). Figure 2 shows the tangential motion at the medial interface for each implant. The PCA and Solution stems, and to a lesser extent the Osteonics stem demonstrated settling during the initial runs. Once settling had occurred, *then all* stems demonstrated repeatable measurements both before and after cycling. Stems with both a medial-lateral and anterior-posterior wedging had the least motion with both types of defects. In the absence of metaphyseal supporting bone, the rotational stability of the prostheses were markedly reduced except for the SROM stem which demonstrated little change. A curved stem appeared to enhance the rotational stability.

DISCUSSION - Rotational and axial stability limiting interface micromotion a crucial to the functioning of revision femoral stems. Certain prosthetic design features allow immediate press-fit stability despite large segmental or metaphyseal bone defects. Stem designs which may subside during cyclical loading, my ultimately achieve rotational stability, but at the expense of possible change in version, length and bone graft position. In similar proximally *deficient prepared* bones, stem design and the ability to achieve metaphyseal fit in AP and lateral planes are paramount in achieving torsional stability with revision femoral prostheses.

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ACKNOWLEDGMENT-Supported by Joint Medical Prod. ADDRESS-Harrington Arthritis Research Center, Phoenix, AZ 85006

38th Annual Meeting, Orthopaedic Research Society, February 17-20, 1992, Washington, D.C.

REVISING THE DEFICIENT PROXIMAL FEMUR

by

David Mattingly, Boston, MA
Joseph McCarthy, Boston, MA
Benjamin E. Bierbaum, Boston, MA
Hugh P. Chandler, Boston, MA
Roderick H. Turner, Boston, MA
Hugh U. Cameron, Toronto, Canada
Timothy McTighe~ Stamford, CT

A SCIENTIFIC EXHIBIT AT THE 1991 AAOS MEETING
ANAHEIM, CALIFORNIA

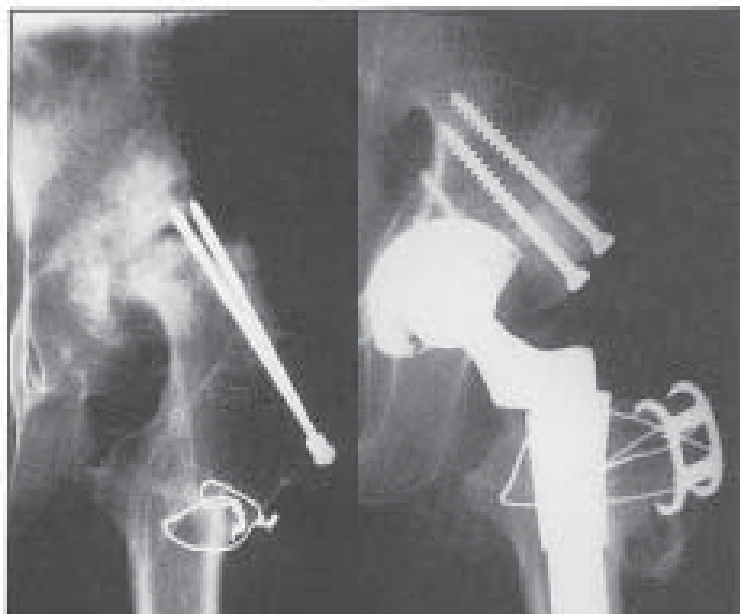
INTRODUCTION

In the last few years, as we encounter more difficult and unusual situations, revision total hip arthroplasty has become increasingly more sophisticated stimulating the use of autografts, allografts, modular and custom implants. However, the goals of revision surgery remain the same as primary arthroplasty: reduction of pain, equalization of leg length, restoration of movement, creation of joint and implant stability.

Defining and classifying femoral defects has been done by a number of authors.^{1,4,5,9,13} However, interpretation of these classifications can be confusing and frustrating due to the need of a reference chart. This exhibit will use descriptive terms (modified AAOS classification) to define the deficient proximal femur. In addition, guidelines will be given as to implant selection for each classification category.

The most common cause of proximal bone loss is due to osteolysis. Although the specific cause of lysis is not known, it has been attributed to a variety of

While revision surgery is technically demanding, this exhibit will demonstrate that it is possible to achieve short term success in treating the deficient proximal femur with a proximal modular cementless stem system.



METHODS AND MATERIALS

Cases were retrospectively reviewed from three different hospitals and six different surgeons in order to evaluate the use of a proximal modular femoral stem system in total hip arthroplasties with bone deficiencies of the proximal femur. Only patients with a segmental proximal femoral bone deficiency and a minimum one year follow-up were included in the study.

Segmental femoral deficiencies were defined as:

- Level A** Slight (bone loss above the top of lesser trochanter)
- Level B** Moderate (bone loss through the base of lesser trochanter)
- Level C** Severe (bone loss below lesser trochanter to the isthmus)
- Level D** Extreme (bone loss below the isthmus)

Hospital and office records were reviewed to evaluate individual results, technical errors, complications and failures. Preoperative, immediate and serial post operative radiographs were also reviewed to define femoral bone stock deficiencies, types of bone graft and radiographic evidence of subsidence and loosening.

Patient Profile.

133 Patients: 68 Males/65 Females
Age: 25 - 84 (average 65)
Follow-up: I - 6 years (average 3 years)

Diagnoses

	# Hips
Aseptic Loosening	102
Failed Inter Trochanteric Fracture	6
Congenital Dislocated Hip	6
Girdlestone Conversion	9
Failed Osteotomy	10
Total	133

Acetabular Components

Original cemented left	13
Original threaded left	4
Bipolar	37
Threaded	19
Fixed, Ingrowth	60
Total	133

S-ROM™ Components

Proximal Sleeve: ZTT-117 SPA-16
Neck Type: Calcar replacement - 82;
Standard - 51
Stem Lengths: Primary (< 200m) - 57
Revision (>200mm) - 76

Segmental Femoral Deficiencies

Level A - Slight	43
Level B - Moderate	43
Level C - Severe	44
Level D - Extreme	3
Total	133

Structural Bone Grafts

Onlay	18
Proximal Replacement	5
Inlay	1
Total	24

IMPLANT SELECTION

Immediate implant stability is an absolute requirement in cementless revision arthroplasty.¹⁴ In order to achieve stability, metaphyseal and diaphyseal fill is required. It has been previously reported that a constant proportional relationship is not present between the shape and size of the metaphysis and diaphysis.¹¹ In addition the revision situation results in alterations in the normal bony

architecture, making fit and fill more difficult to achieve.

The S-ROM™ Total Hip System allows for intraoperative options by design of a modular metaphyseal sleeve that is available in a variety of sizes and shapes.² This proximal sleeve is attached to the stem by means of a taper lock.

FLUTED STEMS

The stem has three distinguishing dimensions:

- 1.) Stem Diameter (proximal and distal)
- 2.) Stem Length
- 3.) Neck Length

All of the stems have a proximal taper, a fluted distal diameter, and a taper lock head fitting. A proximal taper permits the use of a variety of self-locking proximal sleeves that help customize the fit in the deficient proximal femur. In addition, all stems have a coronal distal slot. This reduces bending stiffness by approximately 80%.

With moderate cavitary and segmental bone damage it is difficult to achieve rotational stability of the implant. In this situation some authors have previously recommended distal fixation.⁵ It is our opinion that distal stability is preferable over distal fixation. This can be achieved by fluting the distal

end of the stem. Whiteside¹² and Koeneman⁸ have shown that fluting offers more initial stability in torsion as compared to a fully porous coated stem.



Array of stem selections

PROXIMAL SLEEVES

The variety of sizes and styles of proximal sleeves allows for an intra-operative custom-type fit for each patient. This gives the advantage of adapting the device to the geometry of the patient reducing the need for allograft, autograft and custom devices.

These have been described in detail in a previous scientific exhibit.³



Array of sleeve selections

ASSESSMENT OF BONE STOCK

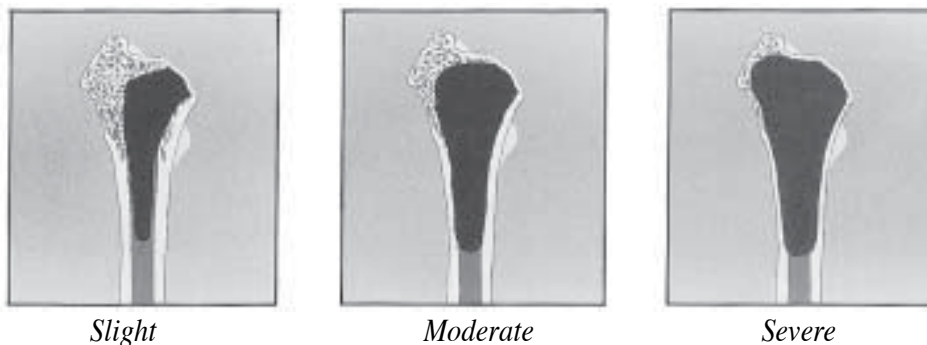
(Modified AAOS Classification)

- | | |
|---|--|
| <p>I. Cavitary Expansion: Slight, Moderate, Severe</p> <p>A.) Metaphyseal</p> <p>B.) Diaphyseal</p> <p><i>Definition: Loss of cancellous and/or cortical bone from within.</i></p> <p>II. Segmental: combination with cavitary</p> <p>A.) Slight (bone loss above the top of lesser trochanter)</p> <p>B.) Moderate (bone loss through the base of lesser trochanter)</p> <p>C.) Severe (bone loss below lesser trochanter to the isthmus)</p> <p>D.) Extreme (bone loss below the isthmus)</p> | <p>III. Cortical Deficiency</p> <p><i>Definition: Any fracture, perforation or loss of cortical substance</i></p> <p>IV. Malalignment</p> <p>A.) Version abnormalities</p> <p><i>Definition: Too much anteversion or retroversion.</i></p> <p>B.) Angular deformity</p> <p><i>Definition: Diaphyseal angle or bow restricts the insertion of the femoral stem.</i></p> |
|---|--|

TREATMENT GUIDELINES

Implant Guidelines

1. CAVITARY EXPANSION: A) *Metaphyseal* B.) *Diaphyseal*



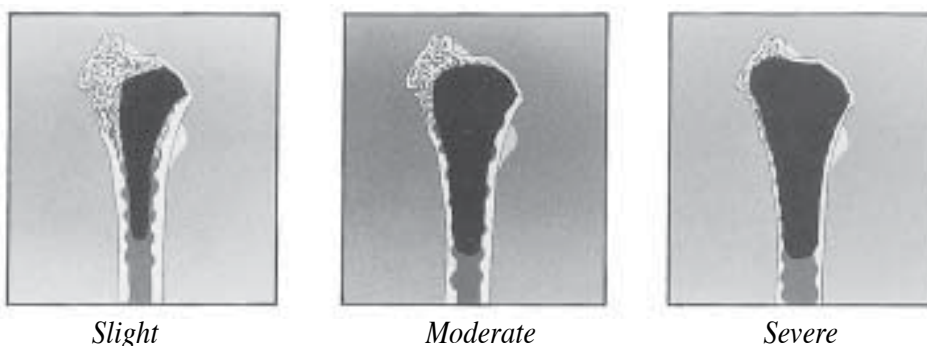
METAPHYSEAL EXPANSION

Treatment:

Slight - Standard stem, B, D or F cone with small or large triangle.

Moderate - Standard or long stem, D or F cone with large triangle.

Severe - Standard or long stem, F cone or upsize cone by use of mm diameter increasing sleeve. Possible inlay graft with cemented sleeve and press fit cementless stem. Possible onlay graft for cortical reinforcement.



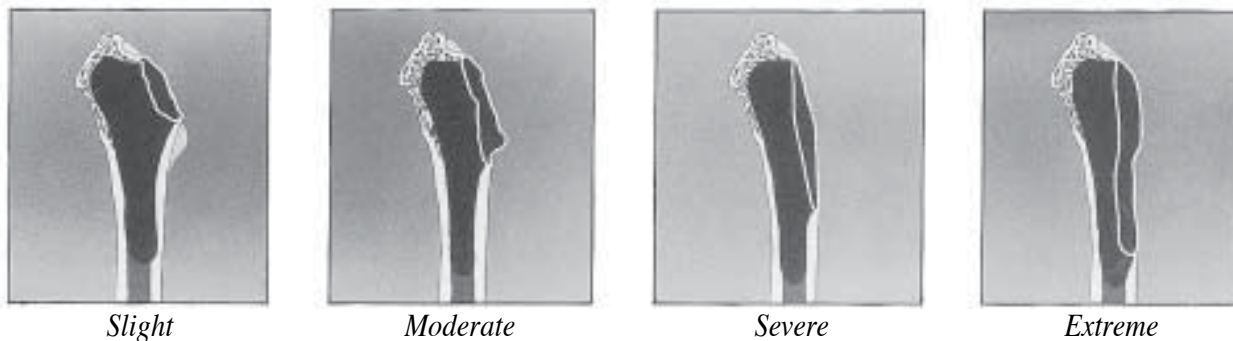
DIAPHYSEAL EXPANSION

Treatment:

Slight - Large diameter stem. Standard or long depending on segmental loss.

Moderate - Larger diameter stem. Standard, long or extra-long depending on segmental loss.

Severe - Largest possible diameter stem. Long, extra-long, or extra, extra-long depending on segmental loss. Possible onlay cortical graft for reinforcement. Possible intramedullary graft.



II. SEGMENTAL

Treatment:

Slight - Standard stem, B, D or F cone with small or long triangle.

Moderate - Calcar long stem. Possible 42 neck, long stem, Possible+12mm head.

Severe - Extra-long or extra, extra-long stem with segmental sleeve or allograft.

Extreme- Extra, extra-long stem modified with locking screws segmental sleeve or allograft.

TREATMENT GUIDELINES *(continued)*



Window



Crack



Fracture

III. CORTICAL DEFICIENCY

Treatment:

Windows less 113 canal diameter - Stem bypass by $2\frac{1}{2}$ canal diameters with or without graft.

Windows greater than 113 canal diameter - Stem bypass by $2\frac{1}{2}$ canal diameters with onlay bone graft.

Crack - Cerclage and possible onlay grafts.

Fracture - Stem bypass at least $2\frac{1}{2}$ canal diameters with cerclage and possible cortical onlay grafts.



Version Abnormalities



Angular Deformity

IV. MALALIGNMENT

Treatment:

Version abnormalities - Index sleeve into position of structural support. Index stem into position of function.

Angular deformities - Osteotomize through deformity stem bypass by greater than $2\frac{1}{2}$ canal diameters.

CLINICAL EXAMPLES

Moderate Cavitory Expansion Metaphysis



Pre-op



Post-Op

Severe Cavitory Expansion Metaphysis



Pre-op



Post-Op

Severe Cavitory Expansion Diaphysis



Pre-op



Post-Op

Segmental Slight



Pre-op



Post-Op

CLINICAL EXAMPLES *(continued)*

Segmental Moderate



Pre-Op



Post-Op

Segmental Severe



Pre-op



Post-Op

Segmental Extreme



Pre-op



Post-Op

CORTICAL DEFICIENCY Crack (Cement)



Pre-op



Post-Op

CLINICAL EXAMPLES *(continued)*

Crack (Stem Perforation)



Pre-op



Post-Op

Fracture (Discontinuity)



Pre-op



Post-Op

MALALIGNMENT Version Abnormalities



Pre-op



Post-Op

Angular Abnormalities



Pre-op



Post-Op

TECHNIQUE

Pre-op Assessment

1. X-ray Review

AP and Lateral view entire femur

- Look for cavitory expansion
- Look for segmental loss
- Look for cortical infraction
- Look for bow malalignment

2. Reference Treatment Guidelines

3. Order necessary inventory (special instruments, implant, grafts)

4. Plan operative staging Example. While removing bone cement, preparation of graft material can take place saving valuable operative time and blood loss.

If adequate help is not available, possible consideration of graft preparation prior to putting patient under anesthesia should be considered.

5. Surgical Technique

In order to manage the deficient proximal femur, an extensive exposure of the hip is necessary. In general, the lateral shaft of the femur may be exposed to facilitate orientation to the canal, to address cortical perforations and to perform osteotomies when needed.

This exhibit will not discuss implant or cement removal. Following removal of old implant, cement and assessing defects, femoral preparation is carried out.

Prior to preparation, consideration should be given to prophylactic wires or cables. If a bowed stem is being used, flexible reamers must be used for canal preparation. It is critical to review pre-operative lateral x-ray to determine if the angle of the bowed implant will match the patients bow. Over reaming the major diameter by 1 or 2 mm is often necessary. If the patients bow angle is greater than that of the implant, an osteotomy should be done through the deformity, and a long straight or bowed stem can be used.

The fluted distal stem has a minor and a major stem diameter. The flute depth is approximately 0.5. mm. Distal stem diameter is determined by diaphyseal reaming, similar in technique to reaming for an intramedullary nail.

The anterior bow of the femur is encountered at approximately 200 mm. Straight distal reamers may perforate the anterior femur. In most cases requiring a long stem a bowed stem is preferred.

The depth of canal reaming should correspond to stem length.

When using a straight stem in hard cortical bone, it might be necessary to ream up 0.5 mm.

The proximal stem diameter establishes the proximal conical reamer series required to prepare the cone of the sleeve.

