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Reconstructive REVIEW

OFFICIAL JOURNAL OF THE

Joint Implant Surgery and Research Foundation

Strategic Alliance with

The Greenbrier Medical Institute

Future Site Selected for Cutting-Edge Medical Initiative

World Class Healthcare, Orthopaedics "Sports Medicine," Rehabilitation, Plastic Surgery, Research & Education

At America's

Greenbrier Resort

Since 1948, the Greenbrier Clinic has been recognized as an industry leader in executive health and wellness through utilizing advanced diagnostics in the early diagnosis, prevention and treatment of disease. Building upon that history of medical excellence, Jim Justice, Chairman and owner of the Greenbrier Resort, has announced the creation of the Greenbrier Medical Institute. The institute's 1st phase is projected to cost about $250 million, employ more than 500 people and include 3 buildings.

This phase will include an expansion of our world renowned executive health and wellness practice, The Greenbrier Clinic, which will be bolstered by a world-class sports medicine program, including an orthopedic surgery center and athletic performance/rehabilitation facility, all led by the Founder of the American Sports Medicine Institute, Dr. Jim Andrews and Chair of Cleveland Clinic Innovations, Thomas Graham. Rounding out the Institute's services will be a first-in-class plastic and cosmetic surgery and Lifestyle Enhancement Academy, helping people look and feel their best. Physicians, universities, research foundations, medical journals and other healthcare industry leaders, all of whom are on the cutting edge of medical technology, research and care, have committed to join the project and establish an international research and education destination or "think tank" to stimulate research, drive innovation, force change and redefine how the world approaches health, wellness and longevity.

The Institute's facility, designed by Willie Stokes, will feature Georgian architecture similar to the resort's façade, a replica of the Springhouse, the site of the famous sulphur springs and special guests suites for patients and their families. Jack Diamond, President and CEO, and Mark Krohn, COO, are leading the development of this exciting project and are actively looking for other physicians and medial thought leaders to be involved.

For more information, please contact:

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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.
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There is no subscription charge for receipt of this publication. This is done as a service keeping with the overall mission of JISRF.

Mission Statement:
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.

Reconstructive Review

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Editorial Comments

John Harrison, BSc (Med), MBBS, FRCS, FRACS, FAOrthoA, FAMA, FACSP

Medical politics has always been a special interest for Dr. Harrison despite a busy orthopaedic practice. Before taking up a Years term of office as National President of Australian Orthopaedics in October 2004, Dr. Harrison completed a three month tour as Honorary Manager and Doctor with the Australian Men's Water Polo team attending pre Olympic competitions in The United States and Europe. Being a past National Australian Water Polo goalie selected for the 1968 Mexico Olympics, attending the Athens Olympiad as an honorary official was a challenging experience from a different perspective.

2004

1968

Past President of AOA

Many Australian orthopaedic surgeons of "mature age" had the pleasure of meeting and inevitably being influenced by the late **Charles Bechtol, MD**. A kind, courteous colleague whom that large tome, "The History of Medicine" reasonably puts in juxtaposition with John Charnley (as a justifiable American version of him) in ushering in modern Total Joint Arthroplasty in to the US in a cautious way even then under the purview of the FDA.

To us, as visitors in search of knowledge about this radical change in orthopaedic technology from other sources than Charnley himself at Wrightinton UK, **Charles** was hugely open and welcoming to all our colleagues in his busy Los Angeles practice and with his academic mind laced with a textbook knowledge of comparative anatomy (from seals to hippopotami) with his lovely wife Louise, charmed all with his explanations of the science behind this huge innovation in orthopaedic work he encouraged us to follow in a logical way.

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

To Australians living upside down on the other side of the world, remote from the USA, like a kindly Dr. Doolittle or more aptly a modern day Charles Darwin, Charles stretched himself from his busy practice for the Infant JISRF foundation in "voyaging" to Australia to join in educational seminars with the Australian Orthopaedic Association on Joint Replacement techniques including revision surgery thoughtfully run by his younger Australian orthopaedic friend and joint surgeon facilitator in Australia, Dr. Bruce Shepherd (also a mentor of mine) and invited us to join in other offshore informative conferences [at an American geographic "half way" in Hawaii] as well as in mainland USA which were very good value experiences for our orthopaedic surgical workforce.

As professionals we should all respect and honour pioneers in our craft of whom **Charles** was a lovable giant and he fortunately had the prescience to select and mentor Mr. Tim McTighe who has had the skills and sense to not only maintain the Foundation but grow it and adapt the valuable knowledge transfer base its membership and affiliations have in the changing world of the electronic media we all struggle to change and adapt to, today.

On behalf of the appreciative and loyal orthopaedic friends and colleagues,

John Harrison

JISRF Announcements

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

Last year was our first publication of the Reconstructive Review. This year we have published one supplement of 72 abstracts from ICJR's May 2012 CME activity in Coronado, California, and now our second full publication.

This is a major undertaking (creating a new journal) and I would like to thank all members of our Editorial Board along with authors that have submitted manuscripts. We are putting the systems into place so our submissions, reviews and rewrites take on a smooth process. I am very encouraged by the positive reactions we have received and by the increased submission activity. I believe Dr. Bechtol would be pleased that his Foundation and its mission lives on:

> *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.*

This Journal as all activities are available to all interested surgeons, scientists and educators. Our focus is on new cutting edge technologies, controversial issues, case reports, and basic science – all with the intent to raise the level of discussion and discovery. Please become a part of this endeavor, we look forward to your interest and participation.

Welcome to Our Newest JISRF Board Member Mr. Jack T. Diamond, Esq.

Jack T. Diamond is a renowned industry leader in innovative health care strategies, solutions, and developments. Mr. Diamond has participated in and led hundreds of global health care projects including the creation of entire hospital campuses, clinical centers of excellence, surgery centers, physician hospital organizations and health management organizations. When health care leaders need a creative solution to a pressing problem, they call Mr. Diamond. As co-founder of the American Bar Association's Health Law Section and principal of numerous health care related businesses, Mr. Diamond recognizes what works in health care in order to navigate the ever changing and complicated regulatory framework of the health care industry. Mr. Diamond is listed in The Best Lawyers in America, Who's Who in American Law, Leading Lawyers in Inside Business Magazine, Ohio Super Lawyers in Law and Politics Magazine and among Manchester's Who's Who Among Executives and Professionals in Healthcare.

Mr. Diamond has authored numerous publications, is a frequent speaker on health law issues throughout the United States, and received his Juris Doctor from Case Western Reserve University School of Law, a Masters in Business Administration from Cleveland State University, and a Bachelor of Science and Bachelor of Arts from Xavier University.

Jack is also President and CEO of the new Greenbrier Medical Institute at the Greenbrier Resort in White Sulphur Springs, West Virginia.

Jack, on behalf of the entire Board of Directors and all our Clinical Surgical Advisors welcome aboard.

Strategic Alliance Announcement

Joint Implant Surgery & Research Foundation

is Pleased to Announce a Strategic Alliance with the

Donaldson Arthritis Research Foundation

DARF, founded in 2005 by Dr. Thomas K. Donaldson, has a focus on outcome studies and basic science with major emphasis on implant retrievals. His ongoing collaboration with Ian Clarke, PhD provides a synergy between the laboratory and clinical surgical science. Both men are Board Members of JISRF and have a significant working relationship with its Executive Director Timothy McTighe Dr. HS (hc).

Ian Clarke, PhD & Thomas K. Donaldson, MD

JISRF, founded in 1971, has had significant experience with continuing medical education, product development, and clinical surgical evaluation of total joint implant devices.

The long term relationships JISRF has with total joint surgeons world wide and the experience of its Co-Directors and research evaluation equipment of the DARF Retrieval Center make for a strong long-term relationship.

Together both groups will provide unprecedented analysis of your Retrievals.

Metal on metal retrieval

www.jisrf.org • www.darfcenter.org

Instructions to Authors

Submission of Articles

The Reconstructive Review uses a web-based service requiring authors to submit their manuscripts electronically. Authors register at www.JISRF.org.

Please use the following format:

1. Title page: List the title and the names of the authors in order of appearance. Provide complete contact information including both hard and electronic addresses.

2. Informed Consent: Any manuscript dealing with human subjects must include a statement that proper disclosure was given and patient consent received.

3. Copyright agreement: All articles published are the property of the Reconstructive Review. However, the journal gives blanket permission for copy as along as proper notification and recognition are provided to JISRF.

4. Disclosure statement: Disclosure by all authors as to any commercial interest must be submitted and signed by the corresponding author. It is the responsibility of the corresponding author to ensure compliance and full disclosure of all co-authors. The disclosure is simple: I have a financial interest in the following commercial companies: Financial interest being define as: royalties, consulting fees, stock or stock options and any direct or indirect instructional support. We do not need to know any detailed information other than you have a financial interest. If you are reluctant to disclose then you probably should not being doing what you are doing.

5. Structure of manuscript:
   - Structured abstract Note: do not include abstract with case reports
   - Introduction
   - Materials and Methods
   - Results
   - Discussion

6. Structure of endnotes (please refer to the following website): http://medlib.bu.edu/facts/faq2.cfm/content/citationsama.cfm

We welcome letters to the editor and acceptance is at the sole discretion of the Editor.

Journal Articles

- Original Articles
- Clinical/Surgical
- Basic Science
- Case Reports
- Historical Reviews
- Surveys
- Commentary
- Letters to the Editor

The emphasis for these subjects are to address real life orthopaedics in a timely fashion and to encourage the participation from a broad range of professionals in the orthopaedic health care field.

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.

JISRF Reconstructive Review Specifications

The Reconstructive Review is currently constructed using InDesign running on a Mac. The document is published on the web, available for download as a PDF at jisrf.org, and printed in limited quantities.

- Trim Size: 8.5" x 11"
- Live Area: 7.25" x 9.25"
- No Bleeds

Ad Specifications

Sizes
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- Half Page Horizontal, 7.25" x 4.25"
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Acceptable Files

All images should be at least 300 dpi (dots per inch)
- JPG
- TIFF
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Any questions regarding these specifications can be directed to media@jisrf.org.

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

Lesson Learned From Retrieval Analysis Of A Dislocating, Large Diameter MoM Revision THA

A Case Report

HIGHLIGHTING ADVANCED DARF RETRIEVAL TECHNOLOGY

Edward J. McPherson, MD, FACS†°
Ian Clarke, PhD*°
Thomas K. Donaldson, MD ‡°

Key Words: *THA, Dislocation, Retrieval, Metal-on-Metal, Wear Patterns, Stripe Wear, Pitting Wear, Trough Wear Phenomenon*

Introduction

Wear debris generated by a total hip arthroplasty (THA) bearing can cause considerable damage to the surrounding soft tissues and bone, compromising patient function and causing long-term pain. In the case of a traditional bearing, a metal (or ceramic) head articulates with an ultra high molecular weight polyethylene (UHMWPE) cup. The polyethylene debris generated is processed by the macrophage, and through a cascade of cytokines, results in an inflammatory response. The inflammatory response causes a surrounding toxic reactive synovitis[7]. Frequently an associated pronounced osteolysis phenomenon occurs, compromising implant fixation[6]. The significant bone loss makes subsequent revision THA very difficult and can affect long term implant survival. The severe osteolysis seen with UHMWPE bearings prompted many surgeons to utilize alternative bearing constructs such as metal-on-metal, metal-ceramic, and ceramic-ceramic bearings.

A metal-on-metal bearing (including ceramic-on-metal) can also cause an adverse wear response. The metal-on-metal bearing is a cobalt chrome alloy, which generates cobalt and chrome particles. These submicron particles can liberate cobalt and chrome ions, which can penetrate the local soft tissues and enter the systemic circulation[7,13]. Locally, the ion particles bond with serum proteins to create hapten complexes. The metal ion hapten complexes are processed by the T-cell lymphocyte, and through a cascade of cytokines, results in a local inflammatory response. The response creates a toxic reactive synovitis that can expand to regional tissues nearby (also known as pseudotumor response)[2,3,10,11,12]. Furthermore, bone tissues can resorb via osteolysis, resulting in significant bone compromise.

Clarke and others have described wear patterns on hard-on-hard bearing constructs that lead to the formation of excess wear debris[1,5,9,14]. Stripe wear is one such pattern typically seen when a bearing repetitively subluxes sub-clinically, meaning the event occurs without the patient sensing that the levering action is occurring. Stripe wear was first described with ceramic-ceramic bearings and has also recently been described with metal-on-metal bearing constructs[4,5,8]. With metal-on-metal bearings, repetitive sub-clinical subluxation is still the mechanism responsible for stripe wear formation, whether it be from a levering mechanism or by a joint distraction phenomenon (head distraction at end of limb swing phase) (Figure 1).

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* Peterson Tribology Laboratory, Dpet. Orthopedics, Loma Linda University, CA
‡ Donaldson Arthritis Research Foundation, Colton, CA
° Partially Funded by JISRF

Acknowledgements: We are grateful for DARF expertise provided by M. Burgett and T. Halim and also to Zygo Electro-Optics Group Manufacturing Center (Zemetrics, Tucson, AZ) for their technical support.

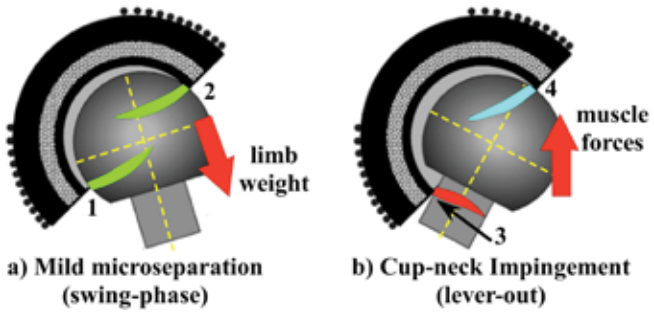


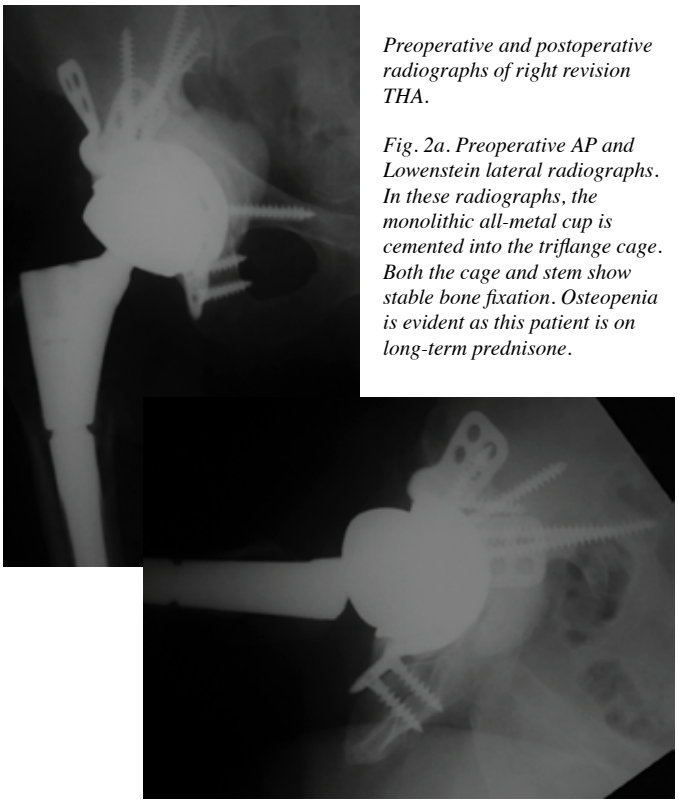
Fig. 1. Diagrams demonstrating the etiology of stripe wear generation on an alternative (hard on hard) hip bearing. Diagram on left (a) shows stripe wear generation as the femoral head distracts out of socket during swing phase. Diagram on left (b) depicts stripe wear forming as a result of hip levering when the bearing is at end range. In both scenarios, the stripe forms when the head makes point contact at the metal edge of the socket.

Another wear pattern mechanism for the metal-on-metal bearing is edge scratching. This occurs when the bearing dislocates and is subsequently reduced. It is thought that scratches generated by the dislocation event could later "self heal" by a polishing phenomenon. Others feel that a dislocated metal-on-metal bearing is doomed for an accelerated wear pattern for the rest of the life cycle of the prosthesis. In this case we describe the wear patterns of a large diameter metal-on-metal bearing that had previously dislocated twice before the bearing was revised. We also describe for the first time a new bearing wear pattern seen in this retrieval specimen.

Case Report

The patient in this case is a 65-year-old female who has suffered from rheumatoid arthritis for over 30 years. She had been treated aggressively with multiple disease modifying anti-rheumatic drugs (DMARD's) including anti-TNF agents, methotrexate and prednisone. She has undergone multiple joint replacement procedures to treat her polyarticular disease.

The right hip was initially replaced in 1990 with a cementless porous coated cup and stem. Her hip was revised 13.5 years later in August 2003 for mechanical loosening as a result of significant polyethylene induced osteolysis. The acetabulum was revised with a cementless porous cup with screws and the stem was revised with a cementless modular revision stem. Her stem healed with stable osteointegration, but her cup failed to successfully integrate. Her cup migrated to develop a protrusio deformity and 20 months later (April 2005) the acetabular cup was revised with a triflange cage (MaxTi, Biomet Inc. Warsaw, IN). A large diameter metal monolithic cup (Magnum, Biomet Inc.) was cemented into the cage. Anteversion was set at 25 degrees with a theta angle of 40 degrees. The head used was a 44mm diameter cobalt chrome alloy metal head with a titanium alloy modular neck adapter. A neck length of minus 6mm was used and impacted onto a 4 degree included angle taper junction (see Figures 2a and 2b).



Preoperative and postoperative radiographs of right revision THA.

Fig. 2a. Preoperative AP and Lowenstein lateral radiographs. In these radiographs, the monolithic all-metal cup is cemented into the triflange cage. Both the cage and stem show stable bone fixation. Osteopenia is evident as this patient is on long-term prednisone.

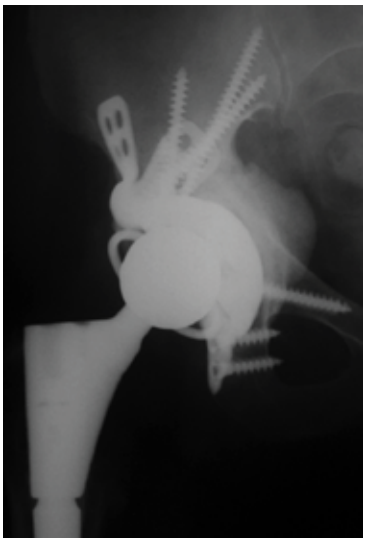


Fig. 2b. Postoperative AP radiograph. The all-metal cup has been replaced with a constrained polyethylene cup cemented into the cage. Notice the metal ring at the periphery of the socket. This is to limit plastic deformation of the polyethylene when the hip is taken to end range.

Her pelvic reconstruction was successful, but the patient dislocated her hip 16 months after surgery when she was in a position of hyperflexion getting out of a low chair. A closed reduction was successful under anesthesia in the operating room. A second dislocation occurred four months later, again while the patient was in a position of hyperflexion. After her first dislocation she noted repetitive intermittent hip clicks with sit to stand. These clicks were not painful. The acetabular cup was revised after her second dislocation. At the time of revision surgery the hip dislocated with the hip at 105° of flexion and internal rotation of 20°. In this position the greater trochanter impinged upon the anterior column of the acetabulum causing hip levering and dislocation. Trochanteric impingement occurred because of lack of hip offset. Observation of the soft tissues around the hip showed no metallosis. There was no toxic reactive synovitis evident. The acetabulum was revised to a constrained acetabular component (Freedom, Biomet Inc.) The neck length of the head was increased to a plus 3mm, which reduced greater trochanteric impingement with flexion and internal rotation. At 3.5 years after surgery, the patient enjoys a pain free hip that remains functionally stable.

Surface analyses of the bearing included wear maps and surface roughness measurements employing a coordinate measuring machine and metal surface scan with scanning electron microscopy (SEM). Regional wear patterns were identified relative to polar and equatorial regions of the cup and head. Wear features included main wear zone (mwz), stripe wear zones (swz), cup rim wear breakout (rbo), areas out of round, and volumetric wear.

The visual inspection showed obvious deep arcuate scratches that occurred during the reduction maneuver. Surface SEM analysis demonstrated that deep gouges were created within the metal head. These "canyon troughs"

Fig. 3. Photograph of retrieved head. Note the long scratches from the reduction maneuver. Also note at the base of the ball, the multiple metal pits. The pitting phenomenon is best described as an asteroid impaction zone. We suspect this area was damaged by free carbide fragments that were crushed between the bearing surfaces.

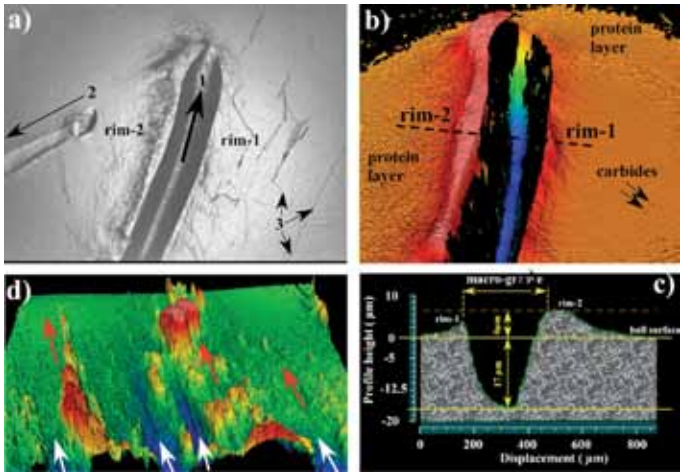


Fig. 4. Surface scanning electron photograph of the explanted 38mm femoral head focusing on deep scratch regions. These longitudinal areas were created during the hip reduction maneuver, and these areas of damage are different from the stripe wear marks that occur from repetitive subclinical subluxation. These deep stripes measured by SEM imaging show twin polar stripes of width 100-250um. These can be 1 to 10 um deep, i.e. the Grand Canyon of the wear track.

also created raised ridges that were points for further wear (Figure 3 and 4). Adjacent stripe wear occurred once the joint was reduced. We describe this as "collateral trough wear phenomenon." Adjacent to the canyon trough, the collateral wear stripes were made generally orthogonal to the canyon trough as a result of normal bearing movement. Also, unique to this retrieval, were large deep pits (Figures 5), which were located at the base of the femoral head. These craters are thought to emanate from carbide particles that had broken

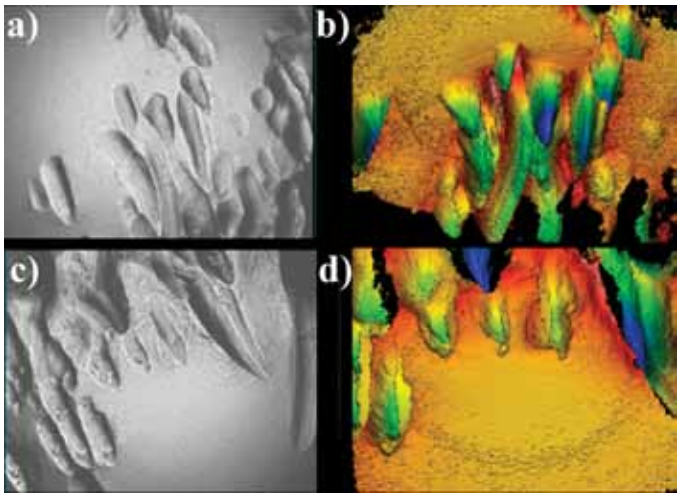


Fig. 5. Surface scanning electron micrographs illustrating the new wear phenomenon of pitting at the base of the head. This pitting area looks analogous to an asteroid impaction zone. We suspect these pits occurred from free carbide fragments getting crushed between the bearing. Another possible source could be methylmethacrylate fragments. However, at the time of revision surgery, the cement mantle within the cage was intact.

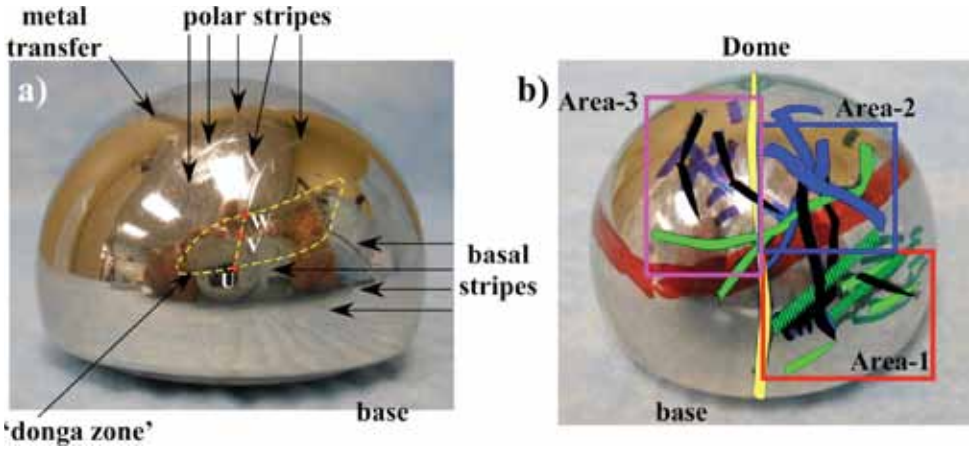


Fig. 6. Photographs of retrieved head. In right photo, stripe wear lines are colored to aid in visualization. Note the multiple wear stripe lines. Interestingly, there are stripe wear lines that cross. These stripe lines have formed as a result of repetitive subclinical subluxation that occurred in multiple directions.

off and became crushed in between the bearing surfaces. To our knowledge, this is the first time this type of wear pattern has been observed from an in-vivo retrieval.

This specimen also demonstrated multiple stripe wear patterns (Figure 6). Even though clinically the senior surgeon felt that the positioning of the stem and cup was reasonable, repetitive subluxation was occurring in multiple directions. The reason for the levering phenomenon was thought to be due to lack of offset in the prosthetic construct. This allowed for greater trochanteric abutment against the pelvis at end flexion and rotation. This resulted in levering of the femoral head creating the multiple wear stripes observed in this case.

Discussion

Large diameter THA bearings are popular among surgeons because they are inherently more stable than smaller diameter bearings. Large diameter bearings confer their stability via two mechanisms. The first mechanism is an optimized head to neck ratio. A large diameter head attached to a narrow neck significantly increases primary arc range and is more stable (Figure 7). The second mechanism is the increased "excursion distance" to lever out of socket. A larger diameter head requires a longer distance to lever before complete dislocation out of socket (Figure 8).

Larger diameter heads however, are more susceptible to multiple stripe wear formation. Smaller diameter heads dislocate much easier and when they do, they are frequently revised. Large diameter heads rarely dislocate. When in a compromised position they sublux but stay

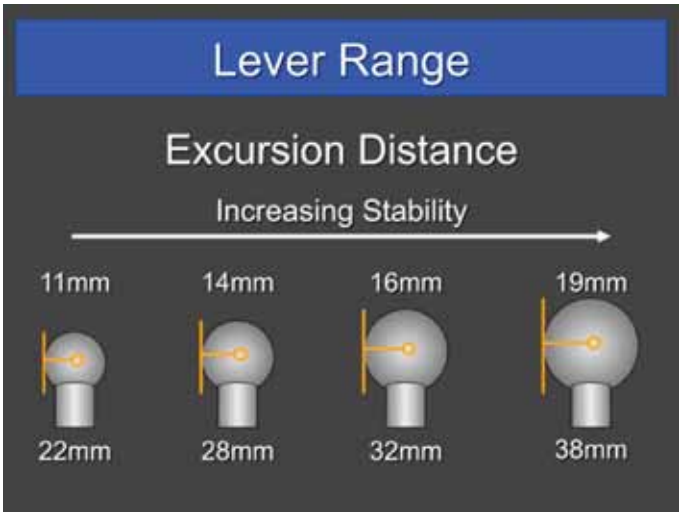


Fig. 7. Photograph demonstrating the effect of increasing head to neck ratio. In this example, head diameter increases while neck diameter remains the same. Hip range improves in proportion to the increase in head to neck ratio. Although the large diameter head may not dislocate, it is susceptible to repetitive levering. Repetitive levering scratches the head at the edge of the acetabular rim.

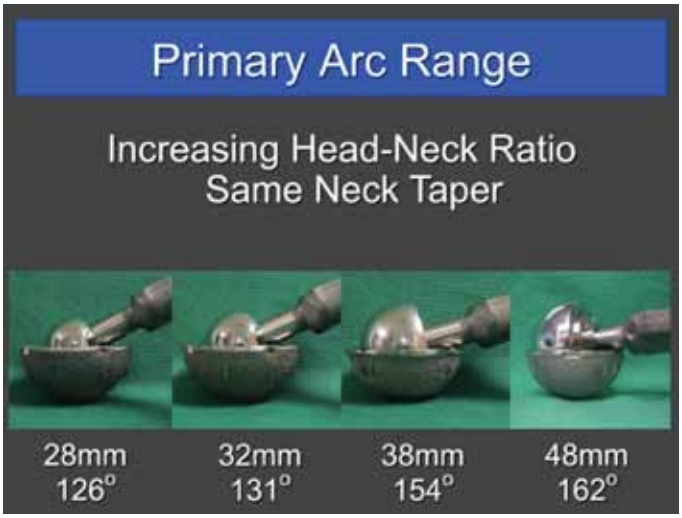


Fig. 8. Photograph illustrating the effect of increasing excursion distance. When the hip starts to lever, the distance the head needs to travel to dislocate is equal to the head radius. As head size increases the head becomes more inherently stable. However, as excursion distance increases, the extent of potential scratching increases proportionally.

located. This creates the condition of repetitive sub-clinical subluxation[8]. Furthermore, a patient may challenge a large diameter bearing in various positions creating the scenario of multiple stripe wear marks. All stripe wear marks are adverse wear regions. The greater the number of stripe regions on a bearing, the greater the risk for increased debris formation. This can result clinically in an adverse wear response.

This retrieval specimen demonstrates that the so-called "in-vivo polishing" effect of a metal-on-metal bearing does not occur. From our review the introduction of the canyon trough from the reduction maneuver was an additional source for in-vivo scratching. This scratching occurred orthogonally to the trough, vastly increasing the surface area for wear debris formation. In a large diameter bearing the extent of the head travel (defined as the absolute distance the femoral head travels during a full arc range) is greater than that of a small head. Thus for any defect created, the larger diameter head will generate a larger area of collateral damage. Finally, we identified a new phenomenon of wear damage to a cobalt chrome bearing. This is the "asteroid impaction" pattern of wear. When carbide particles are broken off from the bearing (as with a dislocation/reduction event), these free asperities get crushed within the bearing causing significant local damage. The findings on SEM were analogous to the appearance of an asteroid that had slammed into the surface of the moon. This "asteroid impaction" is a very adverse wear pattern.

In summary, this retrieval suggests that the dislocation of a large diameter metal-on-metal bearing is a worrisome scenario for wear debris formation. In fact, a canyon trough created by a dislocation combined with repetitive sub-clinical subluxation probably represents the worse case of in-vivo wear debris formation. For the surgeon, a patient with a dislocating large diameter THA should be monitored frequently to check for adverse wear debris formation. We advocate baseline serum metal ion testing after the dislocation event should the surgeon and patient decide not to revise immediately. The patient should then be checked for metal ion levels every 6 months until stable levels are achieved. If metal ions increase to worrisome levels, we advocate revision of the THA bearing. If the patient suffers another dislocation, we recommend revision of the bearing construct.

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The Role of Stem Modularity for THA in a Community Based Practice

Louis Keppler, MD* and Timothy McTighe, Dr. HS (hc)**

Abstract:


Modular Head

Every few years there are concerns raised regarding modular junctions and related findings as to fatigue failure, pseudo tumors, surface corrosion[5,6,7], and metallosis.[1,2,3,4]

This has not been our experience with the use of modular stems. Modular stem means that the stem has two or more parts that are connected by a mechanical junction. Almost all hip stems today feature a modular head, however that does not meet the current definition of a modular stem. This paper is a review of the senior surgeon's practice based in two community hospitals and his experience with four different stem styles and three different modular junctions. The S-Rom® Stem[8,9,10,15], Apex Modular[11] Stem™ , Apex K2 Modular[32] Stem™ and The Apex ARC™ Modular Stem[16].

Since 1986 until May 2012 a total of 1,114 modular stems have been implanted for Primary Total Hip Arthroplasty. To-date there has been no failures of any modular junctions. No fatigue failure, no pseudo tumors, no surface corrosion, no metallosis, etc. We have found the use of stem modularity to be safe and effective in the use in Primary Total Hip Arthroplasty.[14]

Key Words: Modularity, neck, fatigue failure, pseudo tumors, corrosion, metallosis

Introduction:

Modularity or multi-piece stems are becoming commonplace in hip revision surgery[12], with virtually all implant companies offering one version or another. The role of modularity would therefore seem to be firmly established for revision, but what of primary cases?[14]

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

For 26 years the senior author has collaborated with the co-author on proximal modularity in THA. The initial clinical work started in 1986 with the S-Rom® Modular Stem and has progressed over the past twenty six years to include three different stems styles and two different modular junctions: Dual Press[11,32] and Apex ARC™ Neck Stabilized Stem.[16,17]

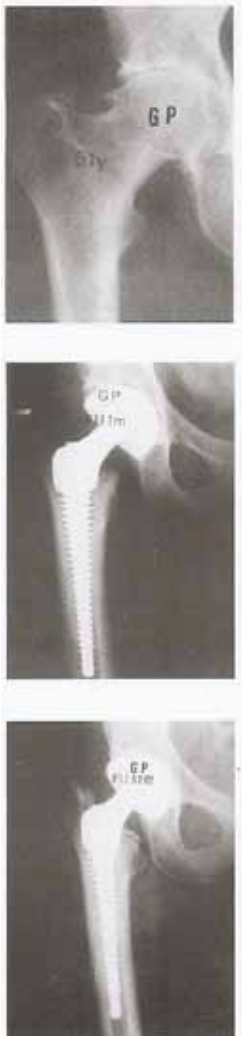

S-Rom® Stem

* Co-Director, The Spine and Orthopedic Institute St. Vincent Charity Medical Center, Cleveland Ohio

** Executive Director, JISRF, Chagrin Falls Ohio

Modular Stem History

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



A screw anchored intramedullary hip stem

1978 Bousquet Design

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

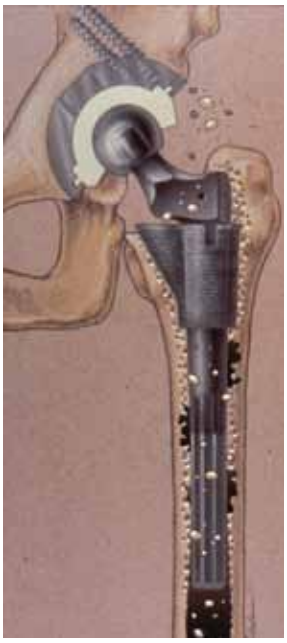
Sivash began development of his prosthesis in 1956 at the Central Institute for Orthopaedics and Traumatology, Moscow, Russia. By 1967 Sivash had selected titanium alloy for the femoral stem and proximal sleeve and chrome cobalt alloy for his socket bearing and femoral head. A major focus was the design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

S-Rom® Evolution

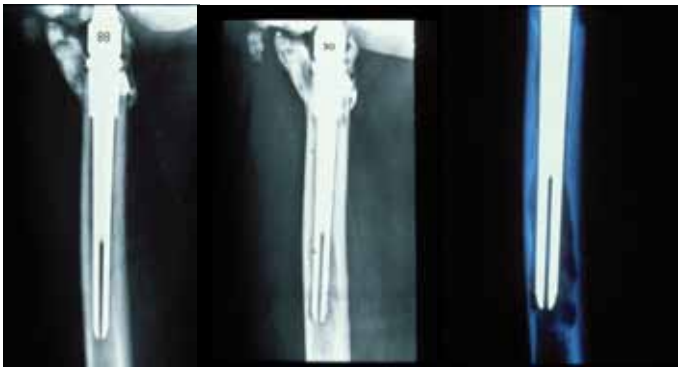
S-Rom is virtually unchanged since 1986

Concerns with the S-Rom® Stem

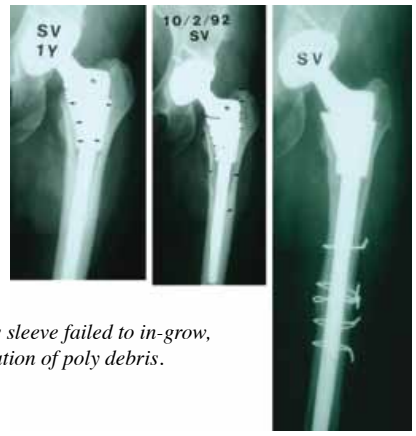
Would modularity (stem-sleeve) produce fretting leading to osteolysis, and/or component failure?



