

# Reconstructive REVIEW

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**Joint Implant Surgery and Research Foundation**

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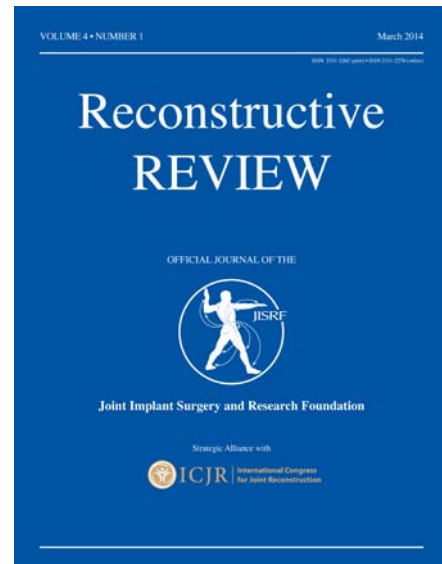
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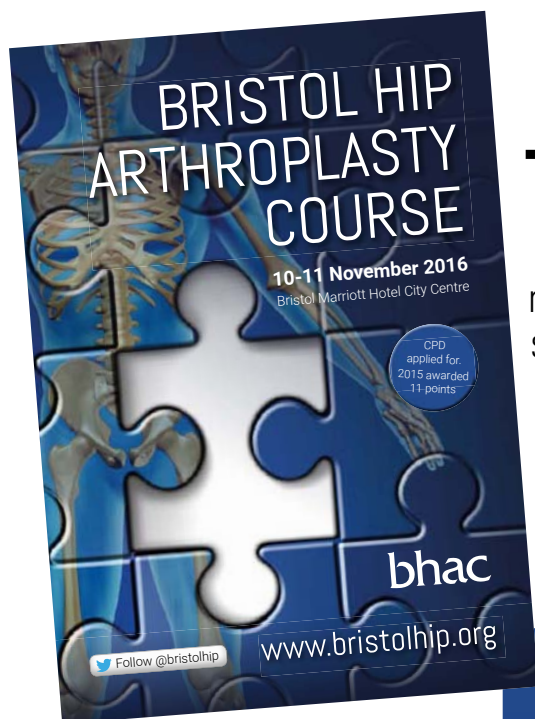
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10-11 November 2016

Bristol Marriott Hotel City Centre, United Kingdom



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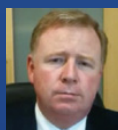
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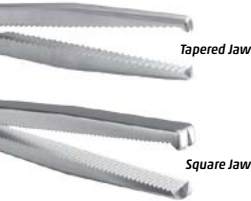
*Heavier design allows for a firmer grasping of bone and soft tissues*

Designed by Mark Powers, MD

### PRODUCT NO'S:

1813 [Tapered Jaw]  
Overall Length: 8.25"  
Law Length: 2.5"

1814 [Square Jaw]  
Overall Length: 8.25"  
Law Length: 2.5"



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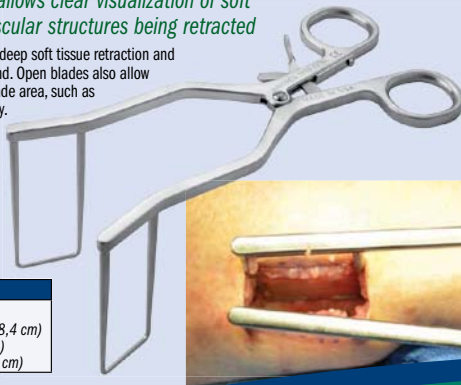
Tapered blades allows 90° deep soft tissue retraction and easy insertion into the wound. Open blades also allow surgeon to work in open blade area, such as for gastroc recession surgery.

Designed by Sarang Desai, DO

### PRODUCT NO:

1858

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Designed by  
Alexander D. Rosenstein, MD

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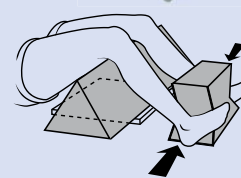
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# Trunnion Corrosion and Early Failure in Monolithic Metal-on-Polyethylene TMZF Femoral Components: A Case Series

Walker P<sup>1</sup>, Campbell D<sup>2</sup>, Della Torre P<sup>1</sup>, Brazil D<sup>3</sup>, McTighe T<sup>4</sup>

## Abstract

We describe four patients who were treated with primary total hip arthroplasty (THA) at two tertiary academic Australian teaching hospitals that experienced premature failure of head-neck trunnions through dissociation of the head-neck taper junction. This retrospective case series has similar clinical presentations and macroscopic pathology with severe head-neck taper junction loss of material, corrosion and early catastrophic failure. It is proposed that the accelerated wear is related to use of varus offset neck in a proprietary beta titanium alloy (Ti-12Mo-6Zr-2Fe or TMZF® Stryker Osteonics, Mahwah NJ, USA) TMZF femoral stem, longer head-neck combination in a relatively active, older, male patient population. In this limited case series presentation was on average 80 months (range 53-92) following index procedure. In three of the four patients, a prodromal period of groin or buttock pain was reported for between 1 week and 2 months prior to acute presentation. Significant metallosis and local tissue damage including gluteal muscle insufficiency was evident. Each stem revised was well fixed. An extended trochanteric osteotomy was required in two of the four cases for stem extraction. We recommend caution and further evaluation on the relationship between TMZF metal alloy and its longevity in higher demand patients with high neck offset, varus stem geometry and large CoCr bearing heads.

**Keywords:** hip, arthroplasty, taper, metallurgy, titanium alloy, corrosion, trunnion, revision

**Level of Evidence:** AAOS Therapeutic Level IV

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## Introduction

Modularity in total hip arthroplasty (THA) design was introduced more than 30 years ago [1,2]. Potential benefits included a greater intraoperative flexibility to adjust leg length, offset and stability, ease of component revision and decreasing overall prosthetic inventory. Modular head-neck tapers vary in their geometry, size, conical angle, finish and metallurgy. An extensive number of tapers are available across the many device manufacturers (Image 1) [3]. The effect of taper length and diameter on the potential for corrosion is controversial. A shorter trunnion length reduces the available taper surface area for interference fit and therefore may predispose to micro motion whereas a longer trunnion with wider taper angle may contribute to mechanically assisted crevice corrosion (MACC) [4,5].

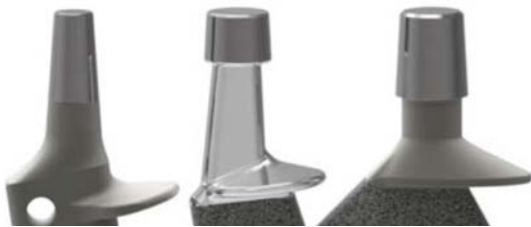


Image 1: Illustration Showing Different Taper Designs by Manufactures. (Courtesy of Chris Burgess, Signature Orthopaedics Ltd.)

Retrieved uncemented titanium alloy femoral stems with a modular cobalt-chromium (CoCr) head have been associated with crevice corrosion at the taper interface [6,7]. Dissimilar metals have a greater propensity for galvanic corrosion however studies have shown same metal alloys are also susceptible to taper corrosion. This supports the most likely mechanism behind corrosion at the head-neck interface being MACC rather than galvanism [8-10]. In certain combinations of high offset titanium alloy stem, with large CoCr heads, fretting and micro motion at the head-taper junction may result in additional factors leading to early implant failure (Image 2).

A proprietary beta titanium alloy (Ti-12Mo-6Zr-2Fe or TMZF® Stryker Osteonics, Mahwah NJ, USA) was marketed as have greater tensile strength and flexibility than standard Ti-6Al-4V alloys to more closely mimic the modulus of elasticity of cortical bone [11]. TMZF was thought to also have a greater fatigue strength, improved wear and abrasion resistance. Two TMZF femoral stems have since been recalled in the United States by the Food and Drug Administration (FDA) – Rejuvenate® modular and AB-GII® modular (Stryker Osteonics, Mahwah NJ, USA) after post-market data showed signs of Adverse Local Tissue Reaction (ALTR) due to fretting and corrosion at the modular neck junction [12]. The Accolade® (Stryker Osteonics, Mahwah NJ, USA) femoral stem was also manufactured

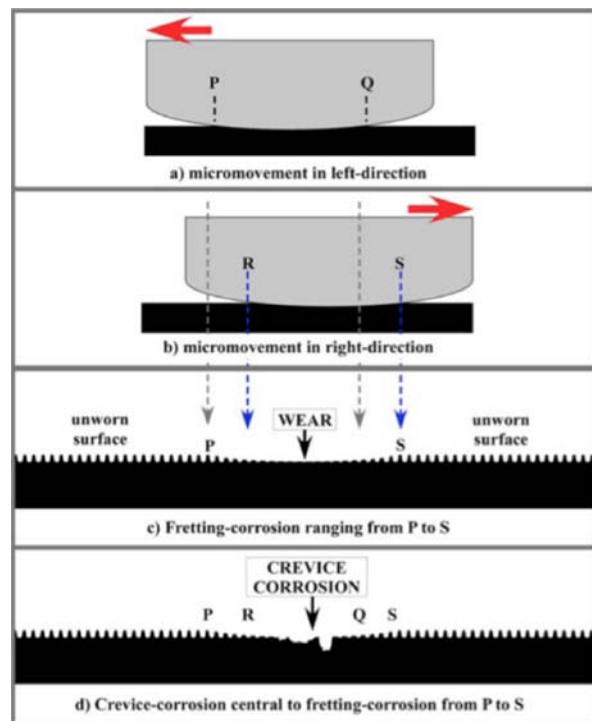


Image 2: Schematic illustrating that oscillatory motions as small as 10-100µ can induce wear and mechanically-assisted crevice corrosion (MACC). Such relative motion is unavoidable because modular junctions inherently introduce parts of different rigidity (size, shape) and different alloys (stiffness criteria). (Courtesy of Ian Clarke & Timothy McTighe)

from TMZF titanium alloy. Through a series of design changes, the Accolade II® (Stryker Osteonics, Mahwah NJ, USA) has replaced the Accolade® stem and is not manufactured from TMZF®. The Accolade® TMZF® was one of the top ten uncemented femoral stems implanted for primary THR in Australia up until 2013, where it subsequently was replaced in the 2014 data by the Accolade II [13].

The aim of this study is to report the experience of two tertiary academic Australian teaching hospitals with premature failure of four CoCr - Accolade® TMZF® THAs through dissociation of the head-neck taper junction.

## Materials and Methods

This retrospective case series of four patients have similar clinical presentations and macroscopic pathology with severe head-neck taper junction corrosion and early catastrophic failure. It is proposed that the accelerated wear is related to use of varus offset neck in TMZF femoral stem, longer head-neck combination in relatively active, older male patients.

The demographics of the four patients are detailed in Table 1.

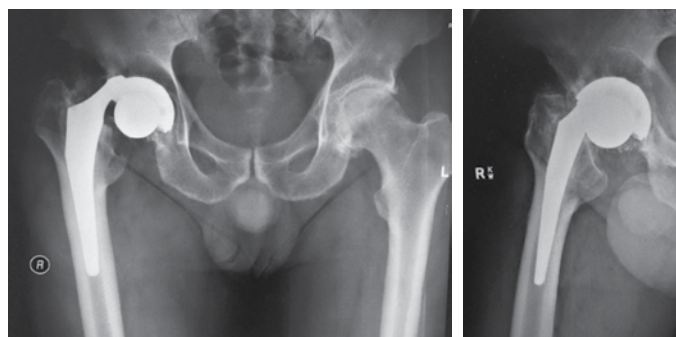
Routine diagnostic cobalt and chromium metal ions

*Table 1: Patient Demographics and Characteristics (NIDDM – Non insulin Dependent Diabetes Mellitus, CCF – Congestive Cardiac Failure, AF – Atrial Fibrillation)*

Patient	Patient Characteristics								
	Age at Primary THA (yrs)	Sex	Presentation	BMI (kg/m <sup>2</sup> )	Comorbidities	Age at Revision THA (yrs)	Duration of THA Implantation (months)	Activity Level	Time to Pain
1	68	M	Ache and buttock stiffness for over 1 month. Spontaneous dissociation	30	Ex smoker, laryngeal cancer	76	89	Very active, walking, gym instructor	1-2 months
2	64	M	Sudden onset buttock pain, with limp	26	Hypertension, controlled NIDDM	72	92	Very active, golf, light sport	< 1 week
3	65	M	1 month groin pain, 1 week clicking with instability and several falls	31	Hypertension, controlled NIDDM	72	53	Moderately active, golf weekly	1 month
4	72	M	Acute dissociation, unprovoked	-	CCF, AF, Vit B12 deficiency, prostate cancer	80	84	Sedentary, no sport	<1 week

were not performed in any patient due to the mechanical nature of each presentation and the obvious need for acute revision. No patient presented with a clinical suspicion of sepsis. Routine blood tests were performed for each patient, with a normal CRP (3.0mg/L, normal <5mg/L) recorded in Patient 1.

Patient 1 was an active obese 76 year old male with a primary right THA implanted without complication over 7 years prior. He complained at presentation of 1-2 months of insidious right buttock pain which was activity related. The patient noted a sudden pain in the right groin and a leg length discrepancy while sitting on a chair. Acute radiographs in the emergency department showed an acute dissociation at the head-taper junction (Image 3).



*Image 3a and 3b: Patient 1 presenting anteroposterior and lateral radiographs dissociated head/neck taper junction of right total hip replacement.*

Patient 1 underwent femoral stem revision through a standard posterior approach with flexible osteotomes. Significant metallosis was debrided (Image 4), and a modular distally fixed stem was implanted. Acetabular liner and head components were also replaced. The original acetabular shell was not affected and thus retained.



*Image 4: Patient 1: Macroscopic appearance at revision of significant metallosis, dissociated neck taper junction, severe taper corrosion and gluteal muscle insufficiency.*

The retrieved femoral stem in Patient 1 showed severe taper corrosion as the cause of the spontaneous dissociation (Image 5). Histopathology confirmed significant metallosis with no sign of active or chronic inflammation.

Patient 2 was an active mildly overweight 72 year old male who played golf and light sport. He underwent a routine right THA 7.5 years prior for osteoarthritis. On presen-



*Image 5: Patient 1: Retrieved femoral stem showing marked corrosion of the neck taper.*

tation Patient 2 described an episode of spontaneous right buttock pain with a limp. Radiography of the right hip prior to the revision showed catastrophic failure of the trunnion with varus malalignment at the head-neck junction (Image 6).



*Image 6a and 6b: Patient 2: Presenting anteroposterior radiographs showing prosthetic head/neck dissociation*

Patient 2 underwent a revision THA with extended trochanteric osteotomy through a posterior approach. Metallosis surrounding the implant and gluteal muscles was debrided (Image 7) and components exchanged. Histopathology showed a moderate degree of chronic inflammation prosthesis detritus.



*Image 7: Patient 2: Revision THA with metallosis, and significant neck taper corrosion.*

The retrieved femoral stem from Patient 2 revealed significant taper corrosion and instability of the head-neck junction with inferior notching of the neck from instability (Image 8). A modular distally fixed stem was successfully

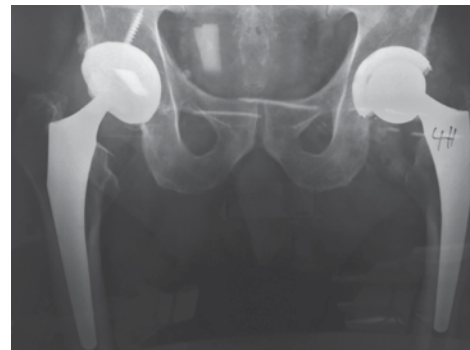
*Image 8: Patient 2: Retrieved femoral stem and acetabular liner with instability evident and dissociation of the head-neck junction.*



implanted with a 32mm head.

Patient 3 was a moderately active obese man who played golf weekly and had an uncomplicated primary left THA performed 4 years prior to presentation. Over one month he developed groin pain with symptoms worsening to a clicking feeling and sensation of instability. Patient 3 sustained a number of falls prior to revision of the left THA. Radiographs of the left THA revealed a varus dissociation of the neck taper junction (Image 9).

*Image 9: Patient 3: Dissociation of the head-neck junction with varus malalignment.*



Patient 3 successfully underwent revision left THA through a posterior approach with an extended trochanteric osteotomy required for stem extraction. Significant metallosis was debrided at the time of surgery throughout the periarticular tissues. The retrieved femoral stem showed significant taper corrosion with notching of the inferior neck due to instability (Image 10).