There are three conical sizes for each stem B, D and F. The differential of each letter/cone size is 2 mm. The conical reamers should be used in a progressive sequence.

The depth of the conical reamer is determined by the bony segmental loss. Example, if bone is missing down to the level of lesser trochanter then the conical reamer is taken to this level. The final conical reamer corresponds to the final cone implant size.

Triangle preparation is done with the calcar cutter. Often this instrument is not needed in revision situations. However, if this instrument is to be used, align the calcar miller for maximum bony containment of the triangle of the sleeve. The alignment of the calcar miller does not determine the final anteversion of the femoral stem. After milling, trial sleeves are used to determine final triangle size. A trial stem can be inserted to determine final head/neck version and head/neck length. A detailed surgical technique on A the instruments has been published.

RESULTS

Harris Hip Rating:

Pre-op: 13-77 (average 45)

Post-op: 65 to 100 (average 85)

	<i>Patients</i>	<i>%</i>
Excellent	51	38
Good	58	44
Subtotal	109	82%
Fair	17	13
Poor	7	5
Total	133	100%

Thigh Pain:

	<i>Patients</i>	<i>%</i>
None	122	92
Slight	6	5
Moderate	4	2
Severe	1	1
Total	133	100%

Definition of Pain Score:

None - Self explanatory

Slight - No pain medicine and does not affect activity

Moderate - Analgesic and does affect activity if overdone

Severe - Analgesic and requires walking aid

Complications:

Femoral Aseptic Loosening: 2/133

Femoral Components Revised: 2/133
(For sepsis reactivation)

Femoral Components

Pending Revision: 1/133

Death - 2 days post-op 1

CXA (recovered) 1

Myositis occificans (Brooker III or IV) 1

Femoral nerve palsy (recovered) 1

Fractures:

<i>Location</i>	<i>Rx</i>	
Greater Trochanter	Screws & Wires	2
Proximal	Wires	18
Proximal	Onlay & Wires	4
Distal	Onlay & Wires	1
Distal	Traction	1
Total		26

Stem Perforations 6

*Subsidence 5

Dislocations 6

Infections (superficial) 1

Infections (reactivation) 2

*Subsidence of 2 to 5 mm; all 5 radiographically stable with Harris scores > 90.

DISCUSSION AND CONCLUSION

Revising the deficient proximal femur presents a major challenge to the revision hip surgeon and the implant manufacturer. Clinical success is dependent on careful preoperative planning, avoidance of major complications, bone preservation and/or augmentation, secure implant fixation and appropriate soft tissue balancing to produce a reliable and stable articulation.

Fractures and perforations remain the most frequent complications associated with complex femoral revision arthroplasty. Of our 26 fractures, approximately 40% occurred prior to final implant insertion. Most of these fractures (20 of 26) involved the deficient proximal femur, were simply treated by cerclage wiring, and did not affect the rehabilitation or clinical outcome of the patient. Fractures and perforations can be minimized by careful attention to the following principles.

- preoperative x-ray assessment of bone deformities and deficiencies
- adequate exposure of the deficient femur
- prophylactic cerclage wiring
- complete removal of endosteal ridges (bone and cement)
- osteotomy or bowed stems for angular deformities
- intra-operative x-ray evaluation

Dislocations following revision total hip arthroplasties range from 2 to 25%. We found the following principles to lower rates of dislocations:

- assessment of intra-operative instabilities with trial components
- restoration of leg lengths and soft tissue tensions
- proper alignment of components
- post operative bracing and casting for select patients with soft tissue deficiencies
- patient education concerning "safe limits" of motion for their reconstruction

Cementless application of the S-ROM™ Total Hip Porous coated devices are limited by U.S. Federal law to investigation use.

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AN INTERNATIONAL MULTI-CENTER STUDY ON THIGH PAIN IN TOTAL HIP REPLACEMENTS

by

Hugh U. Cameron, Toronto, Ontario

Lorence Trick, San Antonio, Texas

Bruce Shepherd, New South Wales, Australia

Alan Turnbull, New South Wales, Australia

Douglas Noiles, Stamford, Connecticut

Timothy McTighe, Stamford, Connecticut

A SCIENTIFIC EXHIBIT AT THE 1990 AAOS MEETING
NEW ORLEANS, LOUISIANA

INTRODUCTION

Thigh pain has not been a clinical problem with cemented femoral components. However, with the increase in femoral cementless surgery over the past 6-10 years, thigh pain has become an increasingly encountered clinical problem. Incidences of 10-30% have been reported with most cementless devices.

At the recent December, 1989, Current Concepts Meeting in Orlando, Florida, Dr. Charles James reported on the following statistics concerning thigh pain:⁶

James - AML™

- 12% proximal 1/3 coating
- 6% 5/8 coating

Engh - AML

- 15% proximal 1/3 coating
- 5% 5/8 coating

Dorr - APR™ (Type C-bone)

- 62% at 6 months

Galante - HG™ Stem (Average follow-up 44 months)

- 76.5% no pain
- 19.3% slight pain
- 1.5% mild pain
- 0.7% moderate pain
- 0.0% severe pain

The purpose of this exhibit is to review different implant designs and materials relative to post-operative thigh pain.

Thigh pain can be a multi-factorial problem.

1. Loose implant
2. Modulus mismatch
3. Infection
4. Spine etiology

However, we will show that two specific scenarios exist for most post-operative thigh pain. The first is implant instability (torsional and /or axial) and the second is modulus mismatch between the implant and the bone at the distal tip of the implant.

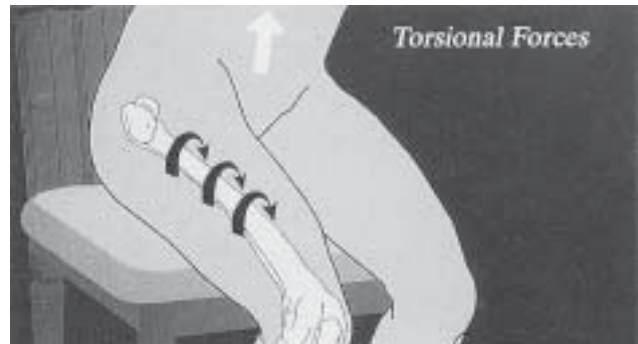
This exhibit clearly demonstrates how

It is generally agreed that fit and fill are necessary to achieve immediate implant stability for cementless devices. Current cementless press fit designs and techniques can achieve excellent stability against axial loading, however, many daily activities produce high torsional loads in the femur which can cause loosening of the femoral component.^{3,4,7}

Achieving a tight proximal fit is difficult due to the varying geometry of the proximal femur. Noble et al, reported that a constant proportional relation-hip is not present between the shape and size of the metaphysis and diaphysis of the femur.⁸

If torsional and/or axial instability is a major cause for femoral component

loosening and thigh pain, then designs and techniques must be developed to achieve a tight proximal and tight distal fit. Whiteside has shown that a tight fit in the metaphysis and diaphysis can be obtained with significant improvement in resistance to torsional loading. This may have a positive effect on clinical results.⁹



Torsional forces

MATERIALS AND METHODS

A total of 1055 patients have been evaluated for thigh pain after receiving a primary total hip replacement. An array of different designs and materials has been used. The selections include 6 different designs utilizing 4 different materials with only 1 design utilizing acrylic cement for fixation.

STEM DESIGN	MATERIAL	FIXATION
1. PCA™	Chrome-cobalt	Porous press fit
2. Harris /Galante™	Titanium alloy	Titanium fiber pads, press fit
3. Isoelastic™	Polyacetal	Press fit
4. Porous Polysulfone™	Composite titanium alloy and polysulfone	Porous polysulfone press fit
5. S-ROM™	Titanium alloy	Porous titanium press fit
6. International™	Titanium alloy	Cemented



NON-CEMENTED STEMS

PCA

PCA is made of chrome cob, available in a variety of right and left femoral stem sizes which are proportional to the physiological shape of the femur to improve initial fixation stability and stress distribution at fixation interfaces.

Varying neck lengths are achieved through a choice of three interchangeable femoral head components which lock onto the femoral stem by a modular taper neck design.

A variety of long stems are available for revision situations.



Ingrown - thigh pain associated with strenuous activity

HARRIS/GALANTE

The HGP™ Stem is a straight stem design manufactured of titanium alloy. It is designed with a Morse taper neck and will accept a variety of head sizes and lengths. The stem is designed with rounded corners, its proximal cross-section is trapezoidal. It has a high rounded shoulder with a straight lateral margin to the tip of the prosthesis. The distal stem is a rounded



4 year Post Op. - Pain free

configuration with four grooves. Flat pads are commercially pure titanium mesh which has been applied in recesses on three sides (anterior, posterior and medial) of the proximal third of the stem. The pads are diffusion bonded to the implant substrate.

The stem incorporates a thin medial collar which is designed to contact the calcar, after precision rasping. The overall geometry and neck and stem lengths are virtually identical to the Harris Precoat™ stem.

POROUS POLYSULFONE

Description

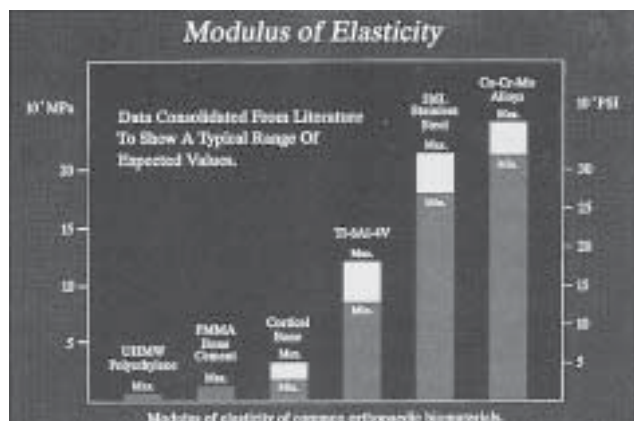
The femoral component is made of titanium alloy with a collarless design with porous polysulfone over 5/8 of the device. The stem is available in six sizes and lengths are proportionate to the size. The design features a modular taper neck that will accept either ceramic or chrome cobalt heads. The physical characteristics of the coating are: 33%, porosity, 250 micron-pore size, low modulus 0 /7 that of chrome cobalt).

Theoretical Advantages

Utilization of a high-strength, porous plastic coating can produce more flexible stems (by reducing metal cross section), thus reducing the modulus mismatch between implant and bone.



15 month Post Op. - Painful when ambulates without aid



Modulus of elasticity

S-ROM

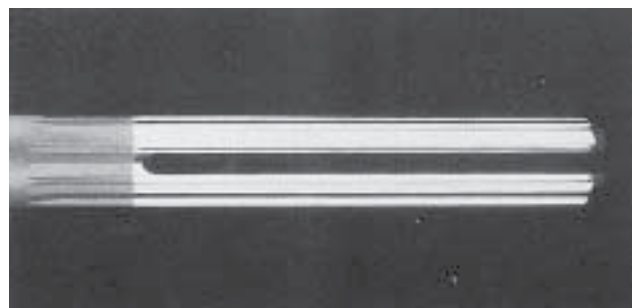
Description

The S-ROM stem has three distinguishing dimensions:

1. Stem Diameter (proximal and distal)
2. Stem Length
3. Neck Length

These stems have a proximal taper, a fluted straight distal diameter, and a taper lock head fitting. A proximal taper permits the use of a variety of self-locking, proximal sleeves to provide optimum load transfer to the proximal femur. The tapered head fitting permits a variation in neck lengths and head diameters.²

The fluted distal stem design has a minor and a major stem diameter. The flute depth is approximately 0.5 mm. There are presently six stem diameters available. Stem lengths are available in standard long, extra long, and extra-extra long lengths. All stems have a coronal distal slot (clothespin). Long, extra long and extra-extra long stems are available in either neutral or bowed left or right.



S-ROM coronal split

The ZTT™ proximal sleeves have two distinct dimensions. First is a conical body that is available in three sizes at 2 mm increments for each stem size. The second dimension is the triangle portion which is available in two sizes on the smaller cones and three sizes on the largest cone.

The array of styles and sizes of the S-ROM proximal sleeves allows the surgeon to build a custom-type fit at the time of surgery for each patient while using standard stock items. This gives the advantage of adapting the prosthesis to the geometry of the patient.

ISOELASTIC

Description

The prosthesis is made of acetalcopolymer. Polyacetal resin has an elastic modulus approaching that of bone. It is highly durable with excellent biocompatible properties. The surface of the proximal part of the stem has 2 turn notches with small connections where bone growth can interlock. The distal part of the stem has a grooved surface. To achieve structural strength in the neck, the component is reinforced by a metallic core that is tapered towards the distal tip. Additional fixation is accomplished by use of two proximal cancellous bone screws.

The prosthesis is available in six diameters and is 150 mm in length. Longer stems (180 turn and 240 mm) are available for revisions.



4 year Post Op. - Painful - Revised to S-ROM

MENTED STEMS

ERNATIONAL

-fixed, cemented stems do not have
1 pain because of two significant
rs. First, the acrylic cement prevents
ficant micromotion that would result
ial or torsional instability. Second,
ern cementing technique involves
ging the femoral canal approximately 1
cm below the distal stem. The cement
eases the differential movement
een the bone and the implant thus
cing likelihood of the femur engaging
tiff distal stem.

: the past four years the senior author
mplanted over 300 cemented stems for
ary total hip replacement. There has
een a single case of end stem thigh
encountered. However, radiographic
ence of loosening in other cemented
ces does correspond with clinical
ptoms of thigh and/or hip pain.



Well fixed cemented
stem - no pain

Loose cemented stem -
painful

SUMMARY OF RESULTS
Percentage of thigh pain

ription	1yr*	2yr	3yr	4yr	5yr
national mented)	-0-	-0-	-0-		
DM	2.3%	0.4%	-0-	-0-	-0-
DM/solid	33.3%	33.3%			
i	5.2%	0.1%	2.7%	-0	
astic	9.0%	7.2%	7.2%	14.8%	
	30.0%	35.0%	34.0%	37.5%	45.8%
	47.0%	52.0%	58.0%		

istical data:

S-ROM w/ coronal split
(Bone Type A, B, C)

<u>Description</u>	<u>1yr</u>	<u>2yr</u>	<u>3 yr</u>	<u>4yr</u>	<u>5yr</u>
None	295	222	200	150	50
Slight	7	1	-0-	-0-	-0
Moderate	-0-	-0-	-0-	-0-	-0
Severe	-0-	-0-	-0-	-0-	-0
Revised	-0-	-0-	-0-	-0-	-0
Total Follow Up	302	223	200	150	50
% Encountering Pain	2.3%	0.4%	0.0%	0.0%	0.0%

S-ROM Solid



Painful (6 months) - Pain subsided by 12 months

S-ROM Modified



Shortened coronal stem - Pain free

S-ROM w/Coronal Split



Pinched closed - Painful (6 months) - Pain subsided by 12 months



Open - Pain free

S-ROM Solid
(Bone Type B, C)

<u>Description</u>	<u>6mo</u>	<u>1yr</u>	<u>2yr</u>
None	1	4	4
Slight	5	2	2
Moderate	-0-	-0-	-0
Severe	-0-	-0-	-0
Revised	-0-	-0-	-0
Total Follow Up	6	6	6
% Encountering Pain	83.3%	33.3%	33.3%

Harris/Galante
(Bone Type A, B)

<u>Description</u>	<u>1yr</u>	<u>2yr</u>	<u>3yr</u>	<u>4yr</u>
None	72	62	35	7
Slight	3	-0-	1	-0
Moderate	1	1		-0
Severe	-0-	-0-	-0-	-0
Revised	-0-	-0-	-0-	-0
Total Follow Up	76	63	36	7
% Encountering Pain	5.2%	0.1%	2.7%	0.0%

Isoelastic
(Bone Type A, B)

<u>Descriptio</u>	<u>1yr</u>	<u>2yr</u>	<u>3yr</u>	<u>4yr</u>
None	158	153	102	23
Slight	13	8	3	-0
Moderate	3	3	1	
Severe	-0-	1	4	-0
Revised	-0-	-0-	-0-	4
Total Follow Up	174	165	110	27
% Encountering Pain	9.0%	7.2%	7.2%	14.8%

PCA
(Bone Type A, B)
(High percentage of stems were undersized)

<u>Description</u>	<u>1yr</u>	<u>2yr</u>	<u>3yr</u>	<u>4yr</u>	<u>5yr</u>
None	58	50	49	40	13
Slight	15	21	17	14	9
Moderate	7	4	7	7	1
Severe	3	2	2	3	1
Revised	-0-	1	1	-0-	1
Total Follow Up	83	77	75	64	24
% Encountering Pain	30%	35%	34%	37.5%	45.8%

PPS
(Bone Type A, B, C)

<u>Description</u>	<u>1yr</u>	<u>2yr</u>	<u>3yr</u>
None	60	42	13
Slight	37	35	11
Moderate	14	11	6
Severe	3	1	1
Revised	-0-	7	10
Total Follow Up	114	89	31
% Encountering Pain	47%	52%	58%

International (cemented)
(Bone Type A, B, C)

<u>Description</u>	<u>1yr</u>	<u>2yr</u>	<u>3yr</u>
None	300	275	200
Slight	-0-	-0-	-0
Moderate	-0-	-0-	-0
Severe	-0-	-0-	-0
Revised	-0-	-0-	-0
Total Follow Up	300	275	200
% Encountering Pain	0.0%	0.0%	0.0%

Definition of Pain Score

None	Self explanatory
Slight	No pain medicine and does not effect activity
Moderate	Analgesic and does effect activity if overdone
Severe	Analgesic and requires walking aid

SUMMARY

In reviewing two separate low modulus composite designs, there was an unacceptable high rate of pain due to aseptic loosening. The Isoelastic stem, however, was statistically better than the PPS. This might be due to the proximal geometry which offers more surface area resulting in increased stability. Both devices, however, have increasing thigh pain and revision rates suggesting implant instability.

