VOLUME 6 • NUMBER 1 April 2016

ISSN 2331-2262 (print) • ISSN 2331-2270 (online)

# Reconstructive REVIEW

OFFICIAL JOURNAL OF THE


**Joint Implant Surgery and Research Foundation**

Strategic Alliance with

VOLUME 6 • NUMBER 1 April 2016

ISSN 2331-2262 (print) • ISSN 2331-2270 (online)

# Reconstructive REVIEW

OFFICIAL JOURNAL OF THE

JISRF

**Joint Implant Surgery and Research Foundation**

Strategic Alliance with

*An Announcement From:*

**Dr Rami M Sorial FRACS FAOrthA**

President, Asia Pacific Arthroplasty Society & Associate Editor-in-Chief, Pacific Rim, Reconstructive Review

&

**Timothy McTighe, Dr. H.S. (hc)**

Executive Director, JISRF,

& Editor-in-Chief, Reconstructive Review

We are pleased to announce that JISRF's journal Reconstructive Review will become the official journal for APAS. We welcome its Members to open free access to all publications and encourage its Members to submit manuscripts for publication in one of four quarterly issues.

We also welcome interested Members to become reviewers for the Reconstructive Review.


**Reconstructive Review Editor-in-Chiefs Role has been Expanded Providing Global Outreach**

Dr. Keith Berand, USA

Dr. Evert Smith, UK

Dr. Rami Sorial. Pacific Rim

Please visit our websites for more information:

www.jisrf.org • www.reconstructivereview.org

# *Strategic Alliance*

## Joint Implant Surgery & Research Foundation

*is Pleased to Continue a Strategic Alliance with the*

DARF
DONALDSON ARTHRITIS
RESEARCH FOUNDATION

## *Donaldson Arthritis Research Foundation*

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

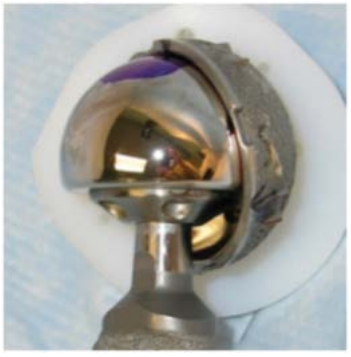
JISRF, founded in 1971, has had significant experience with continuing medical education, product development, and clinical surgical evaluation of total joint implant devices.

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

Together both groups will provide unprecedented analysis of your Retrievals.

www.jisrf.org • www.darfcenter.org

*Ian Clarke, PhD & Thomas K. Donaldson, MD*



*Metal on metal retrieval*

# 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**[1]

| | 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 | • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals<br>• Systematic Review[2] of Level I RCTs (and study results were homogenous[3]) | • High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients)<br>• Systematic review[2] of Level I studies | • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)<br>• Systematic review[2] of Level I studies | • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses<br>• Systematic review[2] of Level I studies |
| Level II | • Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization)<br>• Prospective[4] comparative study[5]<br>• Systematic review[2] of Level II studies or Level 1 studies with inconsistent results | • Retrospective[6] study<br>• Untreated controls from an RCT<br>• Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.)<br>• Systematic review[2] of Level II studies | • Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)<br>• Systematic review[2] of Level II studies | • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses<br>• Systematic review[2] of Level II studies |
| Level III | • Case control study[7]<br>• Retrospective[6] comparative study[5]<br>• Systematic review[2] of Level III studies | • Case control study[7] | • Study of non-consecutive patients; without consistently applied reference "gold" standard<br>• Systematic review[2] of Level III studies | • Analyses based on limited alternatives and costs; and poor estimates<br>• Systematic review[2] of Level III studies |
| Level IV | Case Series[8] | Case series | • Case-control study<br>• Poor reference standard | • Analyses with no sensitivity analyses |
| 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.

# Reconstructive REVIEW.org

Our new website provides a more user friendly platform for viewing and searching all past and current articles. It's based on open source software called Open Journal Systems (OJS) created by the Public Knowledge Project.

OJS was designed for the management and online presentation of open access, peer-reviewed academic journals. The software has a 'plugin' architecture allowing easy integration of key features including tools to facilitate indexing in online directories such as Google Scholar and PubMed Central.


