TSI™ - Tissue Sparing Implant

A New Approach to THA- August 2010 by JISRF

Back to the future in THA (Neck Sparing)

The concept of neck sparing stems is not new. Freeman, Townley, Pipino and Whiteside have all advocated the use of neck sparing stems. Mechanical studies have clearly demonstrated an early advantage to increased axial and torsional resistance with the intact femoral neck.The challenge has been to create a design that loads the medial calcar in compression maintaining the integrity of that bone structure.

The TSI™ Implant (Tissue Sparing Implant) has been conceived and developed in an attempt to create a tissue (hard & soft) sparing approach that provides for more reproducible results as compared to hip resurfacing and more conservation of tissue than conventional cementless stems. The stem is simple in design, reproducible in technique, allows for fine tuning joint mechanics, provides for removal and conversion to a conventional stem if necessary. The novel proximal conical flare improves proximal load transfer and the shape of the stem provides for immediate torsional and axial stability.

August 2010- Timothy McTighe, Dr. H.S. (hc), Executive Director, JISRF

A Collaboration of Past and Present

Collaboration with scientist and surgeons worldwide has advanced this concept into a viable alternative to both conventional cementless THA and hip resurfacing.

Discussions and review of past historical work is a critical pathway to successful new product development. Drs. Freeman, Pipino and Whiteside have shared their work which has led to new design goals for the TSI™ stem.

We have been encouraged by colleagues associated with JISRF and many have been part of the design, development and educational process of this project. Over twenty papers, posters and lectures have been presented in the last 2 1/2 years in four countries. These can be found on the JISRF web site: www.jisrf.org

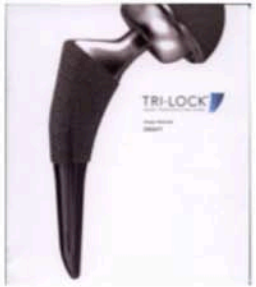
Clinical/surgical results are still early but all are encouraged with this stage of clinical review and we believe this concept will become main stream for THA.
Timothy McTighe, Executive Director, JISRF, Chagrin Falls, OH

Dr. Harry Rubash comes to Cleveland (8-23-10) to learn more about this technique with one of the early clinical/surgical advisors Dr. Louis Keppler- St. Vincent Charity Medical Center

Current Trend is Short Stems

And Certain Trends are Emerging

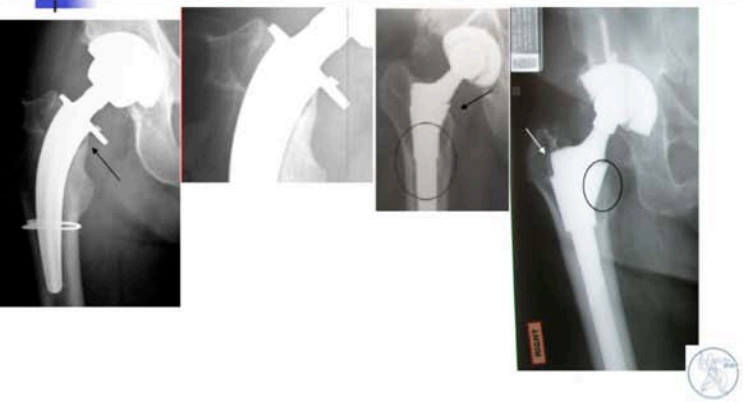
Huggler
Thrust Plate Hip



Short and Bulky
Not Neck Sparing

Mayo Stem Influence

Examples of Stress Shielding



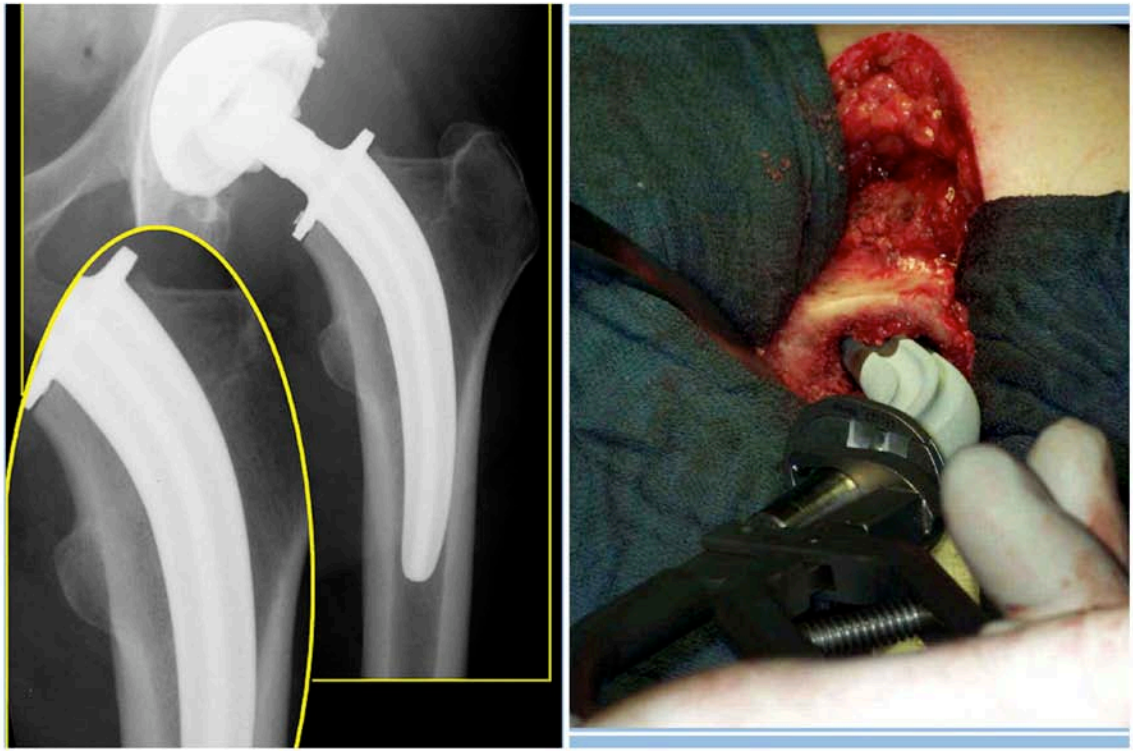
Examples of Stress Shielding

Lack of proximal geometric shape for load transfer

Bone loss in short stems could resort in potential torsional instability in young active patients.

Stress Shielding is an issue that can be improved upon.

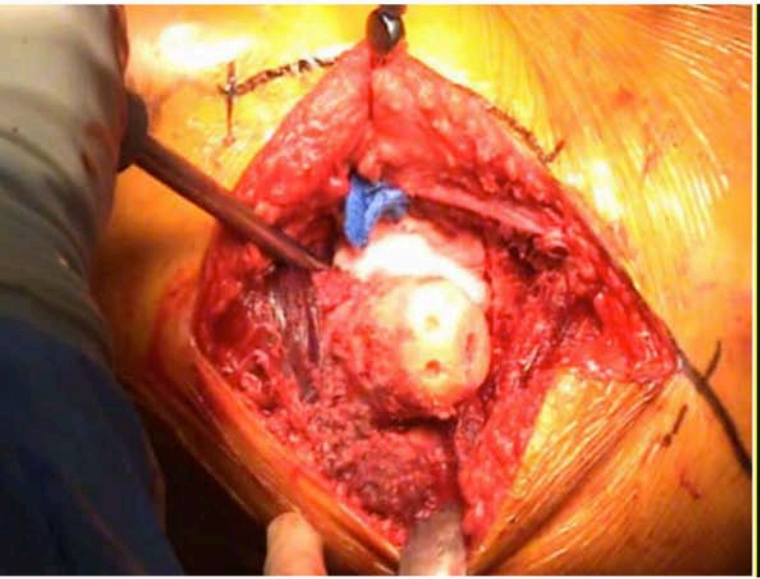
C.F.P.

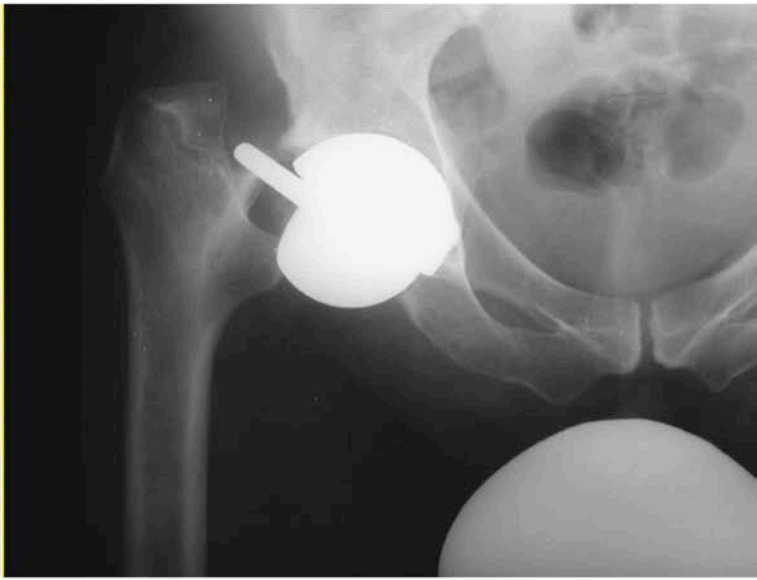


Prof. Pipino's work is the current standard in neck sparing stems.


½x

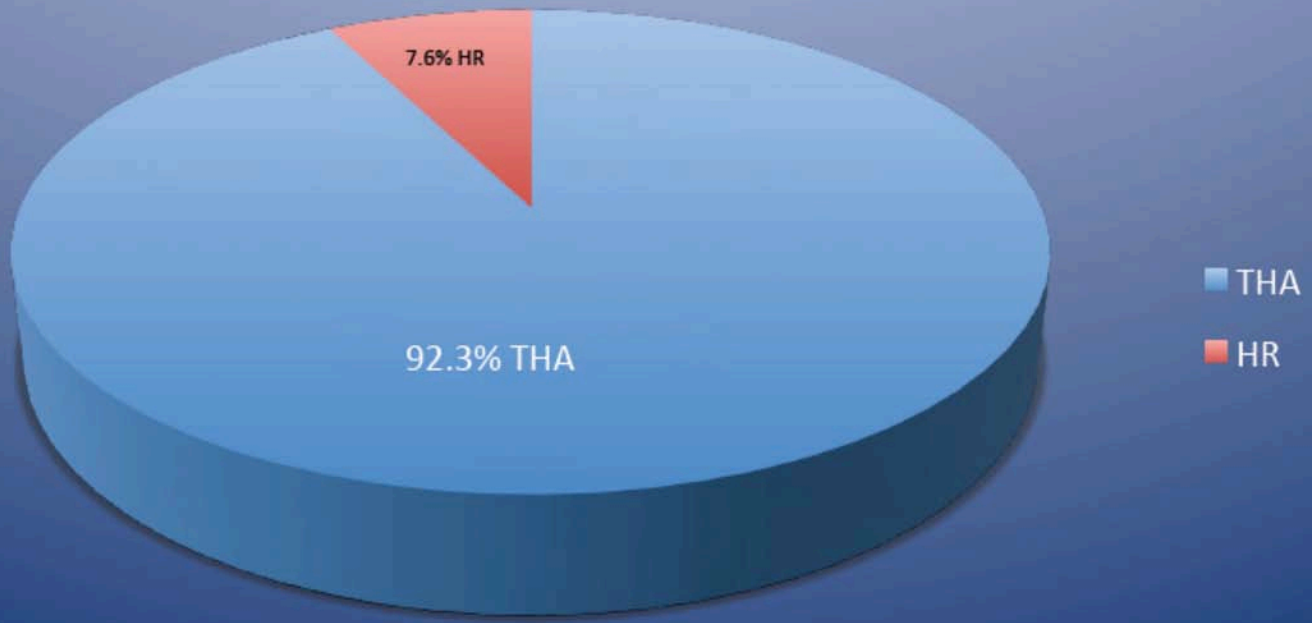

j.Keggi



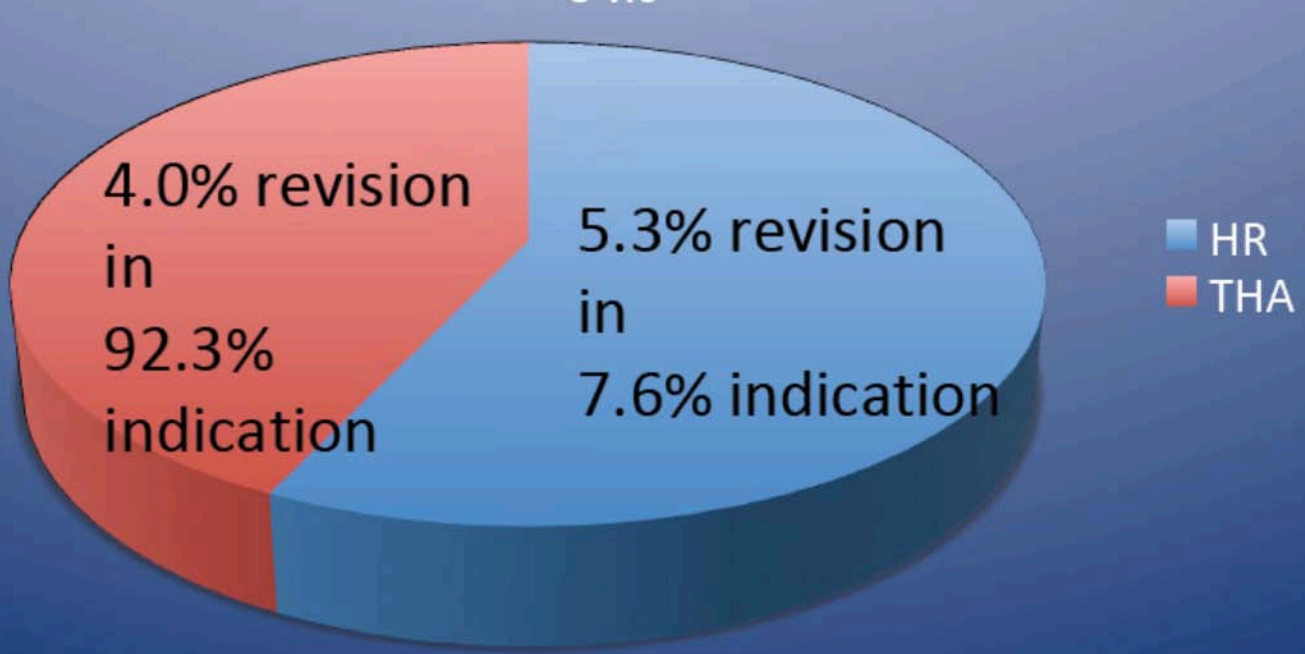


Is this truly a conservative approach?

All THA
2008 Australian Registry



Yearly Cumulative % Revision of PTHA vs. HR in OA Patients



Resurfacing Hip Replacement

- Decreasing use

(8.9% of primary THR 2005)
(8.2% of primary THR 2006)
(7.6% of primary THA 2008)

Resurfacing compared to Conventional THR (OA)

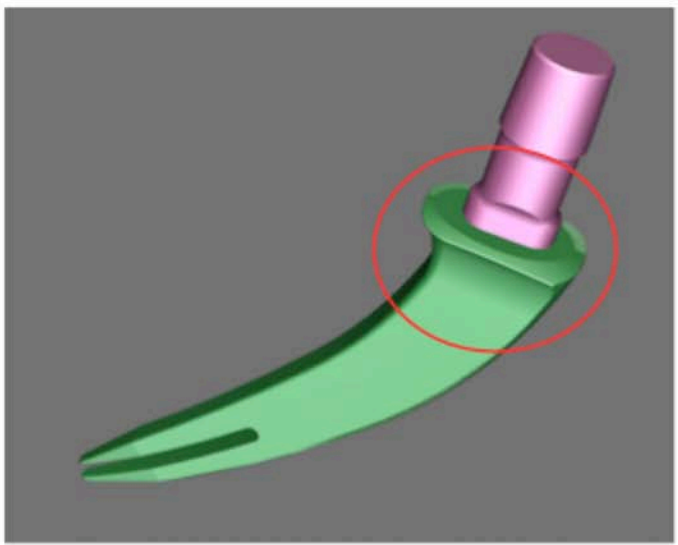
- Resurfacing has a significantly greater risk of early revision compared to conventional hip
- Revision rate for diagnosis other than OA high.
- Males over 65 yrs old have almost a 4x risk of fracture **P<.0001 HR=3.8, 95%CI (2.16, 6.72)**

Females fracture at a significantly higher rate than males than males PP<0.0001 HR=2.190, 95%CI (1.52, 3.16)

1994 designed McTighe conical collar straight stem

***Intrinsic/Primaloc™**

****TSI™ Stem w/ conical Flare**



*Maintains compressive loads on medial neck

**TSI conical flare functions like the conical collar of the Intrinsic stem

FEA modeling demonstrates better proximal bone remodeling for the TSI™ Stem design vs. Pipino Biodynamic stem

