

Reconstructive REVIEW

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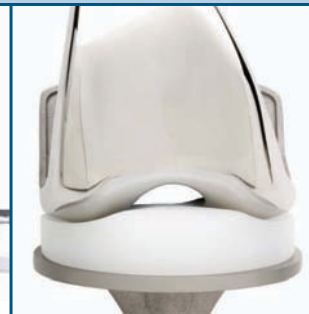
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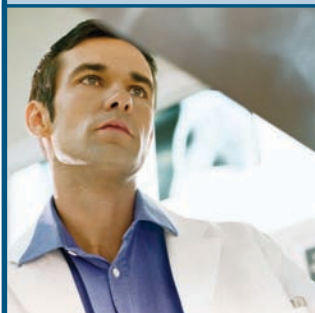
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Reconstructive Review

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- Any images files should be included as TIFF, JPG, or EPS at a minimum of 300 dpi.
- Any questions regarding these requirements please send to tmct@jisrf.org

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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.

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Acknowledgement: Bruce Shepherd and John Harrison



M.A.R. Freeman, MD, FRCS
Editor Emeritus

Editorial Comment:

This new publication has my endorsement and comes in part as a follow-up to a letter to the editor that I wrote in 1966 British Editorial Society of Bone and Joint Surgery with regard to "Which Primary Total Hip Replacement?"

Part of my letter dwelt with the concerns and difficulties of getting papers published. Journal of Repute, which is properly refereed, have substantial rejection rates and if accepted historically have long publication dates.

I raised the issue is there an alternative? Perhaps the surgeon with any "new" prosthesis should himself keep accurate clinical records and then these results would be available through the company or by direct contact from a new surgeon corresponding with one of the initial developers. Obviously, the unsupervised collection of data is not the same as a refereed paper, but it would be for the reader to decide on the merit of the publication.

I look forward to this new endeavor and feel there is a need that this publication might be able to address.

M.A.R. Freeman, MD

Timothy McTighe, Dr. H.S. (hc)
Executive Director, JISRF
& Editor-in- Chief
Reconstructive Review

This is JISRF's 40th year anniversary since its creation by Professor Charles O. Bechtol, MD., and in his memory JISRF wanted to reach for the next step in our communications to the orthopaedic health care community.

The Joint Implant Surgery & Research Foundation (JISRF) is a non-profit organization dedicated to the development of one of the most promising medical concepts developed by mankind "Total Joint Replacement". Since its early days in 1971 JISRF has been an active player in the design, development and teaching of total joint surgery.

New techniques of surgery, nursing care and patient rehabilitation must be taught to the medical professional in as close to real time as possible. The explosion of data is upon us and we all need to set up structures for improved communications and place safeguards to retard the growth of misinformation.

JISRF is committed to bringing together all aspects of scientific endeavor for the betterment of our total joint patients. This Journal is dedicated not only to Professor Bechtol but also to the orthopaedic pioneers from all around the world. There are no advances without the cooperation and collaborations of many.

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 - Results
 - Discussion

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- Surveys
- Commentary
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We will strive to be responsible and reactive to the needs expressed to our editors and all members of JISRF. We anticipate our format will evolve as we move forward and gain more experience with this activity. Your opinion is a critical step to our motivation and overall success so don't hesitate to communicate to us.



Professor Charles O. Bechtol, MD
*A visionary in replacement surgery.....
 who can never be replaced.*



FEA Analysis of Neck Sparing Versus Conventional Cementless Stem

Declan Brazil, PhD¹; & Timothy McTighe, Dr. H.S. (hc)¹,

Acknowledgement: Kevin Ong, PhD, Exponent, Inc., Philadelphia, PA, USA (FEA Bone Response)

Professor Ian Woodgate*, MD, N.S.W., Australia (x-ray review); Adrian van der Rijt*, MD, Wagga Wagga, Australia (x-ray review); John Keggi*, MD, Watertown, CT, USA (x-ray review); Louis Keppler*, MD, Cleveland, OH, USA (x-ray review);

Abstract:

Finite element analysis is a valuable tool in prosthetic design and helps predict specific mechanical behaviors between mechanical testing and clinical observations¹. We have studied the effect of tensile stresses of both conventional length stems with conventional neck resections and compared them to a novel short curved neck sparing tissue

preserving stem design and have found correlation between FEA modeling and plain radiographics. Neck sparing stem with a novel conical flair does improve bio-mechanical conditions in THA as compared to conventional length cementless stems.

Key words: Total Hip Arthroplasty, neck sparing, conventional, bone remodeling, stress shielding, finite element analysis

Introduction:

Finite element analysis is a valuable tool in prosthetic design and helps predict specific mechanical behaviors¹. We have seen an influx of short stem designs for routine use in total hip arthroplasty in the past 5-10 years^{2,3}. Along with the influx of short stems there has also been increased interest in short curved neck sparing stem designs. These neck sparing stems are both bone and soft tissue conserving and are an alternative to both hip resurfacing and conventional cementless stems^{4,5}. With the current MoM concerns we can speculate the market will be looking for an alternative to hip resurfacing^{8,9,10}.

There has been a long history of neck sparing stems particularly in the area of conventional length cemented and cementless stem designs^{2,6,7}. The early pioneers of conventional style stems have been M.A.R. Freeman, C. Townley, and L. Whiteside.

The Godfather of the short curved neck sparing stem has been Professor F. Pipino who's experience dates back thirty years⁴.

To-date, most if not all, neck-sparing stems have been somewhat disappointing in their long-term ability to stimulate and maintain the medial calcar². Partially for that reason a new design approach was undertaken to improve proximal load transfer and to create a bone and soft tissue sparing stem that would be simple in design, amenable to reproducible technique, have contemporary features like modular necks and be cost effective in today's health care climate.

From the:

¹Joint Implant Surgery & Research Foundation
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*Tissue Sparing Implant Study Group
Joint Implant Surgery & Research Foundation

Materials and Methods:

A finite element model was generated to compare stresses generated in conventional cementless stem compared to a short curved neck sparing stabilized stem when restoring the same head center. Comparisons were also done looking at the strain in the bone, consideration of the effects of varus / valgus tilting, consider the bio-mechanical benefit of “Neck Sparing” stem and the bone remodeling of neck sparing with a novel conical flair design to a conventional tapered style cementless stem.

Model Setup (First test)

FEA Model



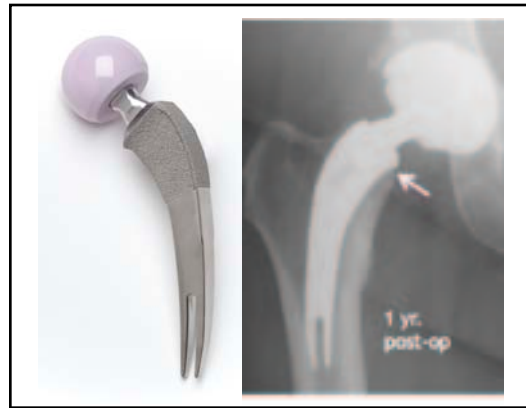
Components used to restore head center were:

TSI™ implant size 1 (range supplied 1 through 5), 22 mm modular neck with + 8 mm head.

Taperloc Stem size 3, high offset with +8 mm head.

Both stems have proximal coated plasma bodies and distal stems uncoated. Both stems were bonded to the bone in coated region and frictionless conditions of remaining part of the stem.

Implant materials: TSI stem is Titanium Alloy with a CoCr modular neck. Taperlock is a monoblock Titanium Alloy both have commercially pure titanium plasma porous surface.



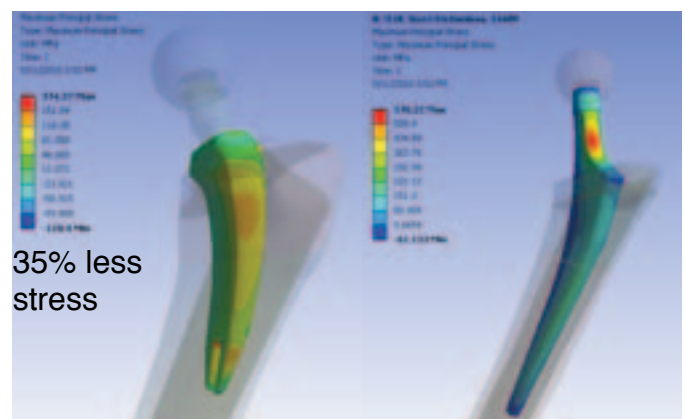
TSI™ Neck Sparing Stem typical view



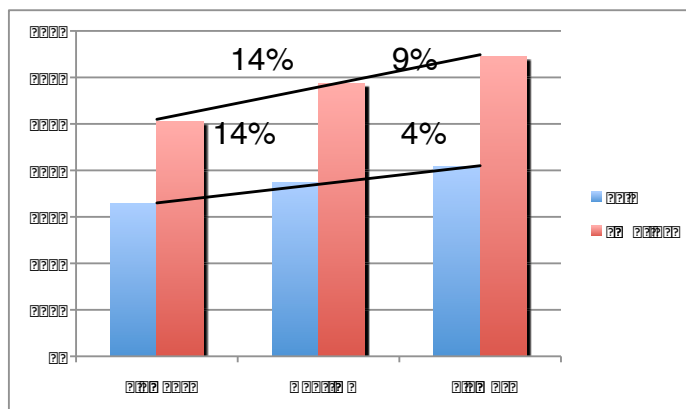
Taperloc™ Conventional stem typical view

Results:

The maximum principal tensile stress in the neck sparing stem was 35% less than that of the conventional monoblock design.



The effect of varus tilting stem was much less for the neck sparing TSI stem compared to the monoblock Taperloc stem.



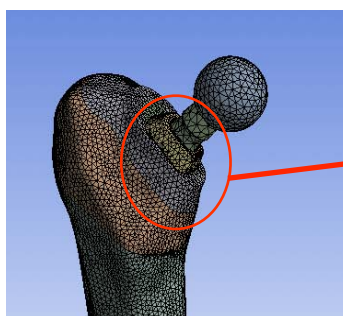
5° tilt shifts head center 1.8 mm



5° tilt shifts head center 2.8 mm

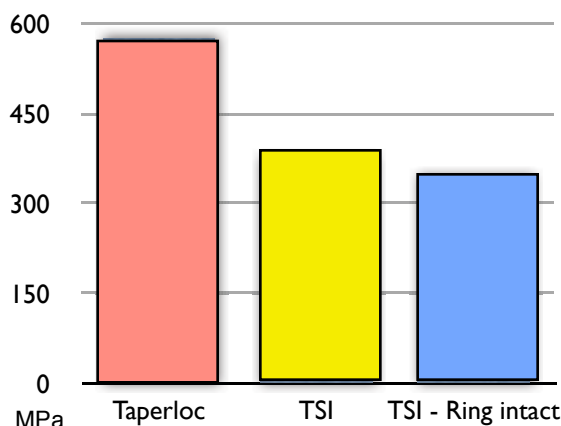
Neck Sparing Advantage

The ring of cortical bone saved in the neck sparing stem has significant bio-mechanical advantage. Pipino refers to this as a tension band. So it benefits us to reduce the chip fractures and not disrupt this band of bone.

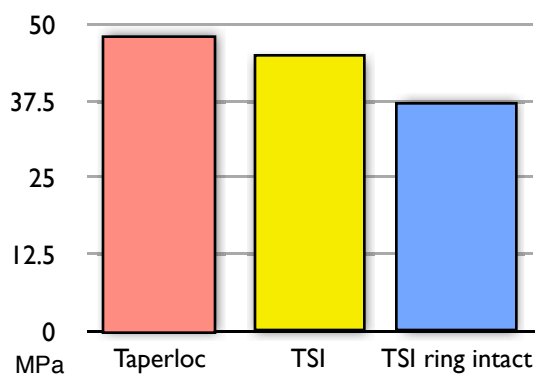


Stress in the Femoral Component

The principal stress in the femoral component was lowest for model with cortical neck ring intact compared to the monoblock conventional cementless stem.

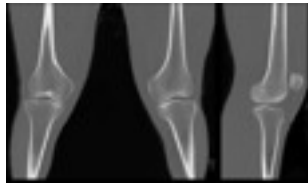


The stress in the distal femur reduces with the TSI neck sparing stem and reduces even more if the cortical rim remains intact.



Small chip fractures reduce the optimal biomechanical benefit of the conical flair.

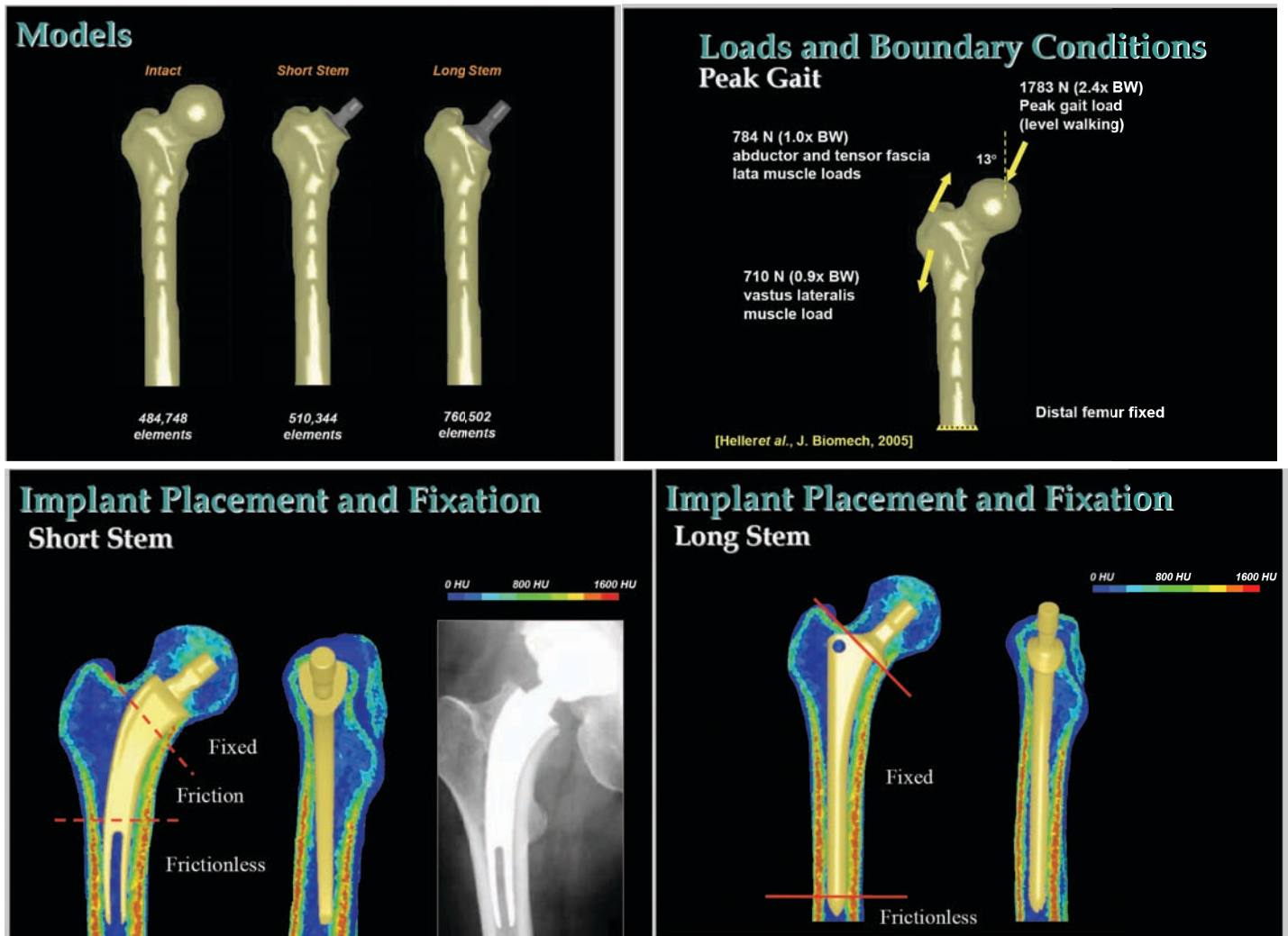
Model Setup (Second test Bone Response) ^{2,11}



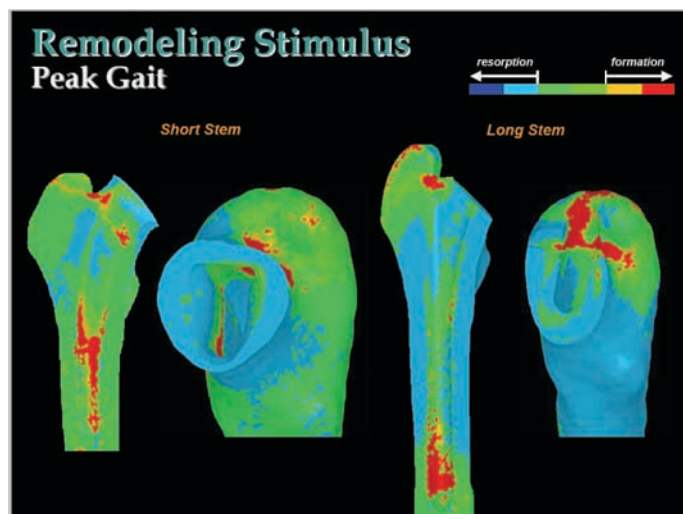
United States
National Library of Medicine

Right hip 39 year old male 5' 11," 199 lbs

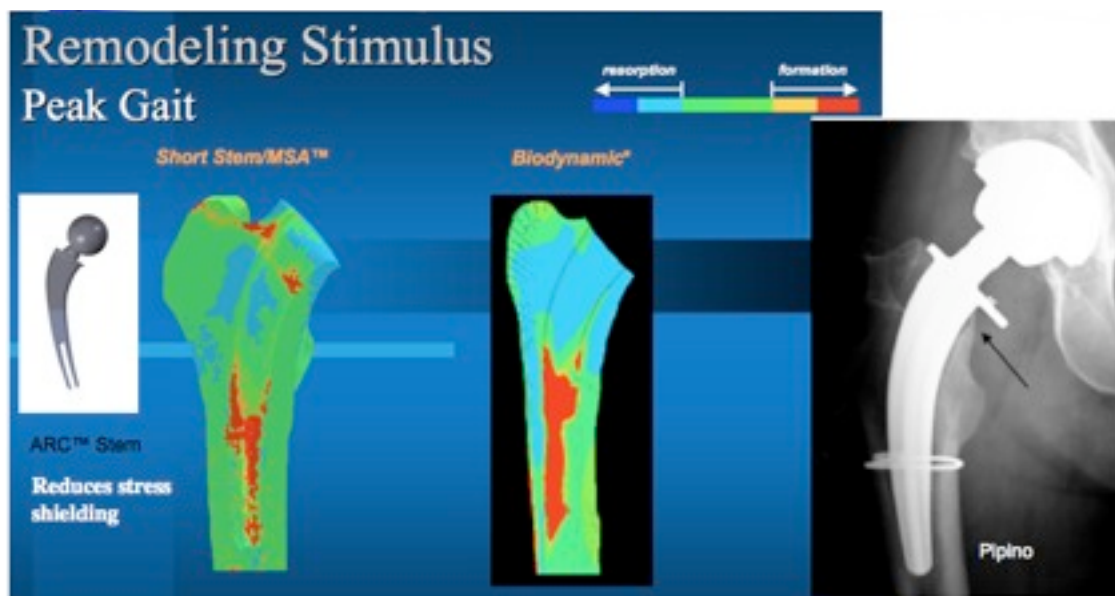
Visible Human Project: Digital image data set of complete human male and female cadavers in MRI, CT and anatomical modes.



The short stem is the TSI™ Neck Sparing Design and the long stem is a AML® fully porous coated conventional cementless style stem.

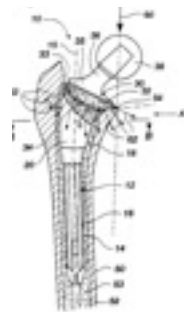
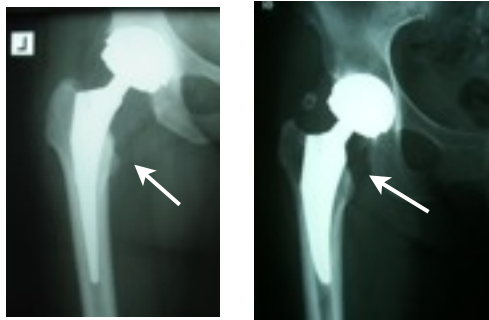


Bone remodeling strains clearly demonstrated better loading conditions with the TSI short stem compared to a AML fully porous coated style stem. This FEA model compares nicely to published clinical bone remodeling response for the AML stem.



The short TSI™ stem marked (MSA™) demonstrates better loading patterns as compared to Pipino's first stem the Biodynamic which was made of c.c. material. The x-ray on the right is his current stem CFP which still has had some medial calcar bone resorption issues. This in our opinion is an example that his flat angled collar does not transfer load as he might have expected. He has had excellent clinical results as related to aseptic loosening and functional range of motion⁴. The medial calcar stress shielding in his current design has not presented any clinical problems to-date.

Some designs, long stem or short, do not load the medial calcar and the neck resorbs.



Previous work McTighe et. al. 1995 U.S. Patent 5,725,594

A monoblock style fit and fill stem with a conical collar did load and maintain the medial calcar. The TSI™ conical flair came from that experience.

Radiographic Examples of the TSI™ Stem

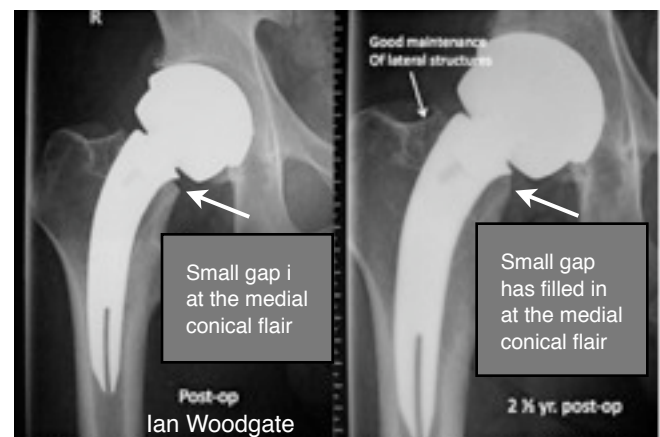
The TSI advanced hip technology (patents pending) has been licensed and there are two commercial version currently in the market place. The ARC™ Stem is produced by Omnilife science™, E. Taunton, MA, USA and the MSA™ Stem is produced by Global Orthopaedic Technology, NSW, Australia. The major design features are the same with some minor differences in level of porous coating and stem sizing. Both are demonstrating equivalent clinical and radiographic results.

ARC™ Stem

MSA™ Stem



Our first case was performed in December 2007 in NSW, Australia by Professor Ian Woodgate. Five initial cases were performed under tight clinical controls to validate our design concept. First generation prototype instruments were utilized and implanted with a large head metal-on-metal bearing. All five cases from a surgical technique point of view were successful. All of these patients have continued to do very well from a clinical review perspective. The following is one example at 2 1/2 year follow up from that first series. This patient is now out almost four years and doing very well.

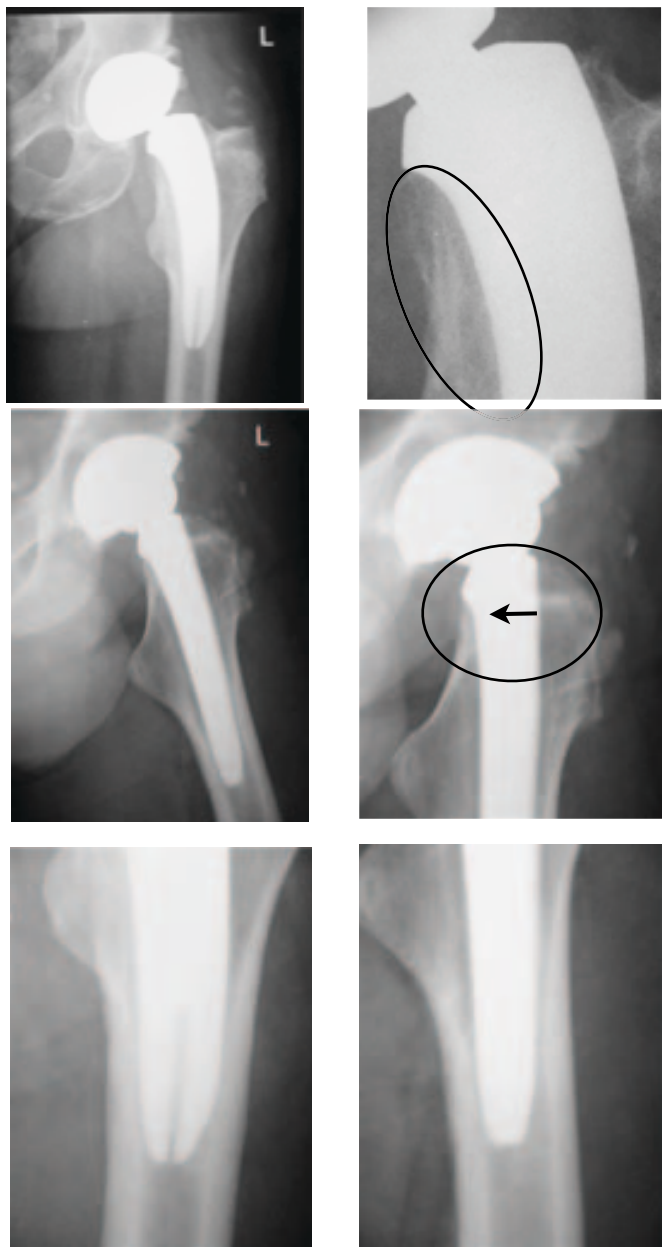


As you can see in this 2 1/2 year follow up, the stem is stable, no subsidence, good medial curve contact slight rounding of medial neck with the appearance of bone filling in the small gap at the conical flair. No distal reactive lines and no sign of distal load transfer. The entire stem below the conical flair appears to be in a bone benign state. This is fairly typical of what we are seeing when some portion of the conical flair engages bone. The flair can be above the resection line but should bottom out somewhere within the conical flair zone.



X-Ray review 18 months post-op on the TSI™ Neck Sparing Stem

(MSA™ Stem) Surgeon: Dr. Adrian van der Rijt, Wagga Wagga, NSW, Australia



Maintenance of medial curve contact, no reactive lines, no distal pedestals, no distal hypertrophy. Proximal lateral shows positive bone reaction with streaming of bone to the implant. Extremely encouraging X-rays.

X-Ray 12 month post-op Review (ARC™ Stem)

Surgeon: John Keggi, MD, Watertown, CT, USA



This x-ray correlates nicely with what we have seen in Australia. The one year post-op appears to be a stable stem with no subsidence and the appearance of the small gap at the medial conical flair has filled in. The rest of the stem shows good maintenance of initial bone contact with some appearance of smoothing of medial curve cortical interface. No distal reactive lines or pedestals.

THA has been one of the most significant surgical procedures ever created and the technology and surgical techniques keep evolving. However specific design features and their potential benefits are only reached if one understands the features and can try to maximize those features. Trying to validate basic science, like finite element analysis, is done by clinical evaluation and review. We believe we have seen some excellent clinical examples that support our design concept of the conical flair in stimulating the bone of the medial calcar.

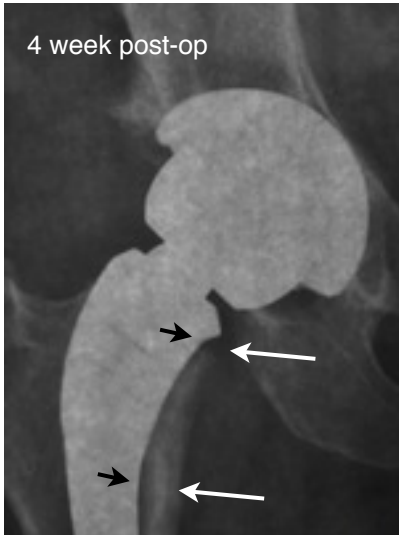


Example of good medial curve contact in a valgus neck shaft angle and was addressed with a valgus modular neck.

