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

Failure Mechanism on Total Knee Arthroplasty

By Timothy McTighe, Dr. H.S. (hc) and Ian Clarke, PhD • July, 2009

Acknowledgement to the following surgeons for their contributions, slides, and opinions that aided in this paper:
Dr. Keith Berend, Dr. Hugh U. Cameron, Dr. Thomas Donaldson, Dr. John Keggi, Dr. Louis Keppler, Dr. John Harrison

Executive Summary

Total Knee Arthroplasty (TKA) has become a well-established treatment modality for surgical correction of knee disorders and pain generated by arthritis and other disorders such as trauma. Today a patient can expect to rely on his new knee to serve him with comfort for a fair number of years if not his entire life. TKA has taken on a predicated level of confidence and certain trends have developed over the years. Success has increased demand and the health care system is challenged to meet current and growing demand for surgery [In fact the epidemiological studies have predicted that hips will grow only a little whereas knees are projected to have a 6-fold increase- see Kutz AAOS Scientific Exhibit 2006].

Surgical techniques are specializing into specific indications or camps for specialized product features. Uni-compartmental, Bi-compartmental, Total Knee with and without replacement of the patella, along with Patella-femoral replacement are some of the product classifications now available. The near future is now with articular focal defect replacement. New materials and techniques will open this area to increased indications as the sport-medicine surgeon finds his way into this growing surgical market.

This review is being drafted as a quick narrative summary and is not meant to be a comprehensive review on the subject. The combined experience of the two authors totals over eighty years in the field of total joint surgery and we feel reasonably confident in our expressed opinions.

First and foremost, all surgery is dependent on surgical technique. Technique is more important than material and design. Poor technique places an increased burden on design and materials, and improved materials and designs can ease the burden on surgical technique but never replace the overall benefit of good technique.

The clinical assessments (in-vivo; ex-vivo) for wear ranged 50-400 mm^3/year for either 'backside' wear or 'overall' knee wear (RSA and retrievals). These values were at least as high if not higher than for total hip replacements. Note that there is no data for 'frontside' knee wear by itself. Clearly there is little known from such 'dimensional' studies of how much change was due to creep or plastic flow as distinct from wear.

Wear estimates for laboratory knee studies fell in the narrow range of 3-10 mm^3/year. Clearly these were at least an order of magnitude less than that reported from clinical studies. Interestingly there has been no insight given as to why such a discrepancy exits in the wear testing literature. However, since these are generally gravimetric wear assessments we believe that they do represent true wear. Whether it is physiologically correct is another question.

We excluded two simulator wear rates from discussion. One by an Italian group produced a wear rate of 24mm^3/Mc with no explanation. One by an American group added hyaluronic acid to the lubricant and obtained wear rates of 64mm^3/Mc. While they may have been on to something the observed changes were so profound and not yet confirmed by any other study such that some caution is justified here.

Introduction to Complexity in Knee Wear Assessment

Knee development over the past decade has included improvements in implant designs and use of polyethylene bearings with superior wear resistance. The latter is one of the major factors involved in knee wear performance, i.e. the choice of polyethylene resin, the method of forming the bearing, method of sterilization, any post-sterilization heat treatments and the shelf aging of the polyethylene before implantation. Obvious improvements have been made in the polyethylene as a result of sterilization with irradiation

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in an inert environment or with non-irradiation sterilization methods. However, controversy remains over whether it is better to highly-crosslink polyethylene bearings to obtain maximum wear resistance or whether it is preferable to use non-crosslinked polyethylenes to maintain better mechanical properties such as tensile strength and fatigue resistance. Some companies sterilize with EtO and Gas Plasma (GP) while others crosslink up to 7.5Mrad (Zimmer).

Clinical wear assessments can be either from radiographic studies (RSA) of ongoing patients or from selected retrievals. Both represent very difficult tasks and the more exacting the method the fewer number of patients or follow-up duration. Unfortunately, obtaining an understanding of wear performance in patient's knee joints can be a daunting task. There are large dissimilarities in implants design, surgical effectiveness, patient populations, variations in follow-up periods, different observers that can reflect observer bias; novel methods of wear assessment and unique definitions for osteolysis. Many retrieval studies have characterized the degree of 'damage' apparent on the surfaces of retrieved polyethylene bearings. However it is readily apparent that such "damage" on polyethylene bearings could be due primarily to plastic deformation and not to removal of polyethylene per se, i.e. no actual 'wear'. Thus, characterizing the 'damage severity' may be totally irrelevant to the wear process in vivo. So thus far, very few studies have actually quantified volumetric wear in vivo. Therefore much of our knowledge on knee wear performance has to come from laboratory simulations.