In using low modulus material it is apparent that it is difficult to achieve the required proximal rigidity needed to achieve implant to bone stability.

Looking at one particular anatomical design we find a higher than average incidence of thigh pain, which progresses from 30 to 45.8% in five years. This would also indicate implant instability.

The two titanium straight stems did considerably better than the curved or low modulus devices. In addition the early thigh pain encountered subsided with time. This pain subsidence was due to bony distal changes which reduce the modulus mismatch between the bone and stiff implant. The clinical scores would also indicate that Noble is indeed correct on his work showing stability of straight stems to be superior to anatomical stems.⁸

Implant to bone stability must be the first priority in utilizing cementless devices. A reduction of the modulus of the distal stem is necessary to reduce modulus mismatch. However, in using composite materials with a low modulus it is difficult to maintain proximal rigidity.

No stems were revised due to thigh pain brought on by modulus mismatch. All stems which were revised had progressive thigh pain indicating implant instability.

Thigh pain (distal modulus mismatch) is a clinical symptom that is not progressive and tends to diminish as the distal host bone remodels due to distal stress transfer. One can predict the patient profile for thigh pain due to modulus mismatch.

1. Type C bone
2. Acute anterior - bow
3. Activity level of patient (moderate to high)
4. Large distal diameter device

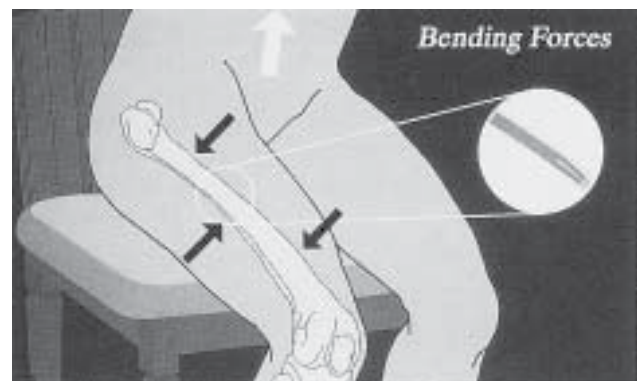
One can effectively reduce thigh pain by:

1. Fit and fill for torsional stability
2. Onlay cortical grafts (increase modulus of bone)
3. Reduce bending stiffness of distal stem (coronal split)

Ways to reduce bending stiffness of stem:

ActionApprox. Reduction
(change from CC)

- | | |
|--|-----|
| 1. C. C. to Ti Alloy | 50% |
| 2. 20% reduction of stem diameter | 50% |
| 3. Ti Alloy w/coronal split | 80% |
| 4. Ti Alloy hollow stem ¹ (theoretical) | 70% |



Bending forces

In comparing the two S-ROM stems (one solid, the other split in the coronal plane), we find a higher percentage of thigh pain in the solid stem. This would indicate that greater than 50% reduction of distal bending stiffness is needed to effectively reduce thigh pain due to modulus mismatch.

The S-ROM and H / G showed far better results concerning thigh pain. We think this is generally due to the effectiveness of straight titanium stem design.

The S-ROM with a coronal split showed best overall results. Initial stability is achieved by fitting and filling the proximal femur with a sleeve similar in concept to fitting and filling with bone cement. Distal torsional stability is achieved by eight flutes which engage the cortical bone. Distal

modulus mismatch is reduced approximately 80% by splitting the distal stem in the same bending plane of the femur; then as the femur bends or bows, the implant bends reducing point contact and pressure.

This has also been done in Dr. Dorr's new revision stem design that also incorporates a coronal split.⁵ His early clinical results are similar to those for the S-ROM presented here.

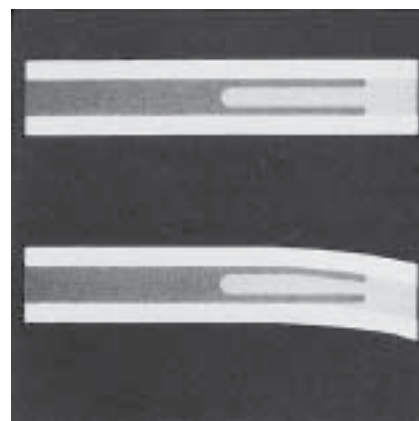
DISCUSSION AND CONCLUSION

There are considerable theoretical advantages of cementless devices versus cemented devices. However, cementless devices must achieve the initial short-term clinical results that can be accomplished by utilizing cement.

Fit and fill are necessary to achieve axial and torsional stability. This does not necessarily mean a reduction in end stem pain due to distal modulus mismatch.

Pain caused by distal modulus mismatch tends to subside as distal bone remodeling occurs.

Reducing the distal bending stiffness by a coronal slot design effectively reduces end stem pain. This suggests that distal modulus mismatch is one of the causes of end stem pain.



At Rest

*Coronal Split
(Clothespin) design
reduces modulus
mismatch,
decreasing the
bending stiffness of
the component.*

Isoelastic and International – These devices not available for distribution in U.S.

PPS – This device is limited by U.S. Federal law to investigational use.

S-ROM, PCA and H/G – Cementless application of these porous coated devices are limited by U.S. Federal law to investigational use.

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DESIGN FEATURES AND EARLY CLINICAL RESULTS WITH A MODULAR PROXIMALLY FIXED LOW BENDING STIFFNESS UNCEMENTED TOTAL HIP REPLACEMENT

By Hugh U. Cameron, Yung-Bok Jung,
Douglas G. Noiles, and Timothy McTighe

A SCIENTIFIC EXHIBIT AT THE 1988 AAOS MEETING
ATLANTA, GEORGIA

"S-ROM™ MODULAR STEM SYSTEM"

INTRODUCTION

For an uncemented femoral component in total hip replacement to be successful, it is universally agreed that initial stability is essential. In order to achieve stability, diaphyseal (distal) and metaphyseal (proximal) fill is required. "Fill" means that the implant approaches the endosteal cortex. The reason for this is that the strength of the intramedullary bone increases with the proximity to the endosteal cortex.

Distal stem diameter is determined by diaphyseal reaming. Modern techniques of intramedullary nail insertion demands removal of a certain amount of endosteal cortex. It seems reasonable, therefore, to insert a hip stem in the same fashion. IM nails are all split to allow some closure thus reducing the risk of splitting the femur. As weight is applied to the femur, the femur tends to flex into the direction of the anterior bow. A stiff metal rod is unlikely to flex, therefore, relative movement between the stem tip and the bone occurs. This can produce so-called, "end-pain." If the stem tip is split in the coronal plane, the split decreases the bending stiffness of the tip of the femoral component. If the component is made of titanium rather than cobalt chrome, the

A short circular cross section stem has minimal resistance to rotation. As rotatory forces on the hip stem are quite high, it seems reasonable to add flutes to the distal stem to provide rotatory stability.

These facts, when combined, define distal stem geometry and insertion techniques. The stem is titanium, circular, fluted, and split in the coronal plane. It is inserted like an intramedullary nail requiring intramedullary reaming of the endosteal cortex and firm driving. A stem of this nature provides distal stability without distal fixation.

The metaphyseal geometry does not necessarily have any relationship to diaphyseal geometry. In order to fill the diaphysis and metaphysis without a custom prosthesis, a large number of implants with different geometries would be necessary for every stem size. In these days of fiscal constraint, this is not possible. The solution to this dilemma is to make the metaphyseal portion detachable or modular. By this means, a variety of different proximal geometries can be created for every stem size. This variety is provided by having a series of sleeves for the metaphyseal region which attach to the stem by means of a taper lock.

Taper locks or Morse cones, which attach modular heads, have been in use in

DESIGN CONSIDERATIONS

A 3' per side taper was chosen. The worst case hoop tension in the sleeve is about 32,000 psi. However, the hoop stress created by the heaviest load applied is never released because of the taper locks, and thus is not a cyclic stress. Therefore, the low fatigue strength of porous coated titanium alloy is not a limiting factor. The tensile strength of the porous coated titanium is over 400,000 psi., and no porous coated sleeve has failed in an extended series of fatigue tests where the stem was taken to failure'.

The initial sleeve used was a conical selftapping threaded sleeve. This proved technically difficult to insert and had a long "learning curve." In spite of this, the results have been very good, especially the virtual absence of thigh pain.

The second sleeve to be tested was the sleeve which roughly matched the geometry of the metaphyseal cancellous bone cavity. In order to insert this accurately, it was realized that hand broaching could not be used, therefore, a proximal conical reamer and calcar miller were developed. The canal is now totally prepared by reaming with no broaching at all.

The sleeves were designed with proximal steps or ridges in order to convert hoop stress in the proximal femur to compressive loads. A few of these have been implanted and have functioned very well. These were called the ZT™.

It was recognized that this sleeve could be porous coated with titanium beads thus increasing interfacial fixation. The coating of the sleeve rather than the stem provided some spectacular potential Solutions to various problems associated with porous coatings.

When porous coating a super alloy, the necessary heat treatments frequently degrade the metallurgy of the substrate metal leading to serious weakening. Coating the sleeve, however, leaves the stem a "superalloy" which is unlikely to fail. Furthermore, as a fully impacted sleeve is subject to uniform noncyclic hoop stress, the chance of crack propagation in this sleeve is remote.

In a shear load mode, bead separation is a potential problem. The static shear strength of

most beaded systems is about 30 MPa. Therefore, dynamic shear leads over 10 MPa are likely in the long run to cause failure at the bead substrate metal interface. The simplest form of protection is to convert shear loads to compressive loads by means of steps.

Lastly, one of the major problems with in-growth implants - retrieval - was solved. Should the hip require removal, the stem can be backed out of the sleeve and the fixation attacked from above and below. If all else fails, the sleeve can readily be cut up in situ with a powerful high speed burr.

A further advantage of this sleeve was noted when doing CDH cases. The femoral neck is frequently anteverted. If the hip is inserted for maximum metaphyseal coverage, it ends up too anteverted and dislocation can ensue. With detachable sleeve, however, the sleeve can be inserted for maximum bony contact and the version of the femoral component can be oriented for optimal function and locked in position by the Morse taper and distal flutes.

HISTORY

Threaded femoral components for intramedullary fixation were first used by McBride² in 1948, and more recently by Bousquet³ and Bornand in Europe. The current S-ROM™ System represents the fourth generation in the evolution of the Sivash Total Hip System since it was introduced in the United States in 1972.

Sivash⁴ began development of a total hip prosthesis in 1956 at the Central Institute for Orthopaedics and Traumatology, Moscow, Russia. By 1967, Sivash had selected titanium alloy material for the femoral stem and proximal sleeve and chrome cobalt alloy for his acetabular component, socket-bearing and femoral head. His major focus included the design of a constrained socket. The Sivash System, introduced in the United States by the U.S. Surgical Corporation, never received major clinical or market success, partially due to the difficulty of the surgical technique, and the positioning of this constrained device. However, one must not overlook three major areas of contribution made by Sivash:

1. Titanium alloy for femoral stem and chrome cobalt for head articulation.

2. Cementless (threaded) petalled acetabular component.
3. Titanium alloy proximal sleeves for enhanced collar calcar contact.

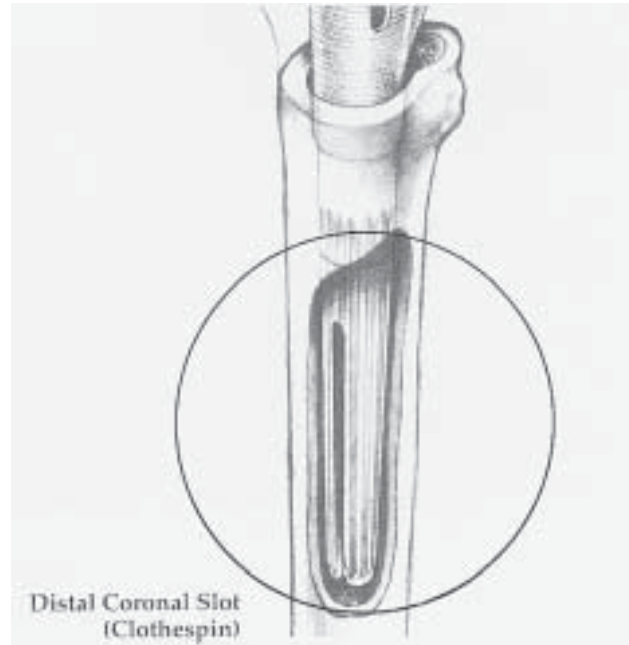
Sivash's work in the area of titanium and chrome cobalt predates the earliest publication of the acceptable combined use of these two materials, by Bultitude and Morris of the British Atomic Weapon Research Establishment in 1969.



Early clinical experience in the United States with the Sivash prosthesis was mixed. The prosthesis was developed and intended for non-cemented use, therefore, the technique was quite demanding. In 1972, the FDA approved the use of bone cement, which resulted in diminishing interest in cementless devices. Further, the original femoral stem was a round tapered peg, which led to a number of noncemented failures due to rotation of the stem in the femur. A number of these prostheses were cemented. Another design feature of this prosthesis was two medial to lateral fenestrations in the distal stem. These fenestrations caused stress concentration in the distal stem when cement in the femur failed proximally, resulting in stem failures.

In 1975, Noiles, working with Russin, redesigned the stem of the Sivash prosthesis to improve its function in cementless arthroplasty by adding features which would prevent failure by rotation of the stem in the femoral canal. The resulting stem, the SRN™,

incorporated eight longitudinal flutes similar to that of the Samson intramedullary rod. Since the stem was intended for cementless use, a multiplicity of macro cross-slots or crenelations were incorporated in the anterior and posterior aspects of the stem. In addition, after some additional laboratory research, a design modification was made to avoid the potential risk of splitting the femur by adding a distal coronal slot, like that of a clothespin.



This modification reduces the bending stiffness by design, insuring minimal distal-load transfer. In addition, Noiles redesigned the circular proximal sleeve to a more acceptable eccentric design. These modifications created what is known today as the SRN Total Hip System.



Dr. Benjamin Meyer⁵ (now deceased) of Birmingham, Alabama, used a self-tapping threaded proximal sleeve in conjunction with the SRN™ Total Hip Stem. A final redesign variant produced a stem with distal flutes and



slot, but without the cross notches or crenelations of the SRN. This stem series, designated S-ROM, is used with a large array of proximal taper-lock sleeves, all of which are designed to optimize proximal fixation in the femur. This stem when used with the S-ROM acetabular series provides stability with enhanced range of motion.

Cameron began his clinical use of the threaded proximal sleeve and the S-ROM Stem in July, 1984. While the threaded proximal sleeve has shown to give excellent short term clinical results, its surgical technique is quite

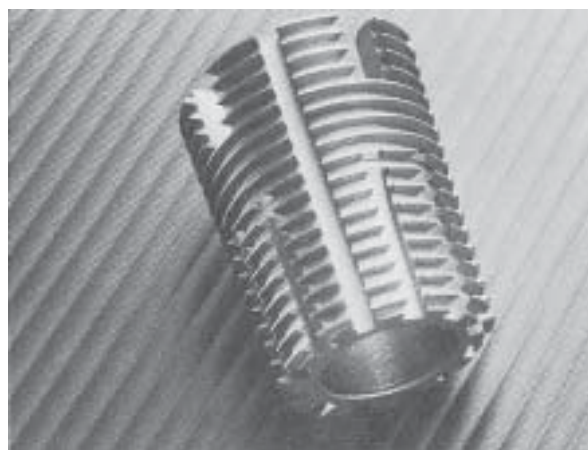


demanding. In an attempt to reduce the surgical demands, a large array of press-fit proximal taper-lock sleeves have been developed. All of which are designed to optimize proximal fixation in the femur. The designs of these proximal sleeves have progressed over the last several years to include press-fit and porous coated anatomical contours, press-fit and porous coated cones and self-tapping threaded cones. This system provides the first truly modular ability to treat the distal and proximal femoral areas separately to achieve a more custom-type fit.

Gorski⁶ has demonstrated the viability of this system in treating total hip replacement for congenital dislocations of the hip in a case report pending publication. Cameron⁷ has also shown the versatility of this system in treating fusion takedowns.

CLASSIFICATION OF PROXIMAL S-ROM™ SLEEVES

SPT (SECURE PROXIMAL THREADED)



The SPT™ femoral sleeves have an exterior self-tapping conical bone screw thread for achieving immediate, secure, mechanical fixation in the proximal femur. The matching stems fit the inner locking taper of the sleeves.