*Image 10: Patient 3: Retrieved femoral stem with marked neck taper corrosion and inferior notching.*

surgery throughout the periarticular tissues. The retrieved femoral stem showed significant taper corrosion with notching of the inferior neck due to instability (Image 10).

Patient 4 was a sedentary 80 year old man with multiple medical comorbidities. He underwent an uncomplicated primary right THA 7 years prior and presented with a sudden episode of unprovoked dislocation. Radiographs at presentation revealed a head-neck dissociation with abnormal wear evident on the taper (Image 11).



*Image 11: Patient 4: Presenting anteroposterior radiograph of the dissociated head-neck junction of the right THA.*

At revision of the right THA, metallosis was debrided and an isolated stem revision was successfully performed with a distally fixed prosthesis and exchange of the



modular primary components. The retrieved femoral stem prosthesis had marked corrosion of the taper with inferior notching (Image 12).



Image 12a and 12b: Patient 4: Retrieved femoral stem prosthesis with taper corrosion evident and inferior neck notching.

## Results

### *Clinical presentation:*

In this limited case series of four failed primary THA patients, presentation was on average 80 months (range 53-92) following index procedure. In three of the four patients, a prodromal period of groin or buttock pain was reported for between 1 week and 2 months prior to acute presentation.

### *Primary THA Implants:*

Each of the four patients had lateralised offset Accolade® TMZF® Plus stems implanted with lateralised offset CoCr heads of between +4mm and +10mm. Index components are summarised in Table 2.

### *Radiographic findings:*

Two of the four patients presented with complete head-neck taper dissociation. The other two presented with impending dissociation, and instability at the damaged taper. Subtle osteolysis was evident in zone 7 of the medial femoral calcar in each case. Advanced imaging or specific laboratory cobalt and chromium ion analysis were not required due to the acute mechanical presentation and need for urgent revision in each case.

### *Histopathology:*

Tissue pathology was performed in three of the four patients which showed an absence of acute inflammation, varying degrees of chronic inflammation and metal debris.

### *Intraoperative findings:*

Significant metallosis and local tissue damage including gluteal muscle insufficiency was evident. Each stem revised was well fixed. An extended trochanteric osteotomy was required in two of the four cases for stem extraction.

### *Post-operative Analysis:*

Metallurgical analysis in particular the marked corrosive changes seen macroscopically on the trunnion of each case is pending and will form the basis of a subsequent paper.

## Discussion

There are several factors that can influence the rate at which corrosion develops at the head-neck taper junction. Metallurgy, implant geometry, bearing couple, implant assembly technique and specific patient factors can all influence the longevity of a THA.

Corrosion at the trunnion interface with dissimilar metals can be a cause of early failure in THA [14]. A modular head on a femoral stem is standard practice in modern THA to provide versatility in definitive implanting, ease component revision and to reduce the prosthetic inventory. A MoP bearing combination utilising a CoCr alloy metal head on a monolithic titanium alloy remains the most common bearing couple in modern THA.

Bearing surfaces also appear to contribute to corrosion with a greater propensity to corrosion found with metal on metal (MoM) than MoP bearing surfaces. Larger femoral head size, dissimilar alloy pairing at the trunnion interface, a varus femoral stem with lateralised offset head have been associated with greater taper corrosion in metal on metal MoM bearing couples [15,16]. Corrosion appears to be more prominent with longer implantation time and with MoM than MoP bearing surfaces. A hard on soft bearing couple such as a ceramic femoral head (with or without an articulating same metal sleeve) on a polyethylene liner may reduce taper corrosion and fretting [15,17].

Techniques of trunnion cleaning during component assembly and femoral head impaction technique may influence head-neck stability. There is a direct linear relationship between impaction force and the force needed for disassembly [16]. Impacting the head-neck components in a dry, clean environment would seem ideal for component assembly [19]. A single impaction force of at least 4kN has been shown to achieve adequate head-taper junction strength in all bearing conditions [20].

Patient factors may contribute to the incidence of MACC by elevated BMI and greater activity level increasing the mechanical stress on the trunnion [14]. This limited case series that show similar macroscopic failure of the trunnion whilst not proving causation, highlights the potential for accelerated MACC corrosion and early THA failure in a particular subset of patients. These are active, elderly and overweight males with a combination of a varus neck

Table 2: Implant Details and outcomes of component revision.

Patient	Femoral Component					Acetabular Component		Outcome	
	Femoral Component	Stem Size	Head Offset (mm)	Taper	Head Outer Diameter (mm)	Acetabular Size (mm)	Liner	Histopathology at Explantation	Revision Details
1	Accolade TMZF Plus Hip Stem	4 high	+10	V40	36	58	Trident X3 0° Polyethylene	Metallosis, no inflammation	Stem revision, complete resolution
2	Accolade TMZF Plus Hip Stem	4 high	+4	V40	40	56	Trident X3 0° Polyethylene	Prosthesis detritus, chronic inflammation	ETO diaphyseal stem, 32mm head
3	Accolade TMZF Plus Hip Stem	4 high	+4	V40	40	56	Trident X3 0° Polyethylene	We were not able to locate the histopath report	Stem revision with ETO, complete resolution
4	Accolade TMZF Plus Hip Stem	5 high	+5	V40	36	58	Trident X3 0° Polyethylene	-	Stem revision, complete resolution

offset, lateralised large diameter CoCr head on the particular TMZF alloy found in Accolade® stem with a proprietary trunnion geometry (V40®).

The time to failure in these four patients was 4.4 to 7.6 years. When implanting novel alloys and taper designs, the authors recommend yearly review after two years with a thorough clinical examination and surveillance plain radiography. Radiographs should be assessed for resorption of the medial calcar, evidence of osteolysis and changes in the surrounding pericapsular soft tissues of the hip. Early targeted investigations to further assess the symptomatic hip or concerns on plain radiographs may include full blood count with differential, C-reactive protein, erythrocyte sedimentation rate and serum cobalt and chromium levels. Advanced imaging studies may include ultrasound examination of the hip capsule and surrounding musculature, scintigraphy and metal artifact reduction magnetic resonance imaging sequences.

Further studies are needed to explore the relationship between the TMZF metal alloy and its mechanical longevity in higher demand patients with high neck offset, varus stem geometry and large CoCr MoP bearing couple.

### Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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# Robot-assisted Total Hip Arthroplasty After Chiari Pelvic Osteotomy: A Case Report

Dettmer M<sup>1</sup>, Pourmoghaddam A<sup>1</sup>, Kreuzer S<sup>1</sup>

## Abstract

Congenital hip dysplasia in younger adults may require surgical treatment. It is believed that 3D-navigated, robotic-assisted surgery for Total Hip Arthroplasty could be useful in cases of pseudo-acetabulum and preceding treatments (Chiari Pelvic osteotomy) due to accurate pre-surgical planning and higher levels of precision associated with the utilized technology, which may improve the odds of positive short-term and long-term clinical outcomes.

We report the case of a 26-year-old Caucasian woman with a Crowe-IV dysplastic hip and pseudo-acetabulum. Earlier interventions included Chiari pelvic osteotomy, femoral osteotomy and femoral lengthening, which were unsuccessful to improve pain and function in the longer term. The surgical approach via robotic-assisted surgery lead to promising results concerning outcomes in the short-term (four months post-surgery) and medium-term (17 months post-surgery) in this specific case.

**Keywords:** Chiari pelvic osteotomy, robot-assisted surgery, total hip arthroplasty, 3D navigation, hip dysplasia

**Level of Evidence:** AAOS Therapeutic Level IV

## Introduction

Congenital hip dysplasia at different grades (high or low) often requires surgical interventions of Chiari pelvic osteotomy and/or Total Hip Arthroplasty (THA) early in life [1]. Since bone-preservation at early stages of life decreases the odds of potential revision surgeries, it has been suggested that Chiari pelvic osteotomy may be a more appropriate treatment approach in younger patients to conserve the hip joint compared to a THA [2].

However, when THA becomes necessary in patients having previously undergone Chiari pelvic osteotomy or other interventions, pre-operative planning may become difficult because the pseudo-acetabulum is significantly different from the true acetabulum and deformities related to congenital hip dysplasia may result in additional intra-

operation complexities. Additionally, determination of the true leg length can be challenging in such cases.

Here, we report the case of a 3-dimensional (3-D) robotic-assisted THA for a Crowe-IV dysplastic hip with pseudo-acetabulum that had previous surgical interventions of Chiari pelvic osteotomy, femoral osteoplasty, and femoral lengthening. We decided to use the MAKOpas-

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ty RIO® robotic arm (MAKO Surgical Corp., Ft. Lauderdale, FL) since we expected that utilizing this technology would enable us to pre-operatively plan the placement of the acetabular shell into the severely dysplastic true acetabulum by creating a patient-specific surgical plan (based on 3D reconstructions of the patient's CT scans). Additionally, we expected to be able to execute this plan with high levels of positional precision and orientation accuracy. We hypothesized that this treatment would lead to good implant alignment, which would result in a reduction of the risk for complications and an improvement of the patient's Hip disability and Osteoarthritis Outcome Score (HOOS) and UCLA activity scores post-operatively in the short and medium term.

## Case Presentation

The patient was a 26-year-old Caucasian female who weighed 130 pounds (59 Kg) and stood 67 inches tall (BMI= 20). She did not report any significant past medical issues besides congenital hip dysplasia with symptoms initially appearing at age 12, requiring multiple procedures. In 2001, she had undergone a Chiari pelvic osteotomy to help relieve her pain from Crowe-IV dysplasia. Subsequently, the patient had femoral osteotomy and femoral lengthening in 2005. These interventions only partially corrected her 60 mm leg length discrepancy and 35 mm radiologic alignment discrepancy. She reported that her pain improved for several years, but the treatments caused formation of pseudo-acetabulum of the right hip and reestablished a leg length discrepancy (Figure 1). Over time, the pain returned with no significant relief from cortisone injections or oral analgesics.

Radiographic images of the right hip showed end-stage osteoarthritis and global joint space narrowing. The im-



Figure 1. Pre-operative X-ray of 26-year old patient with severe hip dysplasia and pseudo-acetabulum

ages also indicated formation of osteophytes on the lateral margin and medial wall of the pseudo-acetabulum, as well as on the femoral head as shown in Figure 1. At this point, we decided to plan and perform a THA using robotic-assisted surgery to reconstruct the normal (true) acetabulum (Figure 2) and to implant a Corin® MiniHip (Corin Group, Cirencester, United Kingdom) neck preserving hip stem.

Pre-operatively, the patient completed a survey that included HOOS and UCLA- activity questionnaires. These surveys are designed to evaluate patients' subjective opinion concerning their hip, associated issues, symptoms and functional impairments. The HOOS survey consists of several sub- sections designed to assess severity of osteoarthritis. These sections are: 1) symptoms, 2) pain, 3) activity of daily living (ADLs), 4) sports and recreation, and 5) quality of life (QOL) [3]. Additionally, the patient indicated that her pain represented a serious limitation and she was unable to perform ordinary functions. She also stated that her limp was moderate and she was only able to walk indoors. The patient's UCLA activity score indicated that she was mostly physically inactive and severely limited regarding activities of daily living.

## Surgical Treatment

In the initial phase of the surgical planning, typically CT-scans and x-rays are used to plan alignment of the implants, associated anteversion (Figure 2a), inclination (Figure 2b), and positioning (figure 2c).

We supplemented this planning stage with a 3-D reconstructed model based on CT-scans. This model could be freely rotated in all directions and was used for inspection of the involved structures and planning of positioning, anteversion, inclination, and optimal bone coverage (see Figure 3).

The navigation system preparation and the surgical technique via a direct anterior approach have been described in detail before [4]. The anterior approach was used because it facilitates computer navigation/robotics in the supine position. Furthermore, this patient had undergone a Smith-Petersen (anterior approach) procedure performed during previous surgery, and the table extension used in this approach assisted in reducing the hip due to the required significant leg lengthening.

The patient was placed in supine position on the operative table with the operative leg attached to the arch table extension (Innovative Orthopedic Technologies LLC, Houston, TX). The procedure was performed using MAKOplasty and a RIO Robotic Arm Interactive Orthopedic System (MAKO Surgical Corp, Ft. Lauderdale, FL

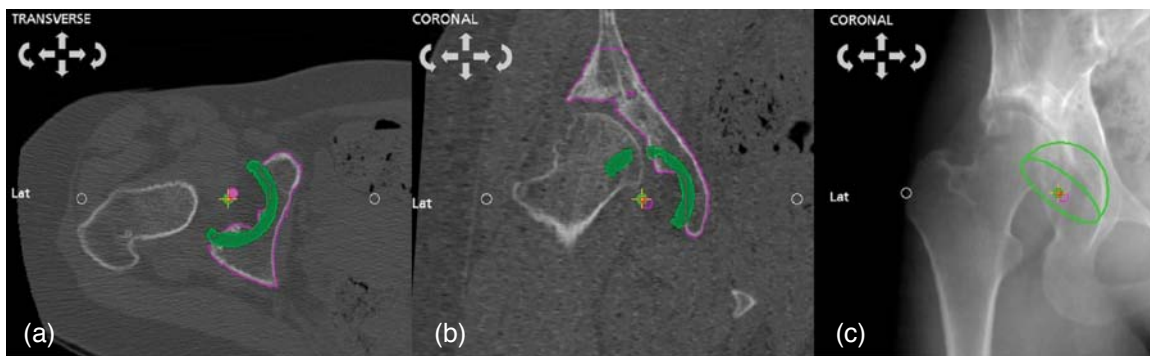


Figure 2. (a) CT-scan, transverse view of the hip including planned acetabulum shell, (b) CT-scan, coronal view of planned acetabulum shell (c) x-ray coronal view of planned acetabulum position.

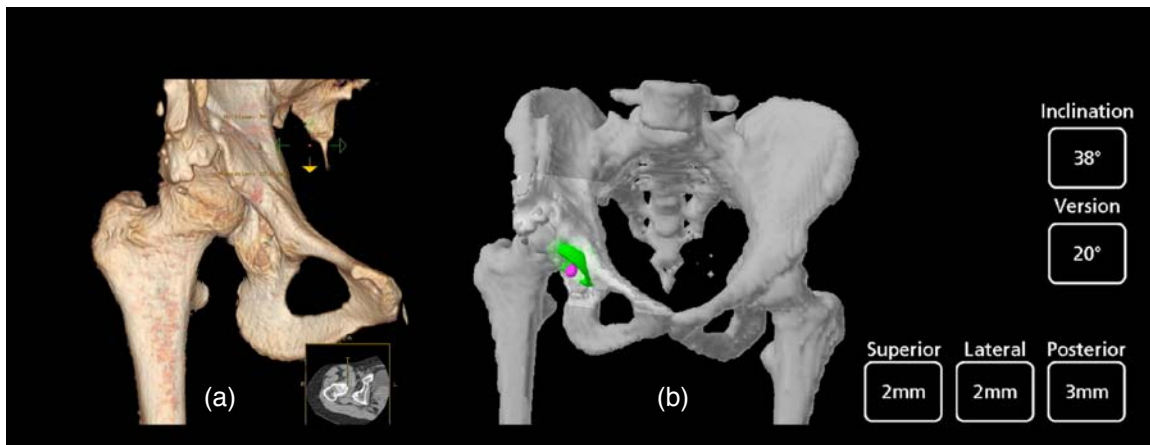


Figure 3. (a) 3-D reconstruction of the hip including pseudo-acetabulum, (b) 3-D reconstruction of the hip including planned cup position

USA). Initially, pelvic trackers were placed into the pelvic bone on the left iliac crest (contralateral hip) utilizing two pins and the registration was performed after surgical exposure of the hip joint was completed. A small reference check point was placed into the proximal femur as well as an ECG lead on the knee cap of the operative leg as a reference points for measuring leg length and offset. Once the femoral neck osteotomy was complete according to the pre-operative plan, the true acetabulum was registered. Visual inspection of the joint during the surgery confirmed pre-operative assessments; the operative findings were consistent with end-stage osteoarthritis disease and significant synovitis. The femoral head and acetabular surface were noted to be deformed with bone on bone articulation. Additionally, there was a significant amount of osteophytes on the femoral neck and acetabular rim of the pseudo-acetabulum.