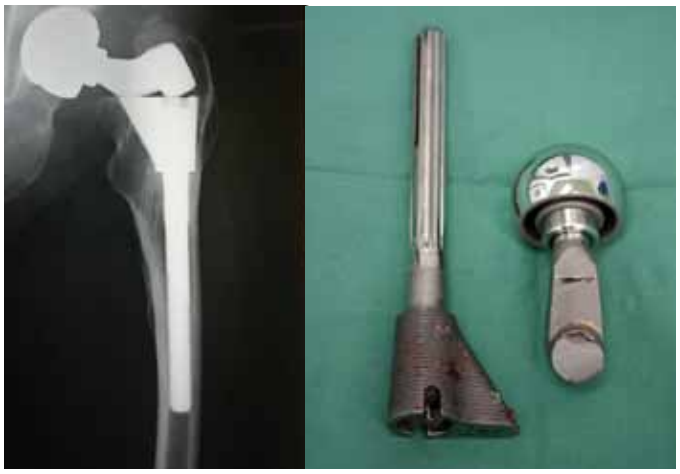
S-Rom Grooved Style had a polished stem with a vertical groove & locking pin. The groove acted as a funnel for migration of poly debris causing distal bone lysis.



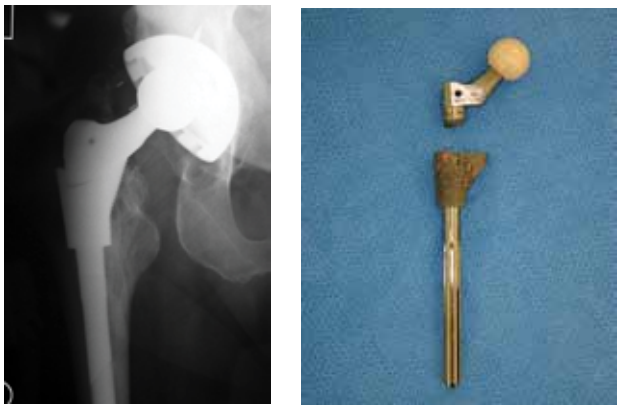
S-Rom grooved style stem progressive osteolysis C. Engh. Groove in the stem allowed migration of debris. Resulting in a stem design change.



Cameron: Porous sleeve failed to in-grow, resulting in migration of poly debris.



Example of a fatigue failure in a young 37 yo male 85kg / failed at 4 years (W. Walter)

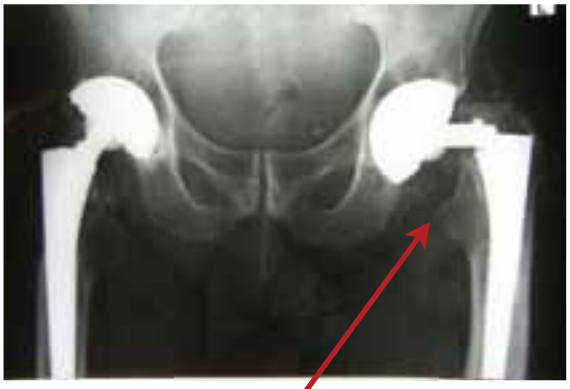


60 yo male failed at 12 years (W. Walter)

There have been a number of reported failures over the years however, the benefits of this stem design has offered significant advantages over the limited reported complications.[1,29,30]

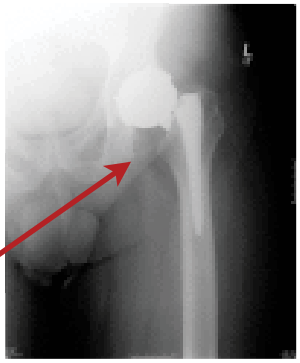
Examples of Modular Site Failures[19,20,21,22,23,24,25,26,27,28,31]

Fatigue Fx. c.c. neck



Surface damage to a head/ neck taper

Fatigue Fx. titanium neck



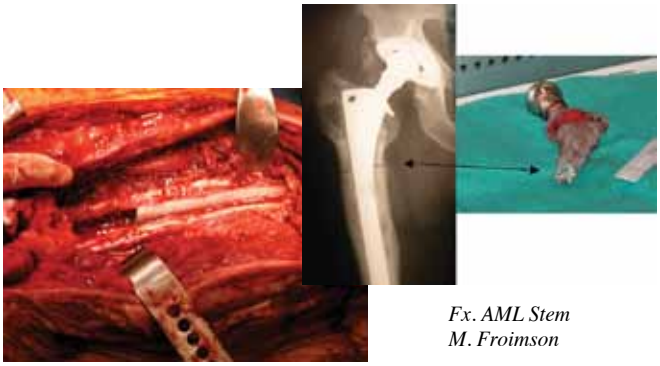
Fx. Profemur Z stem/neck 4 yrs post-op Wright et el.

Fx. de-rotation pin

Many modular stem designs have come and gone.

It is important to understand why some of these designs failed to survive in the market place. All modular junctions are not equal in design and or function.

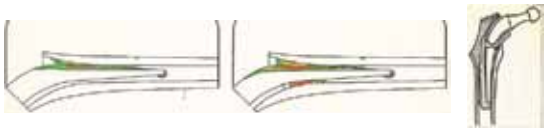
To be fair to modularity, monoblock stems have also met with their own problems.



Fx. AML Stem
M. Froimson

Many stem designs (both modular & monoblock) do not consider removal of a well fixed stem.

Stress patterns as described by Bechtol[13],



Fully Supported Stem / partially supported stem Bechtol described failure mode in the 1970s1

Unsupported stems will fail regardless of fixation, material and/or design.

Modular junctions come in a variety of designs from femoral heads, neck taper sleeves, proximal modular necks, shoulders, metaphyseal sleeves, mid-stem tapers, mid-stem geared non-taper junctions and distal sleeves. Many have adjustable features; anteversion, retroversion at this junction. We continue to have the head-neck adjustment for length and many of these designs incorporate proximal segments with variable "offset" options. While widely used and accepted in the revision stem market, the more extensive modularity is experiencing some problems in the primary market.

The incidence of dislocation of primary hip replacement is quite variable but remains a significant problem. A number of factors have resulted in a decrease risk of dislocation including smaller and improved neck designs, greater head to neck ratio, greater surgical options for leg length, femoral offset, soft tissue solutions such as repairing the capsule and increased popularity of the anterior approach.

Clearly however, implant malposition remains a primary cause of recurrent hip instability.[23]

Materials and Methods

From 1986 to May 2012 a total of 1,114 modular stems have been implanted for primary THA by the senior author.

- S-Rom® Stem (DePuy) = 537
- Apex Modular™ Stem (Omnilife) = 116
- Apex K2 Modular™ Stem (Omnilife) = 341
- Apex ARC™ Stem (Omnilife) = 120

All stems implanted by the same surgeon utilizing the posterior surgical approach. All the femoral stems are manufactured from titanium alloy (ASTM F136).

All acetabular components were cementless porous coated of a variety of designs and bearing surfaces. The acetabular cups in this series is not part of this review process.

Dual Press™ Modular Junction

The femoral neck attaches to the body of the stem through a unique Dual Press™ connection that is simple, robust, and very stable. This modular design allows a large selection of necks, enabling the proper combination of anteversion angle, lateral offset, and neck length/leg length, to restore proper soft tissue tension and joint biomechanics.

S-Rom® Style Taper Design *Dual Press™ Technology*

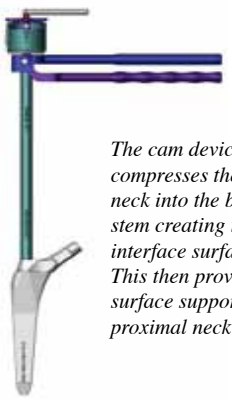
S-Rom style modular junction is that of a taper between the stem body and internal portion of the sleeve.

The Apex Modular™ Stem is the shape of a S-Rom style stem consisting of a circular fluted distal stem with a proximal cone and medial triangle. The difference is in the ability to independently choose stem size, neck offset, version angles, and head size. The Apex Modular™ system allows surgeons to precisely address patient specific anatomical needs to achieve accurate leg length and soft tissue balance with the proximal neck/shoulder modularity. The proximal end of each stem includes an alignment pin that engages with the mating hole on the distal surface of each neck. Neutral necks have a single hole; anteversion necks have two holes for +/- 13° . This ability to adjust neck orientation eliminates the need for separate left and right stems, thus reducing inventory requirements, while enabling better restoration of joint biomechanics. The pin and hole also provide additional torsional stability, as well as control of the version angle.

Proximal Modular Dual Press ™ Necks

APEX K2 Modular™ Hip System

The K2 stem builds on the philosophy of a dual-tapered trapezoidal stem geometry that facilitates primary fixation and rotational stability. A straight forward and efficient broach-only surgical technique is intended to preserve endosteal bone and intramedullary vascularization.



The cam device compresses the proximal neck into the body of the stem creating two bands of interface surface contact. This then provides optimal surface support for the proximal neck.

The Apex ARC™ Stem is licensed technology from Concept Design & Development™ , LLC, Chagrin Falls, Ohio.

The ARC™ Neck Sparing Implant saves bone in Gruen zones 1,3,4,5 & 7

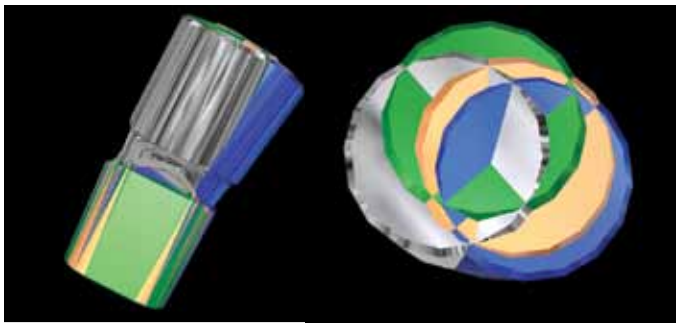
The Apex ARC hip system provides surgeons with the bone and soft tissue conserving benefits without the disadvantages of hip resurfacing, or metal-on-metal articulation, or a steep learning curve, or limited indications.

This stem can utilize any standard surgical approach including the direct single anterior incision or MIS approach.

The modular neck junction is a standard 12/14 Euro taper (ASTM standard for the Cone is size N listed as 5º 40', +2.5' -0' or 5º 40 minutes + 2.5 minutes, -0 minutes.) So the surgeon can choose the bearing material best suited for the individual patient.

Note: Not all 12/14 tapers are equal (variants do exist) companies cannot recommend mixing and matching of different companies product. If you mix and match (off label use) make sure head / neck tapers are compatible.

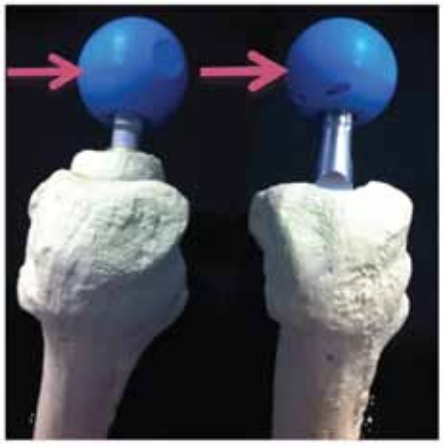
Note: The simplest way to look at compatibility is to ask does the company use ASTM standard for size N taper?



The modular necks are available in neutral standard, long, 8º varus/valgus standard, 8º varus/valgus long, 12º varus/valgus, & 12º anteverted/retroverted.

The design of the Apex ARC hip stem requires less bone to be removed during surgery, provides the opportunity for surgeons to dissect fewer soft tissues, and loads the proximal femur in such as a way as to provide an environment where bone could be preserved over time.

Neck Sparing *Conventional*



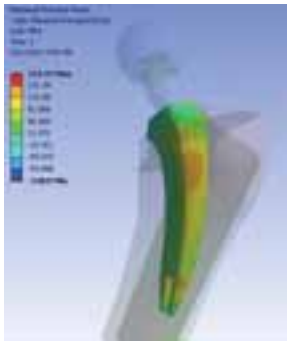
Neck sparing resection. *Conventional neck resection.*

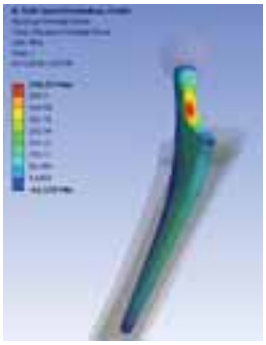
Both Bending & Torsional Moments are reduce with neck sparing vs. conventional resection.

Finite Element Analysis comparing the TSI™ neck sparing design to a Taperlock style stem demonstrated the maximum principal tensile stress in the neck stabilization stem was 35% less than that of the monoblock Taperlock style design.[33]

TSI™ (Apex ARC™) Stem

Taperlock Style Stem





FEA results

Results

S-Rom

- Modular junction failures = 0
- Dislocations = 6 total (3 closed reductions, 3 open constrained sockets)

Stem Revisions

- 4 total (0 for aseptic loosening, 4 late sepsis)

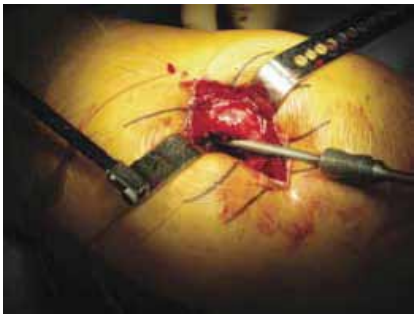
Painful Hip

- 5 pts: Required on-lay grafting for significant progressive end of stem pain.

Painful S-Rom stem required on-lay strut grafting

Apex Modular & Apex K2 Stem

- Modular junction failures = 0
- Dislocations = 3 (Two patients with MoM bearings have had cup revision due to cup spin out. One patient was one (1) year out with an ASR metal acetabular component. Patient presented with increasing groin and buttock pain. X-rays demonstrated that original cup position had changed and did not appear to be ingrown. The proximal modular junction of the K2 stem was disengaged allowing access to the socket. K2 removal instruments provide ease of removal of proximal modular body making cup revision significantly easier with less bone destruction.



K2 Dual Press removal instrument

The Explant cup removal system (Zimmer) was used making removal with minimal bone loss possible.

Explanted cup

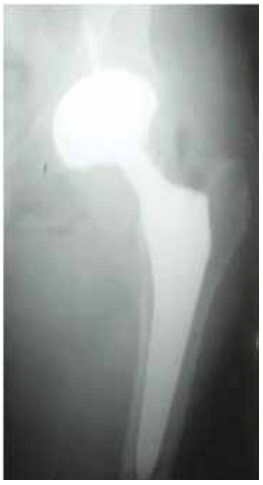
A cementless porous component with adjunct screw and poly bearing was then inserted.

Second patient was female that presented a spun out MoM (Wright Medical) acetabular bearing component at her first post-op visit at seven (7) weeks. Since intra-operative x-rays are taken on all patients it is assumed that cup slippage accrued during the early post-op period and then stabilized. Again the proximal modular junction was disengaged and cup removed with Explant system.

MoM cup spinout

A new proximal modular neck and head were implanted with a cementless porous cup with one (1) screw for adjunct fixation.

One additional patient had multiple dislocations and was revised by disengagement of the proximal modular junction and exchanged with an increased femoral offset and anterverted modular neck.



Revised with new cup & neck neck

- Leg/length discrepancy +/- 7mm = 0
- Aseptic loosening = 0
- Stem Revisions = 0
- Modular neck exchanges = 3

The third neck exchange was for a patient that had a 36 mm metal on poly bearing that met with multiple dislocations. Patient was treated with proximal neck exchanged to an increased femoral offset and anteverted position.

The Apex ARC™ Neck Sparing Stem

- Modular junction failures = 0
- Stem revisions = 2

One stem removed for sepsis.

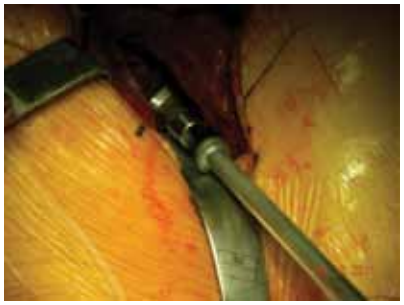
One removed for traumatic dislocation, converted to an Apex Modular Primary stem.

Explanted Stem

- Neck exchanges = 2

Female with a posterior dislocation poly exchanged from neutral liner to a 15º and an increase in 3.5 mm vertical height neck position into max 12º varus position.

Note: At the time of surgery a large soft tissue mass was found anteriorly and was thought to be associated with bowstringing of the anterior superior capsule as an unusual consequence of the posterior capsular repair.



The second case removed the neck for access to the socket (cup & poly replaced along with a new neck).

Poly Exchange

Stryker

Omnilife

Both cases had reduced operating room time since the modular junctions functioned as designed. Proximal modularity allows access for revisions situations reducing overall complications associated with stem removal and increased operating time.

Explanted head, neck & poly

- Intraoperative calcar cracks = 2

Small chip fractures not treated.

- Intraoperative calcar cracks resulting in stem bail out = 2

Both occurred in small female patients where the size 1 stem was too large. Both revisions were converted to primary Apex Modular stem. Since the introduction of the size 0 stem we have not had to bail out of any routine primary cases.

- Aseptic Loosening = 0
- Leg Length Discrepancy +/- 7mm = 0
- Subsidence >5mm = 0

Currently the short curved ARC™ Neck Sparing Stem is used as my primary total hip stem in all Dorr bone classifications (A, B, & C). Patient range from mid twenties to mid eighties.

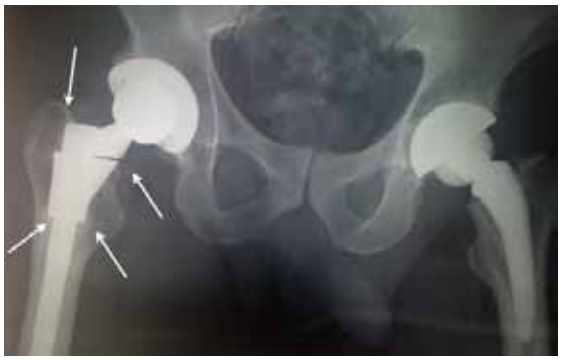
In the smaller female patient, if we cannot get to a 32mm head diameter we will use a Dual Mobile Style Cup. We have used two different styles: One an anatomical style by Stryker and a hemispherical style by Omnilife.

The introduction of the smaller size 0 stem has eliminated the risk of trying to overstuff a size 1 stem into a smaller femoral neck. Overall size is reduced along with elimination of the lateral T-Back.

ARC™ Stem Size 1 vs. 0

The Anteverted / Retroverted (12º) neck has been added to aid in addressing combined version angles and reduces potential mechanical impingement issues.

Modular necks available in different orientations: Neutral, regular & long, 8º varus / valgus regular & long, 12º varus / valgus & 12º anteverted / retroverted



1986 S-Rom 2010 ARC™ Stem

Observations & Summary

In over 1,114 primary cementless total hip arthroplasties performed by the same surgeon in two community hospitals over 26 years, there has never been a related modular junction failure. There have been no signs of pseudo tumors, surface corrosion, metallosis, etc.

I still use the S-Rom® stem for CDH and revision surgery. In Dorr type A Bone, I will select the Apex Modular™ stem. In type C Bone, if I don't believe I can get a solid lock in the neck, I will use the K2 Trapezoid Modular Stem. For all my routine OA cases I am using the Apex ARC™ Short Curved Neck Sparing Stem.

It is not unusual for me to use two or three different modular stems in any given surgical day.

I have met with problems with bearing materials, acetabular components and periprosthetic fractures. However, when it comes to modularity, I have been very selective on the modular junctions that I have used and have found them to be of significant advantage in my clinical / surgical practice. I take intraoperative x-rays on every case and alter my selection of components on average 70% of the time.

All modular junctions are not equal in design and performance. It is critical to understand the design limitations and required surgical techniques to ensure proper performance of modular total hip arthroplasty.

The newer short curved neck sparing stem design has reduced my O.R. time by 15-20 minutes by use of the femur first surgical technique. There appears to be less blood loss and patients are back to full activities quicker.

The advancements of modularity has proven to be beneficial to my practice.

I am aware of the concerns regarding modular junctions and will continue to monitor my patients and report on my experience every few years.

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Clinical Assessment of Proximal Tibial Morphology at Total Knee Arthroplasty

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Abstract:

Introduction

In light of increasing patient demands and expectations in TKA, a detailed understanding of bone morphology may be the key to optimizing tibial component performance. Current tibial components in TKA fail to reproduce native human geometry. Accurate measurements and ratios of proximal tibia dimensions are important as components move towards more anatomic designs.

Methods

A consecutive series of TKAs were performed at one center. Proximal tibial measurements were obtained following proximal tibial resection at the time of TKA. These were compared with demographic parameters including height, weight, and gender.

Results

145 consecutive primary TKAs (21 bilateral) in 124 patients (85 females, 60 males) were analyzed for this study. Statistical analysis revealed multiple correlations and trends. The tibial dimensions increase linearly in males and females as tibial component size increases. The AP/ML ratio (aspect ratio) of the proximal tibia is fairly constant over the range of bone sizes for both males and females. There is no correlation between aspect ratio and tibial size, nor are there statistical differences between the aspect ratios in males and females. Tibial measurements and component size are positively correlated with both patient height and weight for males and females, although a stronger correlation exists for male patients. On average, the asymmetry between the lateral and medial condyles increases as a function of tibial size. This asymmetry increases more dramatically in males than females.

Conclusions

These important clinical observations of tibial morphology can be used in designing component lines that more closely resemble native human anatomy, possibly improving performance.

Summary Sentence

Proximal tibial morphological measurements and ratios provide the design rationale for advanced, conforming components, possibly improving implant positioning, performance and longevity.

Introduction:

Total knee arthroplasty (TKA) is one of the most successful and cost effective[6] procedures in orthopedics. Despite significant clinical improvements in the majority of patients, there remain a minority who are not as pleased with the function of their knee. Multiple factors have converged to create a new patient population with altered expectations and demands of their knee replacements. Patients are undergoing surgery at a younger age, are pursuing physical activity following reconstruction, and are living longer. This shift has prompted the Knee Society to seek a newer and more sensitive score to assess

Investigations performed at the Insall Scott Kelly® Institute New York, New York

the important clinical and functional parameters in the modern TKA patient[9,10].

Knee replacements themselves have also undergone significant changes over the years, though somewhat lagging, and often responding to, specific functional concerns in patients. Early designs featured few sizes which were neither modular, nor side specific. Multiple iterations have subsequently been used, with recent modifications including: higher flexion prostheses[11], gender specific designs[12], improved wear characteristics, and side specific tibial baseplates.

Interestingly, the anatomic bases for these recent changes have long been understood. A morphologic study in 1975 by Mensch and Amstutz[1] analyzed the dimensions of the knee in cadavers and radiographs. They reported gender differences, and asymmetries that were only much later incorporated into designs.

Renewed interest in anthropomorphic measurements has resulted in clinical[2,4,8], and image[3,4,5,7] based assessments of dimensions about the knee. These have focused on American[2,8], Indian[3], Japanese[4], European[5], and Korean[7] populations. Our study sought to closely examine one specific aspect of the knee in greater detail to determine whether specific trends occurred in tibial anatomy that could be used to better design a conforming tibial baseplate at the time of TKA.

Materials and Methods:

Institutional review board approval was obtained for this study.

A clinical study involving measurements of the proximal tibial cut surface following proximal tibial resection, but prior to prosthesis implantation was performed in a consecutive series of TKAs performed by one of four surgeons (GRS, WNS, FDC, MAK). In all cases, measurements were made with a metal ruler with millimeter increments, and recorded at the time of the procedure (Figure 1).

145 consecutive primary total knee arthroplasties (85 female knees, 60 male knees) in 124 patients were analyzed for this study. Height weight and BMI were recorded for all patients pre-operatively. Twenty one patients underwent sequential bilateral total knee arthroplasty during the same operative setting. Patients were excluded if they had prior bony surgery (osteotomy or peri-articular fracture fixation), significant deformity (>15° valgus or varus), or if there was bone loss requiring augmentation.

The surgeons performed the index procedure with a similar technique, the proximal tibia was resected with an extra-medullary tibial cutting guide, and proximal tibial measurements were taken using a standardized protocol. Anterior-posterior (AP) and the medio-lateral (ML) dimension were then taken following proximal tibial resection of approximately 2mm from the lower side at the time of a perpendicular proximal tibial cut with an extra-medullary cut guide. All measurements were rounded to the closest mm after removal of osteophytes. The overall ML width of the tibia and the AP depth of the medial and lateral plateaus were recorded.

The aspect ratio (AR) of the, tibia (ML/AP) was analyzed using all recorded measurements. Measurements were taken by the same investigator (VD). Statistical analysis was performed using Minitab Statistical Software (version 14, Madison, WI). Measurements which followed the normal

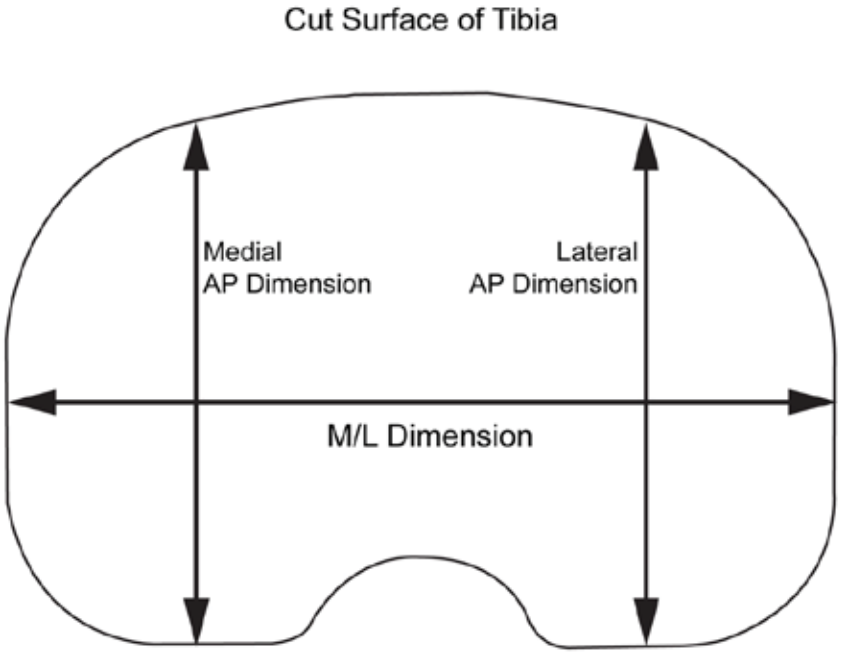

Figure 1: Tibial Measurements

Gaussian shaped curve were analyzed using ANOVA. Those measurements which did not follow the normal curve were analyzed using a non-parametric test, Mann-Whitney U test.

Results:

The mean age for women was 65 years (range 38 to 94) and 63 years (range 40 to 78) for men. The mean AR of the tibia using the medial plateau was 1.51 for men and 1.51 for women ($p > 0.05$). The mean AR of the tibia using the lateral plateau was 1.62 for men and 1.67 for women ($p < 0.05$) There was no significant difference when using the medial plateau between gender, however, when using the lateral plateau there was a statistically significant difference between gender (Figure 2).

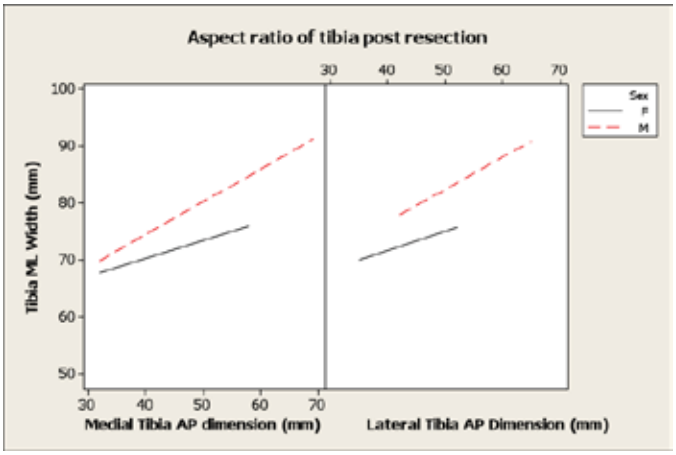

Figure 2: The left panel shows the gender difference using the AR of the tibia using the medial plateau ($p > 0.05$) and on the right the lateral tibial plateau ($p < 0.05$)

Statistical analysis revealed multiple correlations and trends. The tibial dimensions increase linearly in males and females as tibial component size increases. The AP/ML ratio (aspect ratio) of the proximal tibia is fairly constant over the range of bone sizes for both males and females. There is no correlation between aspect ratio and tibial size, nor are there statistical differences between the aspect ratios in males and females. Tibial measurements and component size are positively correlated with both patient height and weight for males and females, although a stronger correlation exists for male patients. On average, the asymmetry between the lateral and medial condyles increases as a function of tibial size. This asymmetry increases more dramatically in males than females.

Discussion:

Previous studies have analyzed the anthropometric measurements of the proximal tibia[1,5,7,8]. In our study, the tibia did not show a difference in AR between men and women when using the medial plateau and a slight difference when using the lateral plateau with women increasing width faster than men.

Tibial component alignment has traditionally been based on fixed anatomic landmarks such as the medial third of the tibial tubercle, though anatomic variations exist leading to mal-rotation if this is the only guide used[15,16]. Unfortunately, a symmetric tibial baseplate forces the surgeon to compromise between bone coverage and appropriate rotation on an asymmetric tibial plateau. TKA performance has been demonstrated to improve with well-aligned prostheses[14] and early failures are associated with mal-rotation[17]. Tibial baseplates that better match the proximal tibial geometry may allow surgeons to better align the prosthesis through a range of sizes and morphologies.

The important clinical observations of tibial morphology that we have made can be incorporated in designing component lines that more closely resemble native human anatomy. The engineering goal is to improve motion characteristics[13] and clinical performance of TKAs. Proximal tibial morphological measurements and ratios provide the design rationale for advanced, conforming components, possibly improving performance and longevity. An anatomically shaped asymmetric tibial component offers the opportunity to maximize bone coverage and assure accurate rotational position.

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Total Hip Arthroplasty for 'Dysplasia' and Congenital Disease of the Hip

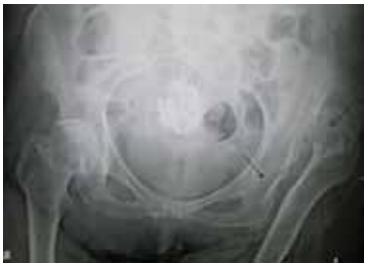
-Review Paper-

Evert J. Smith, MD*; Timothy McTighe, Dr. HS (hc)**

Introduction:

Total Hip Arthroplasty for dysplasia or congenital disease of the hip is technically demanding surgery that requires an in-depth understanding of the complex techniques required to solve the problems of both the pelvis and the femur. It also requires the ability to perform an experienced evaluation of the patient. The 'high dislocation' is the extreme example in this range of surgery. Patients are often young or middle aged; their hip pain and functional disability has so adversely affected their quality of life, they are more often than not keen for surgical intervention.

A careful consent pertaining to specific complications related to each individual patient's pathology is essential, as the surgical solution is not likely to rest with a total hip arthroplasty alone. In the majority of cases, there is often a requirement for treatment of the knees and the thoracolumbar spine as well. Emphasis should be directed toward nerve palsies and the fact that, in the majority of cases, revision surgery will be required.



CDH of the left hip in an elderly person

Terminology:

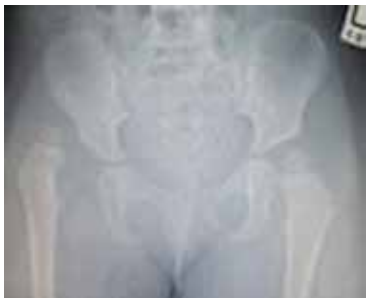
The term *'developmental dysplasia of the hip'* does not describe the congenital origin of the deformity; nor does the term *'dysplasia'* describe the variation of the underlying pathology.

Dupuytren observed newborn infants with displacement of the femoral head from the acetabulum and named this condition *'congenital displacement'*.[1] In 1891, Phelps concluded that the majority of such cases are really dislocations in utero or at birth.[2] Anatomy publications and the findings at operation have confirmed the congenital nature of the deformity (Dunn 1976, Howorth 1947, Massie 1958, Massie and Howorth 1951, Ortorlani 1976).[3,4,5,6,7]

Klisic (1989) argued that the term referred to, up until this time, as *'congenital dislocation of the hip'*, was misleading due to variable pathology.[8]

A dislocation is not always present.

Often when dislocation does occur it is in the postnatal period and is therefore not truly congenital. He recommended the term 'developmental displacement' and over time this title



X-Ray Image Showing Hip Dysplasia in an Infant

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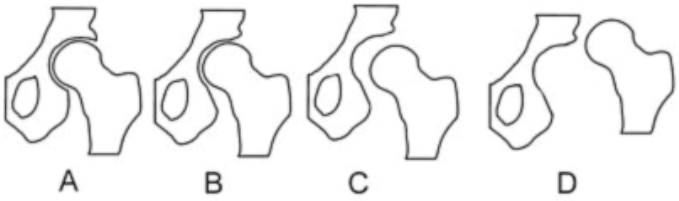
or description became altered to *'developmental dysplasia'*.