X-Ray Review 1 year post-op

Surgeon: William Vincent Burke, MD, Fort Lauderdale, FL, USA

The following is also an example that clearly demonstrates that if the design feature (conical flair) is not used there will not be benefit from that individual feature.



The 4 week post-op clearly shows that the conical flair is well above the resection line. There also appears to be a slight gap in the metaphyseal medial curve region. This likely could have been a result of the rasping preparation for the stem. With this view it is difficult to determine leg length or femoral offset.



One year post-op observations:

Leg length might be slightly long

however,

Shenton's line

appears to be

continuous and

smooth. If the

vertical height

was reduced more femoral offset might be called for.



Stem appears to be stable with no signs of

subsidence. Since the conical flair was above the

resection line the medial calcar has not benefited

from the potential compressive loads from the flair to the medial femoral neck.

The gap from the original resection point to the proximal tip of the conical flair appears to have lengthen with slight rounding of the medial neck.

This appearance would suggest mild stress bone resorption "stress shielding" has occurred. This would be a typical bone reaction seen in most total hip stems and seem to be a very logical reaction in this case.

Of interest is the gap in the metaphyseal medial curve region has disappeared suggesting that the bone has remodeled and filled in that space. This would suggest a stable implant / bone interface with good load transfer. There appears to be a hint of distal hypertrophy just behind the lateral flange of the sagittal slot. When load is transferred distal it is a sign some load is bypassing the proximal geometry.

Generally, proximal stress shielding is not progressing after the first year and this patient appears to have a well fixed stable stem. The issue of slight increase in leg length, slight medial bone resorption and the hint of distal hypertrophy should present no clinical symptoms. It is of interest from a biomechanical observation on bone loading¹².

Observations and Conclusions:

FEA modeling has demonstrated a significant biomechanical advantage with retention of the femoral neck as compared to conventional length and neck resection taper style stem. There is a 35% reduction in principle tensile stresses in the short curved TSI™ neck sparing stem as compared to the conventional length Taperloc™ style stem.

The effect of varus tilting of the head center of a monoblock conventional taper style stem has more than doubled the effect of stress on the femoral component.

Both the short curved neck sparing stem and conventional monoblock taper style stem have roughly the same overall bone / implant contact area and the distal stress in the femur is equivalent.

The FEA bone response also demonstrated better loading conditions for the short curved neck sparing TSI™ stem than the AML® fully porous coated monoblock stem or the short curved neck sparing Biodynamic™ stem. Both the AML and Biodynamic stems are made out of chrome cobalt material as compared to the TSI™ stem being made of titanium alloy.

The X-rays presented are examples of more than 700 cases of the TSI™ style stem (ARC™ & MSA™).

X-rays have demonstrated when the conical flair is engaged with the intact cortical rim we see a positive bone maintenance at the medial calcar region and, in some cases, an upward filling of small gaps at the medial conical flair zone. If the conical flair is above the neck resection line there is potential loss of the benefit of the offloading of compressive forces to the medial calcar. Even in the face of some minor medial calcar resorption when the conical flair is not engaged, there are no overt observations of distal load transfer.

The FEA modeling has demonstrated accurate predictions of actual clinical performance. A formal bone density study will help evaluate the bone response to this novel design feature.



All of these three different style stems work. One design saves more tissue (hard & soft), the TSI™ Stem.

“Remember in accordance with Wolff’s Law, the reduction of stresses relative to the natural situation would cause bone to adapt itself by reducing its mass, either by becoming more porous (internal remodeling) or by getting thinner (external remodeling)”^{12, 13}

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“Neck Sparing Total Hip Arthroplasty Lessons Learned”

By: T. McTighe¹,

I. Woodgate², A. van der Rijt², A. Turnbull², J. Harrison², D. Brazil²

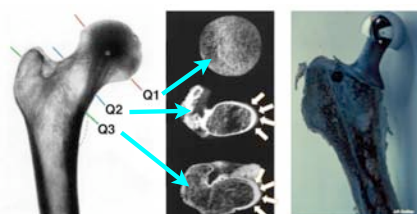
L. Keppler², J. Keggi², K.J. Keggi², R. Kennon², S.D. Stulberg², L.E. Rubin²

Introduction:

Architectural changes occur in the proximal femur after THA and can lead to implant loosening and or breakage.

Previous surgeon designers (Freeman, Townley, Whiteside and Pipino) have advocated the concept of neck sparing stems. However, to-date most neck sparing stems have had disappointing results with regard to maintaining proximal bone mineral density.

Our aim was to identify design features that would improve proximal load transfer, simplify surgical technique, and be economical by inventory size and cost.



Architectural changes in the proximal femur after THA continue to be a problem.



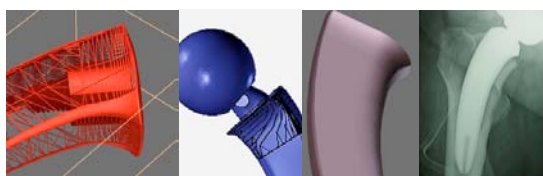
Examples of stress shielding.

Materials and Methods:

Review of previous published work was evaluated along with new FEA modeling providing for a new approach to neck sparing short curved stem design.



The FEA analysis demonstrates better strain patterns compared to fully porous coated straight stem design.



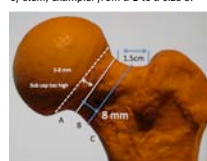
The proximal conical flair is a significant novel feature that provides for transfer of hoop tension into compressive loads to maintain stress on the medial calcar neck.

Three hundred radiographs were evaluated for sizing. Twenty intra-operative trial implantations were performed to aid the development of simplified and reproducible surgical instrumentation. All surgical approaches were utilized. The review process provided for a novel new design that was validated by the fabrication and implantation of five custom stems with post-operative follow-up between twenty and twenty-nine months.

The proximal modular neck allows for fine tuning joint mechanics without disruption of implant to bone interfaces.

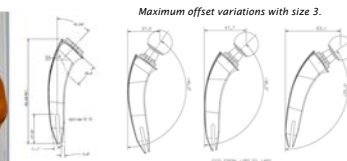


Sub cap is too high. First cut provides maximum conical flair contact design allows flexibility in level of cut but might effect size of stem, example: from a 2 to a size 3.



Note: conventional femur to neck approximately 20 mm below sub cap level or 1.0 to 1.5 cm above UCL.

Maximum offset variations with size 3.



Internal rotation provides for a more accurate measurement for both femoral offset and medial curvature of the neck.

Results:

Over fifty stems have been implanted to date with no revisions. Both anterior and posterior small incisions have been used with no difficulty for access to the socket or proximal femur.



Radiographic review clearly demonstrates the need for 20° of internal rotation for proper measurement of femoral offset and medial neck curve. Surgical intra-operative evaluations demonstrated any standard conventional or small incisions works with this stem.

The anterior single incision is especially attractive since the curvature of the stem reduces the need for as much femoral mobilization required by a straighter stem design.

FEA modeling demonstrated improved proximal strain patterns to the retained femoral neck. Fatigue FEA modeling showed reduced implant strains in the modular neck as a result of a shorter bending moment by design use of neck sparing feature. If there is any concern on length being too long resect another 4-6mm. This a forgiving design that allows for fine-tuning.

Conclusions:

We are encouraged with FEA modeling and short-term clinical/surgical results to-date and believe there are significant advantages in the concept of neck sparing stems. Additional mechanical and clinical /surgical evaluations are underway (fifty stems implanted to-date with no adverse effects.) U.S. clinicals begin in April 2010. We will follow up and report on all cases at least once per year.



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Design Rationale and Early Clinical / Surgical Observations with a Short Curved Tissue Sparing Hip Implant “The Apex ARC™ Stem”



Timothy McTighe, Dr. H.S. (hc)¹, Declan Brazil, PhD¹ &

The Clinical/Surgical Team (Members of TSI™ Study Group)

Tony Aram^{2,3}, MD; Charles Bryant, MD^{2,4}; John Keggi, MD^{2,5}; Louis Keppler, MD^{2,6};

Corey Ponder, MD^{2,7}; Frank Schmidt, MD^{2,8}; and Bradley K. Vaughn, MD^{2,9}

Abstract:

Architectural changes occurring in the proximal femur (resorption) after THA (due to stress shielding) continues to be a problem^{1,2,3,4,5,12}. Proximal stress shielding occurs regardless of fixation method (cement, cementless). The resultant bone loss can lead to implant loosening and or breakage of the implant. We are seeing younger patients with higher levels of physical activity as compared to just a decade ago. This has brought



back a renewed interest in hip resurfacing along with significant interest in minimally invasive surgical approaches and smaller profile implants.

Tissue sparing surgery in THA is credited to Prof. Pipino, from Monza, Italy who has been working on this concept for over 30 years⁶. The Apex ARC™ Stem is built off the pioneering work of Pipino, Freeman, Townley and Whiteside with new novel design features. In this paper, we review design rationale, surgical technique, clinical impressions, learning curves and lessons learned to-date. In particular, our first 650 stems have been implanted, with 500 being reviewed by the posted surgical team over the past 16 months. *Key Words: Total Hip Arthroplasty, tissue sparing, neck preserving, neck stabilized*

Introduction:

Total hip arthroplasty is one of the most effective orthopaedic procedures with a very high success rate as measured by pain relief, improved function and patient satisfaction. However, over the past ten years there has been a significant level of interest in more conservative approaches to hip surgery. Resurfacing, minimal invasive surgical incisions and short stem implant designs.

Patients today demand more out of the hip reconstruction and their increase activity places a higher demand on the implant.

A number of femoral component failure patterns after conventional total hip replacement have been identified. One of the most common is downward migration and varus rotation tilting of the femoral component.

From the:

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www.raleighortho.com

There is a significant increase in the use of short cementless stems and a decrease in hospital stay for the index procedure⁷. The current trend of getting the patient up and out of the hospital and back to their busy life style does place additional biomechanical loads on the artificial device.

Some recent reviews report on primary total hip survival (Kaplan-Meier) on uncemented hips at ten years to be 72% to 86% in patients less than 60 years old and from 90% to 96% in older patients⁸. So we are seeing risk for revision surgery at 10 years to range from 5% to 20%. This is a significant concern.

A number of the current short stems introduced into the market are no more than standard stems cut short. There is concern with the increase in younger and more active patients that these modified short stems be adequate to resist the increased biomechanical loads placed on them?

Modern short stems come in a variety of shapes with varying design features. However, there does not exist a classification system for uncemented short stem implants that would allow comparisons of clinical and radiographic results⁹.



The purpose of this paper is to review a new novel neck sparing total hip stem and the method by which this stem achieves implant/bone stability, surgical technique required, and observations as to early clinical outcomes.

Material & Methods:

A retrospective review of patients who underwent primary THA with a novel short curved neck sparing

“ARC™” total hip stem. The inclusion period was between April 2010 and September 2011.

This is part of previous work by some of the same group presented at the Osteoarthritis Research Society International in San Diego, September 2011.

There has been 650 stems implanted with this novel neck sparing stem design since April 2010 with 500 from the surgical team (seven) posted for review. All surgeons are at different locations and all underwent specific training to familiarize themselves with the stem design and required surgical technique. All seven were part of the initial surgical team to aid in designing and fine tuning of surgical instruments.

Three surgeons utilized the single anterior approach, two utilized the posterior approach and two did some of each. No anterior lateral or direct lateral approaches were used. A variety of acetabular components were used as were a variety of bearing surfaces (MoM, MoP, CoP, and CoC). There were even a few dual mobile style cups used in small profile patients where a 32mm head diameter was not possible.

This stem allows the surgeon to choose the best bearing surface indicated for the individual patient.



Dual-mobile style cup

Out of the 500 patients 350 patients had greater than one year follow up. There has been an increased usage in the past six months with CoP and all surgeons in this review have moved away from MoM in their usage for THA. One surgeon in the group still performs Hip Resurfacing (HR) in males under the age of 65.

The current bearing selection by this group is one surgeon used CoC for young active patients, six utilize CoP in their younger patients. Six use MoP for their older patients and two are utilize dual mobile style bearings in the small female profile. No 28mm or smaller head diameters are recommended with the use of a neck retaining design.

Typical patient profile showed two-thirds being female with an age range overall between 17 to early 90s. Majority were treated for OA.

This stem has been used in all Dorr bone classifications (A,B,&C). The difficulty has been limited to small profile patients where the stem profile has been too large.



This review was limited to looking at stem revision rate for dislocation, aseptic and septic loosening.

Biomechanics:

Why save the femoral neck in THA?

That question was attempted to be answered by Mr. M.A.R. Freeman in his original article titled **“Why Resect The Neck?”** published in 1986 British Editorial Society of Bone and Joint Surgery¹⁰.

In this paper Freeman points out that there were three probable reasons for resection of the femoral neck: 1. Surgical convenience, 2. the fear of mechanical impingement, and 3. the danger of resorption of calcar. He gives a nice historical review of the Moore and Thompson stems and how neck resection evolved into a standard approach.

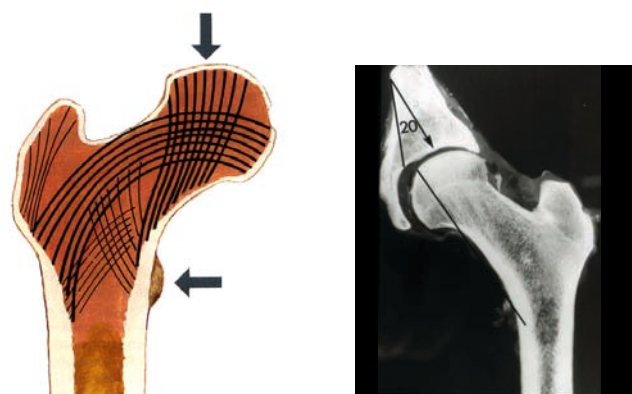
Impingement has largely been addressed by newer acetabular component designs and the use of 32mm and larger head diameters to increase functional ROM. However, careful cup positioning, removal of osteophytes and extensive trial range of motion must be carried out to reduce any chance of mechanical impingement. Also the advent of the modular neck junctions allows fine tuning of joint mechanics and

has become a valuable tool in avoiding impingement issues.

As for calcar resorption we know either too much or too little stress can result in bone resorption.

Wolff's Law:

“Accordance to these forces, the natural trabecular pattern of the bone and the trabecular orientation provide support against the natural functional loading, thus creating the necessary functional stability of the individual bone areas.”

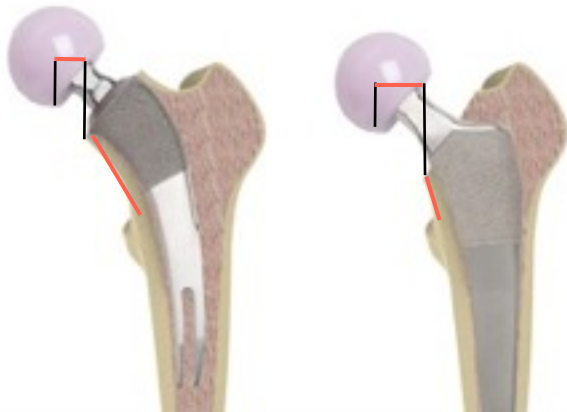


In the proximal femur, the femoral neck and the adjoining medial aspect of the femur in the calcar region show the strongest bone structure with a high load capacity to support the stem.

Femoral neck retention reduces both torsional and bending moments (forces) at the stem / bone interface.

“Remember in accordance with Wolff's Law, the reduction of stresses relative to the natural situation would cause bone to adapt itself by reducing its mass, either by becoming more porous (internal remodeling) or by getting thinner (external remodeling).

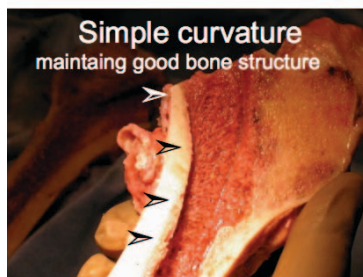
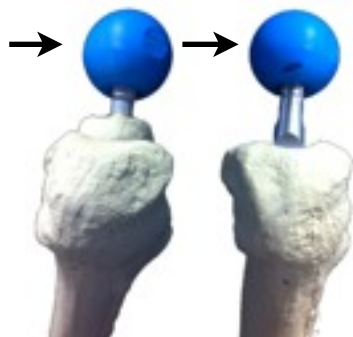




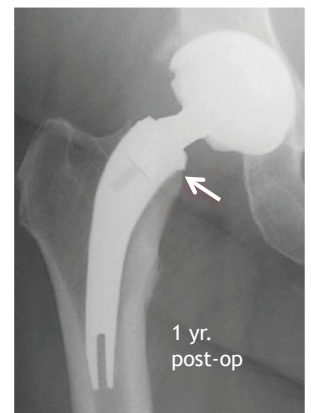
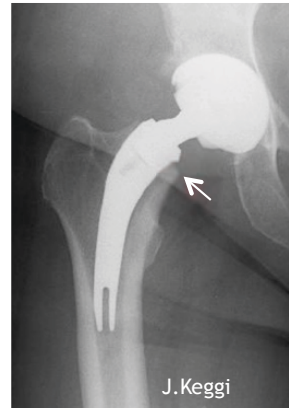
Illustrations comparing neck retention to conventional neck resection.

The neck on the right has been resected at the conventional level; in the one on the left the neck has been retained. Because the difference in the height of resection the length of the moment arms, the varus-turning moment increases by a factor of four when the neck is resected¹⁰. At the same time the area of bone available for supporting the vertical component of the resultant of the forces acting on the implant is almost tripled

The anterior-posterior directed component of the resultant force is represented by an arrow. Neck resection generates a significant torsional moment.



In-Vivo Bone Response



This one year radiographic view clearly demonstrates that the initial gap below the medial conical flair has filled in with bone. The rest of the stem is by all appearance benign. No reactive lines, no distal pedestals and no subsidence.

Design:

The ARCTM Stem is a simple short curved trapezoidal neck sparing design that is tissue conservative (hard & soft) and features a number of unique and novel elements to improve upon short and long-term survivorship¹¹.

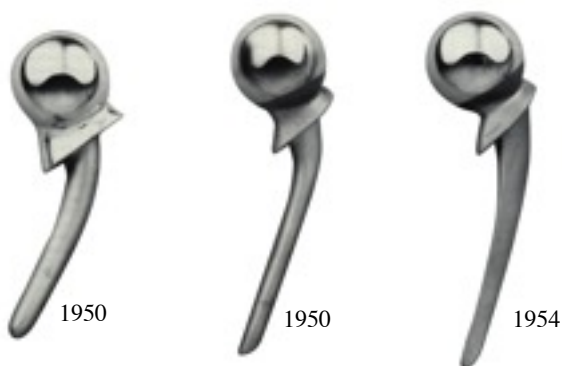
The basic curvature of the stem comes from the historical work of Thompson and Mueller.



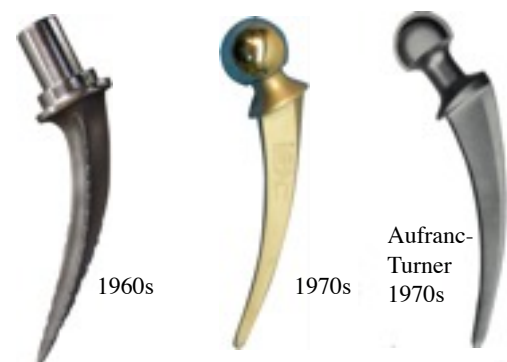
Mueller Rasp / ARCTM Stem

Historically there has been a number of curved stems. The application of the stem and how it was used often left a lot to be desired, however the curve was on target. If porous coating had been around a number of these designs would have

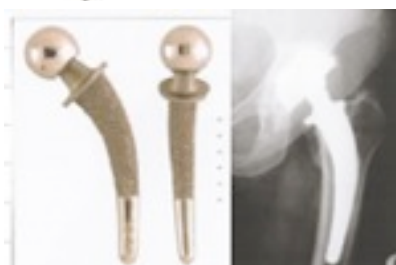
functioned very well. Many were designed as press fit and then later used with bone cement. The curve was a good idea, the Thompson is still in use in parts of the world today.



Dr. Joao de Azevedo Lage, Brazil implanted thousands of his novel curved stem.



Aufranc-Turner 1970s

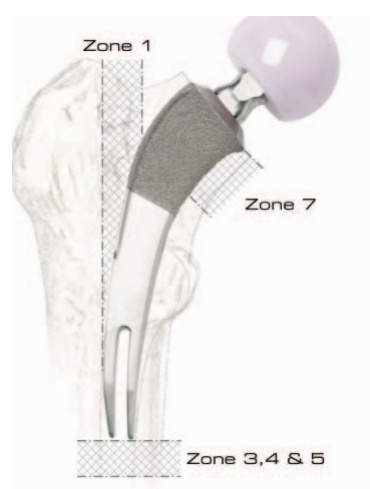


Pipino's Biodynamic stem 70s & 80s



Thompson still used in parts of the world

The curve reduces the need to go lateral where you can risk damage to the musculature and increased bleeding by removal of cancellous bone in the greater trochanter. You are also not forcing blood and fat down the canal as one does with conventional length stems.



No need to go lateral into zone I

The stem shape is that of a curved trapezoidal design that is intrinsically stable. The torsional stability is enhanced by the lateral T-Back feature.

Modular 12/14 taper head

Proximal Coating
Pure titanium
plasma spray /
HA coating on top
of titanium spray
T-Back



Modular neck

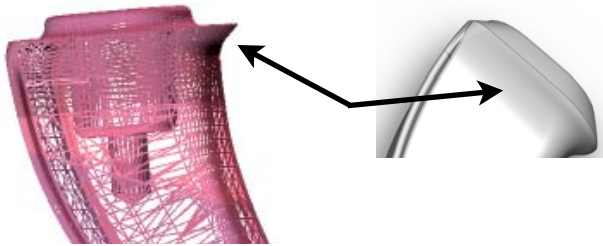
This however has proven to be too aggressive in the small female profile and has been removed on the size 0 stem.

The proximal porous coating is applied circumferentially to the upper third of the stem and is a combination of commercially pure titanium applied first using a plasma spray process after which a thin layer of hydroxyapatite (HA) is also applied using a plasma spray process.

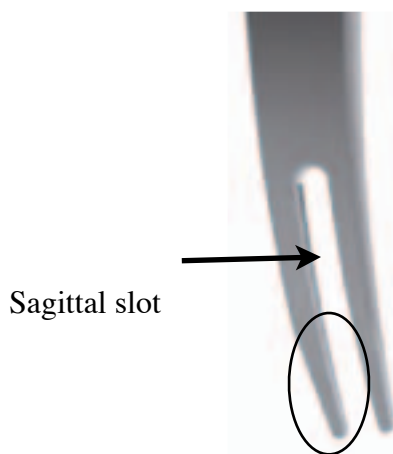
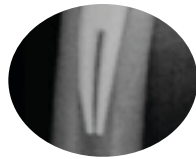
This simple yet novel stem design allows for considerable tissue conservation of both hard and soft tissue. As you can see here in this illustration bone is preserved in Gruen zones 7, 3, 4, 5 and zone 1.

The proximal portion of the stem has a patent pending novel conical flair element that is designed to off load compressive loads to the medial calcar.

This very unique feature has demonstrated positive stress transfer in both FEA modeling and now clinical observations.



Lateral distal relief of 11° reduces any distal tip contact if the stem is in slight varus position. The sagittal slot reduces distal stiffness reducing the potential of distal load transfer and reduces hoop tension in type A bone by allowing stem to pinch in.



Sagittal slot

Lateral relief 11° angle

Why a Modular neck?

Restoration for THA is a challenge with monoblock stem designs. Over lengthening the hip center to achieve joint stability is a significant problem and can lead to both mechanical and legal problems.



Mechanical impingement of the cup and stem or of bone-on-bone is a concern with neck sparing stem designs. Accuracy of femoral stem anteversion and acetabular cup anteversion would ensure mating of the femoral head in the cup without mechanical impingement. This requires both design and technique to repeatedly create this combined anteversion.

Combined anteversion has become more relevant with the use of non-cemented implants especially neck sparing designs. The non-cemented femoral stem must have a stable press fit to obtain bone fixation. A stable press fit means the stem must adapt to the femoral bone geometry which is highly variable; accordingly, there is often less ability to adjust the stem anteversion in uncemented compared to cemented stems. Cemented stems can be rotated within the femoral bone to provide 10° to 20° anteversion. Cementless stems of any geometry are limited by the anteversion of the bone, the anteroposterior isthmus at the level of the lesser trochanter, and the posterior fin of bone in Dorr type A and B bone. Neck sparing stems are limited by the internal cortical dimensions of the anteroposterior isthmus of the femoral neck.



The acetabular cup position has traditionally been anteverted with the assumption the femoral component would be a mean 15° anteverted. The arthritic acetabulum has a mean 12° anteversion and non-arthritic acetabula have mean anteversion of

$19.9^{\circ} \pm 6.6^{\circ}$ with the mean in women being 21.3° and men 18.5° . Therefore, the traditional safe zone for cup placement has been $15^{\circ} \pm 10^{\circ}$ or $20^{\circ} \pm 10^{\circ}$. If the stem has only 5° of anteversion, especially in a woman, the acetabular safe zone of 15° to 20° does not give an acceptable combined anteversion. This risk is compounded in 10% of hips in which the pelvis is tilted 10° or more from neutral and the surgeon's estimate of anteversion can be wrong by 10° . In clinical studies, cup anteversion is not within the desired safe zone as often as 55% to 78% of the time¹⁶.

The only sure way to determine proper orientation of combined version angles is by use of implant trials and conducting a range of motion. The use of modular necks with varying angles provides the best options to the surgeon in real time to fine tune the patient's joint mechanics.

Neck retaining stems like the ARCTM Stem that fits and fills the retained femoral neck are inflexible to alteration of stem version angle. Thus the need for modular necks in a variety of angles: Neutral, Varus, Valgus, Anteverted & Retroverted.



A modular neck also allows for femur first technique since the stem can be implanted and retracted out of the way without the neck interfering with acetabular exposure. It also helps providing another physical landmark for cup orientation.

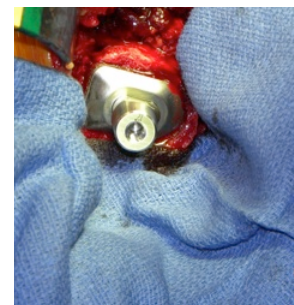


Neck trials can be used on trial stem or definitive stem.

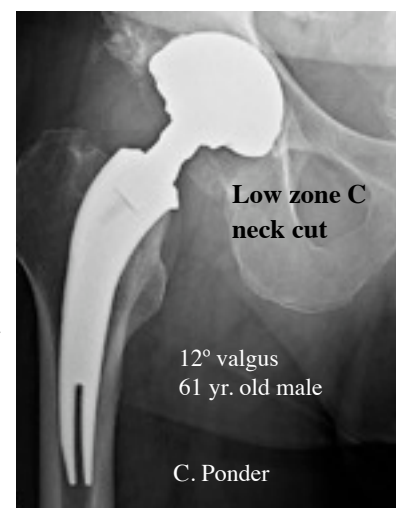


Trial neck in place with definitive cup and stem. The opportunity is still there for fine tuning of joint mechanics.

A modular neck separates the vertical height from the version and femoral offset angles. Providing the ability to intra-operatively restore joint mechanics without disruption of the implant / bone interface. It also provides an opportunity to retain a well fixed femoral stem in an acetabular revision.



There is a tapped threaded hole for extraction and is the same size tapped hole in the stem for extraction.



Example of using modular valgus neck shaft angle to help make up some vertical height.