An initial reaming one size smaller of the final cup size (42mm) was completed. Visual inspection and finger palpation was utilized to assure maintenance of the anterior and posterior wall. At this time the final reamer (44mm) was placed again utilizing the robotic arm to complete the reaming. A size 44mm Corin® Trinity™ cup (Corin Group, Cirencester, United Kingdom) was implanted using the robotic arm. Two additional screws were utilized for additional fixation due to the dysplastic nature of the acetabulum. A 10 degree lipped liner was then impacted into the acetabulum shell for additional posterior stability. Af-

ter preparation of the femoral side, a size 3 standard hydroxyapatite coated MiniHip™ stem, with a 28mm diameter femoral head was implanted. After this trial reduction, the hip was found to be stable in flexion, extension, internal and external rotation, with satisfactory restoration of the leg length (Figure 4) according to the preoperative leg length inequality (13mm).

The surgery led to the reconstruction of a normal acetabulum (true acetabulum), which lead to a decrease in clinical leg length discrepancy, as determined via measurement during the surgery. The patient was partially weight-bearing for the first 4 weeks after surgery with no dislocation precautions in place. The patient was followed up at 4 months and 17 months postoperatively. She demonstrated significant improvement in all clinical scores after 4 months and even further improvements after 17 months, as illustrated in Table 1. She indicated that she resumed all her daily activities and has returned to sports.

## Discussion

Robot-assisted surgery has become a commonly used tool in hip and knee Arthroplasty over the last two decades [5–7] due to the associated advantages of precision of bone preparation, high accuracy of pre-surgery planning and improved navigation in hip Arthroplasty [8,9]. While these advantages have been described in general population set-



Figure 4. Post-surgery x-ray of 26-year old patient with implanted acetabulum shell and Corin® MiniHip™.

		Pre-op	Post-op (4 months)	Post-op (17 months)	Change score
HOOS	Symptoms	35	65	90	+55
	Pain	58	90	100	+42
	ADL	61	93	98	+37
	Sports	32	63	82	+50
	QOL	13	75	88	+75
UCLA		2	6	7	+5

Table 1. Results from subcategories of the HOOS and UCLA Activity Score before, 4 months/17 months after surgery and score change between pre-op and 17 months post-op. Maximum HOOS is 100, Maximum UCLA Activity Score is 10.

tings, we believe it is useful to report the outcome from patients with advanced anatomical deformity and special needs, such as in the current case. This will enable clinicians to determine the technology's capability for improving clinical outcomes in a variety of cases and in the longer-term, and to evaluate longevity of robotic-assisted surgery. Specifically, evidence from either clinical trials or case studies is required to justify the added costs associated with this type of surgery [10].

In the current case, traditional surgery would have been challenging for the team without robotic assistance. The approach presented here was effective due to precise planning of the new acetabulum and placement of the Mini-Hip. Using this technology, the surgeon was provided with accurate quantitative knowledge about current position of the instrument and alignment of anatomical structures. This allowed for high accuracy in this case of severe dysplasia and deformation, whereas the robotic arm provided a failsafe mechanism against manual errors based on haptic feedback.

The success was reflected in the improvement of the patient's self-reported outcomes, both in the shorter-term (four months) and mid-term (17 months). More specifically, the surgical treatment improved pain measures and functional outcomes considerably and allowed the patient to quickly return to pain-free, moderate activity.

## Duration of Surgery

In a series of robotically assisted total hip replacements, after the learning curve, the average operative time is approximately 15 minutes longer than a navigated total hip replacement. Placement of the trackers is about 3 minutes and the registration process is about 10 minutes. In this particular case, the false acetabulum was marked as the acetabulum and during the case the three orientation points needed to be changed, which added another 15 minutes to the surgery. It is difficult to say if the robotic surgery extended the surgical time, but the acetabular prep time (reaming and placement of the socket) was less than 10 minutes. Overall, in the surgeon's estimate, the surgical time was extended by approximately 30 minutes and the overall surgical time was 120 minutes skin to skin with EBL of 450cc, with 155cc given back from the cell saver. Part of the increased surgical time was not due to robotic utilization but due to the surgeon not using additional screws for acetabular fixation initially, which caused the socket to move after the initial reduction. This was clearly a misjudgment by the surgeon, as he considered the initial press fit to be excellent. The cup was then repositioned and three screws were placed for additional fixation. This being a very unique and complex case in a very young patient, the surgeon felt obligated to assure optimal implant position to avoid any potential complication in the future. Although the surgeon is considered an expert in hip replacement, he does not have extensive experience regarding displastic hips with previously conducted osteotomies.

## Additional cost of Robotic-Assisted Surgery

At this point, it is very difficult to determine the cost effectiveness of this procedure. Obviously, it is not cost effective if a robot is purchased only for this type of surgeries or even for general hip replacement. In fact, the operating surgeon in this case no longer uses the robot in routine total hip replacements, since outcome results from our clinic did not differ regarding robot-assisted surgery and "regular" navigated total hip replacement surgery. Therefore, robotic assistance was not considered cost effective.



The main reason to present this case is that this particular technology could be valuable in complex cases such as the presented one if the technology is available in the hospital.

## Conclusion

To our knowledge, this is the first time a case of a patient suffering from Crowe-IV hip dysplasia with pseudo-acetabulum and robotic-assisted THA is reported, whereas previous surgical interventions included Chiari pelvic osteotomy, femoral osteotomy and femoral lengthening. Robotic-assisted, 3-D navigated hip Arthroplasty showed promising results in the current patient. A THA operation (in severely deformed hips) can be safely performed with robotic assistance and a good outcome can be achieved. However, it is not yet clear if robotic assistance will lead to consistently similar outcomes compared to traditional techniques in specific cases such as the one presented here. We have since utilized this approach in cases of previous acetabular fracture to predict the potential need for hardware removal. More research is needed to shed light on benefits or potential limitations of the technology in other specific patient cases. Additionally, it is required to investigate the long-term outcomes resulting from this intervention, specifically in younger patients.

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## Disclosure

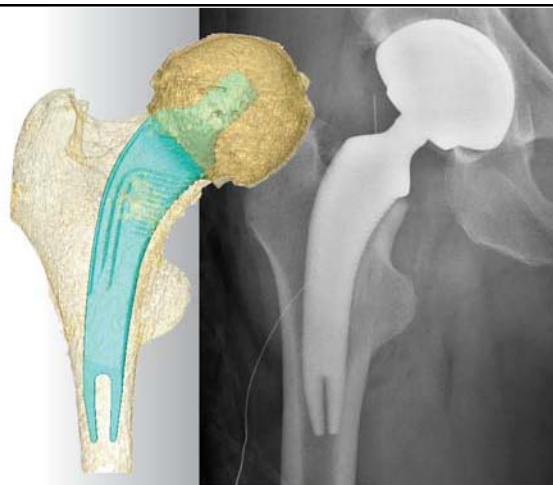
The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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# Tissue Sparing Total Hip Arthroplasty Study Group



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# Combination of Accelerometer-Based Navigation and Force Sensor for Precise Bone Resection and Appropriate Soft Tissue Balancing in Total Knee Arthroplasty

Oshima Y<sup>1</sup>, Fetto J<sup>1</sup>

## Abstract

**Background:** Precise bone resection and appropriate soft tissue balancing are considered indispensable in total knee arthroplasty (TKA). However, in most TKAs, only the experienced-based subjective physical “feel” of the surgeon, or either a computer-based navigation system or a soft tissue balancing system are applied to improve the results. In the present study, a combination of both an accelerometer-based navigation system and an electronic knee balancing force sensor were applied to attempt to obtain optimal outcomes.

**Materials and Methods:** An accelerometer-based navigation system and an electronic knee balancing force sensor were applied in combination in 5 TKAs. Thereafter, the incidence of radiographical outliers of the lower-extremity mechanical axis and the alignments of femoral and tibial components, and the incidence of intraoperative lateral retinacular release were evaluated and compared against those of 5 TKAs performed with the force sensor alone as a control.

**Results:** The posterior slope of the tibia was significantly improved in the TKAs performed with the combination of both devices ( $P=0.004$ ). No lateral release was performed in any TKAs of either group.

**Conclusion:** TKAs performed under the combination of an accelerometer-based navigation system and an electronic knee balancing force sensor can obtain greater the accuracy of bone resection and appropriate soft tissue balancing.

**Keywords:** total knee arthroplasty (TKA); computer-assisted surgery (CAS); accelerometer-based navigation; electronic knee balancing system; bone resection; soft tissue balancing

**Level of Evidence:** AAOS Therapeutic Level IV

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## Introduction

Total knee arthroplasty (TKA) is a successful treatment for advanced arthritis to remove pain and restore function. The longevity of the prosthetic components has been increasing, and the survival rate of the primary TKA was reported to be ranged from 89.5 to 95.3 % at 10 years [1]. However, up to 20 % of TKA patients were not satisfied with the outcome at 1 year post TKA [2], and unfortunately more than 35 % of revision cases were performed within 2 years of primary TKA as early failures [3,4].

The failures in TKA have occurred for several reasons; aseptic loosening, polyethylene wear, instability, infection, arthrofibrosis, malalignment, malposition, deficient extensor mechanism, periprosthetic fracture, and patellar complications. Some of these factors could be minimized by design and material refinements of the components. However, many failures, involving malalignment, malposition and instability were also closely related to such surgical techniques as bone resection and soft tissue balancing [4-6].

For the bone resection, intramedullary femoral and extramedullary tibial alignment guides are most commonly applied. However, the limitations of the accuracy of these conventional methods have been of concern [7,8]. It has been estimated that 10 % or more of TKAs have greater than 3 degrees error in lower-extremity mechanical axis and femoral and tibial component alignments, even when performed by experienced arthroplasty surgeons [7,9].

To improve the accuracy of bone resections in TKA, a computer-assisted surgery (CAS) TKA was first performed in 1997 [10]. The device used for this procedure showed some promise for improvement of accuracy, and thereafter, related navigation technologies have continually improved the positioning of prosthetic components. However, most of these technologies have involved large and expensive equipment. Recently, a relatively low-cost, high reliability handheld device, the KneeAlign 2 (OrthAlign Inc., Aliso Viejo, CA), a compact accelerometer-based CAS, has been employed [15].

To obtain the appropriate soft tissue balancing, there are presently two schools of thought: 1) measured resection and 2) gap balancing. The first, the measured resection technique, employs femoral and tibial resections which are made independently based on anatomic bony references, i.e. transepicondylar axis (TEA), posterior condylar axis (PCA), and trochlear anteroposterior axis (Whiteside's line). Following that, soft tissue balancing is assessed with spacer blocks or trial prostheses. The second, the gap balancing technique, is based on the femoral component being positioned parallel to the resected proximal tibia with

each collateral ligament equally tensioned by tensiometers or laminar spreaders [11]. These methodologies have been developed and modified through scientific studies. However, most of the procedures for soft tissue balancing still depend primarily upon the experience-based assessment of the surgeon's subjective "feel" as an "art form" [12,13].

The eLibra (Zimmer Inc., Warsaw, IN) is an electronic knee balancing system, based on a relatively inexpensive handheld force sensor device to determine the rotation of the femoral component to obtain the appropriate balance by measuring the relative pressures within the medial and lateral compartments before the posterior femoral bone resection [12].

We hypothesized that a combination of the two relatively inexpensive handheld devices might achieve TKA with more precise bone resection and appropriate soft tissue balancing than the conventional procedures, i.e. without any technological devices, or with only one or the other of the two devices. The objective of this study, therefore, was to evaluate the accuracy of the surgical procedure by means of the combination of an accelerometer-based navigation and a soft tissue force sensor for TKA.

## Materials and Methods

The inclusion criteria of this study were patients, who had been diagnosed with primary osteoarthritis and had been indicated for TKA. Five consecutive patients were enrolled as an experimental group. Under spinal anesthesia, all TKAs were carried out by a single surgeon (JF) in October 2014. Five consecutive TKAs, which had been performed by the same surgeon just before the experimental group, were enrolled as a control group. The exclusion criteria were patients with revision TKAs or secondary knee operation. One patient was excluded because of the past history of anterior cruciate ligament reconstruction surgery. All TKAs underwent midline skin incision with medial parapatellar arthrotomy.

The KneeAlign 2 system, which consists of a display console, a reference sensor, and femoral and tibial jigs, was applied for the distal femoral and proximal tibial resections (Fig. 1). For the distal femoral resection, the femoral jig and the distal femoral cutting block were seated at the midpoint of intracondylar notch on the anterior aspect of the posterior cruciate ligament attachment, which is similar to the insertion point for the conventional intramedullary femoral alignment guide system. The display console was attached to the femoral jig, and the reference sensor was attached to the cutting block. The display console and the reference sensor contain accelerometers and

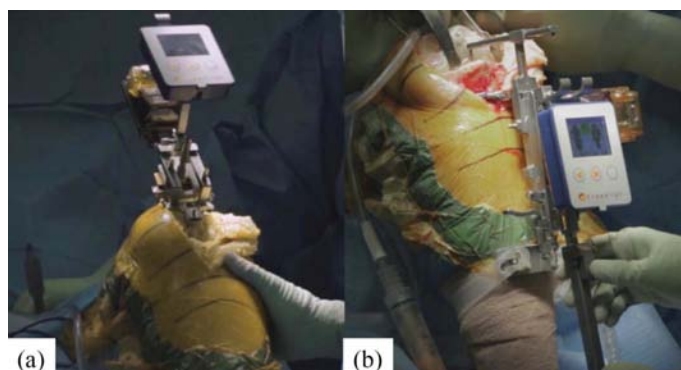


Fig. 1: The kneeAlign 2 navigation system consists of a display console, reference sensor and (a) femoral and (b) tibial jigs (Image provided by OrthAlign Inc., Aliso Viejo, California).

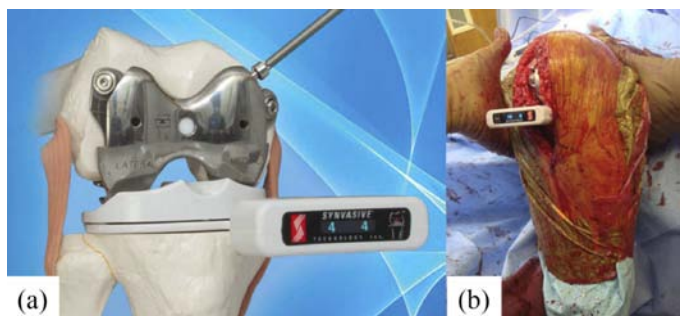


Fig. 2: (a) The eLibra electronic knee balancing system (Image provided by Zimmer, Warsaw, Indiana). (b) Insertion of the sensor in flexion, patella reduction, and leg drop off from the table for adjusting the soft tissue balancing.

communicate wirelessly with each other to determine the cutting block's alignment. After the registration of initial position of the cutting block, the hip center of rotation was determined by flexion/extension and internal/external rotation of the flexed hip. The cutting block was adjusted to 0 degrees in the coronal (varus/valgus) and sagittal (flexion/extension) planes, perpendicular to the mechanical axis, and the distal femur was resected.

Patellae were resurfaced and replaced in all cases at this point before the proximal tibial osteotomy. The tibial jig was placed on the anterior aspect of the anterior cruciate ligament footprint to the proximal tibia, which is also similar to the conventional extramedullary tibial alignment guide system. The proximal tibial cutting block, the display console and the reference sensor were attached to the jig, and the components were fixed with a pin to the tibia. Following that, the tibial axis was determined by registering the anterior aspect of the anterior cruciate ligament footprint to the proximal tibia, and the medial and lateral malleoli. The cutting block was adjusted to 0 degrees in the coronal (varus/valgus) and 3 degrees in the sagittal (posterior slope) planes on the tibial axis, and the proximal tibia was resected.

For the control group, the distal femoral and the proxi-

mal tibial resections were performed with intramedullary femoral and extramedullary tibial alignment guides. The intraoperative target of the distal femur was 5 degrees valgus from the anatomical axis in the coronal, and that of the proximal tibia was 0 degrees in the coronal and 3 degrees in the sagittal planes.

After the distal femoral, the proximal tibial, and the patellar resections were completed, the soft tissue balancing in knee extension was evaluated by the surgeon manually. Following that, the eLibra electronic knee balancing system, which comprises an electronic force sensor, the stainless steel eLibra femoral components and the tibial inserts, were applied (Fig. 2). The patella with a trial component was reduced, the thigh was lifted up, and the leg was dropped off from the table. The medial and lateral pressures were balanced by adjusting the sensor, and then the femoral external rotation angle was decided. The eLibra was then exchanged to the implant manufacturer's provided bone cutting block, and the final femoral resections were completed. The knee joint was taken through a full range of motion, and the intercompartmental load differential was examined with the placing of all trial components. The lateral retinaculum was released if the patella showed subluxation.