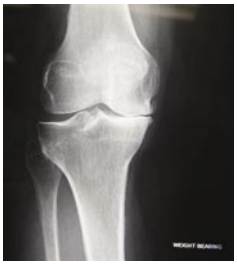
Simulating knee wear in a laboratory test requires knowledge of the many factors that influence joint loading, position, motion and lubrication. The degree of bearing conformity will greatly affect the contact areas, the resulting contact stresses throughout the range of motion, and the knee stability. Also variation in contact loads during various activities such as normal walking, climbing stairs and rising from a seated position, will greatly affect the wear potential. There are alternative knee designs that incorporate mobile polyethylene bearings that articulate with both CoCr femoral and CoCr tibial surfaces, The latter design aims to lower contact stresses in the polyethylene spacer by making it more conforming to the femoral articular surface. It also provides a flat tibial surface, which reduces the anteroposterior constraints. However, this design strategy also has the potential for wear on two bearing surfaces instead of one. There is some concern that fretting type of 'backside' wear between the polyethylene and its locking tibial tray may a potential source of wear debris. Some studies have indicated that this 'backside' wear may be a large portion of the total polyethylene wear. However polishing of the proximal surface of the tibial base plate in contemporary designs may have alleviated such concerns.

Product Review

Uni-Compartmental Knee

Uni-Compartmental Knee Design is limited to one tibio-femoral compartment. There has been and continues to be significant debate over the indications and over all success of this type of surgical treatment vs. conventional total knee. In addition, there are different styles of Uni-Compartmental knee designs.

Experience over the years shows the various risks i) need for further operations for degeneration in other compartments, including retropatellar pain and tibial implant settling with the in-lay all-poly components. The original "Marmor technique" required seating the tibial implant into a trough burred into the tibial metaphysis. This technique can lead to irregularities in the orientation of the implant and may in itself have been a prime cause of early loosening.



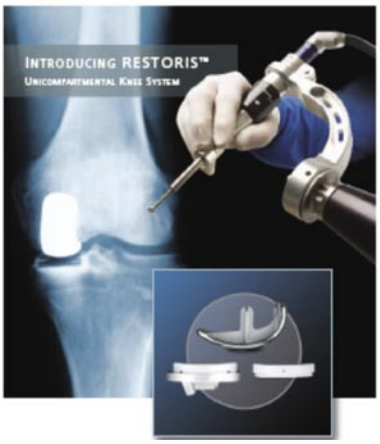
In-lay all poly tibial- cemented

On-lay metal tibial tray-cemented

The Oxford® mobile bearing

Surgical technique is as critical as proper indication for Uni-knees. The tibial implant must be seated at right angles to the anatomical axis of the tibia. As with other knee surgery 'eyeball approximation" has not proved satisfactory. Instrumentation is critical and the trend is even moving towards robotics to ensure correct alignment. Proper implant

orientation takes significant loads off the implant material reducing early mechanical failure due to cold flow, deformation and fatigue failure.



Total Knees Designs

Fixed bearing

Rotating bearing

Hinged rotating bearing

Their is a large spectrum of knee designs and many have come and gone.

They can be summarized as the following:

Linked implants

- Hinged: those that allow flexion and extension but not axial rotation
- Rotating: those which allow flexion, extension and also axial rotation

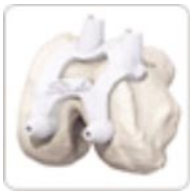
Non-linked implants

- Non-constrained (resurfacing)
- Conforming implants
- Anterior-posterior stabilizing
- Varus-valgus stabilizing

The one thing all current knee designs share is part of the bearing surface (tibial implant) is made of polyethylene. There were some early designs that featured the femoral component made of polyethylene (Charnley, St. George-hinged) and as a result they encountered material failure.

Linked Implants are those in which the femoral and tibial components are bolted, screwed or otherwise fixed together by mechanical means. These early designs were intended for limited function and were an alternative to arthrodesis. These were available from the early 1950's -1980s. Rotation was added to hinged knees with the Herbert (1973), Knoiles (1973), Spherocentric (1973), Attenborough (1978), Rotating Kinematic (1978). These early designs have not stood the test of time but were valuable in helping us to understand the problems of fixation, wear and knee biomechanics. At present, linked implants have a small but significant role in TKA. They are indicated mainly in those knees in which the collateral ligaments are markedly deficient.