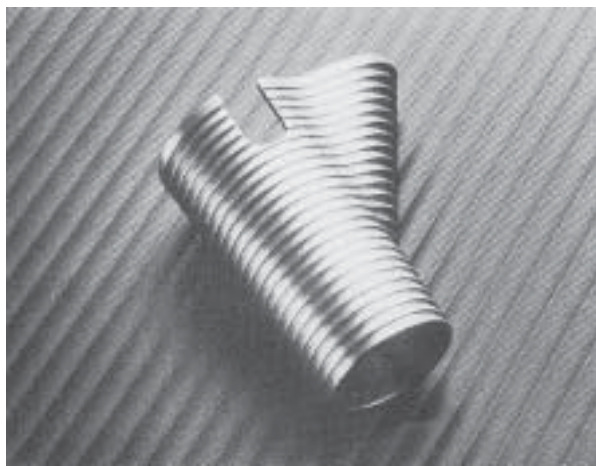
S-ROM femoral stems are available in proximal diameters: 14,16,18,20, and 22mm. The corresponding SPT sleeves are identified by the appropriate proximal diameter, and for each proximal diameter size there are three sleeve sizes which graduate in size by major thread diameter. The sleeves in each proximal size have their major thread diameters designated by a letter code: C, D, and E. Thus, there are 15 SPT sizes.

SPA (SECURE PROXIMAL ARTHOPOR)



The SPA™ sleeves are porous coated cones, and are available in A and B sizes for each of the five corresponding stems: 14, 16, 18, 20, and 22mm. These sleeves are indicated for both primary and revision surgery when one is dealing with little or no metaphyseal portion of the femur.

ZT B-CONE SERIES (ZERO SHEAR)



The ZT™ sleeve is an anatomical design with proximal steps or ridges. The function of the sleeve is to convert unnatural hoop stresses usually created by total hip replacement to compressive stresses, thus reducing the likelihood of resorbative bone remodeling and latent aseptic femoral component loosening.

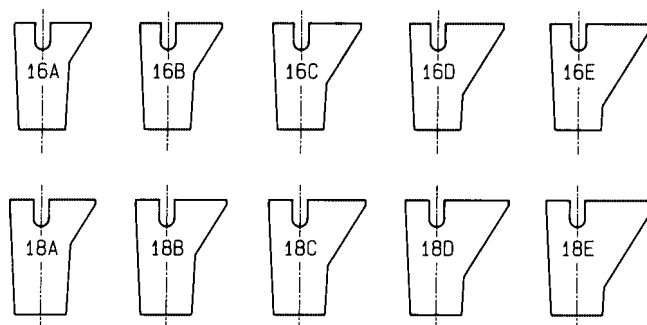
The modular aspect of the style and sizes of these sleeves allows the surgeon the ability to custom-fit both the proximal and distal portions of the femur, and to custom fit both the cone and the calcar region. For each stem

size, the B-Cone series is available in five triangle sizes, ranging from A to E. These sleeves are available for the following femoral sizes: 16, 18, 20, and 22mm. Sleeves for each stem size have a constant cone dimension (B-Cone).

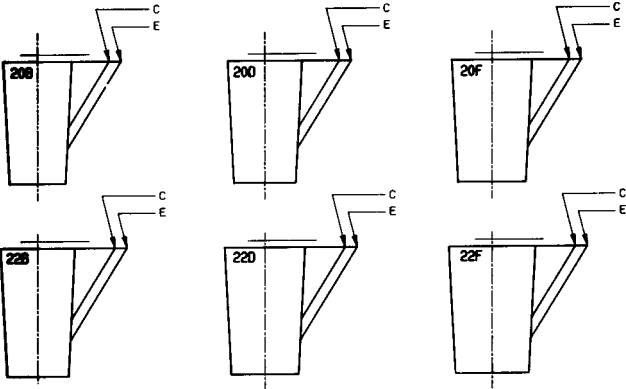
ZTT B-CONE SERIES (ZERO SHEAR TEXTURED)



The ZTT™ B-Cone Series is of identical geometry to the ZT B-Cone Series with the addition of one layer of commercially pure titanium beads sintered to the substrate. While this one layer does not detract from the basic geometry of the ZT, it does allow for enhanced implant interfacial strength. The ZTT B-Cone Series is available in the same size selection as the ZT B-Cone Series.



ZTT GRADUATED CONE SERIES



This series is the same design configuration as the ZTT B-Cone Series. It has been designed to include additional sizes which increase proportionately in both the cone and triangle portions of the sleeve. This series offers three cone diameters with two triangle sizes each, for each corresponding stem size.

EXAMPLE: FOR 20mm STEM

CONE	TRIANGLE Sm. & Lg.
B	C&E
D	C&E
F	C&E

This results in six possible sizes for each stem.

SRN (ALLOGRAFT SLEEVE)



The SRN™ sleeve has been reborn with a new interest and indication as an allograft sleeve. This sleeve has an eccentric collar which allows

collar to calcar contact. It has proven helpful in grossly deficient femurs where bulk allograft is used. The proximal portion of the stem and sleeve are cemented into the allograft, preventing any possible micromotion of the stem and sleeve within the allograft. A step or oblique cut is made in the distal portion of the allograft and the proximal portion of the host femur. The two portions are married together with the distal fluted stem being inserted into the host femur cementless. The distal flutes on the S-ROM stem aid in rotational stability of the device while the SRN collar loads the allograft in compression.

The SRN sleeve is available in one size only for each of the following stem sizes: 16, 18, and 20mm.

The array of styles and sizes of the S-ROM proximal sleeves allow the surgeon to build a custom-type fit at the time of surgery for each patient while using standard stock items. This not only reduces inventory requirements, but also gives the advantage of adapting the prosthesis to the geometry of the patient resulting in a more consistent clinical result.

S-ROM™ STEM DESIGN

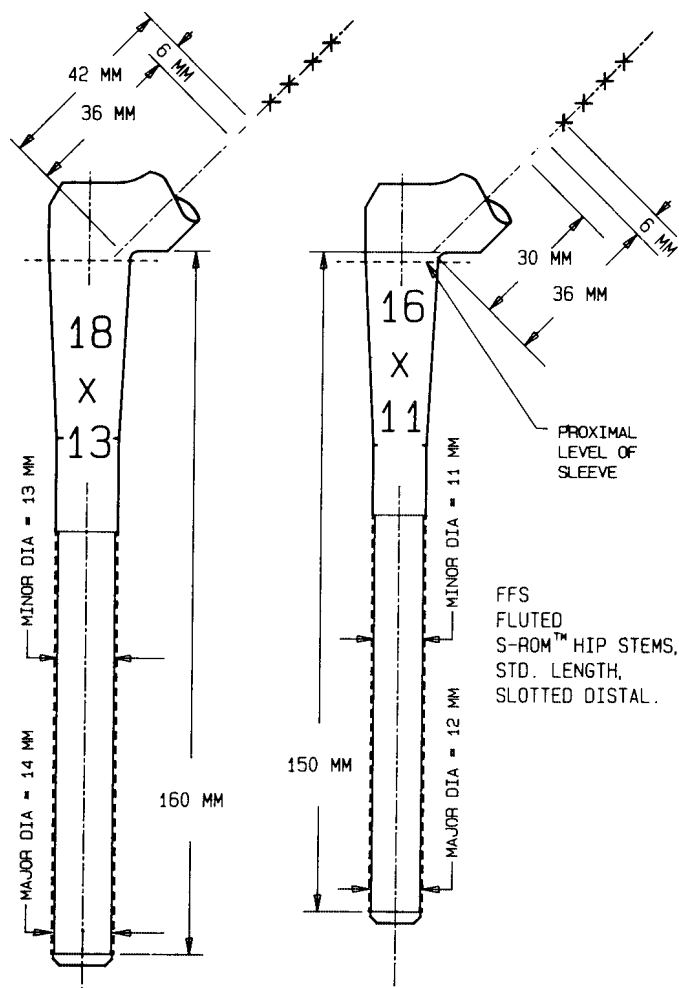
The S-ROM Stem has four distinguishing dimensions:

- 1. Stem Diameter (Proximal & Distal)
- 2. Stem Length
- 3. Neck Length
- 4. Head Diameter

All of these stems have a proximal taper, a straight distal diameter, and a taper lock head fitting. A proximal taper permits the use of a variety of self-locking proximal sleeves to provide optimum load transfer to the proximal femur. The tapered head fitting permits a variation in neck lengths and head diameters.

STEM DIAMETER IS SPECIFIED BOTH PROXIMALLY AND DISTALLY

The first two numbers of the stem size designate these diameters. Example: 18 x 13 x 160mm stem, has an 18mm proximal diameter and a 13mm root distal diameter. The flute depth is approximately 0.5mm. There are presently five proximal diameters: 14, 16, 18, 20, and 22mm.



STEM LENGTH IS MEASURED FROM THE DISTAL SHOULDER SURFACE TO THE EFFECTIVE DISTAL END OF THE STEM

The third number of the stem size designates this length. Example: 18 x 13 x 160mm stem as mentioned above has a 160mm stem length.

The S-ROM stems are available in standard, long, extra-long, and extra-extra long lengths. All stems have a fluted distal circular cross section and also have a coronal distal slot (clothespin). The long, extra-long, and extra-extra long stems are available in either neutral or bowed, left or right.

The femoral head selection determines both the head diameter and the neck length. Femoral heads are available in 22, 28, and 32mm outside diameters. The 22mm head is available in one standard neck length, while the 28 and 32mm heads are presently available in the +0, +6, and +12 neck lengths. Femoral heads are made of forged chrome cobalt alloy, which allows a fine finish resulting in minimal wear debris.

RESULTS FOR S-ROM™ STEMS WITH SPT SLEEVES

CLINICAL RESULTS: SPT SLEEVE (Threaded)

48 Patients I - 3 year follow-up

29 Males / 19 Females

Age: 20 - 87 (average 55)

DISEASE: Primary Disease

Osteoarthritis	34
Rheumatoid Arthritis	8
Avascular Necrosis	6
Acetabular Dysplasia	12

TYPE:

Primary	26
Revision	15
Girdlestone	7

HARRIS RATING:

94%	Excellent
2%	Good
4%	Poor

TRENDELENBERG:

At Six Months	89%
At Twelve Months	4%
At Twenty-Four Months	4%

TECHNICAL ERRORS AT INSERTION:

Varus Position	6 cases
Undersizing	4 cases
Calcar Split	6 cases

TWO PATIENTS (4% have pain)

Both revisions were inappropriate for primary stem

RADIOLUCENCY:

ZONE:	1 - 7	5 - 1
	2 - 9	6 - 5
	3 - 5	7 - 5
	4 - 1	

TWO PATIENTS HAVE COMPLETE
RADIOLUCENCY, THIGH TIREDNESS
AFTER EXERTION.

BOTH VERY UNDERSIZED.



*Failed Surface
Replacement*

*Post-Op: S-ROM Stem
with SPT Sleeve*



*Pre-Op: Osteoarthritic
Left Hip*

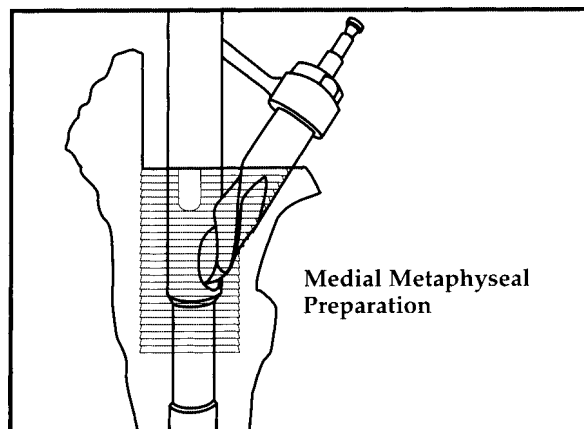
*Post-Op: S-ROM Stem
with ZT Sleeve*

*Post-Op: Distal
Lateral View
(Clothespin)*



PRELIMINARY RESULTS OF THE S-ROM™ STEM WITH THE ZTT™ SLEEVE

Fifty such cases have been done with a
followup of 3 - 15 months. Obviously it is too
early to give realistic results, but no problems
have been encountered. Canal preparation by
reaming rather than broaching has made this
simple and easy and no calcar splits have been
encountered.



In the initial ZTT sleeve, the cone part was the
same for all five triangle sizes for each stem
size. While this has worked well, experience
suggested that, as well as offering a variable
triangle size, the cone size should also vary.
Experience with this is limited, but it does seem
to provide enhanced endosteal contact.

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DIFFICULT HIP REPLACEMENT SURGERY: PROBLEMS AND SOLUTIONS

By Bruce D. Shepherd, Warwick Bruce,
William Walter, Eugene Sherry-Sydney, Australia;
Hugh U. Cameron-Toronto, Canada;
Timothy McTighe-Stamford, Connecticut, USA

A SCIENTIFIC EXHIBIT AT THE 1989 AACIS MEETING
LAS VEGAS, NEVADA

INTRODUCTION

In the last few years, total hip replacement surgery has become increasingly more sophisticated and demanding as we encounter more difficult and unusual situations.

Understandably, cases involving difficult hip replacement do not lend themselves to scientific review with meaningful, statistical analysis. They do, however, give an opportunity to discuss experiences with certain interesting and unusual problems.

This exhibit shows how two separate joint replacement centers, in collaboration with an implant manufacturer, have developed surgical solutions to the following hip reconstruction problems:

- Primary THA
- Revision THA
- CDH THA
- Takedown of Arthrodesis
- Femoral Angular Deformity
- Conversion/Retrievability

The S-ROMTM modular multi-component hip system is now the first choice for difficult hip problems at both Baulkham Hills Private Hospital and Orthopaedic Arthritic Hospital.

There are several different femoral problems in

total hip replacement which can be overcome by component design.

SIZE

Femurs come in a variety of sizes, with some femurs being very small or tiny, such as in high CDH cases. In these situations, the diaphyses are usually reamed vigorously. These patients are frequently young and may be very active thereby subjecting the femoral component to high loads. Therefore, the component must be made of a superalloy. Because they are young, it is preferable to insert the implant without cement. Porous coatings, however, damage the metallurgy, weakening the implant. One solution is to use a modular two-part stem, with the porous coating being applied to the proximal sleeve which then locks in place by means of a Morse-type taper. The sleeve is weakened, but because once locked in place on the stem, it is subjected to uniform non-cyclic hoop stress and, therefore, fracture of the sleeve is unlikely.

In addition, a two-part stem system allows the surgeon great versatility at the time of surgery of fitting the proximal femur while filling the distal canal. (Figures I & 2)

A proportionately long, stiff stem inserted tightly into a femoral canal can result in “end-

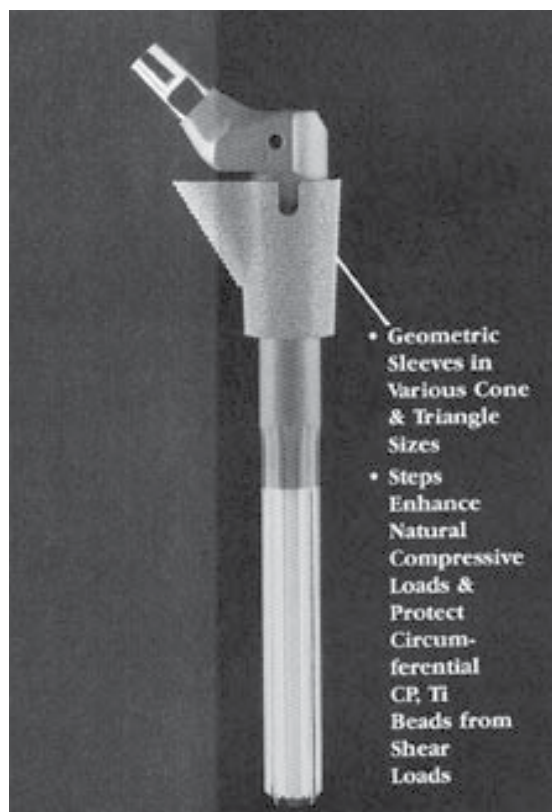


Figure 1.

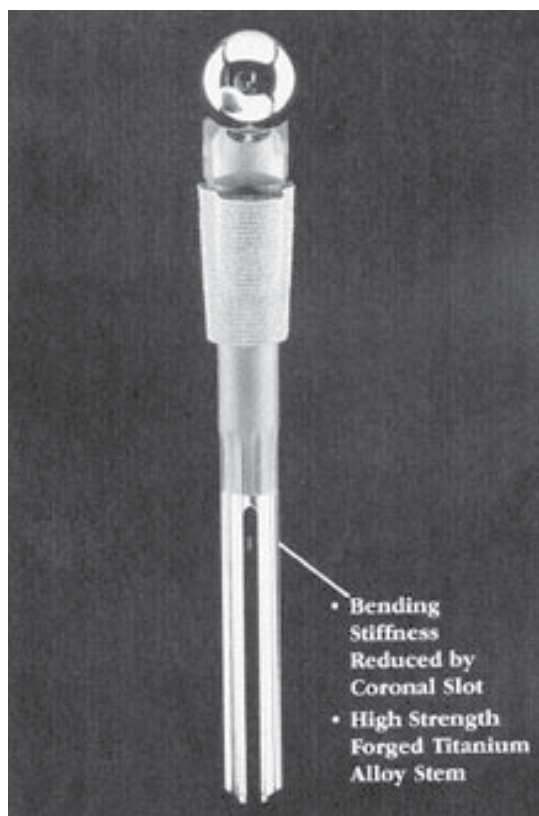


Figure 3.