A fixed-bearing cruciate retaining 3DKnee system (DJO Global, Vista, CA) was implanted with bone cement. A pneumatic tourniquet was only inflated during curing of the cement, usually 12 to 15 minutes.

The standing anteroposterior hip to ankle, and the standing lateral knee to ankle radiographs were obtained 4 to 12 weeks after the surgery, from which the lower-extremity mechanical axis, femoral component varus/valgus alignment, tibial component varus/valgus alignment and posterior slope were digitally measured [14,15]. A picture archiving and communication system (PACS) imaging system (Philips Medical Systems, Sectra Imtec AB, Sweden) was adopted at our institute, and the unit of measurement was 1 degree.

For convention, a varus alignment between the measurement angle and 180 degrees for the mechanical axis and 90 degrees for components was given a positive numerical value; a valgus alignment was given a negative numerical value. Tibial slope was designated negative for an anterior slope and positive for a posterior slope. Target intraoperative alignment of the distal femoral coronal (varus/valgus) and the sagittal (flexion/extension) planes were 0 degrees, and the proximal tibial coronal (varus/valgus) and the sagittal (posterior/anterior slope) planes were 0 and 3 degrees, respectively. Any values greater than 3 degrees from the intraoperative goal were classified as outliers.



## Statistical Analysis

Descriptive statistics were used to describe the difference in the mechanical, femoral and tibial axes, conducted by the paired samples t-tests between the experimental and the control groups. All statistical analyses were performed with SPSS version 19.0 software (SPSS Inc., Chicago, IL) and significance level was set at  $p < 0.05$ .

## Results

Values are expressed as mean  $\pm$  standard deviation.

In the experimental group, there were 1 female and 3 males. One male patient underwent simultaneous bilateral TKAs and these cases were examined separately. Average age was  $75 \pm 2.6$  (ranging from 73 to 79), and BMI was  $34.7 \pm 7.9$  (26.6 to 43.1).

Operation time was  $96.8 \pm 11$  (85 to 111) minutes from the skin incision to the skin suture. Pneumatic tourniquet time was  $13.6 \pm 1.3$  (12 to 15) minutes.

The femoral CAS process from the preparation of the femoral jigs to the distal femoral resection was  $8.2 \pm 1.6$  (6 to 10) minutes. The tibial CAS process from the preparation of the tibial jigs to the proximal tibial resection was  $12.4 \pm 3.4$  (9 to 17) minutes. In one case, the proximal tibia was additionally recut because of inadequate posterior slope after the first cut under the setting of 3 degrees with KneeAlign 2, and thus, it took 17 minutes in total.

On the other hand, the force sensor process from the preparation of the sensor to the exchange to the manufacturer's cutting block was  $3.6 \pm 0.5$  (3 to 4) minutes. The external rotation angle of the femur was  $5.2 \pm 1.3$  (3 to 6) degrees.

The radiographic findings showed that the lower-ex-

tremity mechanical axis was 2.2 degrees valgus alignment (-4 to +1), femoral component was 0.8 degrees valgus alignment (-3 to +1), tibial component was 0.2 degrees valgus alignment (-1 to +1), and posterior slope was 2.6 degrees (1 to 5) (Fig. 3). The mechanical alignment in 1 case was 4 degrees valgus, which was diagnosed as an outlier. Otherwise, all other parameters were less than 3 degrees, which were within the normal range.

In the control group, there were 4 males, and 1 patient underwent simultaneous bilateral TKAs, and these cases were examined separately. Their average age was  $63 \pm 14.8$  (51 to 83), and BMI was  $26.6 \pm 2.5$  (22.2 to 28.7).

The radiographic findings showed that the mechanical axis was 0.2 degrees valgus alignment (-4 to +3), femoral component was 1.8 degrees valgus alignment (-4 to +1), tibial component was 0.6 degrees varus alignment (-2 to +3), and posterior slope was 6.8 degrees (5 to 9) (Fig. 3). As outliers, one patient showed 4 degrees valgus of mechanical axis, 4 degrees valgus of femoral component, and 9 degrees of posterior slope, while another patient showed 8 degrees of posterior slope. The posterior slope of the tibia was significantly improved in the experimental group compared to the control group ( $p=0.004$ ). However, the mechanical, femoral and tibial axes were not statistically different between the experimental and control groups.

There were no lateral retinacular releases performed in either group. Moreover, there were no significant post TKA complications, infections nor venous thromboembolism suffered in any cases.

## Discussion

To improve the accuracy of TKA, the combination of an accelerometer-based navigation and a soft tissue force sen-

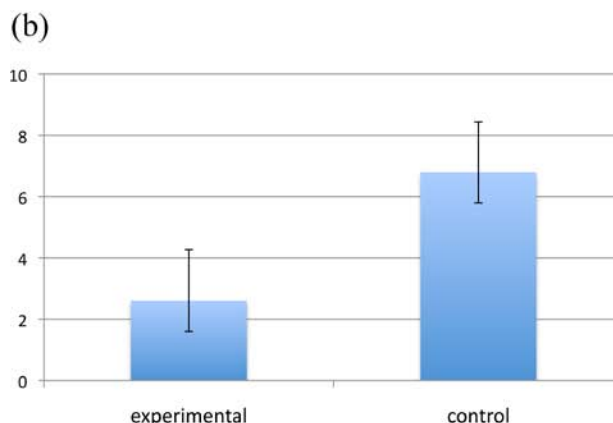
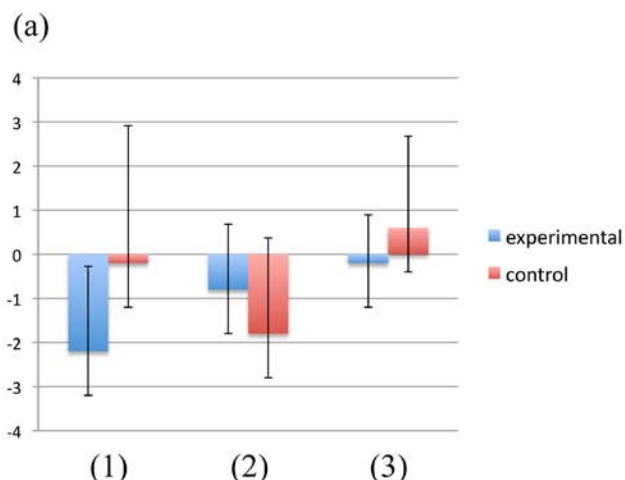


Fig. 3: Comparison between the experimental and the control groups. (a)-(1) mechanical axis, (2) femoral alignment, (3) tibial alignment. (b) posterior slope of the tibia. The posterior tibial slope was significantly improved compared to the control group.



sor were applied to the procedure. Only one radiographic outlier occurred in a single patient in the CAS experimental group. Moreover, soft tissue balances were correctly adjusted without lateral release by use of the force sensor.

Malalignment TKA has been reported to be implicated in polyethylene wear and aseptic implant loosening [16-19]. The external rotation of the femoral component is determined by appropriate soft tissue balancing combined with accurate bone resection. On the other hand, malposition with inappropriate soft tissue balancing results in patellar maltracking, femoral component lift off, anterior knee pain, and knee instability, especially in flexion [11]. Therefore, it is imperative to achieve precise bone alignment and appropriate soft tissue balancing for optimal outcomes in TKA.

Many articles have demonstrated the increased accuracy of bony alignment by CAS compared to the conventional maneuvers [7,8]. Recently, the improvement of clinical function with the accurate mechanical alignment by CAS was published [20]. However, CAS involves some detriments; increased capital cost, longer procedure times, preoperative additional image examinations, intraoperative difficulties of handling bulky devices or sensitive instruments, steep learning curves, and potential tracer pin site complications [5,21].

The accelerometer-based navigation has been adopted, firstly because its accuracy and efficacy have already been confirmed [15,24]. Secondly, these devices are easy to be operated by most orthopedic surgeons with some TKA experience, because these devices are handheld and the maneuvers of bone resections with them are similar to the conventional techniques with intramedullary femoral and extramedullary tibial guides. It has been reported that the time for pinning the tibial cutting block was 3.4 minutes and for completion of tibial resection was 4.6 minutes while using this device, and thus it was considered not to be longer than the conventional instrumentation [24]. In our experimental group, it took 8.2 minutes for femoral and 12.4 minutes for tibial resections, including setting up devices, adjusting the cutting blocks, and cutting the bones. Thus we also deemed these processes to be similar to the conventional methods. Thirdly, based on the accelerometer, the anatomical references can be registered intraoperatively without screws. Moreover, the femoral guide is simply attached to the femoral surface, with no need for intramedullary insertion. Thus, preoperative image preparations and insertions of screws are not required, eliminating the causes of fatty emboli production. Fourthly, this system is compatible with most manufacturers' prostheses.

Recently, it has been tried to involve the process to adjust soft tissue balancing in CAS [13,25], however, most of

the CAS, including KneeAlign 2, have not been designed for soft tissue balancing. Moreover, it is difficult to determine the proper alignment with mediolateral stability in flexion for a hypoplastic lateral condyle with a severe valgus knee deformity [26]. Therefore, the appropriate soft tissue balancing with proper rotation of the femur is a prerequisite for successful TKAs, in addition to the precise bone resections.

For soft tissue balancing, the eLibra knee balancing device has been adopted, firstly because of its efficacy, reproducibility and reduction in need for lateral release [27]. The lateral release is a simple procedure to improve patellar tracking, however, it involves patellar complications; e.g. patellar hypovascularity, fracture and component loosening. Because the flexion gap was adjusted before the posterior femoral resection, the incidence of lateral release was reported to be reduced from 12 % to 3 % with this device [12]. In this study, the patellar stability was achieved, without the lateral release throughout a full range of knee motion for all cases in both groups. Secondly, the eLibra device is intuitive and handheld similar to the conventional spacer blocks. Thirdly, it has been reported to take only an additional 3 minutes to accurately achieve the soft tissue balancing with this device [27]. The technique is easier to learn than the gap balancing technique. It took 3.6 minutes in the experimental group, and it does not affect the total surgical time. Fourthly, this system is compatible with most of the manufacturers' prostheses.

The cost is another inevitable argument for hospitals. Most of the conventional CAS devices are expensive, and can be used only at hospitals with high volume of TKAs. However, most hospitals are not that high in volume. Moreover, most TKA surgeons are not arthroplasty specialists only performing high numbers of arthroplasties. Because both of these systems are inexpensive disposable single-use devices, they are available to apply even in hospitals with low numbers of cases.

This study includes several limitations. This was a preliminary study of cases performed by a single surgeon, with a small number of patients and a short-term follow-up. Thus, we were unable to determine if the accurate TKAs were beneficial for long-term prosthetic survival or the clinical outcomes. However, malalignment, malposition, and instability are definitely factors related to early failure of TKA. Therefore, this data showed the possibility of improving the outcome of TKAs with precise bone resection and appropriate soft tissue balancing.

Traditional CAS systems rely on anatomic registration points to reconstruct the knee. Incorrect selection of reference landmarks results in component malposition and balancing issues. In this study, an additional posterior tibia

cut was performed for one case in the experimental group, because of an inadequate posterior slope of the tibia. It was considered that the register point on the tibia surface was selected more posteriorly than expected. To select inadequate reference landmarks is a pitfall for TKA, and therefore, surgeons always need sufficient anatomical and surgical knowledge and must verify the alignment using conventional guides step by step, even under CAS TKA.

## Conclusions

The combination of an accelerometer-based navigation and a soft tissue force sensor was applied for TKA. Using these technologies, precise bone alignment and appropriate soft tissue balancing can be obtained.

## Disclosure

The authors declare that there are no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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# Restoration of Femoral Condylar Anatomy for Achieving Optimum Functional Expectations: Component Design and Early Results

Durbhakula S<sup>1</sup>, Rego L<sup>1</sup>

## Abstract

**Background:** Many total knee arthroplasty (TKA) systems are used across a variety of markets in which outcome will be influenced by patient morphology and normal activities of daily living, for that patient population. Femoral component sizing in primary total knee arthroplasty is of paramount importance for optimizing complication free post-operative function across all patients. The purpose of this study was to report the early results of a primary TKA system in support of the component design characteristics for achievement of increased functional expectations.

**Methods:** A prospective, continuous series of 176 primary posterior stabilized (PS) TKAs were performed in 172 patients by a single surgeon. Femoral component size distribution was assessed and all patients were followed for a minimum of two-years post-operatively. Total Hospital for Special Surgery (HSS) scores and range of motion (ROM) was assessed for the entire cohort and by gender.

**Results:** There were no patients lost to follow-up. Two patients required incision and drainage for superficial wound infection of the indicated knees. There was no radiographic evidence of component failure. As expected, femoral component size frequency use was skewed by gender with the larger sizes in males. There were no pre- or post-operative clinical or functional differences by gender and at the recent follow-up (avg. 3.8 years). In addition, there was an average significant increase in change of HSS score ( $p < 0.01$ ) and ROM ( $P < 0.01$ ) when compared to pre-operative baseline.

**Conclusions:** The design characteristic for component sizing and functional expectations were confirmed in the reported Western population cohort series. Further continued use and study of this primary TKA system is warranted across all ethnic cultures.

**Keywords:** Total Knee; Condylar Anatomy

**Level of Evidence:** AAOS Therapeutic Level III

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## Introduction

Achieving successful expected outcomes following primary total knee arthroplasty (TKA) requires a balance of simultaneously occurring variables including surgical technique, component size availability and component design characteristics, each influenced by patient gender and anthropomorphic differences. In addition to relieving pain and creating a durable prosthetic composite, restoration of full function is a goal being pushed to its limits. Various TKA component designs have been introduced to address the need for increased flexion up to and beyond 140 degrees. However, most high-flexion component systems are based on standard implant design parameters that were engineered from Western patient morphology data leading to compromises regarding sizing and functional issues in the Middle-Eastern and Pan-Asian patient populations, and across socio-religious functional expectations. [1,5,9,10]

Intra-operative techniques for TKA, to accommodate component sizing availability across standard TKA components, are common for achieving acceptable joint reconstruction outcomes. For example, medial-lateral size availability, especially in smaller component offerings for women creates a marked overhang situation that may result in subsequent complications involving soft-tissue impingement, increased post-operative pain and decreased function. [6,7] In all cases, achieving increased ROM is balanced with component sizing and increased bone resection to accommodate component thickness.

Patient expectations regarding socio-religious needs such as prolonged deep-flexion, sitting cross-legged and squatting requires greater understanding of TKA versus normal knee kinematics. Increasing demands for greater knee function is a necessary outcome of western patients. [9] Engineering of TKA component dynamics is of paramount importance to successfully address the wide variety of patient anatomical needs and functional expectations. However, conflicting reports exist regarding high flexion TKA design and achieving flexion normally seen in standard posterior stabilized TKA systems [2] while other authors report maintenance or decrease in ROM following high flexion TKA. [8]

The purpose of this single surgeon, non-randomized, prospective case series of TKA patients was to report the early results of the Freedom® Total Knee system in support of the component design characteristics and achievement of early flexion expectations.

## Materials and Methods

Between November 2010 and December 2013, the senior author performed 176 consecutive primary TKAs in 172 patients utilizing the posterior stabilized (PS) Freedom Total Knee® system (MAXX Orthopedics, Inc., Plymouth Meeting, Pennsylvania) (Figure 1). The Freedom Total Knee system is manufactured from cast cobalt chromium

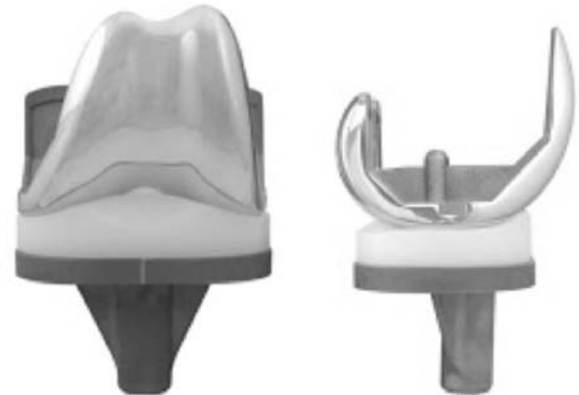


Figure 1. Anterior-Posterior and Lateral views of the Posterior Stabilized (PS) Freedom Total Knee® system (MAXX Orthopedics, Inc., Plymouth Meeting, Pennsylvania).