Remodeling Stimulus
Peak Gait

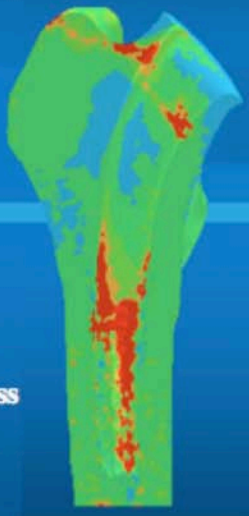
resorption — formation

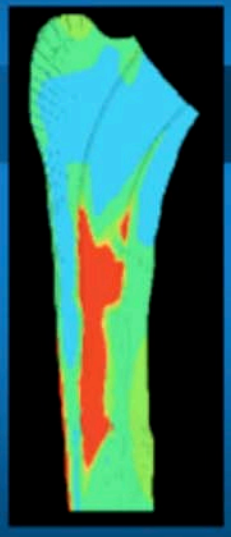
Short Stem/MSA™

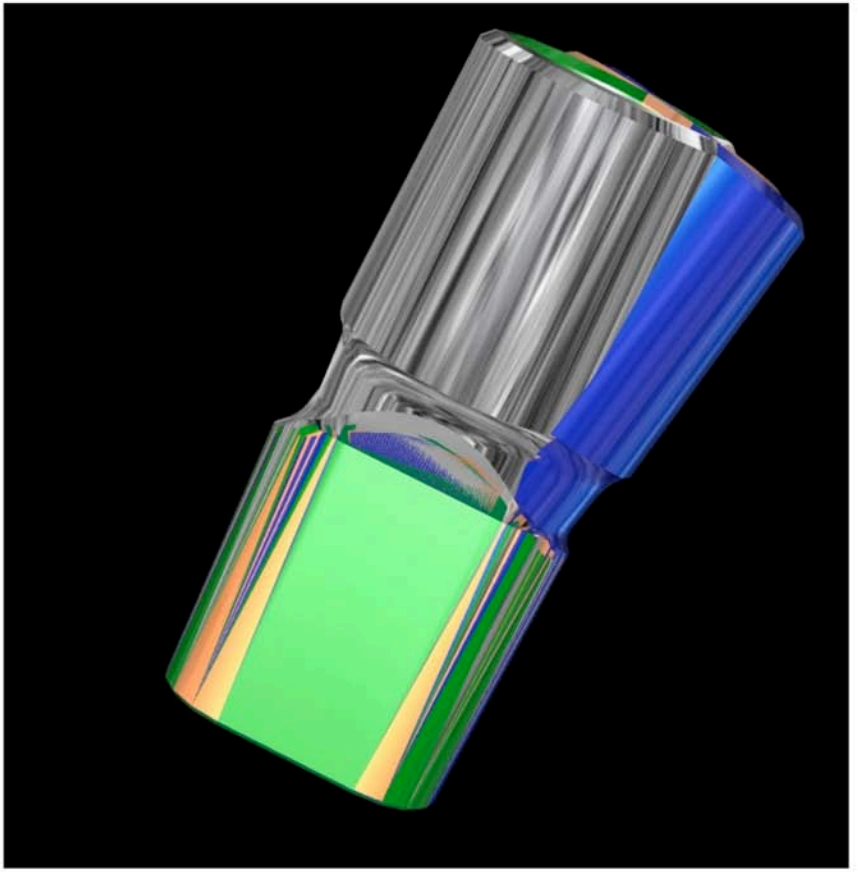
Biodynamic®

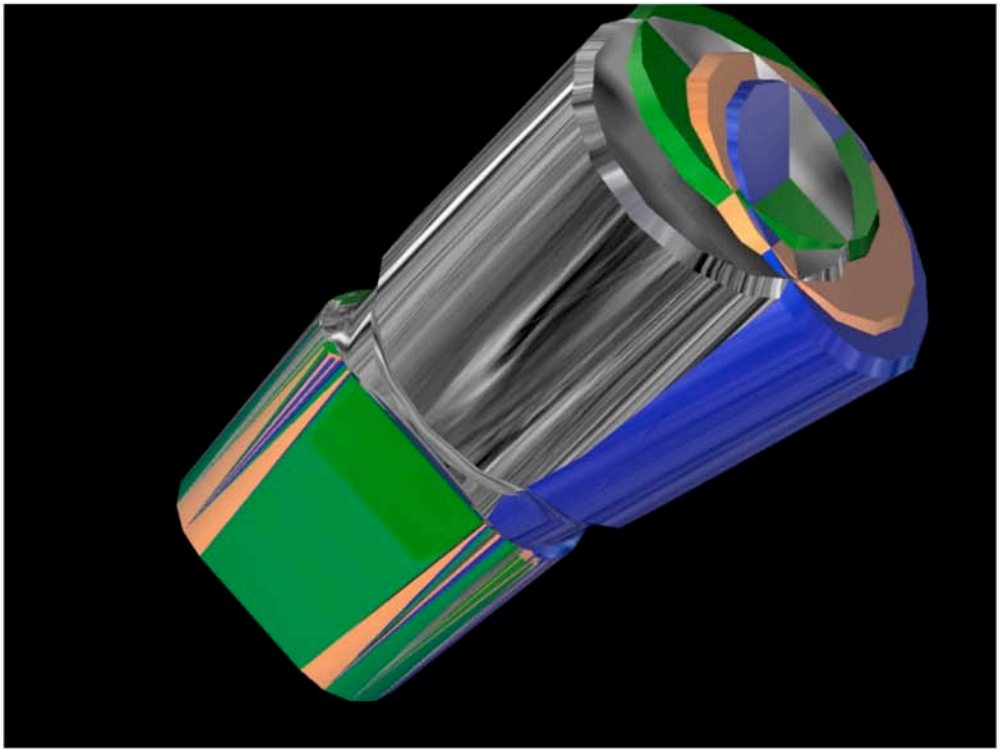
ARC™ Stem

Reduces stress shielding









Modular necks can and do aid in joint restoration.

Special Acknowledgment

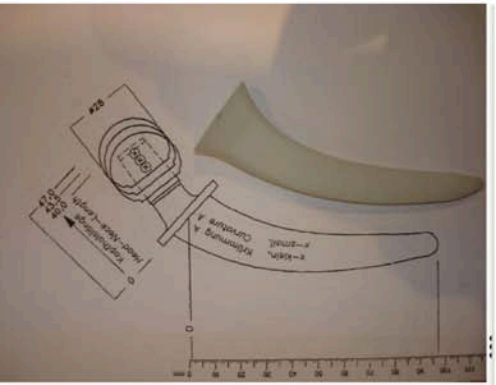
Dr. John Keggi was the first surgeon I discussed this concept with then his Uncle Prof. Kris Keggi, Hugh Cameron and Dr. Louis Keppler. Then to a select group of friends in Australia. Drs. Allen Turnbull, John Harrison and Ian Woodgate.

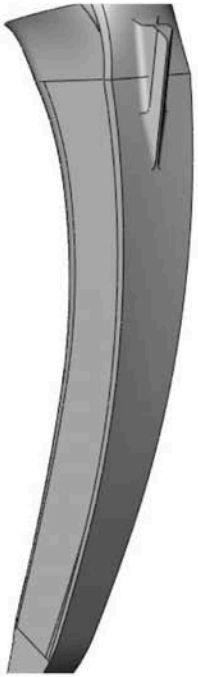
From that point Drs. Ted Kennon, Ed McPherson, Tom Donaldson, Dickey Jones, Larry Trick, Terry Clyburn, Brad Vaughn all gave encouragement to move forward.

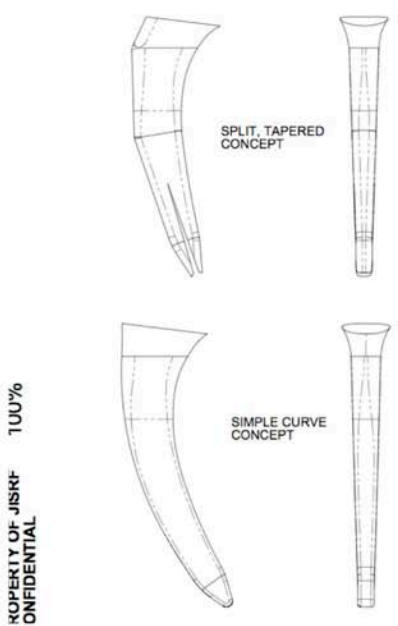
Industry support came by way of Global Orthopaedics in Australia and Omnilife Science in the U.S.A.

Currently there are about 30 surgeons implanting between Australia and U.S. will the first five patients out 2 1/2 years post-op.

A number of studies are underway and will be reported on as data is available.







Early prototypes

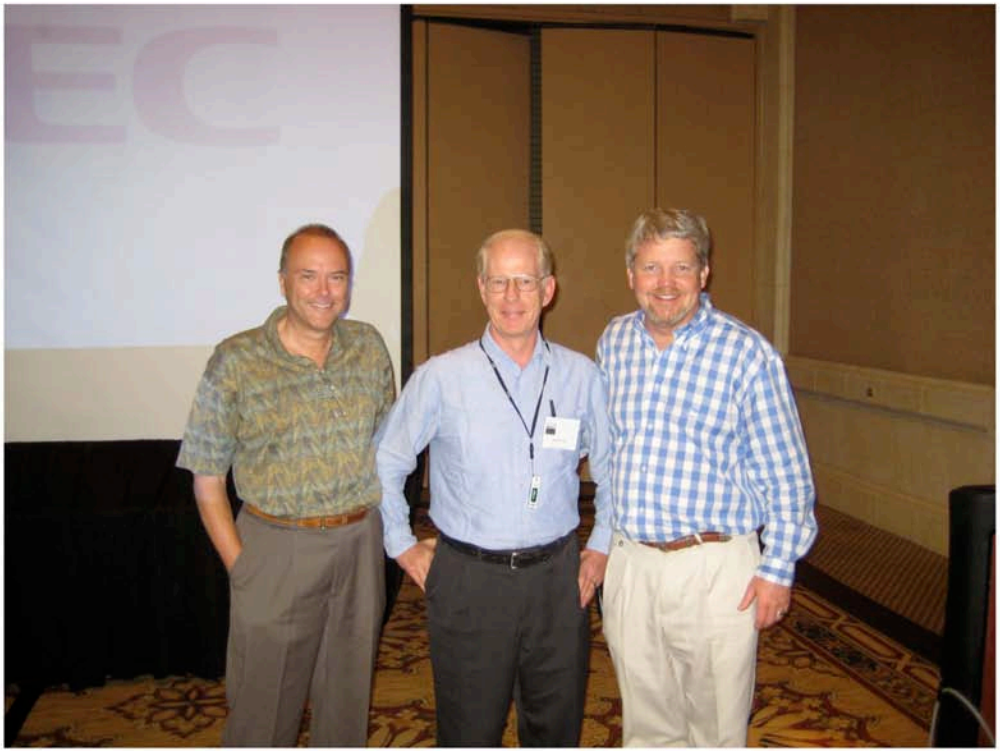
First stem off the Australian production line 2007.

Early days at Yale Cadaver Lab

Drs. Allen Turnbull,
Bruce Shepherd and John Harrison (Past Presidents of the AOA) Sydney, AU

Allen Turnbull visiting Ted Kennon and John Keggi

Early discussions (McTighe, Mike Ribot, Larry Battista & Allen Turnbull) Chagrin Falls, OH
Ribot & Turnbull from Sydney, AU

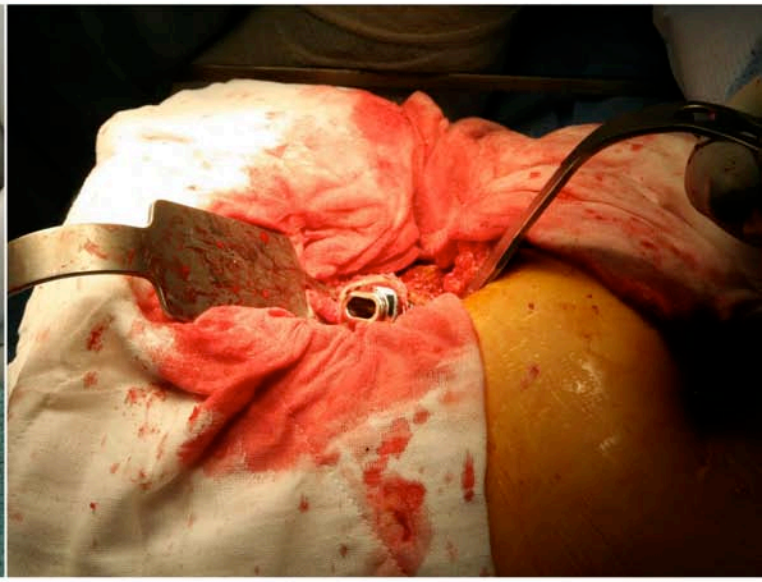


With Drs. Ian Clarke and Tom Donaldson first paper presented at Tom's meeting 2007

Presenting at CME meeting in AU.

Emes, McTighe, Tkach and Vaughn in Au
Visiting Dr. Woodgate and viewing his technique on TSI™

Prof. Ian Woodgate doing the first MSA™ stem December 2007

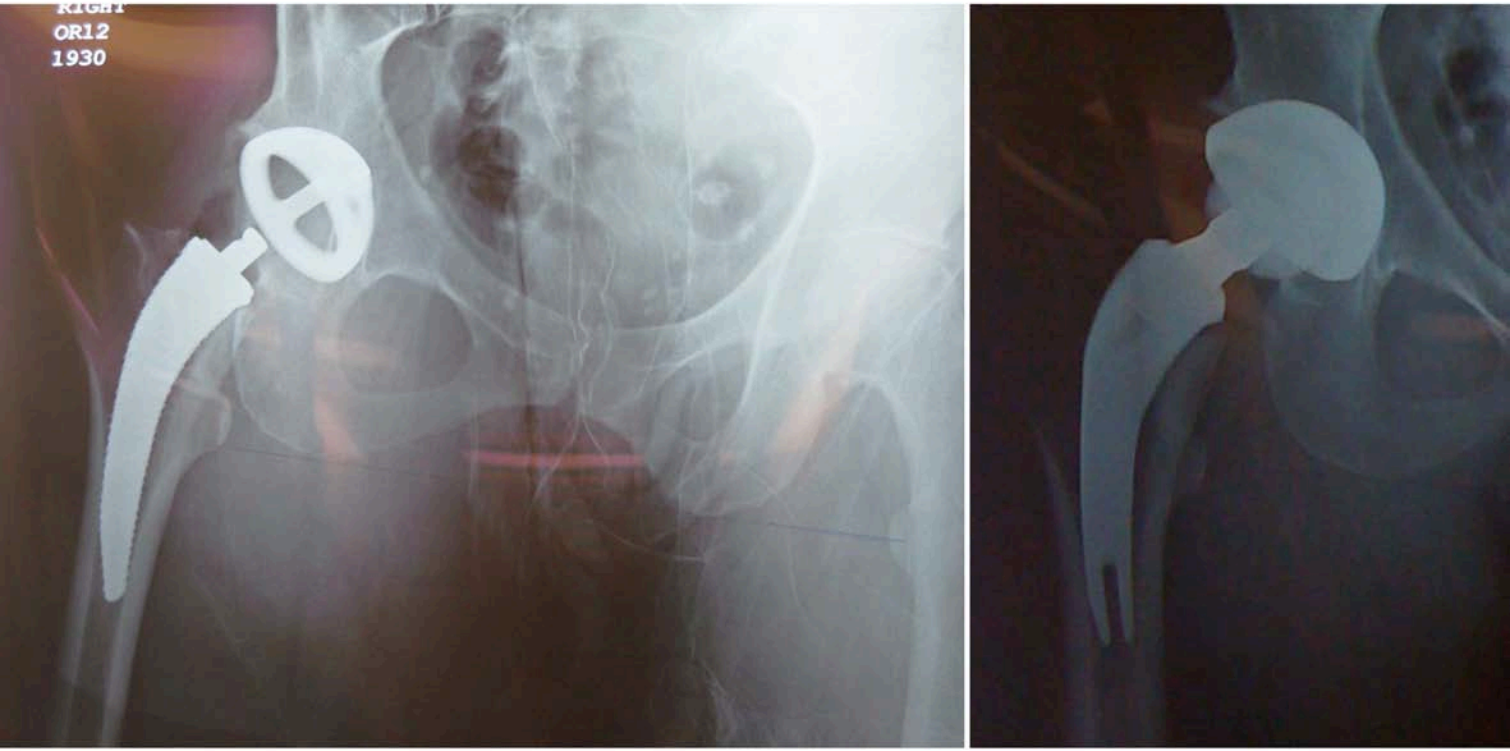


First stem implanted in Australia

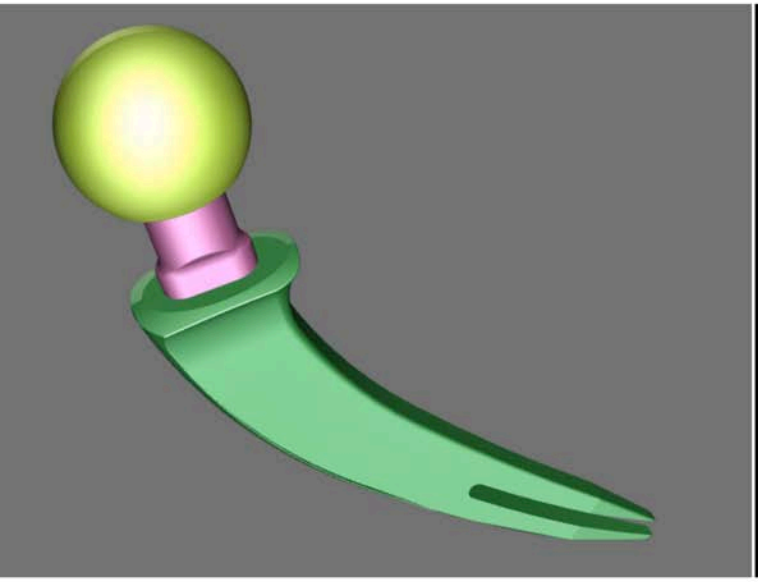
Current MSA™ Stem licensed to Global Orthopaedics