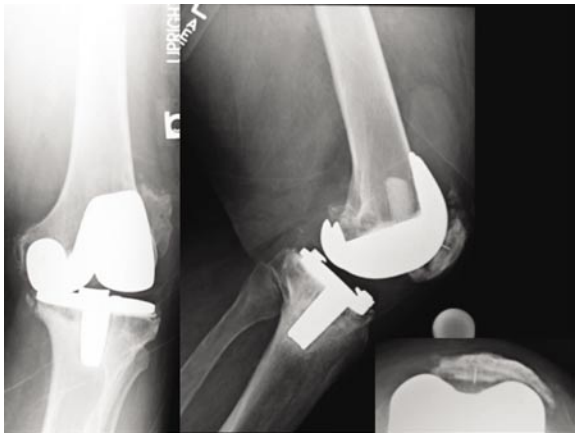
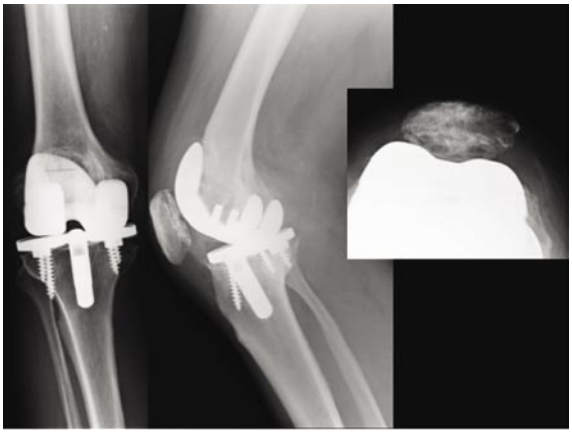
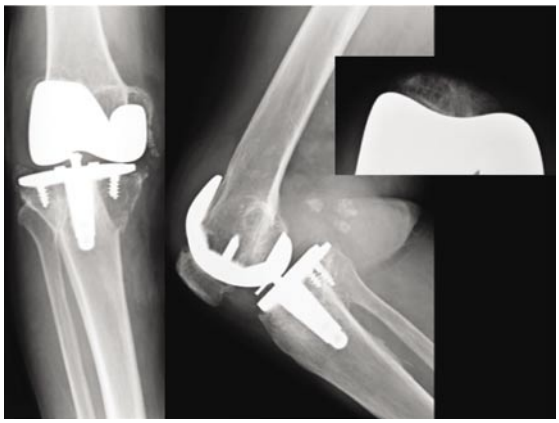
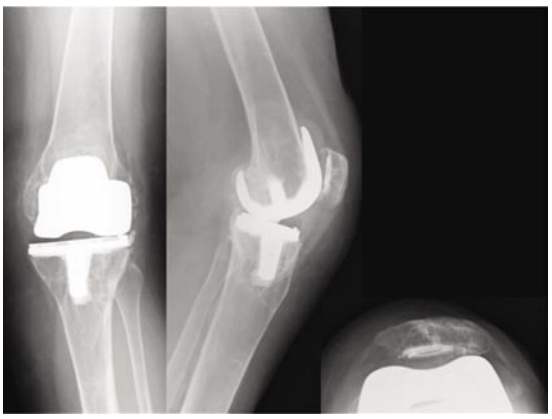
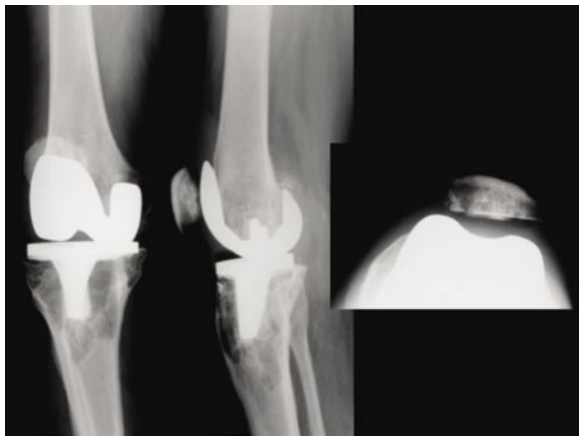
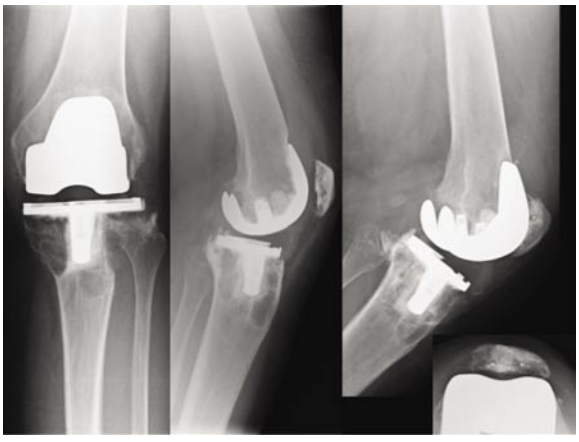
Unlinked implants are those in which the femoral and tibial components are not joined; the components are free to separate from each other but are prevented from doing so by the soft tissues. The term "unlinked" is not synonymous with "non-constrained". A non-constrained implant is one in which the tibial surfaces are relatively flat. These implants require normal cruciate and collateral ligaments. There are now different levels of cupped surfaces to offer mild to significant restraint to varus-valgus, anterior-posterior or translatory forces. Most of these conforming implants require sacrifice of the anterior or both the anterior and posterior cruciate ligaments.