(ASTM F-75 CoCrMo), and the articular bearing surfaces use ram-extruded UHMWPE (GUR 1020). The Freedom Total Knee system was also designed with the intent to address bone conservation while permitting optimal high-flexion motion up to 155 degrees, dependent on the patient's anatomy and cultural activities of daily living, such as frequent and prolonged squatting and kneeling. To achieve high-flexion, the femoral component was engineered utilizing a multi-radius design in which seven tangential radii were incorporated to accommodate changes in rollback across the available surface through the transition from walking through deep flexion (Figure 2). In addition, development of femoral component sizing was optimized to include the anthropomorphic dimensions of Western and Pan-Asian patient populations.

There were 129 females (75.0%) and 43 males (25.0%) with an average patient age at surgery of  $69.7 \pm 7.6$  years (range: 52.3 years to 98.6 years). The average age of the female patient (69.3 years) when compared to the male patients (70.7 years) was not significantly different ( $p=0.311$ ) (Table 1) In this continuous series, four female patients underwent bilateral TKA under the same anesthesia. The pre-operative diagnosis was predominately degenerative joint disease (DJD) in 170 knees (96.6%) and rheumatoid arthritis (RA) in 6 knees (3.4%). The surgical side was evenly distributed across all patients with 86 left (48.9%) and 90 right (51.1%) knees (Table 1).



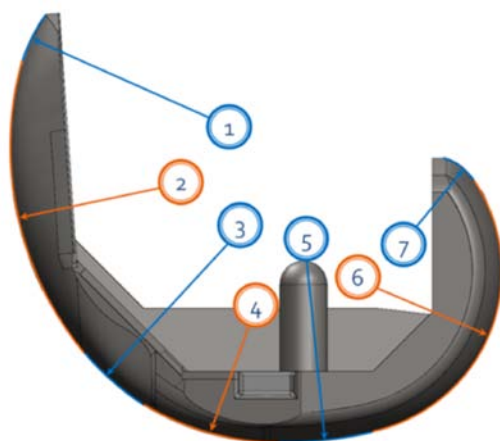


Figure 2. Multi-radius design of the Freedom Knee in which seven tangential radii were incorporated to accommodate changes in rollback across the available surface through the transition from walking through deep flexion. Radii 1, 2 and 3 manage patellofemoral contact, and radii 4, 5, 6 and 7 control femoral rollback and flexion.

Table 1. Patient Demographics – there was no statistical difference in patient age at  $p = 0.311$ . Also, there were 172 patients with 176 TKAs (4 bilateral cases).

	n	Males	Females
<b>Total Patients</b>	172 (100%)	43 (25.0%)	129 (75.0%)
<b>Average Age</b>	69.7 $\pm$ 7.9 years	70.7 $\pm$ 7.3 years	69.3 $\pm$ 7.7 years
<b>Side</b>	R = 86 (48.9%)		
	L = 90 (51.1%)		
<b>Pre-Operative Diagnoses</b>			
<b>DJD</b>	170 (96.6%)		
<b>RA</b>	6 (3.4%)		

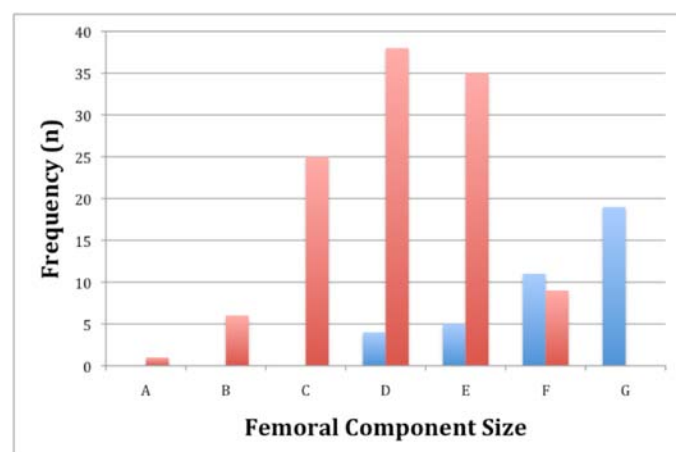


Figure 3. Distribution of component size by gender.

All patient data and radiographic information was de-identified to maintain patient confidentiality and compiled

using Microsoft Excel software (Microsoft, Corp., Redmond, WA). Standard descriptive statistics were used to summarize the population and group comparisons were performed using Student's t-test with a level of significance at  $p < 0.05$ .

## Results

All patients had a minimum follow-up of 2-years with an average time to follow-up of  $3.8 \pm 0.9$  years (range: 2.2 years to 5.3 years). During the follow-up period there were no patients lost to follow-up and no failures. Two patients (1.1%) required subsequent incision and drainage surgery for superficial wound infections. Following these procedures both patients went on to successful clinical and functional outcomes. The frequency of femoral component size use was different between genders and was skewed smaller for female patients versus male patients (Figure 3). There was no radiographic evidence of component loosening, osteolysis or failure in any patient (Figures 4A-D).

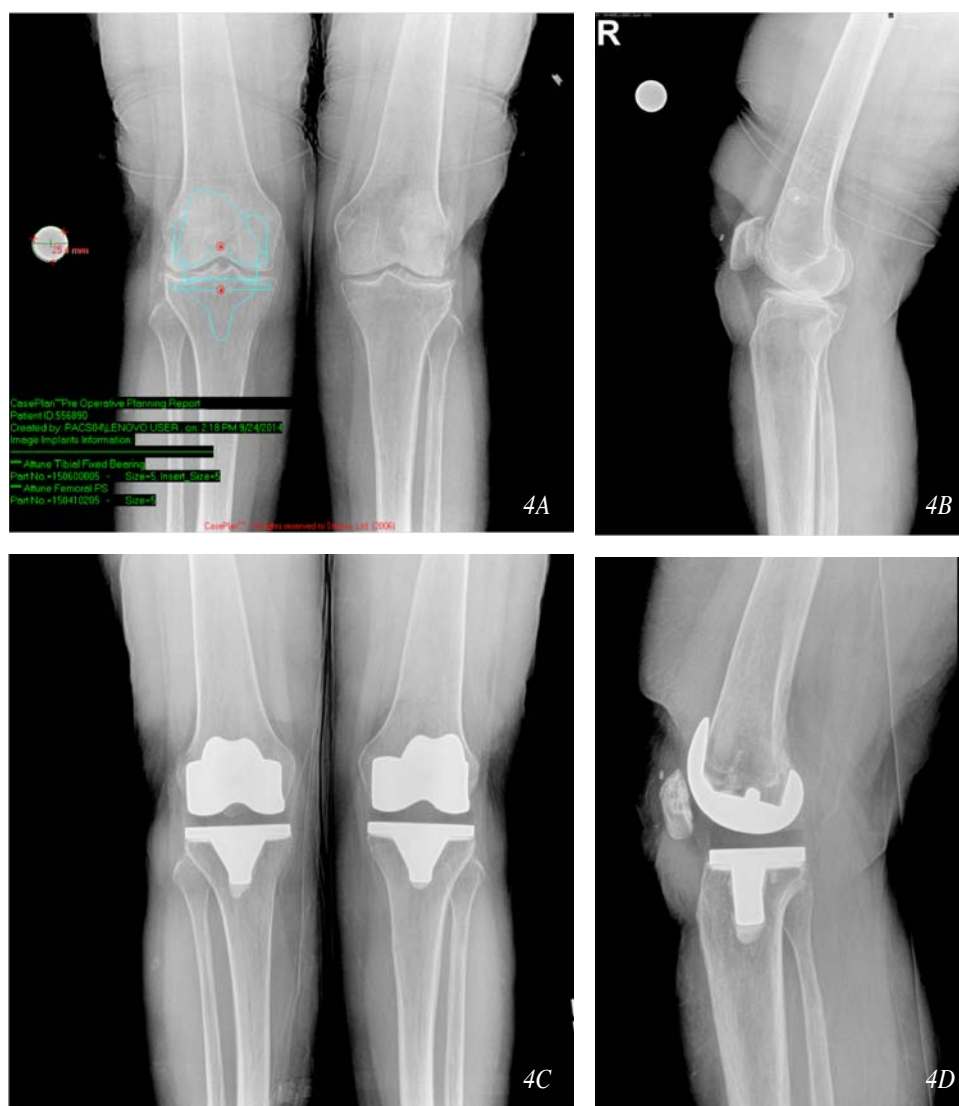
The pre-operative Hospital for Special Surgery (HSS) score was  $49.2 \pm 5.7$  (range: 40.0 to 65.0), which significantly improved to an average of  $88.4 \pm 3.6$  (range: 80.0 to 95.0) ( $p < 0.001$ ). There was no statistical difference in pre-operative ( $p = 0.208$ ), post-operative ( $p = 0.939$ ) or change in HSS ( $p = 0.296$ ) by gender. Functionally, the pre-operative range of motion (ROM) was  $113.8 \pm 6.1$  degrees (range: 95 degrees to 125 degrees), which improved to an average post-operative ROM of  $128.5 \pm 4.1$  degrees (range: 110 degrees to 140 degrees) at the most recent follow-up. The change in ROM was statistically significant at  $p < 0.01$ . There was no statistical difference in pre-operative ( $p = 0.566$ ), post-operative ( $p = 0.702$ ) or change ( $p = 0.484$ ) in ROM by gender. All pre- and post-operative HSS and ROM data is summarized in Table 2.

## Discussion

We present the minimum 2-year early results of a single surgeon, non-randomized, consecutive, prospective case series of patients receiving the Freedom Total Knee system for primary TKA. The results reported show significant improvement in HSS scores and achievement of increased-flexion thus confirming the component design characteristics incorporated by the manufacturer.

Dependent on anthropomorphic variables such as gender and ancestry, many femoral component offerings for primary TKA require a combination of compromising variables including component size and the amount of bone re-





Figures 4A-D. Pre- and post-operative Anterior-Posterior and Lateral radiographs of the Posterior Stabilized (PS) Freedom Total Knee® system (MAXX Orthopedics, Inc., Plymouth Meeting, Pennsylvania).

removal necessary. Optimizing femoral component size for each patient contributes to maximizing outcome and avoiding related complications. However, various authors have reported differences in distal femoral anthropometry across cultures [4,11] with possible soft-tissue and functional complications related to undersizing or overhanging the femoral component. Ho, et al, studied three different commercially available TKA components and reported consistent medial-lateral overhang in resected knees in the Chinese patient population. [4] Similarly in Indian women, Vaidya, et al, reported similar sizing issues in the medial-lateral aspect as well as in the anterior-posterior plane. Interestingly, standard femoral components were more compatible in Indian men. [11] Hitt, et al, reported the comparison of a cohort of patients in which distal femoral morphology was directly compared to five different commercially available primary TKA systems. (Hitt et al., 2003) The data revealed significant overhang of the femoral components in women ( $p < 0.0001$ ) while in men there was complimentary sizing match ( $p < 0.79$ ) when compared to patient morphology. The authors concluded that there are significant variations in the femoral aspect ratio dimensions of the components when compared to anatomic knee morphology. These variations may compromise the balance between component size and optimum post-operative function. In all three reported studies the Pan-Asian patient has significant morphological differences than the Western population that common TKA devices are designed against. The Freedom Total Knee system was designed for bridging the size requirements across Western and Asian population anthropomorphic variations without compromising functional needs. Mid-range component design in the medial-lateral and anterior-posterior distal femoral aspects allows for a transitional size and shape for use across gender and various global populations. While the results

Table 2. Patient Outcomes – Between genders there was no statistical difference in pre-operative ( $p=0.208$ ) or post-operative ( $p=0.939$ ) HSS or pre-operative ( $p=0.566$ ) or post-operative ( $p=0.702$ ) ROM. Change in HSS and ROM from pre- to post-operative follow-up was statistically significant (HSS:  $p < 0.001$ , ROM  $p < 0.01$ ).

	Total Population	Males	Females
Avg Follow-Up	3.8 $\pm$ 0.9 years		
Pre-Op HSS	49.2 $\pm$ 5.7	48.3 $\pm$ 5.6	49.5 $\pm$ 5.7
Post-Op HSS	88.4 $\pm$ 3.6	88.4 $\pm$ 4.2	88.4 $\pm$ 3.4
Pre-Op ROM	113.8 $\pm$ 6.1	114.3 $\pm$ 6.0	113.7 $\pm$ 6.2
Post-Op ROM	128.5 $\pm$ 4.1	128.3 $\pm$ 3.8	128.5 $\pm$ 4.3

of the presented study reveal gender-specific differences in component sizing, similar clinical and functional outcomes at an average of 2-years follow-up were observed independent of gender.

Restoration of activities of daily living (ADL) following primary TKA is a primary contributing factor in overall patient satisfaction and depends on pre-operative patient expectations. In a study of Western patients, Weiss, et al, found that post-TKA patients were unable to perform deep flexion activities and were discontented with the limits involving deep flexion activities. [12] Besides the relief of pain, achieving early and full ROM is a significant hurdle for maximizing patient satisfaction. Conversely, using a component designed for deep flexion, Tarabichi, et al, reported results of achieving high flexion following TKA in Muslim patients requiring achievement of a fully flexed knee for lifestyle needs including praying, social encounters, dining and bathroom use. [9] This did not lead to an increase in post-operative complications and validates the ability to achieve increased kinematics without sacrificing the prosthetic composite. In an effort to conserve bone while achieving a condylar profile that allows for full ROM, the Freedom Total Knee system was designed to accommodate changes in the femoral condylar radii of curvature based on the degree of flexion change and the amount of rollback needed through ROM while minimizing bone resection. The femoral condylar profile of the Freedom Total Knee System integrates seven radii to manage articulation across full ROM, allowing for a large radii or arc to inhibit significant rollback in normal gait and smaller radii for greater rollback as flexion increases into deep, full flexion with smooth transition across the entire femoral condylar profile. The results of the reported study show that early ROM across our patient cohort can be achieved while avoiding common complications associated with component sizing and early restoration of function.

When interpreting the reported results one must consider that this is a single surgeon, non-randomized case series. However, the study included a large cohort (n=172) of continuous non-selected series of patients without loss to follow-up for any reason. There was an imbalance of cases by gender (females n=129, males n=43), and while gender had an affect on femoral component sizing, this variable did not influence outcome regarding ROM or total HSS. Also, the patients included were of a Western ancestry population, so no comparative assessments to Middle-Eastern or Pan-Asian populations were available.

In conclusion, the reported study of patients receiving the Freedom Total Knee system for primary TKA support the design considerations for anthropomorphic considerations while achieving an increased degree of ROM

while minimizing bone resection. Further continued use and study is warranted to confirm achieving similar results across surgeons and multiple ancestral populations.

### Disclosure

One or more of our authors have disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

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# Oxford Partial Knee Replacement as a Gateway to Outpatient Arthroplasty “Lessons Learned Along the Journey”

Berend M<sup>1</sup>

## Abstract

The Oxford Partial Knee Replacement was approved for implantation in the US in 2004 after the surgeon completed an educational training requirement. Since then my knee practiced has expanded to over 50% partial knee. This experience coupled with refinement of surgical techniques, anesthesia protocols, and patient selection has facilitated the transformation to same day discharge for partial knee cases and has quickly transitioned to total hip, total knee, and selected revision surgeries. Patient selection has also expanded for outpatient joints and is now based on medical screening criteria and insurance access. Over a two-year period we have performed over 1,000 outpatient arthroplasty procedures with no readmissions for pain control. Overall readmission rate for all reasons was 2%. Patient satisfaction scores were 98% Great-Good for 2014-15. The combination of a partial knee replacement practice and an outpatient joint program brings the best VALUE to the patients, surgeons, and the arthroplasty system and represents the future of arthroplasty care.