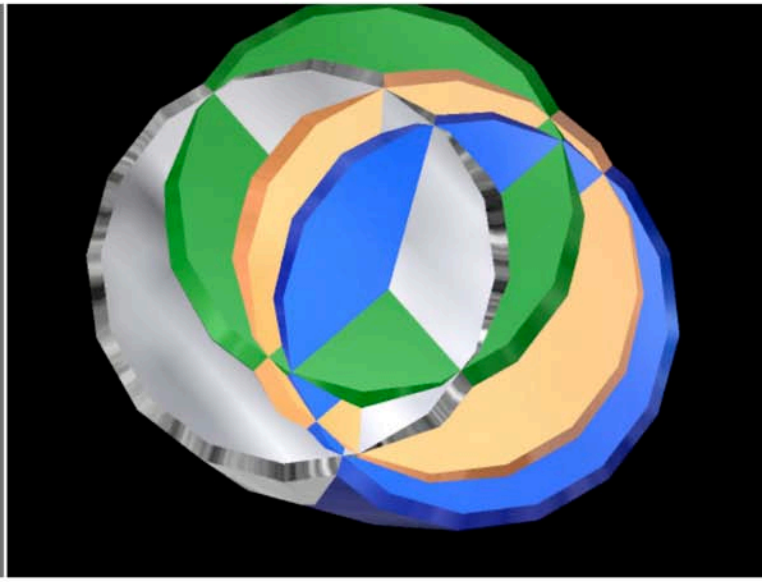
Current ARC™ Stem licensed to Omnilife Science

Lou Keppler doing the first ARC™ in the U.S. April 20, 2010

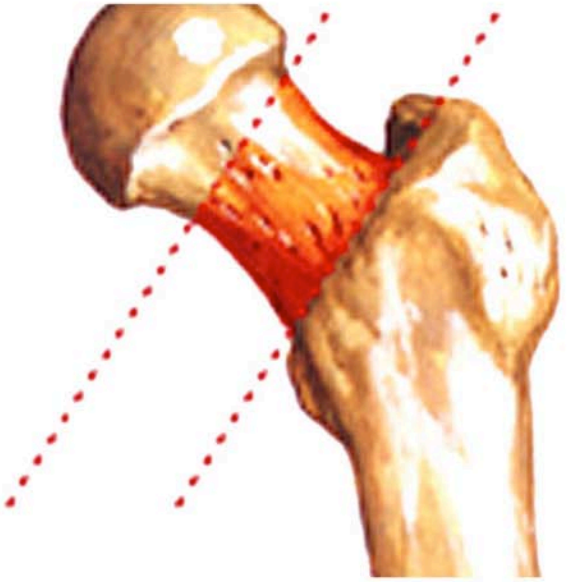


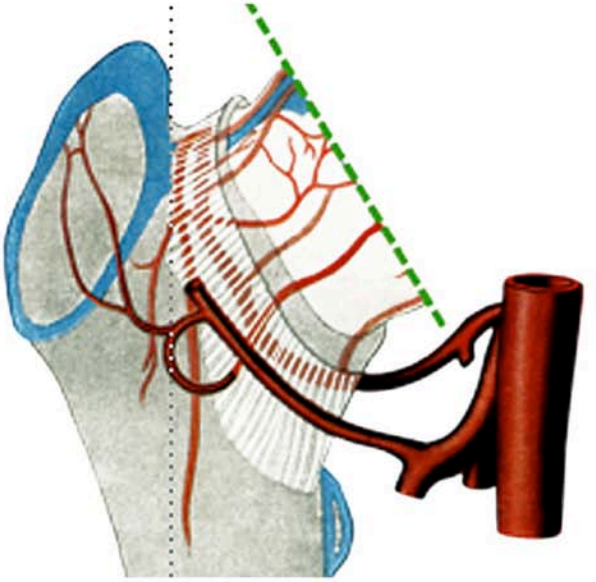
First ARC™ stem trial/ final implant

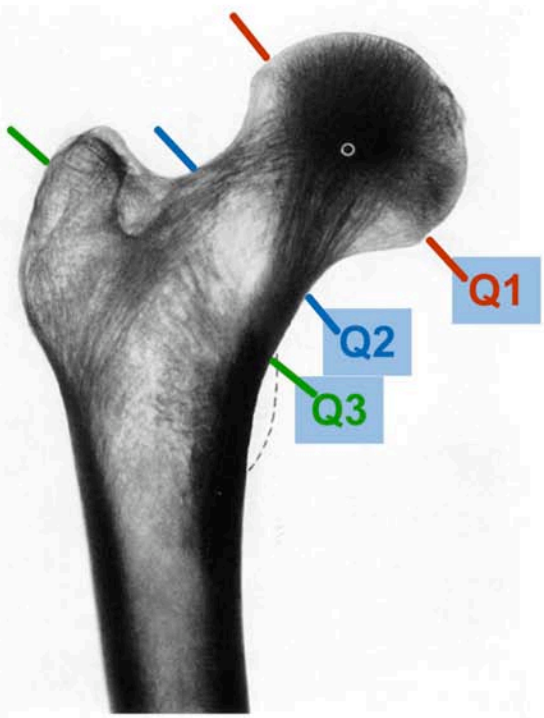


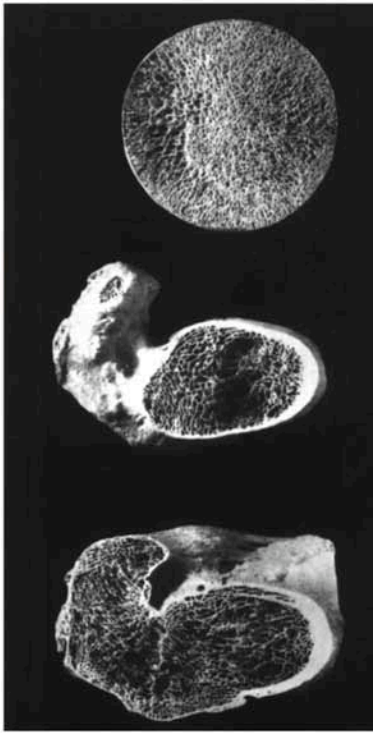


TSI™ Stem (tissue sparing implant)





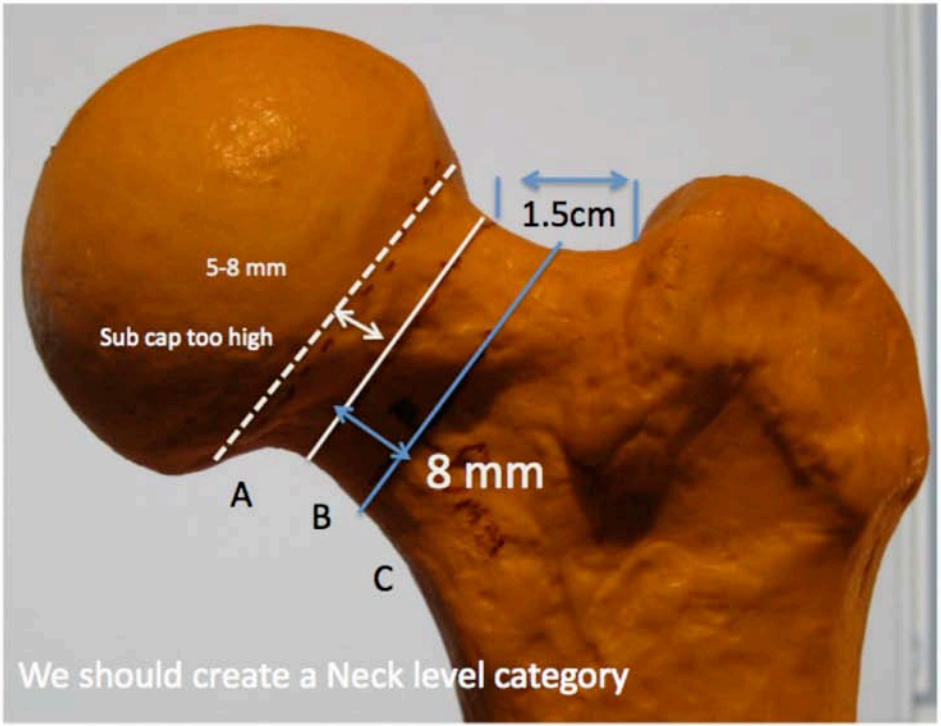


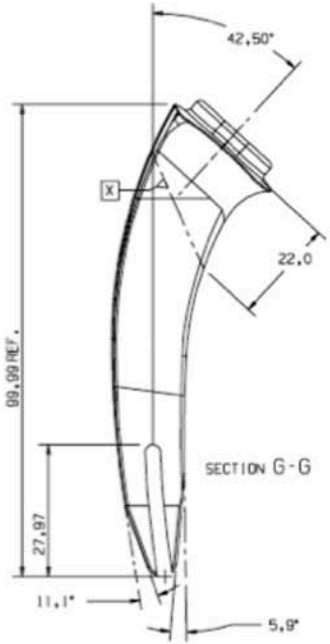


The goal is to be conservative

We can do better than this

Sub cap is too high
First cut provides maximum conical flair contact
design allows flexibility in level of cut but might effect size of stem
example: from a 2 to a size 3

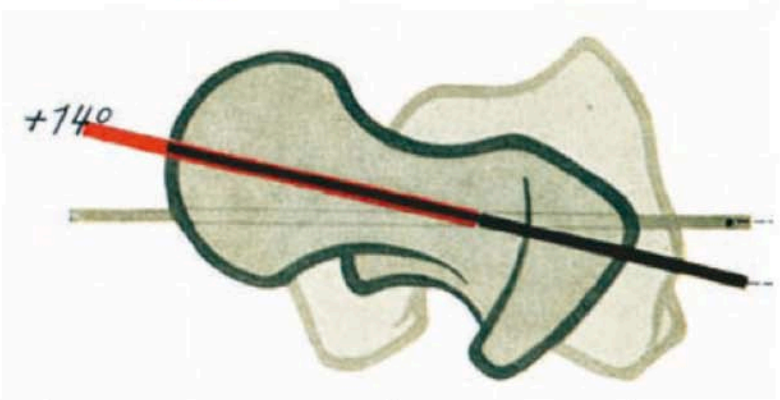


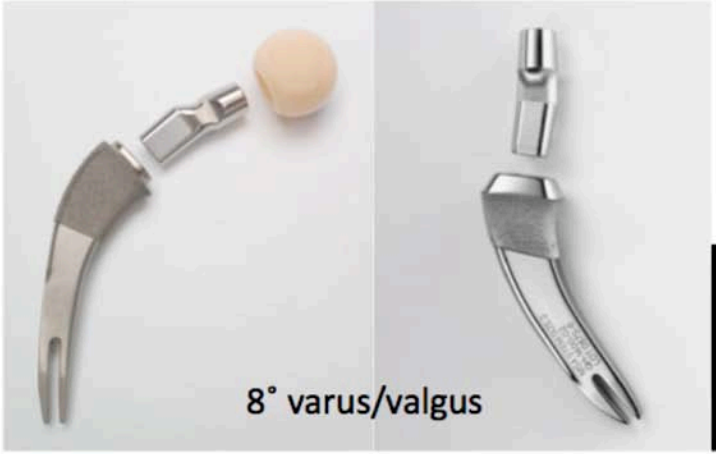


A: 5-8mm below sub cap
B:8-16mm below sub cap
C: >16mm Below sub cap

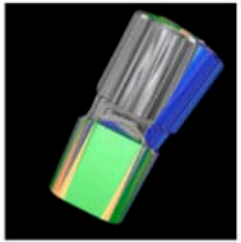
Note: conventional tends to run approximately 20 mm below sub cap level or 1.0 to 1.5 cm above LGT.

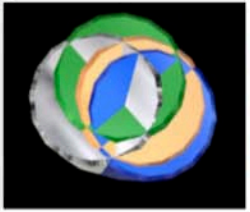
Pipino recommends
His stem has anatomical anteversion designed into the stem





8° varus/valgus



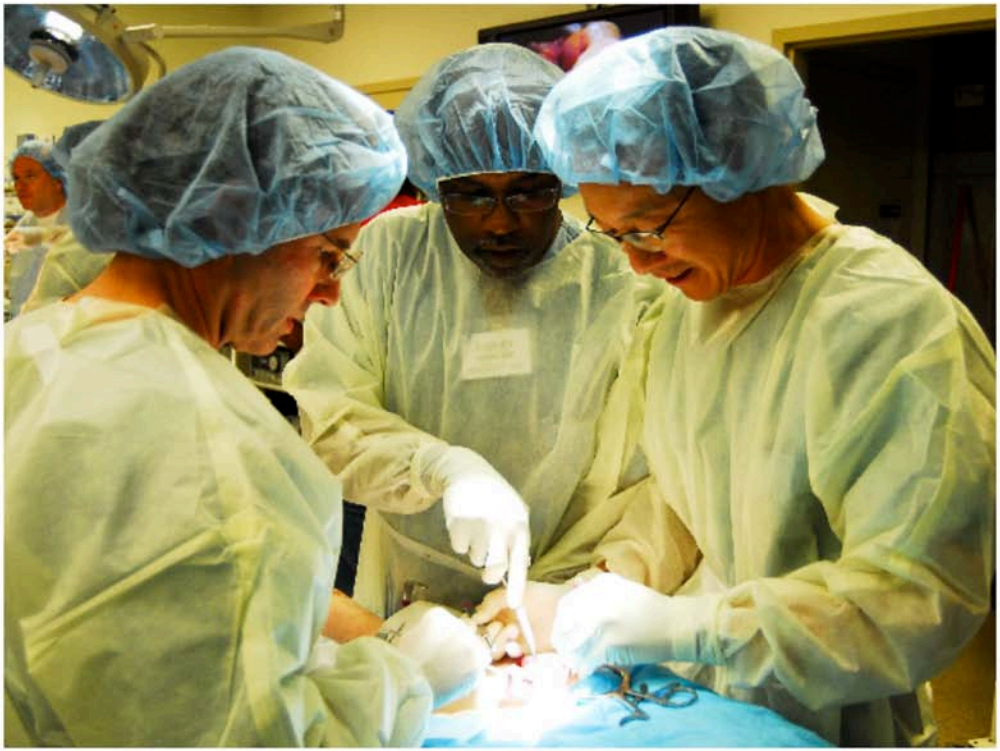


8-15° version
Can be helpful with malposition cup

Ed McPherson, LA, CA doing and intraoperative trial
then converting to a Micro-plasty stem.

Trial ROM

Chicago cadaver workshop and Brad Vaughn's first case.