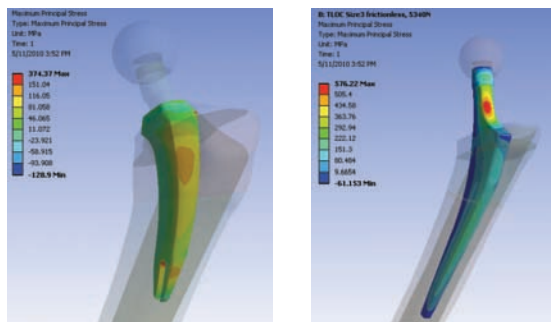
12° valgus
61 yr. old male

C. Ponder

Fatigue Concerns with modular sites:

We have reported on modular junction failures in the past and have seen must modular junctions have problems from time to time. However, we have also reported on monoblock stem design failures in cemented, cementless titanium and chrome cobalt designs. The basic conclusion has been unsupported stems are at increased risk of mechanical failure^{13,14,15}.

Contemporary neck sparing stem designs with modular c.c. junctions can be and have been designed to be stronger than many monoblock titanium stems and many titanium modular neck conventional cementless stems.



35% less tensile stress in neck stabilized stem vs. monoblock

Surgical Technique:

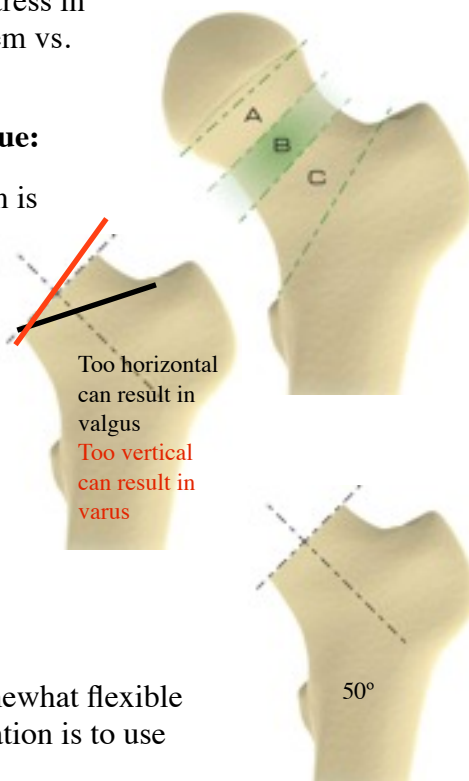
The neck resection is conservative but allows some flexibility to adapted to both patient anatomy and surgical preference.

Zone A: 0-5 mm

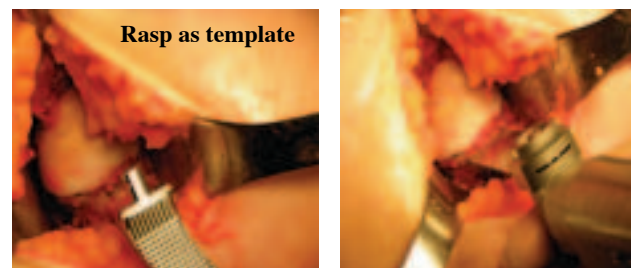
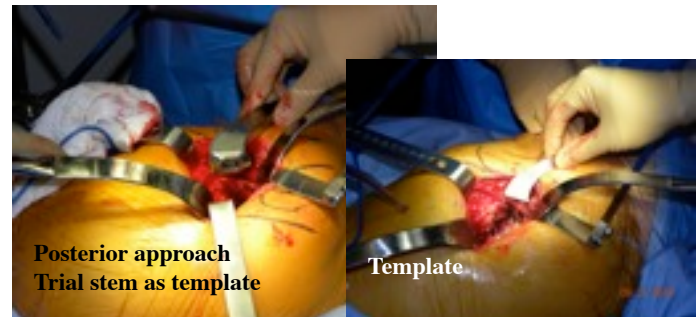
Zone B: 5-10 mm

Zone C: > 10 mm

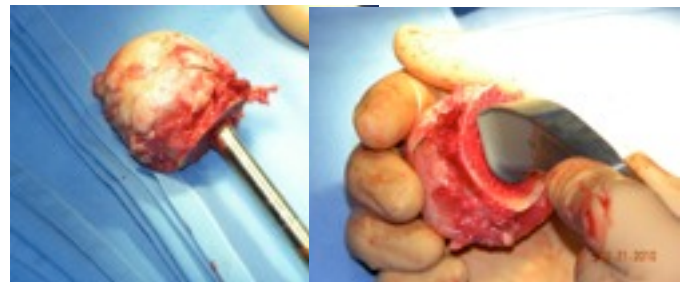
Neck angle is somewhat flexible but a recommendation is to use



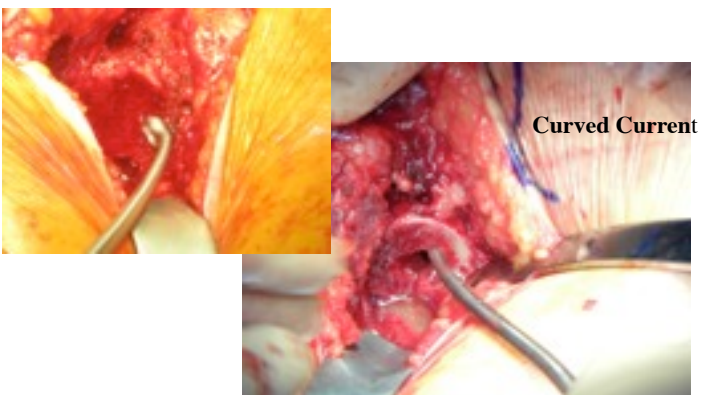
the resection guide or trial stem or rasp for orientation provides for optimal conical flair / bone contact.



After head resection a good technique is to take the head and trial stem and use the trial stem as a template. It provides a rough estimate as to the final stem size.



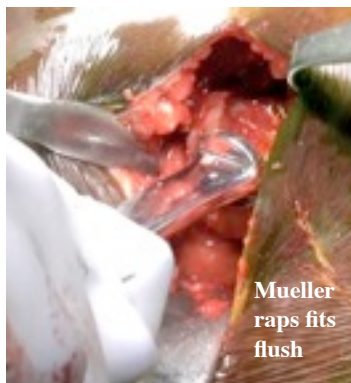
Opening the Femoral Canal can be accomplished by a number of ways and is up to surgeon's preference. A curved current, a curved metal sucker, a trocar drill or a starting AWL can be used to enter the canal.





Care should be used with the AWL in softer bone.

Proximal Canal Preparation is carried out with the use of a rat tail rasp and starter rasp before selection of definitive stem rasps.



Some surgeons prefer using a Mueller style rasp as their starter before going to their **definitive rasp** that shapes the conical flair.

The medial curve needs to be worked, shaping the medial curve of the proximal femur.

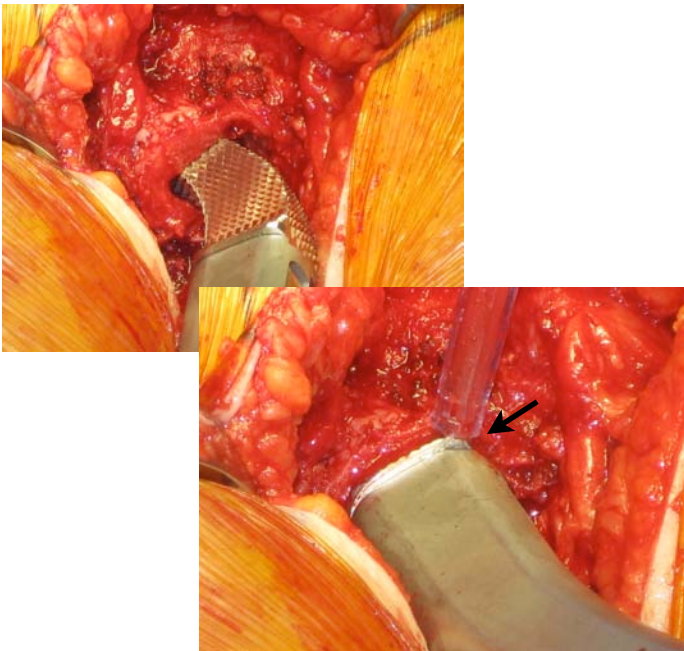


This should be done in a filing motion shaping the medial curve. The curvature of the stem eliminates the need of having to go lateral into the trochanteric bed.

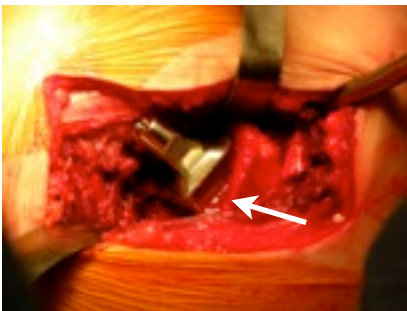


This not only has the advantage of saving bone, but reducing bleeding and reducing potential injury to the abductor soft tissue.

Progressive rasping is carried out till a tight fit in the femoral neck. Remember you are fit and filling the femoral neck not the femoral canal.

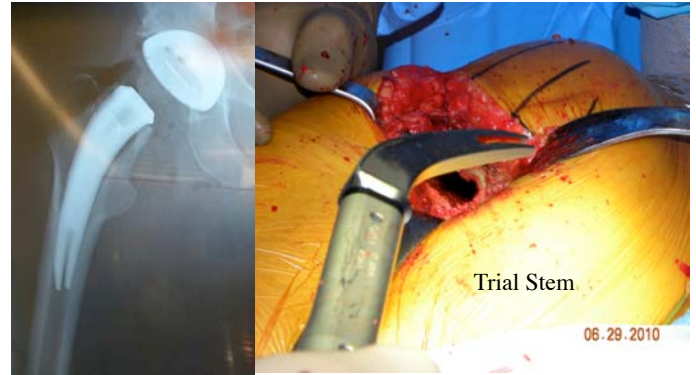
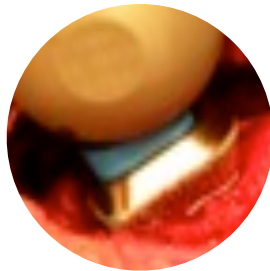


The definitive rasp should fit flush on the conical flange if your initial osteotomy was at the correct angle. If the conical flange is slightly above your resection line do not worry this will not compromise your initial stability.



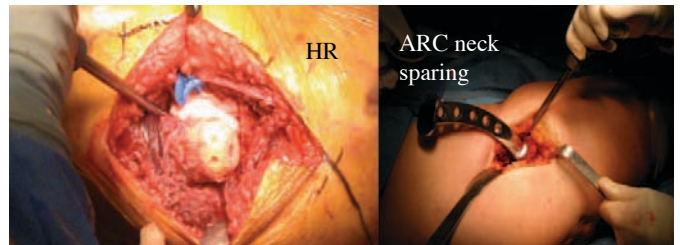
If your initial neck resection is off you could have a gap around the conical flange of the stem.

This does not present a problem with initial stability but will not take advantage of the biomechanical loading feature of the conical flange. Small gaps have been seen to fill in at approximately 8-12 months.

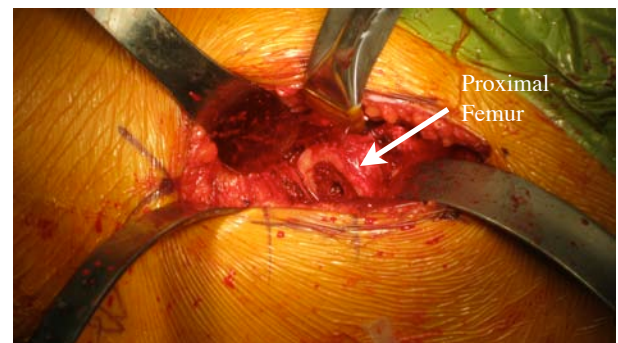


Trial stem in place with trial modular neck.

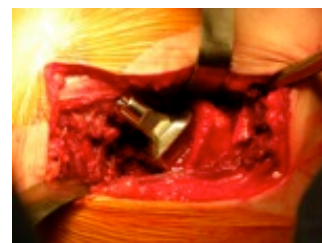
A short curved stem is easier to insert requiring less posterior capsule releases as compared to a straight stem or hip resurfacing.



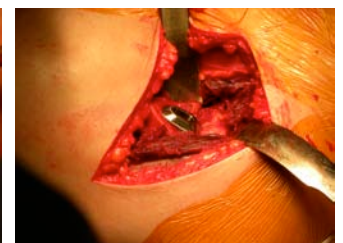
Hip Resurfacing requires considerable soft tissue releases as compared to a small curved neck sparing stem.



No special instruments or table is necessary for exposure or elevation of the femur



Stem insertion



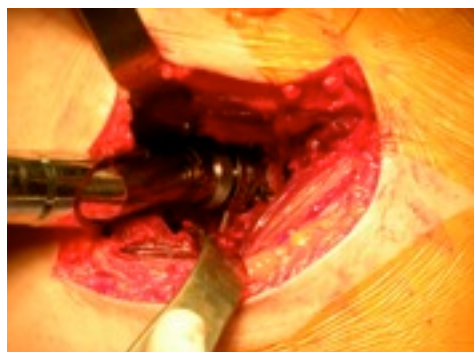
Stem Seated

Acetabular Exposure:

There is no difficulty with a high neck cut in achieving exposure for either the anterior or posterior approach.



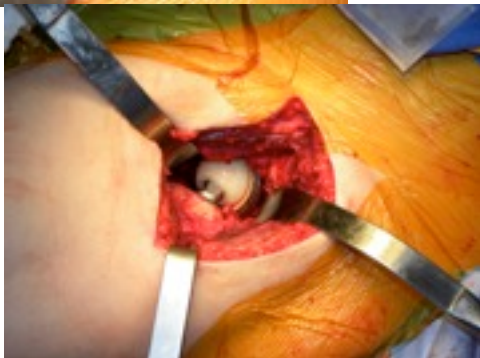
Posterior incision with the trial stem in place *Kepler*



Anterior incision: Stem implanted behind retractor there is no difficulty with exposure for acetabular reaming or insertion of acetabular component. No special instruments or tables are necessary to do a anterior single incision neck sparing short curved stem.



J. Keggi



Ceramic / Ceramic ARC™ Stem with Anterior Single Incision

Results:

650 ARC stems have been implanted since April 2010, 500 by the seven clinical / surgical advisory group, 270 were performed with the single anterior surgical approach and 230 were performed using the posterior approach.

Three surgeons used the anterior approach, three use the posterior approach and one surgeon does some selective cases with the anterior approach approximately 10% of the time.

Anterior Approach

Dislocations = 2

Stem Revisions = 3

Aseptic Loosening = 1

Superficial Infection = 2

Septic Loosening = 0

Leg / Length Discrepancy +/- 7 mm = 9 / 0.3%

Occult fracture distal end of stem = 1

Calcar Fractures wired = 2

Calcar Fractures not wired = 3

Hip pain = 1

Subsidence > 5mm = 3

Intra-op femoral perforation = 3

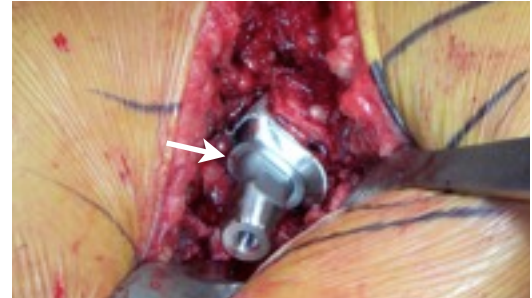
Intra-op calcar fractures resulting in stem bailout = 0

The aseptic loosening case was an intraoperative fracture not recognized at surgery. Patient came in two weeks post-op and had subsided about 5-6 mm and the fracture could be seen at the distal medial calcar. The stem stabilized but never healed and pain was persistent. Revision at five months to a primary cementless KII stem. There was no evidence of bone attachment. Stem was easily extracted and converted to a new primary stem. Patient is doing well. If fracture was recognized a simple wire would have prevented the revision surgery.



Aseptic loosening converted to a K2 primary stem. Pt doing well functioning like a primary patient.

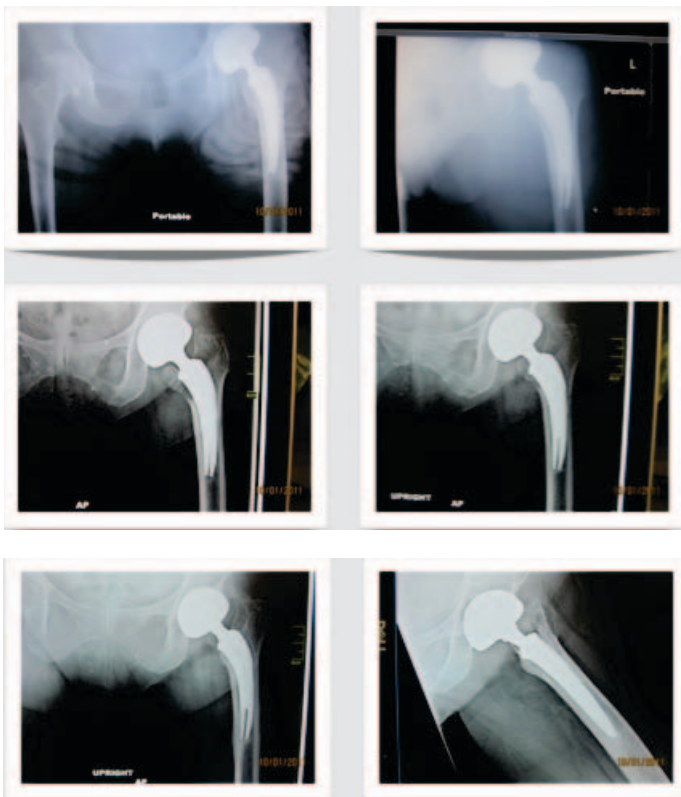
Plan is to go in a replace current modular neck with a longer vertical height. This should resolve her gait problem.



Small chip fractures around the proximal cortical rim do not seem to make a difference at least in short-term stability.

Two intra-operative perforations occurred during stem preparation by two different surgeons both in the single anterior incision approach and both were early in learning curve of the approach and of the stem. Perforation was recognized during trial stem insertion and was picked up on fluoroscopy and both cases the trial was removed and the final stem inserted by passing the perforation. No special precautions were given both patients went on uneventful and are doing well.

Trying to adapt to too many changes at once can be challenging.



Second female patient with an unrecognized calcar fracture subsided approximately 1 cm. Stem has settled and fracture healed. Patient is pain free and full weight bearing but has a trendelenburg sign due to shortening of the abductors.



Trial stem perforation (anterior-medial) caught and corrected with final stem. Patient had uneventful rehab and went on to a good recovery.

The two minor subsidence have stabilized and are functioning well. The curvature and conical proximal flair provide a shape that allows some minor settling to ensure a long-term bone / implant stable interface. Previous external collars have prevented stems from settling into a position of stability.

The two stem revisions were done outside the core group one for dislocation due to joint laxity (not due to any mechanical impingement issues) and one for hip pain due to heterotopic ossification. Both stems were revised to cementless primary stems.



Retrieved stem A had solid bone attachment at 8 months. Stem B was well fixed at 4 months no signs of loosening had the beginnings of bone attachment.

Well thought out retrieval instruments provided for ease of explantation with little bone destruction and left behind enough bone to convert to primary cementless stem length for both cases.



The single anterior approach by our group does not use a table at times a couple of our surgeons have used the Omni-track table mounted hook.

Posterior Approach

Dislocations = 2

Stem Revisions = 1

Aseptic Loosening = 0

Septic Loosening = 1

Superficial Infection = 0

Leg / length Discrepancy +/- 7 mm = 3 / .013%

Fractures distal = 0

Calcar Cracks wired = 0

Calcar Cracks not wired = 1

Hip pain = 1 (process of being worked up/ potential spine problem)

Subsidence > 5mm = 0

Intra-op calcar fractures resulting in stem bailout = 2

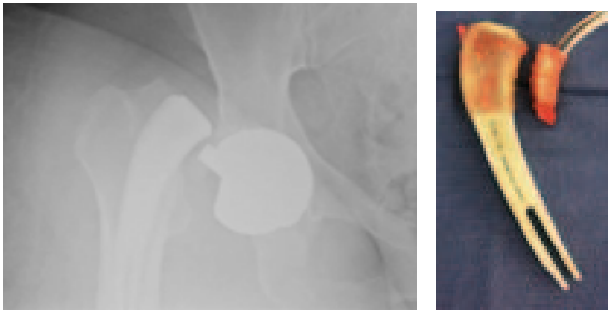
The two dislocations were treated by explanting the femoral neck for exposure to the acetabular components providing better exposure while leaving the stem in place. One cup had spun out and was replaced with adjunct screw fixation and the second had a poly liner exchange to a hooded offset and increased femoral offset used on the modular neck (12° varus). Both cases were made considerably easier as a result of the modular neck design reducing surgical trauma to the patient and reducing overall cost to the hospital.



Complications outside the 500 case review:

One neck stem disassociation. A MoM head cup combination was used and, even though the neck trunions were compatible, the design on the metal head had a truncated shape that prevented the neck from fully seating into the stem. As the disassociation occurred the medial calcar fractured.

Which was successfully converted to a cementless primary stem. Lesson learned.

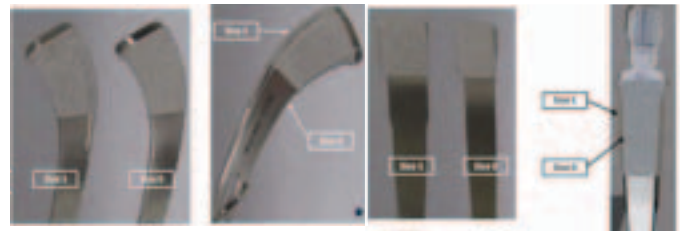


One patient had a fall resulting in a periprosthetic fracture requiring significant revision of total hip stem and previous trauma implants.

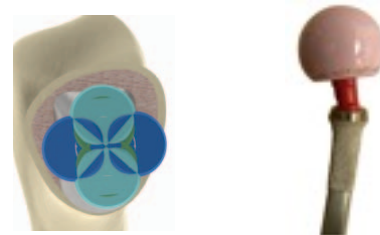


Observations:

The initial experience with this short curved novel neck sparing stem design has demonstrated that the stem and instruments needed some minor changes and additions. The five sizes covered about 90% of primary total hip indications. A small stem was needed for the small female profile. This has been done by eliminating the T-back and reducing the proximal geometry in this size. In addition, the size 1 and size 2 stems the T-Back profile has been reduced allowing better seating and elimination of lateral chip fractures to the cortical rim.



Anterverted / Retroverted neck have been added to aid in addressing combined version angles (12°) and reducing potential mechanical impingement issues.



The use of modular necks have provided increased opportunity to fine-tune joint mechanics without disruption of the implant / bone interface. It has also proven useful for increased exposure to the acetabulum in case of revision surgery. It has provided a one stem approach regardless of surgical incision.

In the anterior single incision approach it has reduced the incidence in having to do extensive posterior capsular releases. In the posterior approach it has provided the opportunity to do a femur first approach.

When the conical flair is engaged with the cortical rim increased bone density occurs.

Four of our surgeon group now use this as their main stream hip implant and our three other surgeons are expanding their indications.

This stem design saves tissue, both hard (bone) and soft tissue as compared to conventional length, short metaphyseal cementless stems, and to hip resurfacing.

This new design approach has the potential benefit for less blood loss, quicker rehabilitation and, if necessary, easier removal and conversion to revision surgery.

Summary

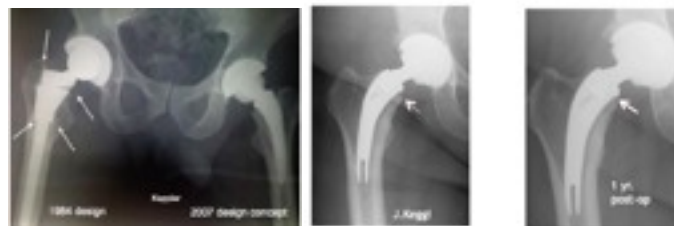
There is a short learning curve for the surgeon (2-3 cases) and an easy transition for the O.R. surgical team with only one pan of instruments.

Six of the seven surgeons feel that these patients with this short curved neck sparing stem have gotten back to full weight bearing and a full active life style quicker than their conventional cementless THA. One surgeons gauges them as equivalent to his conventional stems. All feel that there is less blood loss and operative times have been reduced.

The few explants have proven to be easily converted to a primary stem for revisions. Two intraoperative calcar fractures resulted in a bail out to a conventional primary cementless stem. The modular neck has proven to be beneficial in a couple of cases for access to the socket in revision situations. The modularity of the neck also helps reducing risk of mechanical impingement.

There have been minor incidence of over lengthening the leg (11) greater than 7 mm however, none have had to be revised.

We are encouraged with our initial clinical / surgical observations (patients are happy) and believe the potential and real benefits warrant not only further evaluation but expanded evaluation of this tissue conserving approach to THA.



Example of bilateral hip with S-Rom® & ARC™ and 1 year follow up showing positive bone remodeling

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"Early Learning Experience with a Neck Stabilized THA Stem for Treating Osteoarthritis"

By: T. McTighe^{1*}, C. Bryant^{1*}, D. Brazil^{1*}, J. Keggi^{1*}, L. Keppler^{1*},



Purpose:

Total hip arthroplasty is one of the most effective orthopaedic procedures with a very high success rate as measured by pain relief, improved function and patient satisfaction. However, since the introduction of total hip arthroplasty in the 1940s, a range of design philosophies for femoral components have demonstrated variable clinical results. Aseptic loosening, joint dislocation, thigh pain, bone resorption and femoral component failure have been some of the complications that plague this procedure.^{1,2} The past few years has seen an influx of so-called short stems with very little clarification as to design features, required surgical technique and long-term clinical outcomes. Most devices, meet with some level of learning curve and most systems do little in the way of warning new surgeons as to the perils and pitfalls during the initial surgical phase. This paper is designed to review the lessons learned during the first year of surgical experience with a new neck stabilized implant stem.^{1,2,3,4}

Why the need for a new design concept?

Concerns with survivorship of young active patients

(Kaplan-Meier 72% to 86% in patients <60 yrs. old)⁵

Hips fail for a number of reasons:^{6,7,8,9}

- Loosening of the hip replacement
- Infection of the hip replacement
- Dislocation of the hip
- Breakage or wearing out of the implant
- Damage to the surrounding bone (periprosthetic fracture)

Examples of failures of conventional THA



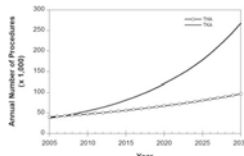
Concerns with Hip Resurfacing^{10,11} (Decreasing indications)

- Broader indications
- Broader selection of bearing material (MoM biological concerns: Aseptic, Lymphocytic Vasculitis and Associated Lesions)
- More conservative approach (Tissue sparing both hard and soft tissue)



Concerns with Rising Health Care Cost

- Hip replacements are expected to increase 174% in the next 20 years¹²
- The number of patients waiting more than nine months for hip and knee replacements in North Wales has increased by 11,700%.
- Less inventory requirements
- Less instruments



Concerns with Retrieval and Conversion for Revisions

- More hard & soft tissue to work with for revision surgery



Timothy McTighe, Dr. H.S. (hc)
Executive Director
Joint Implant Surgery & Research Foundation
www.jisrf.org

1* JISRF Study Group Members Tissue Sparing Implant™ (TSI™) Total Hip Stem Designs

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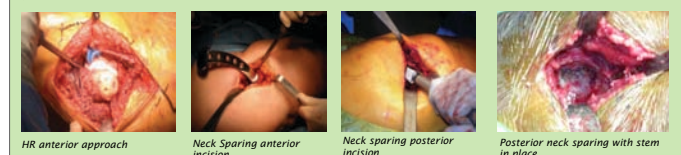
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Methods:

One year follow up on 200 cases by three surgeons at different centers. A novel tissue sparing neck stabilized stem design (ARC™ Neck Sparing) was used in all cases.

Two surgeons used the anterior single incision and one surgeon used a small posterior surgical approach.

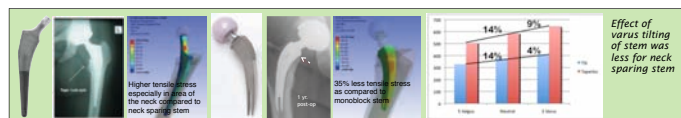
Example: anterior approach for HR vs. single incision anterior approach for neck sparing stem. Posterior approach for neck sparing good exposure on socket with retention of femoral neck.