**Keywords:** *partial knee replacement; surgical technique; outpatient arthroplasty; patient satisfaction*

**Level of Evidence:** *AAOS Therapeutic Level IV*

## Introduction

In 2004 the FDA approved the Oxford Partial Knee Replacement for implantation in the US after surgeons meet an educational training requirement. I was formerly biased against partial knee replacement believing it to be of limited value and indicated in only a small percentage of knees. [1] In the ensuing 12 years my knee practiced has been transformed to over 50% partial knee replacement. (Fig 1) This has largely been related to an improved understanding of the pathoanatomy of “anteromedial” osteoarthritis of the knee [2], comfort with the surgical technique [3,4] and new instrumentation platform [5,6], addition of lateral

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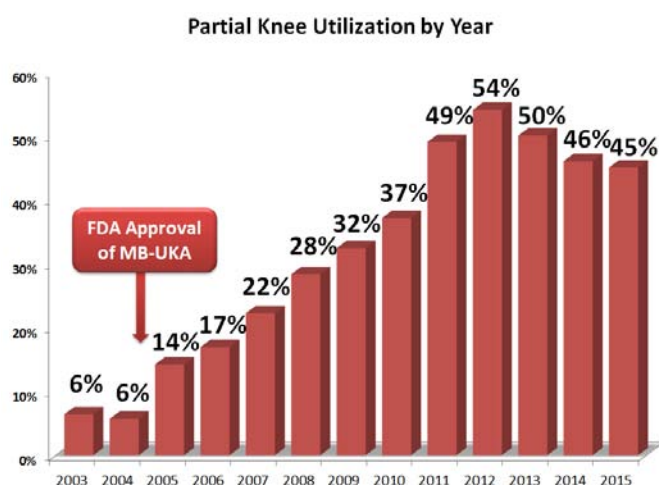


Figure 1. Percentage of Osteoarthritic knees receiving a partial compared to a total knee replacement at the Center for hip and Knee Surgery and Joint Implant surgeons from 2004 to 2015.

partial knee arthroplasty to my practice, and recognition of partial knee replacement being a lower morbidity procedure [7-9].

The hope of restoration of knee kinematics, decreasing polymer wear [10-12] through increased implant conformity, and lower polyethylene stresses are appealing with the Oxford mobile bearing device, which may improve long-term implant performance. Importantly however, mobile bearing UKA does not improve our indications, patient selection, or surgeon performance and are critical elements of UKA clinical success and survivorship. This growth in a desire to retain normal knee ligaments and joint surfaces combined with refinement of surgical techniques, anesthesia protocols, and patient selection has facilitated the transformation to same day discharge [13-15] initially for partial knee replacement which quickly transitioned to total hip and knee and now selected revision knee replacement surgery. This paper is a summary of the thoughts and processes that led to this transformation to partial knee replacement and outpatient arthroplasty becoming the most common procedures in my practice.

## Methods

Patient selection for Oxford mobile bearing partial knee replacement is based predominantly on the pathoanatomy of the disease in medial compartment of the knee. The indication for medial UKA is anteromedial osteoarthritis (AMOA), a clinical condition originally described by White et al. [2] This disease involves complete bone-on-bone arthrosis medially on a weight bearing radiograph, a functionally intact ACL and MCL, and a correctible varus deformity demonstrated on a valgus stress radiograph with

preservation of functional cartilage in the lateral compartment.

Outpatient eligibility is now based on medical screening criteria and insurance access [13-15]. Patient selection focuses on medical suitability and insurance coverage. Currently Medicare only has an outpatient code for partial knee replacement (CPT 27446) and does not have an approved code for primary TKA (CPT 27447) nor primary THA (CPT 27130) in the outpatient setting. Non-Medicare cases are assessed on a case-by-case basis. The medical screening begins with assessment of an acceptable cardiac history, smoking cessation, recognition of obstructive sleep apnea, hemoglobin greater than 12, and stable medical conditions such as diabetes, hypertension, and thyroid conditions. This is done on a case-by-case basis in conjunction with our anesthesia team. Careful screening for benign prostatic hypertrophy (BPH) in males and obstructive sleep apnea (OSA) not treated with CPAP are critical. We do not have an independent BMI cutoff. We believe smoking cessation is critical and it is encouraged.

Candidates should be able to function independently with walker. Each patient and their family or caregivers are invited to attend a pre-op center visit and PT Evaluation. During this they receive pre-op education & equipment assessment, tour the facility, meet the care team, and better understand the family support expectations after discharge from the center while at home. We have not tracked how many patients are offered the outpatient program and choose an inpatient stay.

The anesthetic and multimodal pain control program has been previously reported. [13-15] It essentially involves preoperative medications, intraoperative pericapsular joint injections, and standardized postoperative meds minimizing parental narcotics whenever possible. Additional medications utilized throughout the short stay experience include Tranexemic acid, Tylenol, Toradol, Pepcid, and Decadron. Meticulous timed administration of these meds coordinating anesthesia and nursing care is critically important.

From April of 2013 to June of 2015 we performed 1,029 arthroplasty cases in our outpatient program. The procedures included 446 partial knee replacements, 309 total knee replacements, and 274 total hip replacements. 48% were male. Patients received a detailed survey of their experience with the program that included a patient satisfaction evaluation. Postoperative issues were tracked monthly with surgeon reported readmissions, reoperations, and management of complications.

## Results

Growth of partial knee replacement has grown steadily over the past 12 years and plateaued at approximately 50% of all osteoarthritic knees now receive a UKA vs. a TKA. The overall patient satisfaction for 2014 - 2015 was 98% Great / Good. (Table 1). Overall readmissions were 2%. (Table 2). The majority of these were for an outpatient manipulation of the knee under anesthesia following TKA 9/24 (0.7%).

Table 1: Patient Satisfaction Scores for 2014-2015 with the outpatient surgical program.

2014	1st qtr	2nd qtr	3rd qtr	4th qtr	Average
<b>GREAT</b>	87.7%	88%	82%	81%	85%
<b>GOOD</b>	11.1%	10%	15%	17%	13.3%
<b>OK</b>	0.9%	1%	2.2%	1.5%	1.4%
<b>FAIR</b>	0.4%	0.4%	0.5%	0.2%	0.4%
<b>POOR</b>	0.05%	0.3%	0.3%	0.4%	0.3%
2015	1st qtr	2nd qtr	3rd qtr	4th qtr	Average
<b>GREAT</b>	87.6%	90%	88%	91.8%	89.4%
<b>GOOD</b>	11%	8%	10%	6.4%	8.9%
<b>OK</b>	0.9%	1%	4%	1.3%	1.8%
<b>FAIR</b>	0.4%	0.30%	0.2%	0.3%	0.3%
<b>POOR</b>	0.06%	0%	0.2%	0.2%	0.1%

Table 2: Surgeon reported readmissions following outpatient joint replacement.

<b>Readmissions</b>	24 (2 %)
<b>Manipulation</b>	9 (0.7 %)
<b>Medical</b>	6 (0.5 %)
<b>Wound</b>	5 (0.4 %)
<b>VTE</b>	2 (0.16 %)
<b>Infection</b>	2 (0.16 %)
<b>Pain Control</b>	None, 0 %

## Discussion

### Partial Knee Replacement Program

The indications for UKA have changed significantly over the last decade in our practice [16,17] and may be changing throughout the US for mobile bearing metal backed implants based on emerging data. Traditional or “Classical” indications [18] preclude the use of UKA in patients younger than 60, heavier than 82kg (or BMI greater than 32), patients with radiographic patellofemoral disease, and patients with pain that is not isolated to the medial side of the knee. Although absolutely no data exists

to corroborate these contraindications, surgeons frequently cite Kozin and Scott [18] when deciding whom to offer UKA. A number of studies have been done demonstrating these criteria do not have a negative effect on the outcome of the Oxford PKA. Furthermore, newer consensus guidelines have been proposed based on the evolution in our understanding of partial knee replacement over the past 30 years describing our journey to broader indications for the Oxford partial knee replacement with excellent long term results and survivorship. [19-21]

This shift is apparent in our previous publications. We have previously reported on a retrospective analysis of applying the Kozzin and Scott criteria to our TKA database and found between 4-6% of varus knees would be candidates for UKA. [1] Since that time we have utilized the indication of a more physiologic criteria of “anteromedial” osteoarthritis (AMOA) of the knee with an intact ACL [2]. Our prevalence of UKA has gone from 4-6% in 2004 to over 50% in 2016. What has changed? I believe a better recognition of the unique AMOA pathophysiology that was described by White and Goodfellow [2] many years ago for medial compartment OA has accelerated this change.

Further investigation of BMI and its effect on survival was performed looking a series from Berend et al combined with that of the Oxford group. 2586 consecutive UKA were studied and life-tables were constructed to evaluate the effect of BMI on survival. Survival in 764 UKA with BMI 30-35 was 94%, in 310 UKA with BMI 36-40 survival was 95%, and in 209 knees with BMI >40 survival was 98%. No statistical difference was seen between any BMI group ( $P>0.05$ ). [17]

Beard et al [23,24] examined the role of patellofemoral disease and anterior knee pain on the outcomes of Oxford partial knee replacement. Berend, et al [17] sought to evaluate this in a US population. In this study standardized radiographs from 626 Knees evaluated the influence of the status of the patellofemoral joint on the outcome of the Oxford partial knee. in which a mobile bearing medial UKA was implanted were reviewed by an evaluator blinded to patient outcome or revision status. The evaluator recorded the pre-operative state of the patellofemoral joint using the Altman Classification. The Altman classification grades the patellofemoral joint medially and laterally for sclerosis, osteophytes, and joint space narrowing with a score of 0-4, with 4 representing severe, erosive bone-on-bone disease. Log-rank and Kaplan-Meier analysis were used to evaluate survivorship between knees with significant pre-operative patellofemoral disease and those without. Within this subset of 626 knees, there were 17 revisions at up to 6 years (97.2% survival). In only 384 knees (61.3%) was

the patellofemoral joint normal or Altman 0-1. Survival in this normal PFJ cohort was 93.8%. In 242 knees, or 37.8% of cases, with pre-operative PFJ disease (Altman 2-4) the predicted survival was 97.9%. Of these, 92 knees (15%) had significant disease (Altman 3 or greater) and the survival was 97.0%.

Perhaps most convincing, however, is the stark difference in morbidity and mortality associated with UKA when compared to TKA. Bergeson et al [7], evaluated 1,000 consecutive UKA for 90 day perioperative morbidity and mortality. There were no deaths (0.0%), one DVT (0.1%), and one deep infection (0.1%). Five patients required a transfusion (0.5%) and 7 patients had a cardiac complication including CHF, arrhythmia, or myocardial infarction (0.7%). Thus the early morbidity associated with mobile bearing UKA warrants that this procedure be defined as truly minimally invasive, in contradistinction from TKA. With such a low rate of perioperative complications, surgeons may be over-treating patients with TKA in knees with anteromedial OA who meet the expanded indications for UKA, putting them at undue risk. These liberal indications for UKA, based on the patho-anatomic condition of Anteromedial Osetoarthritis, appear to be a safe and accurate measure of candidacy for UKA. [22] Liddle et al confirmed these findings in recent study Lancet. [9]

Excellent clinical and survivorship results with 98% survival at 6 years are seen with liberal indications using this mobile bearing partial knee replacement [16,25] have been reported by Berend, et al. Longer-term results have been reported by Price and Svard to be 91% at 16-years and no additional failures at 20-years (91%) [19-21]. The high success and low incidence of perioperative complications make this an ideally suited operation with nearly no contraindications in patients with anteromedial OA of the knee. These factors have led to the development of an outpatient partial knee replacement program.

### ***Outpatient Program Development***

Perhaps the most significant developments in joint replacement surgery in the past decade have been in the area of multimodal pain management. This has reduced length of stay in the inpatient hospital environment opening the opportunity for cost savings and paved the way for outpatient joint replacement surgery in appropriately selected patients. The synergy and implementation of the knowledge gained over the past two decades of arthroplasty care make outpatient joint replacement possible and effective. [1,2]

Refinement of surgical techniques, anesthesia protocols, and patient selection has facilitated a transformation to same day discharge for arthroplasty care in our practice.

[13-15] This initially began in September of 2011 with selected Partial Knee Replacement (PKR) cases. The surgical procedures included in the outpatient program have expanded to include primary TKA (Total Knee Arthroplasty), primary THA (Total Hip Arthroplasty), and selected revision cases. The trend for early discharge has already happened for procedures formerly regarded as “inpatient” procedures such as upper extremity surgery, arthroscopy, ACL reconstruction, foot and ankle procedures, and rotator cuff repair. The outpatient program centers on the patient needs, family engagement, essentials of home recovery, preoperative education, efficient surgery, and a surgeon controlled environment with highly standardized care. This is a distinct shift in today’s healthcare environment, which has seen the expansion of regulatory demands; focus on Electronic Health Record (EHR), and discussions of potential future value creation.

The hallmark of this program is meticulous protocol execution and surgeon directed care pathways. Preemptive pain control with oral anti-inflammatory agents, gabapentin, regional anesthetic blocks that preserve quad function for TKA (adductor canal block) and pericapsular long acting local anesthetics with the addition of injectable ketorolac and IV acetaminophen are key adjuncts. Over the past two years utilizing this type of program the majority of our partial knee replacement patients are now returning home the day of surgery. [13-15]

Concerns over readmission are appropriate. The rates of complications and readmissions in our series at 2% are less than reported by other authors for inpatient cohorts [26]. Interestingly we have had no readmissions for pain control since the programs inception. The majority of readmissions were for manipulation done as an outpatient with the remainder being known complications following inpatient or outpatient arthroplasty care and not unique to their outpatient care. The program centers on the patient, their family, home recovery, preoperative education, efficient surgery, and represents a shift in the paradigm of arthroplasty care. It can be highly beneficial to patients, surgeons, anesthesia, facility costs, and payors as arthroplasty procedures shift to the outpatient space. We believe this brings the best VALUE to the patients, surgeons, and the arthroplasty system.

Patient Satisfaction scores were outstanding with this program achieving 98% Great/Good for 2014-15. We believe this brings the best VALUE to the patients, surgeons, and the arthroplasty system and represents the future of arthroplasty care with future growth of both partial knee replacements and outpatient arthroplasty.

In summary, unicompartmental knee arthroplasty (UKA) has seen increasing interest due to better under-

standing of indications, implant and instrumentation design, minimally invasive techniques, and improved reported outcomes. Survivorship with revision of any kind of Mobile Bearing UKA appears to rival that of total knee arthroplasty, despite more liberal indications than those traditionally used. Growth of partial knee replacement has set the stage for the development of a successful outpatient joint replacement program for patients and surgeons alike.

## Disclosure

The author declares that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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# Tourniquet Application During Total Knee Arthroplasty Does Not Benefit Perioperative Blood Loss or Transfusion Requirement with the Routine Use of Tranexamic Acid

Watters T<sup>1</sup>, Levy D<sup>1</sup>, Kim R<sup>1</sup>, Miner T<sup>1</sup>, Dennis D<sup>1</sup>, Jennings J<sup>1</sup>

## Abstract

**Background:** The use of a tourniquet during total knee arthroplasty (TKA) continues to be a matter of debate. Advantages of tourniquet use include improved visualization, decreased intraoperative and total blood loss, and possibly decreased transfusion requirement. However, the recent widespread adoption of antifibrinolytic therapy with tranexamic acid (TXA), may negate these benefits. The purpose of this study was to evaluate perioperative blood loss and transfusion requirement with two different tourniquet application strategies, and surgery without the use of a tourniquet during routine, primary cemented TKA.

**Methods:** A retrospective cohort study was performed of 300 patients undergoing TKA at a single institution after the implementation of a routine intravenous TXA administration protocol and consisted of three groups based on tourniquet usage: tourniquet inflation before incision and deflation following cement hardening (TQ), tourniquet inflation prior to cement application and deflation following hardening (Partial TQ), and no tourniquet usage (No TQ). Each group consisted of 100 consecutive patients. Perioperative blood loss, change in hematocrit and transfusion requirement were compared between groups.

**Results:** Total blood loss (estimated blood loss and drain output) was lowest in the TQ group, however this was only due a slight decrease in intraoperative estimated blood loss. There was no difference in post-operative drain output, or change in hematocrit levels from preoperative values. There were no transfusions in the Partial TQ and No TQ groups, whereas there were 5 transfusions in the TQ group.

**Conclusions:** In the era of routine TXA administration during TKA, tourniquet usage does not appear to have a benefit in regards to perioperative blood loss or transfusion requirement.

**Keywords:** tranexamic acid; tourniquet; blood conservation; total knee arthroplasty

**Level of Evidence:** AAOS Therapeutic Level III

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## Introduction

Tourniquet usage during total knee arthroplasty (TKA) is commonplace among most arthroplasty surgeons in North America. An analysis of practice patterns of members of the American Association of Hip and Knee Surgeons in 2010 found that tourniquet was used in 95% of patients without vascular disease [1]. Proposed advantages of routine tourniquet usage include improved visualization, decreased intraoperative blood loss, lower transfusion requirement, and possibly superior cementation of components. However, tourniquet usage may be a risk factor for postoperative thromboembolism [2,3], and other wound complications related to tissue hypoxia and reperfusion injury [4,5]. In addition, a recent study found that tourniquet usage may result in diminished quadriceps function during the first 3 months after surgery [6]. Two recent meta-analyses of the available randomized controlled trials (RCTs) on tourniquet usage both concluded that the available evidence supports the assertion that TKA with a tourniquet results in a significant decrease in intraoperative blood loss and transfusion rate, albeit with a slightly higher rate of minor wound complications [7,8]. Proponents of tourniquet usage argue that potential disadvantages are outweighed by the benefits of improved visualization and specifically blood conservation, as blood transfusion may increase the risk of postoperative surgical site infection in addition to prolonging length of stay and increasing cost [9].