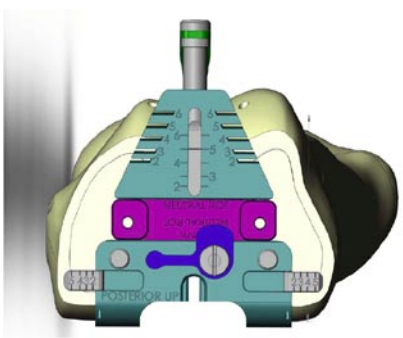


Resurfacing implants have of late been restricted to the Uni-compartmental knee designs but are beginning to be developed once-again for total knee arthroplasty, as early intervention is being advocated by younger joint surgeons and sports medicine surgeons. The advent of better instrumentation and/or custom "personalized instruments" is also moving TKA into a new and fast growing market segment. This technology develops cutting guides from MRI providing for an individual patient approach to TKA. The concept holds that better implant alignment will reduce stress on the implants improving survivorship.

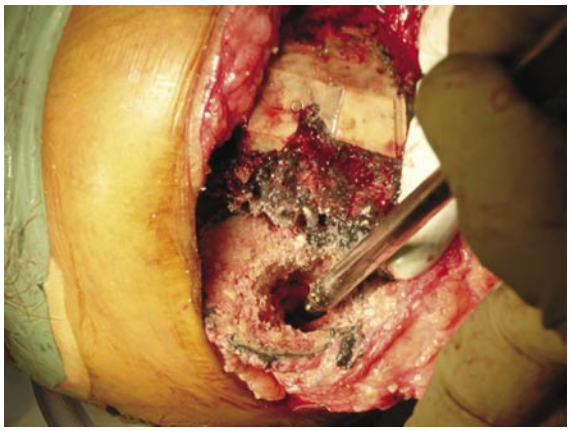
The growing demand for TKA is starting to place a significant burden on our health care system and future demand predicted at over 600% growth in the next fifteen years can end up resulting in some patients not being treated. This is already forcing surgeons and companies to look back at previous designs and results for all polyethylene tibial components. There is a growing concept expressed by the American Association of Hip and Knee surgeons that the older patients (less activity, +70 year old) be treated with all-poly tibial components, thereby reducing the financial burden on the health care system.

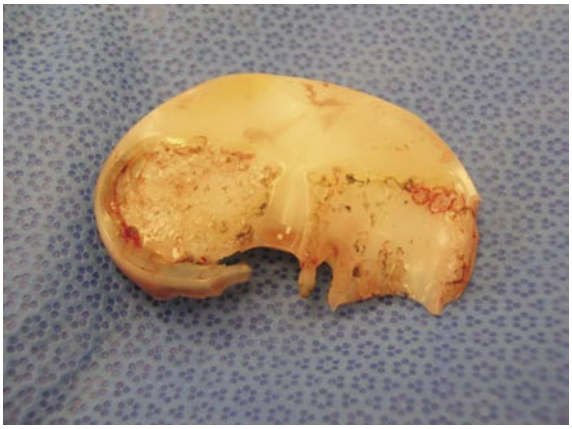
Examples of TKA failures:

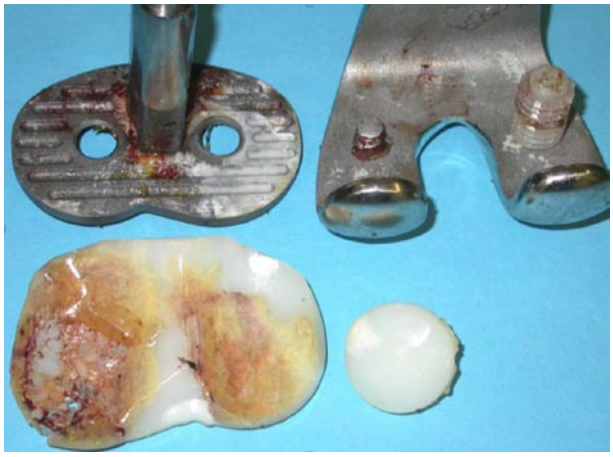









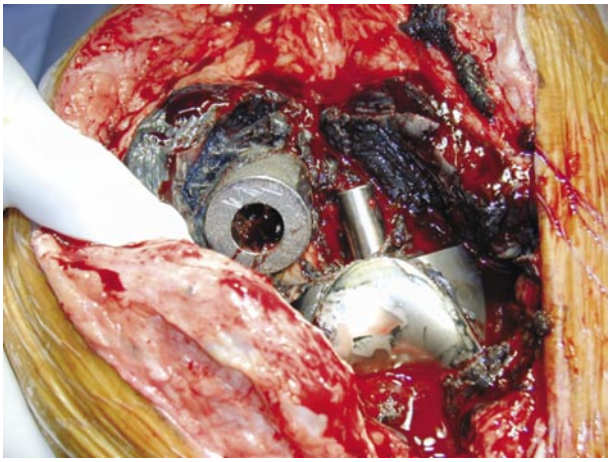

Alignment is critical to insure joint stability and reduce loads on the implants. Instrumentation properly used will enable proper joint reconstruction and joint stability.





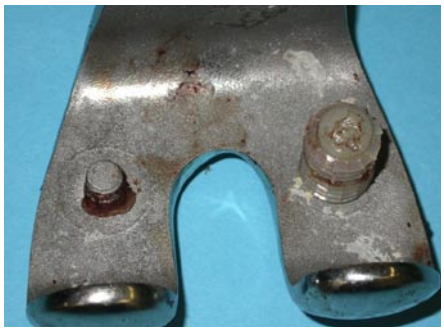


Example of HA coated knee with sever 3 body wear.



Black staining is caused by metal debris.

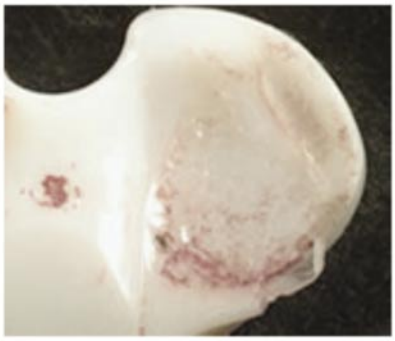
HA vanishes with time and can lead to implant failure



Good design that protects HA material

Examples of material failures

Poly II (carbon reinforced poly)



Heat Pressed Poly

Hylamer Poly

As with total hip implants improved bearing surfaces are being developed to reduce the generation of wear particles. Ceram Tec AG has set itself the goal of increasing the life of artificial knee joints using ceramic femoral condyles with polyethylene. The advanced Biolox® delta is being evaluated in a number of ceramic knee designs.

It is important to remember that most total knees fail due to mechanical overload either caused by mal-alignment and /or overload by patient related activities. Joint instability (resulting in increased implant loads on material) is the critical failure path for total knee implants. New materials have resulted in some early failures as demonstrated above and have made the market place question the basic science to an increased level of scrutiny. Testing new materials in a worst case or increased activity level will become the new standard.

Clinicals and Retrievals for Knee Wear Studies

Measuring wear from retrieved components is a difficult proposition. Not only is it difficult to determine the control knee measurements (unworn: 'before'), estimating the change ('after') due to wear, as distinct to creep or plastic flow, adds additional uncertainties. For example, it is generally believed that crosslinking effects will greatly reduce wear of the UHMWPE insert. Thus it is puzzling to read that one analysis of retrieved tibial inserts apparently demonstrated an 84% reduction in linear wear with EtO sterilized inserts compared to gamma/air (90um/year versus 550um/year). In other words, non-crosslinked knees did better (Williams et al 1998). A secondary limitation is that wear debris is a volume consideration. Studies quoting only "linear" wear data offer little help in this regard.