The term *'dysplasia'* is composed of the Greek words *dt1* (bad) and *pka9rg* (formation). Thus, *'dysplasia'* could be used for the total spectrum of hip deformities. But, to avoid confusion and diagnostic inaccuracies, it is preferable for the term to be reserved for the milder types of hip deformities. Terminology covering the entire pathology of congenital deformities of the hip (or a generally accepted classification of its types), which will improve our communication, treatment planning, and evaluation of results of treatment, is often inaccurate.



Types of misalignments of femoral head to the socket in hip dysplasia [9]
A: Normal B: Dysplasia C: Subluxation D: Luxation

Gaston et al in 2009 published a reliability study arguing that in their opinion the Crowe and Hartofilakidis classifications did not predict the surgical difficulties they encountered when performing surgery on this group of patients. Their classification describes the femur and the acetabulum separately. The acetabulum is divided into: AI - the dysplastic acetabulum. AII - the acetabulum associated with low femoral dislocation. AIIIa - the post-surgical acetabulum with metalwork. AIIIb - without metalwork in-situ.[10]

The femur is classified as: F1 - dysplastic but contained within a true or low acetabulum. FII - the high femur. FIIIa - the post-surgical femur with metalwork. FIIIb - the post-surgical femur without metalwork in-situ. This classification emphasises the surgery that may be required on the femur and reminds the surgeon of previous surgery to both the pelvis and the femur. It showed inter- and intra- observer reliability, comparable to that of the Crowe and Hartofilakidis classification. It should be emphasised that the more severe the anatomical derangement, the less chance of long term survival of the total hip arthroplasty (Chougle et al 2005, Hartofilakidis et al 2004).[12,13]

Type	Proximal Displacement	Femoral Head Subluxation
Crowe I	<10%	>50%
Crowe II	10-15%	50-75%
Crowe III	15-20%	75-100%
Crowe IV	>20%	>100%

Crowe Classification [11]

Despite the various classifications used in different orthopaedic centres, the outcome is ultimately dependent on the experience and skill of the surgeon performing surgery on dysplasia and congenital dislocation of the hip. Clearly the surgeon must take into account all the anatomical distortions of the pelvis and femur, as well as the derangement and alteration of the surrounding soft tissue. In the more severe cases it is important to perform 3D CT scans to aid one in the algorithmic approach to the management of these patients.

Studies:

In cemented total hip arthroplasty (THA), a number of studies have postulated that a high hip centre or a lateralised centre of rotation (COR) adversely affects the longevity of cups in normal (Hirakawa et al 2001, Pagnano et al 1996)[14,15] and dysplastic hips (Iida et al 2000, Hartofilakidis et al 1996, Stans et al 1998).[16,17,18] In one study, shifting the COR more than 5mm superiorly or laterally accelerated aseptic loosening of the stem and peri-acetabular osteolysis (Hartofilakidis et al 1996).[17]

In another publication, lateralisation of the COR was the most significant factor associated with radiographic signs of loosening (Karachalios et al 1993).[19] Similarly, with cementless cups, it has been reported that shifting the COR superiorly or laterally was the most important variable associated with aseptic loosening in DDH (Georgiades et al 2010).[20]

A long-term study of cemented THAs with a mean follow-up of 12.3 years (8 to 24 years) showed a 96% survival of the acetabular component at 15 years, with revision for aseptic loosening. Survivorship of 75% was noted when radiological loosening was used. Risk factors for loosening were identified as trochanteric non-union, lateral placement

of the socket and delayed trabecular reorientation of the bone graft (Iida et al 2000).[20]

Fractured stem

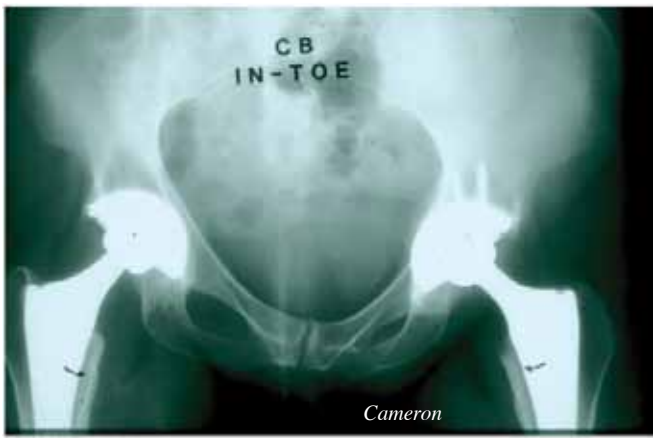
Cameron and McTighe reported on 262 CDH cases from 2-18 year results at the Combined Scientific Meeting for the AOA and NZOA in 2006 and demonstrated that cement in the femoral canal does poorly when the stem is small interfacing with a thin cement mantle. Often you are required to ream heavily to get a cemented stem in, so most of the cancellous bone is gone resulting in a poor cement interlock.[22]

The capacity to alter version is very limited in small canals. In CDH cases a large amount of anteversion may have to be accepted which can result in a post-operative toe-in gait. This condition can lead to frequent falls.

In 2009, a report from the University of Athens Medical School, on a cohort of patients with DDH using cemented THAs, with a minimum 22-year follow-up, documented that 37 (44%) of 84 hips had failed. In 32 hips, 28 acetabular and 30 femoral components were revised because of aseptic loosening; 6 of the loose femoral components were broken. Three hips were infected and converted to a resection arthroplasty, while periprosthetic femoral fractures occurred in two additional hips (Georgiades et al 2009).[22]

Distal stem fixation can also result in a cantilever effect resulting in stem failure.

Proximal load transfer will reduce this cantilever effect.



Cameron

Intermediate follow-up studies using hybrid THAs have reported good results at an average follow up of 10.6 years. Structural allograft was used in 15 of the 100 hips in their cohort of patients. Revisions were performed in 2 hips due to recurrent dislocation. The Kaplan-Meier survivorship analysis, with failure defined as revision surgery, demonstrated that the probability of retention of the acetabular component 15 years after surgery was 98% and that of the femoral component was 100% (Ito et al 2003).[23]

In a study of 56 THAs in patients with DDH, using cementless Harris-Galante type-I cups with structural grafting and cemented stems, the authors reported on 53 of the surviving patients. After an average duration of 10.2 ± 2.9 years, 4 implants had been revised and 2 had radiographic evidence of loosening. Using revision and loosening as end points, the 11-year survival rates were 91.6% and 88.9%, respectively. Of the 50 implants that had no loosening, 14 had measurable cup migration, 35 had no migration, and 1 implant could not be measured. All migrations except one were progressive. With loosening used as the end point, the survival rate at 11 years was 100% for the implants with no migration; however, the survival rate for the cups that had migrated was 69.3% (Hendrich et al 2006).[24]

In another study of 35 patients with a follow-up of 7.5 years (range 5 - 12.3 years), a cementless porous-coated titanium cup fixed with screws and autogenous bulk femoral head graft was used. The survival of the acetabular component at 7 years was 92.6% with revision for aseptic loosening. Forty-one of the 44 femoral stems were cementless - 7.4% were revised; 2 hips for severe polyethylene wear and osteolysis, 1 for aseptic loosening and 1 for breakage of the acetabular shell (Spangehl et al 2001).[25]

In a publication where the follow-up was short (3 to 5 years), the authors used a cementless stem, specifically designed for use in DDH patients. The straight titanium alloy stem had a collar and a wedge shape of 3 degrees. The proximal third was porous-coated, and oval on section. The neck angle was 135 degrees and the offset of the stem varied from 31 to 39 mm. Loosening of the femoral stem occurred in 4 hips, 3 of which resulted from the same technical error. The greater trochanter had been detached so far distally, that the lateral support of the stem was insufficient to provide reliable rotational stability. The fourth loosened stem was small and lacked rotational stability. A 50% failure was documented with their smooth-threaded cup (Paavilainen et al 1993).[26]

In another study, 80 hips with severe acetabular dysplasia (Crowe grades III and IV) were reviewed. In 32 hips, over 20% of the cup was not covered by the acetabulum and was reconstructed with a femoral head graft. In the second sub-group of 48 hips, graft was not used as the socket was adequately covered. The mean follow-up period was around 9 years (range 3–18 years). Early complications were frequent (19%). Early cup loosening was more frequent in adequately covered sockets. Acetabular cup loosening did not correlate with acetabular cup position. Bone-graft appeared consolidated in all cases, but resorption areas were frequently observed. In 78 hips with follow-up, grafted hips showed good results in 69.6% after 16 years, compared with those hips with bone coverage (52.2%). However, there was no significant difference between the groups (Garcia-Cimbrelo and Munuera 1993).[27]

Deviation from the optimal COR when positioning the cup will adversely influence hip loads, bearing surface wear and ultimately implant survival (Bicanic et al 2009, Denham 1959, Johnston et al 1979).[28,29,30] Increasing the femoral neck length and lateral offset appear beneficial in reducing hip load (Johnston et al 1979).[31]

The Pelvis

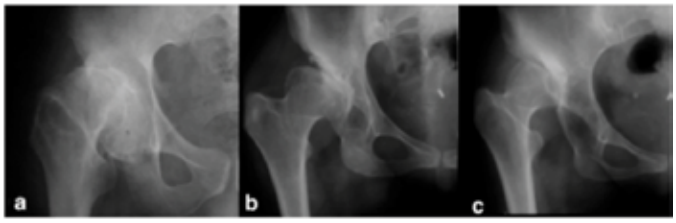
At one end of the spectrum of DDH the socket may be slightly shallow, the centre edge angle of Wiberg is decreased and the extrusion index is increased (Wiberg 1939).[32] The angle of Sharp is altered and as the dysplasia becomes more pronounced, the acetabulum becomes shallower, sloped and less hemispherical (Sharp 1961).[33] In lower dislocations, the diameter of the acetabular socket is increased from superior to inferior and the medial wall of the acetabulum becomes redundant. In high dislocations, the acetabular socket is false. The anteversion of the socket increases and the original foetal socket is rudimentary, reduced in size from lateral to medial and filled with fatty fibrous tissue. By this stage the anterior wall is thinned, porotic and is often residual.

In a false acetabulum, the lever arm for body weight is much longer than the abductors, leading to excessive load. The shearing forces acting on the acetabular cup may lead to early loosening. Abductor insufficiency, leg length discrepancy and limp are reduced when the true or anatomical socket is used (Karachalios et al 1993).[34]

The strongest and most viable bone for use is at the original socket. I always try and restore the true centre of rotation in the original socket. The involved hemi-pelvis is usually smaller than the contralateral hemi-pelvis. However, one is always able to find the true floor by identifying the fatty tissue at the base of the socket. The transverse ligament and the inferior border of the true acetabulum are key landmarks.

Several acetabular socket reconstruction techniques, aimed at improving osseous coverage and support for cemented or cementless cups, have been reported. These include: augmentation of the superolateral margin of the acetabular rim with bulk autograft (Harris et al 1977);[35] superior positioning of the acetabular cup to create a high hip centre (Russotti et al 1991);[36] medialization of the hip centre by the cotyloplasty technique (Dunn and Hess 1976, Hartofilakidis et al 1996)[37,38] or the protrusion socket technique (Dorr et al 1999);[39] impaction grafting (Somford et al 2008);[40] additional use of a reinforcement ring (Gill T et al 1998);[41] or using small diameter cementless or cemented cups alone (Jasty et al 1995).[42] Various methods of acetabular cup fixation are used to optimize the outcome and long-term survival in patients with a ‘high dislocation’.

Hartofilakidis Classification[43] System
Type A- Dysplasia
Type B-Low Dislocation
Type C- High Dislocation



Type A *Type B* *Type C*

A - The femoral head is contained within the original acetabulum.

B - The femoral Head articulates with a false acetabulum that partially covers the true acetabulum.

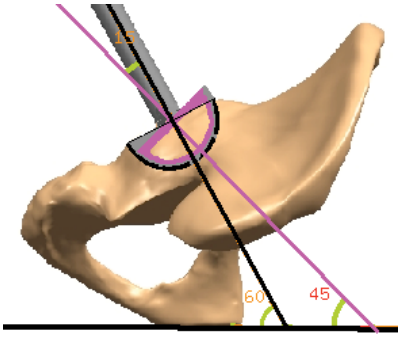
C - The femoral head is migrated superiorly and posteriorly to the hypolastic true acetabulum.

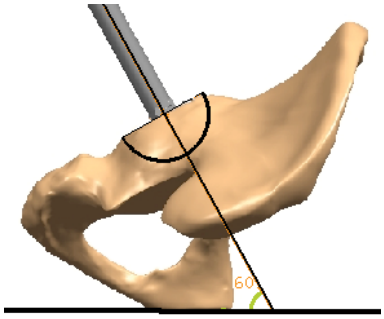
In the dysplastic hip and in patients with a 'low dislocation', we use the Exceed ABT 15° Face Changing cup (15°FC) (Biomet UK).

The design modifications of the Exceed ABT 15° face changing acetabular cup will alter the surgical strategy and treatment of secondary osteoarthritis in patients with shallow acetabular sockets in the future.

The unique design feature of this acetabular cup adjusts the bearing surface, closing the inclination angle by 15° and allows for optimisation of the ceramic liner which is a significant advantage in this group of patients.

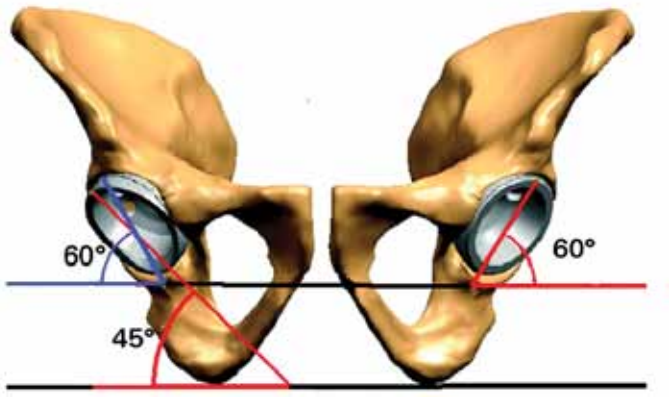
The standard 'directional' reaming technique is modified to perform progressive reaming with the face of the reamer directed parallel to the face of the dysplastic socket (not at 40° abduction or inclination). Typically, when completed, the rim of the final reamer is flush to the acetabular rim, aligned at 50-60° inclination and 15-20° anteversion.





60º inclination & 15-20º anteversion

The 15°FC hemispherical porous coated cementless shell is introduced in the same axis as the reamer (introducer at 50-60° abduction and 15-20° anteversion) to ensure the cup's liner is in the optimal position of 35-45° inclination and 15-20° anteversion (inclination 15° less than the hemispherical shell and introducer) with the porous coated surface of the cup achieving full coverage and host bone contact.



Left: diagram showing the 15° face-changing cup in the optimal position, with a cover angle with the liner of 60° (in blue), and a face-changing angle with the liner of 45° (in red). Right: diagram showing a 'standard' component incorrectly positioned at a high inclined angle of 60° to obtain full contact with host bone.

The cup may require supplementary screws for fixation of the shell, after removal of the blanks from the chosen screw holes, followed by insertion of the appropriate size ceramic liner.

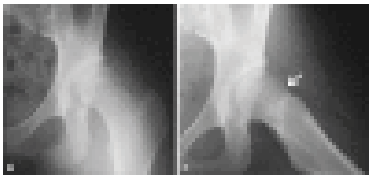
The appropriate positioning of the acetabular implant and alignment of the bearing surface can be reliably achieved with the 15°FC cup in 'dysplasia' and 'low dislocation' DDH. Furthermore, the 15°FC cup eliminates the need for acetabular augmentation with femoral head autograft or bulk allograft, the use of which has been associated with reduced THA

survival (Mulroy et al 1990, Shinar et al 1997).[44,45]

Inclination higher than 45° is associated with a higher rate of wear, irrespective of the type of bearing surface.

The Femur

In general, there is an increased caput collum diaphysis (CCD) angle and obvious coxa valga in the 'dislocated hip'. The proximal femur is anteverted and the greater trochanter is positioned posteriorly. The femoral head is small and the femoral neck is foreshortened and mildly anteverted. In the metaphysis and proximal diaphysis there is a reduction in size.



Small femoral head with shortened neck and mildly anteverted.

The distortion of the anatomy is more often than not associated with abductor deficiency and a leg length discrepancy; the leg is foreshortened, as well as being reduced in size. In 'high dislocation' the abductor function is nonexistent, accounting for the waddling gait. There is often associated thoracolumbar curvature in relation to the leg length discrepancy. It is therefore not uncommon that this group of patients present with lower back pain.

Operation

All cases are performed with a modified Kocher Langenbeck approach. The pelvic bone is marked by a pin in the iliac crest and osteotomy notches are made in the metaphysis and in the diaphysis, at marked points on the bone cortex, to increase the accuracy of bone resection. Care must be taken to minimise periosteal stripping.

The tension on the sciatic nerve with leg lengthening is critical. The sciatic nerve is always identified through the posterior approach and the tension of the nerve palpated at the beginning of the operation. The tactile feel of the tethering and tightness of a 'guitar wire' feel in the nerve should be noted as the leg is lengthened. An iliopsoas release and partial abductor release is nearly always required in the more complex hip. A subcutaneous adductor tenotomy can be performed if this is restrictive.

When performing surgery on the acetabulum with the 15°FC cup it is not necessary to perform graft fixation. If the socket is too small to utilise the face changing method, then alternative acetabular cups are utilised and block graft from the femoral head is fixed with K wires and reamed to allow optimum positioning of the cup followed by definitive fixation of the graft with screws.

If the bone is osteoporotic and weak, it may require seating of the acetabular component deep to the floor. The central part of the floor can be incised to allow the dome of the cup to breach the socket floor. Impaction bone grafting is used and placed in the true floor and milled bone chips are used liberally in the socket as required.

In 'high dislocations', a trochanteric osteotomy is performed as this allows access to the socket, not only for preparation of the socket, but it also allows a clear run at further resection around the proximal femur and for trialing of the stems available for the procedure.

Distal advancement of the trochanter is required, with fixation of the greater trochanter, using an impaction mesh and wires and/or screws, or screws and a plate. A low profile trochanteric grip and plates with cables can simplify the technique in some cases.

Fixation of the trochanter is performed with the hip in extreme abduction. The anterior portion of vastus lateralis may require release. Central tightness of the gluteus medius may also require partial release in order to distalise the trochanter far enough to stabilise it onto the proximal femur.

Placing the stem through the proximal femur and then moving the femur from an abducted position into an adducted position allows the surgeon to visually estimate if further excision of the femur is required. This should be performed in a step-wise manner until reduction of the head in the socket is possible (Masonis et al 2003, Park et al 2007, Crych et al 2009).[46,47,48]

Using these techniques, and by careful surgery, the leg can be lengthened up to 2-3 centimetres in some hips. Collarless straight stems with a varus neck shaft angle, long stems or customised stems, can be used when standard stems do not allow insertion into the femoral canal.

The intramedullary canal may require reaming to widen it in order to achieve fixation of the femoral stem. Given the type and style of stem, an osteotomy to split the femur longitudinally may also be required. If the cementless stem has distal grip and rotational control, then cortical fixation of the femur may not be required.

The wound is closed in sequential layers, more often than not without a wound drain.

Rehabilitation

The patient is usually mobilised full weight bearing on day one or two following check radiographs. All patients require physiotherapy to gently stretch the abductor musculature. Patients with osteotomised femurs are mobilised partial weight bearing, steadily increasing the range of hip movement in flexion, extension, abduction and adduction but avoiding flexion and internal rotation to extremes. By six weeks, exercises can be initiated against resistance and full weight bearing.

'High dislocation' patients often require crutches for a period of 3 months as the abductor muscle strength is increased and the limp and waddling gait is eliminated.

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Overview of Cementless Stems in Total Hip Arthroplasty – Review Paper on the Corial Style Stem

Christian Wright, B.S*., Declan Brazil, PhD*,** and Timothy McTighe, Dr. HS (hc)**

Abstract:

The review summarizes published literature from a range of reputable sources regarding hip prosthesis (stems) of a specific design style (Corail) used currently in cementless Total Hip Arthroplasty.

The short-term results of the best cementless femoral components recorded in the Norwegian Arthroplasty Register as described by Havelin et al, include the Corail, IMT, Profile and Zweyuller stems with revision for loosening <1% at 4.5 years, compared to cemented counterparts.

The critical review of published studies shows equivalence of the predicate Corail stem to the Signature CL2 femoral stem in all critical characteristics is demonstrated to represent the likely clinical performance of the CL2 stem implanted. This is using modern surgical techniques without cement.

Introduction:

Since the introduction of cementless THR in the 1970s femoral and acetabular components have undergone substantial changes and a range of design philosophies have demonstrated variable clinical success with some notable failures to meet design intent.

However, many surgeons have reported excellent intermediate to long-term results associated with the use of tapered stems inserted without cement during primary total hip arthroscopy from 1984 onwards. With an endpoint of aseptic loosening of the stem, excellent survivorship figures have been quoted of up to 99.1% at 10 years although specific details of calculations have not always been included in the published data. One of the most widely used cementless tapered stem is the fully hydroxyapatite coated titanium Corail stem in combination with a variety of acetabular components that will be included in this review.

Materials and Methods:

IDENTIFICATION OF DATA

For each section of the clinical review the data sources for systematic review will be provided. The following are typically data sources that were considered acceptable:

- medical and paramedical databases
- technical papers from relevant Standards Committees
- "grey literature" (theses, internal reports, non peer review journals, the internet, industry files)

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For all the clinical review of the performance of predicate or similar devices the following journals have been selected as source data:

- Journal of Arthroplasty
- Clinical Orthopaedics and Related Research
- Journal of Bone and Joint Surgery (British and American)
- Journal Reconstructive Review

Additionally, the following inclusions criteria were used in selecting appropriate clinical data for the file:

- Publications in English
- All patient populations

The following exclusion criterion was used for clinical data for file:

- In vitro studies

Review:

Various porous coated, grit or sand blasted, bead-sintered or plasma-sprayed surfaces on the femoral component have been utilized in cementless THA and there remains some differences in opinion as to the most effective coating for mechanical stability of the implanted stem that promotes bone ingrowth and achieves long term clinical performance outcomes to at least equivalent to that of the well established cemented stems.

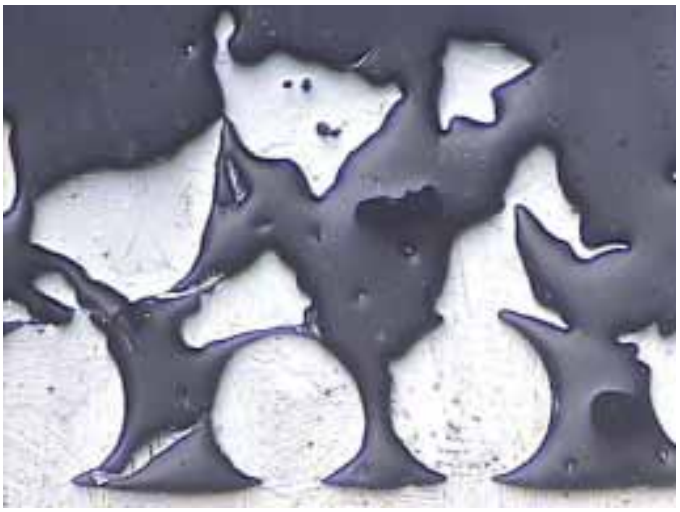
Examples Of Cementless Surface Coatings For THA

Matte Surface Finish / HA Fully Coated

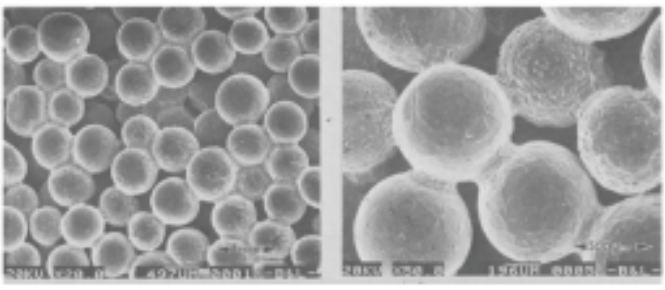
Titanium Plasma Spray / Sintered Porous Beads

Hybrid Coating HA over Plasma Titanium Spray

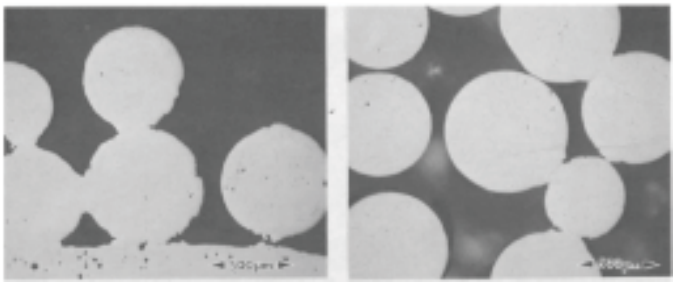
Cross Sectional Views of Surface Coatings



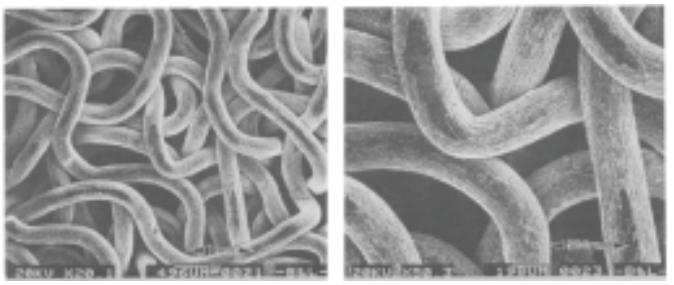
Particle Sintered Coating



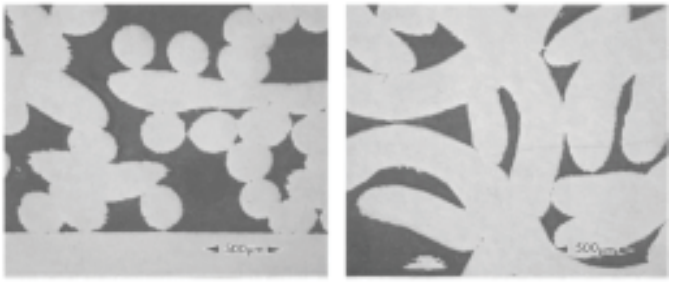
Porous Sintered Coating *SEM Images*



Cross Section



Porous Sintered Wire *SEM Images*



Cross Section

Hydroxyapatite (HA) Plasma Spray

Hydroxyapatite (HA) is a naturally occurring mineral found in bone and tooth enamel comprising Calcium and Phosphate in a ratio of 1:1.67. It is unique in its biocompatibility and has been clearly established to be non toxic, non allergenic and non-inflammatory. Ions released from HA coatings have not been shown to have any detrimental effect on the surgical outcome associated with wear debris. Rokkum et al 1999[1] biopsied 20 hip interfaces up to eight years post operatively and found no evidence of HA particles at a site distant from the bone implant surface.

The Artro group[2] report on the first 12 years of use of the ***Corail*** prosthesis from 7800 THA surgeries carried out from 1986-1998 across an almost Gaussian curve for age distribution of patients from 16 to 104 years old with a mean age of 62 years with 70% of patients indicated with primary osteoarthritis of the hip. It was noted that HA-coated stem performed well in fractures of the femoral neck in the elderly patients and in revision cases associated with septic conditions. No cases of aseptic loosening of the stem were recorded. A reduced incidence of thigh pain has been observed with use of this stem and 63% of patients from this study were pain free with normal motion and function at final follow up. Superior benefits of a HA coating are claimed to provide biological fixation of the prosthesis as well as maintain a living bone bed ensuring long term stability of the implant and the ability to resist infection.

Varying thickness, porosity & crystallinity of HA coatings have been utilized by manufacturers and the ***Signature CL2 (N.S. Whales, AU)*** and our predicate, the ***Corail (DePuy)*** stem has a coating thickness of 155 µm. The thickness of HA coating applied to cementless femoral stems ranges from 50-200 µm with the intention of achieving early fixation of the stem by osteoingration with the bone interface.

The favourable clinical performance of the ***Corail*** stem after 12-15 years is well documented by the Artro group[2, 9] who demonstrated from longer term radiolucency studies that HA also has a role in long term stem fixation and the thickness of the coating probably plays a role. No lucent lines were observed in their studies that could suggest disruption between implant and bone. The coating technology is reproducible and HA debris has not been linked to any specific early component failures in THA.

RSA studies have been used to demonstrate that HA-coated prostheses are significantly more stable than porous coated implants[3; pp 171-207; Geesink R.G.T]. The "perfect" ingrowth of the HA-coated stem, however, is difficult to extract in revision surgery and some osteolysis has been observed to occur. Delamination of the coating is not considered relevant for the coating thickness of the ***Corail*** stem[9].

Many short term animal studies conducted on HA-coated stems[3] have established clear short term benefits of the osteoconductive properties of HA and its ability to achieve bone ingrowth under dynamic load and across a gap around the press-fit stem and bone compared to porous coated titanium stems [3; pp 107-130; Soballe K et al]. Clinical outcomes at 5 years indicate a significant improvement in patient satisfaction, particularly with absence of pain compared to other cemented/ cementless implants.

Data from longer term studies is now available and favourable survivorships have been cited for the ***Corail*** stem of 97.7% - 99.2% @ 10years[2,4] as compared to survivorship of the Biomet Integral stem of 98% @ 10 years[5] and ***Zweymüller*** of 96.4% @10years[4].

Stem	% Change in Bone Density ("Calcar" region)
Zwey-Muller (Ti-6Al-4V matt surface)	24
Corail (Hydroxyapatite fully coated Ti-6Al-4V)	8.0
Optifix (Ti-6Al-4V) proximal only porous coated	14.8
Autophor 900S (Co-Cr alloy- microporotic surface)	18.5

The Norwegian arthroplasty register prospective observational study[4] incorporated a broad range of hip prosthesis marketed between 1987 and 2005 and draws on 13,760 cementless THRs representing 13% of total hip surgeries during this period. The ***Corail*** stem was used in 39% of the cementless THR and the Kaplan-Meier score for 15 year survivorship of 97% with a mean patient age of 54 years are excellent. Its performance against an endpoint of revision for any reason was marginally better than ***Zweymüller***, ***Filler***, ***Taperloc*** and ***Omnifit*** stems that still gave acceptable KM Survivorship figures of greater than 90% at 10 years suggesting that a number of stem design philosophies allow good performance in regard to femoral fixation.

Problems other than loosening such as: thigh pain, femoral osteolysis, stem-derived instability, dislocation and peri-prosthetic fractures were also cited as important failure modes of these stems. The overall survival of cementless THR was rated as poor from this study due to the high number of revisions for the failure of the acetabular bearing surfaces and liners.

Chambers et al 2007[6] said on the success of cementless fixation being attributed to firstly the tapered stem geometry of the Corail stem. Why its self-locking property with variable amounts of subsidence described and secondly to the use of HA coating in superior proximal femoral osseointegration. Reduced subsidence risk and better preservation of peri-prosthetic bone quality reflected radiographically by less proximal stress shielding and superior osseous remodelling around the implant proximally.

Component malpositioning has been noted to be associated with higher failure rates of cementless THA particularly when varus. From a consecutive series of 98 arthroplasties performed with a cementless tapered-wedge stem at a mean follow-up of 7.7 years, Min et al 2008[7], did not find any difference in Harris Hip score values of patients or prevalence of thigh pain in a distribution of stem positions evaluated to be in neutral (63%); valgus (21%) and varus (16%) position. Hence they concluded that a varus stem position did not adversely affect fixation durability or clinical outcome.

Vidalain 2004[8] claims that extraction of a well integrated HA coated femoral implant is always possible through a transfemoral approach. This option minimizes additional bone sacrifice and the reconstruction of the femoral shaft around a new stem is considered to be a straight forward, easily performed procedure.

Karachalios et al 2004[9] carried out a 10 year randomized study on four different cementless stems in regard to the clinical relevance of stress shielding and calcar atrophy known to be a consequence of THR. The authors attribute the etiology of periprosthetic bone loss to two predominant factors, first to "stress shielding" of the proximal femur as a result of changes in loading pattern after implant and secondly to osteolysis

due to presence of polyethylene wear debris. Bone density in Gruen zone 7 (directly under the stem neck proximally, "Calcar" region) is cited as the region of highest bone loss. The table below shows the percentage bone density lost reported by these authors after 2 years associated with commonly implanted stems.

However, progressive recovery of bone density observed after 3 years was demonstrated to continue until almost to baseline values after 10 years. The authors therefore conclude that the phenomenon of stress shielding may have been overestimated in earlier publications considering only early to medium term post operative bone density results [9] as in this longer term study, bone has been observed to adapt its remodelling process to non physiological loading.

Vidalain 2004[8] observing only the clinical performance of the ***Corail*** stem over a 15 year period records a rate of 0.4% cases (out of 243 > 10 years) of major stress shielding. The author tracked bone density loss in several zones around the implanted stem for a period of 5 years and up to 49.9% loss (21.9% loss @ 3 months) was recorded in the Calcar zone in a series of 42 patients post cementless THR. Prevalence of stress shielding is increased in women due to pre-op osteopenia, femoral neck fracture or wide femoral canal. Equilibrium and static bone density was reached after 5 years within this study and the extent of bone loss was associated with increasing female age possibly also with osteoporosis. Implant size was also cited to affect proximal bone loss after THR.

Currently, cementless fixation has become preferred for revision hip arthroplasty. Failure rates for cups are typically three times higher than stem loosening with reported rates from 39-58 %[10]. Revision due to liner wear and pelvic osteolysis is also common.

Bone loss and suboptimal fixation to deficient bone remain challenges for successful clinical outcomes across all indications for use in THA. Modern post surgical management strategies such as local administration of magnesium hydroxide around the bone implant interface have been reported to be beneficial for retention of bone mass in patients with osteoporosis[10].

Timely administration of peri-operative antibiotic prophylaxis has reduced infection rates significantly over the past 5 years. Ritter et al[11] determined the infection rate from total hip arthroplasties from a single surgeon over a 19 years period to 2005 was only 1.77%. A US cohort of 3346 cementless primary THAs carried out during the period 1987-2007 yielded post operative peri-prosthetic femoral fracture rate of 1.2%.

Clinical data as it becomes available for the ***Signature CL2*** stem will be evaluated and monitored according to our post market plan including RSA studies for performance and safety in clinical use from centres in Australia after market release.

The ***Signature*** cementless hip prosthesis range is anticipated to have a reliable, safe clinical performance to at least equivalent to the well established predicate devices discussed in this and related reports since our range has adopted and consolidated the most critical of their design and performance features.