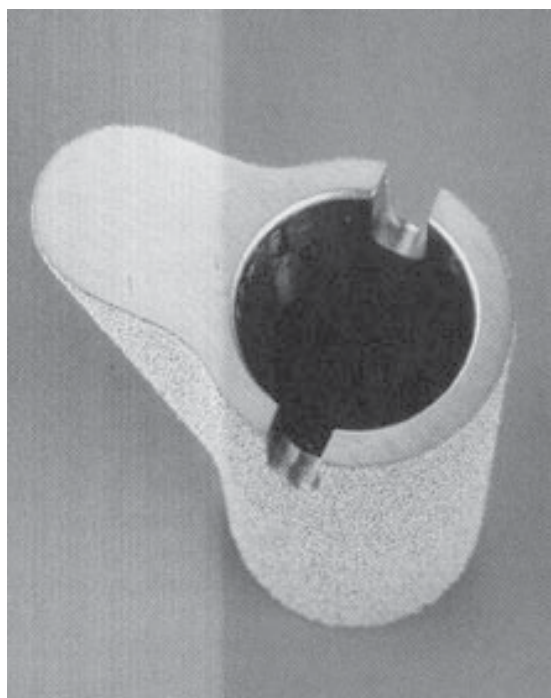


Figure 2.

stem pain” due to differential movement between the implant and the bone. This may be accentuated by vigorous reaming. As the direction of movement of the femur is into the anterior bow, the stem tip is split in the coronal plane. This decreases bending stiffness and appears to eliminate “end-stem pain”. (Figure 3)

FEMORAL ANTEVERSION

Abnormal femoral anteversion in CDH cases is common and may be extreme. This makes uncemented total hip replacement difficult. If maximum metaphyseal fill is achieved, the prosthesis ends up too anteverted. Insertion in correct version means poor metaphyseal fill. Use of a fixation sleeve eliminates this problem. The sleeve is inserted for maximum fill and the stem is locked into the sleeve in the appropriate version. Maximum fit can therefore be achieved. (Figure 4)

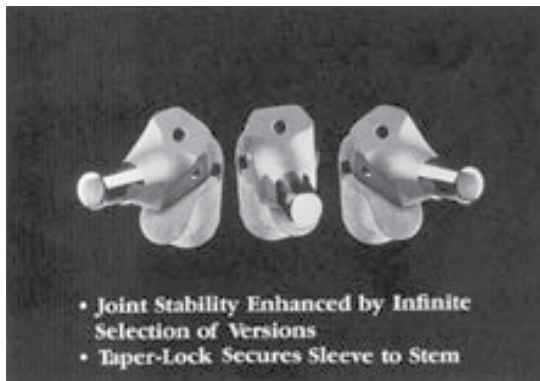


Figure 4.

EMSIONS

Proximal bone loss makes revision surgery difficult. If loss is not too severe, the sleeve can be set out at any angle to rest on the patient's own bone (which can rapidly hypertrophy) rather than allograft bone, which takes a long time to reconstitute. A long neck revision component, with a range of modular neck lengths, allows proper leg length adjustment.

In the deficient proximal femur it is difficult to achieve rotational stability of the implant. In this situation the prosthesis must be stabilized distally. Distal stability is preferable over distal fixation. Distal stability is necessary to allow proximal allograft bone to reconstitute. However, if distal fixation is achieved, proximal loading might be bypassed. With little or no proximal support, huge rotary loads are applied to the distal end of the prosthesis. These are resisted by fluting the distal stem like a Sampson nail and reaming to the minor diameter so that the flutes engage the cortex. (Figure 5)

Fluting must extend a fair way proximal to allow cortical engagement even in very deficient femurs. If necessary, the whole medulla of the distal femur, as it begins to flare above the knee, can be filled with pure cancellous allograft. Obviously, such a long stem necessitates an anterior bow of 70 to 100, beginning at the 200 mm level and the distal end of the stem is designed in the shape of a clothespin which helps minimize anterior femoral perforation.

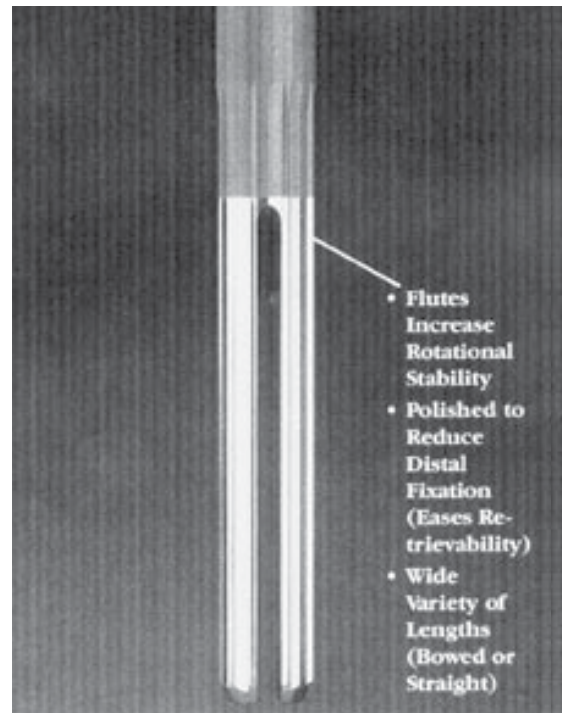


Figure 5.

This clothespin-effect also minimizes “end-stem pain”.

ROTARY AND ANGULAR DEFORMITIES

Rotary or severe angular deformities, and the occasional revision which requires retrieval of a fully porous coated implant, are treated by femoral osteotomy. The sleeve can be securely fixed in the proximal host bone at the orientation that best fits the bone. The stem is inserted into the taper lock sleeve and the proximal bone. This combination is then implanted in the distal bone, where the fluted stem provides rotational stability. The same situation pertains where massive bulk allografts of the proximal femur are used. The proximal stem and sleeve may be attached to the allograft by means of bone cement. The junction between the allograft and host bone is cementless along with the fixation of the distal portion of the stem.

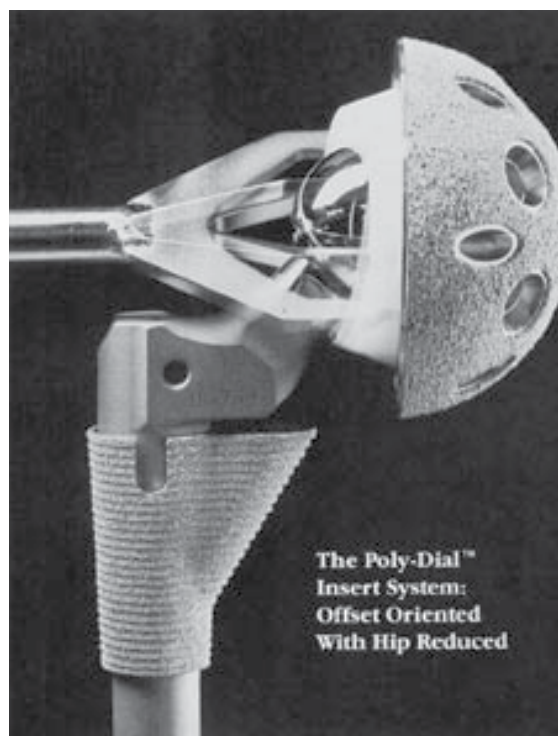


Figure 6.

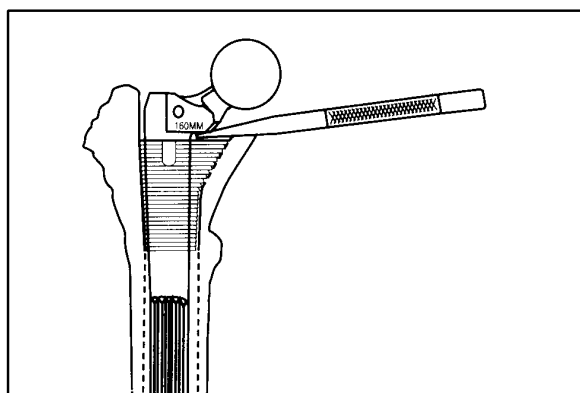


Figure 7.

CONVERSION/RETRIEVABILITY

One of the main difficulties in hip surgery is conversion or retrievability of implants.

Conversion is the need to adjust or reposition some components. Example, dialing a polyethylene offset after the femoral head has been reduced to increase hip stability. (Figure 6)

Page 4

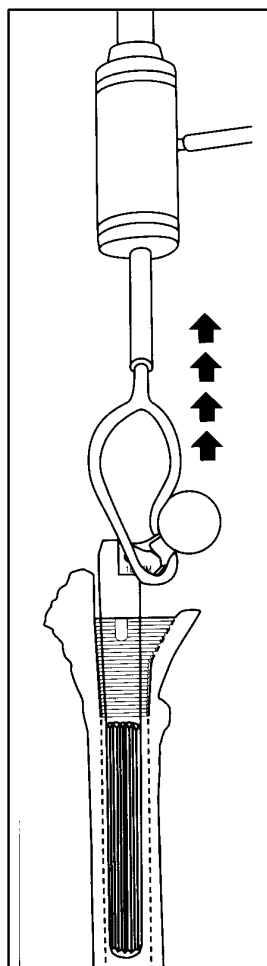


Figure 8.

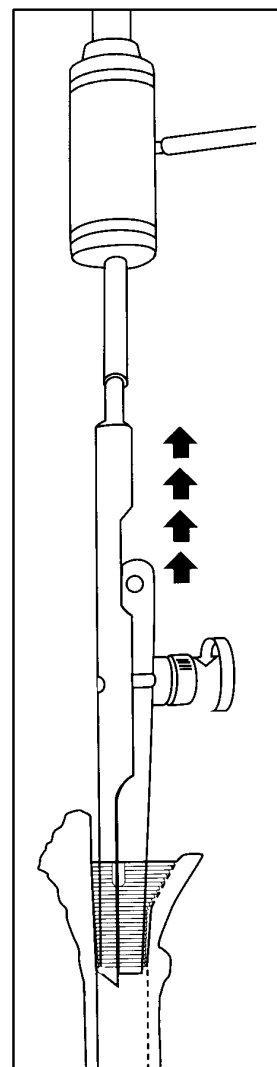


Figure 9.

Any implant inserted into a young person may fail in time. If the fixation does not loosen or the implant does not break, then the plastic bearing will eventually wear out. It is desired, therefore, that revision should be possible with minimal bone destruction. To minimize chances of distal osteointegration, i.e., direct apposition of the bone to the distal stem, the distal portion of the stem is highly polished. A stem can be separated from the sleeve by means of wedges and the hip retrograded with a slaphammer. Ready access to the proximal sleeve then permits loosening with flexible osteotomes or a high-speed burr and removal in retrograde fashion with a proximal sleeve extractor and slaphammer. (Figures 7, 8 & 9)

EXAMPLES OF DIFFICULT CASES

PRIMARY CASE



Problem:

"Fit & Fill"

- Large Metaphysis
- Narrow Canal



Solution:

True Modularity

- Large Proximal Sleeve
- Small Diameter Stem

REVISION CASE



Problem:

Stability

- Deficient Proximal Femur
- Osteolytic Bone
- Fracture

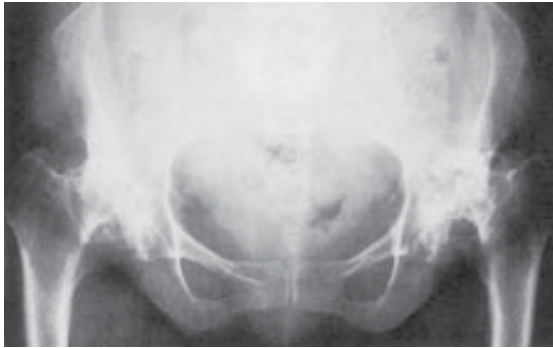


Solution:

True Modularity

- Calcar Replacement with Proximal Sleeve
- Fluted Stem
- Long Stem

SPECIAL CASE



Problem:

Joint Stability

- Offset
- Femoral Version



Solution:

True Modularity

- 135° Neck Shaft Angle
- Infinite Neck Version Selection

RESULTS

Baulkham Hills Private Hospital
New South Wales, Australia

62 Implanted

S-ROM™ Threaded Cups	37 Primary OA
(over the last 20 months)	25 Revisions

77 Implanted

S-ROMT1 Stems	39	Aseptic Loosenings
(over the last	8	Primary OA
20 months)	5	Infected Primaries
	11	CDH
	4	Girdlestone
		Conversions
	8	Fusion Takedowns
	2	Distorted Femoral
		Anatomies

Results to date are encouraging. Patients are ambulating well with greater stability and less discomfort than other primary non-cemented replacements (from our unit). Two revision cases had to be revised: one for recurrent dislocations, which required a simple adjustment or conversion of the Poly-Dia_m insert angular orientation and retroversion of the stem, and the second for a loosened acetabular cup.

We avoid the use of cement in revision surgery by using this system. We are also able to use allograft bone and to reduce our average operating time. Incidence of “end-stem pain” with standard stem is zero.

RESULTS

Orthopaedic Arthritic Hospital
Toronto, Ontario, Canada

339 Implanted

S-ROMT' Threaded Cups	194	Primary OA
(1-4 years,	15	Rheumatoid
average 2.6 years)		Arthritis
	20	AVN
	10	Other
	100	Revisions

241 Implanted

S-ROM Stems	114	Primaries
(1-4 years,	56	CDH
average 2.6 years)	15	Fusion
		Takedowns
	6	Femoral
		Osteotomies
		with Revision
	37	Revisions
	13	Girdlestone
		Conversions

It is too early to give conclusive clinical results. However, our patients are not complaining of thigh pain and are ambulating as well as patients with cemented hips. We are encouraged with our early clinical results and continue to use this system.

The first case was revised due to a femoral shaft fracture below the tip of the stem. The stem was retrieved and exchanged for a cemented prosthesis.

The second case was revised due to a very comminuted femoral shaft fracture, resulting in femoral component sinkage. Stem was retrieved and exchanged for a larger S-ROMT' stem.

The third case was revised due to a reactivation of sepsis; and implant was removed.

The fourth case was a revision of a prior revision treated with a S-ROMT1 threaded acetabular component with allograft. It was revised 2 1/2 years post-operatively due to aseptic loosening. *Interesting note.* - the stem was removed for improved exposure for the acetabulum and then reinserted in the same sleeve.

Findings in the above four cases: all proximal sleeves were firmly fixed in the bone and locked to the stem. No evidence of fretting or metallic debris was found upon removal of the stem from the sleeve.

Incidence of "end-stem pain" with standard stem is zero.

To date, no cups have failed in primary situations.

*Note: Porous coated devices are approved for cemented use only

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Techniques of Insertion and Results with the Threaded Acetabular Component

Hugh H. Cameron,
M.F., Ch.B., F.R.C.S. (C)
Asst. Professor of The
Depts. of Surgery,
Pathology, and
Engineering
Univ. of Toronto
Toronto, Canada

Timothy McTighe
Chagrin Falls, Ohio

In this article, the authors classify the various threaded acetabular component designs, discuss surgical techniques, and share quite successful clinical results.

Threaded acetabular component designs have had a longer history of cementless application in total hip arthroplasty than porous press-fit designs. Europeans have pioneered and championed this concept in both primary and revision surgery. The results of the encouraging findings in Europe have been accompanied by an influx of threaded acetabular components introduced into the United States. It is important to recognize the difference in design concepts and the required surgical technique for each design. In addition, it also is apparent that certain designs have a broader indication (or restricted contraindication) than other designs.

Early experimental results were cited by Sivash,¹ in 1957, and advanced with the work of Ring,² Lord,³ and Mittelmeier.⁴ The first generally accepted threaded acetabular component was developed by Mittelmeier in Germany in 1971. It was a truncated cone, initially made of metal, with the femoral component having a plastic ball. A ceramic version of this prosthesis continues to be used today, and, at least on the acetabular side, reasonable results have been achieved. In 1976, Lord began to use a truncated ellipsoid design made of metal with a polyethylene insert. It initially was partially porous coated, but the pores subsequently were removed with no change in outcome of clinical results. To date, with over 15

years of clinical results, Europeans have remained enthusiastic over threaded devices.

Types of Designs

Threaded acetabular components are divided into four classifications: truncated cones, hemispherical rings, hemispherical shell and conical threads, and hemispherical shell with spherical threads.

The truncated cone should be inserted horizontally, at 35° to 40°, compared with the usual 45° to the vertical. It also should be anteverted 10° to 15°. Conical reaming is required, and the orientation must be correct initially because it cannot be corrected once reaming has begun. Therefore, it is a demanding prosthesis, and in order to properly seat the broad, flat base, the medial wall of the pelvis occasionally must be breached. When it is inserted properly, the results have been reasonably good (Figure 1).