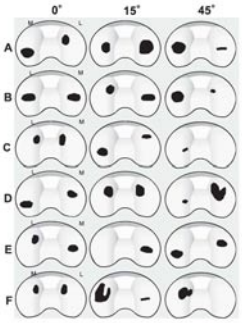
Collier et al (2005) provided a very interesting study of design features using the AMK knee. They asked the question whether polyethylene processing, sterilization method or tray design (backside wear) had made a difference to the prevalence of osteolysis in the AMK design. The roughness of titanium base plate (Ra 1,000nm) that was 10-fold greater than the later CoCr design (< 100 nm). The study was additionally complicated by the use of 4 types of resin (GUR: 1050, 1900, 4120, 4150) and four sterilization methods (EtO = 4, gamma/air = 263, gamma/N_2 = 54 and gas plasma = 44). Shelf age was another factor with the inserts averaging 0.9 years with maximum life at 7.1 years. At 8 years follow-up, the highest osteolysis was a 54% incidence ('confirmed' + 'suspicious') for the combination Ti64 tray with gamma/air. At 8 years, the least osteolysis was 21% for the combination with CoCr tray and gamma/N_2, i.e. reduced by more than half! At lesser time of 6 years, osteolysis was 28% for combination CoCr/GP-sterilized. Thus four conclusions were considered:

a) Osteolysis was 4-fold more likely with AMK gamma/air than gamma/N_2
b) Osteolysis with Ti64 trays was 2.6-fold more likely than with CoCr base plates.
c) Knee hyperextension (impingement) added more risk of osteolysis.
d) It was noted that the non-crosslinked (GP) AMKs did quite well!

It was also interesting that the incidence of osteolysis with the AMK design could be as high as 54% at only 8 years.

A detailed AMK retrieval study set out to measure 'backside' wear (Conditt et al, 2005). A set of 15 retrieved AMK tibial inserts were analyzed with 3-12 years use. Each retrieved insert was scanned for backside wear by a laser profilometer. The backside wear averaged 138 mm^3/year (SD± 95 mm^3/yr). With maximum wear being approximately 3-fold greater than the average, this meant that some cases had wear approaching 420mm^3/year. This is a very large wear rate, particularly for only backside wear of the AMK design. Noted here but not reviewed, a 2nd paper reported backside wear in fixed-bearing TKR as 120 mm^3/yr (Mayor et al, AAOS2005).

For a different approach, Oxford UK attempted RSA measurements of knee wear from x-rays. This would appear at first glance to be an impossible task. Gill et al (2006) used RSA method in 6 well functioning AGC cases (6 years follow-up). They estimated total volume loss could be from 400 mm^3 to 1,056 mm^3. Their best average was given as 600 mm^3, representing a wear rate of 100 mm^3/year. Thus, this overall RSA wear rate for AGC knees was in the same range as the backside wear of the AMK knees. They also provided



Estimated patterns of AGC knee contact for three flexion angles (Gil et al 2006).

an estimate of contact areas in-vivo using knee models and penetration depths through flexion (Fig. 1).

A retrieval study of the Low Contact Stress Knee (LCS; DePuy, Warsaw) suggested that wear of the rotation surfaces ('backside') could be a large portion of the total polyethylene wear (Atwood 2008). They examined damage and wear in a 100 retrieved LCS-RP mobile bearings with in vivo durations ranging 2 -170 months. The inserts were GUR 415 and 1050 machined from ram-extruded bar and sterilized by gamma/air. The backside wear averaged 3 times greater at 2 years (164mm^3/yr) than for durations >2 years (54 mm^3/yr). Once again these wear rates were of the order 100+ mm^3/yr.

Knee Wear	Backside	Frontside	Overall	Upper Limit
Conditt 2005	138			420
Mayor 2005	120			
Gill 2006			100	180
Atwood 2008	54			100

Table 1. Summary of knee wear rates measured either from RSA clinical studies or from retrievals. Note that estimates of 'frontside' wear by itself are not available.

So overall the in-vivo knee wear estimates ranged 50-400 mm^3/year (Table 1). These are at least as high if not higher than total hip replacements.

Laboratory Knee Simulations

Knee simulators allow for more control of various experimental parameters to better examine effects of design and material choices. The limitation is that they may not capture the essential environmental aspects and kinematics that produce wear in the patient. There are two concepts prevailing in design of knee simulation machines. The majority of knee wear studies have been run under displacement control, such that the degree of joint flexion, internal and external rotation and antero-posterior motion are dictated by the servo-hydraulic controller using selected motion profiles as its input. The advantage of this method is that it provides consistent tracking, displacements, velocities and phasing relative to femoral flexion and resultant load. The disadvantage is that these may not represent the motion in the patient or be inappropriate for that knee design.

An alternative strategy in knee simulation machines has been to use load-control as a feedback loop, such that the motions of the knee are dictated by the profile of the femoro-tibial bearing surfaces as it reacts to the various force and torque inputs. It is believed that the advantage of this method is that the bearing surfaces are free to track in a more physiological manner. The disadvantage is that the implant tracking and distances traveled may not predictable for the duration of the wear test.