## Reconstructive Review – Promoted on Four Websites

Reconstructive Review articles are available on these websites:

- APASonline.org
- ICJR.net
- JISRF.org
- ReconstructiveReview.org

## Abstracts Indexed On:

crossref

paperity
open science aggregated

INDEXED IN DOAJ

## And Searchable In:

Google and Google Scholar

# Reconstructive Review

A Journal Published by the Joint Implant Surgery & Research Foundation

# JISRF Founder


## Charles Bechtol, MD

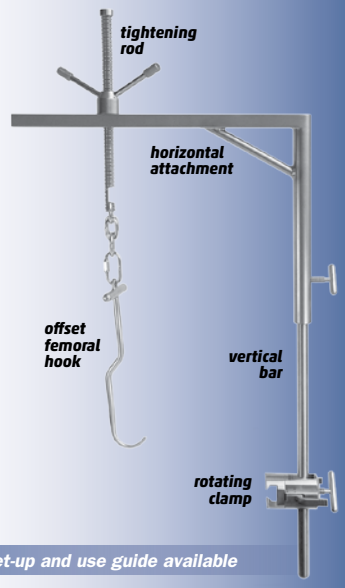
was internationally known in the fields of biomechanics and orthopedic surgery. His engineering and biomechanical research resulted in the development of numerous joint replacement implants and internal fracture fixation devices – instruments that are familiar to orthopedic surgeons the world over. His 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 for more information.


# Wixson Anterior Suspension Hook System

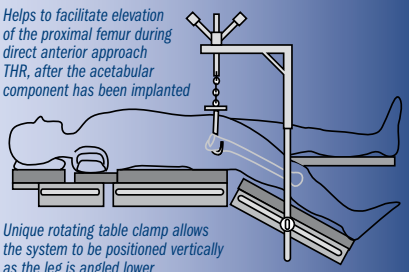
Designed by Richard L. Wixson, MD

*Designed for use with a standard operating room table*




**Set-up and use guide available**

*Helps to facilitate elevation of the proximal femur during direct anterior approach THR, after the acetabular component has been implanted*



*Unique rotating table clamp allows the system to be positioned vertically as the leg is angled lower*

| PRODUCT NO: |
|---|
| 6245-00 [Complete Unit] |

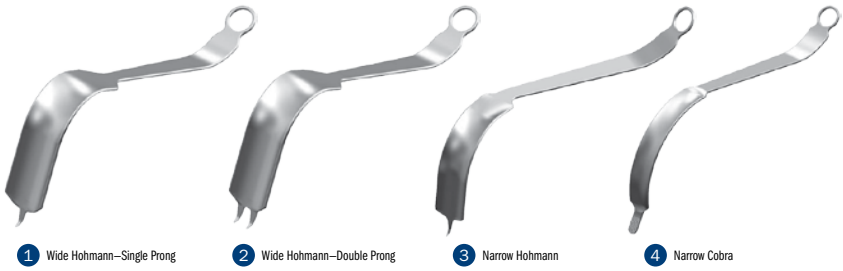
USA MADE

*Compete unit includes: Tightening rod, horizontal attachment, vertical bar, T-handle bolt, offset femoral hook, and rotating table clamp*

# Unger Anterior Total Hip Instruments

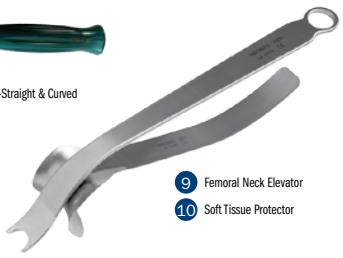
Designed by Anthony Unger, MD

*Universal instrument system specifically designed for Direct Anterior approach THR*