Hemispherical devices are easier to insert because standard spherical reamers can be used and if cup placement is not ideal, removal and reinsertion are possible. The hemispherical ring has a large apical hole, which reduces the stiffness and so potentially can lead to micromotion and possibly polyethylene-wear debris (Figure 2). Although a hemispherical cup may have an apical hole, it is much stiffer and therefore has less of a tendency to deform under load (Figure 3).⁵

Early ring designs had only neutral polyethylene inserts requiring a more horizontal orientation of the cup to ensure joint stability. This type of position

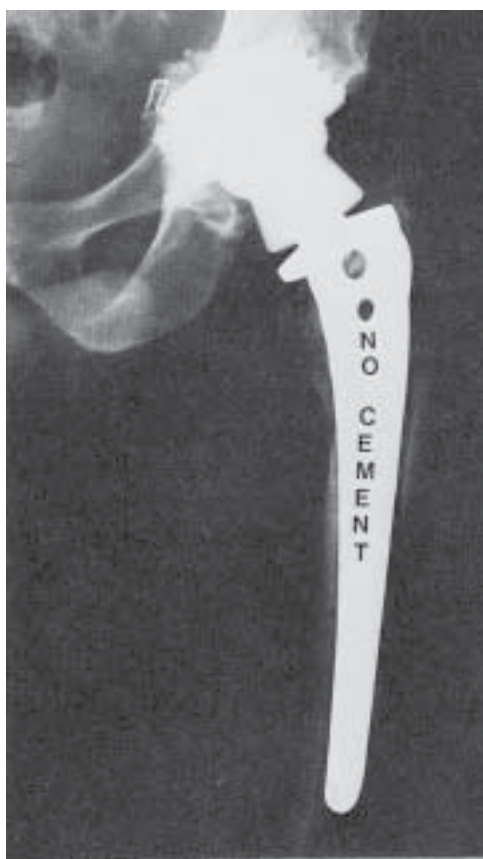


Figure 1 – In this revision case, a Mittelmeier prosthesis was used. It was necessary to breach the inner wall of the pelvis to obtain firm seating. The stem was painful and required revision two years later. At that time, the acetabular component was tight. It functioned well for six years, until the death of the patient.

can compromise bony coverage of the implant, resulting in less implant fixation.

The majority of hemispherical cups have conical threads, which are much easier to design and manufacture. However, the conical thread compromises the maximum potential of seating the entire thread into a hemispherically reamed acetabulum. In 1984, the S-ROM™ Acetabular System was manufactured. It has spherical threads, which allow complete seating of the thread into the bone. This larger thread contact area naturally reduces the load per unit area.

Sinkage into the pelvis is the usual method of acetabular cup failure. Therefore, the buttress angle on the threads should be as horizontal as possible to

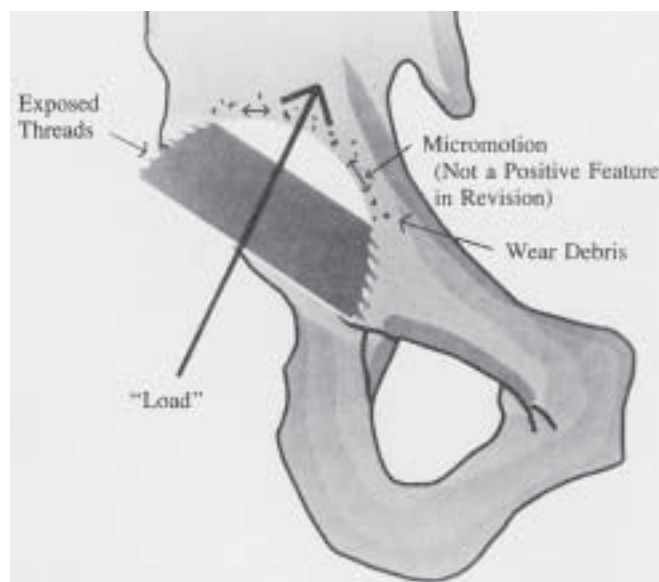


Figure 2 – This threaded ring shows load transmission, resulting in possible micromotion and wear debris.

present a compressive, rather than shear, face to this load. When a threaded acetabular component is inserted without pretapping, bone debris is generated. Grooves to accommodate this debris should be incorporated in the acetabular cup design.

Rotatory torque on the acetabulum must be resisted. The addition of screws or studs that penetrate the metal cup not only help with initial fixation, but also absorb rotatory torque (Figure 4).

The polyethylene liner should be detachable to allow visualization during cup insertion and bone grafting, if necessary. The liner locking mechanism must be such that inadvertent disassociation will not occur. An offset plastic lip is a distinct advantage, acting in a sense like the acetabular labrum. The S-ROM System features a unique Poly-DiaL™ insert that allows the surgeon to dial the 10°, 15°, or 20° offset insert out of the way for ease of relocation of the femoral head and, with the head in place, to dial the offset insert to one of six locations to ensure maximum joint stability. The inserts also can be rerotated and removed without damaging the insert itself (Figure 5).

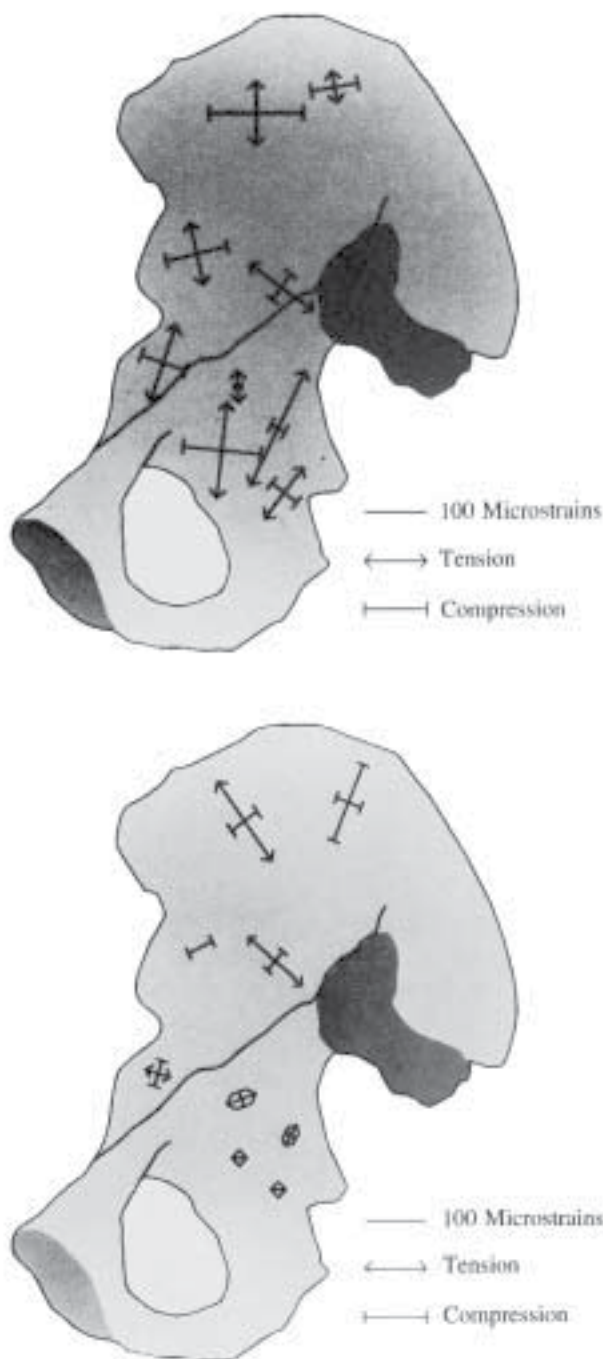


Figure 3 – A strain gauge for a nonnal pelvis (Top) and a strain gauge for the S-ROM threaded cup (Bottom) are shown.

Technique

The threaded acetabular component can be inserted via any standard approach to the hip. The difference from a cemented implant is that the acetabular exposure must be greater. Threaded components have a major diameter, larger than that of the prepared dimensions of the acetabulum. Therefore, it is necessary to face the acetabulum directly for insertion of these threaded devices.

The acetabulum generally is spherical and its opening is oriented closer to 55°, not 45°, downward in the coronal and sagittal planes and anteverted approximately 15° to 20° in the midsagittal plane.

The standard approach used by the senior author is a modified Watson-Jones approach. The incision is curved anteriorly and centered over the greater trochanter. The fascia lata is divided in line with the skin incision. If the fascia is tight, a back cut of 2 to 3 cm may be made.

The anterior fibers of the gluteus medius and the tendon of minimus are released from the front of the greater trochanter and blunt Homan passed above and below the femoral neck extracapsularly. With a Cobb periosteal elevator, the soft tissue is cleared off the front of the capsule and a medium Homan placed on the pelvic rim under direct vision with the spike sitting under the rectus femoris. An anterior capsulectomy is performed. The neck is divided and the head withdrawn. The acetabulum is exposed with a medium Homan on the pelvic rim, a long, sharp Homan inferiorly and a bent Homan posteriorly. A complete capsulectomy is performed. If the psoas is very tight, the tendon can be released. If the gluteus medius is large, a Steinmann pin can be driven into the pelvis above the acetabulum to serve as an additional retractor.

Acetabular Preparation

From preoperative templates, the acetabular size roughly will be known. The acetabular fat pad is removed with sharp

dissection. An acutely curved hemostat is a useful instrument should bleeding be encountered from the artery in the fat pad, which tends to retract underneath the transverse acetabular ligament.

If large osteophytes are present on the edge of the lunate area, their removal with an osteotome is useful to clearly define the floor. Reaming is then begun. Any hemispherical reamer can be used as long as its dimensions are well defined. Progressively larger reamers are used until the reamer is enclosed completely within the acetabulum. The subchondral bone should be left, if possible, but not at the expense of letting the cup sit proud of the acetabular rim. Acetabular irrigation may be performed during reaming, but the bone debris generated by the final reaming should be left as a bone graft.

The S-ROM reamer itself serves as a trial, with the two levels indicating whether or not a low profile or deep profile cup should be employed. A deep profile cup is essentially a hemisphere. Trial cups are available and are 0.5 mm larger in diameter than the exact size of the S-ROM reamer blade on the assumption that the reamer may cut somewhat oversize but cannot cut undersize. This is certainly true in soft bone. Occasionally, however, especially when the bone is hard, trial insertion may be a little difficult, so gentle eccentric reaming may be necessary to allow the cup to be seated fully.

Component Position and Insertion

The optimal position is 45° to the vertical and 10° to 15° anteversion. Frequently, however, some degree of acetabular retroversion is found. The availability of offset polyethylene liners means that slight malpositioning of the threaded cup can be accepted, but it probably would be a mistake to depend too heavily on the plastic lip for stability. Conceivably, this could cold flow with time and end in a later dislocation, although this has yet to be reported.

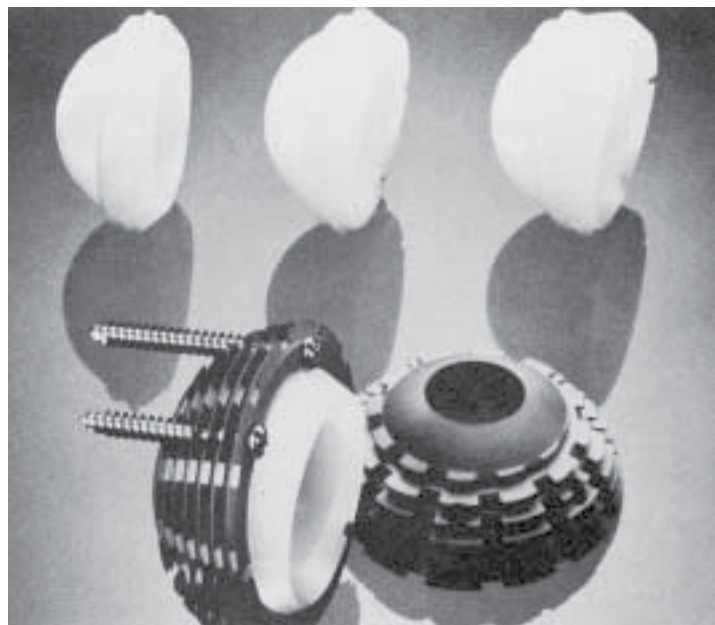


Figure 4 – The peripheral screws for this S-ROM cup not only assist with initial fixation, but also absorb rotatory torque.



Figure 5 – The capacity to adjust the offset insert after femoral component reduction is a significant advantage in allowing determination of optimum stability.



Figure 6 – Multiple screws have been used in this case because the acetabulum was deformed (a shelf procedure was performed years before). The screws penetrate the metal shell. Lying in the grooves in the plastic liner, they prevent further rotation of the plastic. They also help to absorb the rotatory torque forces on the acetabulum.

If the cup is *Dot* inside the acetabulum before threading has begun, it is possible to damage the bony walls. Therefore, the appropriately sized cup should be locked onto the S-ROM cup impactor and driven into the acetabulum with forceful blows of a mallet. The handle of the impactor serves as an aiming device and allows alignment to be checked. It is then disengaged by rotation and withdrawn.

Threading can be performed with a ratchet wrench or a pneumatic impact

wrench. The heads of these devices are not locked onto the cup. If the surgeon, and therefore the drive shaft, wobbles more than 7° , the introducer will disengage. This protects the bony threads. If the driver is locked tightly, the initial bony threads easily could be broken.

The advantage of the pneumatic inserter is that the surgeon need concentrate only on maintaining alignment, rather than also on providing power. The senior author always prefers to check with the offset ratchet wrench in case the pneumatic system has been underpowered. No acetabular fractures have occurred in over 200 cases of cup insertion, although it is theoretically possible, and, therefore, the drive should be removed frequently to visualize the depth of insertion.

If the cup is not seated completely, a bone graft can be passed through the floor and impacted with a punch. If complete coverage cannot be achieved, then consideration should be given to bone grafting. It is probably acceptable to leave up to two threads hanging out in one area. If, however, more than two threads are exposed, then they should be covered with bone graft.

The polyethylene liner is inserted and rotated in place. It is dialed around so that there is no offset superiorly to impede hip reduction. Once the femoral component has been inserted and the hip reduced, the offset can be dialed around to the position of maximum stability of the hip. Once the socket is rotated to its proper position, where the cup spanner slot is in line with the screw hole, at least two bone screws should be inserted to lock the plastic liner. These screws also serve to enhance the rotatory stability of the entire complex (Figure 6).

In revision situations, where bone quality may be less than ideal, it probably is preferable to fill as many of the screw holes with screws as possible. Inferiorly, where the acetabulum is thin and penetration of the pelvis likely, short, tip locking pins, rather than

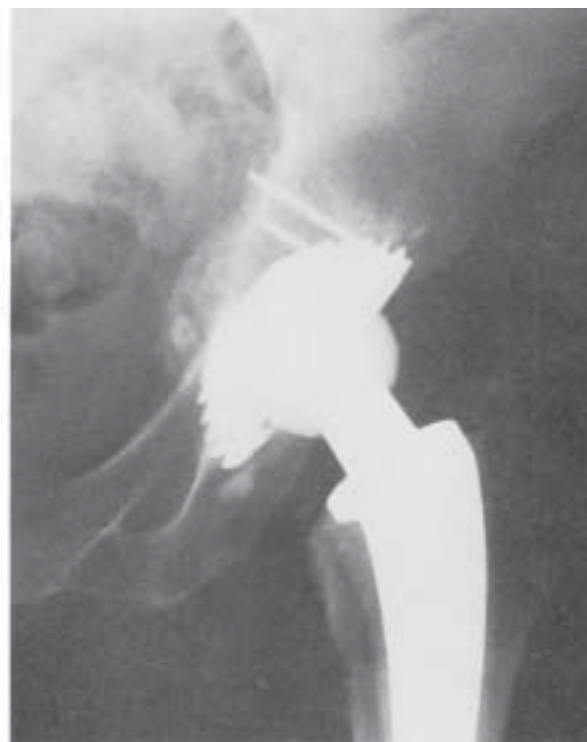


Figure 7 – This hip resurfacing failed, leaving a huge acetabular floor defect (Left). The floor was heavily grafted (Right). Because the acetabular ring was intact, a threaded

cup was used; it obtained an excellent grip. Hemispherical threaded cups are wall bearing. A case such as this is an ideal indication for their use.

screws, should be used to avoid potential vascular damage.

Contraindications to Threaded Cups

Threaded cups must not be used if the acetabulum is too thin to allow proper reaming without large floor perforation. The acetabular size should not be greatly expanded because this may result in the walls becoming too weak to support a threaded cup. If bone grafts encompass more than one-third of the acetabular ring, then a threaded cup should not be used and consideration should be given to a bipolar cup. It is difficult to manufacture a threaded cup with an outer diameter of less than 45 mm because the plastic liner would be too thin. If the acetabulum calls for a smaller component than this, an ingrowth cup is probably preferable. If a grip of more than 600 inch pounds cannot be achieved with the threaded cup due to poor quality bone, some other device, such as a bipolar or a cemented cup, should be used.

Clinical Results

When evaluating uncemented components, it is easier if one side is cemented because the early results of cemented hips are well known. Ninety-eight hybrid hip replacements using an uncemented S-ROM threaded cup combined with a cemented stem have been performed. The follow-up was two to four years. Of the 98 replacements, 67 were primary hip replacements and 31 were revisions. Some bone grafting of the acetabular floor was performed in 60% of primary cases and 100% of revisions (Figure 7). Wall or roof grafts were required in 11%. The majority were not visible as separate structures by six months.