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Rotational Alignment of the Femoral Component in Computer-Assisted Total Knee Arthroplasty

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Abstract:

This study compared two Computer Assisted Surgery (CAS) methods in 212 total knee arthroplasties to evaluate the differences between anatomic landmark axes in determining rotational position of the femoral component. Overall, there were large variations between CAS defined component orientation using an optimized gap-balancing technique and component orientation using anatomic reference axes (range, 16º internal rotation to 16º external rotation). If based on anatomic landmarks, these large variations would have led to asymmetrical flexion gaps in up to 60% of the knees studied. Of the anatomic axes studied, the posterior condylar axis was the only axis not significantly different from CAS optimized orientation. If anatomic landmarks are used for femoral component rotation with either a conventional or a CAS technique, asymmetric trapezoidal flexion gaps may result.

Key Words: *total knee arthroplasty, balancing, component rotation, Computer Assisted Surgery*

Introduction:

Total knee replacement surgery remains an excellent procedure for relief of pain, correction of deformities, and restoration of impaired function due to arthritis. Patients who have undergone total knee arthroplasty (TKA) are experiencing up to two decades of clinical success, with implant survivorship of certain designs topping 90% at 10 to 15 years.[1,2,3,4] Despite the good results, technical difficulties persist, such as the ability to achieve consistent alignment of the components.[5] This is particularly true of femoral component rotation, a variable which can markedly affect surgical outcome and is crucial to ensuring soft tissue balance of the knee in flexion. Inaccurate rotational position of the femoral component can lead to asymmetrical flexion gaps, anterior knee pain, undesirable changes in knee stability, patellar tracking, and patellofemoral contact points.[6,7] Despite its importance, rotational errors of at least three degrees have been reported in up to 45% of cases dependent upon the method for establishing component rotation.[8]

Computer-assisted surgery (CAS) has sought to improve the reliability with which components are implanted during TKA. Indeed, several CAS studies have demonstrated the ability to improve overall mechanical alignment accuracy and precision.[9,10,11] However, an increase in reliability of femoral component position, even with computer navigation, may depend upon the philosophy on which the navigation system operates. Most CAS systems balance the knee to the mechanical axis

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but use an anatomic landmark philosophy for determining rotation of the femoral component. With this philosophy, the anterior and posterior femoral resections are based off one of several anatomic reference axes (e.g., the transepicondylar axis, the anteroposterior axis (Whiteside's line) or the posterior condylar axis). The problem, however, is difficulty in consistently determining these reference landmarks due in part to variations in patient anatomy and bone distortion due to osteoarthritic changes[8,12,13] Although the aim is to have symmetric flexion and extension gaps throughout range of motion, use of anatomic reference axes can result in asymmetric flexion gaps and a poorly balanced knee. CAS with Optimized Work Flow (DePuy, a Johnson & Johnson Company, Warsaw, IN), however, is based on a gap-balancing philosophy. Rotation of the femoral component is determined after balancing the knee to the mechanical axis in extension, then rotating the femoral component so that the ligaments are also balanced at 90 degrees of flexion. The Optimized Work Flow also directs the anterior-posterior position of the femoral component to determine flexion gap width. This process results in extension and flexion gaps which are symmetric and rectangular and balanced throughout the knee's range of motion.

In the current study, CAS was performed using Optimized Work Flow with the computer determining rotation of the femoral component based on extension balancing. Femoral anatomic landmarks were also collected using the computer navigation system; however, these landmarks were not used to determine component rotation but were recorded for reference purposes only. Anatomic landmark axes were then compared to CAS optimized femoral component orientation to evaluate the difference among these landmarks in determining femoral rotational position. We hypothesized that there would be a large variation between the anatomic reference axes and the CAS Optimized Work Flow defined component orientation, indicating that a substantial portion of knees, if oriented, with respect, to a patient's anatomical structures, would not be balanced.

Materials and Methods

This study included all patients operated on by one of two CAS-experienced orthopaedic surgeons (D.P. and M.C.) on whom primary total knee arthroplasty was completed using the DePuy Ci navigation system (DePuy) with an Optimized Work Flow. Two hundred twelve knees, all implanted with PFC Sigma components (DePuy), were included in this study. Data for this study was obtained directly from the CAS system as was acquired during surgery. No patient identifiers or demographic data were obtained so as to protect patient information and to stay within the bounds of the hospital IRB's approval guidelines for this study.

Each TKA was performed using an Optimized Work Flow included several steps. In the first step, the proximal tibia cut was performed and verified. Using a dynamic tensioning device (Fig. 1), the knee was then balanced in full extension to the mechanical axis and the extension gap stored by the computer.

Fig. 1

Dynamic tensioning device used during ligament balancing in CAS optimized workflow.

With the tensioning device still in place, and the patella in an anatomic position, the knee was flexed to 90º and the flexion gap information (symmetry and width) is stored. The computer then optimized the femoral component position. This comprises femoral component size, distal femoral cut which determines the extension gap and the posterior femoral cut and rotation which determines the flexion gap. This results in a balanced extension/flexion gap. This plan was created prior to making any bone resections of the femur. The surgeons have the ability to modify the femoral component position and size to create the optimal position with maximal posterior condylar offset and the least bone resection

The tensioning device independently tensions the medial and lateral compartments with independent

springs which are not linked by a central pivot. The distraction force is 23kg/N using the navigation system, the surgeons registered the location of femoral anatomic landmarks which the computer used to determine anatomic axes. The anatomic landmark axes were used for reference and comparison purposes and were not used to determine component rotation. These reference axes included 1) the transepicondylar axis, defined by the prominences of the medial and lateral epicondyles; 2) Whiteside's line, a line perpendicular to the anteroposterior axis, defined by the trochlear groove and the apex of the condylar notch; 14 and 3) the posterior condylar axis as defined by the posterior-most margins of the posterior femoral condyles. This was obtained by collecting multiple data points over the posterior femoral condyle.

Statistical analyses were performed using SPSS software (SPSS Version 8.0, SPSS Incorporated, Chicago, IL). Because the data were normally distributed, parametric statistics were employed. A one-sample T-test was used to determine whether mean orientation for the anatomic axes were significantly different from zero, indicating an overall mean discrepancy between the reference axis and CAS optimized femoral component orientation. Person's correlation was used to assess relationships among the three anatomic reference axes. Probability values less than 0.05 were considered indicative of statistical significance.

Results

Overall, there were large variations in anatomic reference axes. Relative to femoral component orientation determined by CAS optimized technique to provide balanced and rectangular flexion and extension gaps (that is, position 0; Fig. 2), the transepicondylar axis varied between 12.6º internally rotated to 14.7º externally rotated.

The mean value of the transepicondylar axis was 0.9º ± 5.4º externally rotated. This average was significantly different from 0 (p=0.02, one sample T-test), indicating that there was a significant discrepancy between the mean orientation of the transepicondylar axis and the component orientation determined by CAS optimized technique. In 58.5% of the knees, the transepicondylar axis was not within ± 3º of the optimized CAS orientation.

Relative to the femoral component position determined by the CAS Optimized Work Flow, Whiteside's line varied between 13.5º internally rotated to 16.3º externally rotated with a mean orientation of 1.9º ± 5.2º external rotation (Fig. 3).

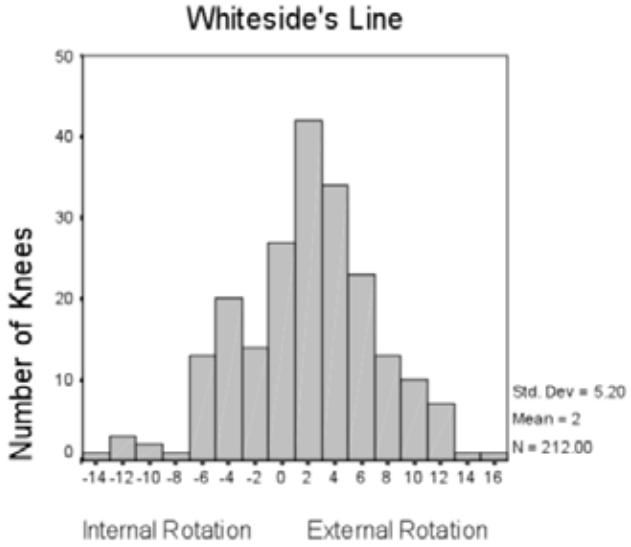

Fig 3: The orientation of Whiteside's line with respect to femoral component orientation determined by CAS optimized technique. Negative values denote internal rotation and positive values denote external rotation.

Again, this average was significantly different from 0 (p<0.01, one sample T-test), indicating a significant discrepancy between Whiteside's line and component orientation determined by CAS. In 60.4% of these knees, orientation was not within ± 3º of optimized CAS orientation.

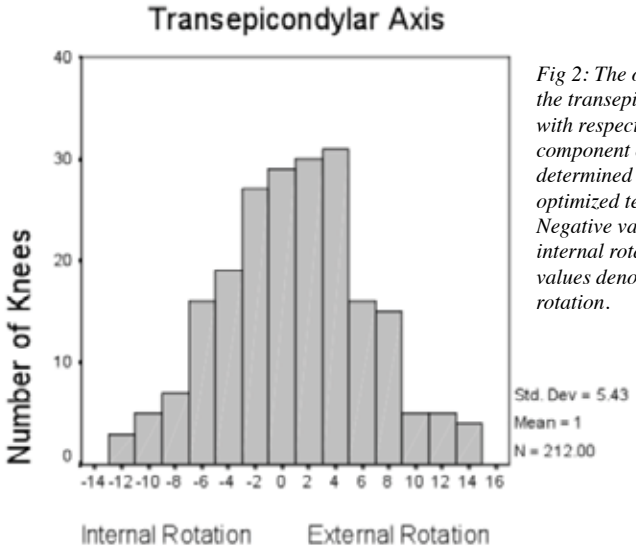

Fig 2: The orientation of the transepicondylar axis with respect to femoral component orientation determined by CAS optimized technique. Negative values denote internal rotation and positive values denote external rotation.

The posterior condylar axis ranged from 15.6º internal to 11.4º external rotation (mean, 0.4º ± 4.3º internally rotated) as compared to the CAS optimized orientation with 48.1% of the knees falling outside ± 3º of the optimized orientation (Fig. 4).

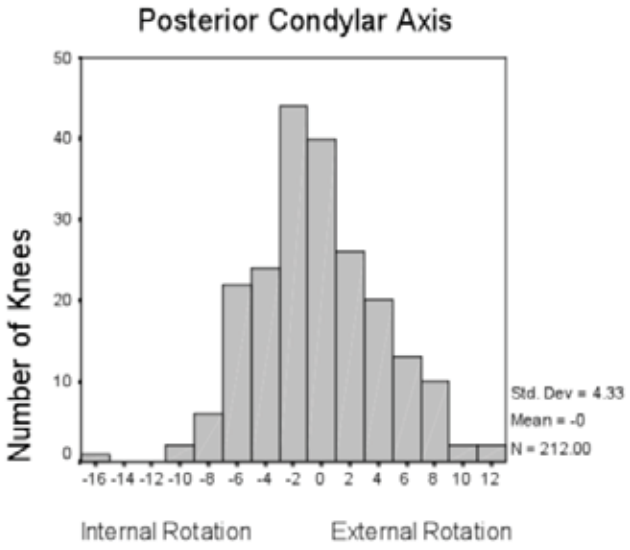

Fig 4: The orientation of the posterior condylar axis with respect to femoral component orientation determined by CAS optimized technique. Negative values denote internal rotation and positive values denote external rotation.

Unlike the other two axes, there was no significant difference between the posterior condylar axis and femoral orientation determined by CAS optimized technique (p=0.23, one sample T-test).

Although the three anatomic reference axes were all significantly correlated with one another (p<0.001 for all correlations; Person's correlation), there was a fair amount of variability between datasets (r2 < 0.40 for all correlations). As an example, Figure 5 demonstrates the variability between measurements of the transepicondylar axis and Whiteside's line. The maximum variation between the three anatomic references axes ranged from 0.5º to 19.9º with an average of 6.1º.

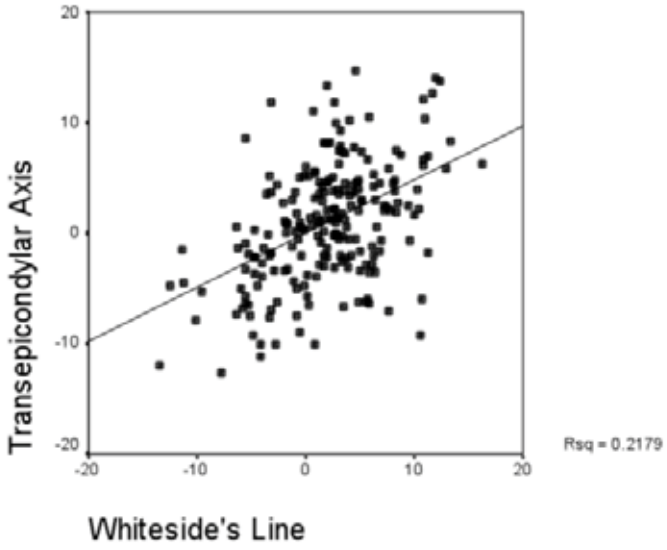

Fig 5: Although there was a significant correlation between anatomic axes (p<0.01), there was a fair amount of variation in the data as evidenced by correlation coefficients less than or equal to 0.40.

The data collected by each surgeon was compared to determine whether there was any difference between the two surgeons. There was no difference p=0.55.

Discussion

The method for determining femoral component rotation in TKA remains controversial, but is crucial to ensuring soft tissue balance while the knee is in flexion. Some advocate a measured resection technique based on anatomic landmarks, while others prefer a gap balancing technique with hopes of obtaining a symmetrical and rectangular flexion and extension gaps. Regardless of opinion, the goal is a well balanced knee, aligned to the mechanical axis that functions well throughout a full range of motion. In the past, anatomic landmarks have been used as a reference in setting femoral component orientation.[14,15] This method, however, has been linked to rotational errors in a substantial number of knees, resulting in trapezoidal rather than rectangular flexion gaps.[8,12,13] While Computer Assisted Surgery (CAS) has been shown to improve overall mechanical alignment accuracy and precision, CAS performed using anatomic landmarks as reference for femoral component rotation can lead to errors similar to conventional methods. As such, CAS may offer no advantages over conventional methods for determining femoral component rotation. This study sought to examine this question by comparing femoral component orientation determined by two CAS techniques.

Using CAS with an anatomic landmark philosophy, this study documented large variations in the orientation of anatomic reference axes. The axes varied from 16º internal rotation to 16º external rotation as compared to femoral orientation determined by CAS optimized gap-balancing technique. This was not entirely unexpected, as surgeons have been shown to be inaccurate in

locating the anatomic landmarks recommended for femoral component rotation.[13,16,17] Kinzel and Ledger et al studied femoral component rotational alignment in 74 total knee arthroplasties in which the femoral epicondyles were marked intraoperatively by the surgeon and the femoral components subsequently positioned parallel to the transepicondylar axis.[17] Postoperatively, axial CT scans were performed to compare the surgeons' determination of the transepicondylar axis with the same axis as determined by the postoperative CT scan. Kinzel and Ledger et al found that in only 75% of the knees were the femoral components positioned within ± 3º of the true transepicondylar axis as determined by the CT scan.[17] The error was also large, varying from 6º external rotation to 11º of internal rotation, suggesting it is difficult to accurately identify this axis in a highly reproducible fashion.[17]

With the current study, computer navigation was used to calculate the orientation of the axes. However, the method still required the surgeon to register his perception of where the anatomic landmarks were located, opening the method to inter- and intra-observer error. Moreover, differences in patient anatomy and existing deformities could have also contributed to errors in determining landmark axes. For example, a varus knee deformity with medial posterior condylar loss can affect the accuracy of the posterior condylar axis. If not taken into account, this could lead to an externally rotated femoral component, medial flexion instability, and femoral component lift off. Conversely, using the posterior condylar axis to determine femoral component orientation in a valgus knee with a hypoplastic lateral femoral condyle could lead to an internally rotated femoral component, lateral flexion instability, femoral component lift-off, and poor patella tracking.

Despite the use of CAS, this study shows that if based on anatomic landmarks, the large variations in femoral component rotation would have led to asymmetrical flexion gaps in many of the knees studied. Whiteside's line and the transepicondylar axes were found to be significantly different from the orientation determined by CAS optimized workflow. This could reflect the fact that surgeons in the current study found Whiteside's line and the transepicondylar axes more difficult to accurately locate intraoperatively than expected, further increasing variability and decreasing potential accuracy. Of the three anatomic axes, the posterior condylar axis was the most reliable, the least variable, and the only axis not significantly different from CAS optimized orientation. Nevertheless, the orientation of the posterior condylar axis was not within ± 3º of the optimized CAS orientation in 48% of the knees, indicating that these knees likely would have asymmetrical flexion gaps. Moreover, this study demonstrates large variability among the three anatomic axes themselves, with the maximum variation among the axes ranging from 0.5º to 19.9º with an average of 6.1º.

We acknowledge one limitation of the current study is the fact that selection of anatomic references is highly surgeon dependent. Siston et al noted that establishing femoral rotational alignment via anatomic structures is influenced by an individual surgeon's skills and preferences and not by the different techniques used to establish this alignment.[16] We acknowledge it is possible that the amount of variation in landmark axes reported in this study could be less if assessed by other surgeons. However, surgeons in the current study were fellowship trained in joint reconstruction, maintain busy arthroplasty practices, and have extensive experience performing TKA utilizing computer assisted navigation. There was also no significant difference in the landmark axes collected between the two surgeons. As such, their variability in determining anatomic landmarks is at least likely to represent the typical joint replacement surgeon.

Ultimately, the significance of the study is demonstrating that there is a large variability in how surgeons determine anatomic landmarks, and the logical inference that computer referencing systems can only be as accurate as the data fed into the system.

In conclusion, this study shows a significant variation in femoral component rotation when comparing orientation defined by anatomic landmarks to orientation defined by a CAS balanced extension/flexion gap technique. If anatomic landmarks are used for femoral component rotation with either a conventional or a CAS technique, asymmetric trapezoidal flexion gaps may result.

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Unicompartmental Knee Arthroplasty: Past, Present, Future

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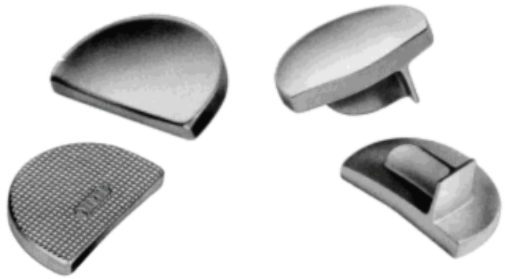
Abstract:

For over fifty years, unicompartmental knee arthroplasty (UKA) has been used to treat single compartment osteoarthritis of the knee. Despite the many years of experience performing UKA, the orthopaedic community has not reached a consensus on the patient selection criteria or operative indications for UKA, due to varied outcome results in the literature. Newly designed robotic-assisted systems are believed to increase the precision and accuracy with which unicompartmental knee arthroplasty can be performed, possibly leading to fewer mechanical failures and improved functional outcomes. However, long-term follow-up is required before definitive conclusions can be reached regarding this new technology. This review examines the history of UKA, reviews early results of robotic-assisted UKA and presents an outlook on future advances.

Key Words: ***unicompartmental knee arthroplasty, total knee, robotic assisted***

History of Unicompartmental Knee Arthroplasty

The theory of unicompartmental replacement of only one side of one compartment of the knee joint came from Duncan C. McKeever in the 1950s, followed up by both McKeever and MacIntosh introducing metallic tibial components that resurfaced only the tibial plateau.[1]



MacIntosh Component / McKeever Component

Metallic tibial resurfacing components implanted in the late 1950s and through the 1960s were fraught with high complication rates and unacceptable functionality.[1]

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Frank Gunston and the Charnley Connection

A young Canadian surgeon (Dr. Frank Gunston) from Winnipeg, Manitoba, Canada on a traveling fellowship to study hip arthroplasty at Wrightington became intrigued with the ongoing problems associated with arthritic knees. During his fellowship, Gunston developed a design for knee arthroplasty reflecting his exposure to UHMWPE and hip arthroplasty.[1]

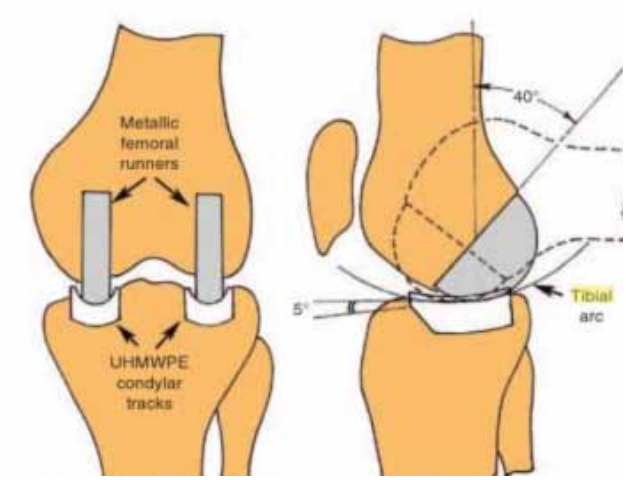
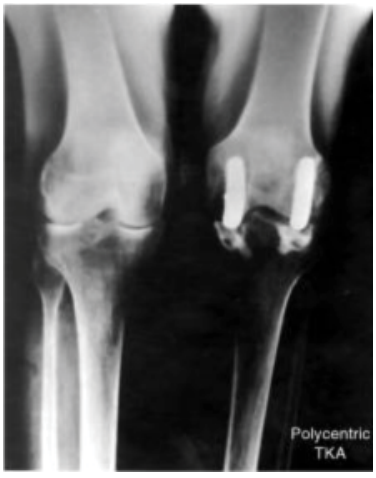


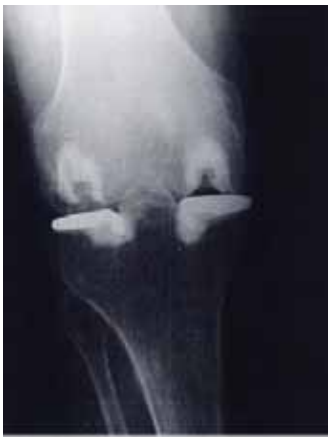
Illustration of Polycentric TKA design by F. Gunston 1969

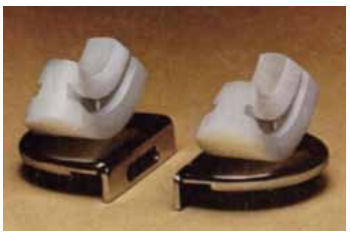


Polycentric Radiographic Post-op view and product

John Charnley had no active role in Gunston's knee work, however, Charnley did develop his own unicompartmental knee that was introduced and distributed by Thackeray as the Load Angle Inlay.[1]

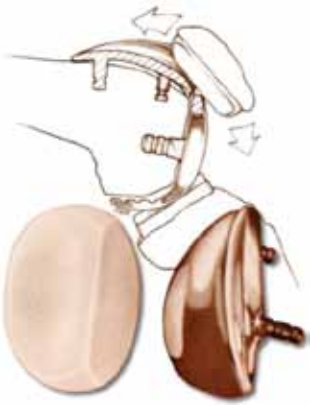
This featured a convex UHMWPE femoral component articulating against a flat metallic plateau.[1] Charnley's design did not survive due to loosening, deformation and wear of the plastic femoral component. However, the tibial (metal) components stood up remarkably well.[2,3]





Charnley's Load Angle Inlay Total Knee by Thackeray, Ltd.

During UKA, one tibiofemoral compartment is resurfaced in order to reduce deterioration of the joint space and to eliminate resultant pathological joint biomechanics.[4,5,6] The medial compartment is most commonly affected by degenerative changes and treated with UKA, followed by the lateral and patellofemoral (PFJ) compartments.[6] Bechtol introduced the first total patellofemoral component back in 1974 which introduced the concept of resurfacing both sides of the PFJ. Subsequently in 1976 Blazina designed an extension of the trochlear component that extended toward the intercondylar notch (Type II). Following these developments, Blazina and associates published the first report of patellofemoral resurfacing.[7,8] However, all compartments can be resurfaced independently.[5]



1974 Bechtol Patellofemoral Component

Historically, UKA was associated with varied clinical results. Although the surgery was a commonly performed procedure in the 1970's and 1980's, its popularity faded as a result of both large numbers of patients ultimately required revision surgery with conversion to total knee arthroplasty (TKA)[5,9,10,11] and the controversy between Marmor and Richards Manufacturing Co.[12]

In the period from 1970 through 1972, Dr. Leonard Marmor, an orthopedic surgeon working with the Richards Manufacturing Corporation, developed a prosthetic device known as the Marmor Modular

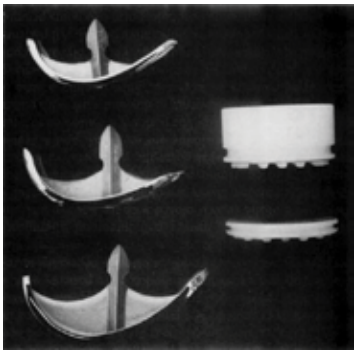
Knee. During 1973, Richards, through engineering error, began manufacturing final metal components of the medium category which were larger than originally designed and which therefore did not match the medium template and trial components. It was thus possible that a surgeon could prepare a bone for insertion of the medium metal component using properly sized medium template and trial components (which were reused from surgery to surgery) and then cement into place a too-large medium final component. The apparent mismatch and controversy over this issue became public knowledge with announcement letters to the orthopaedic community by both Dr. Marmor and Richards Manufacturing Co. in 1975. The medical-legal action that followed scared many users of the Marmor Modular Knee to abandoned this procedure for fear of legal entanglement.[12,13,14] This slowed down clinical surgical evaluations of unicompartmental total knee arthroplasty for a decade.

Marmor Modular Knee Ad from JBJS 1970s

With the advancement of improved technology, a more comprehensive understanding of joint biomechanics and an increased desire for minimally invasive surgery, UKA has undergone a recent resurgence in popularity for the management of degenerative changes of the knee joint.[4,5,10,15]

Early Results

In the early 1970's Marmor introduced a modular UKA implant ("Marmor Knee).[16,17] The Marmor Knee adopted the resurfacing concept and addressed both compartments of the knee. However, Marmor subsequently resurfaced only a single side of the knee. The prosthesis was unconstrained included an all-polyethylene inlay tibial component and a narrow femoral component with a single peg.[18]



Marmor Modular Knee

In 1976, Marmor reported on 105 patients with a minimum of 2 years of follow-up implanted with the Marmor Knee.[19] Successful results with functional improvement and a stable articulation were achieved in 88% of patients. After 10 to 13 years of follow-up, patients implanted with the "Marmor knee" during this period maintained satisfactory results in 70% of cases and 86.6% of patients remained pain free.[20,21] Marmor noticed subsidence of the relatively small tibial component causing early failure.[20,21] There was also an increased risk of wear and loosening (due to cold flow and deformation) of the 6mm polyethylene component leading to revision surgery. Marmor then recommended the use of a thicker polyethylene component.[20,21] In the mid-1980's, the Marmor Knee was available with metal-backing to eliminate creeping and cold flow, which was found to be a problem with the early all-polyethylene design.[22]

Considering Marmor's contributions and innovation to UKA component design and operative technique, he is regarded by many as the godfather of modern UKA. Unfortunately, a patent controversy with Zimmer and contract disputes with Richards over changes of the original Marmor Knee design

overshadowed the early success of this prosthesis and may have hampered the wide-spread use of UKA in the following years.[12,13,14]

Insall et al. reported results from 32 UKA procedures in 1980.[11] Despite losing ten patients to follow-up in the first year, the study showed no change in the mean Hospital for Special Surgery knee score of 48 points between pre- and postoperative assessment. Following UKA, varus angulation had decreased from a preoperative mean of 8° to 4° postoperatively and valgus angulation had decreased from a preoperative mean of 21° to 8° postoperatively. The final clinical outcomes of the 22 UKA performed during the study varied widely: excellent (one knee, 5%); good (seven knees, 32%); fair (four knees, 18%); and poor (ten knees, 45%). Although correction of the anatomical alignment was achieved after UKA in the Insall case series, the clinical patient outcomes were unfavorable.

While the Insall series demonstrated poor clinical outcomes after UKA, other case series reported more favorable results. In 1986, Broughton et al. published a retrospective review of 42 UKA, which were rated according to the Baily knee score.[23] In this study, 32 of the total number of 42 knees (76%) were rated as 'good', and 24 knees continued to maintain a 'good' rating five to six years after the procedure. The remaining eight knees were evaluated seven to ten years after surgery and also maintained a 'good' rating. Only seven of all 42 knees (17%) in this study were rated 'fair' or 'poor,' and three knees (7%) required revision arthroplasty.[23] Similar mid-to-long term clinical results were reported by Bert in a retrospective review of patients undergoing UKA almost a decade later in 1998.[4] In this study, post-surgical outcomes showed 87.4% survivorship of the UKA ten years after the procedure. Murray et al. reported on the outcomes of 143 knees treated with medial sided UKA using the Oxford mobile bearing prosthesis between 1982 and 1992.[24] Patients were followed for a mean of 7.6 years postoperatively and revealed a 97% survivorship. Five revisions were reported; two revisions for progression of osteoarthritic disease in the lateral compartment; one for component loosening; one for an infection; and one for a painful prosthesis without any radiographic abnormalities.

Operative Indications for Unicompartmental Knee Arthroplasty

Adhering to the operative criteria for UKA may be critical for surgical success and patient benefit, as improper patient selection is thought to be a risk factor for early UKA failure.[25,26] Classic indications for UKA proposed by Kozinn and Scott and others included: a patient with a sedentary occupation; age of greater than or equal to 60 years; minimal pain at rest, less than 10° varus deformity; range of motion of at least 90° without a flexion contracture; correctable medial deformity; 50% unicompartmental joint space collapse; weight less than 82 kg; thin body habitus (as obesity is a relative contraindication); diagnosis of osteoarthritis (OA), post-traumatic arthritis or osteonecrosis; and isolated unicompartmental knee pain (Table 1).[4,11,25-31] Furthermore, successful UKA requires an intact anterior cruciate ligament (ACL) and a stable knee that resists femorotibial subluxation.[10,26]

Traditionally, contraindications for UKA included: the diagnosis of rheumatoid arthritis or other inflammatory arthritic conditions; knee pain in all compartments; decreased range of motion with a flexion contracture; obesity; knee instability; ACL rupture; and age of less than 60 years.[4,26,28] Insall et al. reported that four out of seven patients (57%) under the age of 60 who received UKA experienced 'poor' surgical outcomes, whereas six out of 15 patients (40%) over 60 years of age experienced 'poor' results in their case series.[4] Contrary to the Insall et al. series, Berend et al. concluded that failure, which was defined as a UKA requiring later revision or an impending revision, was not associated with age, gender, disease severity or implant design, but with increased body mass index.[32] A body mass index of greater than 32 was predictive of UKA failure and a reduced survivorship. Studies published in the early 1990s also noted that obese patients have a failure rate 1.4 times higher than patients with normal weight.[4,33] Unfortunately, most of the data related to risk stratification for UKA surgery is based upon Level 4 and 5 evidence. The level of evidence coupled with low statistical power in these studies contributes to disagreement and continued controversy in the literature regarding pre-operative UKA patient selection criteria.

Good outcomes for patients initially thought to be outside the UKA operative criteria have been reported in the literature, and these studies have added to the confusion over appropriate UKA operative selection criteria.[26,34] Pennington et al. showed results for 41 patients and 46 knees undergoing UKA, in which all patients were under the age of 60 years.[34] The decision to proceed with UKA was made intraoperatively after direct observation of all three knee compartments. The Hospital for Special Surgery knee score and the University of California at Los Angeles (UCLA) activity assessment were utilized to assess postoperative outcomes. A total number of three knees (6.5%) were revised and one patient (one knee, 2%) was lost to follow-up. In general, the younger patient cohort had favorable clinical outcomes. Specifically, 39 of 42 patients (93%) had 'excellent' results and the other three patients (7%) had 'good' results, based on Hospital for Special Surgery knee score measurements. The UCLA assessment score for all 42 knees that were not revised was 6.6 ± 1.4. For the three patients that underwent revision, the UCLA assessment score was 7.3 ± 1.5.[34] These findings combined with other recent reports, have expanded the classical indications for UKA, as this surgery has been successfully performed on younger patients. Further long-term evaluation of these cases is necessary to determine how UKA will perform clinically in this expanded patient demographic.[10,27,28,35,36,37]

Although the operative indications have recently been expanded (Table 1), surgeons continue to have trouble with the diagnosis and management of unicompartmental knee pathology.

Stern et al. reviewed 228 knees in need of arthroplasty and found that only 6% (13 knees) fit the operative criteria for UKA.[4,38] Bramby et al. and Laskin reported similar findings, with approximately 15% of their preoperative evaluations for knee arthroplasty meeting the operative criteria for UKA.[4,39] The available evidence from the literature supports that proper preoperative evaluation of unicompartmental knee pain is paramount to operative success and favorable clinical outcomes.

	CLASSIC INDICATIONS	EXTENDED INDICATIONS
Age	>60 years old	>40 years old
Weight	<180 pounds	Body mass index < 30kg/m^2
Activity Level	Low to medium levels	Medium to high levels
ACL Status	Intact	Intact
Deformity	<15 degrees	<10 degrees of varus
	Passively correctable	<10 degrees of flexion
	to	contracture
	neutral intra-	
	operatively	

ACL, anterior cruciate ligament

Table 1. Indications for Unicompartmental Total Knee Arthroplasty

Patellofemoral Disease

Contemporary Patella-Femoral Component

The presence of patellofemoral disease has been traditionally regarded as a contraindication to UKA of the medial or lateral compartment due to the risk of early failure.[31,40,41,42] However, Goodfellow and O'Connor and Beard et al. did not find a correlation between patellofemoral disease and outcomes of UKA and recommended that this contraindication may be disregarded.[43,44] In a recent study, Pandit et al. compared 678 mobile-bearing UKA procedures in which at least one traditional contraindications (anteromedial OA, medial osteonecrosis) was ignored to 322 mobile-bearing UKAs without any contraindications.[42] Clinical and functional outcomes, failure rate, and survival were similar in both groups and the authors suggested that traditional contraindications are not required for mobile-bearing UKA.[42] These findings were confirmed by Berend et al., who concluded that radiographic findings of patellofemoral OA can be safely ignored for mobile-bearing UKAs.[41]

Clinical Evaluation for UKA: The "One Finger Test"

The "one finger test" is a useful way to diagnose unicompartmental knee pain.[4] For this test, the patient should be able to localize the joint pain by pointing to the symptomatic area with a single finger.[4,29] If the patient cannot locate the pain with one finger, or grabs the whole knee, UKA may not be indicated.[4] After a thorough history and physical examination, further radiographic evaluation is required with standard plain anterior-posterior and lateral films, varus/valgus stress views, and possible Magnetic Resonance Imaging or Computed Tomography scanning. By combining the clinical history, the radiographic studies, and knowledge of the operative indications, the surgeon can determine the risks, benefits and alternatives to performing UKA.