Dr. Mackel, Bryant and Cho at Cadaver workshop in Chicago


1k x 1k
1
1
WESTE
JANET
OR.WALTER
RT.ORIF HIP
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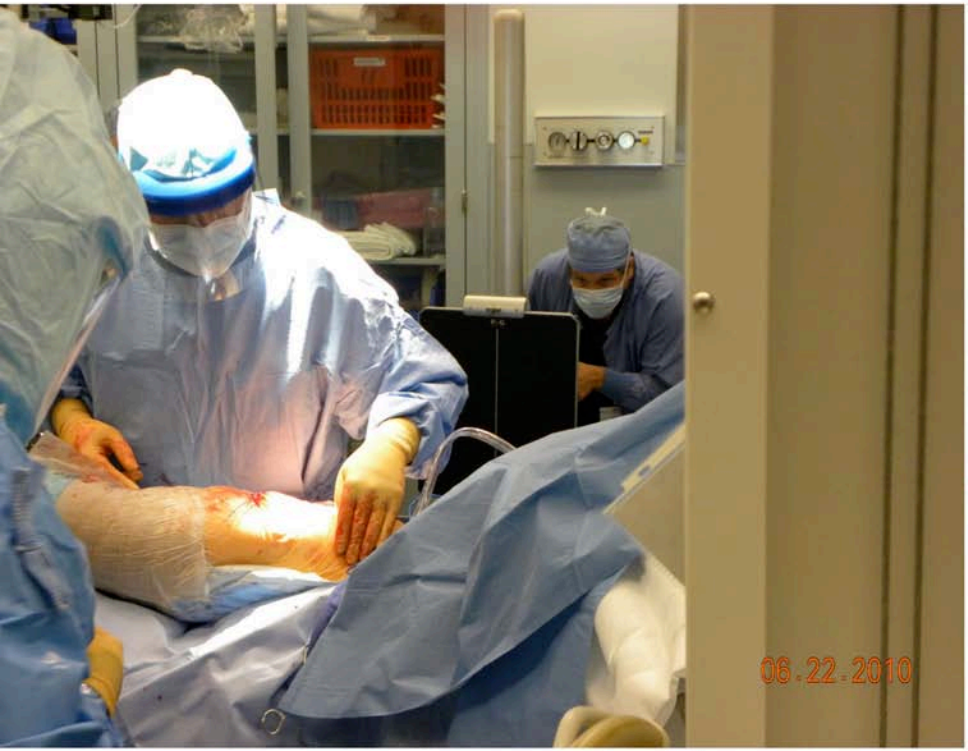
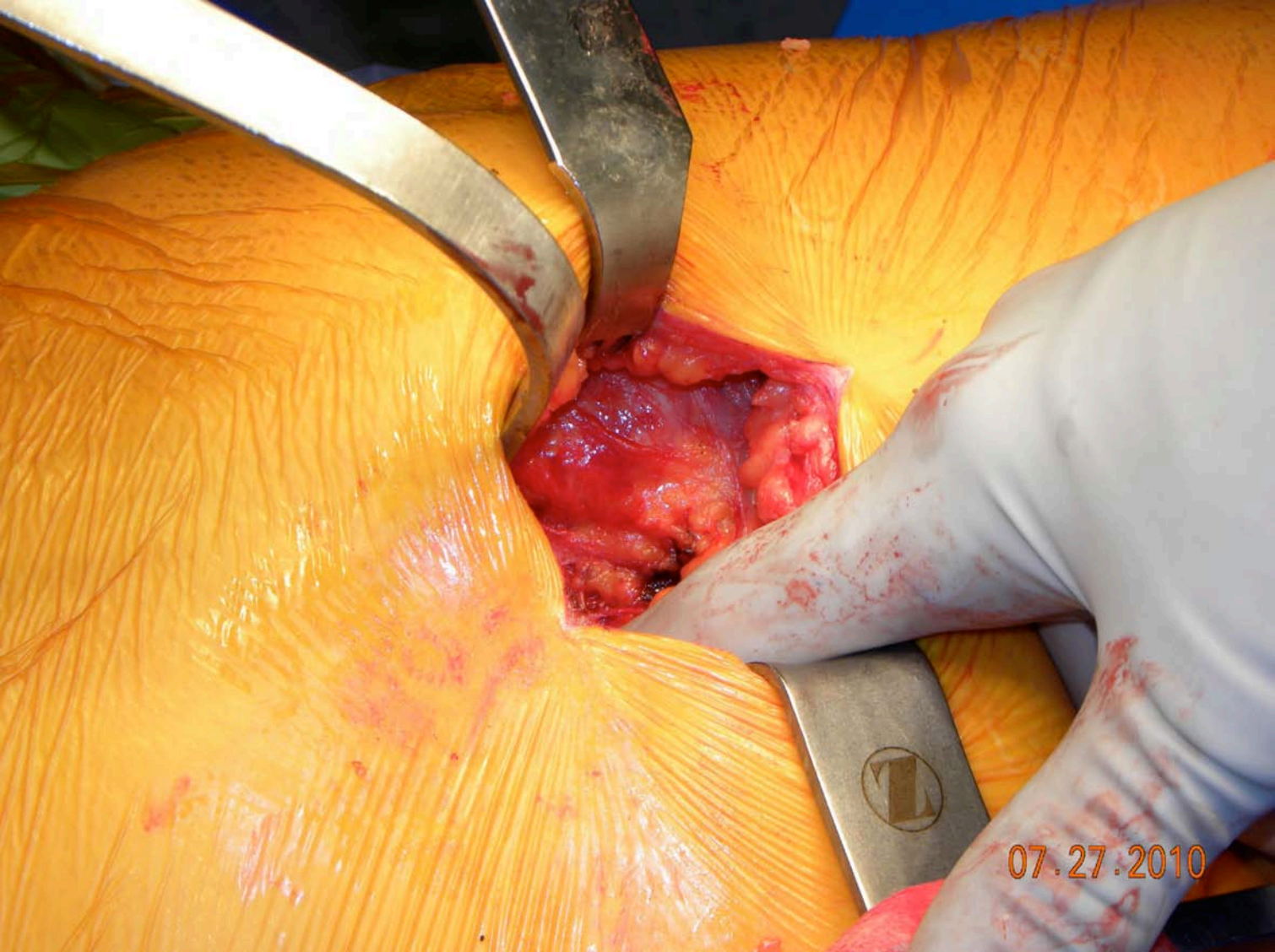
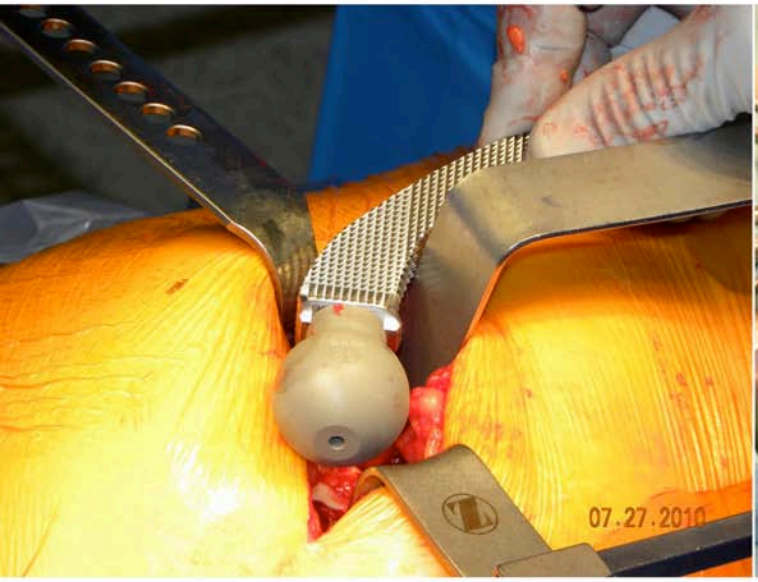
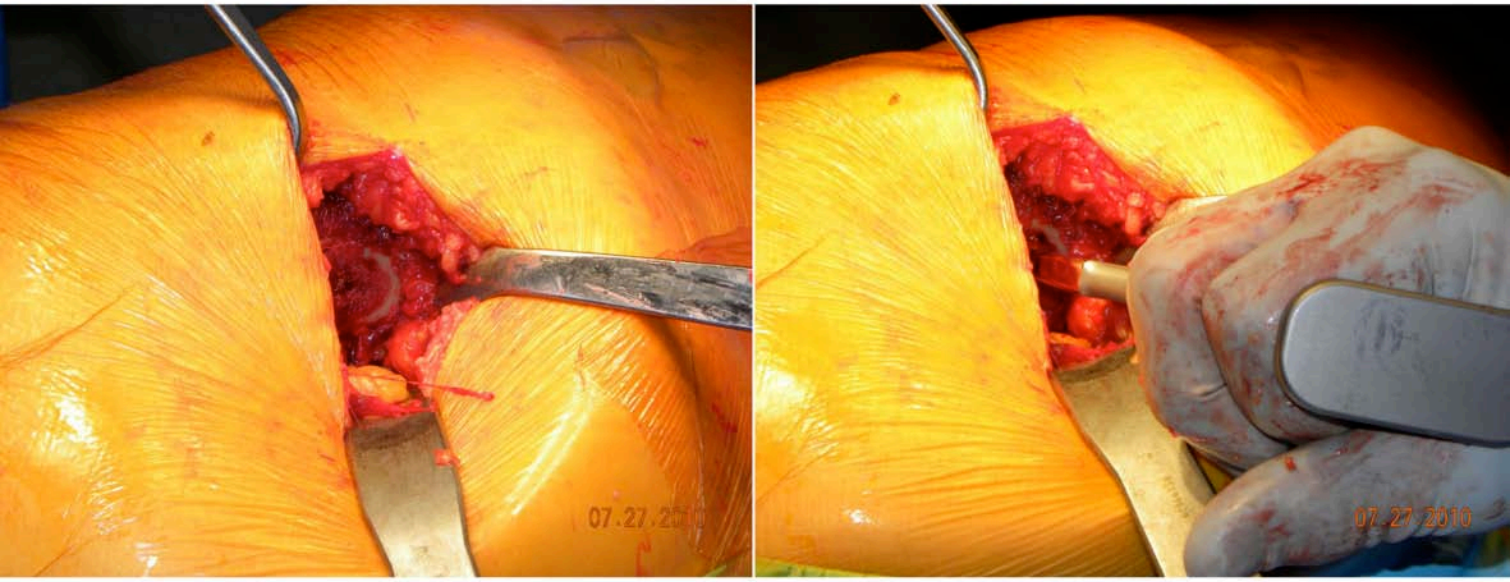


Intraoperative review is helpful

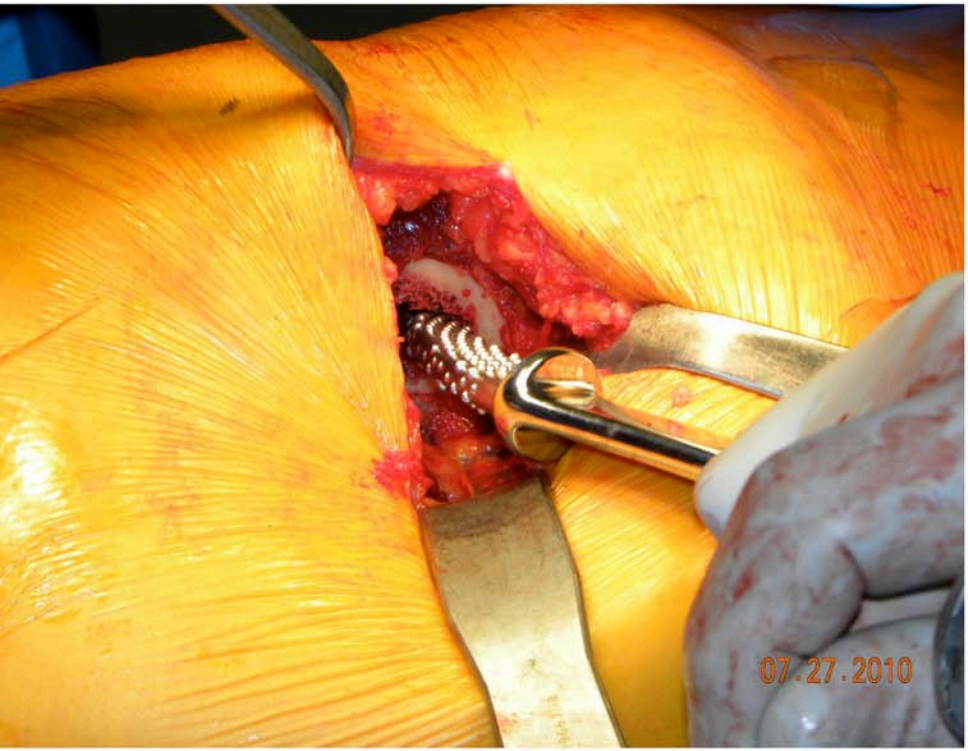

07.27.2010



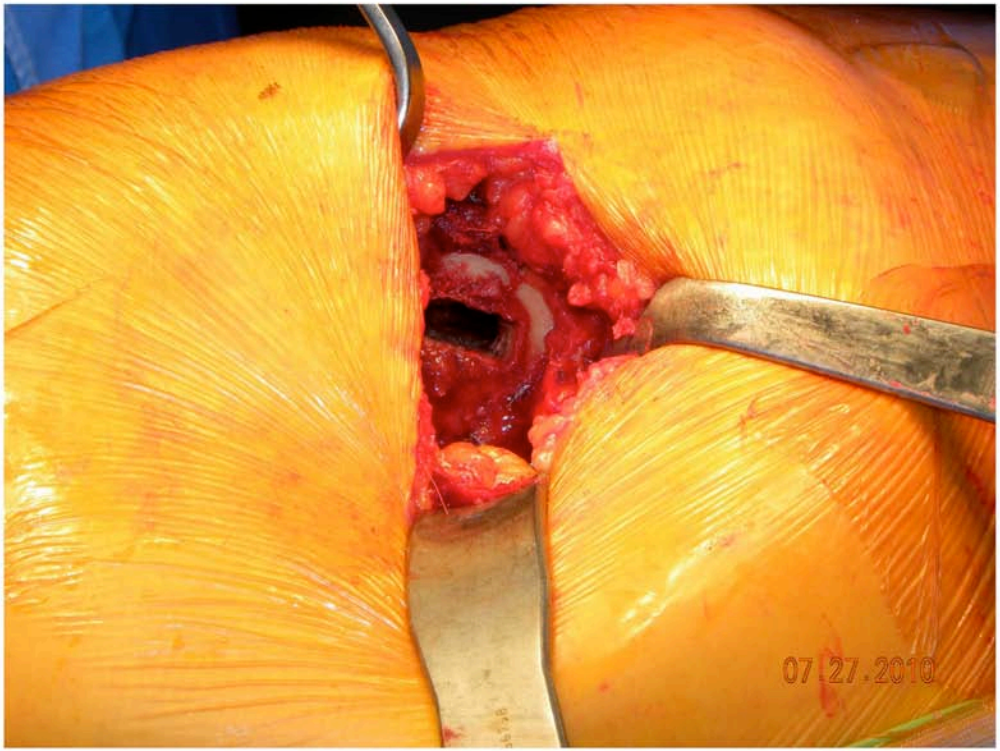
Small posterior approach Dr. Vaughn



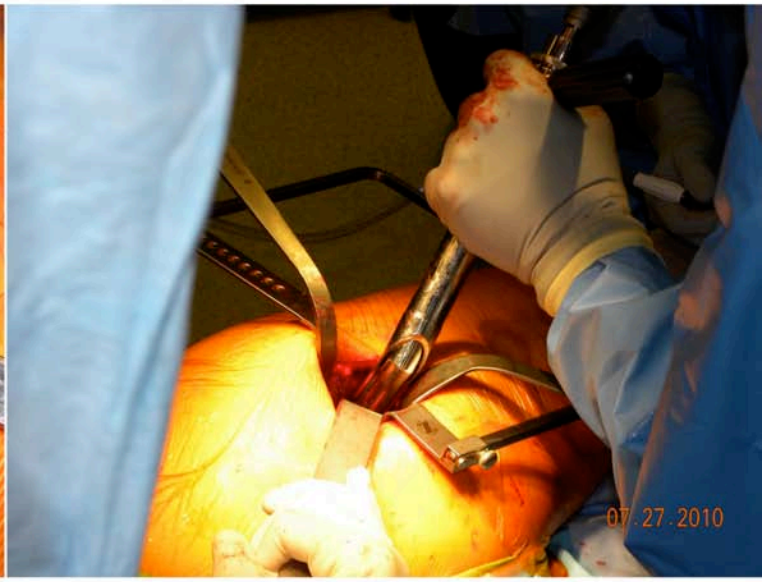
Femur first as advocated by Keppler



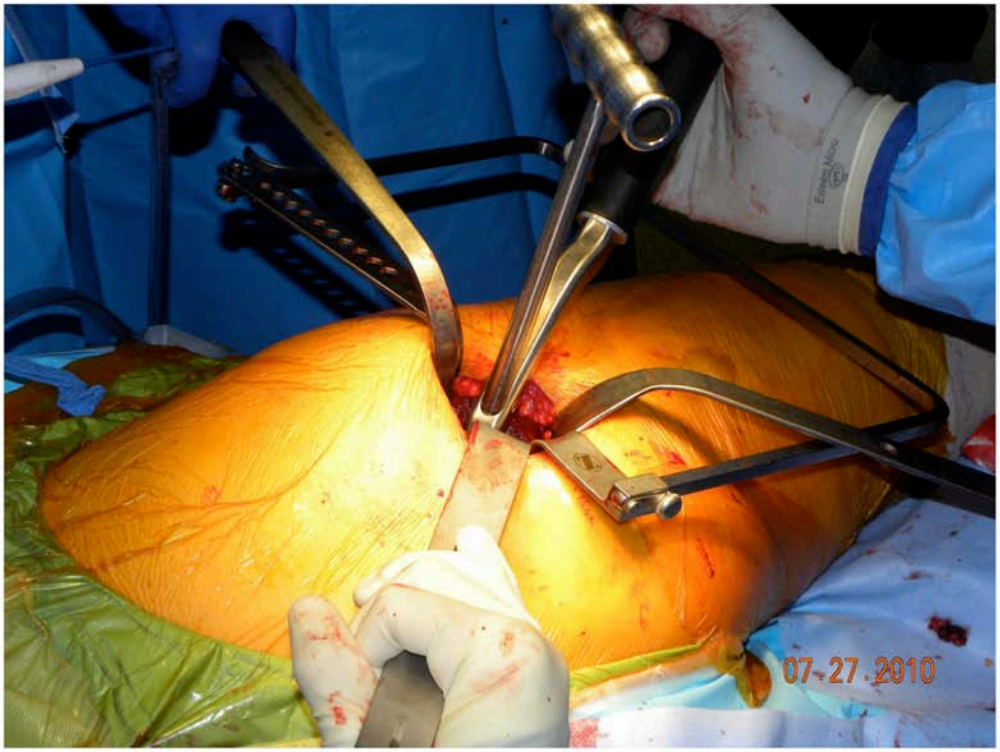
Muller rasp as a starter is helpful.