All were implanted with cementless acetabular components of four different designs and three different bearing surfaces. Intraoperative x-rays were taken on all patients undergoing the posterior approach and half of all anterior approach patients had intraoperative fluoroscopy or plain x-rays taken.

FEA studies were evaluated to determine best stem orientation and instrumentation designed and developed for surgical preparation of femoral stem.

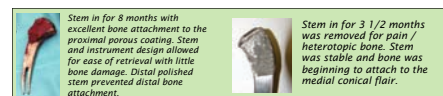
Results: FEA Analysis of Neck Stabilized Stem vs. Conventional Cementless Taper Total Hip Stem¹³



One stem has been revised due to sepsis and was eventually converted to a primary cementless stem. No stems have been revised due to aseptic loosening. Two modular necks were explanted for exposure to the acetabular component due to dislocations, providing better exposure to the socket while leaving the femoral stem in place.



Two stems were removed one for dislocation and one for pain due to heterotopic bone formation. Both revised to conventional cementless primary stems.



Surgical evaluation clearly demonstrates there is no difficulty for access to the socket or proximal femur when using a neck sparing stem design.



Intraoperative evaluation demonstrated the need for a smaller stem size in small female patients.

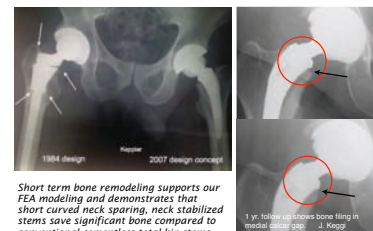
Surgical technique demonstrated three unique learning aspects of utilization of a curved small neck stabilized stem design.



Observations:

The initial year (April 2010 to April 2011) results of a novel modular neck stabilized curved stem design clearly demonstrates that this approach can be used as a main stream treatment for the osteoarthritic patient.

The advantage of neck sparing stabilized stems saves tissue, both hard (bone) and soft tissue as compared to conventional cementless total hip stem designs. This new approach has the potential benefit of less blood loss, quicker rehabilitation and if necessary easier removal and conversational of revision surgery. We are encouraged with our initial clinical / surgical impression and believe the potential advantages warrant further evaluation of this new approach to THA.



Short term bone remodeling supports our FEA modeling and demonstrates that short curved neck sparing, neck stabilized stems save significant bone compared to conventional cementless total hip stems.

Bone remodeling clearly demonstrates advantages to this novel design as compared to conventional cementless THA.

Long term clinical follow up with validate this design concept.



Deactivation of Palacos R Bone Cement with the Addition of Rifampin Antibiotic Powder An In-Vivo Experience

-Case Report-

Edward J. McPherson, MD FACS,

Denise Portugal, MD

Use of antimicrobial impregnated polymethylmethacrylate (PMMA) bone cement in the treatment of orthopaedic infections is widely accepted.¹ Antibiotic powder is routinely added to PMMA, and formed into beads or spacers when treating infected bone or periprosthetic infections. Antibiotics placed into the PMMA elute via a water diffusion process.² This results in high local doses of the antimicrobial agent with reduced systemic toxicity.³ Two stage reimplantation protocols utilizing antibiotic loaded PMMA cement generally provide the highest rates of successful treatment.^{4,5} With the increasing number of resistant organisms, success of this treatment protocol requires antimicrobial therapy targeted at the specific organism found. There exists a great deal of data on the use of certain antimicrobial agents in PMMA cement.^{1,6,7} However, there are few published reports of the addition of rifampin. This is the first clinical report on the failure of Palacos® R cement (Heraeus Kulzer GmbH, Wehrheim, Germany) to set when rifampin is added.

thalassemia.⁵ Before reimplantation, multiple aspirations of the left knee were negative. Multiple c-reactive protein measurements were normal and clinical exam of the knee was benign. At reimplantation, the left knee was re-debrided and reconstructed with a constrained non-hinged knee implant system. The components were cemented in a serial fashion, starting with the tibia. For reimplantation, we mixed 600 milligrams (mg) of rifampin (Bedford Laboratories, Bedford, Ohio) with each bag of Palacos® R cement. The cement turned a dark violet-brown color. The cement was inserted with an injection gun, and the tibial component was implanted. After 35 minutes, the cement was still doughy in texture and the tibial implant was extracted. The cement was easily removed from the bone and prosthesis. The implant was reinserted employing 1 gram vancomycin per bag of Palacos® R cement, which hardened in a typical fashion. All reimplantation cultures were negative. The patient remains free of infection at three year follow up.

Case Report:

A 67 year old female was treated for a recalcitrant infection involving her left total knee arthroplasty (TKA). Her primary TKA was resected. An antibiotic spacer was not placed. At resection, cultures were positive for atypical mycobacterium and coagulase negative staphylococcus. Risk factors for infection included insulin dependent diabetes, obesity (body mass index 44.3) with chronic

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A follow up study was conducted in the operating room. Under constant temperature and humidity, two preparations of Palacos® R cement were evaluated for time to hardening. One bag was mixed with 600 mg of rifampin, with the other used as an unaltered control. These were mixed for approximately one minute, and injected five minutes apart into two sterile emesis basins. Separate mixing bowls and injection guns were used to prevent cross contamination. Evaluation consisted of probing the cement with sterile tonsil forceps to judge the consistency of the cement. The plain Palacos® R cement was evaluated every minute for the first 10 minutes, then every 15 seconds until set. It achieved a non-stick doughy consistency at 5 minutes, firm rubbery consistency at 10 minutes, and set completely at 13.5 minutes. The Palacos® R with rifampin was evaluated every minute for the first 10 minutes, then in increasing intervals after it was evident that there was little progress towards setting. It achieved a non-stick doughy consistency at 5 minutes, a semi-firm surface with spongy interior at 30 minutes, and a firm rubbery consistency at 5 days (fig 1). The cement remained in a firm rubbery state when checked every 5 days up to 30 days. The cement never completely hardened.

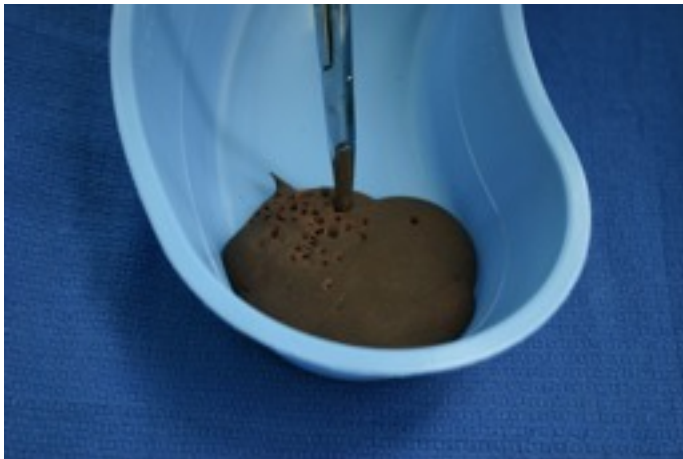


Fig 1a. Sample of Palacos® R-rifampin as it appears after five days of curing. Its outer crust of 0.5 mm feels firm, but can be easily indented.

Discussion:

Use of antibiotic impregnated PMMA bone cement is an important treatment method for orthopaedic infections.

Infection caused by microorganisms with antimicrobial resistance is increasingly common, and has resulted in the addition of various antibiotics mixtures to bone cement. There is limited guidance for surgeons when using novel combinations, and scant literature regarding the addition of rifampin to PMMA bone cement. One study briefly mentions a resulting tarry composite that took several days to set, but does not describe the type of cement used or the testing method.⁴ Another study states only that rifampin is adversely affected by cement curing.⁸ Another recent study reports that complete curing was prevented when rifampin was added to Simplex P™ cement.³ However, this report was not available at the time of this case. None of these studies elaborate on the potential mechanism by which polymerization is affected.

PMMA polymerization is initiated by the reaction of two agents, dibenzoyl peroxide (BPO) in the powder and dimethyl-p-toluidine (DmpT) in the liquid monomer. Although the mechanism of inhibition of this process is not known, rifampin has been described as a scavenger of reactive oxygen species.⁹ We propose that the rifampin reacts with the BPO and/or DmpT to become oxidized rifampin. The initiators are then unable to react with the methyl methacrylate and radical polymerization is inhibited. This results in failure of the cement to set.

Considering this limited experience, we recommend rifampin not be added to PMMA when bone cement is to be used for structural, long term fixation. However, we would consider its use in temporary nonstructural PMMA spacers (beads as opposed to cement blocks) if absolutely needed. Beforehand, a follow up elution study should be performed to confirm that an active rifampin agent is available for antibacterial action. Finally, we recommend caution when adding any antibiotic to PMMA that act as a reactive oxygen species scavenger to avoid similar difficulties with cement curing.



Fig 1b. Same sample of Palacos® R-rifampin showing how the cement puck easily bends without breaking. Once bending force is released, the specimen returns to its resting flat state.

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Surgeon Interview on Current Trends in THA

Charles Bryant*, Louis Keppler*, John Keggi*, Corey Ponder*

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Board-certified orthopedic surgeon specializing in total hip and knee arthroplasty currently practicing in Oklahoma City, OK.

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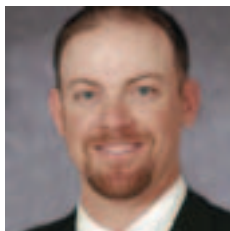
Total joint replacements at the University of Utah in Salt Lake City

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Surgeon Interview:

What approach do you use for your primary THA's?

Bryant:

Direct Anterior Approach

Ponder:

The majority of my primary THA's are performed through the posterior approach. I also do the anterior approach and my split is probably 80% posterior 20% anterior. The biggest factor for me in selecting a patient for the anterior approach is that they are not obese. I also don't recommend it for large, muscular males. I discuss with the patient the pros and cons of both approaches and if they want the anterior approach I'll do it but if they don't see the need for it, I'll do the posterior approach.

Keppler:

Posterior Approach

Keggi:

Direct Anterior Approach

What do you consider to be the "gold standard" today for a bearing surface in THA?

Bryant:

Cobalt chrome on highly cross-linked polyethylene or perhaps ceramic on highly cross-linked polyethylene. I heard a bit of discussion at AAOS this year that there's minimal difference that they can prove between cobalt chrome and ceramic heads against highly cross-linked polyethylene. Still, I tend to use ceramic heads with my younger patients because even a little difference over time matters to me.

Ponder:

For me the gold standard is ceramic on highly cross-linked polyethylene.

Keppler:

The gold standard right now for the young patient is ceramic on cross-linked polyethylene.

Keggi:

Ceramic on ceramic is the best surface. No surface is perfect, ceramic has a certain low instance of fracture, we have seen squeaking, and like all surfaces it is sensitive to cup positioning or component positioning in general. Metal-on-metal is still a good surface but has its difficulties. It has probably a 1% risk of adverse soft tissue reaction. I think metal-on-poly or ceramic-on-poly still has greater wear than any of the hard surfaces. So on balance, I think ceramic-on-ceramic is the best surface. If someone is a candidate for resurfacing and they understand all of the pros and cons of resurfacing, and they are under 55, I will go with resurfacing which is by definition metal-on-metal right now. Any other patient under the age of 65 gets a ceramic-on-ceramic bearing. Patients over the age of 65 will either get a ceramic head on cross-linked poly or a metal head on cross-linked poly.

When do you believe it is appropriate to use a 36 or 40 mm head?

Bryant:

I think for me and a large population of orthopedic surgeons right now, 36 is probably the standard assuming the acetabular component is large enough to accept it without having a poly insert that is too thin. If I had a choice 32 or 36, with the fact that they are aware at some point they may be a candidate for a revision. Younger and younger patients are becoming patients for hip arthroplasty because they are active and want to remain active. The ARC fits into patients who want a variety of surfaces and are possibly contraindicated into resurfacing for a number of reasons. The ARC fills a big niche of patients that are young and need to save bone for later use, and want a stable prosthesis.



We have purposely designed the ARC system to give you numerous neck and head options. Are they truly clinically useful to you or do you think they add complexity to the system?

Bryant:

I definitely think they are clinically useful. I am not as certain whether anteversion of the neck will make as big of a difference, however, I definitely like having the option of the varus neck. Having the ability to help manage the offset better is definitely a useful thing as far as I'm concerned.

Ponder:

Are they useful? Yes. Do they add complexity? No. The modularity has really allowed me to fine tune the offset and length to where I can really match the patient's anatomy to achieve stability. The options that are available to you are actually not that complex compared to some other modular systems on the market.

Keppler:

I think they are useful. In most cases I use a neutral neck but if I need to increase my offset but don't want to lengthen the hip, then having the ability to place it in varus is valuable. If the patient has a valgus proximal alignment then being able to reproduce that so I don't produce too much offset and give them some trochanter pain is valuable.

Keggi:

I think they are useful. I think that modular systems which we have always favored really give that flexibility that allows you to have good stability and good restoration of limb length in the standard length stems. Now with the ARC, I think it's critical especially as we want to avoid impingement either as a factor contributing to stability or as a factor to avoid the failure of hard on hard bearings.

What do you believe is the biggest advantage of the ARC stem?

Bryant:

I think ease of insertion is a real key. It's certainly beneficial for those of us who are doing the anterior approach and can make a real difference in how

much bone and tissue you have to remove in order to insert it.

Ponder:

The biggest advantage is being able to do a total hip that is both bone conserving and soft tissue conserving that I can put in the majority of my patients.

Keppler:

Sparing the bone of the greater trochanter is a big advantage. Not disturbing the abductor musculatures is very important to me.

Keggi:

The fact that it saves a large portion of neck and is most likely easily revisable to a standard stem is a big advantage for me. I think it gives the same bone conserving benefits as a resurfacing but with a much more standard approach, less soft tissue dissection and good revision options later.

What advice would you give to a surgeon new to the ARC?

Bryant:

Go to a seminar and watch someone else do it first, just as you should do with any new prosthesis. I don't consider the ARC to be more complex than any other primary hip system, but there are some technique tricks and pearls that are handy to know. I think the safest way to take on any new system is to be instructed by someone who has already been doing it.

Ponder:

The biggest piece of advice that I would give is anytime you adopt a new technology into your practice is not to try to change too many things at the same time. If you're a posterior approach guy you don't want to try to start using the ARC doing anterior approaches. So don't change your approach with your system. Get comfortable with the device first in the approach that you're most comfortable with and then try to learn the new approach after that.



Keppler:

My biggest advice to them would be to make sure you have excellent stability at the end of the procedure and you don't have any impingement. The procedure is very similar to a standard length stem but it is just as important to perform a full range of motion assessment to check for impingement.

Keggi:

I think that it is important to come to the lab. There are some small but important differences. A lab and a site visit can certainly be helpful. I think the key part for the anterior approach is performing a femoral release first. Also, dislocation of the hip first and freeing up the capsular adhesions and ligament are really helpful from a technical standpoint. From a practice standpoint and a surgeon development standpoint I think it's really a good device to incorporate into one's practice because there are greater numbers of young patients and this will really be a boom to one's practice.

Commentary

By

Timothy McTighe
Executive Director, JISRF



Short curved neck sparing stems are not a new concept in Europe however, it is very new in the United States. The historical neck sparing stems experience in the States has been limited to conventional length stems (Freeman, Townley, Whiteside). JISRF has been lecturing and writing about this short curved design concept for the past four years and we find many surgeons being attracted to the overall design philosophy. So much so, we have created an International Tissue Sparing Implant (TSI™) Study Group. www.jisrf.org

We invite all interested parties to view our study group and to contact me if you wish to become a member.

Tissue Sparing Total Hip Arthroplasty Study Group

The Joint Implant Surgery and Research Foundation has a long history in the study of THA. It began back in 1971 when Professor Charles O. Bechtol, M.D. established JISRF as a nonprofit scientific and educational foundation.

JISRF continues this study with the formation of a new study group of international surgeons and scientists. Findings will be posted on the foundation's web site at www.jisrf.org.



Surgeons interested in learning more contact the Executive Director at www.jisrf.org

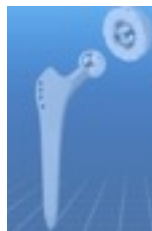
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This stem might appear to be a radical design however, it is very incremental in its design features. I would encourage all interested parties to review the individual features and the potential benefits provided by these features.

This then allows one to start to consider whether this stem might be a valuable tool in their treatment modality for THA.

Modern day total hip designs provide good to excellent results in the high 90 percentile at 15-17 year results. The short curved neck sparing style stems can provide for conserving more tissue (hard & soft) so if or when a revision is called for there is more infrastructure to work with. We must always be thinking about the next step and how best to prepare for that step.

I believe in Professor Pipino and Freeman's life long work and believe we are on the path to making their contributions main stream in the field of total hip arthroplasty.



Clinical Review of the Zweymüller Femoral Stem

Christian Wright, BS*; Dale Lambert, BS*; Declan Brazil, PhD*,¹
&

Professor Kristaps J. Keggi^{2,3}, MD; John Keggi, MD^{3,4}, Timothy McTighe*

Abstract:

This review summarizes published literature from a range of reputable sources regarding hip prostheses (stems) utilized currently in cementless Total Hip Arthroplasty. The critical review of published clinical studies shows Zweymüller style (Alloclassic and SL-Plus) stems in all critical characteristics.

Since the introduction of cementless total hip arthroplasty in the 1970s, a range of design philosophies for femoral and acetabular components have demonstrated variable clinical success^{1,3}.

The Zweymüller stem was introduced to the global market in 1973⁸. Since its introduction the Zweymüller stem has been implanted in over 700,000 patients⁹ and has undergone minor design updates. The first generation Hochgezogen was a straight stem with a rectangular cross section tapering in the sagittal plane. The stem was forged from titanium alloy (Ti-6Al-4V) with a grit-blasted surface finish. In 1986 the second generation Alloclassic-SL (StepLess) was introduced¹⁰. The Alloclassic evolved from the Hochgezogen to taper in both the sagittal and frontal plane and to replace the Vanadium with Niobium in the Titanium alloy due to cytotoxicity concerns¹¹. The SL alludes to the way the stem sizes increase steplessly and proportionally to allow downsizing without sacrificing stability⁹. The latest generation of the Zweymüller stem, the SL-PLUS has been selected as the predicate for the Signature Pegasus stem. The SL-PLUS differs slightly from the Alloclassic geometrically, with slight modifications to the neck, proximal surface and cross section^{3,12}.

Recently cementless components have been yielding clinical results on par and in some cases even surpassing their cemented predecessors^{2,4,6}. As a result, cementless THA is gaining in popularity^{1,7}. The short-term results of four of the best cementless femoral components recorded in the Norwegian Arthroplasty Register as described by Havelin et al, included the Corail, IMT, Profile and **Zweymüller** stems with revision for loosening <1% at 4.5 years which was comparable to cemented counterparts.

The review presents the findings of a literature review conducted to evaluate the clinical performance and survivorship outcomes of the later generations of the **Zweymüller** stems.

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Gaining initial and secondary stability is important to the clinical success of a hip stem implant¹⁴. The **Zweymüller** stem gains initial stability both axially and rotationally. The **Zweymüller** stem is double tapered to gain axial stability [9]. Early subsidence of the stem is frequently reported^{15,16}; however, it stops once the stem contacts cortical bone, and early subsidence of this stem has not been shown to negatively affect the clinical outcome¹⁵. For rotational stability the **Zweymüller** has a rectangular cross section⁹. Rotational stability is provided according to the ‘square peg in a round hole’ philosophy. The stem is press fit into the intramedullary canal until the corners of the stem contact cortical bone, thus locking it in place⁹. A combination of the above design features allow initial stability and hence full weight bearing immediately post-operatively⁴, even in patients with osteoporotic bone⁹.

The initial stability ensures osseointegration is possible leading to long-term secondary fixation and stability.

The **Zweymüller** stem’s grit blasted surface promotes osseointegration and rapid secondary stability⁸ without the risk of coating delamination¹⁷. Svehla et al¹⁸ evaluated the pull out strength of small cylindrical implants made of Ti-6Al-4V with 5 different surface finishes (grit-blasted, grit-blasted with HA, Porocoat, Porocoat with HA and smooth) in an ovine model. It was found that the grit-blasted implants had improved pull out strength compared to the smooth implants. Porocoat and HA coating further increased the implant’s pull out strength; however, the study covered a period of only 12 weeks. Longer term clinical follow-ups of the **Zweymüller** stem with a grit blasted surface show excellent secondary stability as proven by high rates of radiographic osseointegration^{6,15,17,19,20} and often lower rates of revision for aseptic loosening than popular cemented stems^{4,5}. Based on clinical and radiological follow-ups the **Zweymüller** stem is shown to have sufficient immediate and long term stability⁶.

The **Zweymüller** achieves stability due to a diaphyseal press fit¹⁶. As a result, the proximal femur is shielded from compressive stresses thus leading to bone remodeling in accordance with Wolff’s law²¹. The bone remodeling observed is typically cortical atrophy in the proximal femur and diaphyseal cortical hypertrophy^{4,12,16,19,22,24}. However, the stress shielding is not associated with instability^{12,19,25,26} or poor clinical outcomes⁴ and typically stabilizes after two years²³.

Zweymüller et al²⁷ investigated the progress of radiolucent lines that tend to be seen around the **Zweymüller** stem. Based on the radiographic outcomes of 95 patients, he concluded that consistency in radiolucent lines between 6 and 10 years is an indicator for long-term implant survival. Vervest et al [28] used DEXA (Dual Energy X-ray Absorptiometry) technology to examine the bone mineral density in the femur after implantation of a **Zweymüller** stem. The study of 32 patients that underwent an unilateral hip replacement allowed the contralateral hip to be used as reference. The study found that at 10 years the most notable reductions in bone mineral density were in zones 6 and 7 (calcar region) and zone 2; however, this was not associated with any clinical consequences or radiographic abnormalities.

Karachalios et al²² documented a 10-year prospective, random study in which 80 female patients diagnosed with osteoarthritis were assigned to four groups. Each group had a **Zweymüller**, **Corail**, **Optifix**, or **Autophor 900S** hip stem implanted. Each group showed the highest bone loss in Gruen Zone 7 (proximal femur) at two years follow-up. After two years the bone loss stabilized and the bone density steadily recovered. The same phenomenon was observed in stems that depend on a proximal HA coating for fixation, however to a lesser extent. In no cases did the stress shielding result in unsatisfactory clinical outcomes. The cause of periprosthetic bone loss is multifactorial, and based on the results of the study the author suggests the clinical and theoretical relevance of stress shielding is overestimated in literature.

It has been hypothesized that adding a proximal HA coating to the **Zweymüller** stem would reduce proximal bone atrophy by promoting osseointegration. Christ et al²⁹ and Steens et al²¹ have evaluated the effectiveness over the medium term of adding a proximal HA coating to the SL-plus stem. Both studies found that the HA coating improved osseointegration, increased the bone mineral density and reduced the occurrence of radiolucent lines in the proximal femur. Neither study linked the HA coating to improved clinical outcomes; however, the authors agree that a longer term follow-up is necessary to determine if the superior radiographic findings lead to improved clinical outcomes.

Periprosthetic osteolysis results in bone loss around an implant and can lead to a loss of stability and eventual revision²². In clinical studies following patients with **Zweymüller** stem implants, cases of osteolysis were rare, mild, and did not have a clinical relevance^{6,11,15,20,23}. A leading cause of periprosthetic osteolysis is wear debris generated from polyethylene acetabular cup liners. Hip stems with high levels of osseointegration inhibit the distribution of wear particles distally along the stem; therefore, femoral osteolysis is less prevalent around well osseointegrated stems³⁰.

Stem migration is frequently observed with the **Zweymüller** stem^{15,16} as is typical for tapered stems. The stem is secured in the femoral canal by pressing against the cortical wall, thus creating compressive stresses at the bone prosthesis interface. Due to the viscoelastic nature of bone, the compressive stress is relieved and the stem subsides further down the femoral canal. The tapered design allows the stem to regain stability after initial subsidence¹⁴. As a result, stem subsidence is not an unusual finding with the **Zweymüller** stem; however, it is typically non-progressive¹⁵ and ongoing subsidence is not observed after the 2nd post-operative year¹⁶.

The surgical approach for accessing the hip joint is largely based on the surgeon's preference. The direct lateral^{5,31,32}, anterolateral^{4,6,15,31,33,34} and posterolateral^{34,35} approaches to implanting the **Zweymüller** stem have been reported in clinical

literature. Many surgeons have developed less invasive mini-incision approaches to implant the **Zweymüller** stem^{25,36,39}; however, with the large lateral trochanter flair insertion in a single direct anterior approach can be very difficult requiring more posterior soft tissue releases. The surgeon must be aware of the consequences of their chosen surgical approach. The muscular trauma endured during the procedure may lead to redistribution of muscle forces and subsequent bone remodeling. Perka et al⁴⁰ showed that the transgluteal approach leads to significantly lower bone mineral density in the proximal femur when compared to the anterolateral approach.

The **Zweymüller** stem uses a "fit without fill" surgical technique. The intramedullary canal is prepared by impacting the cancellous bone using a broach by this technique. In contrast, many competing cementless stems use a "fit with fill" surgical technique in which the intramedullary canal is prepared by clearing its contents. The "fit without fill" technique boasts many advantages over the latter technique, including preserving endosteal blood supply, improving initial stability and fitting a variety of bone shapes⁹. The endosteal blood supply is preserved because the contents of the intramedullary canal are less disrupted by the **Zweymüller** surgical technique. Hence the **Zweymüller** stem can gain initial stability in a wide variety of femoral bone shapes because the canal is broached to the size of the stem, as opposed to the "fit with fill" technique where the stem depends on fitting the irregularly shaped femoral canal for stability.

In 1998, Bourne et al⁴¹ established an algorithm for deciding whether a cementless or cemented stem should be used, based on experience and a review of the current clinical literature. They suggest that cementless stems should be used in patients younger than 75 years with Dorr type A or B bone shapes and good quality bone stock. Bourne et al suggest that patients older than 75 years with cylindrical type C bone and poor bone stock are better suited to cemented hip replacement. Many surgeons employ this philosophy. Delaunay et al³⁴ avoided using the

Zweymüller stem in patients with poor bone stock in favor of a cemented alternative and Garcia-Cimbrello et al¹⁵ do not use cementless stems in older patients or those with cylindrical femoral canal. However, Zweymüller²⁷ and Suckel et al⁴ reported success using the **Zweymüller** stem regardless of patient specific conditions including anatomy, age, bone quality, comorbidity or mobility. After a short term follow-up, Huo et al²⁶ also showed that the **Zweymüller** stem yielded 95% stability and no thigh pain even in a patient demographic consisting of largely bone type B or C (70% and 24% respectively).

The **Zweymüller** stem only requires contact with the cortical wall at the corners of the stem's rectangular cross section. The stem does not have to fit the shape of the intramedullary canal therefore it is suited to a wide variety of bone shapes⁹. Wick et al¹⁰ and Swanson³⁷ reported using the **Zweymüller** stem in patients with type C bone without complications particular to the bone shape.