The use of UKA today

Contemporary Uni Design

Between 1997 and 2000, UKA comprised approximately 1 – 6% of the knee arthroplasty cases performed in the United States.[45,46] In 2007, almost 45,000 UKA procedures were performed, approximately 8% of all knee arthroplasties. In 2009, the number of UKA further increased to approximately 51,300 cases, and this number is estimated to climb to 55,100 cases in 2010.[47] The number of UKA procedures being performed annually is estimated to grow at a rate of 32.5% per year, which is greater than the 9.4% growth in the number of total knee arthroplasty (TKA) procedures performed annually.[48] However, in a poll at the 2010 Annual Meeting of the American Academy of Hip and Knee Surgeons, 212 of 256 respondents (82.8%) reported that performing UKAs comprised of only 0 - 9% of their practice.

In other countries, the procedure is performed with greater frequency than in the United States. The Norwegian Registry reported that UKA accounted for 11.8 % of the 38,122 knee surgeries performed between 1994 and 2009.[49] Similarly, the Australian registry showed that primary UKA comprised 11.4% of all knee replacement surgeries in that country.[50]

However, UKA could possibly be performed more often, as a large percentage of patients who meet the operative criteria for UKA are not given the surgical option. Often, these patients are treated at centers without the surgical expertise or equipment to offer UKA.[51]

Unicompartmental Knee Arthroplasty versus Total Knee Arthroplasty

Numerous surgical benefits associated with UKA have increased its popularity. These advantages include less perioperative morbidity, reduced blood loss, shorter postoperative recovery and rehabilitation, increased post-surgical range of motion, and reduced surgical costs compared to TKA (Table 2).[4,5,10,25,27,28,52,53]

Decreased tissue disruption
Increased postoperative range of motion
Reduced blood loss
Reduced surgical costs
Shorter postoperative recovery and rehabilitation time

Table 2. Advantages of UKA compared to total knee arthroplasty

Specifically, a Minnesota registry documented a 2.8 day mean length of hospital stay for 240 UKA cases, compared to a 4.5 day length of hospital stay for TKA.[54] The Minnesota registry also documented a mean blood loss of 350 mL during the 240 UKA cases, compared to 613 mL average blood loss in 87 patients undergoing a total TKA described by Hinarejos et al. and a mean blood loss of 1747 mL for 30 TKA patients published by Kalairajah et al.[54,55,56] The data suggest that performing UKA will result in less blood loss when compared to TKA, although these reports represent case series with varying power, performed at different institutions, by separate investigators.

UKA may be a preferable alternative to TKA in selected patients. In 1991, Laurencin et al. followed 23 patients, who received UKA in one knee and TKA in the contralateral knee, for 81 months.[57] The surgeries were performed by the same surgical team during the same hospitalization. Inpatient care and rehabilitation protocol remained the same for both knees throughout the hospital course. Range of motion after UKA increased from an average of

106° preoperatively to 123° postoperatively. The range of motion on the contralateral TKA increased from a mean of 104° preoperatively, to 109-113° postoperatively, depending on whether the patient underwent concurrent patellar resurfacing.[57]

Dalury et al. reported on the outcomes of a cohort of 23 patients who underwent TKA in one knee and UKA in their contralateral side.[58] At an average follow-up of 46 months for TKA and 42 months for UKA, patients reported positive results for both surgical interventions. In particular, the UKA patients experienced an increase in the mean postoperative range of motion (123.5° + 9°). These results were comparable to the postoperative range of motion after TKA in the contralateral knee, which was 119.8° ± 7°. There was a similar increase in Knee Society Scores for both procedures, with UKA increasing from 45.9 to 89.7 and TKA knees increasing from 42.4 to 90.3. Despite having comparable outcome measures, 12 out of the 23 patients (52%) in the study expressed a preference for their UKA over TKA. The remaining 11 patients (48%) in the cohort expressed no preference, whereas TKA was not chosen by any patient as the preferred procedure.[58] A report from 2005 surveyed patients who had undergone both UKA and TKA; the majority of study participants stated that the UKA felt more like a "natural" knee.[4]

The subjective feeling of UKA as being more normal compared to TKA can be explained by joint biomechanics. Patil et al. found that tibial axial rotation and femoral rollback more closely resemble normal anatomy in UKA compared to TKA.[59] In addition, UKA is less disruptive to native knee anatomy because only one-third of the knee joint is replaced, the cruciate ligaments remain intact after surgery, and the menisci of the untreated compartment are preserved.[4,27,28]

Dalury et al. and Laurencin et al. offer compelling evidence in support of performing UKA.[57,58] The methodological design of each of the two studies was unique in that the study cohort underwent two different interventions on each of their knees, allowing for an internally controlled case series.

This design allows for less variability in the data, resulting in improved statistical power with fewer subjects. The problem with a repeated measures study design is that the two interventions, UKA versus TKA, cannot be considered truly independent, as they both occurred in the same individual. In these types of studies, it is difficult to separate how one intervention has influenced the other.

Besides pain relief, functional recovery remains an important component of operative success after knee arthroplasty. The goals of orthopaedic surgery are to restore normal joint motion, return the patient to full function, prevent further degenerative disease, and provide the patient with an expedited return to work and recreational activities. Hopper et al. conducted a study to determine how easily patients returned to low-impact sports after either UKA or TKA.[60] Patients who underwent UKA returned to sports in a mean time of 3.6 months, compared to 4.1 months for TKA patients. The amount of time spent participating in low impact sports for UKA patients rose from an average of 85 minutes per week preoperatively, to an average of 92.1 minutes postoperatively. Recreational participation time decreased from a mean of 62.7 minutes preoperatively, to a mean of 37.5 minutes per week postoperatively for TKA patients. Pain during sporting activities was experienced by only 24.1% of UKA patients as compared to 42.9% of TKA patients.[60] These studies concluded that patients undergoing UKA returned to sports faster, were able to participate in physical activity for longer periods of time, and had less joint pain with greater knee function.[60,61]

Limitations Preventing the Widespread Adoption of the Unicompartmental Knee Arthroplasty Procedure in Clinical Practices

While UKA may have advantages as a surgical option for selected patients who meet the operative criteria detailed previously, TKA remains a popular operation for unicompartmental pathology. The widespread performance of UKA has been limited by the technical difficulty of performing the procedure. In particular, UKA has less tolerance for acceptable component positioning when compared to TKA, as improper

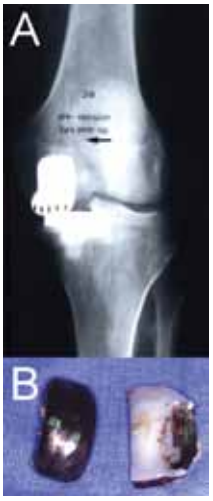


Fig. 2 Wrong component sizing or positioning may lead to edge loading (A) resulting in increased wear and implant failure (B).

component positioning, by as little as 2°, can result in UKA failure (Figure 2).[5,37,46,62-68] Failures of UKA occur when there is medial-lateral mismatch, inadequate stability of the components, heterogeneous polyethylene wear, improper patient selection (such as performing UKA for bilateral osteoarthritis), aseptic loosening, and tibial subsidence (Figure 3A and 3B).[4,27]

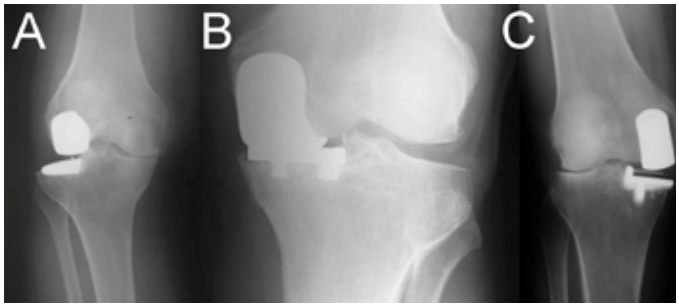


Fig. 3 Disease progression of the other compartment from overstuffing, over-correction or misbalance (A), early loosening (B) and wrong component positioning may lead UKA failure. Fig. 3C

Improper alignment is considered to be the leading cause of UKA failure (Figure 3C).[28,61]

Maligned components often lead to impaired joint biomechanics, and eventual knee pain.[5,69,70] Reports in the literature have associated a technically poor UKA operation with accelerated polyethylene wear, an accelerated progression of the pathology to the contralateral compartment, and, in some rare instances, femoral fracture.[5,28,63,71,72,73] Strict adherence to operative technique and acceptable tolerances are required to maximize the benefits of UKA. Preservation of adequate bone stock is crucial to surgical success, leading to a shorter recovery and rehabilitation time.[25,28,45] Further, excessive bone resection often results in poor tibial component stability, which has been associated with a more difficult conversion to TKA if revision arthroplasty is eventually required.[4,68] The technical demands of performing UKA, coupled with the small margin for error, have limited the widespread adoption of this surgical intervention for unicompartmental knee pathology and many surgeons and patients remain wary of the historically inconsistent post-surgical results published in the literature.

Use of Robotics for Unicompartmental Knee Arthroplasty

Historically, UKA has been considered a technically demanding procedure that poses a challenge to the orthopaedic surgeon. More recently, the development and use of robotic-assisted technology[74] has made performing UKA technically less demanding and various studies have reported improved radiographic outcomes, more consistent component placement, and fewer outliers[26] (Figure 4).

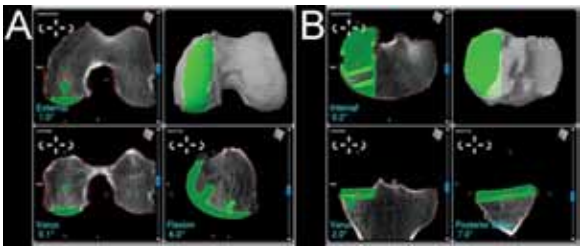


Fig. 4 Intraoperative screenshots of the robotic system showing the computer model of any anatomy based on preoperative CT-scans and allowing for precise positioning of the femoral (A) and tibial (B) components.

For example, Bellemans et al. reported implant positioning and alignment to fall within 1° error of neutral alignment for all cases performed with robotic-assistance.[75] Furthermore, Cobb et al. demonstrated that the number of radiographic outliers following UKA decrease significantly with the aid of robotic systems.[26] However, the results of this study should be interpreted with caution, as it remains unclear if these more favorable radiographic outcome measures correlate with greater functional improvement.[26,76]

Computer assisted surgery systems, also called passive surgery systems, monitor operative procedures and allow for intraoperative assessment and feedback during adult reconstructive surgery (Figure 5).[67,74,77]

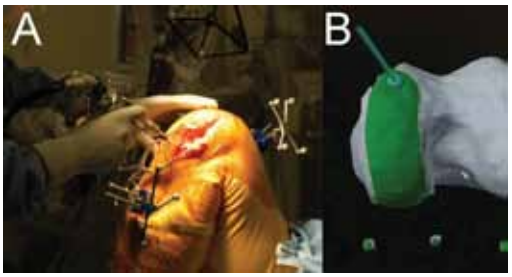


Fig. 5 Example of a system that uses a robotic arm with a high speed burr and gives the surgeon tactile feedback (A) when the planned resection depth is reached (B).[74]

The individual design of passive surgery systems is proprietary, however, these systems track various parameters (i.e. component positioning, bone geometry) during operative procedures.[78] Computer-based intraoperative systems may offer greater accuracy over conventional templating methods, thus, passive systems may be utilized during UKA to more accurately and precisely place components.[66,77,78] Better component placement during UKA has been associated with clinical success.[37,67,77,78,79] Specifically, Pearle et al. and Cobb et al. found that intraoperative computer-guidance enabled component positioning to within 2° of the preoperative plan in all cases.[26,37] In these studies, up to 60% of UKA components were determined to be improperly positioned when computer navigation was not used.[26,37] Other studies have reported that femoral and tibial component alignment, tibial slope, and lower extremity mechanical axis was improved when passive surgery systems were used during UKA.[80-85]

Robotic systems have also been designed to aid surgeons during UKA. Using templates prepared from a computer-tomography scan, the robot provides both tactile and haptic response during the procedure in order to assist the surgeon in matching their preoperative plan. Ligament balancing and range of motion are also obtained intraoperatively with the UKA prosthesis in place. Early reports of radiographic outcomes have been promising when the robotic system has been utilized.[61,86,87] Lonner et al. conducted a radiographic comparison of 31 consecutive patients who underwent robotic-assisted UKA to 27 consecutive patients who underwent manual UKA.[86] The authors found that there was almost three times greater variation in tibial component using the standard method, suggesting that robotic-assisted surgery leads to more consistent component placement. However, these findings have not been correlated to clinical outcomes. Additionally, Roche et al. reported on the one-year outcomes of 223 robot-assisted UKAs.[87] At the most recent follow-up, none of the patients required revision surgery and there was a statistically significant improvement in clinical outcome scores. However, until mid-term results are available, many institutions will find it hard to invest in this new technology.

Conclusion

UKA has the potential to become the preferred operation for the treatment of limited degenerative knee disease. With robotic assistance, UKA component placement may become more accurate and precise. Data relating improved short-term radiographic outcomes to enhanced functional outcomes and improved patient satisfaction is limited; thus more studies with longer follow-up are required before UKA is more widely performed. Favorable outcomes using new robotic technology may encourage orthopaedic surgeons to offer their patients UKA as a treatment option for unicompartmental joint pathology. However, mid-term and long-term data are not currently available for robotic-assisted UKA and further investigations are needed.

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Resection Guide For the ARC™ Tissue Conserving (Neck Sparing) Total Hip Stem***

-Case Report-

Robert L. Pierron, MD*, and Timothy McTighe, Dr. HS (hc)**

Abstract:

Neck sparing total hip designs have been advocated as the next step in tissue preserving total hip arthroplasty[1,2,3]. In the proximal femur, the femoral neck and the adjoining medial aspect of the femur in the calcar region show the strongest bone structure (Fig. 1) with a high load capacity to support the stem. There are considerable short-term biomechanical advantages concerning reduced bending and torsional moments of the femoral implant/bone interface[4] with resection at that level, however, historical review has demonstrated less than desirable bone maintenance over time[5]. According to Wolff's Law, the reduction of stresses relative to the pre-implant anatomy would cause bone to adapt itself by reducing its mass, either by becoming more porous (internal remodeling) or by getting thinner (external remodeling)[7]. The ARC™ Neck Sparing stem has a novel internal conical flair that engages the medial calcar and is designed to offload compressive loads maintaining a positive stress transfer to the medial calcar[6]. The combination of neck resection level and angle are important considerations for neck preserving stem designs. This case report demonstrates a new resection guide that has proven to be simple and reliable.

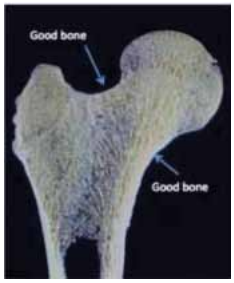

Fig. 1

Key Words: femoral neck, stress transfer, resection guide, conical flair

Introduction:

Tissue conserving neck sparing (Fig. 2) surgery in THA is credited to Prof. Pipino, from Monza, Italy who has been working on this concept for over 30 years[1]. The Apex ARC™ Stem is built off the pioneering work of Pipino, Freeman, Townley and Whiteside with new novel design features. The proximal portion of the stem has a patent pending novel conical flair element (Fig. 3) that is designed to off load compressive loads to the medial calcar. This unique feature has demonstrated positive stress transfer in both FEA modeling and now clinical observations[5].


Fig. 2 Neck Sparing Curved Stem


Fig. 3 Conical Flair

Proper neck resection level and angle are important steps in the surgical technique to ensure maximum bone contact with the proximal conical flair[7]. This case report will highlight the advantages of a new neck resection guide designed by the senior author and is now used routinely in the surgical preparation of the ARC™ Tissue Conserving Femoral stem.

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Surgical Technique:

The neck resection is conservative but allows some flexibility to adapt to both patient anatomy and surgical preference. The level of resection (Fig. 4) and the angle of resection should be accurate to ensure optimal conical flair contact. If the angle of the resection is too vertical you can have the stem in slight varus and if the resection is too horizontal the stem (Fig. 5) can be in slight valgus. Neutral or slight varus is the preferred position[7]. (Fig. 6)

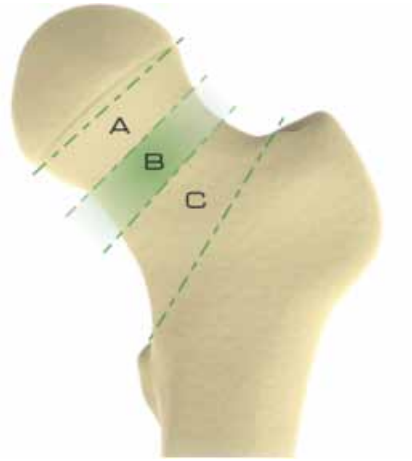


Fig. 4 Possible Levels of Neck Resection (B is preferred)

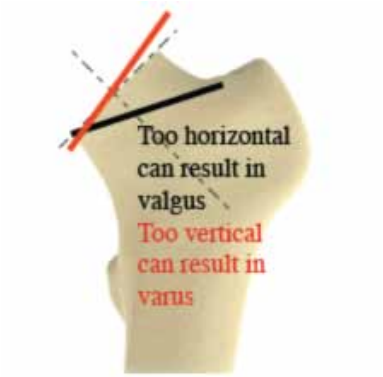


Fig. 5

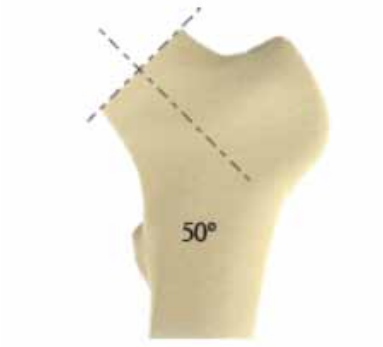
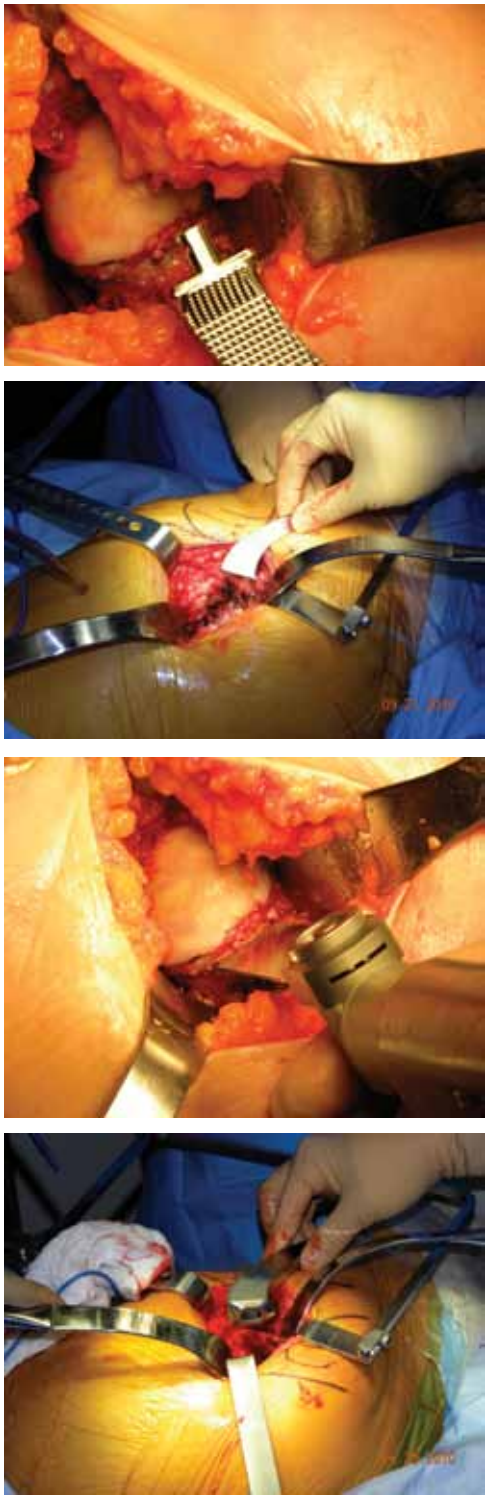


Fig. 6 Proper Angle Perpendicular to Neck

Prior alignment techniques have used a rasp, stem template, or trial stem as a gross resection guide. (Fig. 7)



Rasp as resection guide, Anterior approach

Template

Resection

Trial Stem posterior approach

Fig. 7

These techniques have been helpful, however, they can be difficult to use because of size and exposure.

(Fig. 8) Shows stem slightly above the neck resection. This has not proven to be a problem clinically, but the ideal position has the conical flair engaging the medial calcar. There are examples that a small gap can and does fill in by remodeling (Fig. 9).

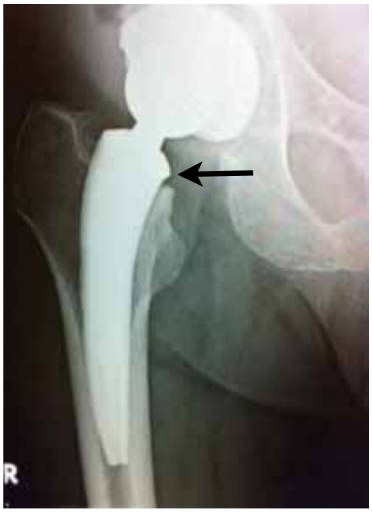


Fig. 8 Conical Flair Proud of Resection Line

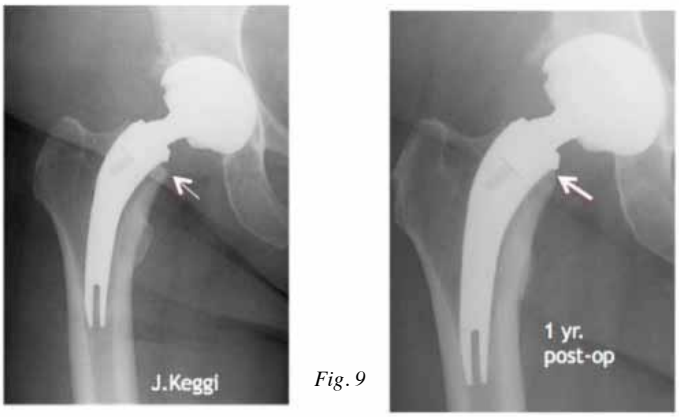


Fig. 9

(Left) Gap at the Medial Calcar (Right) Gap Filled in at 1 year Follow Up

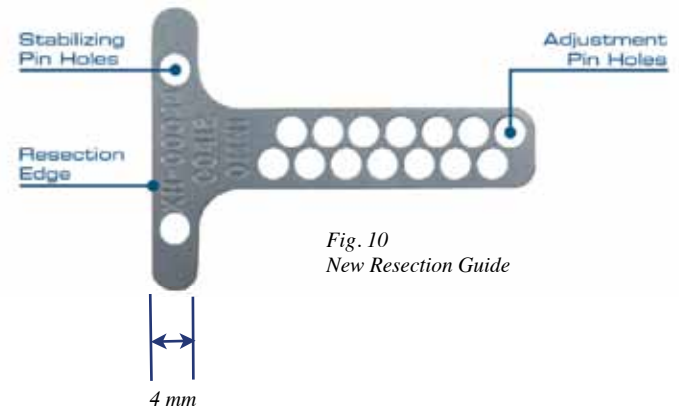


Fig. 10
New Resection Guide

This guide can be used with any surgical approach that dislocates the femoral head before neck resection.

Step 1:
Locate Femoral Head Center, and place an unthreaded Steinmann pin (3.2 mm).

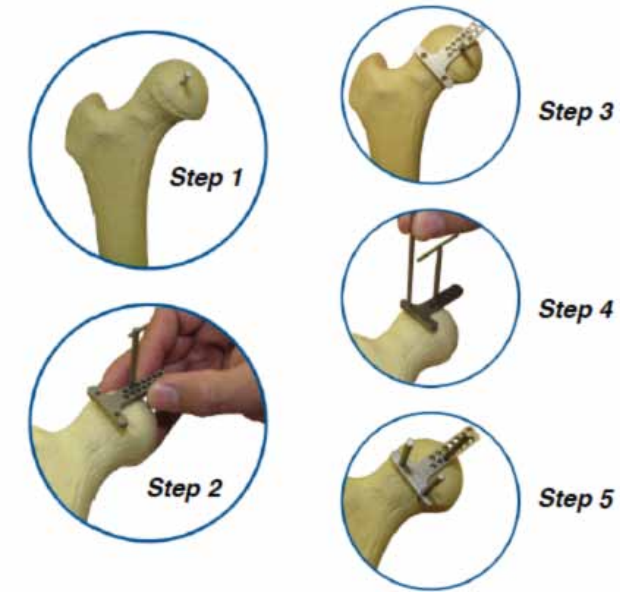
Step 2:
Slide guide onto the head center pin, using any of the adjustment pin holes. Adjust pin position until the guide's resection edge is located 5-8mm below the subcapital level or in the location determined during preoperative planning. Pin holes are located in 2mm increments.

Step 3:
Orient the guide so it is perpendicular to the neck axis.

Step 4:
Secure the guide by driving either one or two pins in the Stabilizing Pin Holes. Alternatively, a second pin through one of the other adjustment holes will adequately stabilize the guide.

Step 5:
Make resection along the Guide Resection Edge, or use guide to mark resection level with a surgical pen or electrocautery.

Note: Resection edge bar is 4 mm in height. When the proximal edge is placed at the articular cartilage/neck junction, the saw cut should be approximately 5 mm subcapital.[8]



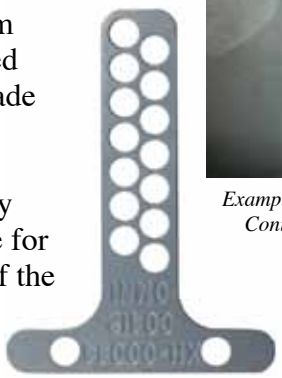
Resected Head and Guide

Observation and Results:

This guide has been used with repeated success and now is in routine clinical use.

We have found this device to be very helpful in achieving intimate contact between the proximal conical flair of the stem and the resected neck. It has made our resections more accurate which in theory should provide for maintenance of the medial calcar.

Example of Contact Between Conical Flair and Neck Resection.



ARC (Head-Pin) Resection Guide

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Simultaneous Bilateral Direct Anterior Total Hip Arthroplasty Utilizing a Modular Neck-Sparing Arthroplasty Femoral Stem

-Case Report and Literature Review-

Lee E. Rubin, MD*, John R. Tuttle, MD**, Scott A. Ritterman, MD***

Introduction:

Total hip arthroplasty for the management of bilateral hip osteoarthritis has been described in the literature since the 1970's, utilizing either a simultaneous (single anesthetic) or staged (multiple anesthetics) technique. Utilization of a direct anterior approach to the hip joint allows for simultaneous bilateral total hip arthroplasty, without the need for re-positioning or re-draping the patient during the operation. The procedure is performed in a sequential fashion focused on a single side, with completion of the procedure before immediately proceeding to the contralateral side.

The use of femoral-neck sparing arthroplasty design spans greater than 30 years,[1] with a focus on preservation of proximal bone stock for younger, active patients who are undergoing arthroplasty at a young age and may need future revision surgery. Success rates reported by Dr. Pipino in his series included 97% satisfactory radiographic results, and an implant survival rate of almost 100% at 25 years.

The modern, press-fit, modular neck-sparing arthroplasty design has been available in the United States and Australia for nearly 3 years, and enables the surgeon to perform intraoperative customization of the hip biomechanics for each case. Additionally, the standard 12/14mm trunnion allows the surgeon to choose the femoral head and bearing material, allowing options for metal on polyethylene, ceramic on ceramic, ceramic on poly, or ceramic on metal couples, in order to help avoid the use of metal on metal couples that have demonstrated higher complication rates in the recent literature.

To the best of our knowledge, we present the world's first case report of a simultaneous, bilateral, direct anterior total hip arthroplasty utilizing a modular neck-sparing arthroplasty femoral stem design.

Case Report:

A 32 year-old man presented for evaluation after having been previously diagnosed with advanced bilateral avascular necrosis of his proximal femoral heads. His management had already included a comprehensive medical and metabolic workup to assess for causes for the avascular necrosis, but none had been elucidated. He denied any known exposure to high dose corticosteroids and had no history of alcohol intake. He had previously undergone core decompression procedures at an outside institution on both the right hip (18 months prior) and the left hip (14 months prior) in the

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recent past, without any significant improvements in his clinical function or symptoms.

He reported that his pain had continued in severity to a point where it had become "impossible to walk," and that the cracking and grinding within his hips felt as if he "was walking on glass." He was reliant on progressively increasing doses of oxycodone, and was almost totally debilitated by the pain, relying on two crutches for maintaining the little ambulation he was capable of. His past medical history was significant for anxiety but was otherwise unremarkable.

Examination demonstrated a markedly antalgic gait pattern, profound difficulty arising from a chair, and reliance on two crutches while upright. From a seated position, he was able to flex 10 degrees to 100, had 0 degrees internal rotation, 20 degrees external rotation, and 20 degrees of abduction. Crepitus within the hip joints was both palpable and audible during examination. His prior incisions were healed, and he was intact to light touch and motor function in both lower extremities.

Radiographs were obtained, including an AP pelvis with AP and frog lateral images of each hip (Figures 1-3). These demonstrated severe avascular necrosis with collapse and prior decompression tracks with healed lateral cortices. No retained metal was evident in either hip. Both joints had severe secondary osteoarthritis, with joint space narrowing, subchondral cystic changes, and dense sclerosis.

The patient requested that both hip surgeries be performed during the same procedure if possible. Written informed consent was obtained, including

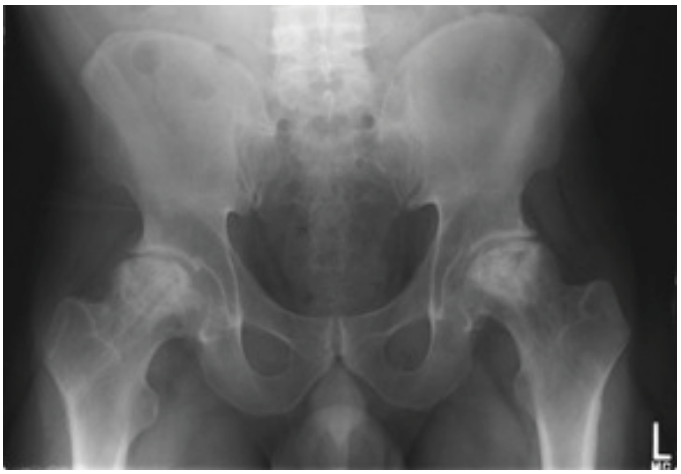

Figure 1 - preop AP pelvis.

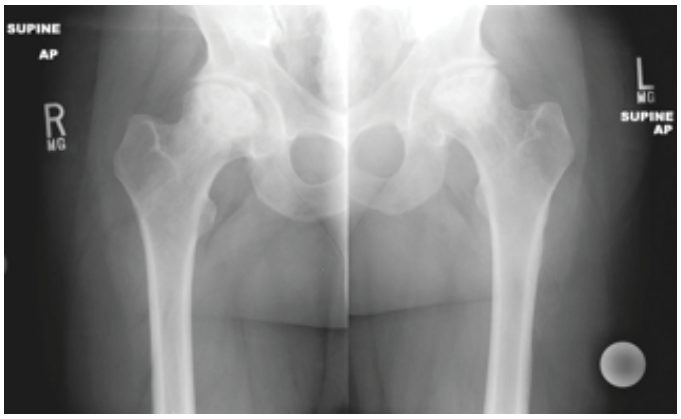

Figure 2 - preop AP hips.

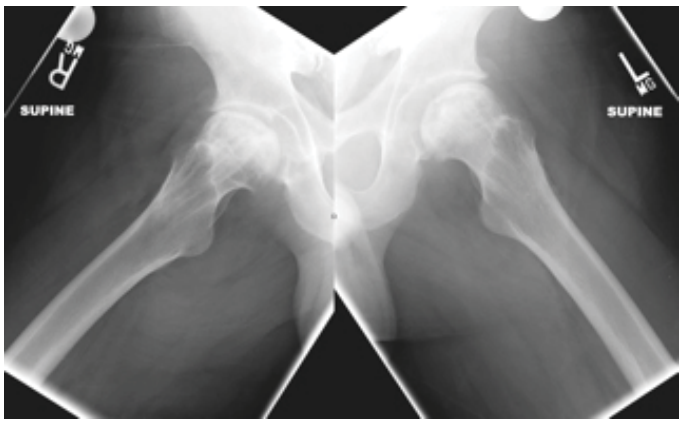

Figure 3 - preop LAT hips.

written consent for anonymous publication of his case. Selection of a direct anterior surgical approach was made to facilitate the performance of simultaneous bilateral total hip arthroplasty. The bone preserving implants were selected since the bone stock within the femoral necks was well preserved and had dense cortical structure despite the avascular necrosis with collapse seen within the femoral heads.

Operative technique involved supine positioning on a standard operating table. Neuraxial anesthesia via an epidural catheter was utilized for intra- and post- operative pain control, in conjunction with general endotracheal and local / peri-articular injections during the procedure. A foley catheter secured superiorly and centrally on the abdomen with gauze and Ioban adhesive. A gel bump was placed centrally beneath the sacrum and the patient was positioned with the right hip elevated for the initial right hip arthroplasty procedure. An oblique incision and a direct anterior approach was performed, with resection of the diseased femoral head and a complete capsular release for femoral mobilization. A 50 degree subcapital resection was

utilized in preparation for implantation of the Neck Sparing Arthroplasty stem, with preservation of his femoral neck. An intraoperative shoot-through AP radiograph was obtained with the final trials in place to assess the position and fill of the femoral component within the right proximal femur (Figure 4).

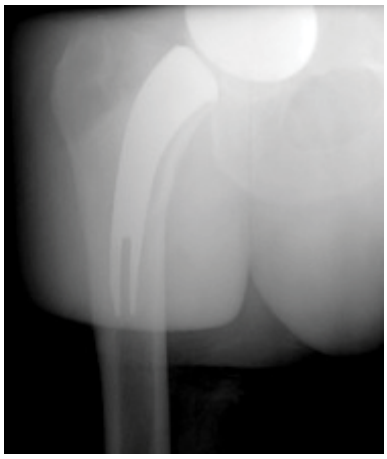

Figure 4 - intraop trial.

Once the right total hip arthroplasty had been completed and closed, the left hip was elevated on the sacral bump, and the left total hip arthroplasty was performed using an identical technique. A single 18 gauge prophylactic cerclage wire was placed around the left femoral neck due to a small divot that occurred in the anterior femoral cortex following removal of the left femoral head. There was no intraoperative or post-operative evidence of fissure or fracture. Both hip wounds were closed utilizing a multi-layer series of absorbable sutures and dermabond advanced skin glue for cosmetic closure.