The overall Harris rating was 91% excellent, 4% good, 3% fair, and 2% poor. Four patients had groin pain; one settled with ten days of bed rest. One possible L3-4 disc herniation was explored, and nothing abnormal was found. His pain subsequently settled. One patient has unexplained groin pain

and in one revision case the prosthesis has migrated and thus is probably loose.

Acetabular radiolucency has been studied using the Charnley method⁷ and has shown a progressive decrease. At three months, 7% show radiolucency in zone 1, 11% in zone 2, and 6% in zone 3. By two years, 0% show radiolucency in zone 1, 2% in zone 2, and 1% in zone 3. Admittedly, on routine x-rays, it is very difficult to see whether slow migration is occurring. If this is happening, one would expect to see an increase in radiolucency in zone 3. However, the locking screws are not particularly strong in bending and shear and act as a fairly sensitive guide. To date, only one screw fracture, in the loose case, has been noted.

Future Developments

Although the early results with the S-ROM threaded cup have been good, concerns must exist that late migration, as is seen with cemented cups, will occur. After all, the acetabulum is flexible and the cup stiff. One way of reducing acetabular flexibility is to convert it from a horseshoe to a complete ring. Bone grafting under the transverse acetabular ligament may help this, as may the use of locking pins on either side of the transverse acetabular ligament.

A second method is to increase the surface area of contact between metal and bone; the greater the contact area, the less load per unit area. This could be done by making the smooth part of the cup porous, but this adds greatly to the cost.⁷ If the smooth areas are roughened, more or less the same effect is

achieved at a much lesser cost. Both these alternatives are being explored presently and obviously further follow-up studies will be required to learn whether there is any advantage in doing so.

Further developments contemplated include the use of a hydroxyapatite spray coating on the cup. Hydroxyapatite coatings are not particularly strong and might well be sheared off the threads during insertion. However, hydroxyapatite would remain intact and protected in the depth of the grooves and in the depth of the roughened areas. Again, whether or not this provides any advantage will have to be determined by clinical studies.

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RECONSTRUCTIVE REVIEW

Leadership Through Design

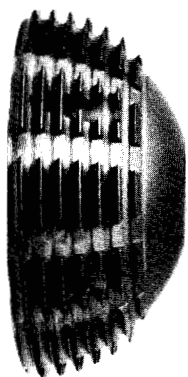
November 1986

Joint
Medical Products

Threaded Acetabular Component Design Concepts

By Tim McTigue

Threaded acetabular component designs, as compared to porous press fit designs, have had the longer history of cementless application in total hip arthroplasty. The Europeans have pioneered and championed this concept in both primary and revision surgery.



Sivash¹, in 1957, developed a helical thread on the outer cup surface with a 7 millimeter pitch and a 10 millimeter depth. Difficulty in surgical technique led to a 1962 model which included 4 rows of circumferential blades giving the appearance of a mushroom cap. An important design feature was screw holes through the cutting threads or petals for additional fixation, if needed. (Figure 1)

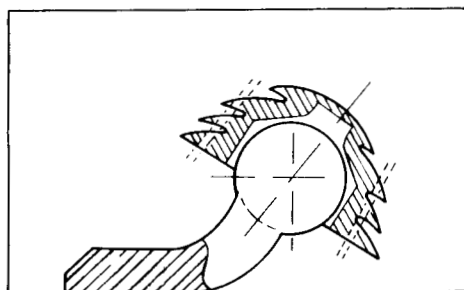


Figure 1

In 1964 Ring² began his clinical series using a threaded design in association with a femoral component of Moore's design.

However, Lord and Mittelmeier have been credited with popularizing this concept, both in Europe and the United States.

Lord³ began his clinical series in 1976, implanting well over 800 devices between 1976 and 1984.

Lord and Mittelmeier have both reported comparable results, with approximately 90% good-to-excellent results for primaries, and 75% good-to-excellent results for revisions.

The Mittelmeier device is a truncated cone, made of ceramic material which articulates with a ceramic femoral head. The Lord device is a threaded ring of a truncated ellipsoid design, made of metal with a polyethylene insert which articulates with a metal or ceramic head. Both surgeons continue to use these devices today.

In North America, Hugh Cameron⁴ was the first to implant and report on his experience using the ceramic Autophor system developed by Mittelmeier. Cameron has not experienced any problems with the threaded ceramic cup. However, problems have occurred on the femoral side resulting in Cameron's disuse of this system. He continues his investigation of threaded devices by use of the S-ROMTM AndersonTM acetabular component.

The success of the Europeans using these threaded devices has spurred increasing enthusiasm and usage, particularly in revision surgery, in the United States.

Bierbaum, Cappello, Engh, Mallory, Miller, and Murray are a few of the pioneers of clinical usage of threaded devices in the States. Each has encountered different degrees of success with various designs.

It is the opinion of this editor that there are major areas of concern that must be fully discussed and understood by the operating surgeon concerning design and surgical technique for threaded devices to insure a successful, long term clinical result. The failure to appreciate and use the proper surgical technique and/or indication can predispose these devices to failure.

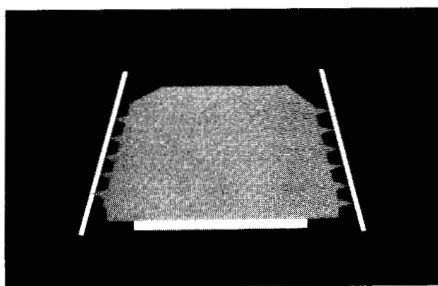
First and foremost in the successful implantation of a threaded device are exposure and surgical technique. Acetabular exposure must be greater for these devices than for conventional cemented cups. Threaded components have a major, or outside diameter, larger than that of the prepared dimensions of the acetabulum. It is, therefore, necessary to directly face the acetabulum for insertion of these threaded devices.

The acetabulum is generally spherical in shape and its opening is oriented closer to 55°, not 45°, downward in the coronal and sagittal plane and anteverted approximately 15°-20° in the mid-sagittal plane

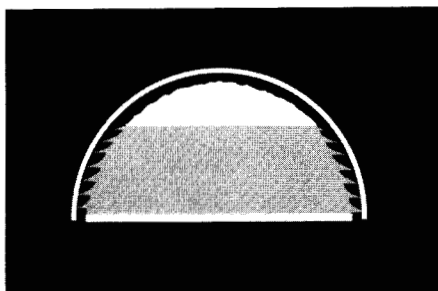
There are four basic classifications of threaded cup designs. It is crucial to understand the difference in these designs and, most of all, to understand the particular design chosen for implantation. A complete understanding of the design will enable the surgeon to maximize surgical techniques to achieve a good result.

Classification of Threaded Cups

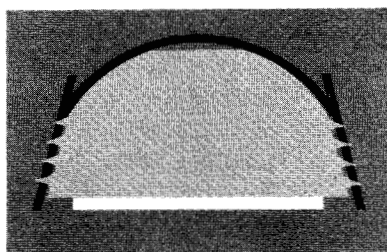
A. Truncated cone (Figure 2)



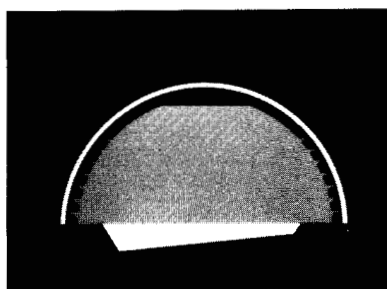
B. Hemispherical ring (Figure 3)



C. Hemispherical shell with conical threads (Figure 4)



D. Hemispherical shell with spherical threads (Figure 5)



A. Truncated Cone

This is the design of most European systems, including both Lord and Mittelmeier devices. Whether the truncated cone design is a cup or a ring, the geometry of a truncated cone makes the design inherently very stable. However, it does require more bone removal than a hemispherical design.

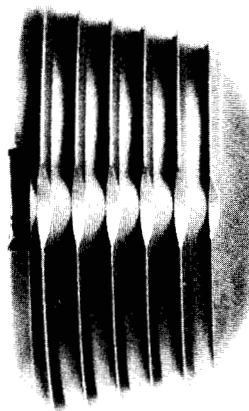


Figure 6

Figure 6 shows a close-up photo of a truncated cone produced in the U.S. Please note the smooth base conical surface at the root of the threads which is intended to abut the bone.

These designs generally require additional reaming and/or pre-tapping for the device to insure a better fit and apposition to the bone.

Although very successful in Europe, these designs have not met with great acceptance in North America. The surgical technique is quite demanding to insure proper seating for a truncated cone. If reamed spherically the threads engage very little bone (Figures 7, 8).

Figure 7



Figure 8



If deepened with the reamer, contact between implant and bone is increased. However, bone stock is sacrificed (Figures 9, 10). It appears the device must penetrate subcondral bone and the medial wall to insure maximum thread purchase (Figure 11).

Figure 9

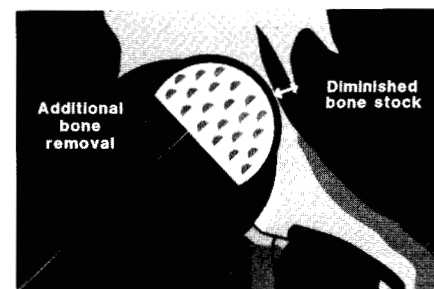
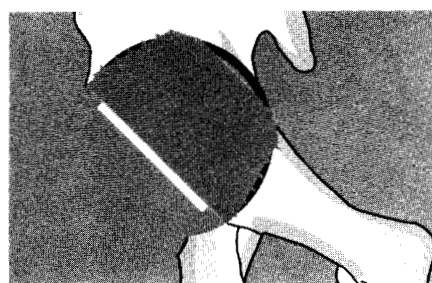


Figure 10



Figure 11



B. Hemispherical Ring

The Mec-Ring® from Germany appears to be the most popular ring design. It is a threaded ring spherical in shape with a large apical hole. This apical hole allows the poly insert to protrude through the ring, thus interfacing with the prepared acetabular bony bed.

A close look at this design (Figure 12) raises some questions and concerns. The thread buttress angle provides for maximum pull-out resistance. However, is this the mode of loading for threaded cups? Since the majority of the loads placed on the acetabular component are in compression, would not a different thread profile be more appropriate for proper load transfer? The extremely large apical hole allows for more load transfer to the thin fossa as compared to designs that have either a small hole or an enclosed dome.

The designs with a smaller hole do not allow the poly inserts to protrude through the hole. These are classified as cups, not rings.

In revision situations where the subcondral bone is diminished or lost, loading should be transferred to the periphery to protect or shield this area.

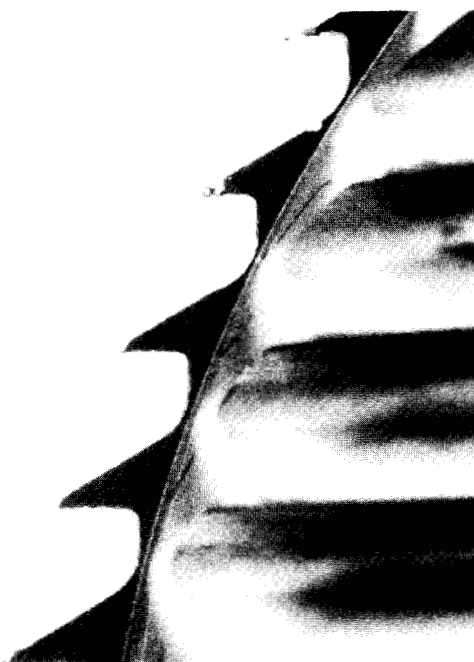
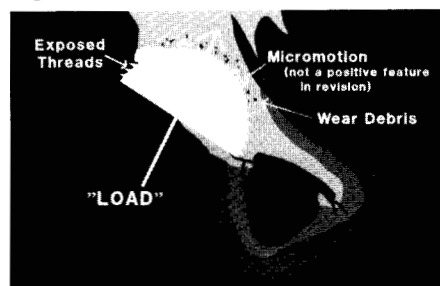


Figure 12

Earlier designs had only neutral angle poly inserts requiring a more horizontal orientation of the cup to insure joint stability. This type of positioning can compromise bony coverage of the implant, resulting in less implant fixation. In addition, if any micromotion occurs between poly insert and bone, the possibility of wear debris exists (Figure 13).

Figure 13



C. Hemispherical Shell with Conical Threads

This is the design of most U.S. manufacturers. The hemispherical shell is an advantage over a truncated cone because it allows preservation of the subcondral bone by reaming hemispherically. The conical threads are much easier to design and manufacture as compared to spherical threads. However, the conical thread does compromise maximum potential of seating the entire thread into a hemispherically reamed acetabulum. Because of this fact Joint Medical discontinued making conical threads over two years ago. Figure 14 shows a closeup of a competitive U.S. design; again note the smooth base spherical surface of the root threads which is intended to abut the bone. Some manufacturers are not taking into consideration the amount of bony debris that is created during the thread cutting insertion process of seating a threaded acetabular component. Also, most manufacturers use a cheese-grater type reamer that is designed to remove bony debris. These reamers were initially designed to be used with bone cement, not with threaded implants.

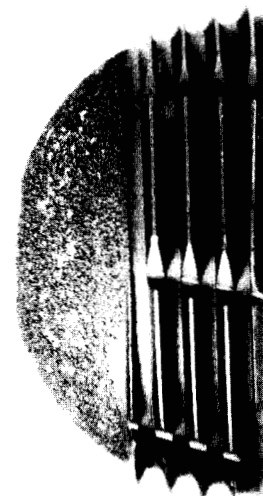


Figure 14

D. Hemispherical Shell with Spherical Threads

This, in our opinion, is an optimum design for a threaded device (*Figure 15*). The S-ROM Anderson cup is the first hemispherically domed shell with spherical threads. Note (*Figure 18*) that the thread buttress angle provides maximum resistance to the compressive loads going into the acetabulum.

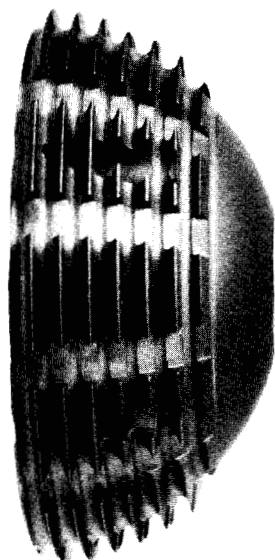
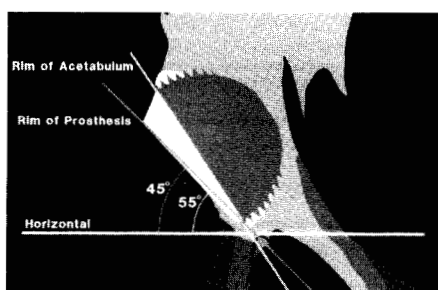


Figure 15

This design together with the POLY-DIAL™ Socket lends itself to optimum positioning of the metal shell and maximum purchase of spherical threads in a spherically reamed cavity (*Figure 16*). The apical hole is small enough to reduce loads that are transferred through the apex; however, the hole is still large enough for visualization and access for bone graft material.

Figure 16

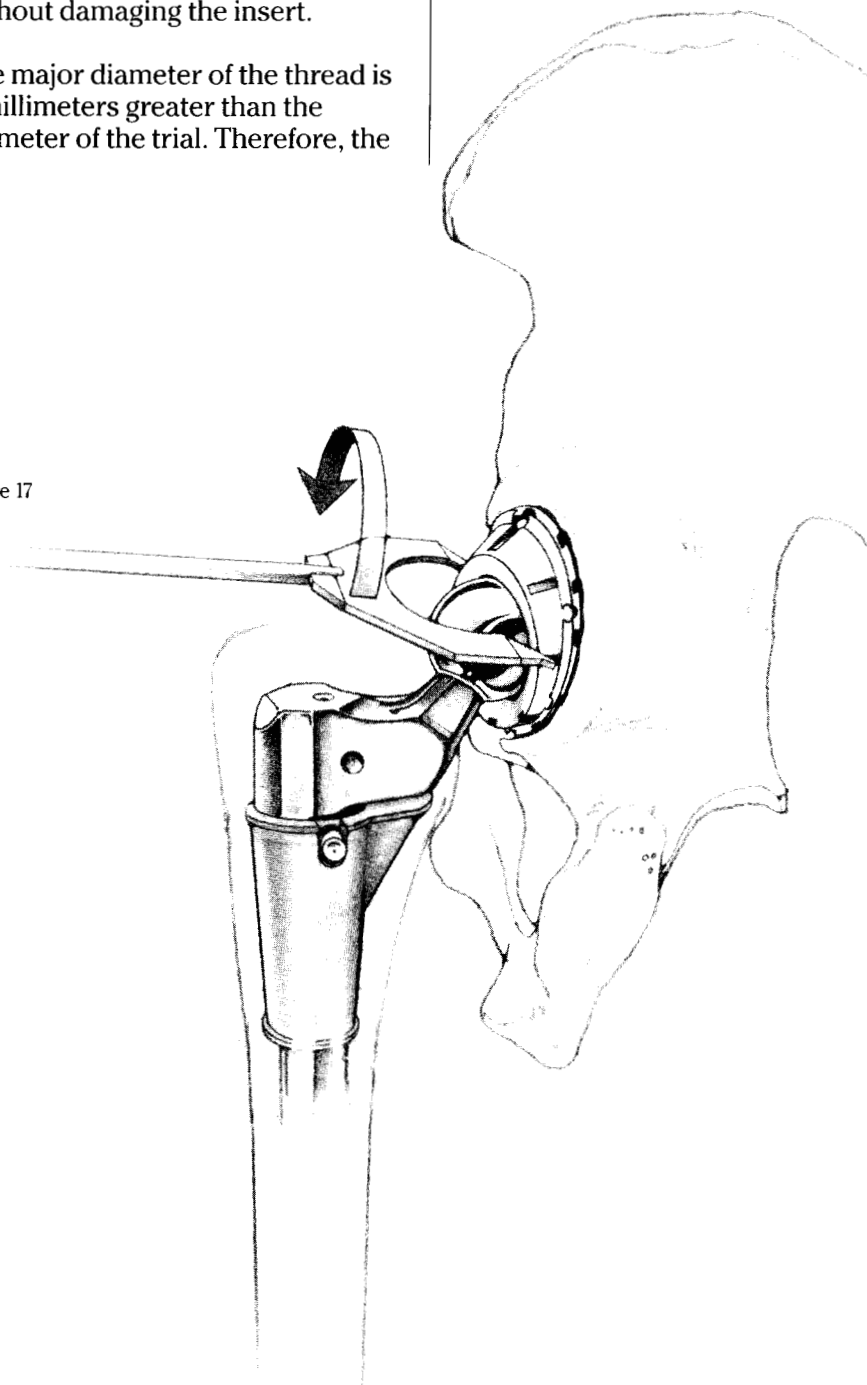


The S-ROM system also is the first and only system that features the unique POLY-DIAL insert system (*Figure 17*). This truly unique and patent-pending system allows the surgeon to dial the 10°, 15° or 20° insert out of the way for ease of relocation of the femoral head and then, with the head in place, to dial the offset insert to one of six locations to insure maximum joint stability. POLY-DIAL inserts can also be rotated and removed without damaging the insert.