The recent widespread adoption of routine antifibrinolytic therapy with tranexamic acid (TXA) during total joint arthroplasty has had dramatic effects on blood conservation. TXA is a synthetic drug which inhibits fibrinolysis and clot degradation and may be administered in intravenous (IV), topical, or oral forms. Numerous studies in recent years have highlighted the effectiveness of TXA in decreasing perioperative blood loss and transfusion requirements without significant risk of adverse events or perioperative thromboembolic phenomena [10]. A recent meta-analysis of RCTs evaluating the effectiveness of TXA in primary TKA showed that, when compared to placebo, TXA reduced blood loss by roughly 500 mL and resulted in 1.43 less units of blood transfused per patient [11].

As such, the purported benefits of decreased blood loss and resultant decreased transfusion requirement with traditional tourniquet use during TKA may no longer be significant in an era where the use of antifibrinolytics during elective knee arthroplasty is routine. The purpose of this study, therefore, was to evaluate perioperative blood loss and transfusion requirement with two different tourniquet application strategies, and surgery without the use of a tourniquet during cemented, primary TKA after the im-

plementation of a routine intravenous TXA administration protocol at a single institution using a modern protocol for total joint arthroplasty.

## Materials and Methods

A retrospective cohort study was conducted of 300 patients undergoing primary, cemented TKA after the initiation of a standardized, perioperative IV TXA administration protocol which was implemented at our institution in August 2014. All surgeries were performed by one of four high-volume, fellowship-trained arthroplasty surgeons. During this time period, tourniquet use practices varied among surgeons in our practice: one surgeon routinely used a tourniquet throughout the procedure; one surgeon routinely used a tourniquet only for cementing; and two surgeons did not routinely use a tourniquet at all. Each study group, therefore, consisted of 100 consecutive patients undergoing primary, unilateral TKA based on tourniquet usage: tourniquet inflation before incision and deflation following cement hardening (TQ), tourniquet inflation prior to cement application and deflation following hardening (Partial TQ), and no tourniquet usage (No TQ). Patients were excluded from the study if they had a history of congenital or acquired coagulopathy, liver or renal failure, history of preoperative anti-coagulation, or a contraindication for TXA (ie color blindness, history of stroke) or tourniquet usage (i.e. severe peripheral arterial disease or prior lower extremity bypass). Patients undergoing simultaneous, bilateral TKA and uncemented TKA were also excluded.

TXA was administered on a standardized perioperative regimen of 1 g IV at the time of skin incision and 1 g IV at the time of closure. In addition to sequential compression devices and early mobilization, DVT prophylaxis regimen included chemoprophylaxis which was initiated on post-operative day 1. The choice of chemoprophylactic agent was based on risk stratification with the vast majority of patients being treated with aspirin. All procedures were performed under spinal anesthetic with an adductor canal block.

Basic demographic data (including age, sex and BMI) was obtained through our institutional database and individual chart review was subsequently performed on all consecutive patients identified as meeting inclusion criteria. Preoperative hemoglobin (Hb) and hematocrit (Hct) values, and operative time were compared across groups as independent variables. Tourniquet time was recorded for the TQ and Partial TQ groups. Outcome measures included intraoperative estimated blood loss (EBL), post-opera-

tive hemovac drain output, total blood loss (EBL + drain output), change in Hct on postoperative day 2 from preoperative values, and transfusion requirement. Descriptive statistics were obtained for demographic data and independent variables, and outcome measures. Group sample distributions were compared using Kruskal-Wallis (median) or Pearson's Chi-squared tests where appropriate. The treatment effect of the 3 study groups was analyzed with respect to the outcome measures using analysis of variance (ANOVA) followed by multiple comparisons using pairwise t-test with Bonferroni correction and Tukey's HSD, or Fisher's exact test where appropriate.

## Results

All surgeries were performed between August 2014 and June 2015. Demographic data for the 3 tourniquet treatment groups is provided in Table 2. The mean age of the Partial TQ group was 67.3 years, which was older than the TQ and No TQ groups (63.0 and 63.6, respectively), and was statistically significant ( $p=0.008$ ). The mean BMI of the TQ group was 31.9 kg/m<sup>2</sup>, which was greater than the Partial TQ and No TQ groups (28.4 and 29.8, respective-

Table 1. Proposed Advantages and Disadvantages of Tourniquet Usage in TKA

Advantages	Disadvantages
Decreased intraoperative blood loss	Higher rate of deep venous thrombosis
Lower transfusion rate	Increased risk of superficial wound infection
Shorter operative time	More pain and swelling
Improved cementation of components	Decreased quadriceps function and recovery

Table 2. Patient Demographics

	Age	Male (n)	Female (n)	BMI
No Tourniquet	63.8†	43	57	29.8‡
Partial Tourniquet	67.3†	35	65	28.4‡
Tourniquet	63.0†	37	63	31.9‡

† - denotes statistical significance between No TQ and TQ versus Partial TQ

‡ - denotes statistical significance between No TQ and Partial TQ versus TQ

Table 3. Blood Loss Parameters

	Pre-op Hgb	Pre-op Hct	EBL	HV Output	TBL	Post-op Hct	Delta Hct	Transfusions (n)
No Tourniquet	14.8	43.3	141†	194	334.2	32.58	10.66	0
Partial Tourniquet	14.6	42.9	136.5†	225.1	361.6‡	32	10.93	0
Tourniquet	14.5	42.9	93.7†	188.3	282‡	32.42	10.53	5

† - denotes statistical significance between No TQ and Partial TQ versus TQ

‡ - denotes statistical significance between TQ and Partial TQ

ly), and was statistically significant ( $p=0.002$ ). There was no statistically significant difference between the number of male and female patients in each group.

Operative time was slightly longer in the No TQ group (67.1 minutes), compared to the Partial TQ and TQ groups (63.2 and 64.5, respectively), and was also statistically significant ( $p=0.009$ ). The average tourniquet time in the Partial TQ group, where the tourniquet was only inflated for cementing of the prosthesis, was 12.6 minutes. The average tourniquet time in the TQ group was 54.1 minutes.

Preoperative Hb and Hct values were similar among the 3 treatment groups (Table 2). EBL was higher in the No TQ group (141.0 mL) and Partial TQ (136.5 mL) than in the TQ group (93.7 mL). However, there was no difference in postoperative hemovac drain output between groups (ANOVA  $p=0.198$ ). The significant differences in EBL translated to differences seen between groups in TBL. However, ANOVA testing with multiple comparison tests revealed that the only significant difference in TBL was between TQ and Partial TQ.

The differences between the groups in EBL and TBL did not appear to translate to a clinical difference between the groups. Postoperative Hct was similar for all 3 groups and, likewise, there was no difference between the treatment groups with respect to change in Hct from preoperative values (ANOVA  $p=0.733$ ). Furthermore, there were no transfusions in either the No TQ or Partial TQ groups, whereas 5 patients in the TQ group required blood transfusion post-operatively. The average number of units transfused per TQ patient was 1.8.

## Discussion

Tourniquet usage is common amongst arthroplasty surgeons during TKA. From a subjective standpoint, the use of a tourniquet provides a bloodless surgical field and optimizes visualization during the procedure [9]. A recent meta-analysis of the available RCTs comparing TKA with and without use of a tourniquet was performed by Jiang et al [8]. Their results demonstrated that TKA with use of a tourniquet has decreased intraoperative blood loss, transfusion rate, and operative time, but also appeared to result



in slower early functional recovery with an increased rate of deep venous thrombosis and minor wound complications. However, of the 26 independent RCTs included in the overall meta-analysis, only 5 had been published since 2010. The purpose of our study was to evaluate blood loss and transfusion requirement with and without tourniquet after implementation of a contemporary blood conservation protocol utilizing IV TXA.

While there are more historical studies documenting the efficacy of TXA in reducing blood loss and transfusion requirements [12,13], the literature on the subject has increased dramatically over the past few years [10], as the use of TXA has become nearly universal at centers throughout North America. Studies have shown a low risk of thromboembolic complications with TXA use, even with less aggressive chemoprophylactic regimens using aspirin [14]. In a large retrospective cohort study of more than 13,000 elective hip and knee replacement patients at a single center, Duncan et al. showed that the odds of post-operative VTE and 30-day mortality were unchanged with IV TXA administration [15]. Efficacy in terms of blood loss and reduction in transfusion requirement has also been shown with topical administration during TKA in several recent RCTs [16,17].

The results of our study suggest that, in the setting of routine intraoperative anti-fibrinolytic administration, while perioperative blood loss may be lower with use of a tourniquet, the difference is relatively small and may be clinically negligible. There was no difference between the TQ, Partial TQ, and No TQ groups with respect to post-operative drain output or change in hematocrit values from preoperative levels (Table 2). Moreover, there were no transfusions in the Partial TQ and No TQ groups postoperatively. There were 5 transfusions in the TQ group, despite this group having on average the lowest quantitative perioperative blood loss. Because all of these patients were treated by a single surgeon, this may represent a selection bias based on a lower threshold for post-operative transfusion by the treating surgeon. At our institution, the decision to transfuse blood products to a patient cannot be standardized and remains a clinical decision requiring informed consent based on a diagnosis of symptomatic anemia requiring transfusion made by the treatment team. Nonetheless, no patients that underwent TKA without tourniquet (No TQ), or that underwent TKA with tourniquet inflation for cementing only (Partial TQ) were transfused in this large series of consecutive patients, despite the fact that these two groups had greater intraoperative blood loss and would theoretically be at higher risk for transfusion.

While tourniquet use during TKA is clearly a historical norm amongst arthroplasty surgeons, recent attention has

been given to the potential detrimental functional effects that result from its routine use. In a prospective randomized study of 28 patients undergoing same-day bilateral TKA where tourniquet was used throughout the procedure on one limb and not on the contralateral, Dennis et al. found lower post-operative quadriceps strength on the limb with the tourniquet that persisted at 3 months after surgery [6]. A recent study by Huang et al, comparing 3 different tourniquet application strategies using a “mini-midvastus” approach, found that serum inflammatory and muscle injury markers were lowest in the group where tourniquet was used only for cementation and not for the entire procedure [18]. Another recent randomized trial evaluating tourniquet use only for cementation during TKA found no difference in terms of surgical time, hemoglobin change or total blood loss compared to prolonged tourniquet use and reported one case of compartment syndrome in a patient that had tourniquet inflation until closure [19]. The authors of that study suggested that tourniquet inflation for cementation only may be beneficial for providing a bloodless field during implant fixation without the risks of prolonged tourniquet use. However, a recent prospective RCT using radioisometric analysis at 2 years post-op found no difference in tibial component migration between cemented knees done with and without a tourniquet, suggesting the surgery without the use of a tourniquet does not influence implant fixation in the short-term [20].

Limitations of this study include those inherent with a retrospective study design. We concede that the methods used to assess blood loss intraoperatively and post-operative may lack precision as a result of factors such as blood loss on drapes, plugged postoperative drainage systems, etc. We believe reporting the change in preoperative to postoperative hematocrit change is more accurate and therefore report these findings as well. In addition, surgeries were performed by one of four surgeons, and therefore minor variations in surgical technique may have some influence on perioperative blood loss. Lastly, as stated above there may be a selection bias with regards to the threshold for transfusion by the surgeon who routinely used the tourniquet, as the decision to transfuse a patient is not standardized at our institution and is based on the clinical judgement of the treating physician based on a diagnosis of symptomatic anemia requiring transfusion and requiring informed patient consent. Further research is justified to see if a more standardized blood product utilization protocol would improve our blood conservation program further.

## Conclusion

In the era of improved perioperative blood conservation methods with spinal anesthesia and anti-fibrinolytic therapy using TXA, prolonged tourniquet use during TKA does not appear to have a significant clinical impact on perioperative blood loss and transfusion requirement, and may not be justified based on known higher rates of wound complications and slowed functional recovery.

## Disclosure

The authors declare that there is no conflict of interest regarding the publication of this paper. For full disclosures refer to last page of this journal.

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## Modular Necks and Corrosion - Review of Five Cases

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*Acknowledgment: John Keggi<sup>3</sup>, Louis Keppler<sup>3</sup>, Bradley K. Vaughn<sup>3</sup>, and Edward McPherson<sup>3</sup>*

### Abstract

This report updates previous articles and commentary presented on Modular Necks from our Tissue Sparing Implant Study Group. In July 2012 we reported that at two years post-op we had encountered no modular neck taper failures or any signs of fretting corrosion, or pseudo tumors associated with the ARC™ Stem.

Today we describe five patients out of five hundred and forty-two who had total hip arthroplasty revision [titanium alloy stem, cobalt-chromium modular neck (c.c.) and c.c. modular head (32 mm or 36 mm), highly-cross-linked polyethylene liner, metal titanium plasma sprayed cementless metal cup]. All patients' were female and all demonstrated progressive hip pain or late instability. All had debridement of the periarticular soft tissue, stem extraction with new primary length cementless stem replacement. At revision and early follow up all patients are doing well, however, we recommend heighten awareness in all active female patients with modular neck stem junctions.

**Keywords:** modularity, tapers, corrosion, modular necks

**Level of Evidence:** AAOS Therapeutic Level IV

### Introduction

Corrosion of metals has many different mechanisms that all have independent driving forces. One such corrosion mechanism that has recently been attributed to the decline in the clinical acceptance of modular-neck hip implants and recall of two products by Stryker Orthopaedics (Mahwah, NJ) is that of fretting corrosion—that is, component damage within the modular connections. [1]

Stem-neck modularity has been under heightening scrutiny since 2012 with the Safety Alert of the Stryker Rejuvenate modular neck-stem implant [2]. This alert was issued within two years of product introduction into the

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USA market. The Safety Alert defines the potential hazards as follows: “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)[3].

Proximal neck-stem modularity has a long history in the market dating back to the proximal modular body of the McBride Hip in 1948 and was followed in 1978 by Bousquet and Bornand with the development of a proximal modular neck-stem that featured a proximal body that was attached to a stem via a conical mounting post. 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. [4,5,6].

These were early cementless stem designs and not widely used so there is limited clinical reports on these early modular junctions [4]. These modular designs were bulky with matching metallic alloys. To our knowledge there has never been a report of corrosion or modular junction failure with these early bulky modular junctions. Figure 1.



*Figure 1. Illustration of Proximal Modular Neck Body 1978 by Bousquet & Bornand (Courtesy JISRF & Chris Burgess, Signature Orthopaedics Ltd.)*

Modern day designs (2000) have been used primarily in conventional cementless titanium alloy stems with either titanium alloy or cobalt-chromium (c.c.) modular necks. The issues that have plagued these modular neck designs have been fatigue failure of both titanium alloy, and c.c. along with fretting corrosion of the cobalt-chromium necks used with the titanium alloy stems [6,7]. Figure 2 & 3.

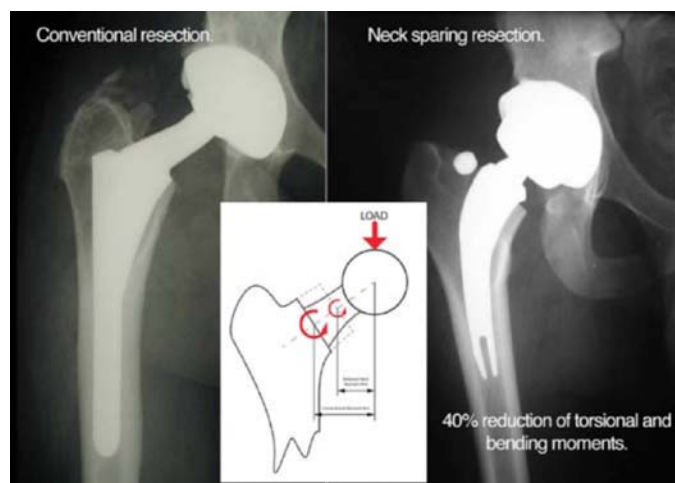


*Figure 2. Fatigue Failure of C.C. modular neck used with a c.c. Cemented stem.(R-120™ Encore Orthopaedics) (Courtesy JISRF & H.U. Cameron)*



*Figure 3. Retrieval of taper corrosion with dissimilar metals—cobalt-chrome alloy modular neck on titanium stem. (Courtesy WL Walter)*

The use of modular necks in neck-preserving stem designs has had fewer problems in both areas of fatigue and fretting corrosion as compared to conventional neck resection stems.. The neck-preserving stem reduces both torsional and bending loads reducing the overall stress placed on the modular taper junction. [7,8,9] Figure 4.