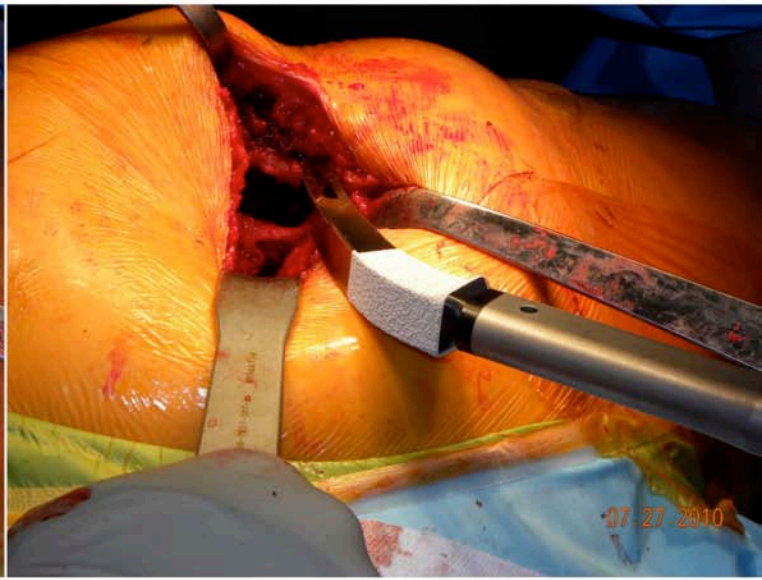
Shape is intrinsically stable



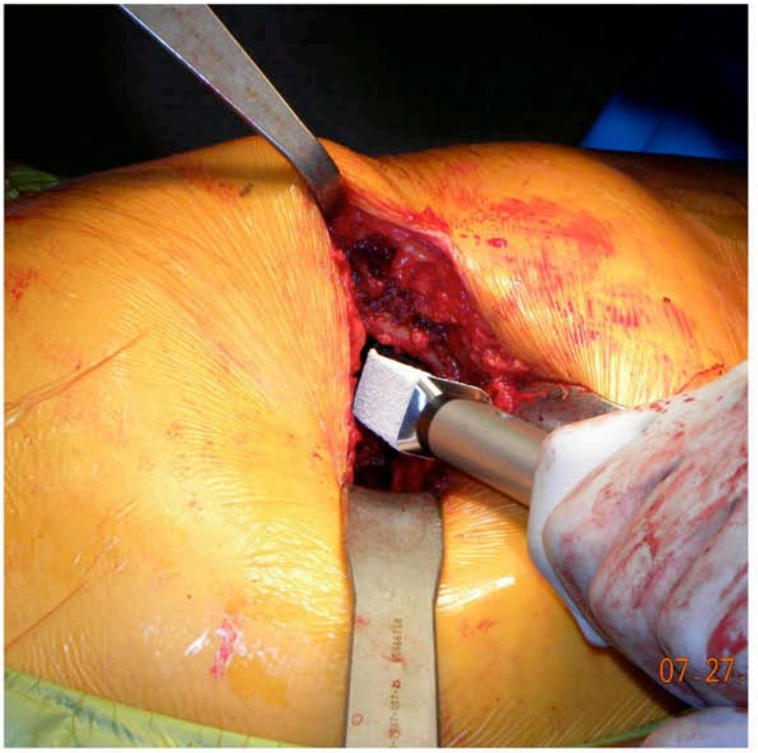
Socket prepared after femur (posterior approach)



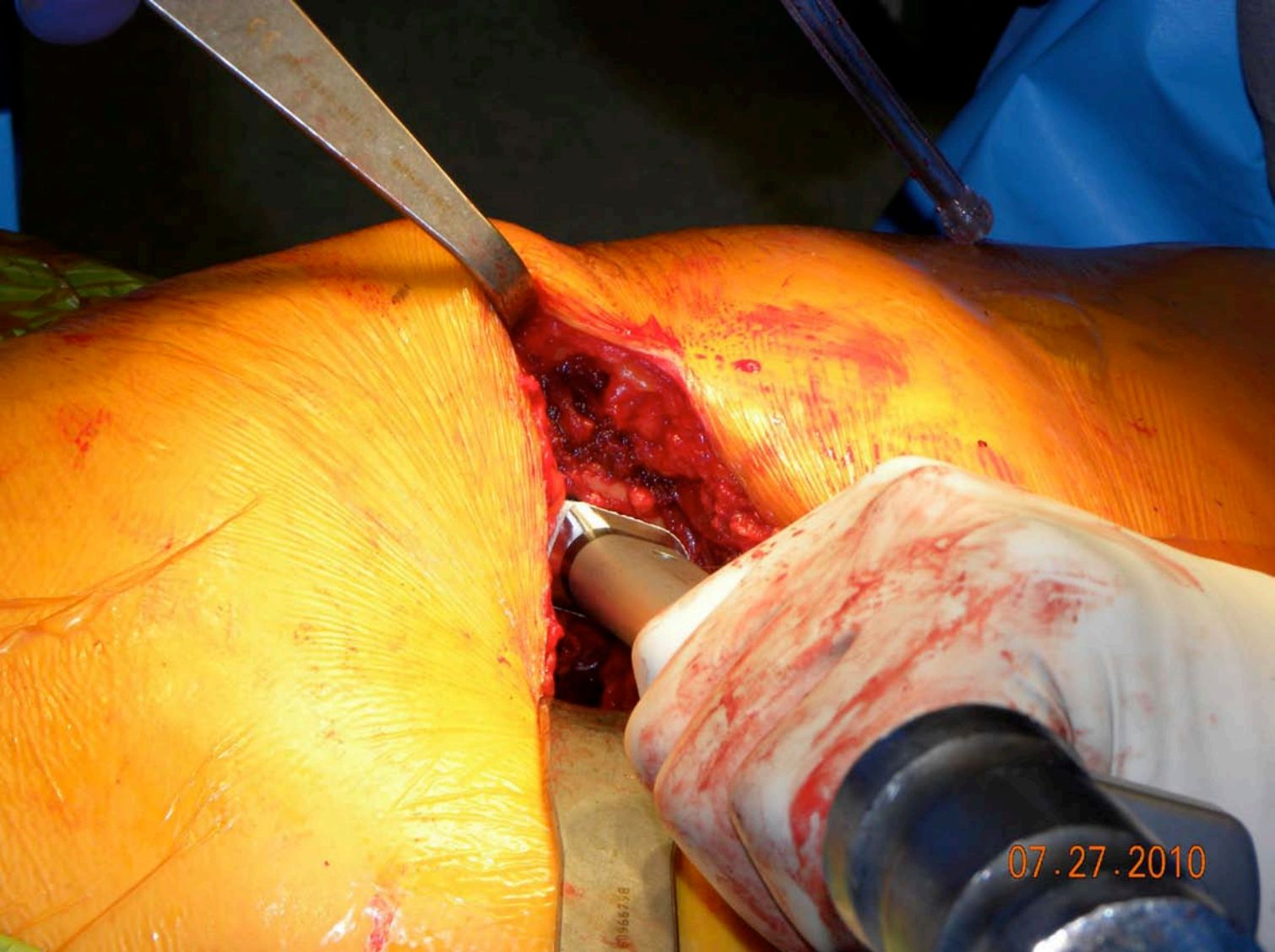
Cup insertion no problem with high neck cut



Trial rasp in place and insertion of final stem



Final stem provides for a press fit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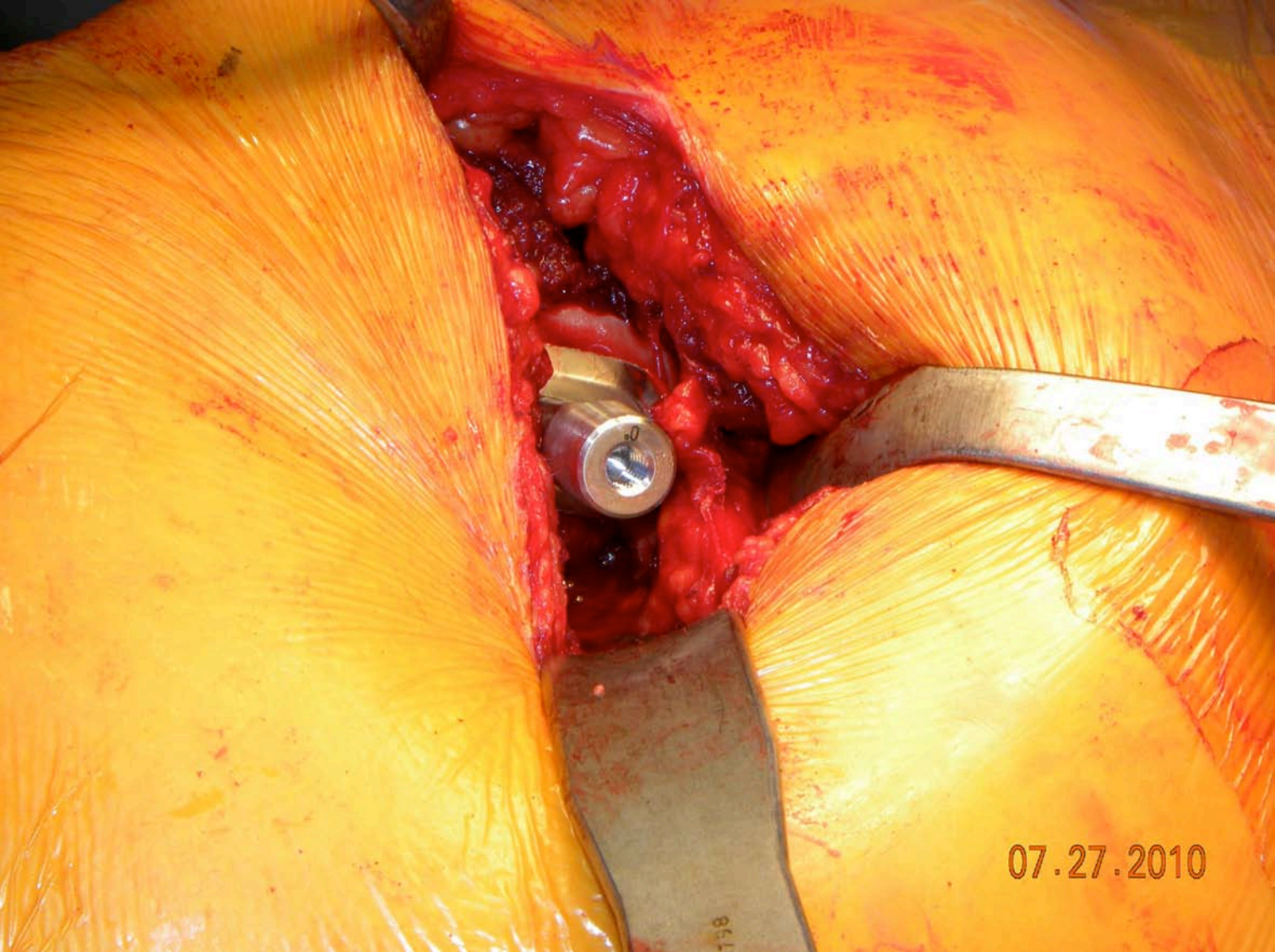
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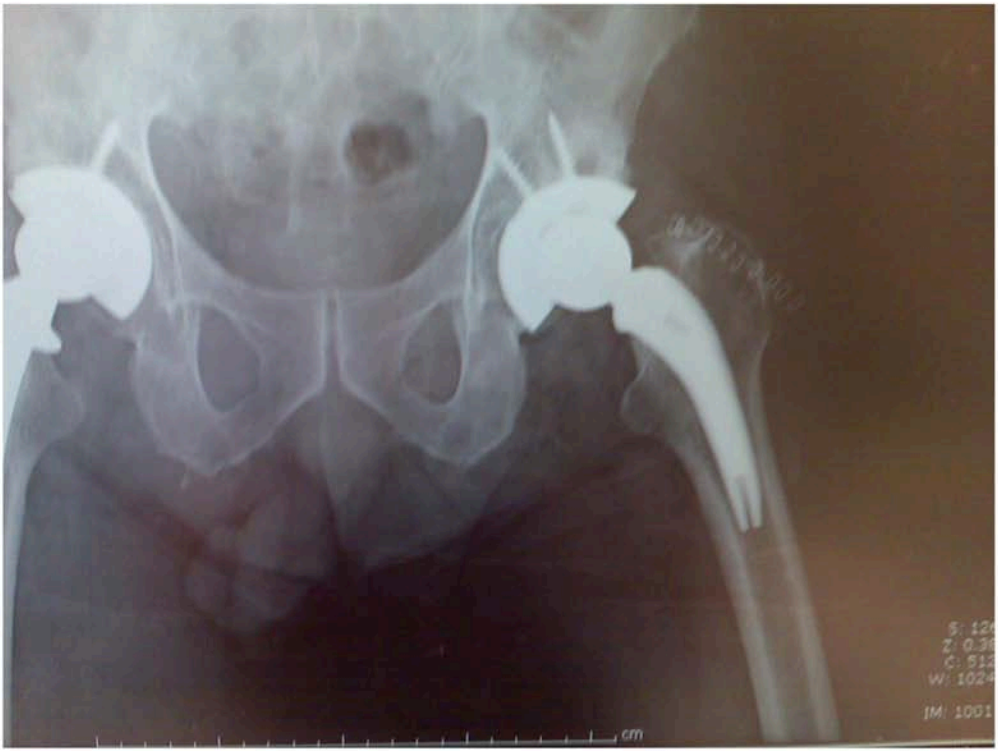
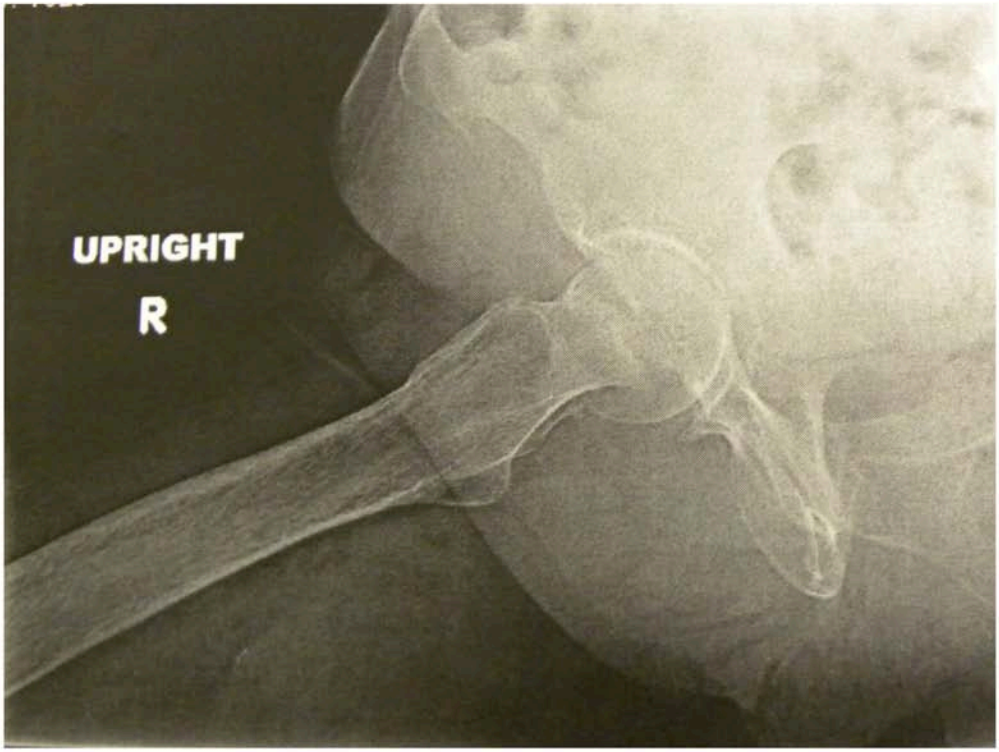
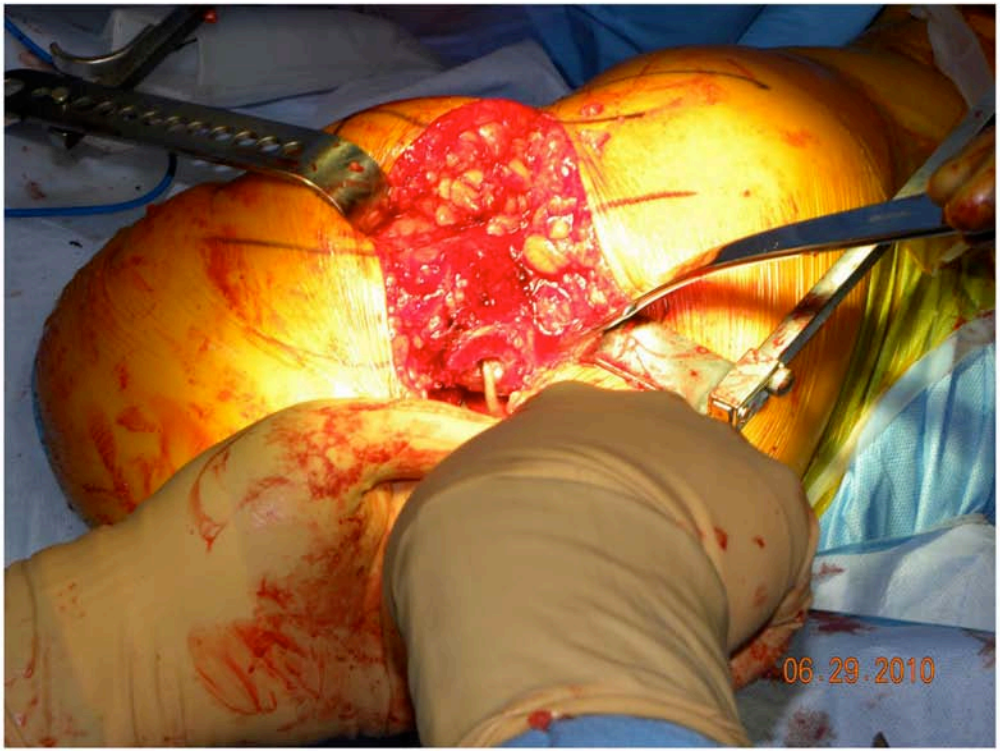