Given the level of computer control, there are many scenarios that can be used to input knee motions and loadings. This complexity can have a confounding effect when attempting to correlate data between different studies. Kinematic inputs for knee simulators are usually limited to level gait. This raises the question of whether incorporation of activities of daily living (stair ascent, descent, kneeling, rising from chair) would be more severe than for just normal walking tests? In this regard, the frequently quoted International Standards (ISO 14242-1-3. ISO 14243-1) have become quite useful.

It is interesting to ask whether wear rates for walking plus stair climbing would be more severe than for just normal walking tests? In such a study, Cottrell et al (2009) compared NexGen CR Augmentable (CR) to 5 NexGen Legacy PS (LPS: Zimmer, Warsaw). All specimens were 25kGy gamma/N_2 tibial inserts. Three wear tests were conducted: one using standard gait (ISO 14243–1) and two using a combination of

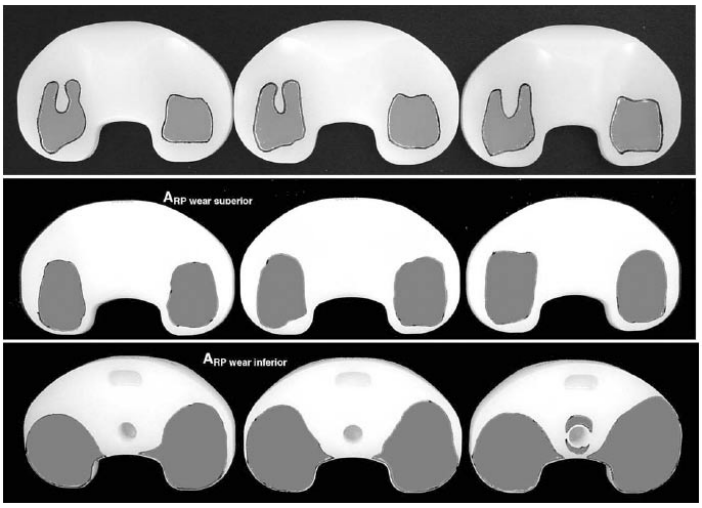
AUTHOR	YEAR	BRAND	STERILE	WEAR MIN	WEAR MAX	WEAR AVG
Affatato	2008a	913-MP	EtO	23.7	25.3	24.4
Affatato	2008b	Multigen-Plus	EtO	2.4	3.3	3.1
Cottrell	2005	NextGen-PS	25/N2	gait only		10.4
Cottrell	2005	NextGen-CR	25/N2	gait only		6.1
Cottrell	2005	NextGen-PS	25/N2	gait+stairs		6.6
Cottrell	2005	NextGen-CR	25/N2	gait+stairs		5.5
Cottrell	2005	NextGen-PS	25/N2	gait+stairs		5.2
Cottrell	2005	NextGen-CR	25/N2	gait+stairs		4.1
Grupp	2009	Columbus-CR	30/N2	gait		9.7
Grupp	2009	Col.Mobile-CR	30/N2	gait		6.6
Desjardin	2006	NKI	NS	gait		9.4
Desjardin	2006	NKI	NS	gait		64.8

Table 2. Summary of knee wear rates from various simulator studies.

gait plus stairs. The authors concluded that wear rates were higher in standard gait compared to gait with added bouts of stair climbing (Table 2). Thus normal walking appeared to be the best estimate for a 'worst case' scenario.

Desjardin et al (2006) speculated that adding hyaluronic acid to bovine serum would make a more realistic lubricant. Using 4 Zimmer knees, they obtained average wear rates of the order for 9.4mm3/Mc for standard serum in normal gait (21mg/ml albumin protein). These may have been reasonable wear rates (type of UHMWPE not stated) but with HA-serum the wear rates increased to 64mm3/Mc[3]. The authors may have viewed this as a 'worst case' wear scenario but that does not seem a reasonable hypothesis.

Affatato et al (2008a, b) offered wear rates averaging 3 and 24mm^3/year. There was no explanation for the later having such high wear rates (Table 2). So with those 2 exclusions, the overall knee simulator wear estimates fell in the narrow range 3-10 mm^3/year (Table 2). Clearly these were at least an order of magnitude less than that reported from clinical studies (Table 1). There has been little insight given as to why such a discrepancy exits.