Acetabular implants utilized in the case included the Depuy (Warsaw, IN, USA) Pinnacle size 56mm outer diameter hemispherical acetabular shells with +4mm lateralized cross-linked polyethylene liners. Femoral implants included Size 2 Omni Life Science (East Taunton, MA, USA) Apex ARC stem in both hips, with a 8 degree retroverted modular femoral neck on the right and a neutral "standard" modular neck on the left. A +4mm by 36 mm Delta ceramic femoral head was used on the right and a +8mm by 36mm Delta ceramic femoral head was utilized on the left.

Gross blood loss was 1800mL, and net blood loss was 400mL after 1400mL of autologous blood was returned to the patient intraoperatively using a cell saver technique. No allogenic transfusions were given during his hospitalization. The patient stayed 4 days in the hospital and was discharged to home with visiting nursing and therapy services. Deep venous thrombosis was achieved with enteric-coated aspirin 325mg twice daily in combination with intermittent pneumatic compression boots, active lower extremity exercises, and ambulation during his recovery.

The patient has progressed significantly over the first few months since his surgery, with a steadily decreasing narcotic dose from his preoperative baseline. He has transitioned to outpatient physical therapy and has continued to make progress towards normalizing his gait pattern and improving his hip strength, endurance, and overall function. Range of motion is once again smooth and no longer affected by crepitus, locking, and pain. Radiographs from his 4 week postoperative visit included an AP pelvis with AP and supine frog lateral views of both hips (Figures 5-7), demonstrating that the components are well-seated in an anatomic position.

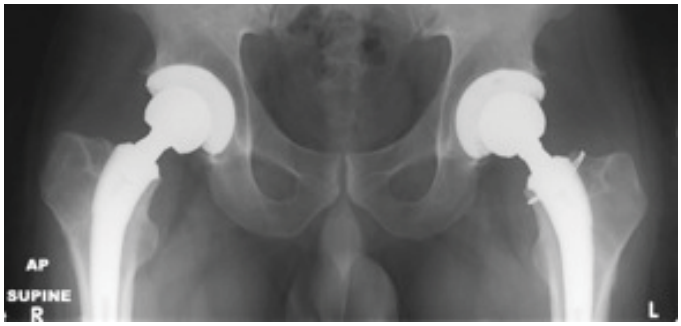

Figure 5 - postop AP pelvis.

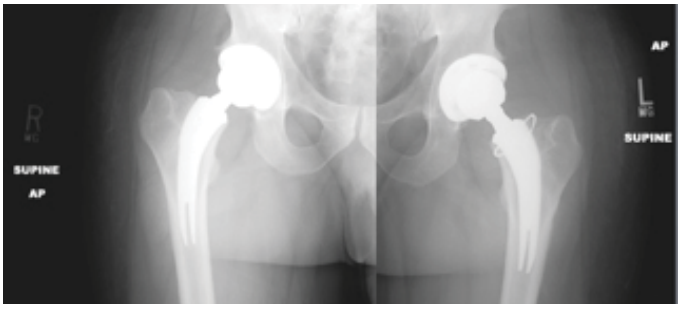

Figure 6 - postop AP hips.

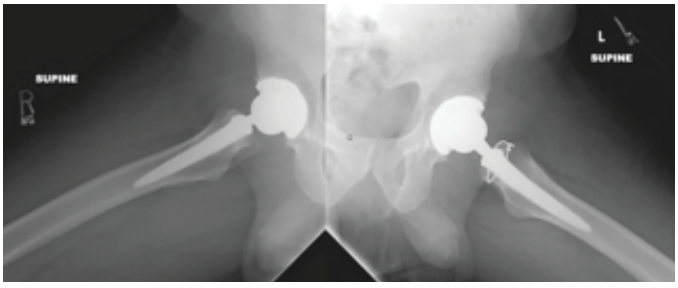

Figure 7 - postop LAT hips.

Discussion:

Bilateral total hip arthroplasty was described in the 1970's and was presented as an option for younger, healthier patients who could sustain undergoing a larger surgery.[2, 3, 4] When compared with the single procedures at that time, the duration of surgery in the one-stage procedure was not quite doubled, while the blood loss was increased by about one-third, and the length of stay lengthened by about one week. However, the total length of stay in the hospital was reduced by about one-half in comparison with single-admission two-stage replacements and the incidence of local and systemic complications was similar across the groups, as were the clinical and roentgenographic results. This was felt to be favorable at that time, and judicious use of the technique also helped reduce hospital costs associated with two admissions, two anesthetics, and two trips to the operating room for the patient.

Ganz et. al.[5] analyzed one stage versus two stage bilateral hip arthroplasty in 1996 and found that there were no differences in operative, early local, or general complications among the groups. In particular, no higher incidence of pulmonary embolism or deep vein thrombosis was found in the 1 stage group. Preoperatively, very stiff hips (total range of motion < 50°) gained significantly more motion in the 1 stage group than in the 2 stage groups. The degree of pain reduction was the same in all groups, but patients in the 1 stage group had a significantly better capacity for walking after their procedure. Average total hospital stay was 5 to 6 days less for the patients in single stage group, which, combined with using the operating room only once, resulted in a reduction of overall hospital costs by more than 30% when using the 1 stage procedure.

Other modern reviews of this technique have also lent support to the safety of performing the procedure. Alfaro-Adrian et. al.[6] showed that bilateral total hip replacement was equally safe whether performed as a 1-stage or 2-stage procedure. This was the case in both the low-risk (ASA 1 and 2) and high-risk (ASA 3 and 4) patient subgroups. From their perspective, one-stage bilateral THR was cheaper and involved less time in the hospital. In a follow-up to an earlier study, Ritter et. al.[7] compared the morbidity, mortality, and outcomes of 900 simultaneous bilateral total hip arthroplasties in 450 patients and 450 unilateral total hip arthroplasties. Pulmonary complications were significantly higher in the simultaneous bilateral group (1.6% vs 0.7%; $P < .0312$). Patients with mortality in the first postoperative year were significantly older (69.8 vs 62.3 years; $P < .0012$). Long-term patient survival, the prosthetic survival, and functional outcomes were not significantly different between groups.

In contrast, Berend et. al.[8] showed that significantly more inpatient complications and adverse events occurred in patients undergoing simultaneous bilateral THA in the lateral decubitus position. There were significantly higher transfusion requirements, and more patients failed to reach physical therapy goals during admission, requiring more transfers to rehabilitation facilities. Need for subsequent hip surgery was also significantly higher in simultaneous bilateral patients. In addition to these negative results, the hospital system realized a 28% reduction and the surgeon suffered a 15% reduction in potential reimbursement.

Simultaneous bilateral total hip arthroplasty may have advantages where both hips are symptomatic for younger patients, who are inherently more fit to sustain a larger surgery. Schwarzkopf et. al.[9] reported on a follow-up of 30 patients who underwent simultaneous bilateral total hip arthroplasty with hydroxyapatite implants and were followed for an average of 19.4 years. Using the Kaplan-Meier survivorship analysis, with revision for any reason as an end point, survivorship was 94% at 12 years, 88% at 15 years, 74% at 18 years, and 61% at 23 years. All revisions were for the acetabular component, and the survivorship for the femoral component was 100% throughout the 23-year period.

Long-term results of the modular neck-sparing arthroplasty design are not yet available, but utilization of the press-fit, hydroxyapatite coated stem design for young patients should lead to high long-term femoral component survival rates based on the data presented above. Additionally, since the surgeon can select high-performance low-wear bearing surface combinations such as ceramic on ceramic and ceramic on cross-linked polyethylene, the long term survival of the components also

should be enhanced by the improvements in the bioengineering of the bearing surfaces.

The use of a direct anterior surgical approach in combination with neuraxial anesthesia and autologous cell saver harvest to facilitate performance of simultaneous bilateral total hip arthroplasty may allow for reductions in OR time, blood loss, length of hospital stay, and complication rates compared to laterally based approaches to the hip joint. Additionally, the direct anterior approach is also likely to improve the short term recovery for patients undergoing a bilateral procedure by preserving the peri-articular musculature compared to other historic techniques.

The present case demonstrates the utility of the direct anterior approach in performing simultaneous bilateral total hip arthroplasty, without the need for traction tables or expensive intraoperative exposure devices. The patient's uneventful hospital course and outstanding early progress suggests that this technique can be successfully repeated for carefully selected young, healthy patients affected by severe bilateral hip disease. The costs for the hospital and the surgeon's reimbursement may impact the decision to pursue this type of intervention, but it can be safely performed with outstanding clinical and functional results for carefully selected young patients.

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

In Vivo Dissociation Of A Dual Articulation Bearing In Revision THA

-Case Report-

Edward J. McPherson, MD, FACS*, Sherif Sherif, MD*

Key Words: Dual Articulation, Dual Mobility, Active Articulation, THA, Revision, Dissociation, Dislocation

Introduction

Revision total hip arthroplasty (THA) can be a difficult reconstructive procedure that challenges the skills of even the adroit orthopaedic surgeon. Revision THA for aseptic failure after acetabular/pelvic fracture is one of the more difficult challenges in the realm of hip reconstruction. The high complication rate associated with this complex reconstruction remains the dominant obstacle for obtaining consistent satisfactory outcomes. The specific problems of boney defects, pelvic malalignment, heterotopic ossification, soft tissue scarring, and muscle atrophy compromise the goals of revision THA, which include osteointegration of implant to host bone, restoration of hip joint biomechanics, and joint stability[12].

Recurrent dislocation in revision THA is one of the more frustrating complications for both the patient and the surgeon, and it remains so even today. Despite this, there continues to be developments in surgical technique and prosthetic design to enhance prosthetic hip stability. One prosthetic design, the dual articulation hip bearing, was developed to enhance THA stability. The dual articulation concept was developed by professor Gilles Bousquet and engineer André Rambert in the late 1970's[14]. The dual mobility design incorporates two articular surfaces within the THA bearing. The acetabular cup is composed of a metallic bearing that articulates with an ultra high molecular weight polyethylene (UHMWPE) ball. Within the UHMWPE head is an inner ball that is enclosed within the polyethylene (figure 1). This design concept increases hip primary arc range before impingement.

Figure 1 - Picture of dual articulation hip bearing concept. In this example, a UHMWPE head is articulating with an all-metal porous coated acetabular cup. Within the polyethylene head is enclosed an inner ceramic ball that is assembled ex-vivo at the time of surgery. Courtesy Biomet, Inc. Warsaw, IN..

The Bousquet dual mobility concept has been used over the last 20 years in Europe with successful clinical outcomes[6,7,9,11]. In the United States, the dual articulation bearing design received FDA clearance in 2011. However, as with the addition of any modular part, there is the potential for new in-vivo failure mechanisms. With the dual mobility construct, the new failure mechanism is dissociation of the inner head[1,10]. We report in this case an early traumatic dissociation of a dual mobility bearing utilized in a complex revision THA. To our knowledge, this is the first reported case of a traumatic in-vivo disassembly of a dual articulation bearing THA.

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Case Report

A 52-year-old male underwent a complex revision right THA for mechanical hip pain and functional debility. His problem began 33 years prior when he was involved in an accident in which he was struck by a car while riding his motorcycle. His right hip and pelvis were fractured. He was treated with pelvic and acetabular plating. Three years later, in 1981, a hemiarthroplasty procedure was performed for osteonecrosis. In 1984, he underwent revision THA for mechanical loosening. His pelvic plate hardware was removed at the time of revision THA. In 2004 another revision THA was performed for mechanical loosening resulting from osteolysis. Since his last revision hip surgery, he has never been free of pain around his hip. The patient noted progressive hip stiffness with increasing functional weight bearing pain.

On exam the patient walked with an antelgic gait using a lofstrand crutch in his left hand. The right leg measured 1.8 centimeters (cm) short. Passive hip range was irritable. The patient guarded with flexion and rotation testing. Hip range was limited: flexion measured 50°, extension 0°, external rotation 15°, internal rotation 0°, abduction 25°, and adduction 0°. Aspiration cultures were negative and quantitative C-reactive protein and westergan sedimentation rates were normal. Preoperative radiographs showed a medialized acetabular cup with screws and a revision stem with a lack of offset such that the greater trochanter appeared fused to the lateral ilium (Figure 2). A model of the right hemipelvis was created from a high resolution CT scan. This revealed significant segmental bone defects involving the acetabulum and pelvis. These deficiencies were treated with a custom triflange porous pelvic implant (Biomet Inc. Warsaw, IN.).

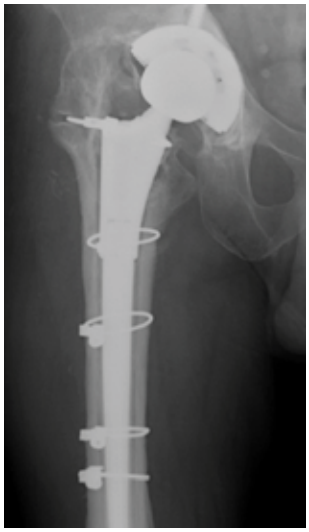

Figure 2 - Preoperative radiograph of the revision THA with post-traumatic pelvic deformities. Note the loss of femoral offset that has allowed the greater trochanter to abut the lateral ilium. Also note the relative protrusio of the acetabular cup. The patient had marked limitation of hip range along with debilitating pain.

In the revision, the pelvis was reconstructed with a cementless triflange porous pelvic implant (PPI). A large diameter monolithic metal bearing (Magnum, Biomet Inc.) was cemented into the triflange PPI. The femoral stem was revised with a modular revision stem (Arcos, Biomet Inc). A dual articulation bearing (Active Articulation, Biomet Inc) was mated to the cup (Figure3).

Four weeks post-operatively the patient dislocated his hip while disembarking from the back seat of a car. He was taken to a local emergency room where radiographs confirmed a hip dislocation (figure 4). The closed reduction maneuver was performed in the emergency room suite under sedation. By patient report, the reduction was difficult, requiring multiple attempts and considerable force. After the initial reduction the patient had several subsequent dislocations over the next 3 weeks that

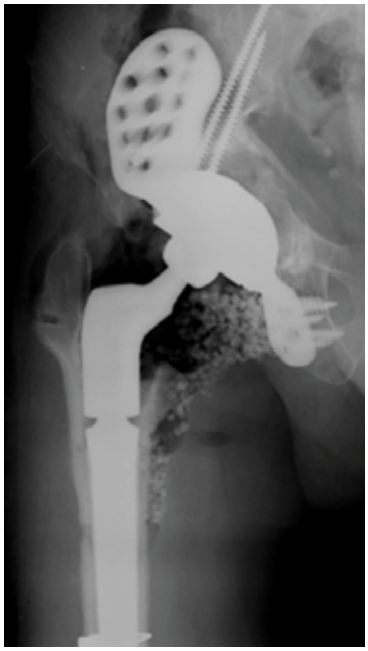

Figure 3 - Postoperative radiograph showing pelvic reconstruction and revision THA. The pelvis is reconstructed with a triflange porous pelvic implant (PPI). The femur is revised utilizing a proximal cone to optimize hip offset and anteversion. A large diameter monolithic metal cup is cemented into the PPI. A dual articulation bearing is in place. Only the inner ball is visualized as the outer ball is made of UHMWPE. Note the dissolvable antibiotic beads (Stimulan, Biocomposites Inc. Keele, England) placed into the hip joint.

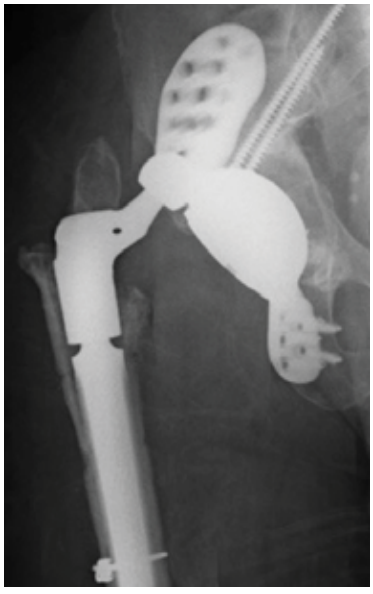

Figure 4 - Radiograph of dislocated revision THA. Lateral radiographs confirmed that this dislocation was posterior. Note the greater trochanter has been fractured. This occurred during a prior closed reduction attempt.

were, by patient report, easy to reduce. Additionally, since the first reduction the patient noted the right leg was short and he felt an intermittent hip grind with sit to stand. Eight weeks post-operatively the patient was examined in the office. The right leg appeared clinically located, but a grinding sensation was felt with passive range. The right leg was short. Radiographs showed an eccentric position of the inner ball. The inner ball of the dual mobility bearing was articulating with the metallic cup. Furthermore, there was a fracture involving the greater trochanter and the lateral femoral cortex (figure 5).

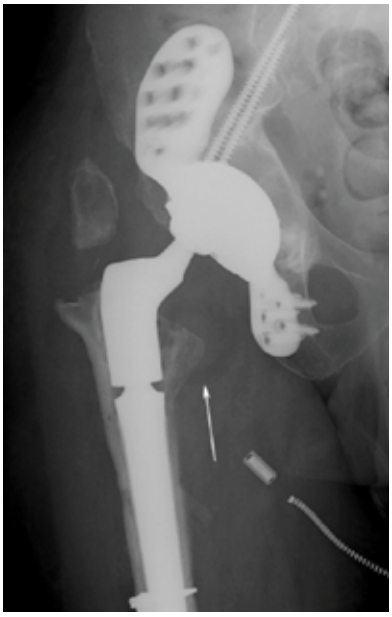

Figure 5 - Post reduction radiograph. Note in this radiograph how the inner head is eccentrically positioned. The inner head is now articulating upon the all-metal acetabular cup. This is pathognomonic of an inner head dissociation. Note the arrow which points out the round dark shadow around the lesser trochanter. This shadow is the dissociated polyethylene ball that is resting below the cotyloid fossa.

The patient's hip was explored and revised. Exam of the hip intraoperatively showed that the inner head of the dual mobility bearing had dissociated from the polyethylene head. The polyethylene head was trapped inferiorly below the acetabular cotyloid fossa. The Magnum cup was grossly scratched as the inner ceramic ball was articulating with the metal cup. The femoral stem was stable despite the fracture of the greater trochanter. The triflange PPI was also stable. Figure 6 shows the retrieved dual mobility bearing. The hip was revised. A constrained acetabular cup (Freedom, Biomet, Inc.) was cemented into the triflange PPI. The greater trochanter was reduced and fixed with a cable claw plate (Arcos System, Biomet, Inc.) with a bolt securing the claw into the lateral aspect of the femoral stem (figure 7). At six months post-operatively, the hip remains stable.

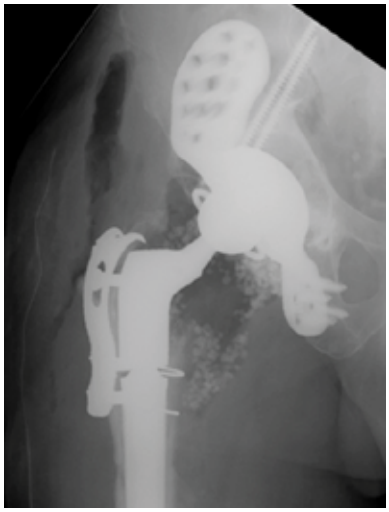

Figure 6 - Postoperative radiograph showing revision. The acetabulum has been revised to a constrained acetabular cup. Note the locking ring around the femoral head. The greater trochanter has been secured with a trochanteric claw plate. A bolt secures the claw into the lateral portion of the femoral stem. Note again, dissolvable antibiotic beads (Stimulan) have been placed into the hip joint.

Figure 7 - Retrieved dual articulation bearing. Multiple metal smears are seen on the ceramic head which was articulating upon the metal cup.

Discussion

The dual articulation bearing construct in THA had enjoyed favorable popularity with most use being centered around France[4,5,13]. It is estimated that over 25,000 dual articulation bearings have been inserted worldwide (personal communication Stryker Inc, Kalamazoo, MI and Biomet Inc, Warsaw, IN). There are good mid-term (99.6% survival at 5 years) and long-term (85.4% survival at 15 years) outcomes in high dislocation risk populations[3,8,14]. Dislocation rates with the dual articulation bearing are favorable, reported as low as 1.15% in 16 years[2,14]. Dissociation of the inner ball is a rare but reported complication with the dual articulation design. Interestingly, the reported inner head dissociations have occurred relatively

late in the life cycle of the prosthesis. The reported incidence of inner head dissociation is 0.2%, with the reported dissociations occurring between 8 to 16 years after surgery[7]. Dissociation resulted from wear and deformation of the UHMWPE head that enclosed the inner head. The inner head can also dissociate by traumatic levering if the outer head is dislocated and entrapped by the surrounding pelvic structures. This mechanism of dissociation has not been reported until now. Assembly of the inner ball into the UHMWPE head requires considerable force. Approximately 75% of the inner ball is enclosed within the UHMWE head and a very high force is needed to "squeeze" the inner head into the polyethylene. The stated compression force to assemble the inner ball into the polyethylene head is approximately 162 foot-pounds for the Active Articulation bearing (personal communication Biomet, Inc.) and 200 foot-pounds for the Dual Mobility bearing (personal communication Stryker, Inc.) The force to lever out the inner ball once reduced is approximately 150 foot-pounds for the Active Articulation bearing and 180 foot-pounds for the Dual Mobility bearing (personal communication Biomet Inc & Stryker Inc). We believe the dissociation in this case was a result of an entrapped polyethylene head combined with a very forceful levering of the leg during the initial reduction maneuver. The considerable force is evident by the fracture of the greater trochanter that occurred during the reduction maneuver. The stability of the retrieved bearing was impressive. The senior author did not appreciate a difference in the subjective force to reassemble the retrieved bearing compared to a new dual articulation bearing.

The orthopaedic surgeon and emergency room physician need to recognize when a patient presents with a dislocated dual mobility construct. Since the "achilles heel" in the design is its relative lower lever out force for the inner ball, the THA reduction maneuver should be modified. Specifically, forceful angular and levering maneuvers of the leg should be avoided. Remember also, since the dual mobility head is larger than the typical THA head, successful reduction is generally more difficult. We recommend that only one or two reduction attempts be made in the emergency room or radiology suite. If unsuccessful, we advocate that the reduction maneuver be undertaken in the operating room with muscle relaxation under fluoroscopic guidance. If again the reduction maneuver is unsuccessful, an open reduction procedure is required. Lastly, if the hip is reduced with closed measures, the post reduction radiograph must be carefully evaluated. If after the reduction the small ball is seen eccentrically positioned upon the outer metal cup, a bearing dissociation has occurred. This requires an open revision procedure.

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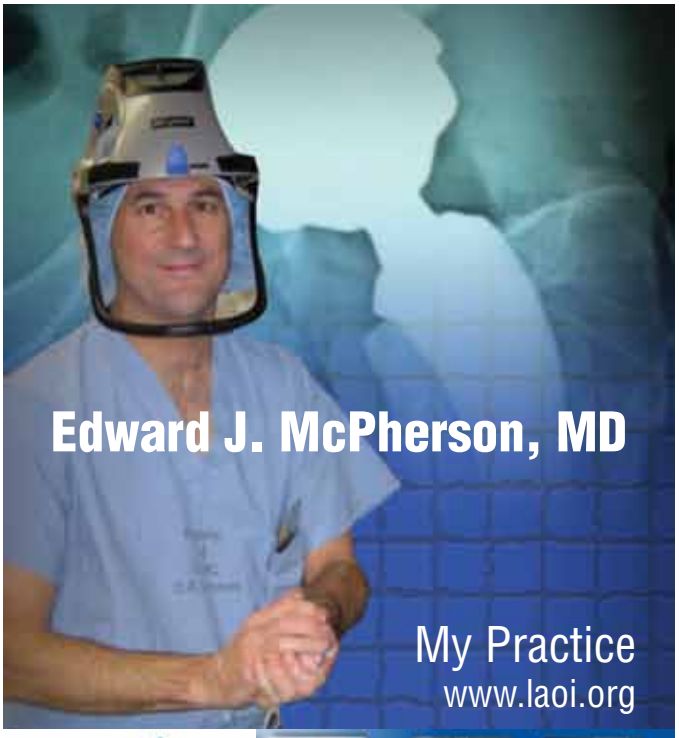

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As an Orthopaedic surgeon in Los Angeles, CA, I'm grateful to practice medicine in an area with exceptional healthcare. My choice is to practice at St. Vincent Medical Center. My research is in collaboration with JISRF, Founded here in L.A. in 1971 by Prof. Charles O. Bechtol, MD.

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Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee Meeting

June 28, 2012

Metal (MoM) Bearings Questions and Discussions

An Interview Facilitated by Timothy McTighe

Timothy McTighe Dr. HS (hc)

- Executive Director, JISRF
- Publisher and Editor-in-Chief for Reconstructive Review, JISRF
- Affiliate Member AAHKS
- Affiliate Member Mid-American Orthopaedic association
- Affiliate Member Australian Orthopaedic Association
- Member Orthopaedic Research Society
- Member Society of Biomaterials
- Member International Society for Technology in Arthroplasty

Timothy McTighe was present on June 28, 2012 for the FDA Advisory Committee Meeting on Metal -on- Metal Bearings. As part of the ongoing dialogue, JISRF has decided to conduct an interview on this day's activities and publish this interview in its July edition of the Reconstruct Review.

JISRF published an interview on May 31, 2010 on the subject of MoM with eleven surgeons and their comments can be viewed at: http://www.jisrf.org/activities/052010.htm

As we all know there is considerable debate and concern with the postoperative adverse reactions that we are seeing world wide with the use of MoM bearings. JISRF has conducted this interview with six highly respected surgeons and one world class Tribologist based off the discussions held at the recent FDA Device Panel Meeting.

Advisory Committee Member:

Michael B. Mayor, MD

- William N. and Bessie Allyn Professor of Orthopaedic Surgery,
- The Geisel School of Medicine at Dartmouth
- Adjunct Professor of Engineering
- Michael.B.Mayor@Dartmouth.edu

Presenter at Panel Meeting:

Bernard N. Stulberg, MD

Lutheran Hospital
Cleveland, OH

Professional Societies

- American Academy of Orthopaedic Surgeons
- American Orthopaedic Association
- American Association of Hip and Knee Surgeons
- Hip Society
- Knee Society
- International Society for Technology in Arthroplasty
- Orthopaedic Research and Education Foundation

Special Interests

Repair of failed or infected joint replacements and complex hip and knee replacements.

In Attendance at Panel Meeting:

Thomas K. Donaldson, MD

Donaldson Research Center
Colton, CA
- Private practice since 1991
- Board Certified Orthopedic Surgeon who has been in practice in the Inland Empire.

Affiliations
- Director and Founder of DARF
- American Academy of Orthopaedic Surgeons
- American Association of Hip and Knee Surgeons
- Joint Implant Surgery & Research Foundation
- American Medical Association
- San Bernardino County Medical Society

Ian C. Clarke, PhD

Donaldson Research Center
Colton, CA
- Professor in the Joint Research Center at Loma Linda University
- CO-Director, DARF
- CO-Director of Basic Science, JISRF
- CO-Assistant Editor, Reconstructive Review, JISRF

Community Total Joint Surgeons:

John Keggi, MD

Community Orthopaedic Surgeons: Orthopaedics New England
Middlebury, CT
- Attending Orthopaedic Surgeon
- Waterbury Hospital, Waterbury, Connecticut
- New Milford Hospital, New Milford, Connecticut
- St. Mary's Hospital, Waterbury, Connecticut (Courtesy Staff)

Lou Keppler, MD

St. Vincent Charity Medical Center
Cleveland, OH
- Co-Director, The Spine and Orthopedic Institute
- Orthopedic Surgeon
- Member JISRF Clinical/ Surgical Advisory Panel and Tissue Sparing Implant (TMI™) Study Group

Ed McPherson, MD

L.A. Orthopedic Institute
Los Angeles, CA
- Director of Orthopedic Surgery
- Member JISRF Clinical/ Surgical Advisory Panel and Tissue Sparing Implant (TMI™) Study Group

The Original 8 Questions from the FDA to the Advisory Panel:

1. Please summarize the key differences, if any, between US and Outside the United States (OUS) practice which should be taken into account when reviewing/interpreting the data, and which impact the ability to extrapolate OUS data to the US population, including differences in patient population, surgeon experience/preference/technique, and the devices themselves.
2. Based on published registry reports as well as information presented to the Panel today, please discuss the additional data fields which would be appropriate (and practical) to add to existing hip implant registries or include in new registries being developed.
3. For patients who have received a MoM Total Hip Replacement, but are asymptomatic please discuss the optimal follow-up regimen (s) based on current available information.
4. For patients who have received a MoM Total Hip Replacement, but are symptomatic please discuss the optimal follow-up regimen (s) based on current available information.
5. For patients who have received a MoM Total Hip Resurfacing System, but are asymptomatic please discuss the optimal follow-up regimen (s) based on current available information.
6. For patients who have received a MoM Total Hip Resurfacing System, but are symptomatic please discuss the optimal follow-up regimen (s) based on current available information.
7. For patients being considered for primary hip arthroplasty, please discuss:
   a. Patient or population characteristics which are more likely to achieve the most favorable outcome and/or for whom the risks most likely outweigh potential benefits with a
      i. MoM THR System
      ii. MoM Resurfacing System
   b. Pre-operative laboratory or imaging tests which should be considered in identifying appropriate candidates for MoM THR/ MoM Resurfacing System.
8. Please discuss the key information which should be conveyed to physicians and/or patients as part of product labeling for MoM hip systems, including
   a. Contraindications
   b. Warnings
   c. Precautions
   d. Directions for Use
   e. Outcomes Data
   f. Other

The following is going to be a brief review of the historical development of metal on metal bearings so we might better understand how and why we ended up in our current situation. Remember those that don't remember the past often are doomed to repeat it.

Historical Review of MoM Bearings

1930's Phillip Wiles from the UK designed and inserted the first THA. Prior to this date, prosthetic replacement surgery was of the hemi-arthroplasty type with only one arthritic surface being replaced and the results were unsatisfactory.

George Kenneth McKee

GK McKee was a trainee with Wiles and following his appointment as Orthopaedic Surgeon in Norwich, England, began development of total hip replacement designs. He developed various uncemented prototype total hip replacements in the 1940's and 1950's. McKee presented his results to the BOA meeting in Cambridge in 1951. The results in those early days were initial relief of pain followed by loosening and mechanical failure. Haboush introduced polymethylmethacrylate for fixation of hip endoprosthesis in 1953 and Charnley popularized this use of bone cement. McKee's cement fixed McKee-Farrar THR from 1960 was the first widely used and successful THR. This THR had a Thompson stem, a chrome cobalt metal on metal articulation and both the acetabular and femoral components were fixed with cement.

Peter Ring

Peter Ring from Redhill, Surrey, provided the next development in hip arthroplasty. He distrusted bone cement and developed a self locking total hip replacement for uncemented fixation.

Professor Sir John Charnley

Professor Sir John Charnley was convinced that the metal on metal articulation of the McKee joint was unsatisfactory. He performed experiments to show that the McKee joint had a high frictional torque in the laboratory and he predicted that this frictional torque would eventually loosen the fixation of the McKee components in their bony bed.

He was convinced that the natural elastohydrodynamic lubrication with synovial fluid could not be used to reduce the frictional torque of the metal on metal articulation and he began his search for self lubricating bearings.

This search took him into the field of polymers and his first attempt at hip arthroplasty in the early 1950's was a Teflon on Teflon bearing used as a resurfacing for the arthritic femoral head and acetabulum. Unfortunately the Teflon on Teflon bearings wore out within two years.

Sivash Stem 1960s

SRN Stem 1970s

The Sivash hip was the first C.C. head with a titanium stem "constrained socket".

Eventually lead to the development of the S-Rom® Stem System.

Derek McMinn FRCS

Dr. Derek McMinn qualified from St. Thomas's Hospital in London. Practicing as a Consultant Orthopaedic Surgeon since 1988, his special interest has been joint reconstruction surgery.

He always loved taking on the challenge of patients with complex hip and knee problems - complexities that often demanded improvisation and innovation. The stemmed reconstruction acetabular cup for the grossly deficient socket is one of his innovations.

His pioneering of the Birmingham Hip Resurfacing has revolutionized the management of hip arthritis in young active patients. In addition to his busy private practice, he works part-time in the UK National Health Service at the Royal Orthopaedic Hospital, Birmingham.

MoM Interrogatories by McTighe

Question 1

This was a significant challenge by FDA to ask 22 members of the Advisory Committee for Orthopaedics and Rehabilitation Devices (all with varied backgrounds and experiences to attempt to develop a consensus regarding these nine questions. How did you feel about the challenge and do you feel the panel came together with a consensus about the questions posed by FDA?

Dr. Mayor: As a product of two twelve hour days, stirring together a mix of presentations from FDA and invited proponents and skeptics, I saw the response of the panel, an amalgam of remarkable diversity and expertise, to be a very substantial consensus. It allowed orthopaedic clinicians, radiologists, epidemiologists, toxicologist/ pharmacists, industry and consumer interests to pool their perspectives and convictions toward a well supported overview of the history, evolution and current challenges confronting FDA, the scientific and clinical community, patients and the public.

Question 2:

To Donaldson and B. Stulberg, both of you have performed Hip Resurfacing (HR) and I believe you have used different devices. Can you explain your interest in HR and what was your decision making for device selection?

Dr. Donaldson: Living in southern California near Dr. Amstutz, I was well indoctrinated in the enamor of hip resurfacing. I have utilized the Conserve-Plus(Wright Medical), Burmingham (Smith and Nephew) and was involved in the IDE study utilizing the Recap(Biomet-not FDA approved) hip resurfacing. Clearly the reported data supports the Burmingham above the others in outcomes and this is my resurfacing implant of choice.

Dr. Stulberg: I have used resurfacing Arthroplasty in my practice in a very specific and somewhat limited group of patients since 2002– Mostly male, and mostly under the age of 50. I began as part of the CORMET IDE, and with the exception of a few BHRs, my experience has been primarily with the Cormet device. My results are included in those reported as part of the IDE study and published results, demonstrating the importance of technique and patient selection. In the population I selected they have worked well, despite the fact that the instrumentation for the early patients was rudimentary. Currently I do not perform resurfacing Arthroplasty but refer those interested and appropriate patients to one of my partners who use the BHR exclusively.

Question 3:

To all of our surgeons: It seemed to me that part of the market selection for MoM bearings had very little to do with the alternative selection for a new bearing surface. What I mean to say is the HR group desired to save bone in the younger more active patient primarily and the THA group wanted large head diameters to reduce hip dislocations. Comments?

Dr. Mayor: Both surface replacement and stemmed total hips are inspired by dual desires; a consuming interest in minimizing the generation of particulates and minimizing the incidence of post-arthroplasty dislocations. In conversation with my clinically active colleagues they assert they were driven by both considerations in inseparable combination. Having both surface replacement and stemmed approaches offered the full spectrum of treatment modalities to solve both problems in a wide variety of patients.