Fully porous coated stem on opposite side

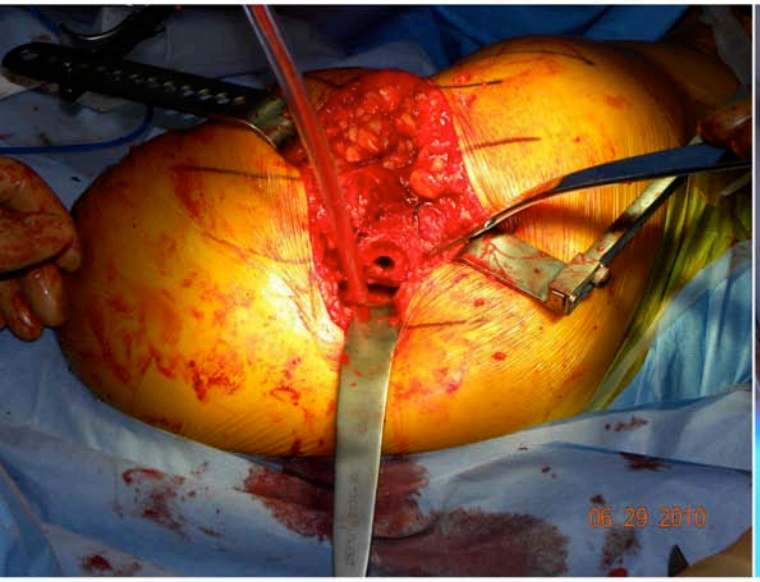


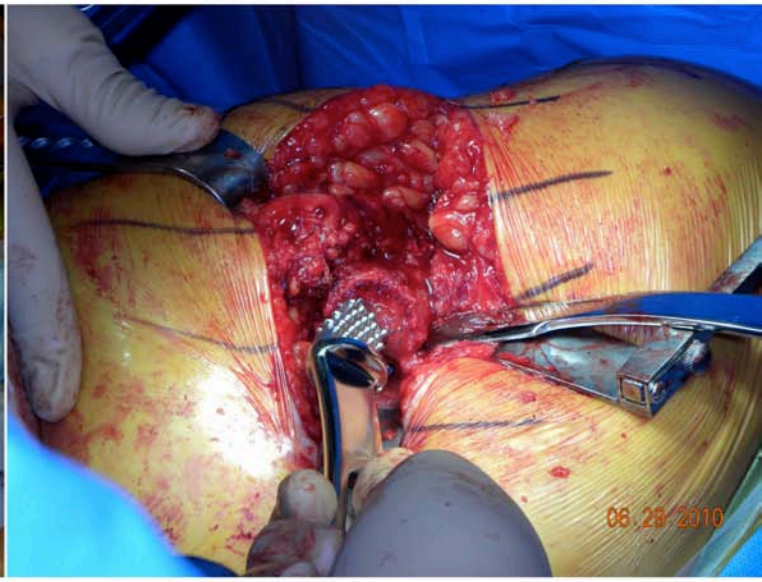
Keppler sub cap fx.


06.29.2010

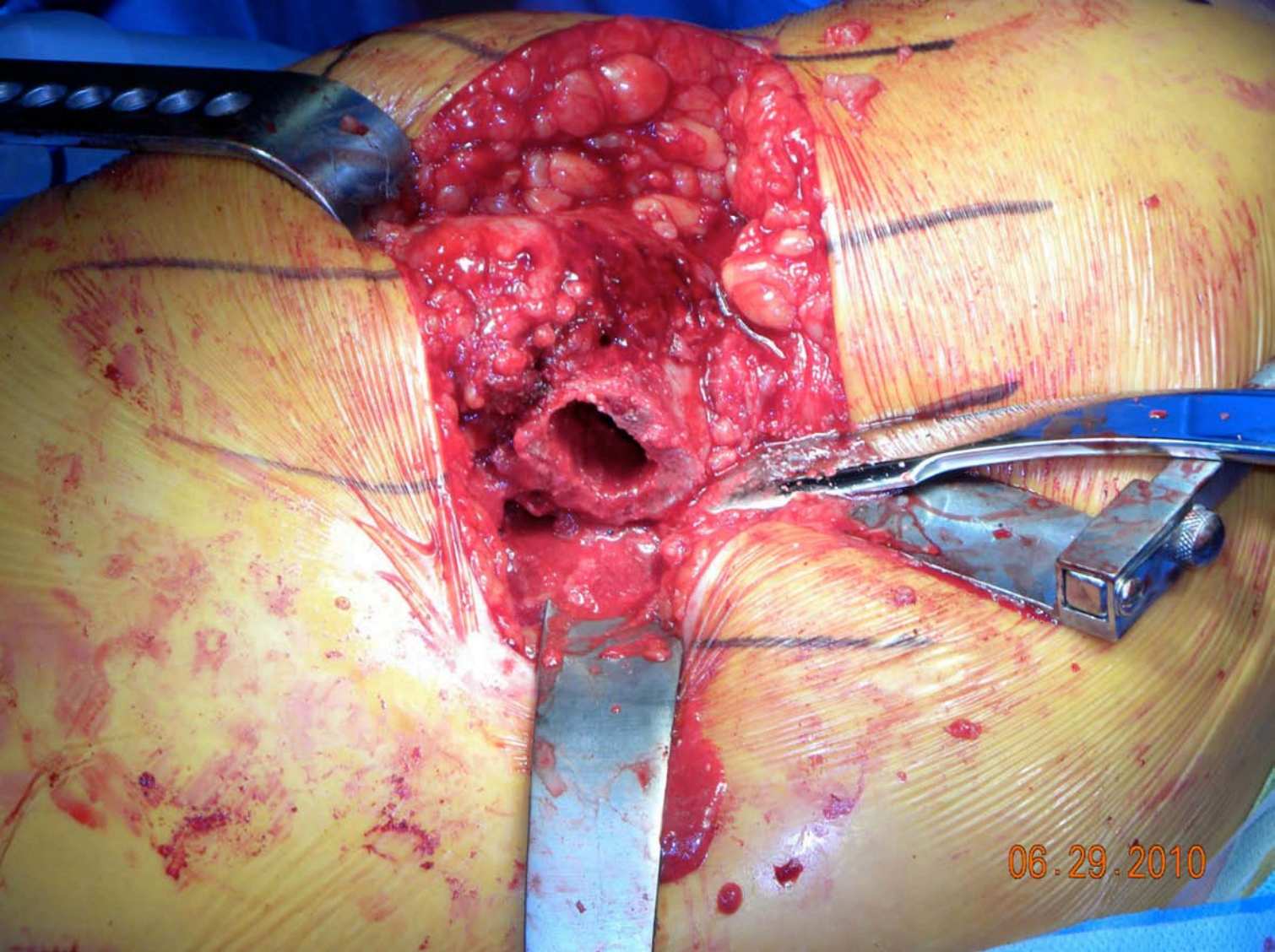


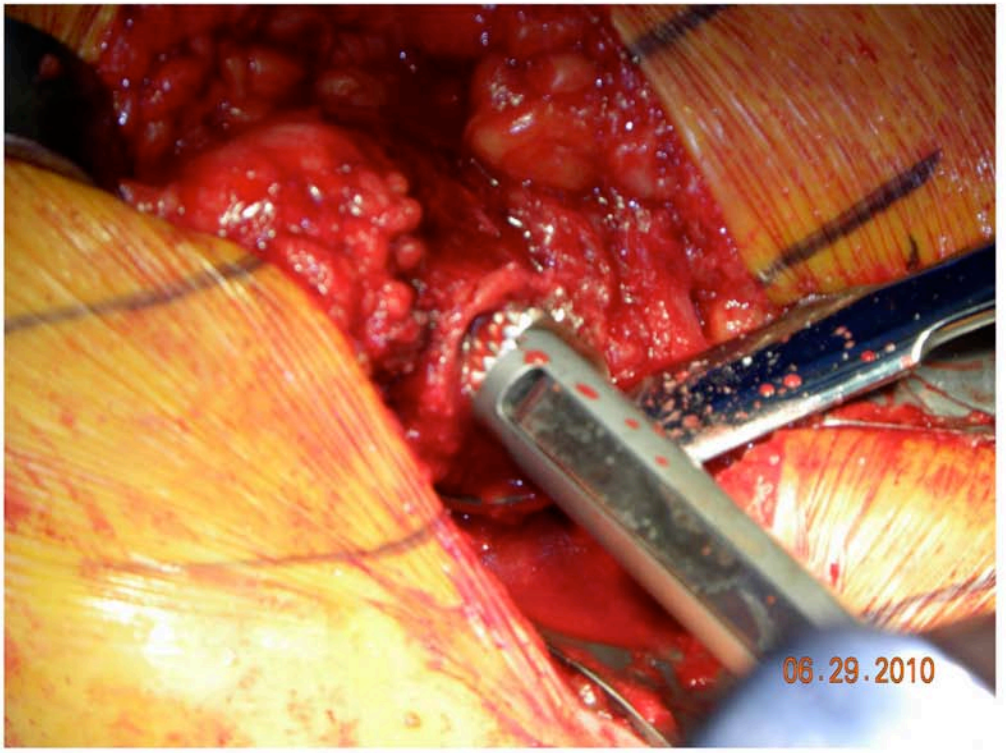
Curved curette used to open the femur



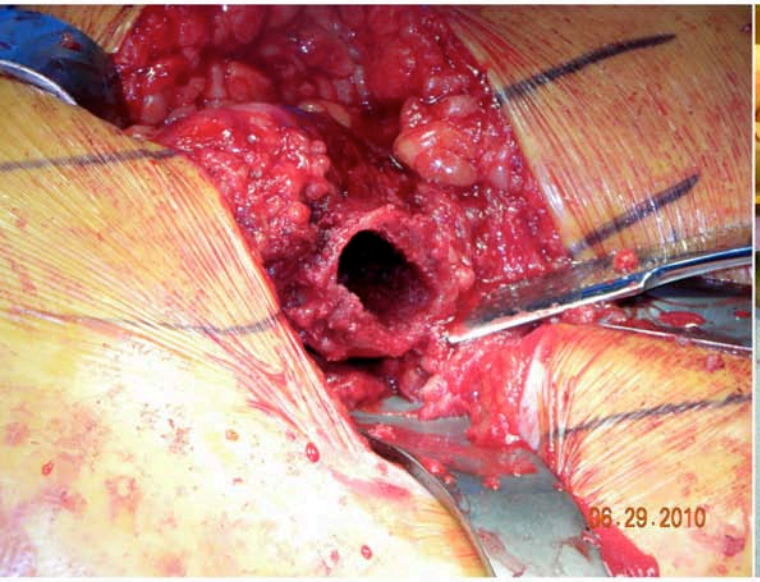


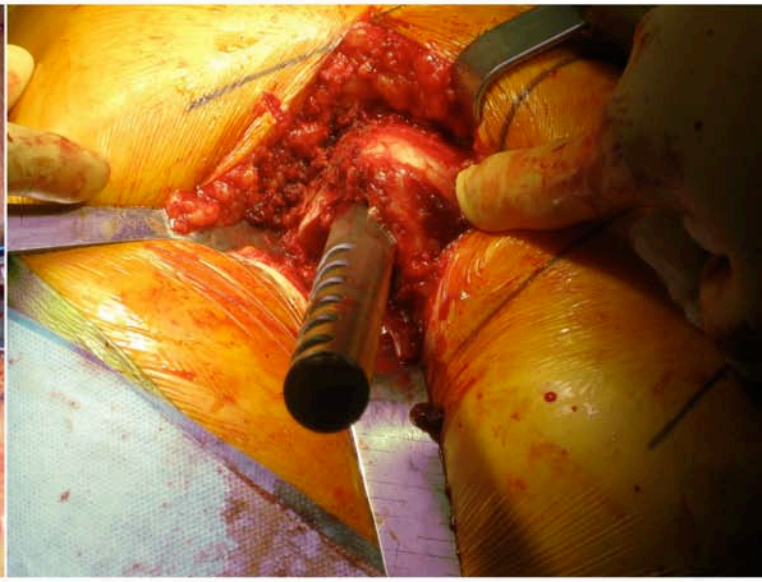
Muller rasp


06.29.2010

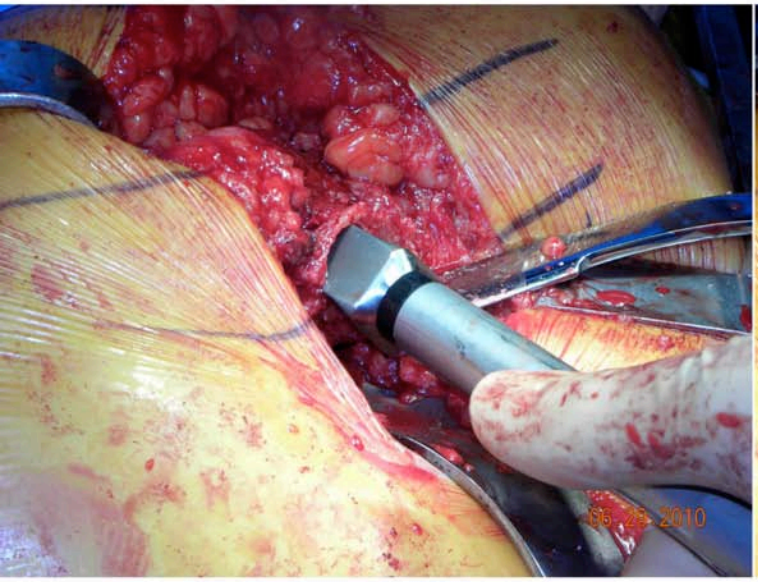


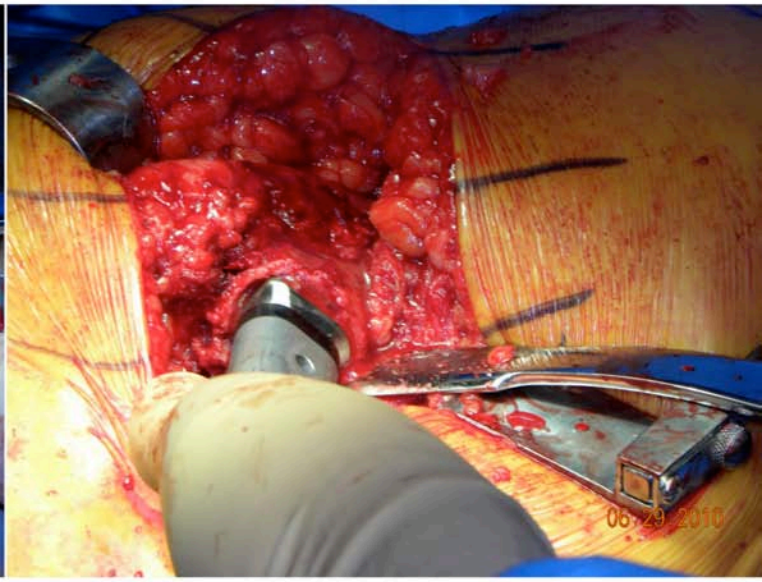
ARC™ rasp



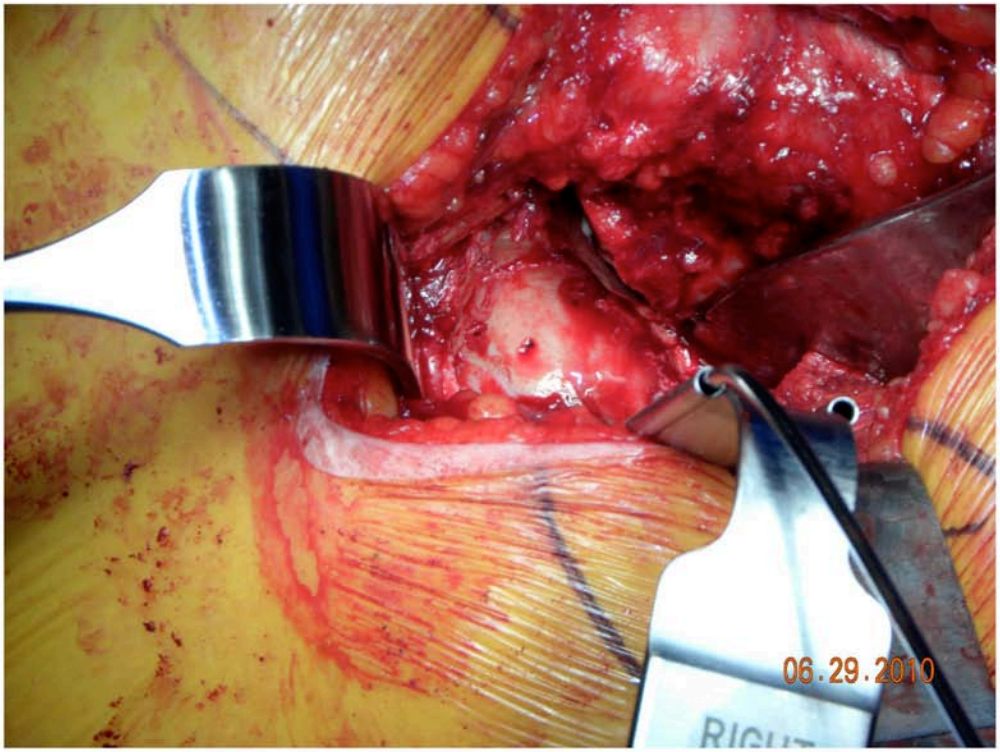


The ARC™ stem reduces the need to go lateral as seen in this second picture (S-Rom style)