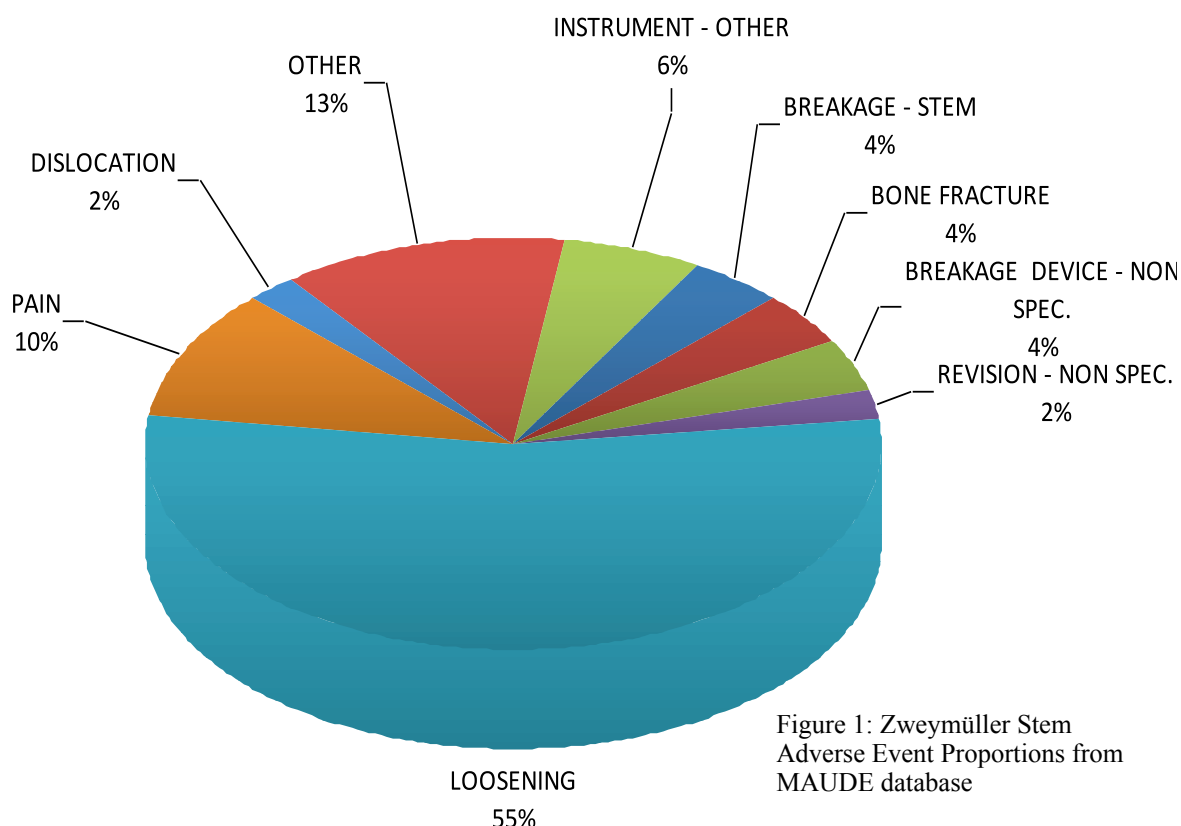
Cementless stems are commonly chosen for younger more active patients¹⁴. Revision surgery can often be accomplished without complications associated with a cemented implant like excessive bone loss or need to perform a fenestration of the femur to remove the distal cement plug. Widmer et al⁴² found that with use of the **Zweymüller** stem, sportsmen achieve better outcomes than non-active patients, including significantly reduced prevalence of osteolysis. The **Zweymüller** stem demonstrates its applicability across a range of ages where it has been reportedly used in patients as young as 15 years³⁵ and as old as 99 years⁴.

Turchetto²⁴ has reported her experience with the **Zweymüller** stem used under special conditions including malunion, coxa vara, osteoporosis and dysplasia. After osteotomy if required, each of the 16 cases of malunion observed by Turchetto were corrected using the **Zweymüller** stem. Coxa vara correction is made easier by the lateralized offset version of the stem, which allows the surgeon to reconstruct the offset while avoiding impingement between the greater trochanter and ilium. Turchetto

states that osteoporosis is not a contraindication for the **Zweymüller** stem, which is confirmed by Swanson who has allowed immediate weight bearing in patients with osteoporotic bone⁹. Turchetto suggests that the Zweymüller stem is appropriate for patients with dysplasia after an adjunctive osteotomy is performed to position the stem correctly. Perka et al³¹ performed a prospective study of 139 dysplastic hips over 9 years. They found an improvement of Harris Hip Score from 34.0 to 84.1 postoperatively, and a Kaplan-Meier survivorship of 100% with revision for aseptic loosening as the endpoint.

Based on an FEA model, Hu et al⁴³ have found a high stress concentration along the edge of the stem where it contacts the cortical wall which may result in a higher rate of periprosthetic fracture. Delaunay et al^{8,16} have reported a high incidence of femoral fracture during **Zweymüller** stem implantation; however, this is uncommon across surgeons and the author suggests it may be due to the surgeon's learning curve. Other surgeons have reported no problem with regard to femoral fracture¹⁹.

To evaluate the likely failure modes of the **Zweymüller** stem, the FDA's MAUDE database was reviewed to collate the adverse events occurring between 1992 and 2011. The findings are compared to the **Zweymüller's** competitors.



Incident Type	Stem Type				
	Zweymuller	Taperloc	Corall	Synergy	Secur-Fit
Breakage - Stem	4.2%	6.5%	14.8%	0%	3.7%
Breakage - Neck	0%	0%	33.2%	3.6%	1.2%
Breakage - Device, non-spec.	4.2%	3.2%	1.1%	14.3%	0%
Bone Fracture	4.2%	9.7%	13.4%	17.9%	18.3%
Dislocation	2.1%	0%	2.2%	14.3%	0%
Loosening	54.2%	9.7%	10.1%	10.7%	13.4%
Disassociation	0%	0%	0.7%	0%	1.2%
Pain	10.4%	25.8%	1.4%	0%	18.3%
Revision, non spec.	2.1%	0%	4.0%	3.6%	0%
Other	12.5%	32.3%	10.8%	7.1%	36.6%
Instrument - Broach	0%	6.5%	2.5%	10.7%	4.9%
Instrument - Other	6.3%	6.5%	1.8%	17.9%	2.4%

Table 1: Zweymüller stem and competitor's adverse event profiles from MAUDE

The findings tabulated from the MAUDE database are given as a percentage of the total number of incidents reported, not as a percentage of the total number of stems implanted. Therefore, the data can be used to determine to which failure modes each stem is susceptible, but not conclusions regarding the frequency of failures. The competitors were chosen to represent the varied design philosophies within the cementless stem market. The *Corail* and *Taperloc* are similar to the *Zweymüller* by design, however they are coated in HA and Titanium beads respectively. The *Synergy* and *Secur-Fit* stems were selected to represent the “fit with fill” design philosophy.



Example of a fractured Zweymüller

The most common adverse event for the *Zweymüller* stem is revision due to loosening, which accounts for over half of the adverse events reported to the FDA between 1992 and 2011. However, the *Zweymüller* stem has clinical performance history of superior Kaplan-Meier survivorship out past 10 years^{5,12,23,44}. Hence femoral loosening as a percentage incident per total implants is relatively low and aseptic loosening remains a known adverse event for every femoral stem design. The prediction by Hu et al⁴³ that the *Zweymüller* stem would be prone to failure by periprosthetic fracture is not supported by the surgical experience in the US and adverse event records to date (See Table 1).

Patients who receive a *Zweymüller* hip stem are highly satisfied with the outcome of the surgery. The number of patients who report on-going post-operative pain is very low^{15,17,19} and the occurrence of disabling thigh pain is rare¹⁷. A high degree of

function is returned to the patient as demonstrated by post-operative Harris Hip Scores ranging from 84 to 90 in the function domain^{4,5,19,20,23,31,44}.

While the collection of clinical data in various regional and national joint registries has been valuable in establishing survivorship benchmarks for orthopaedic implants and detecting early poor performing designs, one should be cautious in drawing strong conclusions from the data in isolation of details available from published controlled clinical studies as many confounding factors may not be considered. We reviewed the English, Australian and Norwegian joint registries for relevance to the *Pegasus* style femoral implant. Survivorship data published in 2010 in the English National Joint Registry 7th annual report⁴⁵ covering implant survivorship from 2003 to 2009 from the UK describes the overall survivorship for a hip replacement as 97.1% at 5 years, but decreases to 96.6% at 5 years if only cementless hip replacements are considered.

The *SL-PLUS* generation of the *Zweymüller* stem was the 4th most commonly used cementless stem. The survivorship for the *SL-PLUS* stem is slightly below the average for cementless stems at 95.6% after 5 years. Australian data was collected from the 2010 AOA joint registry report⁴⁶ covering implant survivorship from September 1999 to December 2009. The average survivorship for a hip replacement was 96.5% at 5 years, 95.6% at 7 years and 94.6% at 9 years. In 2009 the *Alloclassic* and *SL-PLUS* were the 5th and 6th most commonly used cementless stems in Australia. The Australian registry reports survivorship by stem and cup pairing. Using the Australian data as a guide, one could expect a survivorship between 93.8 – 98.3% at 5 years depending on which design of cup paired in the THA. Hallan et al [3] presented the data for all cementless stems used in Norway between 1987 and 2005. Survivorship of 95.2% at 7 years, 94.0% at 10 years and 91.7% at 15 years were reported for the *Zweymüller* stem.

The **Alloclassic** stem is the second generation of the **Zweymüller** series of stems and has the most clinical follow-up data. The survivorship of the **Alloclassic** has been described as amongst the very best when compared to published results in recent literature⁴⁴ and is as good or better than modern cemented techniques^{5,21}. Kaplan-Meier survivorship of 100% have been reported at 9.3 years³¹, 11.2 years¹¹, 13.1 years⁴⁴, and 15 years²³ with aseptic loosening of the stem as the endpoint. Survivorship at intermediate follow up (5-10 years) is also very high, ranging from 91.5% to 100%^{13,14,16,25,27} where survivorship's at the low end of the range have revision for any reason as the endpoint^{19,34}. Using revision for any reason as the endpoint underestimates the femoral survivorship because revisions are more often for the cup or liner as opposed to the stem^{5,23,31,44}.

Reigstad et al⁵, provide long term follow-up clinical data from a 75 patient study (average age of 52). With an active patient demographic (age < 60 y.o.) the **Alloclassic** stem has a demonstrated KM survivorship of 95% at 18 years for femoral revision for any reason. Reigstad et al, conclude that the **Zweymüller** performs comparably to the best cemented stems. Below is a listing of the survivorship data compiled from recent published literature for the **Alloclassic** stem

The latest version of the **Zweymüller** series of stems is the **SL-PLUS**, which was first introduced in 1992 hence this stem has far less clinical data available than its predecessors. Korovessis et al⁴⁷ reported 91.6% survivorship at 6.4 years with revision for any reason as the survivorship endpoint. The author proposed that the inflated revision rate of the stem was due to a systemic immune reaction to the wear debris generated by the metal on metal articulation, which has been confirmed by other findings⁴⁸. In contrast, Steens et al²¹, found that no **SL-PLUS** stems required revision after 6 years when the majority of the patients received a conventional ceramic on polyethylene articulation. Few longer term studies of the **SL-PLUS** stem have been completed. Zwartelee et al [33] found that after 10 years only one stem required revision, resulting in a survivorship of 99.8%.

Author	Year	Kaplan-Meier Survivorship	Follow-up (years)	Survivorship Endpoint
Delaunay et al [8]	1998	99.3%	8	Revision due to stem aseptic loosening
Delaunay et al [17]	2001	100%	10	Revision due to stem aseptic loosening
Delaunay & Kapandji [34]	2001	91.5%	9-10	Revision for any reason
		99.3%	9-10	Revision due to stem aseptic loosening
Grubl et al [20]	2006	98%	15	Revision of stem for any reason
Garci-Cimbrelo [15]	2003	94.1%	12	Revision for any reason
Perka et al [31]	2004	100%	9.3	Radiographic loosening of the stem
Karachalios et al [22]	2004	100%	10	Revision for any reason
Pospischill et al [23]	2005	100%	15	Revision due to stem aseptic loosening
Vervest et al [11]	2005	100%	11.2	Revision due to stem aseptic loosening
Pieringer et al [44]	2006	95.6%	13.1	Revision for any reason
		100%	13.1	Revision due to stem aseptic loosening
Reigstad et al [5]	2008	95%	18	Revision of stem for any reason
Suckel et al [4]	2009	98%	17	Revision for any reason
Floren et al [25]	2006	100%	10	Revision due to stem aseptic loosening
Girard et al [35]	2010	100%	9	Revision due to stem aseptic loosening

Table 2: Alloclassic Hip Stem KM-Survivorship

Korovessis et al¹², provides retrospective data at 11 years from 172 hip replacements using the **SL-PLUS** stem and conventional ceramic on polyethylene articulation. The **SL-PLUS** showed durability and was reported to be effective in reducing the incidence of cortical hypertrophy in Gruen zones 3 and 5 when compared to the **Alloclassic** stem. The reported KM survivorship was 98% at 11 years with an endpoint of revision for aseptic loosening. The following table lists further survivorship data for the **SL-PLUS** stem.

Author	Year	Kaplan-Meier Survivorship	Follow-up (years)	Survivorship Endpoint
Korovessis et al [47]	2007	91.6%	6.4	Revision for any reason
		92.5%	6.4	Revision due to stem aseptic loosening
Korovessis et al [12]	2009	98%	11	Revision due to stem aseptic loosening
Zwarte et al [33]	2008	99.8%	10	Revision of stem for any reason
Steens et al [21]	2010	100%	6	Revision of stem for any reason

Table 3: SL-PLUS stem survivorship

In a thorough review of 27 clinical papers and data from the Danish, English, Norwegian, Swedish and Australian joint registries, Janda et al⁴⁸, collated and compared the survivorship for the various generations of the **Zweymüller** stem. They found that for the range of **Zweymüller** stems the average survivorship was 96% at 10 years, and that the **Alloclassic** had the highest survivorship (96.6% survivorship at 10 years). The author proposed that the revision rate for the **SL-PLUS** is inflated in recent literature because it is commonly used with the **Sikomet** low carbide metal on metal articulation which provoked wear reactions, so much so that manufacturer modifications were required. If only studies involving the **SL-PLUS** without metal on metal articulation are considered the difference

between the **Alloclassic** and **SL-PLUS** in terms of survivorship are not statistically significant.

The SL-PLUS differs from the Alloclassic only in minor aspects of its geometry [10]. Changes from the Alloclassic to the SL-PLUS include increasing the proximal surface and cross sectional area [3], and rounding the corners in an attempt to address the bone remodeling commonly associated with the use of the Zweymüller stem [12]. However, in a study comparing the radiographic outcomes of the Alloclassic and SL-PLUS stem, Wick et al¹⁰, found that the SL-PLUS stem has greater bone atrophy and radiolucencies in Gruen zones 2 and 6. The author proposes that increasing the cross sectional area of the stem increased its stiffness and resulted in greater stress shielding. The author noted that the increased bone atrophy could increase the likelihood of aseptic loosening and hence, discontinued use of the SL-PLUS stem in favor of the proven Alloclassic. Conversely, Zweymüller et al²⁷, found that the occurrence of radiolucent lines with use of the SL-PLUS stem was almost identical to that of the Alloclassic.



Typical example of post-operative x-ray appearance

Personal note by: *Kristaps J. Keggi, M.D., Dr. Med. (h.c.)*

Professor of Orthopaedics and Rehabilitation

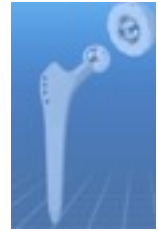
Yale University School of Medicine

President and Founder - Keggi Orthopaedic Foundation

I was very enthusiastic about the device (Alloclassic). It was the first non cemented hip without any significant thigh pain. It may have had some settling (minimal), was easy to insert, worked well without loosening, etc..

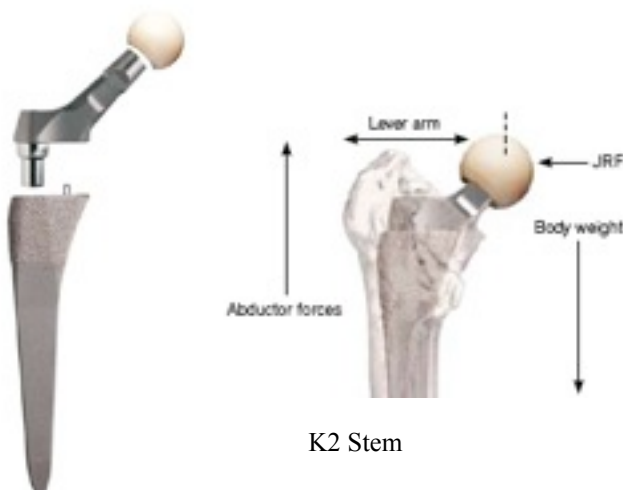
The problem I have with the SL-Plus is the configuration of its proximal portion which can caused some of the implants to get "hung up" in the intertrochanteric area and on the calcar preventing seating/settling/solid fixation in the diaphyseal region. That to me has been the cause of early failure, loosening, etc.. Having recognized this, I tend to leave the prosthesis a little "proud," get solid seating down in the shaft and leave room for some settling should our impaction not have been totally complete. I would assume most the surgeons using the SL-Plus or its SNR equivalent have learned that lesson and if their data were to analyzed, say from 2008 to 2011, it would probably show a lesser failure rate than in earlier years.

You definitely must include the use of the Z-hip for total hip revisions. That was one of the things that also impressed me during my visits to Vienna. Zwymueller showed me some really amazing reconstructions with his stem and as a result I still use it in some of my revisions. In the late 90's I was also presenting my first thirty consecutive revisions with the Zwymueller stem at Yale Meetings, the Society for Arthritic Joint Surgery and the 30th Annual Mtg. of the Eastern Orthopaedic Society in 1999 (Vienna, Austria).



It was my experience with the Zwymueller that lead to the development of the Apex K2 proximal modular stem.

Eliminating the lateral profile reduced the amount of bone and damage to the abductor soft tissue and the addition of the proximal "Dual Press" modular shoulder facilitated insertion for the anterior approach and allowed fine tuning of joint mechanics. In fact, the basic stability of the Zweymuller (Trapezoidal shape) has been carried over into the short curved ARC™ stem (curved trapezoidal shape with a proximal conical flair) that provides the same three point lateral fixation in a more tissue conservative stem style.



K2 Stem



ARC™ Stem

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Clinical Evaluation of All Polyethylene Tibial Components in TKA

-Review Paper-

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Abstract:

This review summarizes published literature that reports on clinical studies and/or randomized controlled trials from 1989 to end 2009 regarding the clinical performance history of several designs / brands of an all-polyethylene (AP) Tibial component used as part of a primary cemented Total Knee System implanted using established Total Knee Arthroplasty procedures.

From the mid 1970's knee systems for replacement of knees diagnosed with osteoarthritis, rheumatoid (inflammatory) arthritis, osteonecrosis, avascular necrosis and other degenerative joint conditions used

a plastic tibial component articulating on a chrome - cobalt femoral component. Resurfacing of the patella if required also used a plastic artificial patella button attached surgically with PMMA bone cement.

Projections of increase in TKA of +600% increase in annual surgeries over the next 15 years has focused significant interest in reconsideration of using this style tibial component in the growing elderly population.

Key Words: *Total Knee Arthroplasty, polyethylene, tibial component, clinical performance*

Introduction:

Early 1970s generation of total knee implants consisted of two basic components: Chrome cobalt femoral component and an all polyethylene tibial component. The patella was for the most part ignored. These were classified as bi-condylar total knees and some like the Bechtol Knee had two different style tibial components. One was flat and the second design had more A/P stability with a contour shape.

Patella femoral pain remained a problem and the patella femoral component was born in 1974.



Bechtol Bi-Condylar and Patella Femoral System



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www.jisrf.org Founded in 1971 (Non-Profit)

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** Executive Director

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Often the patella femoral system was used with either Bi-Condylar Knee designs or the Uni-Condylar Marmor style implants. Trying to balance four to six components in one surgery was a challenge and was eventually addressed by the introduction of the Total Condylar Style Knee by Charles Townley, M.D. with his Anatomic Total Knee Design.

Review:

The gold standard by the 1980s was the Total Condylar Prosthesis. Originally this was semi-constrained, cruciate-sacrificing, tri-compartmental design and the tibial component was an All-polyethylene (AP) monoblock with a central stem or square keel with a wave-like under surface to cement to the resected tibia. Later the term referred generically to an AP monoblock tibial component in which the cruciate ligaments were also retained. Excellent long term survivorship after 15 years of 90.6% was reported by Scuderi et. al., for the Total Condylar Device. The authors also noted that good surgical technique including component positioning, knee alignment, soft-tissue balance and minimal tibial resection, are essential to obtain a long lasting arthroplasty in addition to design of the prosthesis.

However, some other AP tibial component designs did not prove to be as durable as the Total Condylar with significantly higher early failure rates and poorer long term outcomes due to excess wear of the plastic TC. Manufacturing and packaging of this component, in particular sterilization technique, was found to be highly influential on the wear characteristics of early design AP TCs. Components sterilized in air were prone to rapid oxidation, leading to generation of in-vivo wear debris, osteolysis, loosening and ultimate failure of the tibial components after TKA. The main cause of failure of early TKA was failure of the AP TC and polyethylene (UHMWPE) oxidation could have contributed to stress fracture of the plastic.

More recently, AP TCs have been gamma irradiated in an oxygen-free environment and the moderate levels of cross-linking achieved have been shown to

enhance the durability of polyethylene implants in-vivo.^{2,3} Other early shortcoming of the all-poly tibial design are cited to be related to poor fixation resulting in aseptic loosening, condylar collapse and the development of progressive radiolucent lines, which was considered an early indication of mid-term failure of the device.⁴

Around 1997, the Press Fit Condylar (PFC) knee system by DePuy was changed to PFC Sigma range due to modification of the femoral component that included a deep and extended trochlear groove with a matching single radius dome all-polyethylene patella. The patellar articular surface has a central convexity and peripheral concavities to allow better patella-femoral contact. An AP tibial component was included in the range with thicknesses from 10-15 mm manufactured from GUR402 grade UHMWPE that was vacuum packed and gamma irradiated. It has a cruciform keel-style post and a flat-on-flat articulating surface. A number of institutions have conducted studies to compare the performance of this and other AP TC to the equivalent modular metal backed (MB) TC version of modern knee systems due to the potential cost benefits of the AP monoblock and the emergence of backside wear and prevalence of osteolysis using MB modular tibial implants.

Kaplan Meir Survivorship of All Poly Tibial Component

Table 2 presents the survivorship outcomes of several longer term studies involving AP TC designs in primary TKA to treat predominately knee pain and lost of functional range/mobility associated with osteoarthritis but also from a range of other degenerative joint/bone diseases.



Example of all poly PS tibial component

Table 2. Kaplan-Meier Survivorship Data from Clinical Studies involving All-Polyethylene Tibial Components # in Primary Total Knee Arthroplasty.

Major Author	Year	Device	Age years (range)	Kaplan-Meier Survivorship (95% C.I.)	Survivorship endpoint
Scuderi et al	1989	224 total condylar FB/ CR prostheses with AP TC (1974-1978), 289 PS AP TC (1978 -1981), 917 PS MB TC (1981-1986)	67 (20-87)	AP- 90.6% @15yrs	Revision or expiration
§Faris et al	1991	363 total condylar FB CR	N/A	AP- 94.7% @ 12 yrs	Revision or expiration
Ranawat et al	2005	AP PFC modular (23); Sigma PFC (31); patella AP button	57 (47-60)	AP- 1.8% failure rate @ 5yr	Revision for any reason
Dalury et al	2009	PFC Sigma Knee -AP	76 (> 70)	AP- 99.4% @ 7 yr	Revision for any reason
Gioe et al	2009 and 2000	PFC Sigma knee FB – AP; & MB	69 (>60)	AP- 91.6% @ 10 yr; MB - 88.9% @10 yr	Revision for any reason
Shen et al	2008	PFC; AP - PS	AP 62.0 (56-68) MB 60.4 (55-66)	AP -93.5% @ 5yr MB -93.75% @ 5 yr	Revision for any reason
Faris et al	2003	AGC Biomet AP or MB ; All total thickness=8mm	70.3 (34-91)	AP- 68.1% @10yr	Revision for any reason
Bettinson et al	2009	Kinemax Plus* AP and MB	69.3 (50-93)	AP=94.5% @ 10yr MB=96.8% @ 10yr	Revision for any reason

*symmetrical patellofemoral articulation

§*Semin Arthroplasty*. 1991

Code; FB- Fixed Bearing; TC- Tibial Component; PS- Posterior Stabilized;
MB- Metal Backed TC; AP- All polyethylene TC

#Comparison with an equivalent design Metal Backed Tibial Component is included from applicable studies.

The Bad One!

Faris et al	2003	AGC Biomet AP or MB: All total thickness = 8mm	70.3 (34-91)	AP =68.1% @ 10 yr	Revision for any reason
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The authors attribute the high rate of clinical failure of this implant to the flat coronal plane geometry and low conformity of this tibial component, which contributed to peripheral-edge loading. The same coronal plane flat-on-flat geometry is also a feature

of the metal-backed (MB) AGC tibial component, which has been reported with a high rate of failure long-term survival. High stresses and discontinuities in the cement mantle promote crack initiation and propagation.

The PFC Sigma All-Poly knee system in patient populations over 60 years old gave excellent Kaplan Meier Survivorship rate of 91.6% at 10 yrs⁵ similar to those reported for the Total Condylar device and in very elderly patient population (age > 70 years) Dalury et. al ², reported survival rates as high as 99.4% after 7 years. Bettinson et. al ⁶, recently demonstrated similar consist long-term performance of an All Poly tibial component from the Kinemax Plus knee system (fixed bearing with symmetrical patella-femoral articulation) which was available in the 1990s with both AP and MB matched designs.

Shen et. al⁷, has also reported favorable outcomes mid-term with a Posterior Stabilized PFC Sigma knee system with an AP TC in an Asian population aged <70 years old. It is well known that the most challenging population for survivorship are those targeting patient less than 55 years old and a midterm study reported by Ranawat et al ⁷, comparing the modern PFC Sigma to the original style PFC with an AP TC option has a comparatively low failure rate of <2% after 5 years. These authors state in head-to-head comparisons, no study has been able to demonstrate clinical superiority of a metal-backed tibial design^{2,7} and there is only one all poly study reporting on the outcomes from a single centre of 536 primary knee replacements with the AGC by Biomet that has demonstrated inferior long-term survivorship ⁸.

Faris et al ⁸, report the survivorship for an endpoint of revision for any reason, of the AGC prosthesis of only 68.1% at an average of 10 years post operative. The authors attributed the high rate of clinical failure of this implant to the flat coronal plane geometry and low conformity of this tibial component, which contributed to peripheral-edge loading. The same coronal plane flat-on-flat geometry is also a feature of the metal-backed (MB) AGC tibial component, which has been reported with a high rate of long-term survival.

In the case of the AP TC, however, peripheral-edge loading without the benefit of the load-diffusing effect of metal backing transferred load more directly to the subchondral region on the medial side

of the knee. 73% of all revisions in this study were due to TC failure beneath the medial tibial plateau with collapse and failure of the subchondral bone, suggesting that the load transfer was particularly important at the periphery of the medial plateau. The AGC was compression-moulded AP TC sterilized by gamma irradiation in argon with a minimum thickness of 10 mm and was designed with the same geometry as the moulded MB AGC total knee replacement. This would suggest that the clinical performance of a specific AP TC is design sensitive.

Failure Modes – Micromotion and Subsidence Studies

A common problem with cemented fixation of joint prostheses is that shear forces may be transmitted to the bone-cement interface and this can induce micromotion and aseptic loosening of the implant which ultimately may lead to early implant failure. A high-resolution method such as Roentgen Stereophoto-grammetric Analysis (RSA) is a well established technique to evaluate micro movement of a prosthesis with a resolution of 0.1 mm and precision of around 0.03 mm. This method is well suited to the knee, as orthogonal radiographic analysis is easy in a limb, radiation exposure is low for the patient and hence it is well tolerated on follow-up visits. It has been shown to be a reliable and reproducible predictor of late onset implant failure. Progressive migration of a knee implant of > 1 mm at two years, as detected by RSA motion analysis, is known to be associated with early loosening and subsequent clinical failure⁹.

In metal backed tibial designs, micro-movement at the linear tray interface is known to liberate polyethylene debris, despite the apparent security of the mechanism for capture of the liner. The size of this debris is within the biologically active range with respect to macrophage stimulation, which is likely to account for the observed increase in osteolysis seen from the time modularity was introduced in tibial components.