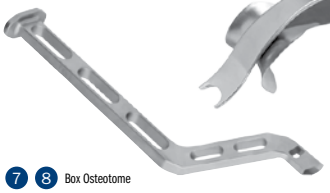


1 Wide Hohmann–Single Prong
2 Wide Hohmann–Double Prong
3 Narrow Hohmann
4 Narrow Cobra

5 6 Canal Finder Rasp–Straight & Curved

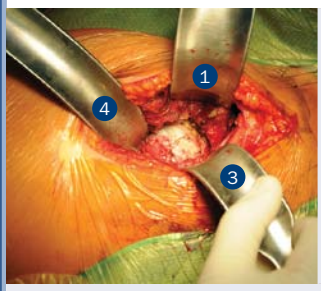


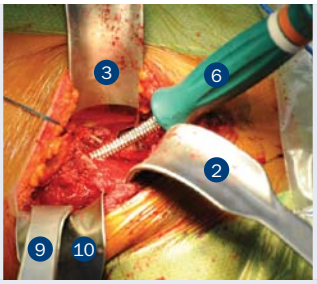
9 Femoral Neck Elevator
10 Soft Tissue Protector

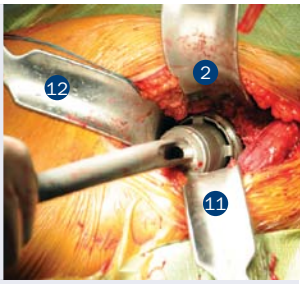


7 8 Box Osteotome

11 12 Offset Narrow Hohmann–Right & Left




| PRODUCT NO'S: |
|---|
| 1 3001 [Unger Wide Hohmann–Single Prong]<br>*Blade Width: 43.6mm*<br>*Blade Depth: 5"*<br>*Overall Length: 13.5"* |
| 2 3008 [Unger Wide Hohmann–Double Prong]<br>*Blade Width: 33.6mm*<br>*Blade Depth: 5"*<br>*Overall Length: 13.5"* |
| 3 3002 [Unger Narrow Hohmann]<br>*Blade Width: 24.5mm*<br>*Blade Depth: 4"*<br>*Overall Length: 13"* |
| 4 3003 [Unger Blunt Narrow Cobra]<br>*Blade Width: 22.5mm*<br>*Blade Width at Tip: 12mm*<br>*Blade Depth: 5.25"*<br>*Overall Length: 14.5"* |
| 5 3004 [Unger Canal Finder Rasp–Straight]<br>*Overall Length: 11"*<br>*Handle Length: 5"* |
| 6 3004-01 [Unger Canal Finder Rasp–Curved]<br>*Overall Length: 11"*<br>*Handle Length: 5"* |

USA MADE

| |
|---|
| 7 3005-R [Unger Box Osteotome–Right]<br>*Overall Length: 12"* |
| 8 3005-L [Unger Box Osteotome–Left]<br>*Overall Length: 12"* |
| 9 3006 [Unger Femoral Neck Elevator]<br>*Blade Width at Widest: 25mm*<br>*Overall Length: 13"*<br>*Handle Length: 9"* |
| 10 3007 [Unger Soft Tissue Protector]<br>*Blade Width: 50.5mm*<br>*Blade Depth: 1.75"*<br>*Overall Length: 10.125"* |
| 11 3009-R [Unger Offset Narrow Hohmann–Right]<br>*Blade Width: 24.5mm*<br>*Blade Depth: 4"*<br>*Overall Length: 13"* |
| 12 3009-L [Unger Offset Narrow Hohmann–Left]<br>*Blade Width: 24.5mm*<br>*Blade Depth: 4"*<br>*Overall Length: 13"* |

ISO 9001:2008 • ISO 13485:2003

Scan to Launch Our Website

**FREE TRIAL ON MOST INSTRUMENTS**

INNOMED®



103 Estus Drive, Savannah, GA 31404
www.innomed.net info@innomed.net

912.236.0000 Phone
912.236.7766 Fax

**Innomed-Europe** Tel. +41 41 740 67 74
Fax +41 41 740 67 71

**1.800.548.2362**


The Reconstructive Review (ISSN 2331-2262 print, ISSN 2331-2270 online) will be published four times a year by the Joint Implant Surgery & Research Foundation (JISRF), 46 Chagrin Plaza #117, Chagrin Falls, Ohio 44023.

## Editorial Correspondence

Please direct any requests for inclusion, editorial comments or questions to Timothy McTighe, Dr. HS (hc), Executive Director, JISRF, 46 Chagrin Plaza #117, Chagrin Falls, Ohio 44023, tmct@jisrf.org.