Dr. Donaldson: Hip Resurfacing is appealing for the bone preserving nature of the procedure. The metal on metal articulation seemed to be the solution for the previous failed metal on polyethylene attempts for hip resurfacing. The large ball metal total hip alternative was initially meant to be a solution in the case of a neck fracture from hip resurfacing. The large ball alternative to hip resurfacing quickly took center stage and hip resurfacing was left for a much smaller select group of patients. No surgeon was disappointed in the overnight elimination of the dislocation risk!

Dr. Stulberg: I agree with Dr. Mayor, that both desires were part of the discussion with young patients undergoing THA. Please remember that some of the usage was driven by the availability of the devices. Resurfacing with MoM bearings was largely an IDE option ONLY for patients between 2000 and 2005, while several manufacturers offered

large head MoM THA in 2003. As interest in larger head devices to prevent dislocation became of interest across all bearing surface types, it was natural that the use of larger head diameters offered in MoM Arthroplasty would be part of that discussion.

Dr. Keggi: Both HRA and THA surgeons and patients were interested in large heads for stability and what was subjectively described as a more natural hip motion of an anatomically sized head. While some surgeons moved to the direct anterior approach to reduce dislocations, others adopted MoM to reduce dislocations associated with the posterior approach. HRA does also have the advantages of bone preservation and a higher tolerance for activity compared to THA, but these are only currently achievable with a MoM construct as well. Overall, MoM was the only available material combination for either HRA or THA that could meet those particular goals in certain settings.

Dr. McPherson: I have a very healthy revision practice, and the major influences for me to change were the frequent cases of massive osteolysis and pelvic bone destruction that occurred in poly metal THAs, as early as 8 to 10 years! At the same time, hip dislocation was still a significant problem in both young and older populations. For me, I chose the large diameter metal-metal THA, which for me solves both problems, [if] the hip is correctly positioned and hip offset is optimized. Even though there has been a pushback with metal-metal technology, I remind you that there is still no perfect bearing construct. All have an Achilles heel. Don't throw out the baby with the bath water. There are surgeons out there that can make a metal-metal THA work well, very well.

Question 4: (for Dr. Clarke)

Dr. Clarke as one of the leading experts in Tribology you and your staff have conducted many wear studies on MoM bearings. I can recall in one such study that I participated with you and Dr. Bowsher we did a study on off the shelf HR MoM system. I believe that was the first time an off the shelf device was tested. Can you please describe what the typical process was for companies looking for testing data to submit for their 510K applications?

Dr. Clarke: With regard to tribology studies, our standard test suitable for submission to various regulatory bodies has been our 5 million load cycles under standard simulator test mode in which we report the volumetric wear rates of balls and cups along with the morphology of the CoCr wear debris from run-in to steady-state wear phases. Now with the analytical tools in the DARF Center we can provide dimensional studies via a precision CMM tool, roughness studies by white-light interferometry and wear analyses by SEM and EDS imaging.

Question 5: (for Dr. Clarke)

Dr. Clarke, one of the findings in our study seemed to support your labs findings with other MoM bearings, that regardless of carbon content, regardless of manufacture, regardless of head diameter 1 out of 6 samples in the wear testing met with break away or run away wear. Is my recollection correct and can you briefly review this finding? Second part of this question, why was this finding not recognized as a red flag to clinical application on MoM bearings?

Dr. Clarke: This question of breakaway wear in MoM bearings has been a confounding phenomenon (estimated to be 20% of our MoM wear samples) since we first published this finding (Anissian et al, 1999). During one such breakaway event during a lab visit, Dr. Donaldson made his historic comment that he "hoped none of his patients would get such MoM bearings". We have noted the same breakaway wear phenomenon from virtually all laboratories that publish their MoM wear rates. There is no information on this confounding MoM problem in national or international standards. It has taken more than 12 years for this phenomenon to be recognized and discussed at the national level. Indeed, this topic just came up for discussion at a recent meeting of the ASTM organization (Section F04.22).

The overall challenge appears to be that a) our societies, industry and regulatory bodies are very slow to react to information that does not fit into conventional thinking and b) most test labs work to established standards and regulatory guidelines (ASTM, ISO) such that there is no incentive to perform studies 'outside-the-box'. In other words, we are boxed in by the need to perform to standard

guidelines, thereby hoping to readily obtain regulatory approvals.

Question 6:

Many have suggested that if the US had a Joint Registry like the ones in Australia or the U.K., we could have reduced our exposure to the current clinical situation we find ourselves in. I question the logic of that statement since both the U.K. and Australia have well regarded Joint Registries and they find themselves in the same clinical situation. Any comment from our panel members?

Dr. Keggi: The US registry is just getting underway and our practice and our institution are pleased to be participating in the early phases. It will be critical in a market the size of ours to identify problems as quickly as possible for poorly performing implants or techniques in order to improve care and avoid problems for patients who are otherwise generally well-served by newer technologies as they emerge. A US registry would not have necessarily spotted MoM problems sooner. In this country the vast majority of hip resurfacings were carried out with well-performing implants. Europe and Australia had a broader experience that included higher percentages of the implants that ultimately prompted concern. MoM THAs were performed in the US with a wider variety of implants compared to HRA. US surgeons were quick to report their experiences with MoM THA as the problems emerged and a registry would not have acted any more quickly, I believe. A US national registry will still have numerous benefits for all parties as long as we understand its limitations and work to be a consistent as possible in data collection and follow up.

Dr. Mayor: It seems fundamental that registries for prosthetic implants are a basic necessity. Are registries a perfect form of monitoring? No. What are their faults? To properly reflect the performance of any class of implants the design of the registries is critical. Participation needs to be as broad as possible, and sufficiently "granular" to clearly spot the devices going in and coming out, reflecting right/left specificity and with a broad reach to capture data from a mobile population. That said, the users of the registries will have to set thresholds that determine performance figures which may fall out of acceptable bounds. Durable devices whose revision is accomplished reasonably readily with good outcomes post-revision, with long-term function both before and after revision are not the same as those with short time-spans to a significant incidence of revision and whose revision is tortuous, difficult and with unpredictable outcomes.

Dr. Stulberg: I think that registry information has been useful, but there are a number of ways to get good information about the performance of an operation that are not registries, and there are differing populations of surgeons and patients in each of our environments. Failure of an operation is usually multifactorial, patient, technical and device issues playing in to that failure. Finding ways of measuring each of those factors over a broad population rapidly, is challenging, for all countries. IDE studies for very new or for potentially high-risk devices, are costly and time consuming, but provide data that is important to the safe and effective use of devices. We enjoy the availability of a wide range of products for implantation in the US, and it seems to me that strategies to carefully evaluate device performance in the hands of those who will use them most, not necessarily in the hands of the experts who design or promote the devices, give us the best sense of how valuable that device will be for patient use. I am not certain that any approaches currently offered meet that objective.

Dr. Clark: Your point is well made. Three years ago at the Bristol Hip Meeting, I was advised that MoM THA devices were no longer being used in the UK. However they were still being used in the USA at that time. In the history of the ASR resurfacing device, the Australians first blew the whistle that something was wrong. Then the UK joined in with their data and then the problem came to the USA and then as of the last FDA Panel Meeting, the FDA is currently reviewing all issues related to MoM THA and RSA devices.

Dr. McPherson: The problem with the wear debris inflammatory process whether it is with poly, metal or a future bearing material, is the incubation period. Small scale IDE PMA trials will review results up to perhaps 5 years, but not much longer. When devices are released to the orthopaedic community, these constructs are "truly tested" and adverse wear debris problems come to light. However, these problems often take 5 to 8 years to reveal themselves. The joint registry, like a radar

screen, shows that an attack is coming, but it cannot prevent the launch of the attack. The joint registry just tells us where to focus our efforts.

Dr. Keppler: I do not believe most United States surgeons take into account out-of-United States practices. We do have different patient population expectations. The United States patient population is very consumer-centric. I don't believe that additional data fields need to be added to hip implant registries. I believe that present registries are sensitive enough to indicate relatively early problems developing with any particular implant.

Question 7:

For all surgeons. Do patients still come in asking either HR or THA for MoM, and if yes, how do you advise them?

Dr. Donaldson: Patients do come in asking about hip resurfacing. For the most part patients have heard enough that they want to make sure they are not getting a metal on metal hip. Clearly the younger male still is a candidate for MoM hip resurfacing in my practice. I believe the performance in young males has been outstanding and should be discussed. I do not believe that MoM HR should be used on females despite many successes in my practice to date.

Dr. Stulberg: My experience is similar. There are patients who still want to consider resurfacing, and come to our practice asking if they are candidates. I believe, as does Dr. Donaldson, that there are populations for whom this is an excellent procedure. I refer those as I have mentioned above. I no longer use or advise the use of MoM THA in my patient population.

Dr. McPherson: Right now, more patients are coming in and asking not to have a metal-metal bearing. In Los Angeles, my patients value quality of life such that they want to enjoy all that our state has to offer. Stability still is a major concern to patients and me. Therefore, I will utilize a large diameter metal-metal THA if the patient understands that I need to monitor serum metal ion levels [and] the patient understands that I may have to change that bearing if serum metal levels are too high (i.e. bad bearing mating or runaway wear). If not, my go to bearing is a dual articulation bearing.

Dr. Keppler: At the present time, I would not recommend metal-on-metal total hip replacement system or metal-on-metal resurfacing system to any of my patients.

Dr. Keppler: Contraindications to metal-on-metal are obviously those patients who had a metal sensitivity or women of childbearing ages. Warnings would include the potential for abnormal wear with the increase in heavy metal ions and the possible systemic side effects from this abnormal ion levels. Additional warnings would include the potential for early failure and the need for revision, the potential local damage to soft tissues and bone associated. Standard total hip precautions would pertain to metal-on-metal hip systems. But additional precautions relative to recommended monitoring of heavy metal ions may also be included. Direction for use should include the manufacturer's biomechanical studies which include the biomechanically optimal position of placement as well as safe zones for acceptable function. Unsafe zones need to be clearly identified. Outcome data obtained either through the use of the product outside the United States or from IDE data should be included in produce information. Specifications with respect to the handling of any retrieved devices should be included such that these devices are available for study.

Question 8: (for Dr. Clarke)

Dr. Clarke was there an over valuation or justification by the theory of MoM with fluid-film lubrication and if yes, how did this misdirect our attention?

Dr. Clarke: It was much more than just what fluid-film theory had to offer, which most surgeons don't really buy into in any case. There were i) publications in JBJS reporting on 20 to 30-year follow-ups with successful MoM cases like the McKee-Farrar, ii) there was what was seen as break-through technology for resurfacing concepts using the thin CoCr cups and iii) there was virtually 100% surgeon buy-in that the large-diameter femoral head replacements would banish the related problems of cup placement with its triad of risks (impingement, subluxation and dislocation). Also just ahead of clinical studies of the highly-crosslinked

polyethylenes, there was iv) a realization of the debris-driven osteolysis problem in the earlier generation of polyethylene cups. It is also to be noted that there were plenty of red flags regarding the toxicity Co and Cr and published case reports on 'pseudotumors' with McKee-Farrar devices in the 1970's. So yes there was a very strong redirection of interest into the MoM technology.

Question 9:

With metal ion testing it was recommended that once a patient was symptomatic ion levels should be monitored. My question is, should ion levels be evaluated from a baseline of preoperative levels and monitored say at one year and two years to help establish a baseline comparison for different devices?

Dr. Keggi: At this moment there is not a benefit to pre-operative testing. The run-in period is approximately one year for most MoM bearing pairs but we are only beginning to accumulate data specifically related to the trunnion interface and modular junctions. To this end, periodic post-op monitoring can be valuable clinically and scientifically. Clinically, we obtain ion levels at one year post-op and at intervals thereafter depending on the results, clinical symptoms (if any) and MRI findings. Routine MRI screening of asymptomatic MoM patients is not common presently, but MRI scanning of patients with a history of rising levels or of symptoms is indicated to detect pseudotumors or large fluid collections that may represent complications of the MoM construct.

Dr. Mayor: There certainly could be a valid scientific argument made about the value of that data, but would those measures accrue any value to any individual patient? The recommended ion level that would trigger clinical concern has been pretty thoroughly vetted, resulting in recommendations that levels much above 5 to 7 micrograms per liter should focus clinical attention on that patient's implant, with rising levels bringing more concern to bear. It would be useful to know when the "bedding in" phase of implant wear faded to a steady state, but it would not be of such great usefulness to any individual patient to seriously effect decision-making.

Dr. Stulberg: I think a single baseline postoperative value is probably sufficient. We measured levels extensively and serially in patients undergoing uncemented arthroplasty, in the 1980s and found that preoperative and 1 year studies were useful, but earlier postoperative studies often reflected metal debris from other sources (such as surgical instruments). Elevated levels occurred only with device failure. As a monitoring tool, one would be concerned only if there were an increase in levels over a steady-state, baseline value. I think that a single specimen, measured by a vetted laboratory, and collected in a standardized fashion, would be sufficient for most patients, and I would repeat those studies only if symptoms raised concern for device related complications. As long as the initial specimen was at least 1 year following implantation I would find it a believable baseline. While a preoperative value might be of scientific interest, we really are only interested in what happens to that patient after the device is implanted.

Dr. McPherson: Preoperatively, most experts would agree that serum cobalt and chrome levels are going to be near normal range and it is not worth the cost to society to measure all patients preop. As Ian Clark and Tom Donaldson have shown, run in wear lasts for about one million cycles. This takes 1-2 years depending on patient activity level. Therefore for me the earliest time to measure serum ion levels would be at three years. I want to point out that I do not solely rely on serum ion levels. If the patient complains of new onset pain or starts to limp, I immediately start an evaluation to assess for toxic reactive synovitis. Also, the serum level of ions that we consider as "toxic" is still fuzzy. Like poly debris, some patients can tolerate a higher debris load than others.

Dr. Keppler: For asymptomatic patients, ion studies are drawn as a baseline. The patients are counseled relative to their ion studies and based on the results of that study additional studies may be recommended.

Question 10:

Dr. Goodman raised a good question during one of the sessions on cost concerns with obtaining MRI's for all patients (potential 750,000) symptomatic and asymptomatic. I believe the Panel was instructed not to consider cost as part of any recommendation to FDA. Do you agree cost consideration should not be part of any health care discussion.

Dr. Keggi: Clinical testing protocols should rely primarily on sound reasoning and data and should be aimed at producing results that are useful for decision-making. Unselective MRI scanning of all MoM patients would be excessively expensive and would not help the decision-making process. So, I this case, the cost is a factor to reasonably consider. A bigger cost of unselective testing is the "Cascade Effect" where testing produces falsely- or insignificantly positive results that oblige more invasive testing and/or procedures and which in turn, ultimately, cause complications. We must consider all of the implications of policy recommendations and strive to avoid the unintended consequences.

Dr. Mayor: My sense is that it is absurd to think we can act responsibly and ignore the cost of any of our recommendations, particularly if that cost seems to approach astronomical levels. Beyond the simple issue of monetary burden, the logistics of getting MRI imaging with special protocols to suppress metal artifact is daunting, at least, or prohibitive in real terms. It would be interesting to see a rigorous cost/benefit analysis generated to better assess the impact of such an effort.

Dr. Stulberg: To be fair, the FDA may have been asking for a full accounting of the scientific validity and reproducibility of using MRI on the entire patient population, so as not to confuse the issues of cost and practicality with the actual ability of the test to be applied across a broad range of practice environments predictably. I agree with Dr. Mayor that it would irresponsible for a formal recommendation to skirt the issues of the financial and logistical burdens this would place on the health care system.

Dr. McPherson: I feel strongly that the cost burden to society is a major concern, as our health care budget will soon exceed 20% of GDP. If we mandate an expensive monitoring process for a procedure, this is to me an unacceptable burden to the healthcare budget. One of two things must happen. Either we abandon the procedure because it is cost prohibitive, or we find an algorithm that is practical and economical. It is my duty as a surgeon to make sure that this decision stays within the orthopaedic community and does not fall into the hands of a governmental bureaucratic committee.

Dr. Keppler: For patients who are symptomatic, MRI examination is performed. If joint effusion exists, then revision is typically recommended. If patients are asymptomatic, metal study, after ion study is obtained and is not thought to represent a significant elevation patients are re-studied in one year. If a significant elevation in ions is noted on the baseline study, more frequent follow up is recommended. If patients are significantly symptomatic, revision surgery is typically recommended.

Question 11: (for Dr. Clarke)

Dr. Clarke, you and Dr. Donaldson have an FDA contract I believe to analyze MoM brands (BioMet, DePuy, S&N, and Zimmer) with diameters 28 mm to 54 mm. Is this a retrieval study or a wear study?

Dr. Clarke: Actually the DARF Center has two FDA contracts, one for wear assessment in MoM explants and one for pre-clinical studies of MoM wear, as related to ASTM test methods (ASTM section F04.22).

Question 12: (for Dr. Clarke)

I also believe you have a contract to develop a clinically relevant adverse test for MoM devices in hip simulators? Do you believe it is possible to develop a predictive model to predict clinical failure?

Dr. Clarke: Turning that statement around, one can see that it would be impossible to devise a relevant pre-clinical test for a device if there was no prediction on which failure mechanisms would arise in its future. Thus I believe that it is entirely feasible, once we understand the MoM wear mechanisms that occur in vivo, it will be possible to devise a physiologically-relevant set of wear tests. I would also predict that this MoM know-how will aid our understanding of how to test the

polyethylene and ceramic bearings and produce more clinically-relevant tests for those devices also.

Question 13:

One final question to all. Today, if you personally needed a hip arthroplasty at your age, activity and current knowledge, what bearing material would you pick?

McTighe: I will start this answer off by saying I would be happy to have any of our surgeon panel members do my hip. I would not want a HR, I have never been impressed with this procedure. I would want a bearing that at 60 years of age would last me my life time (20 years). I think a ceramic head 36mm on a highly cross link polyethylene acetabular component that allows 6mm to 8mm of poly thickness.

Dr. Keggi: If I were involved in contact sports or still ran marathons, I would still choose a resurfacing. Having hung up my running shoes for lower impact exercise, I prefer a ceramic-on-ceramic construct. Presently, alumina COC is the only fully ceramic couple available in the US and it performs very well. I look forward to the availability of Delta COC in the US which will perform even more reliably.

Dr. Mayor: I'm 74, will be 75 in October. I manage a thirty acre woodlot and burn several cords of wood each winter, which I fell, limb, buck, split, stack and move prior to ignition. My father did the same to beyond 85 years of age, and died six weeks short of his 100th birthday. My right hip is not at risk, as it bears no weight with an above knee amputation distal to it. I'd select a surgeon skilled in THR from an anterior approach, and request a moderately cross-linked poly liner articulating against a ceramic head. I'd prefer a ceramic head with a titanium sleeve factory inserted. I would not choose an anti-oxidant additive, but would request a polyethylene with few or no free radicals residual to any cross-linking process.

Dr. Stulberg: I agree with Dr. Mayor. I'd pick a surgeon skilled in THA, in an environment he/she controlled well, using his/her favorite approach, and would ask for an uncemented titanium implant, HA coated on the femur, with a ceramic head appropriately sized to allow 6-8mm of highly cross-linked UHMWPE – and no bigger than 36 mm. At my age and golfing skill level that will easily last me 40 years.

Dr. Donaldson: Tim without a doubt today, I would still consider a hip resurfacing, however as a total, ceramic on vitamin E polyethylene. If we had 36 ceramic on ceramic I might go down that avenue but I don't think the thin delta shell is finalized!

Dr. McPherson: I have been using metal-metal THA constructs routinely since 1998. I follow my patients regularly, and I feel comfortable with my outcomes. If I needed a total hip today, I would have the following construct:

- Metal-metal THA with Magnum (Biomet) monolithicall metal cup
- Cementless proximal porous short stem with restoration of hip offset (or slightly increased if needed)
- A meticulous surgeon who understands prosthetic femoral acetabular impingement and would sculpt (with osteotomes) my acetabulum and proximal femur to eliminate hip levering. An adept surgeon is the most important part of the success equation

Of course I would be awake with a spinal. I would have mirrors or a live camera feed so that I could "make suggestions" during the procedure! (lol).

Dr. Keppler: Currently on all THA I use a neck sparing short curved stem with either a 36mm ceramic or chrome cobalt femoral head on highly cross linked polyethylene and certainly would choose this approach for myself.

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

ACCME Annual Report Data 2011

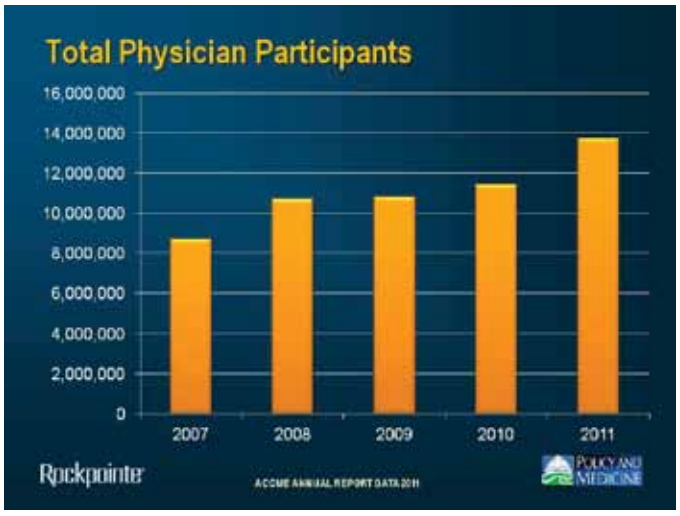
Thomas Sullivan*

The Accreditation Council for Continuing Medical Education (ACCME) published its 2011 Annual Report Data, which includes data on the size and scope of the continuing medical education (CME) enterprise nationwide.

The report shows that in 2011:

- CME Economy grew by 4.8% to $2,349,580,281
- Commercial support for CME decreased by 9.4%, - $78,443,279 less than 2010
- Commercial support now represents 32% of the total CME funding, down from 51% of total funding in 2007
- Physician attendance increased by 20.2% - by 2,307,884 attendees to 13,741,621
- Non Physician attendance increased by 21.7%, 1,702,892 attendees to 9,558,789
- 38% of attendees participated in courses produced by Publishers/MECS, 30% courses by universities and 28% from hospitals.
- 37% of physicians attended regularly scheduled events such as grand rounds, followed by 34% received credit for internet enduring materials, 16% for courses, and 9% for Journal CME.

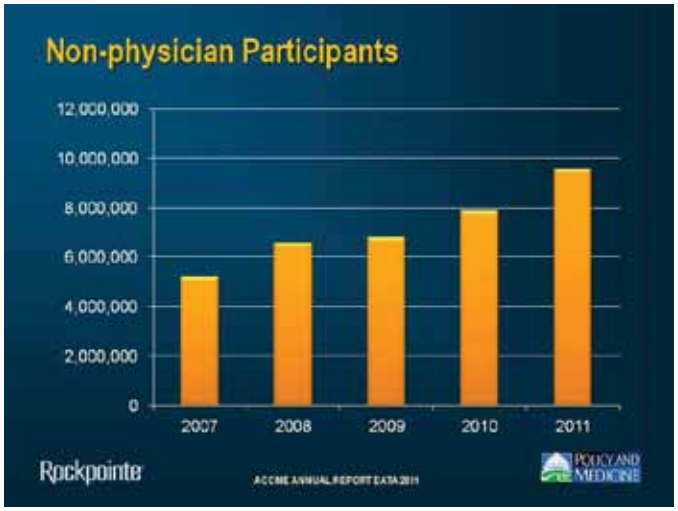
For the first time, the 2011 Annual Report Data aggregates state and national statistics, including total numbers of accredited CME providers, activities, hours of instruction, and participants. This data shows that there are more than 2,000 accredited CME providers across the country that offered more than 130,000 activities in 2011, almost a 5% increase from 2010. Accredited CME providers report that their 2011 activities educated more than 23 million participants including more than 13 million physicians and more than 9 million nonphysician health care professionals.



* Policy and Medicine
www.policymed.com

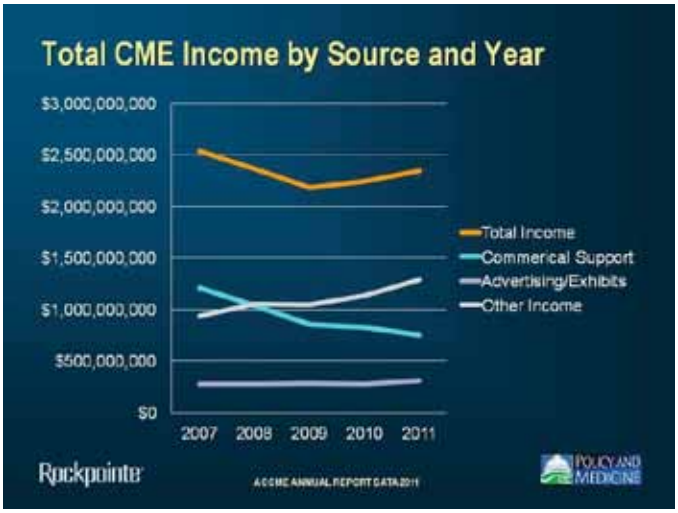
In addition, the 2011 Annual Report Data features separate data sets about the CME delivered by ACCME-accredited providers and by state-accredited providers, offering an overview of the CME system at both the national and state levels.

The ACCME directly accredits providers that offer CME primarily to national or international audiences of physicians and other health care professionals. The ACCME also recognizes state and territory medical societies as accreditors for providers that offer CME primarily to learners from their state or contiguous states. All accredited providers within the ACCME accreditation system are held to the same high standards and are required to report information about their programs that the ACCME collects and analyzes in order to produce annual report data.



The 2011 Annual Report Data includes an overview of commercial support received by ACCME-accredited providers. The data shows commercial support distribution by numbers and types of activities, hours of instruction, and participants. The ACCME is able to publish this commercial support overview because of the Program and Activity Reporting System (PARS). Launched in 2010, PARS is a Web-based portal designed to centralize and streamline the collection, management, and analysis of program and activity data from accredited CME providers. The structure of PARS and the CME community's adoption of PARS enable the ACCME to produce new information.

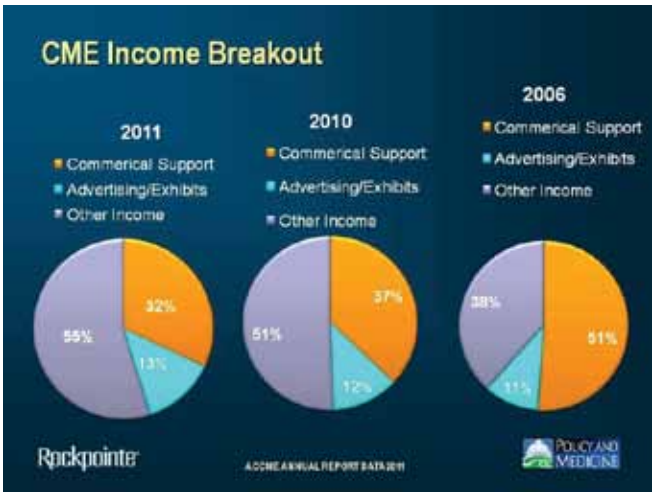
The 2011 Annual Report Data marks the 14th year the ACCME has been collecting, analyzing, and publishing information about accredited providers, and offers more than a decade-long perspective on the evolution of the ACCME accreditation system. The annual data reports are produced as a service to accredited providers and other stakeholders. ACCME Chief Executive Murray Kopelow, MD, commented on the release of 2011's report.



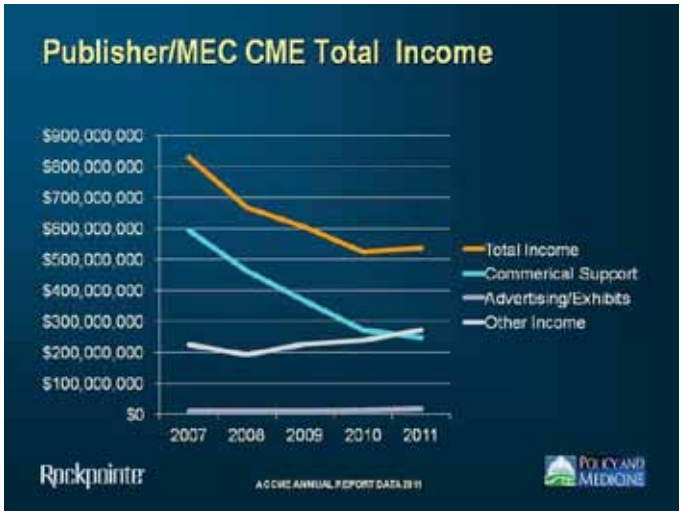
2011 Report

Although the total income of the CME industry increased by $107,252,031, 4.8% to $2,349,580,281 between 2010 and 2011, the total income has decreased by -$189,618,375, and 7.5% since 2007. Commercial support of CME continued to decline, by $78,443,279, this represents a 9.4% reduction from $830,849,917 in 2010 to $752,406,638 in 2011 and a total reduction of a full $458,938,566, 37.9% since 2007.

Making up for this lost income, however, were increases in Advertising/Exhibits (11.7% in 2011 and 12.7% since 2007) and Other Income (13.5% in 2011 and 37% since 2007).

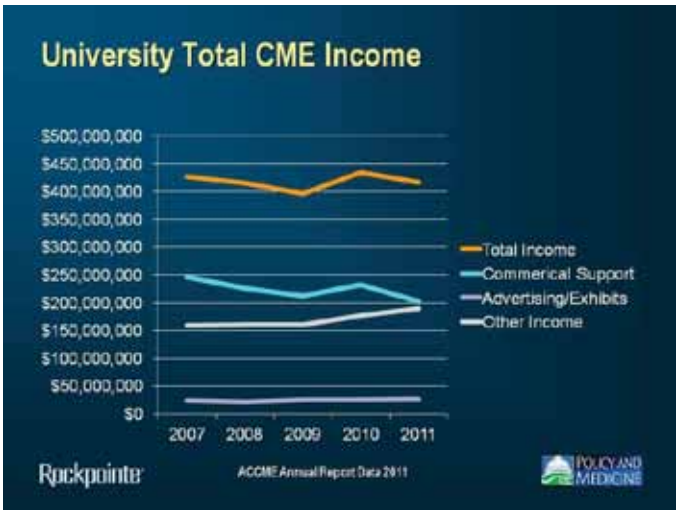


Commercial support now represents only 32% of the total CME enterprise, a 5% decline since 2010 and a 19% decline since 2006.



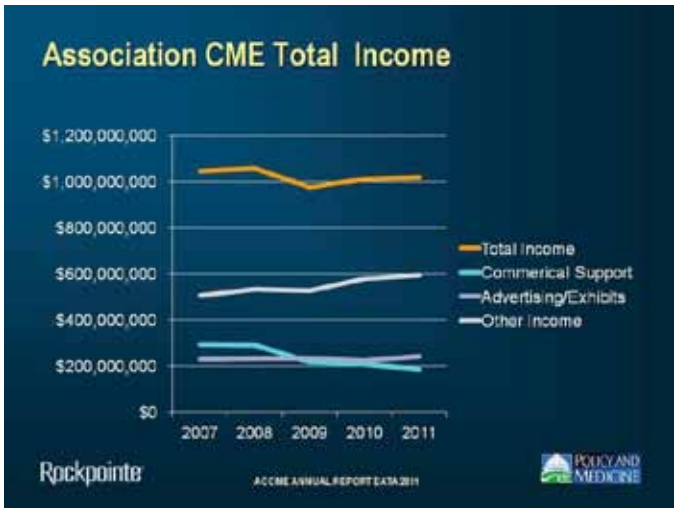
Publisher/MEC

For publishing/medical education companies, total income increased 2.4%, however, total income since 2007 has decreased 35.3%. Commercial support declined 8.9% in 2011 and has declined a whopping 58.3% since 2007. Moreover, whereas commercial support was 71.5% of the enterprise in 2007, it was 46.1% in 2011. The income has increased minimally in advertising and exhibits (3.2% in 2011) and other income (50.7% in 2011).



Medical Schools

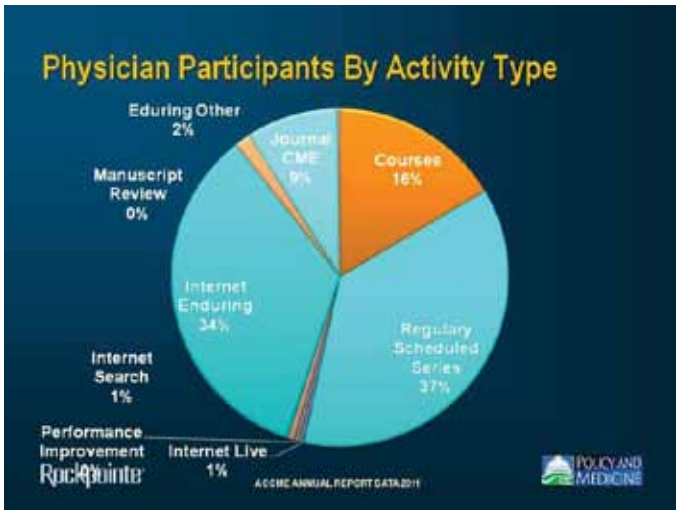
For schools of medicine (universities), total income decreased 4% in 2011. Commercial support declined 13.3% in 2011 and 17.9% since 2007.



Associations/Nonprofits

For Nonprofits (physician membership organizations and other non profits), total income increased 0.7%, however, it has decreased 2.7% since 2007. Commercial support decline 10.7% in 2011 and has declined 36.9% since 2007.

The number of activities, total hours of instruction, and total physician participants have continued to increase since 2007.



Type of Activity

The grand total types of activities supported directly by accredited CME providers are broken down below:

- Courses: 49,644 activities, with 287,793 hours of instruction and 1,673,014 physician participants
- Regularly scheduled series: 20,780 activities,

with 416,814 hours and 4,403,799 physician participants
- Internet (enduring materials): 18,569 activities, with 39,163 hours of instruction, and 3,568,207 physician participants
- Enduring materials (other): 6,310 activities, with 33,471 hours of instruction and 1,131,683 total physician participants
- Journal CME: 3,537 activities and 883,972 physician participants

Activities by Organization

The total numbers of directly sponsored activities based on type of CME provider and the top three formats of CME offered are as follows:

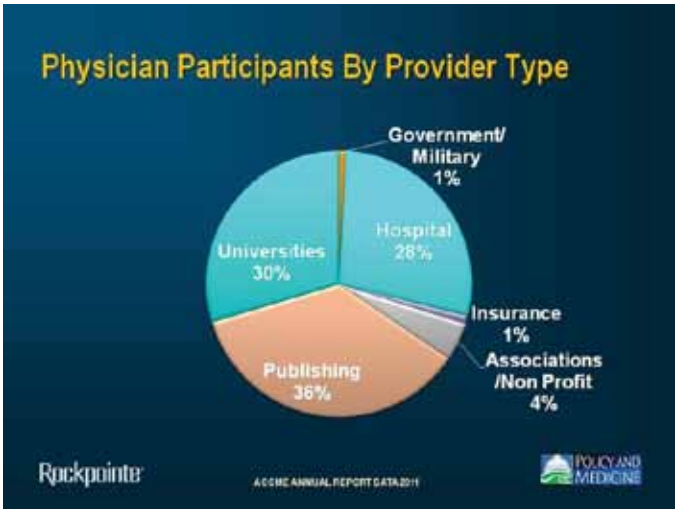
- Hospital/health care delivery system: 44,982 activities. Courses (24,414); Regularly scheduled series (13,784); internet (enduring materials) (3,390)
- School of medicine: 17,100 activities. Courses (7,769); Regularly scheduled series (6,208); internet (enduring materials) (2,249)
- Publishing/education company: 16,916 activities. Courses (4,811); internet (enduring materials) (7,980); enduring materials other (3,272)
- Nonprofit (physician membership organization): 12,405 activities. Courses (5,169); internet (enduring materials) (3,021); enduring materials (other) (1,150); journal CME (2,464)
- Government or Military: 3,362 activities. Courses (2,511). Most hours as well for courses (22,962).