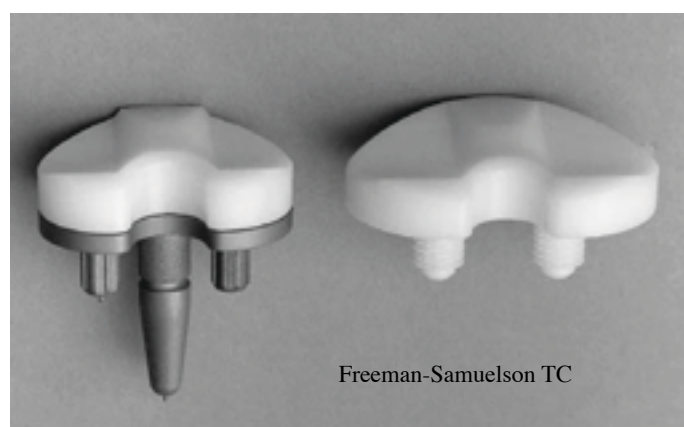
Muller et al, noted that the All-poly non-modular prostheses are perhaps technically more difficult to implant and do not offer the intra operative flexibility

of metal-backed tibial implants. In the case of primary TKA, however, the authors believe that there are significant clinical and economic benefits in avoiding modularity. These include failures associated with backside wear, liner dissociation, reduced polyethylene thickness or excessive bone resection. The table below is an excerpt from their publication⁹ and largely reflects the consensus of published opinion regarding the pros and cons of the All-Polyethylene tibial component versus metal backed to date.

The RSA study carried out by Norgen et al¹⁰ demonstrated that AP tibial components perform equally well as or some cases better than MB counterparts in regard to patterns and magnitude of migration. This finding is supported by literature data¹¹, Adalberth et al 2001 presented on different knee designs used in TKA with varying degrees of conformity i.e. the AGC design with flat-on-flat unconstrained articulation and the Freeman-Samuelson Mk IV design with conforming articulation in the sagittal plane and line to line contact in the frontal plane. This study further strengthens support for the contrary view that MB tibial components offer superior performance to an AP. All-poly also eliminates the risk of backside

wear and increased risk of osteolysis inherent with all MB tibial designs.

Norgen et al¹⁰, concluded from analysis of the failures ascribed to AP implants in the literature, that it is evident these failures were usually related to technical errors in achieving correct alignment of the knee, rather than caused by the absence of a metal backing per se (as MB was introduced to confer protection from shearing of the polyethylene and the bone by distributing stress more evenly across the bone-implant interface). The modern TKA instrumentation allows much better and reproducible alignment of the components.



All-polyethylene (AP) Tibial	Metal-backed (MB) Tibial
Advantages	
No backside wear	Liner selection after tray insertion
No liner dissociation	Compatible with mobile bearing total knee replacement
Increased polyethylene thickness/	Addition of augments/additional fixation possible
More conservative bone resection	
Lower unit cost	Allows for cementless fixation
	Possible improved stress distribution to bone
	Possibility for liner exchange
	Possible smaller inventory
	Excellent long-term clinical results
Disadvantages	
Non-modular	Liner dissociation/dislocation
Possible difficulty retrieving posteriorly extruded cement	Backside wear
Few long-term clinical results	increased osteolysis
	Reduced polyethylene thickness
	Increased bone resection to accommodate adequate polyethylene thickness

Ryd et al 1995¹² demonstrated in a RSA study of 143 implants followed for up to 11 years that all the prostheses which were revised for mechanical loosening could be identified by RSA one to two years after operation, before the onset of symptoms. Mechanical loosening occurred exclusively in prostheses which migrated continuously and 20% of those identified in their study later became clinically loose requiring revision. The study included a range of brands including Total Condylar (19%), PCA (23%), Freeman Samuelson (22.3%) with half using cementless devices and approximately 14.6% with All Poly TC in a population with age range of 63 - 75 years. Further analysis showed that cementless components migrated significantly more than cemented during the first year, reaching a mean of about 1.7 mm. The cemented components had a mean migration of 0.7 mm (Mann-Whitney U test, $p < 0.0001$). Subsidence was determined along the vertical axis, but was reported with considerable scatter in both directions. Subsidence, of a mean of 1.0 mm, occurred almost exclusively in the cementless group, while cemented components seldom subsided. The author's suggest that continuous migration represents defective fixation which is established very early, possibly even during the operation.

Failure Modes – Osteolysis

From the early 1990's osteolysis has been reported in knee components inserted with cement with a prevalence from none to up to 16% of TKA cases. It is thought that debris gains access to the metaphyseal bone by way of voids in the cement mantle or by direct invasion of the metaphyseal bone by histiocyte-laden synovial tissue. Polyethylene, PMMA cement and metal debris are all known to elicit an inflammatory response that leads to bone resorption around the prosthesis by macrophages. The severity of this response depends on the size, shape, type and quantity of the released particles. The predominant mode of failure in TKA is thought to be fatigue rather than abrasive and adhesive wear. Wear debris generated is typically three times larger than from THA (using simulators) and delamination is the primary cause of most PE related knee failures.

This process occurs from material fatigue and repetitive stress that initiates and propagates subsurface cracks and tends to result in delamination of large flakes of PE $> 0.5\text{mm}$.

The femur is prone to osteolysis in the region of the femoral condyles and near the attachments of the femoral collateral ligaments whereas osteolysis of the tibia tends to occur along the periphery of the component or along the access channels to the cancellous bone.¹³

Most patients are asymptomatic in early stages of this disease and the presence of osteolysis can be seen on plain radiographs with some difficulty however this later approach tends to underestimate the extent of the disease. Improvements in manufacture of PE inserts and AP components from cross linking in an inert atmosphere have allowed for substantial improvements in crack initiation properties however with some compromise in the yield strength of the material. Thickness of the PE is also a major consideration for wear properties and Bartel¹⁴ has shown that the contact stresses in polyethylene increase exponentially as thickness of the implant decreases. They concluded that a thickness of more than 8 mm of polyethylene should be used in clinical practice. There is little evidence to suggest that osteolysis is more prevalent in TKA with AP tibial implants and in general the AP devices have been reported to have generated less osteolytic wear than their modular counterparts¹⁵.

All Poly versus Metal Backed Variants of Fixed Bearing Non modular Tibial Components.

It can be seen from the studies comparing the AP to the MB tibial component from Table 2 that the AP variant of the predicate PFC Sigma total knee is highly comparable in survivorship performance to its MB counterpart in particular in the shorter term⁷ even in a younger patient population. During radiological assessment, no sign of subsidence of the tibial components was found in this Asian study. Shen et al, found in their in-vitro study that the load distribution on the proximal tibia is similar between the AP and the MB tibial components group provided the thickness of the AP tibial component is

≥10 mm. They observed radiolucent lines surrounding tibial components mainly in cases of rheumatoid arthritis (71.4%), which they attributed to poor bone quality and subsequent osteolysis induced by wear debris rather than loading of the tibial material.

The All-Poly performed slightly better or similarly to the Metal-backed variant with survivorship values >90% at 10 or more years in the limited number of published studies of longer duration typically in older patient populations. There seems little justification for the additional cost of the metal-backed tibial component in regard to performance or safety concerns now that improvements in the manufacture in UHMWPE tibial devices have been introduced. The modern All-Polyethylene tibial component is a safe, effective implant that should be considered as an option by the surgeon for most patients requiring primary TKA coupled with a suitable femoral design.

The Future:

There is little doubt that the future in total knee replacement surgery will be greatly influenced by economics both short and long-term. Surgical technique (alignment, instrumentation), material and design will always play a factor but might be secondary concerns after financial. We are already seeing a significant movement trying to classify TKA as a generic procedure. At risk are the experience and training of the total joint surgeon and design features and benefits of individual implants. There is a perception already that one surgeon and one design is no better or worse than another. As long as decisions are being made in the purchasing office, cost will be the hospitals major concern.

This leads us to believe the all polyethylene tibial component will have a significant role in the future.

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Failure Mechanism “Revisited”

Total Knee Arthroplasty

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Louis Keppler, MD⁴; John Keggi, MD⁴; and Robert Kennon, MD⁴

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Abstract:

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.

Introduction:

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.

Primarily, 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 mm³/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.

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Wear estimates, for laboratory knee studies, fell in the narrow range of 3-10 mm³/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 exists 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 24mm³/Mc with no explanation. One by an American group added hyaluronic acid to the lubricant and obtained wear rates of 64mm³/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 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 polyethylene to maintain better mechanical properties such as tensile strength and fatigue resistance. Some companies sterilize with EtO and Gas Plasma (GP) while others cross-link 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 needed 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.



Medial compartmental bone loss.

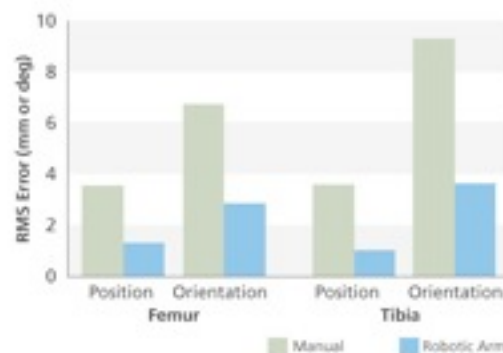
Examples of Uni-Compartmental Designs



Proper implant 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.



Robotics are now being used in the planning process and provides for “virtual” cutting guide eliminating the need for conventional and or custom cutting blocks. Time will tell if this style automation will produce better outcomes. It will come down to a cost benefit ratio.



Dunbar NJ, Pezalla MD, Ranoff D, Condit M, Banks S. Is USA More Accurate With Robotic Assistance? Presented at the Orthopedic Research Society, New Orleans, LA, 2010.

Total Knee Designs



There 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 element 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 15 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.



Most major and some mid-size companies are working hard to develop smart instruments along with surgical navigation technology. The basic belief is the better the alignment the better the outcome.



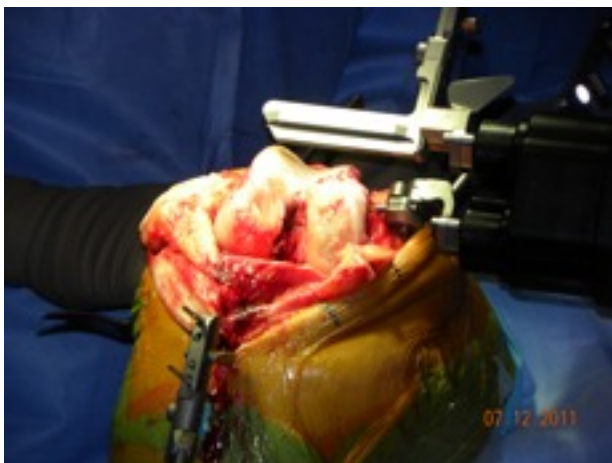
Tibial Alignment Technology

Technique “Alignment”

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



Analog hand held instruments are slowly being obsoleted by newer high tech automated technology.



Example of the IBlock® automated cutting guide. This is an intelligent instrument allowing intraoperative customization in conventional TKA using real-time virtual planning technology.

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.

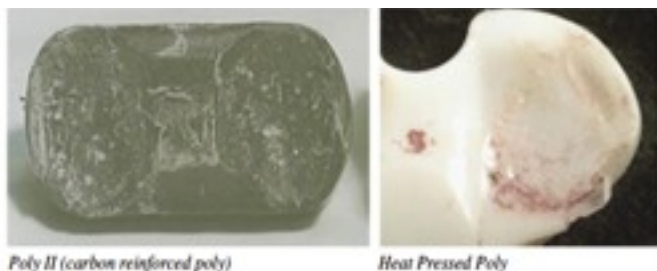


Examples of material failures:



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.

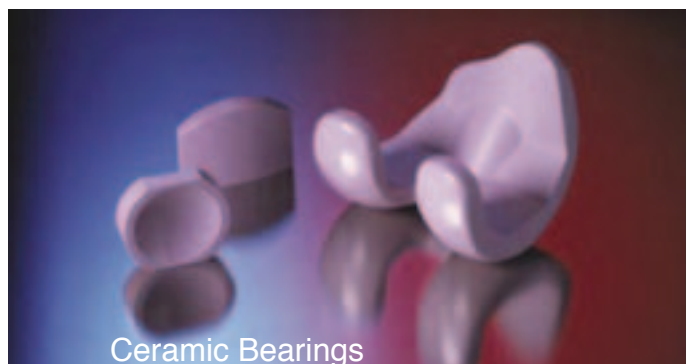


Poly II (carbon reinforced poly)

Heat Pressed Poly



Hylamer Poly



Ceramic Bearings

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).

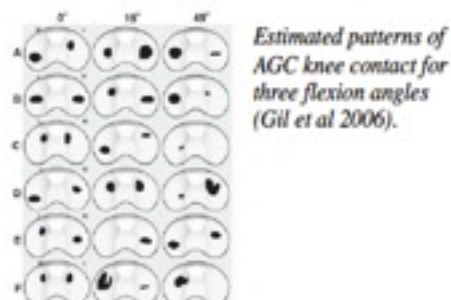
The study was additionally complicated by the use of 4 types of resin (GUR: 1050, 1900, 4120, 4150) and four sterilization methods (EtO= 4, gamma/air = 263, gamma/N₂ = 54 and gas plasma = 44). Shelf age was another factor with the inserts averaging 0.9 years with maximum life at 7.1 years. At 8 years 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/N₂, 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:

- Osteolysis was 4-fold more likely with AMK gamma/air than gamma/N₂
- Osteolysis with Ti64 trays was 2.6-fold more likely than with CoCr base plates.
- Knee hyperextension (impingement) added more risk of osteolysis.
- 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 mm³/year (SD± 95 mm³/yr). With maximum wear being approximately 3-fold greater than the average, this meant that some cases had wear approaching 420mm³/year. This is a very large wear rate, particularly for only backside wear of the AMK design. Noted here but not reviewed, a second paper reported backside wear in fixed-bearing TKR as 120 mm³/yr (Mayor et al, AAOS 2005).

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 mm³ to 1,056 mm³. Their best average was given as 600 mm³, representing a wear rate of 100 mm³/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 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 wear of the rotational surfaces (backside) could be a large portion of the 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 (164mm³/yr) than for durations >2 years (54 mm³/yr). Once again these wear rates were of the order 100+ mm³/yr.

So overall, the in-vivo knee wear estimates ranged 50-400 mm³/year (Table 1). These are at least as high if not higher than total hip replacements.

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.

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 femoral-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 be 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)

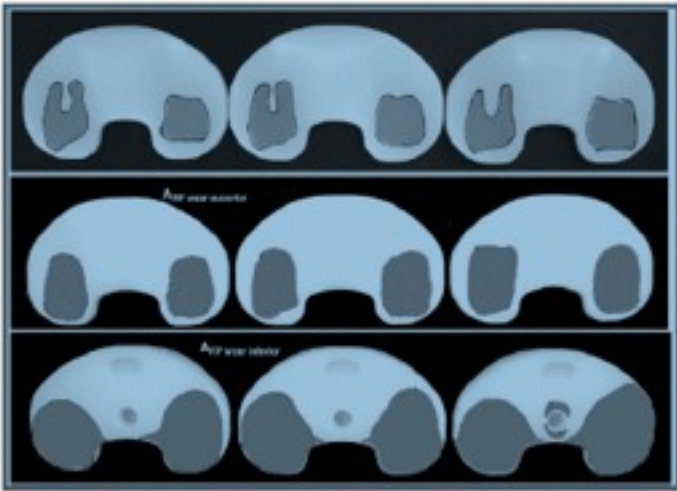
to 5 NexGen Legacy PS (LPS: Zimmer, Warsaw). All specimens were 25kGy gamma/ N₂ tibial inserts. Three wear tests were conducted: one using standard gait (ISO 14243-1) and two using a combination of gait plus stairs. The authors concluded that wear rates were higher in standard gait compared to gait with added bouts of stair climbing (Table 2). Thus normal walking appeared to be the best estimate for a 'worst case' scenario.

AUTHOR	YEAR	BRAND	STERILE	WEAR MIN	WEAR MAX	WEAR AVG
Affatato	2008a	913-MP	EO	23.7	25.3	24.4
Affatato	2008b	Multigen-Plus	EO	2.4	3.3	3.1
Cottrell	2005	NexGen-PS	25/32	gait only		10.4
Cottrell	2005	NexGen-CR	25/32	gait only		6.1
Cottrell	2005	NexGen-PS	25/32	gait+stairs		6.6
Cottrell	2005	NexGen-CR	25/32	gait+stairs		5.3
Cottrell	2005	NexGen-PS	25/32	gait+stairs		5.2
Cottrell	2005	NexGen-CR	25/32	gait+stairs		4.1
Grupp	2009	Columbus-CR	30/32	gait		9.7
Grupp	2009	Cal-Mohale-CR	30/32	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.

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/Mc₃. 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 24mm³/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 mm³/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 exists.



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™ Retrieval 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.

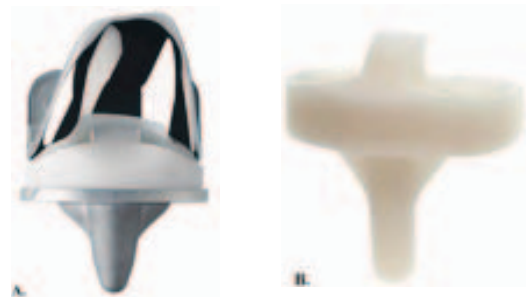
Two similar PCA cases were reviewed by Tulp (1992) one with 7mm thick Poly and one with 9mm thickness. Both presented at 3 years with loss of polyethylene thickness on the medial side, evident bone loss with synovitis and pain. Sections showed a well-formed 300um thick surface layer with an underlying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

A Look Back to the Future "Implant Subsidence in All Polyethylene Tibial Component Cement Mantles



Charnely's application of PMMA to artificial joint fixation in 1959 was a milestone achievement in the development of joint replacement surgery. 50 years later, despite its recognized shortcomings PMMA remains the material of choice.

- High stresses and discontinuities in the cement mantle promote crack initiation and propagation.
- Mixing and chilling monomer in PMMA preparation has shown to reduce porosity.

We can address some of these factors by designs being adapted into improved tibial components.

Design comparison between current design and new novel concept design to reduce stress concentrations in the cement mantle.

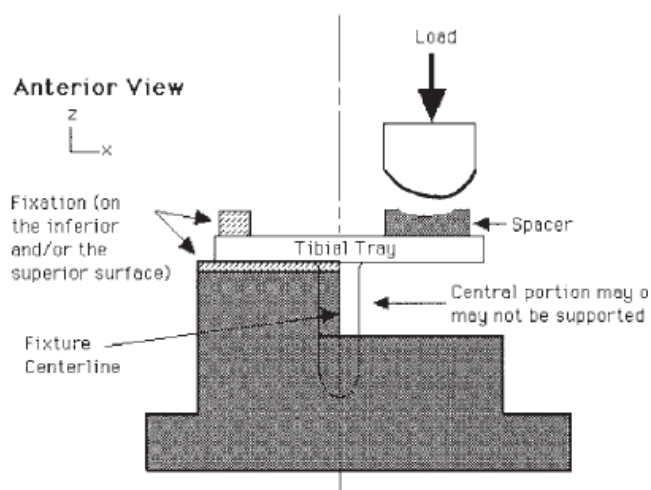
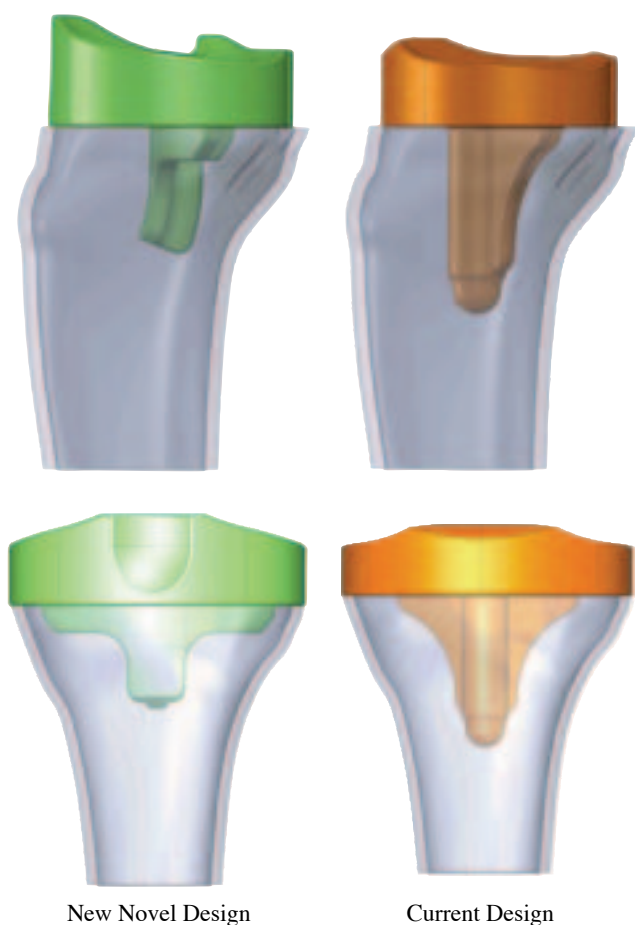
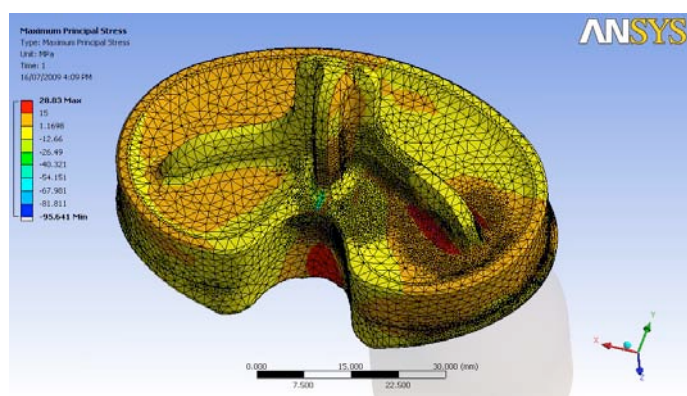


FIG. 2 Schematic of Test Setup With a Central Keel



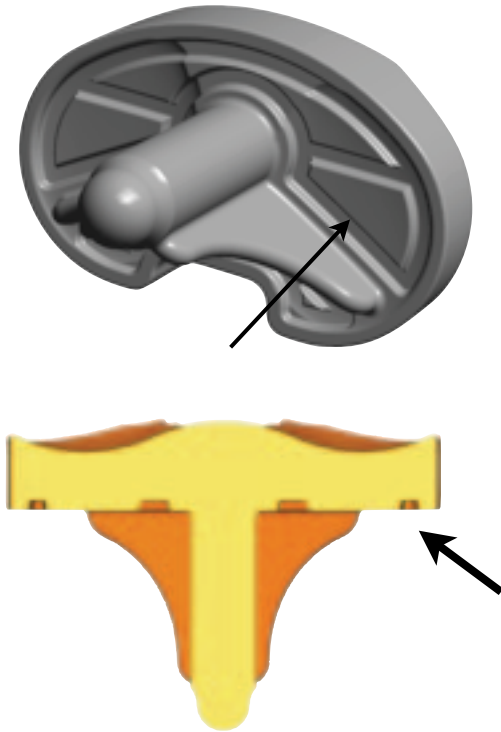
If we anticipate going back into a greater usage rate of all poly tibial components we need to anticipate that today's life styles will place more stress on total knee implants. With this in mind a new novel concept was developed to reduce stress concentration at the implant / cement / bone interface. In addition, taking into consideration the trend on tissue sparing approaches a smaller profile was also adapted.

Certain proven features remain although modified to meet design goals.

Cement has no adhesive properties it is a filler and functions best under compression loads.

Design Consideration for Cement Mantle

Current design



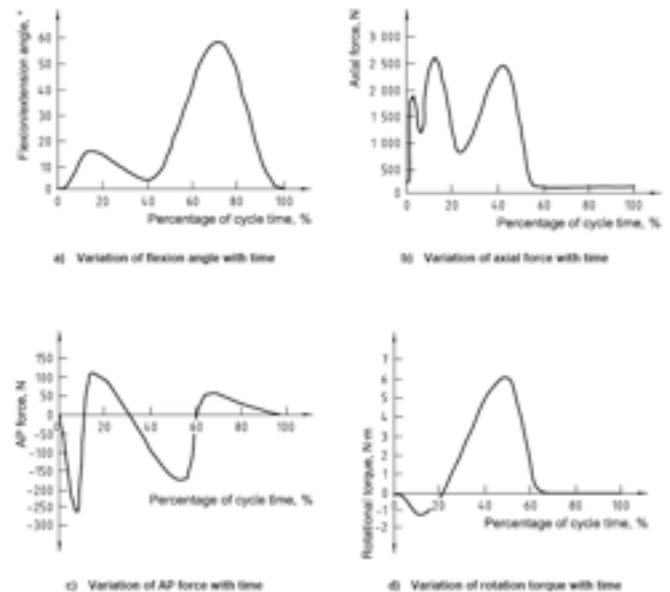
Channels for cement in traditional AP tibia.

New Novel Design “Less Stress”



Domed cement / implant interface, no channels

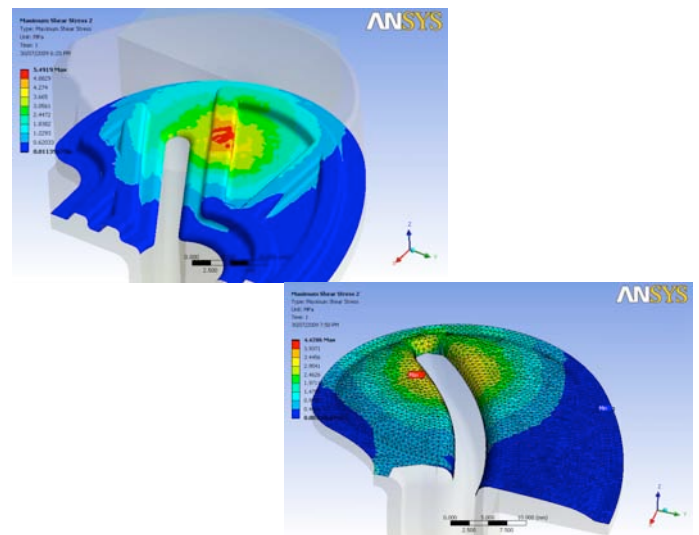
Stress Analysis of cement mantle - ISO14243-1



41% of gait cycle produces highest loads:

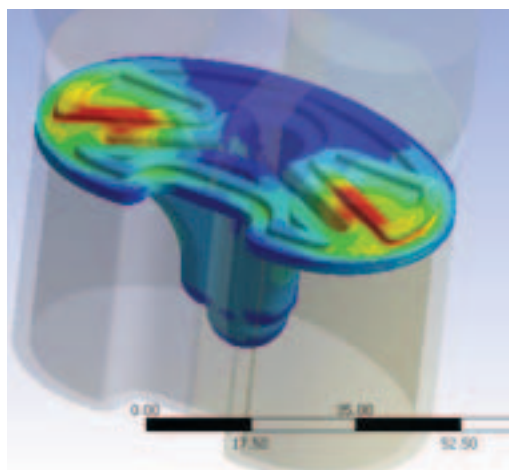
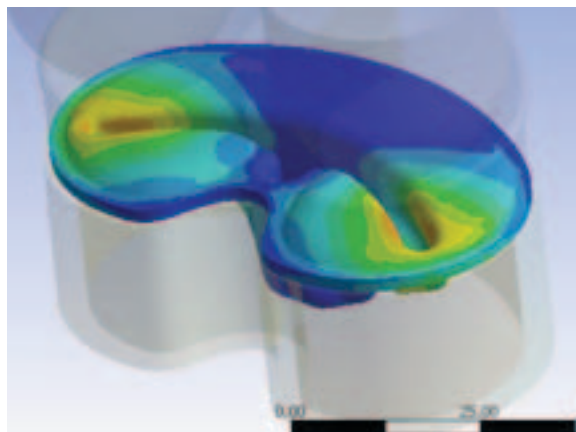
- Axial force = 2281N,
- AP force 108N, - Torque = 5.1Nm

Results

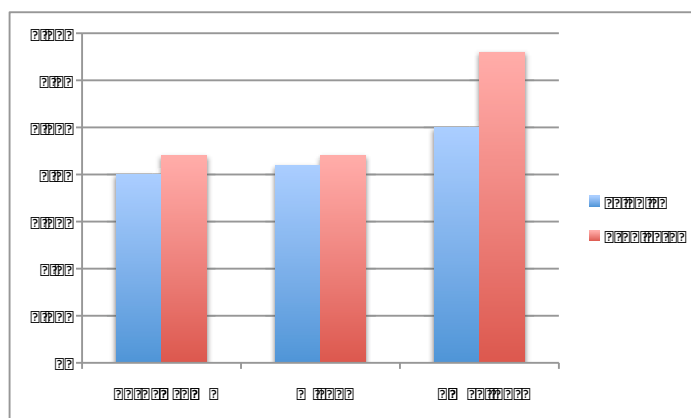


20% reduction in stresses in cement mantle for identical component sizing and boundary conditions.