*Figure 4. Two Postoperative X-rays showing different level neck resections and offsets resulting in less bending and torsional moments in the neck-sparing implant. (Courtesy of JISRF)*

The purpose of this commentary is to report our experience with a short curved neck-preserving cementless stem (titanium alloy) used with a modular neck junction of a different material (c.c.) resulting in suspected corrosion failure of the modular neck-stem junction. Figure 5.



*Figure 5. Explanted ARC stem 5 years post-op (Omni, Raynham MA.) Courtesy of B. Vaughn*

## Materials and Methods

This is a case series of five patients treated with primary cementless total hip arthroplasty (THA) between April 2010 and June 2016. Stem was the Omni ARC™ neck-sparing stem (titanium alloy stem with hydroxyapatite coating applied to the porous coating and a c.c. modular neck) Figure 6.



*Figure 6. Omni ARC™ Stem (Omni, Raynham MA) Titanium Alloy Stem with HA and pure titanium plasma spray coating with a c.c. Modular neck.*

There were 542 primary arthroplasties performed at four centers during this time frame. Revision procedures on these five patients were performed between December 2012 and August 2016.

Patients presented with clinical symptoms for progressive hip pain or late instability. Three of the five patients were tested for serum or blood cobalt and chromium ion levels. Two patients demonstrated increased metal ion levels. One patient had normal levels. The average time between primary THA and revision surgery was 4.6 years (range 3.4-6.2 years). This is similar to previous reports on trunnion corrosion with head-neck modular taper junctions. [10]

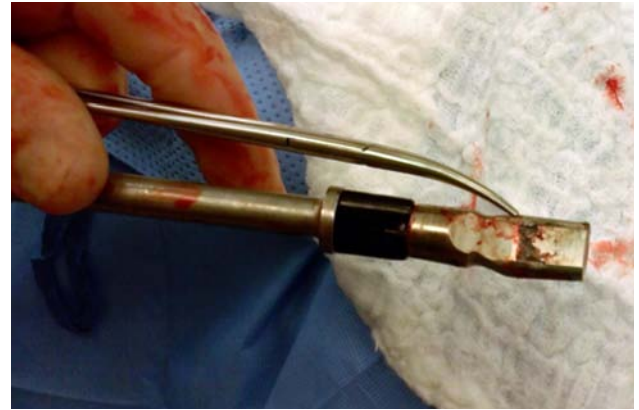
All stems were well fixed and revised by indexed surgeons to a contemporary cementless monoblock style stem. In all four cases there was minor discolored staining of implants and surrounding tissue. Figure 7

*Figure 7. Tissue and bone debris showing slight staining from corrosion action of modular neck-stem taper. Courtesy of B. Vaughn*



## Intraoperative Findings

All femoral stems were well fixed with minor black staining of surrounding tissue and retrieved modular necks. Four of the modular necks were angled positions with one being neutral. Minor abnormal looking tissue was debrided with no abductor muscle necrosis observed. Figure 8



*Figure 8. Extracted modular neck with black staining. Courtesy L. Keppler*

Material analysis was not preformed on the explanted devices. The neck-stem taper junction of each device was found to be well fixed with no signs of gross motion. Instrumentation allowed for ease of stem extraction with minor bone damage and conversion to a cementless primary stem length design. Figure 9.



*Figure 9. Retrieval instruments allow for ease of extraction. Courtesy JISRF*

## Discussion

Corrosion of taper junctions does occur and can result in significant pain and disability for patients. Reports of neck-stem modular junction corrosion in neck-preserving stems is uncommon however our case report of five patients out of five hundred and forty-two (1.0% revision rate) does demonstrate that there is a risk factor and appears to be more susceptible in active women. Historical publications demonstrate that females respond more fre-

quently to metal sensitivity than males. [11, 12]

The etiology of neck-stem modular taper junction corrosion in our small series is unclear. Implant design features, neck angle, material, length, offset, head diameter, gender and patient related activities may influence the overall risk of modular junction corrosion. Although we feel the clinical use of modular neck-stem components has performed better in neck-preserving designs as compared to conventional neck resection designs it is obvious that neck-preserving modular neck designs are not without risk of corrosion at the modular junction site.

Ongoing research and testing on enhanced modular neck designs are demonstrating significant reduction in fretting abrasion debris and should be available in the near future. [1,8] We have also seen design improvements in two specific designs that have had identified clinical failure problems and have made design changes that to resolve those problems. [1,13] Figure 10 & 11

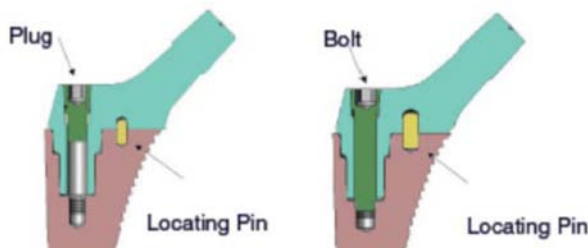


Figure 10. Illustration showing old Dual-Press design to new improved design increasing torsional resistance from 95 ft-lbs to 216 ft-lbs.

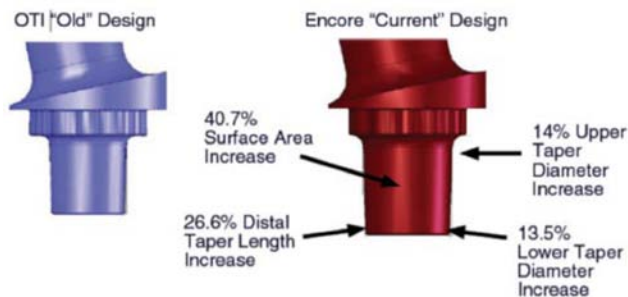


Figure 11. Illustration showing modular taper improvements from the original OTI™ design to the Encore improvement design. (Courtesy of JISRF)

## Conclusion

Modular neck-stem taper junctions are not without risk, however, the potential benefit of fine-tuning joint mechanics (as with head-neck modularity) warrant not only continued use but active research to develop enhanced designs that will reduce or eliminate the current fatigue and corrosion concerns of these modular junctions. The monoblock version of this stem can address many varieties of proxi-

mal femoral anatomy. In specific cases where the modular version is required to properly reconstruct hip biomechanics, we recommend heightened awareness of revision risk for highly active females.

## Disclosure

One or more of our authors have disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

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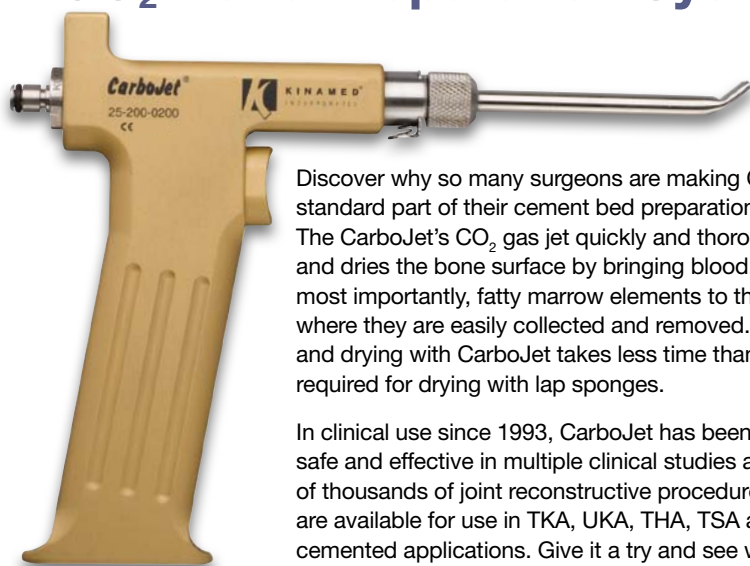
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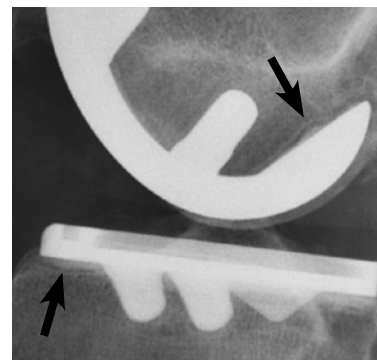
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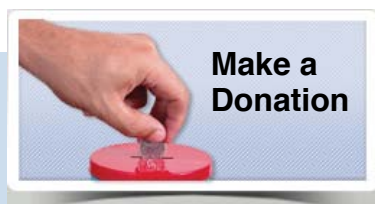
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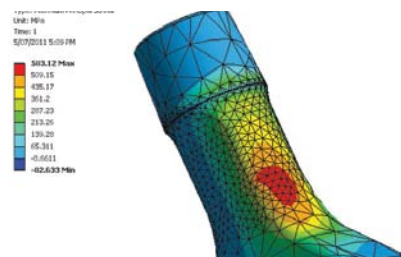


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## ICJR LIVE MEETINGS AROUND THE GLOBE

MEETING	DATES	LOCATION	COURSE CHAIRS & DIRECTORS
<b>2016</b>			
24th Annual Perspectives in Total Joint Arthroplasty: Updates in Knee Replacement	Oct 21-22	Fall River, KS	J. Christopher Banwart, MD Kenneth A. Greene, MD
ICJR/KOA Instructional Course	Oct 20	Seoul, Korea	Henry D. Clarke, MD Dae Bae, MD
5th Annual Shoulder Course Featuring Advanced Concepts™ in Sports Medicine	Nov 3-5	Las Vegas, NV	Richard J. Friedman, MD, FRCSC Raffy Mirzayan, MD John W. Sperling, MD, MBA Joseph D. Zuckerman, MD
ICJR Middle East	Nov 3-5	Dubai, UAE	Samih Tarabichi, MD
ICJR Instructional Course at the 11th International Congress of the COA	Nov 17	Beijing, China	Henry D. Clarke, MD Donald Kastenbaum, MD Yixin Zhou, MD
<b>2017</b>			
9th Annual Winter Hip & Knee Course	Jan 12-15	Vail, CO	Raymond H. Kim, MD Fred D. Cushner, MD Mark W. Pagnano, MD
Current Solutions in Foot & Ankle (a collaboration between ICJR and FORE)	Jan 26-28	Tampa, FL	Michael P. Clare, MD Craig S. Radnay, MD
5th Annual Revision Hip & Knee Course	Apr 6-8	Rochester, MN	Arlen D. Hanssen, MD George J. Haidukewych, MD R. Michael Meneghini, MD
ICJR Japan	Apr 14-15	Tokyo, Japan	Shuichi Matsuda, MD
MAOA Pre-Course: The Knee	Apr 19	Amelia Island, FL	Ryan M. Nunley, MD
5th Annual South/Real Life Orthopaedics Hip & Knee Course	May 18-20	Charleston, SC	Arlen D. Hanssen, MD George J. Haidukewych, MD R. Michael Meneghini, MD

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# Levels of Evidence

Reconstructive Review has adopted the American Academy of Orthopaedic Surgeons (AAOS) Levels of Evidence for Primary Research Question. These guidelines will now be part of the review process for manuscript submission.

**Levels of Evidence For Primary Research Question<sup>1</sup>**

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> <li>High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals</li> <li>Systematic Review<sup>2</sup> of Level I RCTs (and study results were homogenous<sup>3</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>High quality prospective study<sup>4</sup> (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients)</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level I studies</li> </ul>
Level II	<ul style="list-style-type: none"> <li>Lesser quality RCT (e.g. &lt; 80% follow-up, no blinding, or improper randomization)</li> <li>Prospective<sup>4</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level II studies or Level I studies with inconsistent results</li> </ul>	<ul style="list-style-type: none"> <li>Retrospective<sup>6</sup> study</li> <li>Untreated controls from an RCT</li> <li>Lesser quality prospective study (e.g. patients enrolled at different points in their disease or &lt;80% follow-up.)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard)</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>	<ul style="list-style-type: none"> <li>Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses</li> <li>Systematic review<sup>2</sup> of Level II studies</li> </ul>
Level III	<ul style="list-style-type: none"> <li>Case control study<sup>7</sup></li> <li>Retrospective<sup>6</sup> comparative study<sup>5</sup></li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>Case control study<sup>7</sup></li> </ul>	<ul style="list-style-type: none"> <li>Study of non-consecutive patients; without consistently applied reference “gold” standard</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>	<ul style="list-style-type: none"> <li>Analyses based on limited alternatives and costs; and poor estimates</li> <li>Systematic review<sup>2</sup> of Level III studies</li> </ul>
Level IV	Case Series <sup>8</sup>	Case series	<ul style="list-style-type: none"> <li>Case-control study</li> <li>Poor reference standard</li> </ul>	<ul style="list-style-type: none"> <li>Analyses with no sensitivity analyses</li> </ul>
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; e.g. failed total arthroplasty, are compared to those who did not have outcome, called “controls”; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

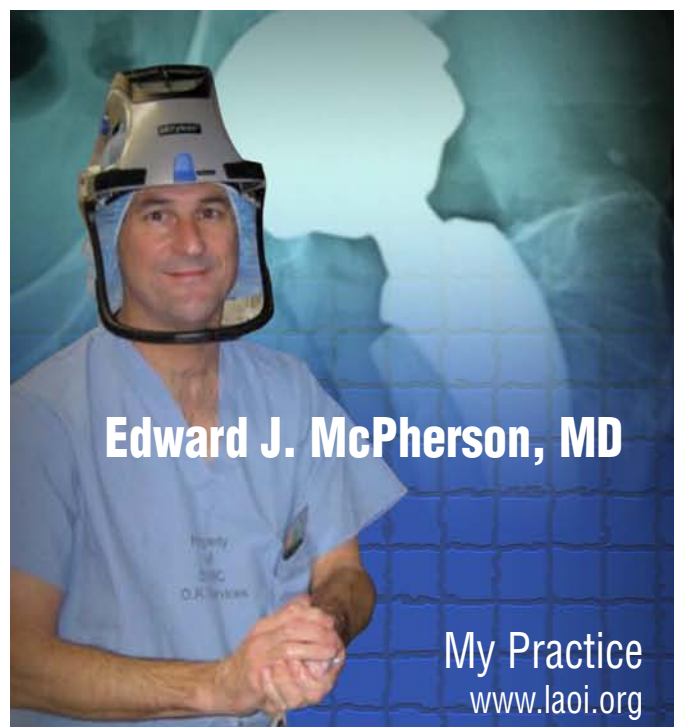
# JISRF Founder



## Charles Bechtol, MD

was internationally known in the fields of biomechanics and orthopedic surgery. His engineering and biomechanical research resulted in the development of numerous joint replacement implants and internal fracture fixation devices – instruments that are familiar to orthopedic surgeons the world over. His innovations included shoulder and knee prostheses, the Bechtol Total Hip system, the Bechtol “fluted” bone screw, and the Bechtol “continuous strength” bone plate.

Visit [www.jisrf.org](http://www.jisrf.org) for more information.



**Edward J. McPherson, MD**

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[www.stvincentmedicalcenter.com](http://www.stvincentmedicalcenter.com)



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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JISRF and the Reconstructive Review take disclosure very serious and often readers don't appreciate the indirect benefit writers receive in publications. Many of our contributors are officially associated with JISRF by the membership on study groups, editorial committee and or clinical / surgical advisors. JISRF is dependent on donations and commercial funding. The overall success of this funding benefits indirectly all that are associated with activities produced by JISRF.

## Disclosure for Authors

Article 1, page 13.

Walker [1]; Campbell [1]; Della Torre [1]; Brazil [1]; McTighe [1]

Article 2, page 19.

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Oshima [1]; Fetto [1]

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Durbhakula [3] Surgeon Advisor; Rego [1]

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Berend [1]

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Watters [1]; Levy [1]; Kim [1]; Miner [1]; Dennis [1]; Jennings [1]

Article 7, page 49.

McTighe [2] Equity in Concept, Design & Development, LLC, Equity in Omni, Royalty in Concept Design & Development, LLC; Brazil [2] Equity in Concept, Design & Development, LLC

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## Future Site Selected For This Cutting-Edge Medical Initiative



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 medical thought leaders to be involved.

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