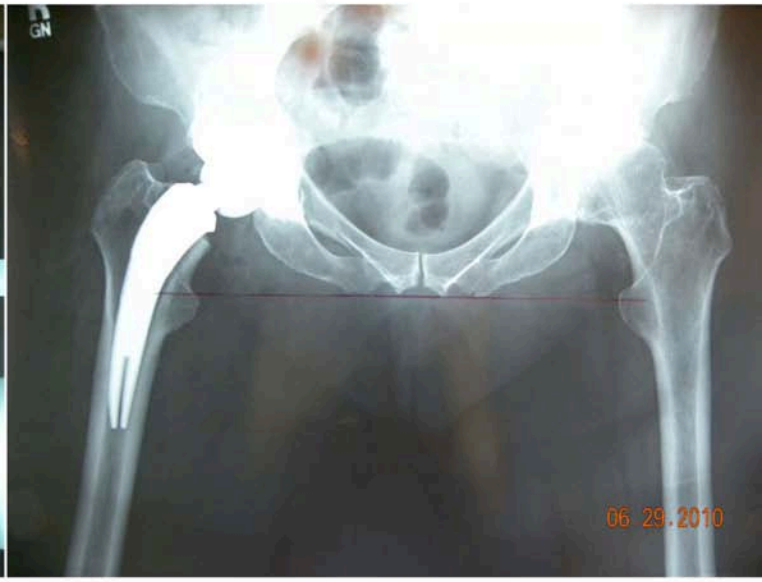




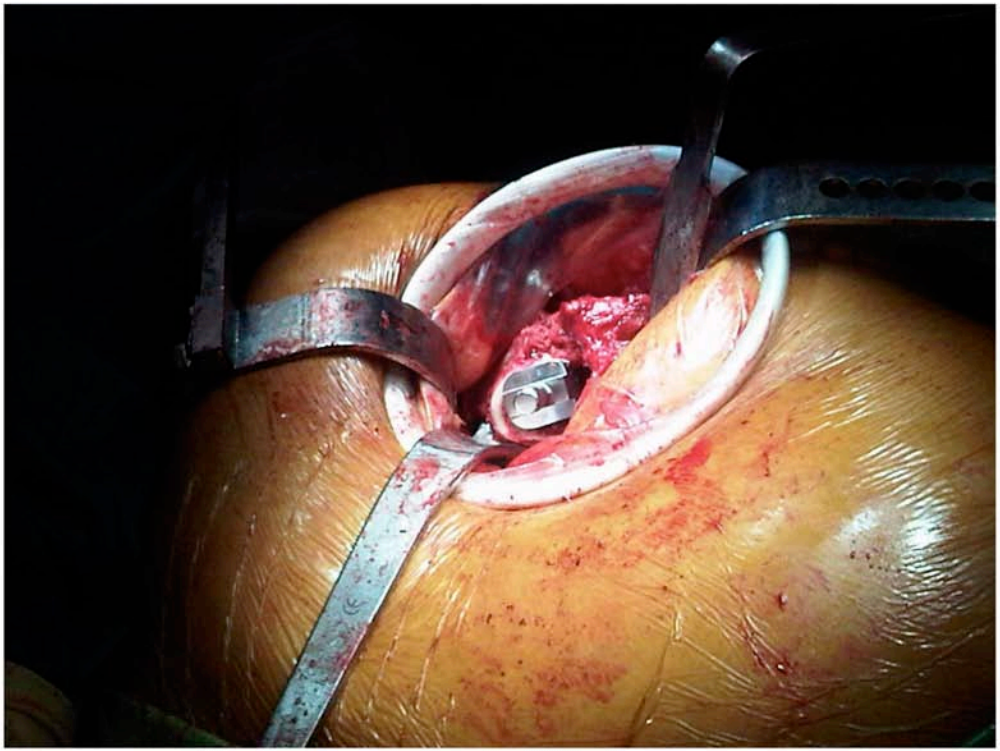
Trial stem insertion



Trial stem in place good exposure of the acetablum

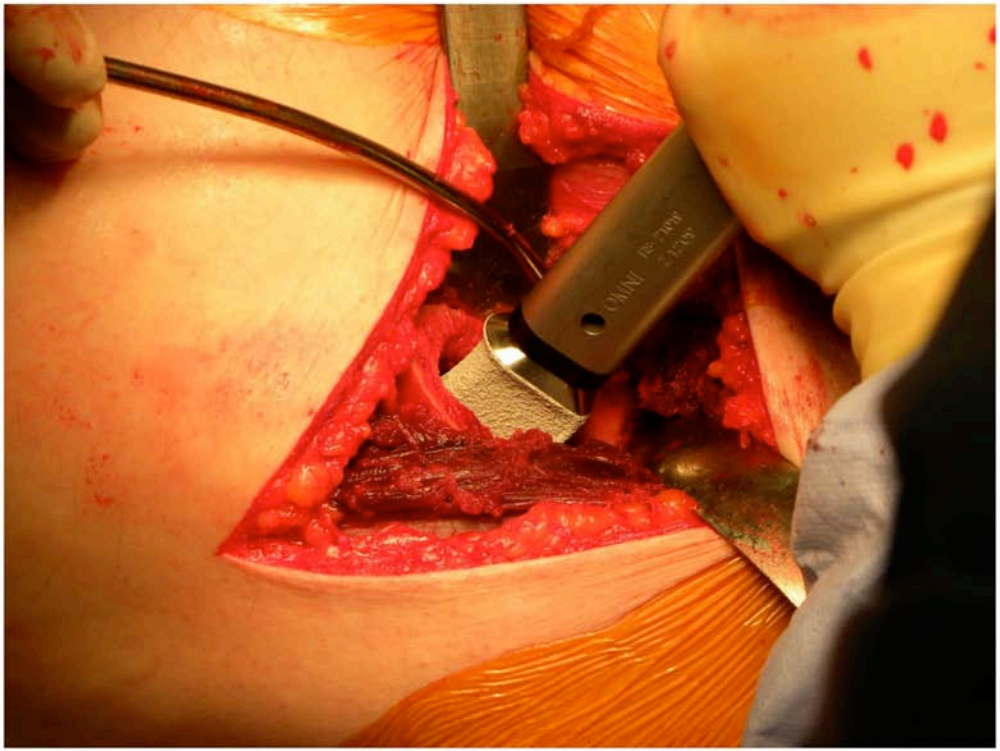


Trial stem and final implant

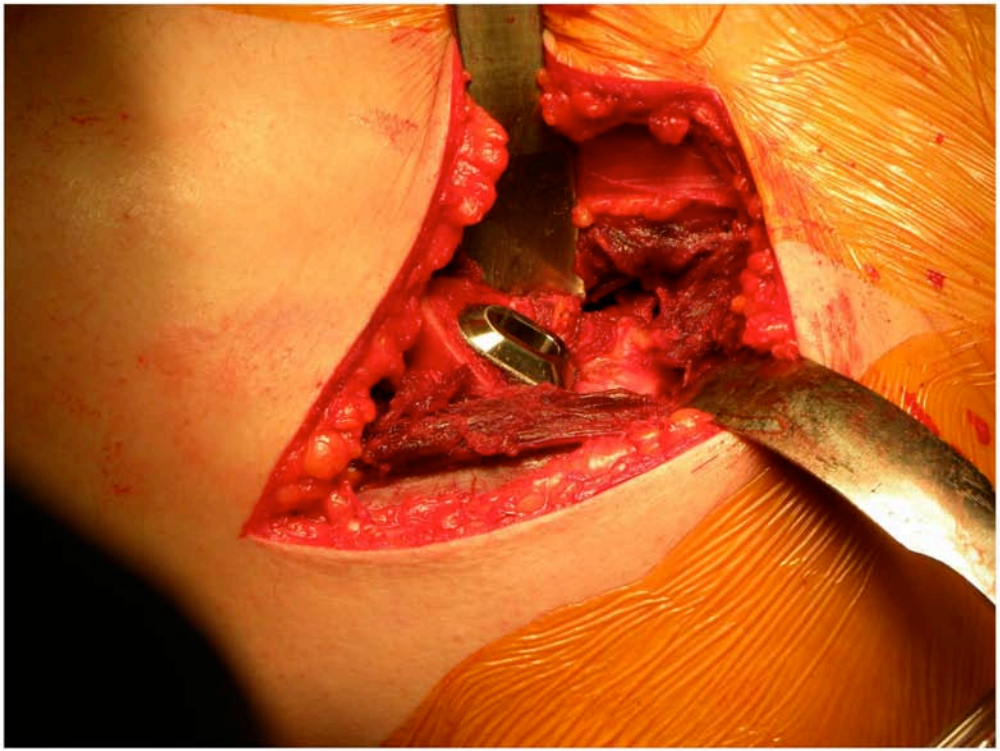


Anterior approach by Charles Bryant, MD

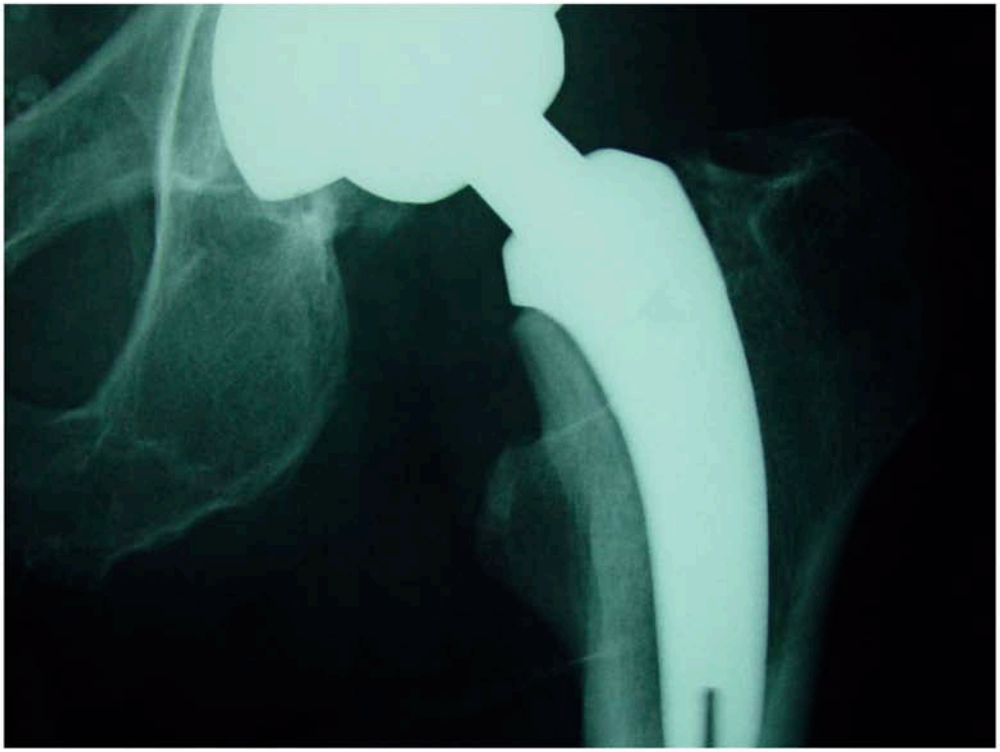

35
17
OEC



Anterior approach by John Keggi, MD

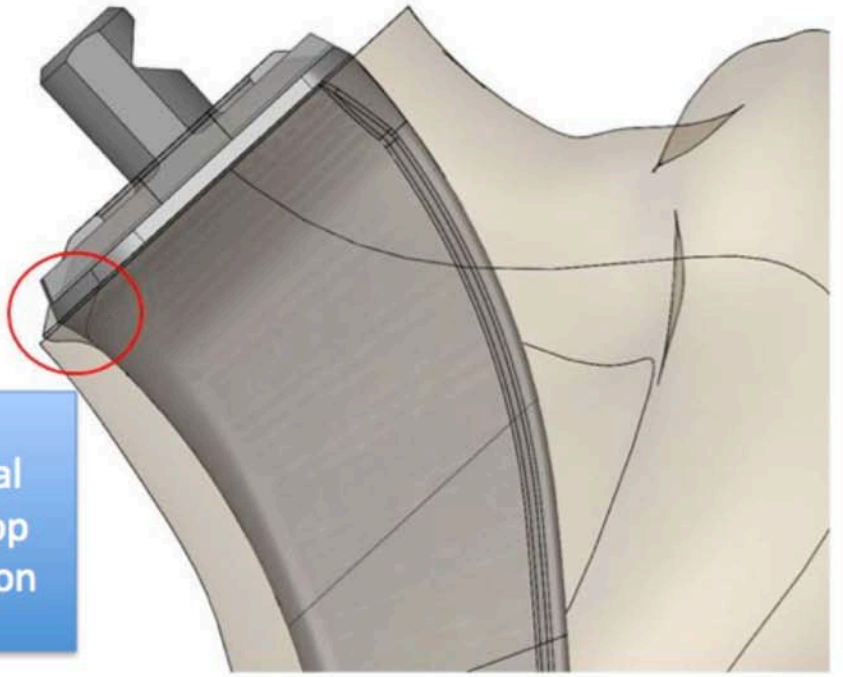


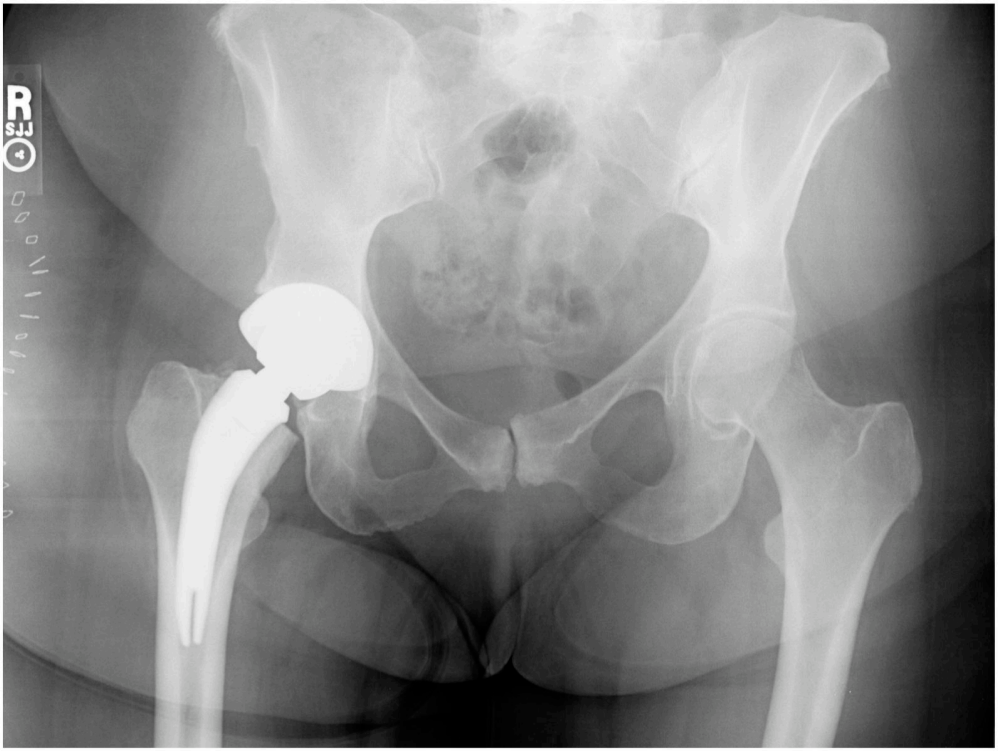
Final stem seated by John Keggi, MD



two year post-op with good maintenances of proximal medial bone.