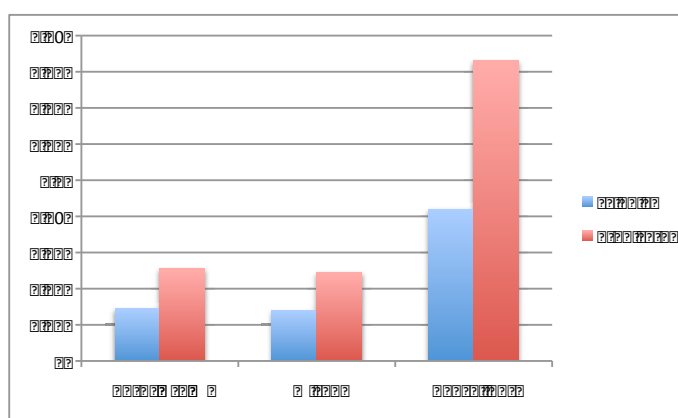
Positions of Features



Insert Deflections



PMMA Mantle Deflections



Decreasing bone stiffness

Decreasing bone stiffness



Observations

- Engineering perspective all poly tibial components can carry in-vivo loads.
- Unique design features do reduce cement mantle stresses.
- Resulting component is engineered to perform better than current all poly component.

However, outcome is significantly effected by:

- Surgical technique “Alignment”
- Cementing technique
- Patient selection (bone quality / activity level)

Summary on new novel design:

- Lower stress in cement mantle compared to current design
- No stress concentrations in cement mantle due to geometry
- Reduced deflections in both insert and cement mantle due to geometry
- Curved insert post for MIS placement of insert.



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.

Cost will continue to be a problem and might slow down the advancement of newer technologies like robotics and navigation.

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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The first and only IV formulation
of acetaminophen available in the US

Improved pain relief, reduced opioid consumption¹



Significant pain relief*¹

- OFIRMEV 1 g + patient-controlled analgesia (PCA) morphine demonstrated significant pain relief vs placebo + PCA morphine ($P < 0.05$ over 6 h)¹
- OFIRMEV 1 g + PCA morphine showed greater reduction in pain intensity over 24 h (SPID24)¹ compared to placebo + PCA morphine ($P < 0.001$)²

Reduced opioid consumption*¹

- OFIRMEV 1 g + PCA morphine significantly reduced morphine consumption vs placebo + PCA morphine (–46% over 6 h, $P < 0.01$; –33% over 24 h, $P < 0.01$)¹
- The clinical benefit of reduced opioid consumption was not demonstrated

Indication

OFIRMEV is indicated for the management of mild to moderate pain; the management of moderate to severe pain with adjunctive opioid analgesics; and the reduction of fever.

Important Safety Information

OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation. Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment.

Do not exceed the maximum recommended daily dose of acetaminophen. Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death.

OFIRMEV should be administered only as a 15-minute intravenous infusion.

Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy.

The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients.

The antipyretic effects of OFIRMEV may mask fever in patients treated for post-surgical pain.

Please see Brief Summary of Prescribing Information on adjacent page or full Prescribing Information at OFIRMEV.com.

*Randomized, double-blind, placebo-controlled, single- and repeated-dose 24-h study (n=101). Patients received OFIRMEV 1 g + PCA morphine or placebo + PCA morphine the morning following total hip or knee replacement surgery. Primary endpoint: pain relief measured on a 5-point verbal scale over 6 h. Morphine rescue was administered as needed.

[†]SPID24= sum of pain intensity differences, based on VAS score, from baseline, at 0 to 24 h.

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OFIRMEV
(acetaminophen) injection
1000 mg/100 mL (10 mg/mL)

Brief Summary (For full Prescribing Information refer to package insert.)

INDICATIONS AND USAGE

OFIRMEV® (acetaminophen) injection is indicated for

- the management of mild to moderate pain
- the management of moderate to severe pain with adjunctive opioid analgesics
- the reduction of fever.

CONTRAINDICATIONS

Acetaminophen is contraindicated:

- in patients with known hypersensitivity to acetaminophen or to any of the excipients in the intravenous formulation.
- in patients with severe hepatic impairment or severe active liver disease.

WARNINGS AND PRECAUTIONS

Hepatic Injury

Administration of acetaminophen in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death. Do not exceed the maximum recommended daily dose of acetaminophen.

Use caution when administering acetaminophen in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia (e.g., due to dehydration or blood loss), or severe renal impairment (creatinine clearance \leq 30 mL/min).

Allergy and Hypersensitivity

There have been post-marketing reports of hypersensitivity and anaphylaxis associated with the use of acetaminophen. Clinical signs included swelling of the face, mouth, and throat, respiratory distress, urticaria, rash, and pruritus. There were infrequent reports of life-threatening anaphylaxis requiring emergent medical attention. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. Do not use OFIRMEV in patients with acetaminophen allergy.

ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Hepatic Injury
- Allergy and Hypersensitivity

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed cannot be directly compared to rates in other clinical trials and may not reflect the rates observed in practice.

Adult Population

A total of 1020 adult patients have received OFIRMEV in clinical trials, including 37.3% (n=380) who received 5 or more doses, and 17.0% (n=173) who received more than 10 doses. Most patients were treated with OFIRMEV 1000 mg every 6 hours. A total of 13.1% (n=134) received OFIRMEV 650 mg every 4 hours.

All adverse reactions that occurred in adult patients treated with either OFIRMEV or placebo in repeated dose, placebo-controlled clinical trials at an incidence \geq 3% and at a greater frequency than placebo are listed in Table 1. The most common adverse events in adult patients treated with OFIRMEV (incidence \geq 5% and greater than placebo) were nausea, vomiting, headache, and insomnia.

Table 1. Treatment-Emergent Adverse Reactions Occurring \geq 3% in OFIRMEV and at a greater frequency than Placebo in Placebo-Controlled, Repeated Dose Studies

System Organ Class – Preferred Term	OFIRMEV (N=402) n (%)	PLACEBO (N=379) n (%)
Gastrointestinal Disorders		
Nausea	138 (34)	119 (31)
Vomiting	62 (15)	42 (11)
General Disorders and Administration Site Conditions		
Pyrexia*	22 (5)	52 (14)
Nervous System Disorders		
Headache	39 (10)	33 (9)
Psychiatric Disorders		
Insomnia	30 (7)	21 (5)

* Pyrexia adverse reaction frequency data is included in order to alert healthcare practitioners that the antipyretic effects of OFIRMEV may mask fever.

Other Adverse Reactions Observed During Clinical Studies of OFIRMEV in Adults

The following additional treatment-emergent adverse reactions were reported by adult subjects treated with OFIRMEV in all clinical trials (n=1020) that occurred with an incidence of at least 1% and at a frequency greater than placebo (n=525).

Blood and lymphatic system disorders: anemia

General disorders and administration site conditions: fatigue, infusion site pain, edema peripheral

Investigations: aspartate aminotransferase increased, breath sounds abnormal

Metabolism and nutrition disorders: hypokalemia

Musculoskeletal and connective tissue disorders: muscle spasms, trismus

Psychiatric disorders: anxiety

Respiratory, thoracic and mediastinal disorders: dyspnea

Vascular disorders: hypertension, hypotension

Pediatric population

A total of 355 pediatric patients (47 neonates, 64 infants, 171 children, and 73 adolescents) have received OFIRMEV in active-controlled (n=250) and open-label clinical trials (n=225), including 59.7% (n=212) who received 5 or more doses and 43.1% (n=153) who received more than 10 doses. Pediatric patients received OFIRMEV doses up to 15 mg/kg on an every 4 hours, every 6 hours, or every 8 hours schedule. The maximum exposure was 7.7, 6.4, 6.8, and 7.1 days in neonates, infants, children, and adolescents, respectively.

The most common adverse events (incidence \geq 5%) in pediatric patients treated with OFIRMEV were nausea, vomiting, constipation, pruritus, agitation, and atelectasis.

Other Adverse Reactions Observed During Clinical Studies of OFIRMEV in Pediatrics

The following additional treatment-emergent adverse reactions were reported by pediatric subjects treated with OFIRMEV (n=355) that occurred with an incidence of at least 1%.

Blood and lymphatic system disorders: anemia

Cardiac disorders: tachycardia

Gastrointestinal disorders: abdominal pain, diarrhea

General disorders and administration site conditions: injection site pain, edema peripheral, pyrexia

Investigations: hepatic enzyme increase

Metabolism and nutrition disorders: hypoalbuminemia, hypokalemia,

hypomagnesemia, hypophosphatemia, hypervolemia

Musculoskeletal and connective tissue disorders: muscle spasm, pain in extremity

Nervous system disorders: headache

Psychiatric disorders: insomnia

Renal and urinary disorders: oliguria

Respiratory, thoracic and mediastinal disorders: pulmonary edema,

hypoxia, pleural effusion, stridor, wheezing

Skin and subcutaneous tissue disorders: periorbital edema, rash

Vascular disorders: hypertension, hypotension

DRUG INTERACTIONS

Effects of other Substances on Acetaminophen

Substances that induce or regulate hepatic cytochrome enzyme CYP2E1 may alter the metabolism of acetaminophen and increase its hepatotoxic potential. The clinical consequences of these effects have not been established. Effects of ethanol are complex, because excessive alcohol usage can induce hepatic cytochromes, but ethanol also acts as a competitive inhibitor of the metabolism of acetaminophen.

Anticoagulants

Chronic oral acetaminophen use at a dose of 4000 mg/day has been shown to cause an increase in international normalized ratio (INR) in some patients who have been stabilized on sodium warfarin as an anticoagulant. As no studies have been performed evaluating the short-term use of OFIRMEV in patients on oral anticoagulants, more frequent assessment of INR may be appropriate in such circumstances.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C. There are no studies of intravenous acetaminophen in pregnant women; however, epidemiological data on oral acetaminophen use in pregnant women show no increased risk of major congenital malformations. Animal reproduction studies have not been conducted with IV acetaminophen, and it is not known whether OFIRMEV can cause fetal harm when administered to a pregnant woman. OFIRMEV should be given to a pregnant woman only if clearly needed.

The results from a large population-based prospective cohort, including data from 26,424 women with live born singletons who were exposed to oral acetaminophen during the first trimester, indicate no increased risk for congenital malformations, compared to a control group of unexposed children. The rate of congenital malformations (4.3%) was similar to the rate in the general population. A population-based, case-control study from the National Birth Defects Prevention Study showed that 11,610 children with prenatal exposure to acetaminophen during the first trimester had no increased risk of major birth defects compared to 4,500 children in the control group. Other epidemiological data showed similar results.

While animal reproduction studies have not been conducted with intravenous acetaminophen, studies in pregnant rats that received oral acetaminophen during organogenesis at doses up to 0.85 times the maximum human daily dose (MHDD = 4 grams/day, based on a body surface area comparison) showed evidence of fetotoxicity (reduced fetal weight and length) and a dose-related increase in bone variations (reduced ossification and rudimentary rib changes). Offspring had no evidence of external, visceral, or skeletal malformations. When pregnant rats received oral acetaminophen throughout gestation at doses of 1.2-times the MHDD (based on a body surface area comparison), areas of necrosis occurred in both the liver and kidney of pregnant rats and fetuses.

In a continuous breeding study, pregnant mice received 0.25, 0.5, or 1.0% acetaminophen via the diet (357, 715, or 1430 mg/kg/day). These doses are approximately 0.43, 0.87, and 1.7 times the MHDD, respectively, based on a body surface area comparison. A dose-related reduction in body weights of fourth and fifth litter offspring of the treated mating pair occurred during lactation and post-weaning at all doses. Animals in the high dose group had a reduced number of litters per mating pair, male offspring with an increased percentage of abnormal sperm, and reduced birth weights in the next generation pups.

Labor and Delivery

There are no adequate and well-controlled studies with OFIRMEV during labor and delivery; therefore, it should be used in such settings only after a careful benefit-risk assessment.

Nursing Mothers

While studies with OFIRMEV have not been conducted, acetaminophen is secreted in human milk in small quantities after oral administration. Based on data from more than 15 nursing mothers, the calculated infant daily dose of acetaminophen is approximately 1 – 2% of the maternal dose. There is one well-documented report of a rash in a breast-fed infant that resolved when the mother stopped acetaminophen use and recurred when she resumed acetaminophen use. Caution should be exercised when OFIRMEV is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of OFIRMEV for the treatment of acute pain and fever in pediatric patients ages 2 years and older is supported by evidence from adequate and well-controlled studies of OFIRMEV in adults. Additional safety and pharmacokinetic data were collected in 355 patients across the full pediatric age strata, from premature neonates (\geq 32 weeks post menstrual) to adolescents. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients < 2 years of age.

Geriatric Use

Of the total number of subjects in clinical studies of OFIRMEV, 15% were age 65 and over, while 5% were age 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Patients with Hepatic Impairment

Acetaminophen is contraindicated in patients with severe hepatic impairment or severe active liver disease and should be used with caution in patients with hepatic impairment or active liver disease. A reduced total daily dose of acetaminophen may be warranted.

Patients with Renal Impairment

In cases of severe renal impairment (creatinine clearance \leq 30 mL/min), longer dosing intervals and a reduced total daily dose of acetaminophen may be warranted.

OVERDOSAGE

Signs and Symptoms

In acute acetaminophen overdose, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and thrombocytopenia may also occur. Plasma acetaminophen levels $>$ 300 mcg/mL at 4 hours after oral ingestion were associated with hepatic damage in 90% of patients; minimal hepatic damage is anticipated if plasma levels at 4 hours are $<$ 150 mcg/mL or $<$ 37.5 mcg/mL at 12 hours after ingestion. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis, and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

PHARMACOKINETICS

The pharmacokinetics of OFIRMEV have been studied in patients and healthy subjects from premature neonates up to adults 60 years old. The pharmacokinetic profile of OFIRMEV has been demonstrated to be dose proportional in adults following administration of single doses of 500, 650, and 1000 mg.

The maximum concentration (C_{max}) occurs at the end of the 15 minute intravenous infusion of OFIRMEV. Compared to the same dose of oral acetaminophen, the C_{max} following administration of OFIRMEV is up to 70% higher, while overall exposure (area under the concentration time curve [AUC]) is very similar.

The pharmacokinetic exposure of OFIRMEV observed in children and adolescents is similar to adults, but higher in neonates and infants. Dosing simulations from pharmacokinetic data in infants and neonates suggest that dose reductions of 33% in infants 1 month to $<$ 2 years of age, and 50% in neonates up to 28 days, with a minimum dosing interval of 6 hours, will produce a pharmacokinetic exposure similar to that observed in children age 2 years and older.

NONCLINICAL TOXICOLOGY

Carcinogenesis

Long-term studies in mice and rats have been completed by the National Toxicology Program to evaluate the carcinogenic potential of acetaminophen. In 2-year feeding studies, F344/N rats and B6C3F1 mice were fed a diet containing acetaminophen up to 6000 ppm. Female rats demonstrated equivocal evidence of carcinogenic activity based on increased incidences of mononuclear cell leukemia at 0.8 times the maximum human daily dose (MHDD) of 4 grams/day, based on a body surface area comparison. In contrast, there was no evidence of carcinogenic activity in male rats (0.7 times) or mice (1.2-1.4 times the MHDD, based on a body surface area comparison).

Mutagenesis

Acetaminophen was not mutagenic in the bacterial reverse mutation assay (Ames test). In contrast, acetaminophen tested positive in the *in vitro* mouse lymphoma assay and the *in vitro* chromosomal aberration assay using human lymphocytes. In the published literature, acetaminophen has been reported to be clastogenic when administered a dose of 1500 mg/kg/day to the rat model (3.6-times the MHDD, based on a body surface area comparison). In contrast, no clastogenicity was noted at a dose of 750 mg/kg/day (1.8-times the MHDD, based on a body surface area comparison), suggesting a threshold effect.

Impairment of fertility

In studies conducted by the National Toxicology Program, fertility assessments have been completed in Swiss mice via a continuous breeding study. There were no effects on fertility parameters in mice consuming up to 1.7 times the MHDD of acetaminophen, based on a body surface area comparison. Although there was no effect on sperm motility or sperm density in the epididymis, there was a significant increase in the percentage of abnormal sperm in mice consuming 1.7 times the MHDD (based on a body surface area comparison) and there was a reduction in the number of mating pairs producing a fifth litter at this dose, suggesting the potential for cumulative toxicity with chronic administration of acetaminophen near the upper limit of daily dosing.

Published studies in rodents report that oral acetaminophen treatment of male animals at doses that are 1.2 times the MHDD and greater (based on a body surface area comparison) result in decreased testicular weights, reduced spermatogenesis, reduced fertility, and reduced implantation sites in females given the same doses. These effects appear to increase with the duration of treatment. The clinical significance of these findings is not known.

OFIRMEV (acetaminophen) injection

Manufactured for:
Cadence Pharmaceuticals, Inc.
San Diego, CA 92130

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OFIRMEV
(acetaminophen) injection



Commentary on A Lack of Leadership Often Has “Unintended Results”

Timothy McTighe, Dr. H.S. (hc)¹,

Acknowledgement: Bruce Shepherd, MD, and John Harrison, MD, NSW, Australia (True Leaders)

Abstract:

Leadership has been described as the “process of [social influence](#) in which one person can enlist the aid and [support](#) of others in the accomplishment of a common [task](#)”.^[1] Many have tried to define leadership and the qualities that make a Leader. One

critical factor to recognize is the lack of leadership and the unintended results caused by this lack.

This paper will reflect on my observations and opinions as to current situations and conditions in the orthopaedic health community as a result of a lack of leadership.

Introduction:

A leader is a person who influences a group of people towards a specific result. It is not dependent on title or formal authority. Most cannot define what makes a leader but they say they recognize a Leader when they see one. Some say Leaders are born other say Leaders are defined and groomed by a process, if you have the will, self-study, education, training and experience you can become a Leader.

This is a look at the current conditions. We find the overall orthopaedic health care community and some observations that brought us to these conditions.

This is an account of some of the experiences from my 41 years in this business of orthopaedics. My career started as a Naval Corpsman in 1969 and working continuously in a variety of positions from Corpsman, Orthopaedic Technician, Independent Sales Representative, Associated Distributor, Director of Marketing, V.P. of Sales & Marketing, V.P. Clinical Surgical Development. President & CEO of a Medical Device Company, Executive

Director of a non-profit scientific and education foundation, member of a number of professional societies and founder of a IP development company.

These are my own opinions and do not represent endorsement by the JISRF Board or any other individual or organization.

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Review

The reputation of the orthopaedic surgeon has been tarnished, and the reputation of the orthopaedic device industry has been tarnished. Surgeon fees have declined, sales prices for implants are under attack and eroding, funding for research is down, funding for CME activities are down and health care employee unemployment is up. Patent development costs are up, product development costs are up and regulatory costs for new product introduction is up.

What has put us into this current situation, in my opinion, the lack of Leadership. However, we still have time to turn things around.

Obviously, there was a serious problem as perceived by the United States Attorney's Office (USAO). In New Jersey in March 2005 they issued subpoenas to the five largest orthopaedic devices manufactures (S&N, Stryker, Biomet, J&J & Zimmer). The subpoenas requested consulting contracts, professional service agreements, and remuneration agreements between the respective companies. Subpoenaed were orthopaedic surgeons, orthopaedic surgeons in training, even medical school students using or considering the surgical use of hip or knee joint replacement or reconstruction products made or sold by the companies for the period beginning January 2002 through March 2005. This investigation has been ongoing and other companies have been added to the list. Major R&D projects were put on hold, CME activities were not supported to the same level and the cost of compliance increased significantly. Companies paid fines to avoid prosecution and agreed to supervision by monitors, many surgeon contracts were cancelled. Many of these agreements, although legal by contract law, were now deemed to be against public policy (USAO) which basically supersedes contract law.

Now we find a large group of surgeons faced with declining fees, cancelation of consulting agreements and faced with question of how are they going to supplement their income? The creation of a new business model Physician Owned Distributorships (PODS). On top of all this, the orthopaedic health

care community is now faced with the largest orthopaedic device recall ever "ASR™ MoM Bearings." This could easily cost over two billion dollars to resolve all the potential claims.

This has placed serious concerns about the competence of the device industry, the FDA (all regulatory bodies), and the orthopaedic surgeon community as to their ability to evaluate and determine appropriate technology for their patients. This is all fuel to both the media and the legal community.

So where do we see the leaders within the orthopaedic community? Are they standing up and providing the encouragement to take a stand to help set things right? There is, in my opinion, some promising activity supported by the American Association of Hip and Knee Surgeons "AAHKS." Dr. Richard Santore and the Leadership of AAHKS have stepped up their activity and, every year at their annual meeting, present significant information to the membership at large. I encourage all total joint surgeons to become members and support this group and their activities.

Current Trends

Times are different, we all need to stay involved and participate in the process. One step we can do to reduce legal exposure is full disclosure. As a general rule, if you are afraid to disclose you probably should not be doing what you are doing. Failure to warn can be one of our greatest exposures.

Be aware, public policy established by the Justice Department is overriding contract law. Ethical standards are being dictated by the Justice Department not by professional societies. The health care field, in particular physicians, can no longer play by the same rules that govern other inventors and developers of technology.

There are now restrictions of payment of royalties, restrictions on stock options, restrictions on ownership, restrictions on travel and entertainment.

Beware, so-called watch dog groups are out there looking for controversy. Also with society facing runaway health care cost, the Government and Insurance industry want to downgrade your (surgeon & inventors) activities, education, and experience to “generic.” In this way they can justify keeping fees and implant prices down. If they can state there is no difference in surgeon quality or implant quality then pricing structures can remain flat. This tends to be short sighted and can and will contribute to long-term increase in health care costs.

Negative exposure at all levels of society has put the credibility of private health care at risk, “Doctor bashing” is in vogue.

There are groups that are seeking to shut down the relationship between physicians and industry. One such group is ProPublica, they are tracking the financial ties between doctors and medical companies. It is not hard for some of these groups to take information out of context and present a negative image.

Example of some titles of their reporting:

Emails Show Drug Company Used Third-Party Medical Groups to Influence Regulators, Undercut Rivals

by [Marian Wang](#)

Spending: Shuttle bus ads

[St. Jude, Inc.](#)

[Medtronic](#)

[Boston Scientific](#)

[Boehringer Ingelheim Pharmaceuticals, Inc.](#)



\$50,000

\$50,000

\$50,000

\$12,500

Total: \$162,500

ProPublica, May 25, 2:30 p.m.

Reports Detail More Drug Industry Ties to Medical Societies

by [Nicholas Kusnetz](#)

ProPublica, May 20, 12:58 p.m.

Medical Schools Plug Holes in Conflict-of-Interest Policies

by [Charles Ornstein](#) and [Tracy Weber](#)

ProPublica, May 19, 1:01 p.m.

This kind of scrutiny is not limited to the orthopaedic device industry:

Cardiac Society Draws Bulk of Funding From Stent Makers

by [Charles Ornstein](#)

ProPublica, May 13, 1:27 p.m.

Financial Ties Bind Medical Societies to Drug and Device Makers

by [Charles Ornstein](#) and [Tracy Weber](#)

ProPublica, May 5, 9:48 p.m.

How the Heart Rhythm Society Sells Access

Recent Heart Rhythm Society Annual Conference
May 2011

Spending: Johnson & Johnson exhibit spaces/lounges

\$275,000

Educational support

\$36,000

Banner ads

\$25,000

Newspapers

\$20,000

Glass clings

\$15,000

...and more...

Total: \$386,750



➤The Heart Rhythm Society's annual conference is a marketing bonanza for drug companies and medical device makers. Last year, firms spent \$5 million festooning the conference with ads and on exhibits, sponsorships or educational grants.

"This style of reporting is not in the best interest on anyone but the special interest so-called watch dog groups that they themselves benefit financially."

McTighe

Many states have moved to pass bills restricting pharmaceutical and device marketing including limiting funding to continuing medical education (CME) activities.

Now some states are concerned that there has been an overreaction and there is a movement to repeal some laws.

Massachusetts House Votes Overwhelmingly to Repeal the Code of Conduct AKA the "Gift" Ban

➤Enacted in 2009, the Massachusetts "gift ban" has been a controversial piece of legislation that has had significant impacts on the pharmaceutical and medical device industry in Massachusetts. After going into effect on July 1, 2009, the Massachusetts (PCOC) required the reporting of payments of more than \$50 made to any health care practitioners by industry. Payments were then published on the states website in late November, 2010.

Violations would carry a penalty of \$5,000.

➤As the [Massachusetts Restaurant Association](#) (MRA) noted, the current **law prohibits** a pharmaceutical or medical device manufacturer agent from **paying for meals** that are offered, consumed, or provided outside of the health care practitioner's office or hospital setting. **These companies are not allowed to hold educational and informational presentations in the restaurants that are surrounding the hospitals.**

➤Accordingly, MRA recognized that the **"misabeled 'gift ban' has been devastating to restaurants and thousands of middle-class employees," in Massachusetts.**

In my 41 years in the orthopaedic health care field and having my share of dinners discussing hip and knee technology, I cannot recall any surgeon using my device as a result of a dinner. In fact, since most hips and knees have good to excellent outcomes, 90-97% results at 15 years, I find the lead time to get a surgeon to change to a new device is about 1-2 years. Maybe I have not taken my surgeons to the right restaurants. *McTighe*

➤Increased cost to all health care companies in the formation of compliance personnel.

➤Decrease in innovation in significant high technology devices.

➤Decrease in commercial funding for CME Activities.

With respect to the number of CME activities which received commercial support:

- In 2010, 68 activities received commercial support vs. 145 in 2008
- In 2010, 26 of these activities would have been solely supported vs. 48
- In 2010, 42 activities would not have been offered without commercial support vs. almost all 48 programs in 2008.

➤Commercial support is down from ave. of 58% to 28%.

Once commercial support is reduced, schools and centers can no longer support the resources or staff necessary to offer adequate or similar programs to faculty, staff, and surrounding community health care professionals.

If commercial support continues to decline, and the number and kind of CME courses continues to decline, America's leading medical schools and centers will face significant problems training and educating our health care professionals.

With a growing population, and increasing number of elderly and sick, America needs “a workforce of competent health professionals” that can use and learn the best health care practices that effectively cure and prevent disease and promote well-being.

In order to achieve this success, an integrated system of interaction between the medical industry, private practice providers, academics, insurance industry, and, yes, the government need to pull together.

Past practice of greed and corruption should not take away the necessary incentives to encourage collaboration and cooperation between all stake holders.

What is necessary is Leadership at all levels. Complacency has been the most significant problem, we must all strive to stay involved and encourage our colleges to get involved or support those that do.

Sitting back does not help anyone. Get involved and stay involved.

Now lets take a look at “PODS”

Tom Donaldson and I had a stimulating debate on this subject at his recent meeting: Update in Hip and Knee Arthroplasty & Bearing Surfaces
September 7-9, 2011, Mammoth Lakes, CA

**Physician Owned Distributorships
“Caution is called for”**

Fact: They are controversial but are they legal, and if they are, should we be encouraging their use?