The major diameter of the thread is 5 millimeters greater than the diameter of the trial. Therefore, the

penetration of each thread is 2.5 millimeters relative to the dome and flute spherical surface. The actual thread minor diameter, or root diameter, is such that the root of each thread lies 0.5 millimeter below the dome and cutting flute's spherical surface, thus allowing 0.5 millimeter space for bone chips from thread cutting to accumulate (*Figure 18*). This, again, is a unique design feature found only in the S-ROM Anderson acetabular cup.

Figure 17



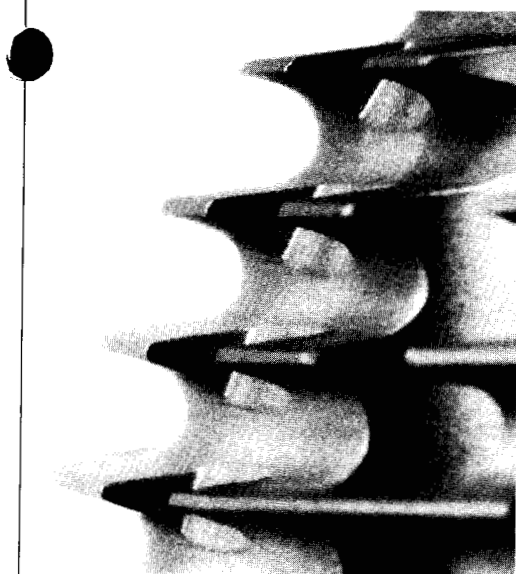


Figure 18

If basket reamers are used to enlarge the acetabular bony bed, the final reamer should be the S-ROM or Myra type which does not collect bony debris. This bony debris will function as a biological graft which will be entrapped between the threads and grooves of the Anderson cup during insertion. It is also recommended that irrigation should be used during reaming to reduce the possibility of burning the bone.

If a femoral allograft has been used in a deficient acetabulum, longer bone screws are available to help stabilize the graft (Figure 19, 20). To date, this is a unique design feature found only in the S-ROM Anderson cup.

Figure 19

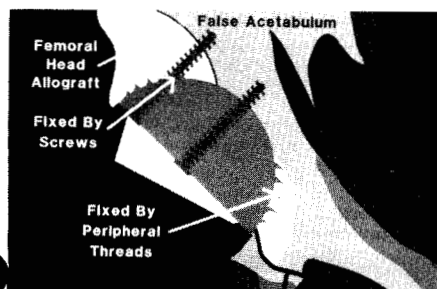
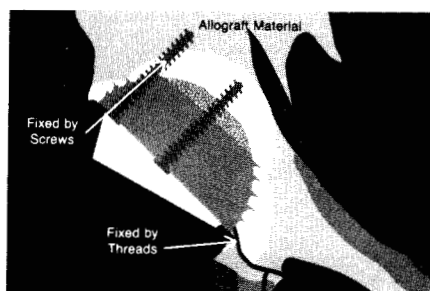


Figure 20



Threaded acetabular components are not all the same, just as porous and cemented designs are not all the same. It is vital to fully understand the chosen design and the required technique for that design to insure a good, long lasting result.

Another unique concept for threaded acetabular components is the S-ROM SuperCup™ threaded device (Figure 21). There is no question that this design is a highly sophisticated and exciting concept. This device will be featured separately in a future *Reconstructive Review* article.

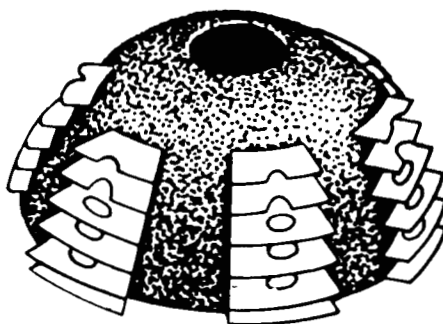


Figure 21

Key Words

truncated (trun' cā-ted) 1. cut short or appearing as if cut short. 2. having the vertex cut off by a plane: said of a cone or pyramid.

cone (cōne) 1. a solid with a circle for its base and a curved surface tapering evenly to an apex so that any point on this surface is in a straight line between the circumference of the base and the apex. 2. a surface described by a moving straight line passing through a fixed point (called the vertex) and tracing any fixed curve at another point.

geometrical cone



conical (con' i-cāl) 1. shaped like a cone.

ellipse (el·lipse') 1. the path of a point that moves so that the sum of its distance from two fixed points is constant. 2. a closed curve produced when a cone is cut by a plane inclined obliquely to the axis and not touching its base.

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A Radiographic Technique For Threaded Acetabular Components

By Robert C. More, M.D.
Harlon C. Amstutz, M.D.



Purpose

With the increased use of threaded acetabular components, it is important to have reliable means to objectively assess the quality of result. For the radiographic analysis, the most important parameters to evaluate with serial radiographs include: 1) shift in position of the component, and 2) quality of the bone/component interface. The grid radiograph has greatly facilitated the evaluation of subtle changes in component position¹. The present study was undertaken to devise a method for reliable interface analysis.

Methods

On a routine AP radiograph of a hip with a threaded component in place, the bone/component interface is not usually seen well, because the threads appear overlapping, and the bone between the threads is obscured (Fig. 1). The reason is that the threaded cup (like all acetabular components) is usually inserted into the acetabulum with some amount of anteversion. The more anteversion that is present, the more that the threads overlap.

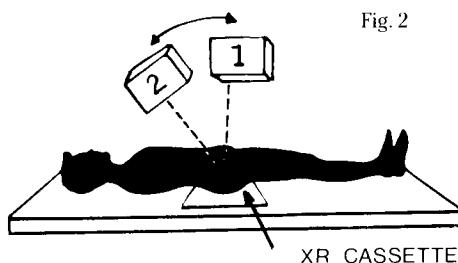


Fig. 1 Mecron Threaded Ring

This can be demonstrated by simply holding a threaded device in front of you, rotating it to simulate different orientations in a pelvis, and viewing the threads of the component.

It is apparent that in order to see the threads in profile, and to see the bone/component interface between the threads, the x-ray beam must be parallel to the plane of the threads. This can be accomplished by moving the x-ray tube in two possible directions:

1. Standard AP Radiograph
2. Caudad Radiograph



1. Standard AP Radiograph
2. Oblique Radiograph

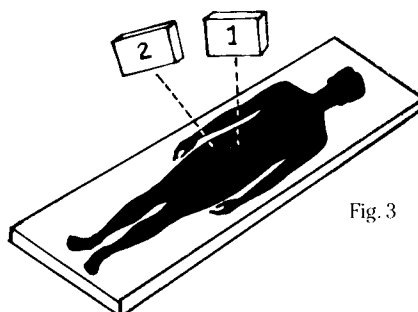


Fig. 2

Fig. 3

Since the x-ray tube does not move in this fashion, the patient must be rolled on the table to obtain an oblique. (Fig. 4)

1. X-ray Tube Overhead

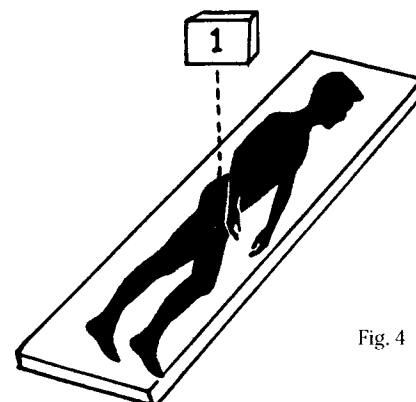


Fig. 4

For this study, a threaded screw-ring component was placed into a dried cadaver pelvis with 20° of anteversion. Serial radiographs were taken of the cadaver pelvis with: a) varying degrees of caudad tilt to the x-ray tube at increments of 2.5 degrees, and b) varying degrees of obliquity of the pelvis at increments of 2.5 degrees.

Results

A. Caudad Radiographs.

1. The only angle of tilt which visualized well the threads in profile was 20°. At 17.5 or 22.5 degrees, the threads overlapped and obscured the bone between them. Thus, there was little room for error in terms of angle of tilt.

2. It was evident that with increased anteversion of a component, increased caudad tilt would be required. This would have the undesirable effect of magnifying the image of the component, since the x-ray cassette would be further away from the component (Fig. 2).

3. Since the cassette is not perpendicular to the x-ray beam (Fig. 2), the image of the component is distorted (superior aspect more magnified than inferior aspect).

B. Oblique Radiographs.

1. The threads were seen best in profile at 20 degrees oblique pelvic tilt (pelvis rotated towards the acetabular component). However, the radiographs at 15, 17.5, 22.5, and 25 degrees were all acceptable in visualizing the bone/component interface between the threads. Thus, the angle of obliquity was not as critical; there was more room for error.

2. The amount of magnification of the component is less than on a standard AP radiograph, since the acetabulum is rotated closer to the cassette (*Fig. 4*).

3. Since the x-ray tube is directly overhead, the beam is perpendicular to the cassette, and there is no distortion in the shape of the component (*Fig. 4*).

Discussion

Clearly, oblique radiographs have several advantages over quadrad radiographs. Based on this study our current procedure for radiographing the threaded cups is as follows:

1. The amount of anteversion is estimated from the AP radiograph by examining the ellipse that is formed by the image of the mouth of the component. The anteversion can be estimated as either large or small, or can be determined precisely by measuring the ratio of the minor to major axes. (*Fig. 5*)

2. If there is a small amount of anteversion present, a 15 degree oblique radiograph is used; if there is a large amount, a 30 degree oblique is used. The patient is rotated towards the side to be radiographed.

Fig. 5

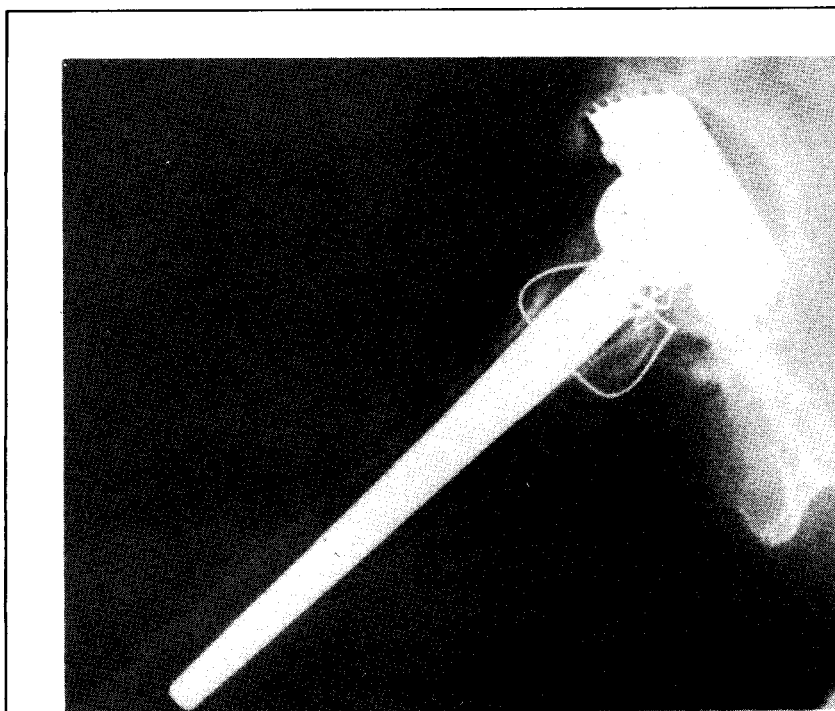
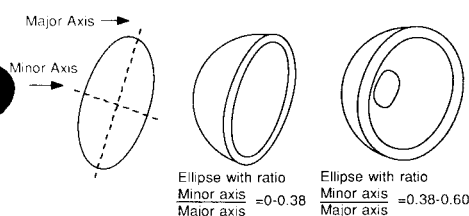


Fig. 6 Mecron Threaded Ring

3. The amount of obliqueness can be reproducibly obtained by placing wedges under the pelvis of the patient. We have constructed ours from Lucite®, but sturdy foam wedges at 15 and 30 degree angles are available commercially. The angle of obliqueness is checked with an inclinometer placed on both anterior superior iliac spines of the patient.

4. For the 30 degree oblique we have found it useful to flex and abduct the patient's hip, and rest the thigh against the table. This helps stabilize the pelvis during the radiograph.

5. If the patient is able to abduct sufficiently, the oblique radiograph can be combined with the modified frog leg lateral, which is the best lateral view of stemmed femoral components. This decreases the x-ray exposure to the patient.

6. Either the 15 or 30 degree oblique is usually sufficient. Rarely, in cases when the anteversion of the component exceeds 40 degrees, it has been necessary to take 45 degree oblique views. This can be done by combining the wedges. We have found it to be more difficult to

reproducibly obtain 45 degrees of obliqueness, and the inclinometer on the iliac spines is especially useful.

Conclusion

With this simple technique, we have been satisfied with the quality and reproducibility of the serial radiographs. Figure 6 shows the oblique radiograph in the same patient as in Figure 1. The threads are well visualized in profile, enabling the bone/component interface to be well seen. A radiolucency is visualized on this view, especially around the inferior threads, which is not seen as well on the AP film. Clinically, this patient has symptoms consistent with loosening of a Mecron screw-ring.

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Upcoming Events Co-Sponsored by JMP

"Uncemented Total Joint Replacement," postgraduate CME seminar. *November 24-26, 1986 - The Registry Resort, Scottsdale, Arizona.* Presented by Harrington Arthritis Research Center. Course Co-Chairmen: Allan M. Weinstein, Ph.D. and Anthony K. Hedley, M.D. For enrollment information, contact Barbera Hawn at (602) 254-0377.

"Current Concepts in Implant Fixation," postgraduate CME seminar. *December 11-13, 1986 - Marriott's Orlando World Center, Orlando, Florida.* Presented by: The Mt. Sinai Medical Center, Cleveland, Ohio. Course Director: A. Seth Greenwald, D.Phil. (Oxon). For enrollment information, contact Deborah L. Donerson at (216) 421-3968.

"Current Cementless Concepts and Controversy in Total Hip Arthroplasty." postgraduate CME seminar. *March 23-27, 1987 - Sandals Royal Caribbean Resort Hotel, Montego Bay, Jamaica.* Presented by: Joint Implant Surgery and Research Foundation. Course Co-Chairmen: J. Dennis Bobyn, Ph.D. and Charles A. Engh, M.D. For enrollment information, contact J. Dennis Bobyn, Ph.D. at (703) 979-0761 or Charles O. Bechtol, M.D. at (213) 874-5031.

"The Early Results with an Uncemented Acetabular Screw Cup," by Hugh U. Cameron, Charles A. Engh and Thomas H. Mallory. A scientific exhibit at the *1987 AAOS Meeting in San Francisco.*

Next Issue

- Interview with leading orthopaedic surgeons discussing CDH and its surgical treatment.
- Clinical review by leading orthopaedic surgeons of S-ROM Threaded Acetabular Components with a minimum of six month follow-up.

Editorial Comment

*R*econstructive Review would like to thank Doctors More and Amstutz for their contributing article in this publication.

We welcome your comments and suggestions concerning this publication. Additional copies are available upon request.

Timothy McTighe
Editor

**Joint
Medical Products
Corporation**

860 Canal Street
Stamford, CT 06902
(203) 359-1794



Joint Implant Surgery and Research Foundation
46 Chagrin Plaza #118
Chagrin Falls, Ohio 44023
www.jisrf.org