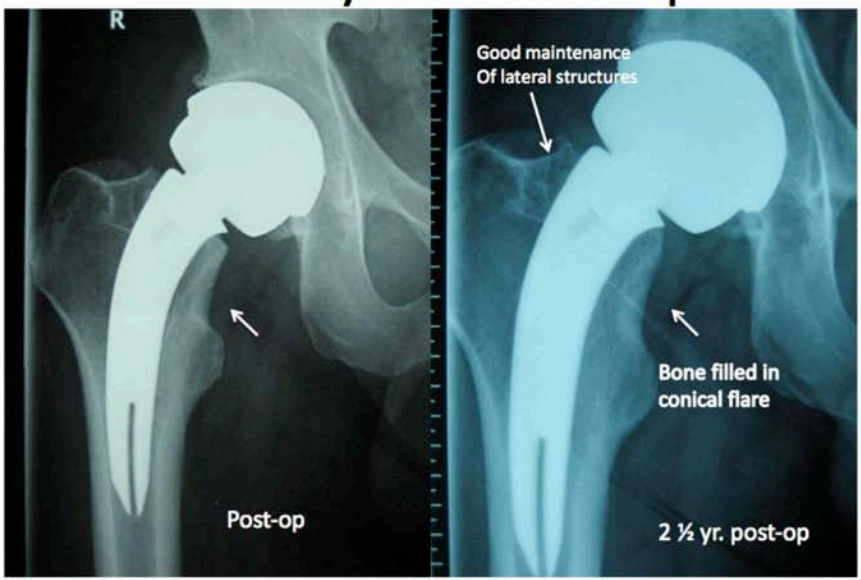
This is the novel conical flare that transfers hoop tension into compression





Lou Keppler case post-op

2 ½ year follow up



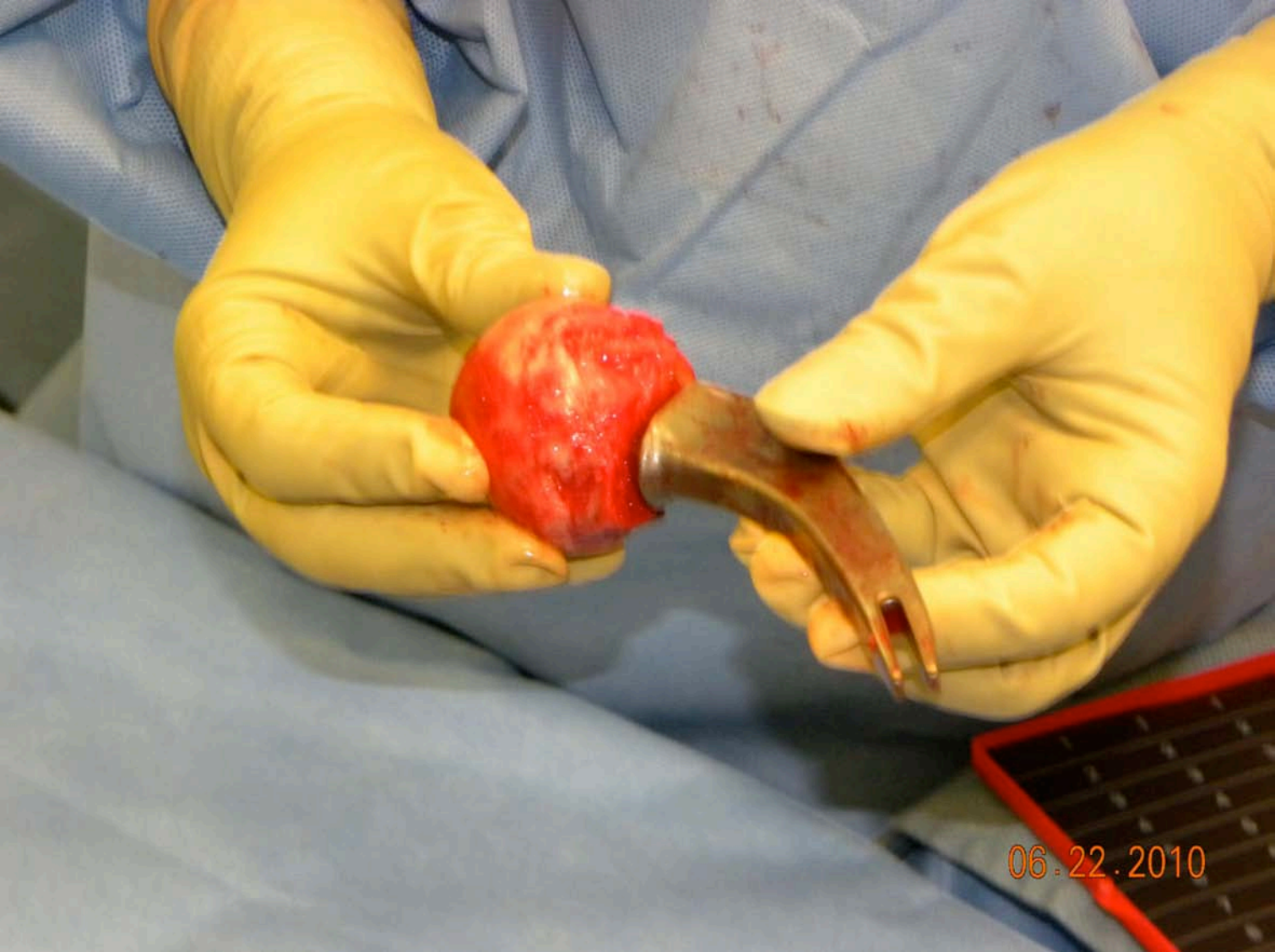
No distal reactive lines no sign of distal load transfer. Good medial curve contact slight rounding of medial neck and appearance of bone filling in gap at conical flare.

Trial ROM

Since you are retaining more neck it is important to ensure no mechanical impingement is encountered by an extensive rang of motion.

In the posterior approach check for anterior osteophytes.

There have been no reported problems but we do recommend a 32mm head or larger.


06.22.2010

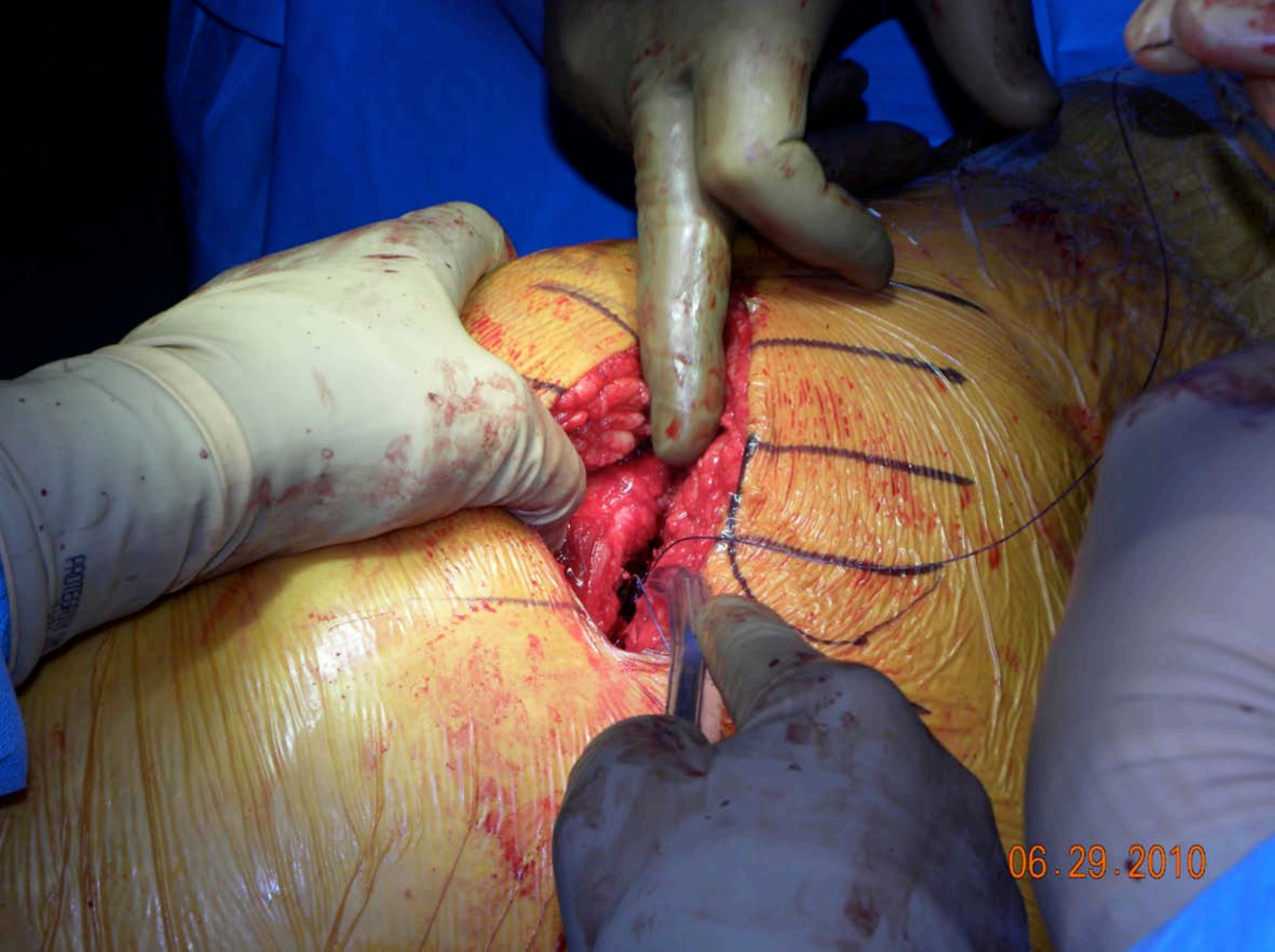
Short stems

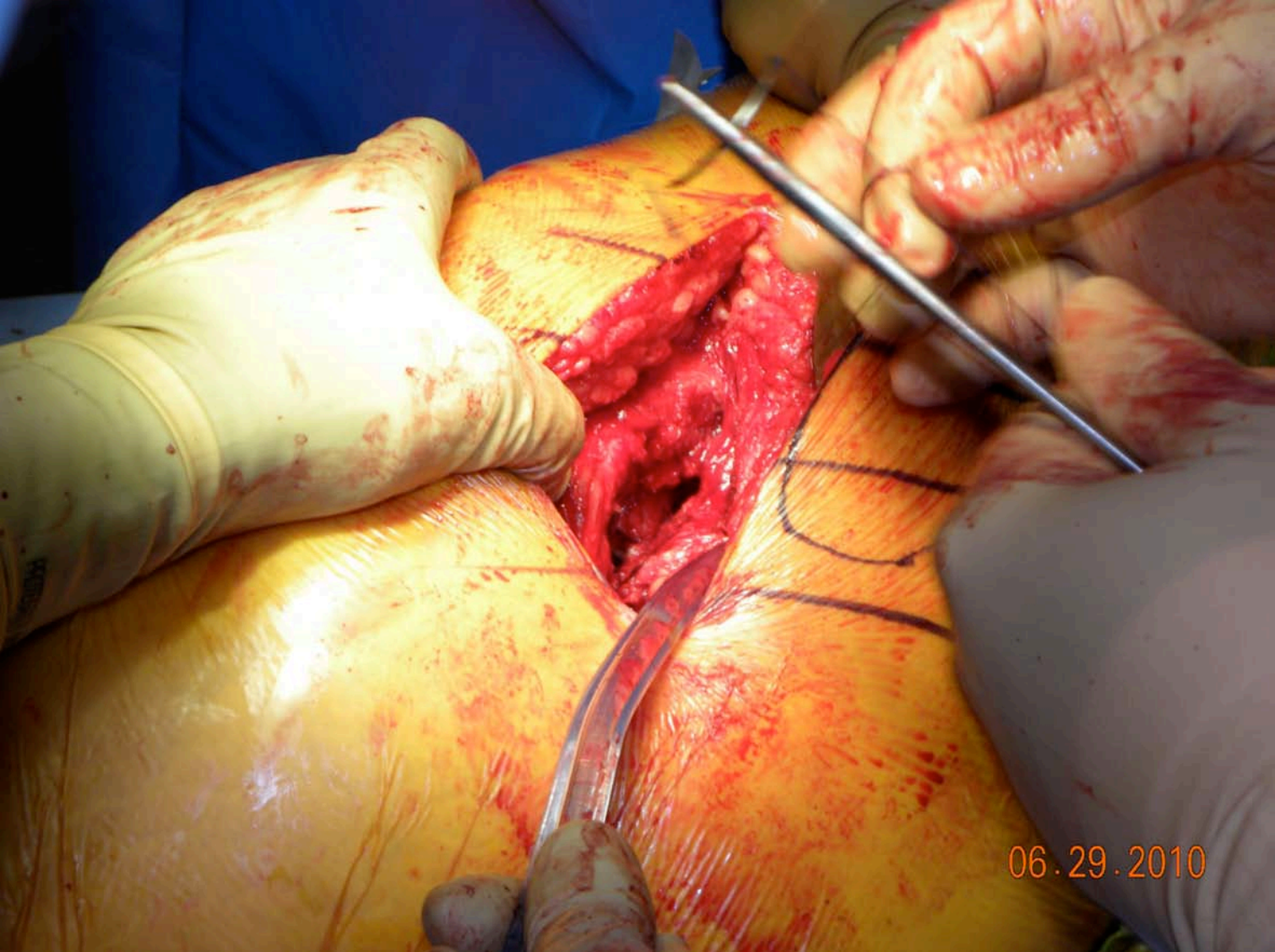

06.29.2010


06.29.2010


06.29.2010


06.29.2010


06.29.2010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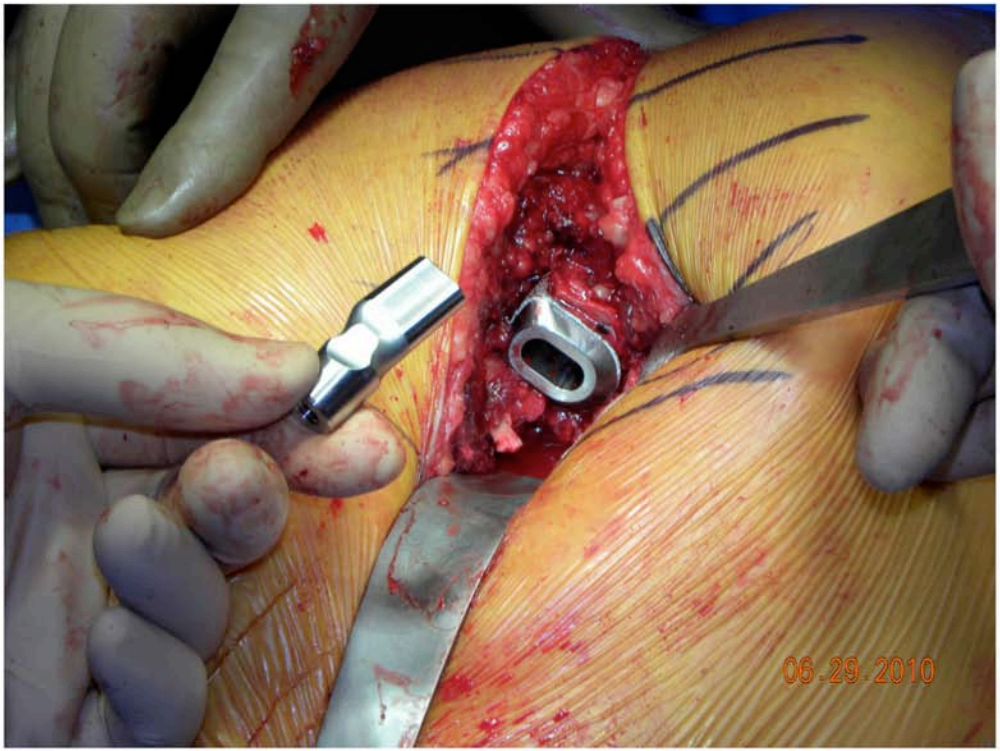
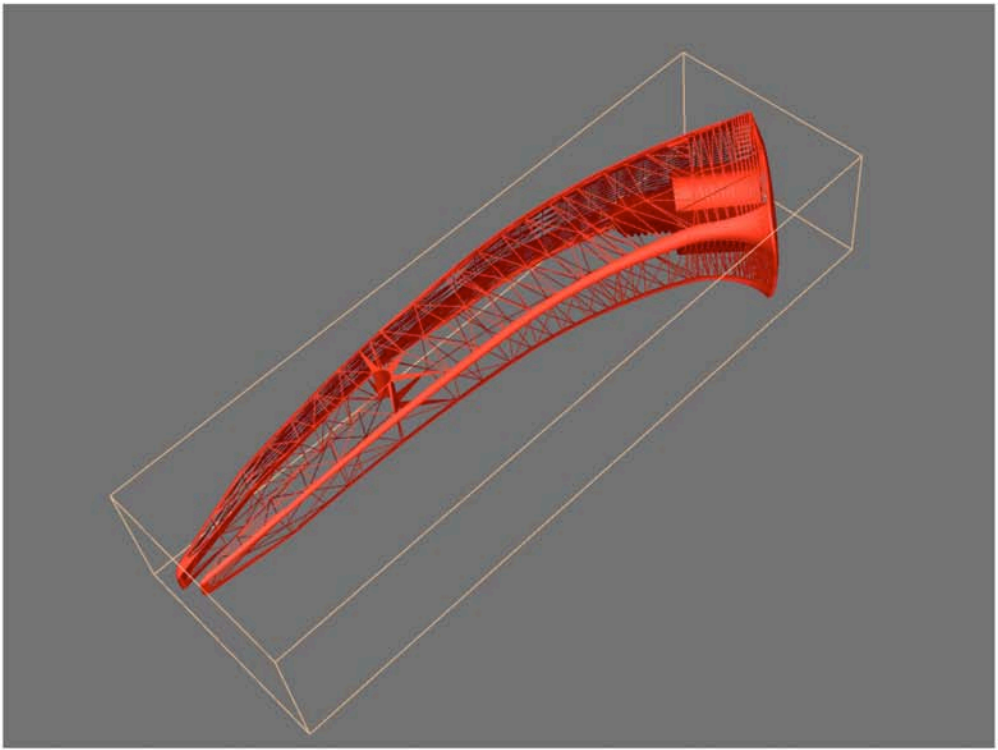


The learning curve is about three cases

Significant stability is achieved and at no time do you burn a bridge as to conversion to a standard total hip stem.



As the S-Rom did back in the mid 1980s we believe the TSI™ stem concept will bring about significant trends and improve outcomes for THA.

TSI 8/2010

Timothy McTighe, Executive Director, JISRF
Patents pending TSI™ Stem