I would direct interested readers to a recent article by Douglas W. Jackson, MD, in the September 2011 OrthoSupersite. His article touches on many of the points that we have raised.

First lets look at the controversy. Five U.S. Senators asked the Inspector General of the Department of Health and Human Services to open an investigation into the legalities of physician-owned distributorships. Middleman entities that allow surgeons to profit from the medical devices they use on their patients.

The Senate Finance Committee is concerned on the proliferation of such entities in spine and orthopaedic surgery. The concern has to do with creating "financial incentives for physician investors to use those devices that give them the greatest financial return," they may violate an anti-kickback statute and other federal fraud and abuse laws, the report warns.

Remember the Justice Department has already ruled that it is against public policy for physician inventors to be paid on their inventions used by them on their patients. With that understanding, why would any physician think it would be proper to receive commissions, dividends or any kind of financial payment on product that he sold to his hospital and then used on his own patients? We are not the only ones that think this action is very questionable.

A recent quote by Tom Scully a senior counsel at the law firm Alston & Bird who headed the Medicare program from 2001 to 2004. "You can't possibly think this is OK." "I understand that the docs feel squeezed and want to make more money, but they're racing toward a cliff. This can't possibly hold up."

Some physician owners argue that they have a legal opinion and they are safe. Many lawyers are not sufficiently sophisticated or knowledgeable about the nuances of the Anti Kickback Statute (AKS) to render a reliable opinion. Others are willing to tell their clients what they want to hear.

Who gets in trouble if your legal opinion is wrong? Not the lawyer, you the Physician “investor” are held accountable.



Lets look at the argument for PODs. Physicians say they want to save their hospital money!

The impression “image” for and against

They can save money and cut the fat

What fat? Implant prices are falling!

Surgeon fees are down we need to make more money!

The impression PODs are a kickback

The truth is usually in the middle

Not all PODs are created equal

Which side of the argument do you want to be on?

The only favorable argument for involvement is that they may save money for the hospital. The Justice Department does not care if they save the hospital money. Their primary (AKS) concern raised by PODs comes from the financial incentives received by physician investors to use a particular manufacturers' products, not from an incentive to refer patients to a particular hospital.

Why Take The Risk?

The AKS carries both criminal and civil penalties, including fines of up to \$50,000 per violation, damages of three times the amount of remuneration paid, and imprisonment for up to five years. Violations also may result in exclusion from Medicare, Medicaid and other government health care programs.

When it comes to this type of investment surgeons should consider the way they think about new hip and knee technology. What are the risks and what are the benefits long term, not short term. There are more than enough examples in the public media that have demonstrated very negative consequences for these types of activities.

Facts to consider

Government workers that perform these audits make considerably less money than the physicians under review.

Have you ever gone through an IRS audit and won?

Why would you want to exposure yourself to this?

You are not only putting yourself at risk you are exposing the health care industry and your colleagues!

In my opinion, if a physician wants to get into the medical distribution business he should do it outside his community, this reduces any risk of influence on his behalf. *McTighe*

Now lets look at another troubling potential concern. Insurance carriers having more of a say in determining health care technologies. Many of us already think the health care industry is too involved in medical decision making. These companies are, for the most part, for-profit and even the non profit organizations need to make money to stay in business. Tom Donaldson and I know first hand about non profits since we both run our own foundations. They don't run on good intentions they need money just like any business entity.

Insurance companies are already challenging reimbursement for new technology.

In the United States we are faced with hospitals by passing surgeons and dealing directly with implant companies on bids and contracts. Since increasingly more surgeons are becoming employees, they have less authority on technology selection at their institution. We are now seeing the CEO, CFO and Purchasing Managers receiving significant financial compensation if they are successful in getting reduced pricing in place. Often these decisions are contrary to the wishes and desires of the surgical staff. Who is responsible for the selection of technology if something goes wrong? Does the orthopaedic surgeon have an indemnification clause in place and has he warned the patient as to the selection process of the technology used during their case?

We are starting to see in South American the surgeon being removed even farther from the decision making process. There is a growing trend for device companies to be negotiating directly with the insurance carrier. So as the patient sees their surgeon, they present their insurance card, and the surgeon and hospital can only use what is directed by the insurance carrier.

Where is the Leadership that is allowing this to happen? Some larger device companies are partial this process, they can “bundle” products together and not have to worry about maintaining advanced technology. They are not selling advance technology they are selling commodities.

Here is a recent news release and, on face value, can be very misleading:

Orthopedics This Week (National Trade), October 3, 2011

“Insurers Making Own Hips & Knees?”

http://ryortho.com/largeJoints.php?news=1471_Insurers-Making-Own-Hips-and-Knees

By Biloine W. Young

Three Australian health insurers have teamed up to develop less expensive generic hip and knee replacements. Company executives believe this will eventually cut their growing prostheses costs by \$1 billion a year. The developers are basing the design of the generic hips on older products and selling them for 20% to 25% less than rival hips—a saving of around \$2,480 per device.

The three health funds, Medibank Private, BUPA and Australian Unity have provided 90% of the capital funding for the new prostheses company, called Joint Research, to develop the generic hip and knee replacements.

Medibank Private Managing Director, George Saviddes says the number of hip and knee replacements will increase in coming years as the population of those older than 65 doubles while the number of people older than 85 quadruples. He expects that, in the next generation, people will be using an average of three of these devices in their lifetimes. "When you add those three things together, it's looking like a very steep curve. But we have an opportunity to do something about it," he says.

Saviddes calculates that if out-of-patent equivalent joint replacements can gain one-third of the market, his health fund will save \$100 million a year. Within ten years the three health funds could be saving \$1 billion a year which would help keep insurance premium costs under control.

The Australian health safety watchdog, the Therapeutic Goods Administration, has approved two of Joint Research's generic hip devices. One is cemented and the other is cementless. The cemented generic hip is based on the off-patent Exeter hip which was developed more than **40 years ago**. Joint replacement registries show it has one of the best long-term histories of clinical success. Since the hips went on sale in August, Joint Research has sold 250.

First it sounds like the insurance carriers have an active role in this company. This group also has some private surgeon investment money. It is my understanding that the surgeon investors are not involved with the intent to be paid on product that they implant in their own patients. However some of these surgeons have received severe media criticism and they wish they never got involved. Also it is my understanding that past management went through some of the initial investment with little performance to show for it. Lesson learned here is if it sounds too good or too easy it usually is not a good idea.

They also state part of their product selection process is to use product-off-patent that has been around 40 years. Well, I have been in this field for 41 years. It is my opinion that hip and knee total joint surgery has been the most significant procedure development in modern times however, there is not a 40 year old hip or knee that is as good as our current technology. If this statement were true it would be remarkable to say the least.

I had a 1965 Ford Mustang and although it was a good car and one I enjoyed immensely it does not meet the standards of today's cars. I still have a 1978 Honda 750 motorcycle. It is still a fun bike and safe but it does not have the features of today's cross country motorcycles.

The aerospace industry has evolved, manufacturing technologies have advanced, medicine, biologics have advanced, electronics have advanced. Does anyone really think that total joint devices from forty years ago are better than current technology. Lets look at the profile of the typical total joint patient. Today's patient expects and demands more. The life style and activity level is much higher than the patient profile from forty years ago. We can and are building better devices than what was produced in the past. We can also make these device last longer and do less tissue damage so real health care cost associated with revision surgery came come down.

This makes me wonder about the real issue Leadership!

Individuals can effect significant change. We just experience the passing of one of the most significant leaders in recent history, Steve Jobs, Founder, Leader and innovator of Apple products. Here was a man that never said lets except 40 year old technology. He demanded the best and brightest to rise to this call and he defined features and benefits. He made industry more productive he made society more productive and he did not worry about building the least expensive product. He knew the best method would be costly but would, in the long run, out produce the "me too" products and pay for themselves.



The following is going to highlight two orthopaedic surgeons that have demonstrated their leadership to protect not only their chosen profession but the larger calling of their profession, to protect their patients.

Dr. Bruce Shepherd and Dr. John Harrison both of Sydney Australia and both past Presidents of the Australia Orthopaedic Association.

Bruce Shepherd first came to my attention in 1987 at the AAOS Annual Meeting. My dear friend and the Founder of JISRF, Professor Charles O. Bechtol, was attending a dinner I was hosting for our S-Rom Total Hip Study Group Members. Dr. Bechtol and Dr. Shepherd became fast friends, it the beginning of a wonderful 25 year relationship. Bruce was, and still is, larger than life. Not only was he committed to the advancement of total joint technology, he was also very concern with the movement of the Australian health care system into a medicare movement.

Bruce has been described as a lone figure arguing that Medicare was the beginning of the nationalization of the medical profession with a resultant explosion in medical costs. Bruce has continued to campaign against government controlled health system with its waste and lack of empathy for patients.

The sign of this Leader was to create organizations and put himself at the head to get these organizations off the ground. Some of these were the Shepherd Centre for Deaf Children and Their Parents, The Forum for Deaf Education, The Australian Doctors Fund, The Australian Society Of Orthopaedic Surgeons and the Council of Medical Procedural Specialists. Other organizations which he paid a significant role as President were The Australian Orthopaedic Association, The New South Wales Branch of the Australian Medical Association and the Federal Australian Medical Association.

To this day, Bruce Shepherd has managed to preserve a reasonable amount of clinical freedom for the medical professional.



The Australian Gang celebrating Bruce's 75th B'day. Left to right: Allen Turnbull, Bill Walter, Bruce, me, Warwick Bruce, John Harrison and John Ireland below center. All great men with a common denominator, their love and respect for Bruce Shepherd.



A quite moment shared with Allen Turnbull and Bruce. Allen refers to Bruce as his father of orthopaedics.

The Shepherd Centre, NSW, Australia

The Shepherd Centre was founded in 1970 by Dr Bruce Shepherd AM and his late wife Annette. Both of their children were born profoundly deaf and at that time there was no suitable program in Australia for teaching deaf children to speak.



Bruce and a couple of his students from the Centre.

2010 marked the 40th anniversary of the Shepherd Centre. The Shepherd Centre has helped over 1,500 children for over 40 years. 70% of children enroll in The Shepherd Centre program before they are 12 months old.

Bruce's first Charnley Hip June 1, 1970 at Auburn Hospital.



Bruce went on to perform several thousand THA over his career. But that first one stand out in his memory.

Bruce began his leadership in CME activities by being asked by the AOA in the late 1970s to chair a course on joint replacement. He invited Sir John Charnley from England and Mark Coventry, Chief of Surgery at the Mayo Clinic. This lead Bruce and John Harrison to an overseas orthopaedic tour.

During the 1980s, Bruce took on the Australian Government with regards to their overreaching in trying to control the orthopaedic surgeon.

By 1984 Bruce and a number of colleagues were successful in getting roughly 500 doctors to resign from the public hospitals. This grew to over 1,500 by 1985. In the end the Government agreed to repeal legislation controlling doctor's fees for private patients in public hospitals and elsewhere. In addition, the Government agreed to establish a Medial Services Committee. The committee would be composed entirely of medical officers and would be consulted by the Health Minster concerning all changes relevant to medical practice in public hospitals.

Our orthopaedic surgical societies can learn by reviewing these recent struggles in Australia.

Bruce went on to serve as President of the Australian Orthopaedic Association. On May 25, 1997 we performed our first S-Rom® total hip arthroplasty together at Baulkham Hills Hospital. Bruce was instrumental in establishing training of the S-Rom system and that hip still enjoys significant success Down Under.

Bruce was instrumental in my career as was John Harrison and all the orthopaedic gang. Bruce was a co-inventor with me on a proximal modular stem and we received patents back in 1997.



(Modular Prothesis: Co-Inventors: Timothy McTighe, Bruce Shepherd et al., Number: 5,653,765.)

Bruce was very instrumental in the success of the S-Rom® and overall success of Joint Medical Products Corporation. Many changes to instruments and implants came about because of the surgical / clinical input from Dr. Shepherd. In the 1980s, under contract law companies could establish a royalty agreement to a surgeon for his contributions even if he was not part of the original creation of that device. I offered Bruce a royalty contract because I felt his contributions were significant. He replied "Tim I like the S-Rom and use it because of its merit, I don't want to be accused of using it because of a contract."

He also wanted no payment on his contribution to the patent on our Modular Prosthesis. He was and is a man of true character and knows the overall responsibility he had to use the best possible technology for his patients. This is not to say he does not enjoy investing and making money, Bruce is a capitalist and we both have made some investments together, and made money. However, he never got caught up into the fray of royalties of consulting fees. He was always a surgeon first, politician second and investor was last on his list.

John Harrison

John became another strong leader following in the footsteps of Bruce Shepherd. John was another friendship brought about by my relationship with Professor Bechtol and Bruce Shepherd.

This relationship also goes back to the 1980s, I have watched John support Bruce in his political fights and also in his commitment to continuing education and the advancement of orthopaedics.

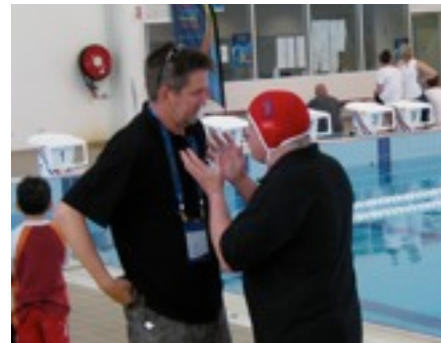
John started his medical career at the Royal North Shore Hospital Sydney in 1970 and still practices at Baulkham Hills Hospital in NSW, Australia. Since 1987, when I started traveling to Australia, I've had the pleasure of being in that country about twenty times in the last twenty-four years. I don't ever recall a trip where I did not see and spend some time with John.

John has always been interested in sports, his two loves of water polo and Rugby. John was a goalie for the National Australian Water Polo team at the 1968 Mexico Olympics.



Once again, John helped out with the 2004 Olympics for three months as Honorary Manager and Doctor with the Australian Men's Water Polo team, pre Olympic competitions in the United States and Europe. He was also an honorary official at the 2004 Athens Olympiad.

John still enjoys getting into the water and competing, 2009 World Games both in the water and having a discussion with one of the officials.



John rose to the President of the Australian Orthopaedic Association in 2005. To my pleasure that was the same year I was invited to become an Affiliate Member of the AOA.

John and his lovely spouse Deb visiting in 2005 before the AAOS meeting in Washington, D.C.





My wife Cathy and I celebrating with John at one of the many B'Tie functions during his Presidency.



John was taking this picture at the combined AOA & NZOA in New Zealand that year. We were lucky to have Dr. Robert Bourne (President COA) and his wife, and dear friend Sam and Mary, with Debbie, Cathy and myself.

I point out some of these photos and activities because of the overreaction from the Justice Department Probe and the restrictions that are being placed on the health care community. This professional community is having unfair burdens placed on its many members and contributors to a better humanity. Doctors, nurses, scientists and industry colleagues are professionals that work unbelievable hours and often are never compensated for some of those hours. You become friends with mutual professional goals to make a difference. This is a difficult way of life and, yes, there are many



benefits that come to professional successful individuals. We socialize together, what is wrong with that. Even at social functions you can't get a group of surgeons together that some of the talk doesn't come back to medicine. "I have that infected hip how are you treating your patients?"

The point of this commentary about Leadership is we need to demonstrate to our younger colleagues that they need to be part of the system. We need to encourage and acknowledge those who are willing to stand and be heard. We are not all Leaders so we need to support and foster leaders. We need to challenge decisions that place undue risk on our patients, colleagues and our profession.

Where is the proof that the government, or for that matter the legal profession, has a better track record on standards of behavior than the medical profession? At least the medical profession has a code of DO NO HARM.

The legal profession teaches there is merit in **frivolous activity**.

I challenge our Professional Societies to establish guidelines on Physician Owned Distributorship and not to wait again for the legislature branch of government or the Justice Department to make decisions that should be down at a local professional level.

We can learn by example from around the world. That is why I bring attention again to the current events within the Australian Orthopaedic Association. They have become a Leader in their Joint Registry and now are leading once again to control more of their profession.

I have great respect for the Australian Orthopaedic Association and believe they are currently demonstrating the necessary Leadership to have more control and reduce outside influences on their profession. I encourage all to follow their journey as a model of involvement.



AOA–RACS Relationship

Preface

I believe that the time has come for orthopaedic surgeons to determine their own professional future. Orthopaedic surgeons, represented by AOA, are ideally placed to make decisions about their own training and education program and manage the program without inappropriate red tape or intervention from others outside the orthopaedic profession.

Our current arrangements with the Royal Australasian College of Surgeons (RACS) where the final say lies with RACS committees and the RACS Council in a rigid system does not allow for this kind of self-determination. Our attempts to resolve this situation with RACS are revealing the potential for solutions, which may be satisfactory for all parties.

Within this framework, I believe that it is both professionally and legally possible for AOA to determine the nature of training, education and credentialing of specialist orthopaedic surgeons without leaving the RACS family of specialist and general surgeons. That for many members may be the most desirable position.

The information uncovered through AOA's Due Diligence process tells us that such autonomy,

through direct Australian Medical Council (AMC) accreditation, does not have to result in separation from RACS, although it would lead to a different kind of relationship—one based on cooperation rather than authority. However, RACS believes that direct accreditation is tantamount to separation and that is their current position.

My job as President of AOA is to lead the further growth of our specialty and to work to get the best possible outcomes for our profession. I do not believe that it is in our best interests for things to stay as they are.

We also acknowledge the aspirations of others and have met with the leaders of the other RACS surgical

It was pleasing to be able to have direct dialogue with RACS on this important matter at the meeting of AOA and RACS Council Executive members which occurred on 7 September 2011 and a program of continuing dialogue is expected to continue. That meeting was positive and professional and clarified our respective positions. Although seeking AMC accreditation remains on the Board's agenda as one of a range of options, it was mutually satisfying to find both AOA and RACS agreeing to explore sensible alternatives that aim to meet the needs of both institutions.

For the past three months, since the Due Diligence process was completed, we have been actively seeking the views of members on our options for change. Many of you have sent in letters and submissions, the majority of which are now reproduced in this publication. We have presented a number of options and discussed them with many of you at Branch meetings and conferences, and we will continue to consult widely throughout September.

As you know, the Board will meet at the beginning of October to consider the matter and your preferences will play a big part in our deliberations.

We are gauging members' views through a plebiscite (first mooted by me at the Queensland Annual General Meeting a year ago) that is open not only to full voting members but also to associate members



and to registrar affiliates. We are not simply interested in the numbers, but also in the spread of views across the membership. For the first time, younger members have the opportunity to make a significant difference to their own future.

Our profession is a broad church and I expect that views will differ. Professionals do what is best for those in their care ahead of themselves, and I do expect you to put the best interests of your profession ahead of personal feelings or fears.

I urge you to participate in the plebiscite. The decision about direct accreditation and our future relationship with RACS is not yet made, despite rumors to the contrary. Please think carefully and make your views known to the Board through this plebiscite. Your responses are fundamental to the journey ahead.

Bill Cumberland AOA President

Note: Lead by **Bruce Shepherd**, John Harrison, Allen Turnbull and many others were all calling for a separation from the Royal Australasian College of Surgeons (RACS) and called for a vote at the AOA meeting in 2008. Again, Bruce has taken on controversial roles and history has shown him to be right on target.

Does this ring true today?

Private Medicine Under Siege.

“At the present time throughout _____ the private hospital system is threatened by the recent denial of proper rebates to patients undergoing private treatment by Medicare. As a consequence doctors who work in the private system are threatened. General Practitioners in all areas are struggling because there are too many and they are under-rewarded. It is the stated intention of the Federal Government that they set up a salaried service in competition to general practice and by the same unfair subsidization that now occurs in the hospital sector will be able to squeeze private general practitioners. I fear that this may occur to such a degree that these doctors in desperation will

seek salaried employment by the State. Is the federal A.M.A. doing anything about this?

This is part of a reply letter from Bruce Shepherd to the Australian Medical Association September 1987 when the Federal AMA accused Dr. Bruce Shepherd, President Elect of the N.S.W. Branch of the AMA of destabilizing the A.M.A.

Being a Leader is often very difficult and at the time not very rewarding. Another area of Leadership by Bruce was the Medical Indemnity Crisis.

“At the close of 2000 Australia’s largest medical indemnity insurer, UMP, concerned about its depleting reserves and future liabilities, put a pay up call on its doctor members equivalent to an extra 100% of their 2000 premium. For Obstetricians and orthopaedic surgeons, this was the equivalent of \$44k extra in insurance costs.”

“Seeing no resolution to the problem, the Chairman of the Australian Doctor’s Fund and former AMA President, Bruce Shepherd, spoke publicly regarding the personal toll litigation was having on his colleagues. “The threat and experience of unjustified litigation is something that many doctors never recover from, and the patients become the losers’.

“We hear a lot about the cost of medical treatment, but there is a deafening silence when it comes to the staggering cost of defensive medicine driven by the fear of litigation” - (BDS 03/26/02)

Bruce Shepherd has not been publicly recognized for his contributions to Tort Law reform but those around and students of this Leader know and can affirm his influence. *Stephen Milgate, 11/18/09 & Tim McTighe*

Bruce did not wage these fights alone but he is credited with being the Leader that went up against the Health Ministers of the Hawke Labor Government that was trying to nationalize the medical profession.

I consider myself a student and friend of Bruce Shepherd. He has influence many aspects of my life

and I continue to learn by reflecting on his actions and character.

Bruce presently resides in Bowral, in the Southern Highlands of New South Wales with his wife, Jennifer.

Bruce's story is one of triumph, of sadness, of achievement and failures; achievements that have lead to Australia being pre-eminent in the care of deaf children throughout the world and an achievement that has maintained an independent medical profession in Australia giving a service at least equal to any other country in the world.

Make a trip to go and visit one of the great places in this world and tie your trip into a visit during the Australian Orthopaedic Association annual meeting. You will never regret the experience.



Tom Tkach and myself presenting a poster on Intraoperative techniques for a proximal modular THA Stem.



During the 2009 AOA meeting a stop off at the Sydney Opera House.

A small traveling group from the States: Ron Emes, myself, Tom Tkach and Brad Vaughn.

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Article 1.
Freeman, [1]; McTighe [3]

Article 2.
Brazil [3]; McTighe [3]; Ong[3];
Woodgate [1]; Rijt[1]; Keggi, J.[3];
Keppler[3], Ponder[2]; Burke[1]

Article 3.
McTighe[3]; Brazil[3]; Aram[3];
Bryant[3]; Keggi, J.[3]; Keppler[3];
Ponder[3]; Schmidt[3]; Vaughn[3]

Article 4.
McTighe [3]; Brazil[3]; Aram[3];
Bryant [3]; Keggi, J.[3]; Keppler[3];
Ponder[3]; Schmidt[3]; Vaughn[3]

Article 5.
McTighe [3]; Bryant[3]; Brazil [3]
Keggi.j. [3]; Keppler[3]

Article 6.

McPherson [1]; Portugal[1]

Article 7.
Bryant [3];Keppler [3]; Keggi,J [3];
Ponder [3]

Article 8.
Wright [1]; Lambert [1]; Brazil [1];
Keggi, K. [1]; Keggi,J. [1]; McTighe
[1]

Article 9.
Brazil [1]; McTighe [1]; Keggi [1];
Keppler [1]; Kennon [1]

Article 10.
McTighe [3];Brazil [1]; Clarke [1];
Keppler [1]; Keggi,J. [1]; Kennon [1]

Article 11.
McTighe [1]

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Letter to the Editor

10/17/11

Dear Tim McTighe & John Keggi,

As curiosity, I am sending an X-ray of a patient I saw 3 days ago in who I implanted two bipolar Lage prosthesis through Hueter approach 15 and 10 years ago in Right HIP and left HIP respectively due to aseptic necrosis when patient was 34 and 39 years. He weights 160 Pd and is very active. He feels some discomfort on his Right HIP only when he walks more than two hours continuously. He searched another colleague from his insurance who indicates a revision! That is why he returned to me. Would you revise it. The interesting fact of this case is the inner poly is perfect and probably served as a Shock absorber since the acetabulum is ok. The bipolar is locked since it is identical a last X-ray I have from 2008 (this X-ray is from august 2011)



Truly yours

Lafayette Lage



Dear Lafayette,

Thank you for sending in such an interesting case for review. The Lage prosthesis is not a device that we are familiar with here in the States. It appears to be a neck sparing design and interesting in that with the extensive distal hypertrophy there appears to be no obvious proximal stress shielding. Both stems appear to be stable. Since the patient is active with only minor discomfort after two hours of continuous walking "revision surgery should be considered cautiously." Since his bipolar appears to be frozen he is more than likely meeting with some mechanical impingement issues. There is always a danger in doing more harm than good in a revision. If he is symptom free with reduced activity and he is willing to accept that reduced activity we would probably not revise him at this time but watch him closely. If he is unwilling to reduce his activity then we would consider revising his bipolar to a cementless fixed acetabular component. We would also be prepared to exchange the femoral component if necessary. Although that appears to be stable and well fixed.

Regards

John & Tim

JISRF

always teaching always learning



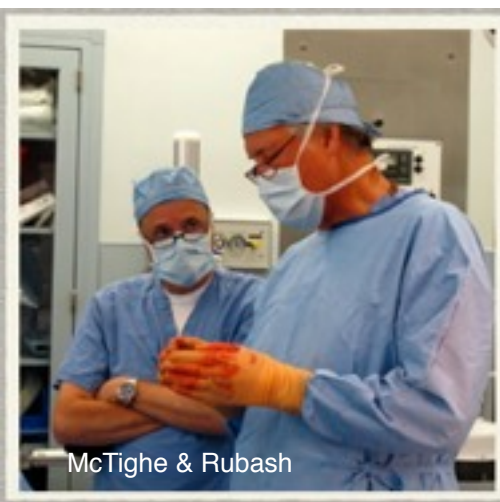
Lesson Learned
educational Seminar
held prior - to the
2010 Annual AAHKS
Meeting

Lessons Learned TSITM™ Stem

Timothy McTighe, Dr. H.S., (Jc), Executive Director, JISRF Chagrin Falls, OH, USA

November 2010

JISRF hosted Professor Rubash last year in Cleveland, OH on a visit to watch and learn on the concept of neck sparing THA from Louis Keppler, MD.





2012 Meeting Calendar

January 12 – 15, 2012

4th Annual Winter Hip And Knee Course
Vail, Colorado

January 15 – 18, 2012

ICJR/Orthopaedics Today Hawaii
Maui, Hawaii

February 7-11, 2012

American Academy of Orthopaedic Surgeons
(AAOS)
San Francisco, CA

March 8 - 10, 2012

3rd Annual Advances In Orthopaedic Trauma And
Arthroplasty
Miami, Florida

March 22 - 23, 2012

2nd Annual Cleveland Hip And Knee Course
Cleveland, Ohio

April 13 - 15, 2012

3rd Annual Spring Hip And Knee Course
Kiawah Island, South Carolina

April 18, 2012

ICJR/MAOA Back To Basics Arthroplasty Course
Bonita Springs, Florida

April 27 - 29, 2012

ICJR/Orthopaedics Today San Diego
San Diego, California

May 18 - 20, 2012

2nd Annual Marshall University Arthroplasty Course
White Sulphur Springs, West Virginia

June 27 – 30, 2012

American Orthopaedic Association
Washington, DC

September 13 – 15, 2012

ICJR Shoulder Course
Las Vegas, Nevada

October 4-6, 2012

Orthopaedic Trauma Association (OTA)
Minneapolis, MN

October 19 - 21, 2012

13th Annual ISK Sports Medicine, Total Knee And
Hip Course
New York, New York

November 2-4, 2012

American Association of Hip and Knee Surgeons
(AAHKS)
Dallas, TX

November 15 - 17, 2012

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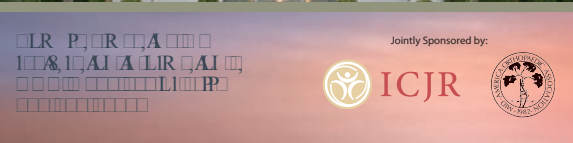
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