Overall, Courses were the most popular format for offering directly sponsored CME (49,644); followed Regularly scheduled series (20,780); internet (enduring materials) (18,569); enduring materials (other) 6,310; and Journal CME (3,537).

Hours of Instruction

Overall, Regularly scheduled series offered the most total hours of instruction for directly supported CME (416,814), followed by courses (287,793); and internet (enduring materials) 39,163. The breakdown by type of CME provider is as follows:

- Hospital/health care delivery system: 314,214 hours; most hours are Regularly scheduled series (211,633)
- School of medicine: 273,489 hours; most hours Regularly scheduled series (193,045)
- Nonprofit (physician membership organization): 92,417 hours; most hours courses (57,983)
- Publishing/education company: 52,681 hours; most hours courses (23,169); internet (enduring materials) (10,497); enduring materials (other) (14,386)
- Government or Military: 25,435 hours; most hours courses (22,962)
- Non-profit (other) 18,692 – most hours courses (12,190)



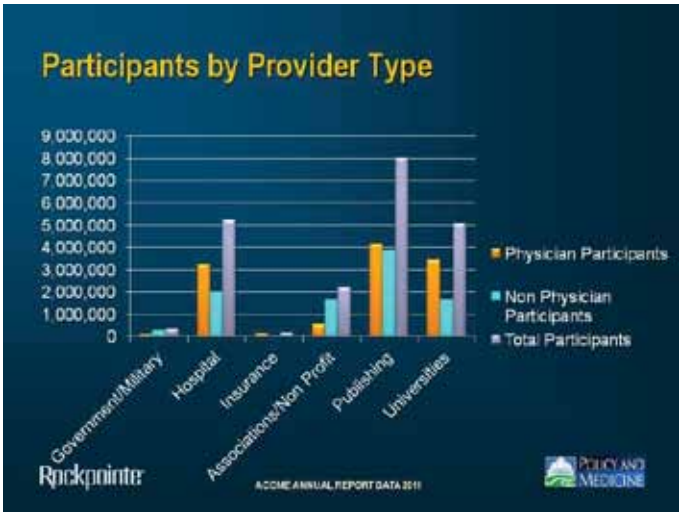
Physician Participants

Below is the number of total physician participants attending CME programs based on the provider of the CME.

- Publishing/education company: 3,776,293 participants; most participants: internet (enduring materials) 2,638,619; enduring materials (other) 812,492; courses (136,312)
- Hospital/health care delivery system: 3,053,328 participants; most participants: Regularly scheduled series (2,194,391); courses (48,532); internet (enduring materials) 150,218
- School of medicine: 2,520,108 participants; most participants Regularly scheduled series (2,090,214); courses (242,817); internet (enduring materials) 158,200
- Nonprofit (physician membership organization): 1,965,699 participants; most participants journal CME (682,359); courses (625,027); internet (enduring materials) 357,280

For jointly sponsored events, the total physician participants are as follows:

- School of medicine : 911,800 participants; most participants internet (enduring materials) (592,096); Regularly scheduled series (150,420); courses (119,825)
- Publishing/education company: 376,041 participants; most participants journal CME (225,544); internet (enduring materials) 87,856; courses (35,090)
- Nonprofit (physician membership organization): 247,121 participants; most participants courses (151,458); internet (enduring materials) (61,510); reg sched courses (15,158)
- Hospital/health care delivery system: 178,323 participants; Regularly scheduled series (92,041); courses (64,254); internet (enduring materials) (18,518)
- Non-profit (other): 49,480 participants



Overall, publishing/education companies have the most physician participants (4,152,334) followed by:

- School of medicine – 3,431,908
- Hospital/health care delivery system – 3,231,651
- Nonprofit (physician membership organization) – 2,212,820
- Non-profit (other) – 322,585
- Not classified – 170,103
- Insurance company/managed care company – 127,645
- Government or Military – 92,575

Commercial Support Reporting

Through 2010, ACCME-accredited and state-accredited providers reported the monetary value of in-kind commercial support they received, and included that amount in their total commercial support numbers. Beginning in 2011, due to a modification in ACCME commercial support reporting requirements, accredited providers no longer included the monetary value of in-kind support and reported only the dollar values for funds actually received. The nature (required) and source (optional) of in-kind commercial support is now reported qualitatively. Examples of in-kind commercial support include equipment, supplies, facilities, and other nonmonetary resources provided by a commercial interest in support of the CME activity. Therefore, comparisons between 2011 commercial support numbers and previous years will not be valid.

The total commercial support with monetary value of in-kind commercial support excluded is as follows:

- Publishing/education company – $248,015,575
- School of medicine – $201,688,456
- Nonprofit (physician membership organization) – $124,913,669
- Not classified – $64,363,362
- Non-profit (other) – $60,471,672
- Hospital/health care delivery system – $52,568,251

- Insurance company/managed care company – $348,502
- Government or Military – 37,150

ACCME-Accredited Providers Only

The following numbers apply only to ACCME-accredited providers. In 2011, other income made up 53% of total income, commercial support 33%, and advertising and exhibits 13%. Other income has increased steadily over the years with an increase of 4% in 2011 from 2010.

There are 687 ACCME-Accredited providers. The number of ACCME-accredited providers grew steadily until 2007. The ACCME lost 49 providers (7%) since 2007, including 7 providers (1%) between 2010 and 2011. Most of the loss in numbers has been from the following provider types: nonprofit physician membership organizations, publishing/education companies, and hospital/health care delivery systems. The numbers of schools of medicine, government or military providers, and insurance/managed-care companies has remained fairly steady. There has been a small decrease in nonprofit other providers and a slight increase in the number of not classified organizations.

When providers voluntarily withdraw their ACCME accreditation, the ACCME ascertains the reason whenever possible. The most common reason providers give is corporate changes, such as mergers and acquisitions. In addition, smaller providers sometimes withdraw because they have decided to offer CME through partnerships (joint sponsorships) with larger accredited providers. For that reason, the decline does not necessarily represent a reduction in physicians' and other health care professionals' access to CME. The number of physician and nonphysician participants in CME activities has increased steadily over the years, although participant numbers remained virtually flat between 2010 and 2011. The numbers of activities and hours of instruction increased between 2010 and 2011.

The majority of providers (80%) bring in $1 million or less each year in commercial support, with almost half of providers (48%) bringing in $100,000 or less. One-fifth of providers (20 %) bring in more than $1 million per year in commercial support, with the smallest percentage of those (2%) bringing in $10 million or more.

Data showed the percentage of revenue that each provider type receives from commercial support, the percentage of activities receiving commercial support by provider type, and the total hours of instruction (with commercial support) offered by provider type, represented by the circle size. Data showed that nonprofit physician membership organizations receive the smallest percentage of their revenue from commercial support and produce the smallest percentage of commercially supported activities (excluding government or military providers—see note), while not classified providers receive the largest percentage of their revenue from commercial support and produce the largest percentage of commercially supported activities, although they offer fewer overall hours of instruction.

Medical schools receive about half of their income from commercial support, about 20% of their activities are commercially supported, and they produce the most overall hours of instruction. Commercial support accounted for fewer than 1% of activities and less than 1% of total revenue for government or military providers.

In 2011, the majority of CME activities (79%) did not receive commercial support, accounting for approximately 80% of physician participants, and 75% of nonphysician participants. Twenty-one percent of CME activities did receive commercial support, bringing in approximately 20% of physician participants, and 25% of nonphysician participants.

Comment

The CME Economy is growing ever so slightly, which given the current financial circumstances we may be nearing a bottom. The trend for the reduction in commercial support by companies fails to take into account that those resources and courses supported by industry may no longer be in existence or available to clinicians. There is a down side potential for physicians not getting the latest information on therapies that could potentially save patients lives.

By performance, we can see from this report that the Medical Communication Companies are becoming the engine for this market sector and have been able to reach the largest number of clinicians.

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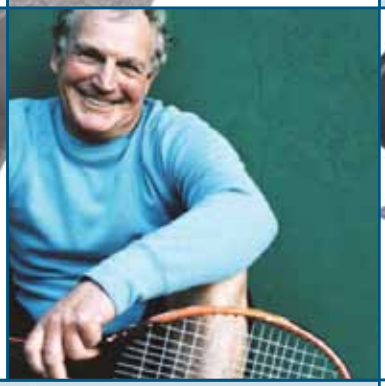

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Joint Implant Surgery & Research Foundation
Chagrin Falls, Ohio, USA

Physician Migration Toward Hospital Employment

Don Urbanowicz*

The Trend

A growing number of physicians are abandoning small private practice and becoming direct employees of large hospital systems.

The latest signs of the continued migration came from a number of surveys and reports generated over the past twelve months. An early 2011 Medical Group Management Association survey found that the share of physician practices that were hospital owned increased to 55% in 2010 – up from 50% in 2008 and approximately 30% in 2003. In addition, a large US-physician recruiting firm said the share of its doctor searches that were for positions with hospitals reached 51% for the 12 months ending in March of 2011, up from 45% from a year earlier and 19% in 2004. Concurrently, the number of searches for physician groups and partnerships dropped. Another national survey of 2,400 physicians found that nearly 3 out of 4 were planning on retiring, working part-time, closing their practices to new patients, becoming employed and/or seeking nonclinical jobs in the next 1 to 3 years.

Cleveland Clinic Main Campus

Studies conducted in late 2011 found that 70% of national hospitals and health systems plan to employ more physicians over the next one to three years, while 67% of hospitals and health systems are seeing more requests from independent physician groups about employment opportunities. The data follows another late 2011 report that showed 32% of first-year residents surveyed said they prefer to be employed by a hospital – up from 22% in 2008.

A Recent Example

One specific example of physician migration is in Memphis where the three major hospital systems (Methodist Le Bonheur Healthcare, Baptist Memorial Health Care Corporation and the Saint Francis hospitals) have significantly increased physician employment: to 400+ in late 2011 from 84 at the end of 2010.

Orthopaedic Surgeon Migration

Have orthopaedic surgeons followed the migration trend? Yes, but at a rate of less than half the overall physician population. An AAOS study in 2008 showed that only 16% of orthopaedic surgeons were employed directly by hospitals or an academic medical center. My best guess is that the number increased to slightly over 20% in 2010. The foundation of orthopaedics has always been the small group practice or solo practitioner. Orthopaedic surgeons seem to be continuing to relish their independence, at least as compared to the overall group – and at least for now.

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The Rationale & Benefits To Hospitals

The overall migration trend is tied to the needs of and potential opportunities for both the hospital and the physician. Hospitals are seeking to position themselves for a new business model for practicing medicine – Accountable Care Organizations (ACOs) – entities designed to change the incentives that influence how physicians and hospitals operate. ACOs will attempt to "organize" physicians, hospitals and other health care providers to deliver better and more efficient health care while reducing Medicare costs and improving care.

Elliott Fisher, shown here with Dartmouth Atlas founder Jack Wennberg, is credited with coining the phrase Accountable Care Organization.

In addition, proposed bundled payments will attempt to align payments for services delivered across an episode of care, such as a total knee replacement, rather than paying for services separately. Bundled payments will provide the physician and hospital with an additional incentive to coordinate care.

Acquiring physician practices may also benefit hospitals in the following ways:

- ability to lock-in inpatient and outpatient volume and revenue, including ancillary services
- maintain or grow share in existing markets; expand to new markets
- neutralize competition
- carve out more lucrative specialty niches
- reduce supply chain costs

Benefits To Physicians

For physicians, the frustrations resulting from the duties of practice ownership are increasing. Negotiating with insurers, securing payments from patients, and acquiring the latest technologies are becoming more burdensome. Government- backed loans to physicians offices have surged more than 10-fold (from $60 million to $675 million) in the past decade, a red flag that at least some physicians are in financial distress. The dynamic of reimbursement reductions, practice restrictions and investment limitations is facilitating a physician's decision toward hospital employment.

For physicians, the benefits of direct hospital employment may include:

- guaranteed salary; more regular work hours; retirement plans
- ability to focus on patient care rather than non-medical duties
- risk reduction from reimbursement cuts
- savings on malpractice insurance
- elimination of solo or small practice start-up costs and partnership issues
- possible repayment of medical school loans

Potential Issues For Physicians and Hospitals

However, "trade-off's" have been voiced by physician's who are considering becoming direct employees of hospitals. These include:

- lack of equity
- possible commitment to a long-term contract
- potentially heavier Medicare oversight
- role of "product champion" diminished; adoption decisions regarding innovative technologies may be ceded to hospital CFO
- fewer product choices
- less independence

Several risks were also identified for the hospital. These include lower production from physicians, reduced efficiencies and increased legal exposure.

What Does The Future Hold?

Despite the issues and risks identified, physicians will continue selling-out to hospitals. Boston Scientific management recently estimated that the migration for all physicians will top-off at between 70 and 75% in 2015.

My best guess is that 35 to 40% of orthopaedic surgeons will be employed by hospital systems or large medical groups by 2015. Some orthopaedic surgeons feel that number is conservative and could reach 60%. The bottom line: current regulatory

and economic changes are pushing physicians to join larger organizations; it may be the only way for many to afford the expertise, tools and systems required to remain viable in tomorrow's medical practice environment.

It is also expected that larger hospital organizations will become more powerful, gain greater leverage and continue to force price reductions. Further reductions in patient length-of-stays are also expected. Hospitals will practice "lean management" to improve operational effectiveness.

Delivery incentives will change. Team-based care -- including partnerships between primary care physicians, specialists, hospitals and non-physicians -- will be incentivized. Quality outcomes will be reimbursed – not volume. Outcomes data will be more transparent as providers' performance is expected to be measured against nationally accepted standards.

Comparative effectiveness, which compares the benefits and risks of different treatment methods, will increase the scrutiny on existing and potential future products.

Finally, device companies will become more proactive in driving cost out of the development process. Products commercialized in the future will be simpler, easier-to-use, clinically better and less expensive.

Implications For Device Companies

There are also implications for device companies. The migration trend has and will continue to translate into increasing price pressure, a consolidation of vendors (with further squeeze of smaller players), slower product adoption and a diminished "bond" between physician, rep and device company.

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

- Memorandum -

Modular Necks

To: TSI™ Study Group Members
From: Timothy McTighe Dr. HS (hc) & Declan Brazil, PhD
July 17, 2012

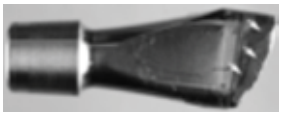
Coming off the recent problems with MoM bearings we are now seeing some concerns with modular necks. This should not be a surprise for some of us have been concerned with certain designs and materials used in modular junctions for some time now. However, with that said we have not faced the same level of media coverage in the past that we have seen with the MoM issue. This in our opinion will have an impact on all modular style implants. We intend to keep all our members informed to the best of our ability as to the modular neck junction used in the TSI™ modular neck technology as commercialized by Omnilife Science (The ARC™ Stem) in the US and Global Orthopaedics (The MSA™ Stem) in Australia.

Posted on our web site: www.jisrf.org under the TSI™ Study Group we have over 30 references on presentations at CME activities from around the world. Updates, papers and case reports will also be highlighted in our next Reconstructive Review scheduled to be published in the next couple of weeks.

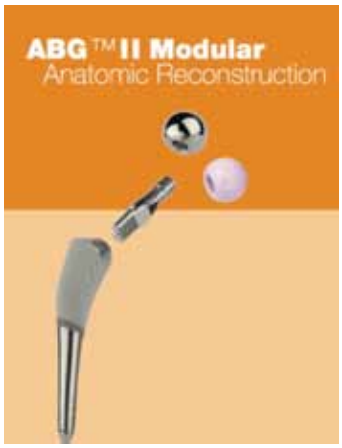
Our first patients were treated in December of 2007 over four and one half years ago. In Australia we have had one report of a revision case that met with some subsidence do to an intraoperative crack that was not recognized at the time of surgery. The surgeon involved felt it was an early learning curve situation and has not come across any more problems with the stem. There have been no reports of pseudo tumors or any reported concerns of modular junction problems with the MSA device.

The US experience with the ARC™ Neck Sparing Stem began in April 2010. So we are out over two years. We have report on over 1,200 stems implanted in the US at this years April 2012 World Congress on Osteoarthritis in Barcelona, Spain. In that series we reported on five (5) explanted stems. Details can be viewed on web site: www.jisrf.org TSI study group page. None of those cases had a problem with the modular junction except one case that had a head/neck disassociation do to a mismatch of components. This has been published in a number of our papers and lectures. There have been no clinical signs of pseudo tumors, fretting, corrosion or ongoing hip pain.

Here is some basic information as to modular necks in THA. Modular necks have a long history in the international market. Some designs have met with problems over the years and have been redesigned and improved. I have seen concerns with the Cremascoli titanium modular necks as far back as 1993.



The recent concern is about the Stryker ABG II and Rejuvenate Stems. These are both stems designs that have a track record with Stryker and a chrome cobalt modular neck has been added to their designs. Both of these are conventional cementless style stems with a traditional neck resection.



June 2008 - The FDA approves the Rejuvenate Modular Hip System based on the design's similarity to an already approved product: Wright Medical Technology's Pro-Femur Total Hip Modular Neck System. The Pro-Femur has had serious issues with corrosion at the modular sites resulting in a host of problems, including fractures and adverse tissue response.

April 2012 - Stryker Orthopaedics issues an urgent Safety Alert for its Rejuvenate Modular Stems and Necks.

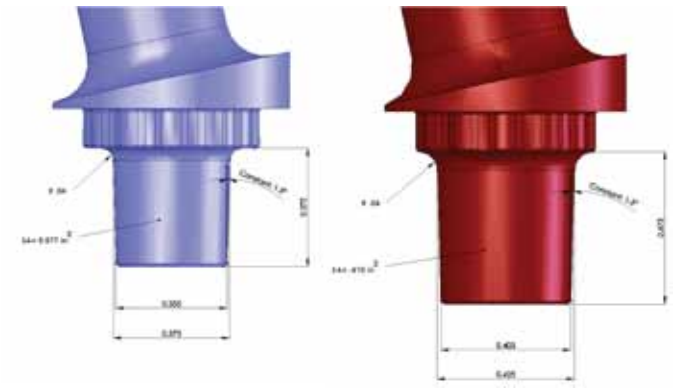
The Safety Alert defines the potential hazards as follow:"Excessive metal debris and/or ion generation. Fretting and/or corrosion at or about the modular neck junction may lead to increased metal ion generation in the surrounding joint space. Contact between metal ions and tissues and structures during an implant's service life may result in an Adverse Local Tissue Reaction (ALTR), the inflammation of associated tissues experiencing immunological response (metallosis, necrosis, and/or pain). An ALTR may result in the need for revision surgery. Excessive fretting debris. Fretting may lead to increased metal debris in the joint space (concentration of debris exceeds individual patient threshold) resulting in osteolysis [bone dissolution]. Osteolysis may be asymptomatic and may result in the need for revision surgery.)"

Retrieved Rejuvenate Neck & Dual Mobility Cup

We have seen other modular necks meet with fatigue problems like the OTI/Encore chrome cobalt design.

OTI old style

Encore Redesign



Both the diameter and the taper length were increased by a significant percentage. Since the redesign to my knowledge there have been no more fatigue failures of the neck.

Here you can see in this Cremascoli style taper the percentage of the overall length of the modular neck that engages with the taper is less than 1/3 of the neck length.

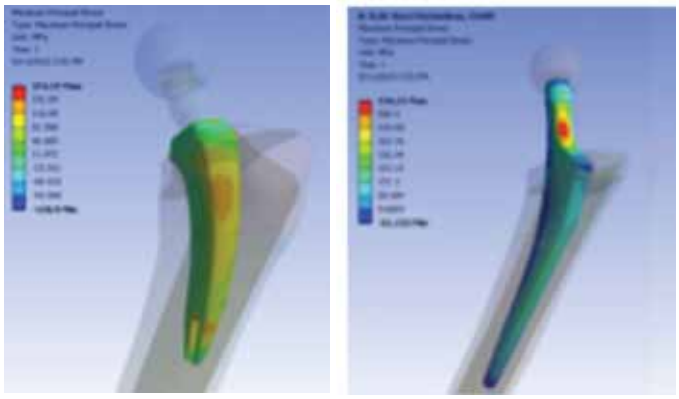
Taper stability is a function of surface contact area. The more surface the better the stability.

Neck Sparing stems have less risk because there is a reduced bending and torsional moment.

Here is the MSA™ Neck Sparing Modular Neck in a short neutral style. As you can see more than 50% of the overall modular neck engages with the taper.

In the ARC™ Neck Sparing Stem we see similar percentages of taper engagement approximately 50%.

As a general rule most conventional style stems with a traditional neck resection have between 15-20% taper engagement. The TSI™ Neck Sparing Technology with both the MSA and ARC style necks have approximately 50% taper engagement. Dependent on what length of neck used. Even the longest TSI neck sparing design has more engagement than the shortest conventional style stem with a traditional neck resection.



FEA testing published comparing neck sparing to conventional stems looking at stress in the femoral neck. The principal tensile stress in the neck sparing stem was 35% less than that of a conventional monoblock design.

Does this mean that we will not have any problems in the future? No, you can never say never but we do feel we have designed a device that has considered more than other designs.

The TSI™ Design technology is out more than four (4) years in Australia with the MSA™ Stem and more than two (2) years in the US with the ARC™ Stem. There have been no reports of taper failure or any signs of fretting corrosion, pseudo tumors on unexplained hip pain.

We believe that modularity at the neck stem junction provides enhanced opportunity to fine tune joint mechanics and reduce risk to mechanical impingement.

Why the need for modular necks? All you have to do is see the current usage rate to validate the need.

- Neutral neck: 33%
- Neutral Long (3.5mm): 6% new size
- 8º varus/valgus neck: 16%
- 8º varus/valgus long (3.5mm): 5% long new size
- 12º varus/valgus neck: 16%
- 12º anterverted/retroverted neck: 23%
- So as a combination of angled necks selected = 66%

Some would think that with a neck sparing stem you would just follow the natural anteversion of the femur and use a neutral neck. Just the opposite. You do not have the versatility to position your stem within the femoral neck to adjust for version. To achieve combined version angles between the femur and the acetabulum the intraoperative adjustability helps to achieve head center restoration.

Besides the independent review of the TSI™ Study Group there are two commercial entities Global Orthopaedic Technology and Omnilife Science following their cases.

At this early stage of clinical surgical observation all parties are cautiously optimistic.

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

- Commentary -

Physicians Owned Distributorships Are They The Same As Physicians Dispensing Drugs?

Timothy McTighe, Dr. HS (hc)[§], John Harrison, MD[∞], Thomas Donaldson, MD[‡]

Worth mentioning that modern trends in "**The Business of Medicine**," although carefully crafted by modern men to stay within legal boundaries, when viewed by many often morally and ethically test "tolerances" of same. This applies to the blunt consideration as to whether the modern orthopod who hopefully still wishes to behave appropriately as judged by his peers and colleagues, really should risk his reputation by getting involved in ownership of an implant distributorship where many critics may doubt his ability to practice without major conflict with his patients and their best considerations in care.

The history of Medicine from early eras still carries some "take home messages and principles" we should stray from at our peril… and this applies to the Hippocratic Oath[1], a seminal document on the ethics of medical practice, was attributed to Hippocrates in antiquity although new information shows it may have been written after his death. This is probably the most famous document of the Hippocratic Corpus. While the Oath is rarely used in its original form today, it serves as a foundation for other, similar oaths and laws that define good medical practice and morals. Such derivatives are regularly taken today by medical graduates about to enter medical practice and some have suggested a Hippocratic Oath be established for scientist.[2]

The Hippocratic Oath in one of its derived form

[Classic translation into English]:[3]

I swear by Apollo the Physician and Asclepius and Hygeia and Panaceia and all the gods, and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant:

To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art – if they desire to learn it – without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken the oath according to medical law, but to no one else.

I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

I will neither give a deadly drug to anybody if asked for it, nor will I make a suggestion to this effect. In purity and holiness I will guard my life and my art.

I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work.

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Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep myself holding such things shameful to be spoken about.

If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.

In the 1870s, many American medical schools chose to abandon the Hippocratic Oath as part of graduation ceremonies, usually substituting a version modified to something considered more politically and medically correct, or an alternate pledge like the Oath of Maimonides.[4]

The Hippocratic oath has been updated by the Declaration of Geneva. In the United Kingdom, the General Medical Council provides clear modern guidance in the form of its *Duties of a Doctor*[5] and *Good Medical Practice*[6] statements.

Physician Owned Distributorships (PODS).[7,14,15]

It is a controversial area, with many states struggling as to their legal status. In addition, questions are being raised as to the moral issue of physician's involvement.

There is no question that we have seen a power inversion in the health care field with insurance carriers, hospital administrators and legislators (both state and federal) introducing laws to reduce the "rights" of medical professionals to earn reasonable income provoking schemes to extend medical income earning in less traditional ways as a reactionary defense. Additionally, we are now faced with non-medical personnel making medical decisions that can and do effect more than just that of health care cost.

History teaches us in medieval times and forward the emerging physician prescribed, made and sold his own "remedies" but was supplanted by the later alchemist and history shows that in medicine, as in life, once you vacate a fertile field another species will soon fill it and produce in your absence.

In orthopaedics we have slowly resiled from rehabilitating our own patients and that void has been filled by the creation of rehabilitation specialists and we have improved our lot as modern orthopaedic surgeons see it by supers-specializing and in so narrowing our individual skill base from the breadth of our education programs we were involved in, left fertile apertures for lesser entities in podiatry, sports medicine variants and musculoskeletal exponents to promote themselves into traditional orthopaedic areas often more effectively than we have defended our skill base and (rightful) dominance.

Recent historical practices from the 1960s and 1970s showed that orthopaedic surgeons bought not only their soft goods (slings, splints, etc.) but also their total hip implants. Those were the days that the Charnley, Müller and Bechtol Hip Systems were sold non sterile wrapped in cheese cloth pouches with a few instruments also in soft cloth wrapping sold to the surgeon and he carried them around in the trunk of his car going to his hospital.[8] So historically there is a precedent for orthopaedic surgeons, general surgeons and general practitioners to buy their own supplies and sell them to their patients. So way is this practice wrong today?

If we remember back in the 1950s to the 1980s it was considered honorable to be a physician. No one accused physicians of making too much money and certainly the reputation of this group of individuals was above reproach, hard working and dedicated.

Historically, surgeon designers were just that designers of product build off the need to provide solutions for the needs of the patient. Charnley, Bechtol, Townley, Müller were true designers of their product and they made money (royalties, consulting fees, ownership equity) off their product. However, as the competition got more intense industry as always became more creative. Under contract law it was legal to enter into a services contract with well know surgeons to champion your product. Royalties were now being paid legally for marketing and clinical/surgical related services.

During these boom years the orthopaedic surgeon community sat back as a group and let the fee for serves model deteriorate.[9,10] By the 1980s the health

care industry became big business with big money and everyone was out to get a piece of the pie. Abuses and greed were being seen at all levels of the health care field. The Justice Department found many faults on both the side of industry and that of the surgeon community.[11] Some suggest that if orthopaedic surgeons followed the 1956 American Medical Association instruction "Physicians may not take money except for direct patient care services," the embarrassment of a Justice Department inquiry could have been avoided".[12] New standards have been established by industry, professional societies, hospitals, academic institutes, journals and governing bodies restricting certain activities and establishing full disclosure policies.[13]

One of the more restrictive policies that went into effect was the restriction of payment for non-developmental intellectual property (Ip) activities. The Justice Departments policy on royalty payments was now restricted to development and licensing rights of that Ip to a commercial business. No longer could surgeons become champions of a product and receive royalty payments as a result of marketing related activities. Restrictions were also placed on surgeon consultants and the level of their fee structure.[13]

Surgeons were now faced with a declining fee for services model and some of the lucrative business relationships of the past with industry gone.

There are still two institutions in our opinion that need oversight the hospital and the insurance carrier. It is interesting to note that with the so-called run away health care cost that we are seeing an unprecedented expansion at the hospital level. Private rooms, automated robotic inventory systems, marble floors, shopping centers, flat screen televisions etc. throughout the facility. We are also seeing a restriction of fair trade by the hospital with policies that restrict newer companies and technology from getting into the hospital.

Third Party Influence is also flexing its muscle. With the rise of medical insurance, another aspect of personal responsibility for costs of care waned, similar to the rise of social welfare from which has gone our parents sense of guilt if receiving it to a notion of "right" to get it and so in health care as a right instead of a privilege to which we contribute by lifestyle and choice by and large other than for a few of society's number who are dealt a bad hand at birth or through unavoidable misfortune whom we all want to assist.

The insurance company has recognized the strength of society demanding access to health care and with the Affordable Heath Care Act[16] now the law of the land has moved to take advantage of this situation. We are seeing the insurance carrier and health care industry (Drugs & Devices) negotiate directly side stepping both the surgeon and the hospital. In our opinion both the government and insurance industry would like to make all surgeons and all devices generic in order to pay the lowest possible price. They do not want to acknowledge training, experience, features and benefits have an added value. So with the continued erosion of fee for services some are looking aggressively how to supplement their income.

Today we are faced with a very different model and issue as compared to the physician of the past. Hospitals have access to top implants and products and do not need the physician to be the go between. The implant company goes directly to the hospital and supplies product lines that far exceed what the old-timer and even modern time physician can supply. These companies are supplying what is considered top line and monitored with tight quality control. The "pods" that we have seen offer a single line of hip or knee with no revision options. These product lines are customarily 20 years old design and hence don't answer the modern design needs expected today. Secondly and possibly more importantly, the quality of the devise often meets only the minimal standard. ASTM, ISO and FDA requirements are the basic steps necessary for product approval. Often these organizations do not offer advanced biomechanical testing or post-market surveillance. This is becoming a new requirement throughout a number of countries including the US with the FDA's recent post market surveillance requirement on MoM bearings. Often when discussing quality issues with certain directors of a "pods" about the quality of their product they are in the dark. One example: One of our Co-authors asking a Director of a Pod about the quality of his polyethylene used, he replied: "I am being told it is just like one of the first generation highly cross linked polyethylene". This was followed up with how do you know? His reply was that he really didn't. There were no tribology testing or clinical papers to give him assurance of quality. The

real test of quality of a product is its performance lifespan. Unfortunately the inferior quality may not show up for 5 years after which someone else pays for the revision.

From the total joint surgeon's perspective, most never go into a primary or revision cases without anticipated plan A through D. For example, modern knee designs and product lines offer multiple articulations and components to allow for the unexpected finding in the middle of the case. This allows the surgeon to adapt to the particular instability and solve it often times with just a polyethylene design change. If you are working with a "POD" knee, you only get one femoral design and one polyethylene style. This does place an added burden on the hospital to make sure back up material is available. Smaller community hospitals do not routinely carry back up inventory. We all know that anything and everything can go wrong even in a routine primary total joint surgery. No surgeon should expose his or her patient to a potential harmful situation without proper backup plans.

The surgeon is often faced with today the hospital administrator restricting the selection of devices based off contracts and bundling of products. This non-medical practice can and has an effect on altering a surgeon's treatment care plan. The decision on medical devices should not fall to non-medical personnel (government, hospital, or insurance companies).

Over the last few years Physician Owned Distributorship Models (PODS) started appearing. This was very surprising to me with the recent Justice Department probe into both the pharmaceutical and medical device industry. Certainly the last decade has seen a considerable erosion of public opinion concerning ethical behavior in the health care field. No longer does the physician sit on a pedestal.

So why would some surgeons think this business model of buying product and selling the product that you use to your hospital would be acceptable to public opinion??? Remember it is not allowable to pay a surgeon a royalty on product he uses so why would he think he could receive a commission on what he uses.

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."[7]

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 Stature (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.

"Insurers Pay Big Markups as Doctors Dispense Drugs"

The New York Times recently ran an article[17] on this subject taking a very critical point of view. Some physicians carry and sell drugs directly to the patient. This is often done as a service of convenience to the patient and many specialty physicians like plastic surgeons and dermatologist supply specialty products not available at drug stores.

There are also a growing number of physicians along with drug distributors that are setting up shop to dispense drugs on a larger scale directly to the patient. At a time of soaring health care bills, some critics outraged at this practice are asking for government reform restricting physicians from the practice of dispensing drugs.

We are suggesting that there can be legitimate reasons for physicians to maintain the privilege of supplying drugs to their patients. However, run away profits that take advantage of the patient must be stopped.

What in our opinion should happen is the same common sense approach used to control medical device cost at hospitals. A capitation system needs to be in place along with a full disclosure policy.

Allow physicians to carry and sells drugs directly to the patient with a maximum captivated selling price. Lets say the price is based off local fair market value not to exceed plus twenty percent (+20%). There must be a full disclosure statement posted and presented for the patient's acknowledgement

and signature. This policy would prevent run away profits being made by the physician and taking advantage of their patients. You can go as far as requiring physicians who want to dispense drugs to require them to post full disclosure on their web site stating their selling price vs. fair market value.

Yes, there are some loopholes that would need to be fixed such as ***average wholesale price,*** but this can be done with very reasonable changes to current state regulations. In states that are refusing to restrict runaway physician charges, there needs to be more public awareness brought down on their refusal. Public opinion will demand proper controls put in place. If the states find some legal loophole not to address these runaway charges then at least legal demand that the physician post full disclosure will help inform the patient.

Let's fix the abuse and not overreact to a potential benefit for many patients.

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Reconstructive Review
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Article 1.
Harrison, [1]; McTighe [1]

Article 2.
McPherson [1]; Clarke [2]; Donaldson [2]

Article 3.
Keppler [2]; McTighe [2]

Article 4.
Long [1]; Dasa [1]; Wentorf [1]; Scuderi [1]; Scott [1]

Article 5.
Smith [3]; McTighe [1]

Article 6.
Wright [1]; Brazil [1]; McTighe [1]

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Article 12.
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Article 14.
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Article 15.
McTighe [3]; Brazil, [3]

Article 16.
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