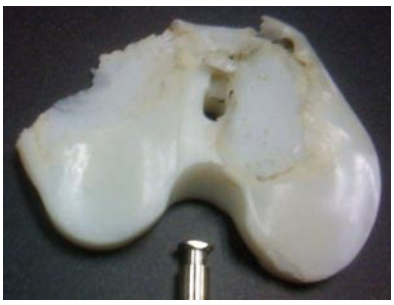


Contact areas for fixed and mobile-bearing Columbus knee designs run in simulator study (Grupp et al, 2009). The mobile insert (Rp) is shown with superior frontside contact and inferior backside contact.

Grupp et al (2009) provided some interesting contact areas and imaging of worn morphology (Fig. 2). For direct comparison between fixed and mobile bearing knees of same design. They also compared frontside and backside contact areas.

Delamination in Total Knee Replacements

Delamination is a form of wear damage in which a thin layer in the surface separates from the deeper layers. This is the severest form of damage to be encountered in total knee replacements. It appears predominantly in inserts processed by gamma sterilized/air in which free radical damage has oxidized the Poly (Bell et al, 1997). Pin-on disc wear tests showed that progressively aged Poly had increased wear until delamination damage finally resulted.



AMK™ Retreival by Dr. Donaldson.

Some early studies noted delamination in only 4% of retrieved Total Condylar inserts by 5 years (Hood et al (1983). Bloebaum et al (1991) noted that generally only about 2% of tibial inserts showed delamination. However in a study of 33 PCA inserts, the same group noted that 53% PCA's showed severe delamination within 4 years of use. They noted a zone 250um to 580 um distance below the surface of these heat-pressed Poly inserts.

Two similar PCA cases were reviewed by Tulp (1992) one with 7mm thick Poly and one with 9mm thickness. Both presented at 3 years with loss of polyethylene thickness on the medial side, evident bone loss with synovitis and pain. Sections showed a well-formed 300um thick surface layer with an underlying poorly formed surface of some 600um thickness.

Klug's et al (1992) reported on one case with bilateral PCA knees. At 5 years both the 3.5mm thick medial and lateral plateaus had worn through due to a large flaking type of delamination. Debris ranged from micron to millimeters in size and there was massive osteolysis present.

Gillis et al (1999) studied the IBI, IBII, PFC and AMK knee designs. They noted that only the PFC and AMK showed some evidence of delamination

Akisu et al (2001) reported on a 7=year result with an AMK knee revised for cystic changes and pain. The 10mm thick Poly insert retrieval (sterilized in air) showed deformation and delamination wear and tissues showed many Poly debris and osteolysis. Delamination was present in central medial and lateral aspects and labeled as "severe delamination". Backside wear was labeled as "mild abrasion".

Overview

It is known from the work of Bartell et al (1986) that there are significant sub-surface shear stresses up to 1mm deep in tibial inserts. Thus the interaction of such peak shear stresses with an adulterated sub-surface zone appeared to result in catastrophic delamination wear in certain knee designs. The most commonly reported appears to be the heat-pressed PCA knees. However other designs with gamma/air sterilized Poly inserts were also implicated at less than 10 years of use, e.g. AMK and PFC types.

Summary

The wear in gamma-irradiated-in-air polyethylene bearings from unicondylar and total knee replacements is influenced by the shelf age of the polyethylene, the age of the patient (activity) and the postoperative angulation of the reconstruction. Although polyethylene bearing material has not been gamma radiated in air for the past 8-10 years, wear debris is still a significant factor to the survivorship of TKA.

Surgical technique, patient related activity and articulation constraint still place high demands on design of knee systems and material properties. The growing demand for TKA will continue to place increased burdens on the health care system to deliver simple, reproducible and cost affordable knee implants. Improvements in design, materials and surgical technique in a ever tightening fiscal market will remain a significant challenge. There however will remain a high demand for improved product in the younger more active private pay health care market.

The Future

There can be no doubt as to the potential for increased surgical intervention in TKA. As a result, we believe in the combination of incremental improvements in technique, design and material.

Increased mechanical testing of implants in a variety of different positions and under varying loads will aid and hopefully reduce surgical and clinical complications.

Current and future developments will focus on early intervention with cartilage replacement in the form of cartilage transplantation and the refinement of artificial cartilage implant replacements. All metal tibial implants of the past (metal articular inlays) have proven unsatisfactory. However newer materials like polycarbonate urethane (PCU) have stimulate new design concepts like the NUsurfae™ Implant from Active Implants. A clinical series has begun using this soft compliant material as a cartilage implant for early meniscal disorders of the knee.

Modifications to techniques, design and material need to be carefully documented and followed by clinical evaluations. Changes can only be justified if we are prepared to collect, analyze and publish their results.

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