## Correspondence

Direct any questions regarding the submission process, or requests for reprints to David Faroo, Director of Communications, JISRF, 46 Chagrin Plaza #117, Chagrin Falls, Ohio 44023, dfaroo@jisrf.org.

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

For information on how to submit articles to the Reconstructive Review please review the following or visit http://www.reconstructivereview.org.

## Submit Articles to the Reconstructive Review

Please visit ReconstructiveReview.org to submit an article for review and publication in the Reconstructive Review. All material to be considered for publication should be submitted via this online submission system.

Before submitting an article to Reconstructive Review, please follow the instructions below.

### *ARTICLE TYPES*

Reconstructive Review accepts the following categories of articles:

- Original Articles
- Basic Science
- Case Reports
- Clinical/Surgical
- Commentary
- Controversial Issues (i.e. modularity, tapers, MoM)
- Healthcare Policy/Economics
- Reviews
- Letters to the Editor
- Surveys

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

We will strive to be responsible and reactive to the needs expressed to our editors and all members of JISRF. We anticipate our format will evolve as we move forward and gain more experience with this activity. Your opinion is a critical step to our motivation and overall success, please do not hesitate to communicate with us.

### *INSTRUCTIONS FOR SUBMITTING ARTICLES*

Please read the following information carefully to ensure that the review and publication of your paper is as efficient and quick as possible. The editorial team reserves the right to return manuscripts that have not been submitted in accordance with these instructions.

**File Formats**

- All articles must be submitted as Word files (.doc/.docx) with lines of text numbered. PDF's are not acceptable for submission.
- Figures, images, and photographs should be high quality .JPG images (at least 150 dpi, 300 dpi if possible). All illustrations and line art should be at least 1200 dpi.

**Article Preparation**

Articles submitted will need to be divided into separate files including cover page and manuscript. Figures, images, and photographs should be submitted separately.

- *Cover Page* - includes article title, lists all authors that have contributed to the submission and provides all authors information including their title, full name, their association with the paper, their full postal address and email. Please list all authors in the order that you want them to appear.
- *Manuscript* - EXCLUDES ALL AUTHOR INFORMATION. The manuscript is used in creating the file for peer review – a double blind process. Your submission should follow this structure:
  - Title
  - Abstract (**ALL ARTICLES MUST INCLUDE AN ABSTRACT**)
  - Introduction
  - Materials and Methods
  - Results
  - Discussion
  - References (for styles please refer to the website http://www.nlm.nih.gov/bsd/uniform_requirements.html)
- *Figures, Images and Photographs* - Please do not embed figures, images, and photographs in the main manuscript. They should be uploaded as individual files.

Once you have prepared your manuscript according to the information provided above, please go to our website ReconstructiveReview.org and click on the Register link. Once you have registered you will click on the Submit New Manuscript link. Detailed instructions on how to submit your manuscript can be found at ReconstructiveReview.org.

### *INFORMED CONSENT*

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

### *COPYRIGHT AGREEMENT*

Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review follows the Creative Commons Attribution-NonCommercial CC BY-NC. This license allows anyone to download works, build upon the material, and share them with others for non-commercial purposes as long as they credit the senior author, Reconstructive Review, and the Joint Implant Surgery & Research Foundation (JISRF). An example credit would be: "Courtesy of (senior author's name), Reconstructive Review, JISRF, Chagrin Falls, Ohio". While works can be downloaded and shared they cannot be used commercially.

### *DISCLOSURE STATEMENT*

Disclosure by all authors as to any commercial interest must be made by the corresponding author and all co-authors.

Note: When the paper is submitted to Reconstructive Review, the co-authors listed will automatically receive an email which will contain questions relating to the 'Disclosure statement'.

It is the responsibility of the corresponding author to ensure compliance and full disclosure of all co-authors. From your author main menu you will be able to monitor the responses received from the co-authors that you associate with your submission.

## Reconstructive Review Production Specifications

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

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

Ad Specification

- Full color or black and white - available sizes:
- Full Page, 7.25" x 9.25"
- Half Page Horizontal, 7.25" x 4.25"
- Half Page Vertical, 3.25" x 9.25"

Any questions regarding these specifications should be directed to media@jisrf.org.

## General Statement

The ideas, opinions and statements expressed in the Reconstructive Review do not necessarily reflect those of the publisher and or editor of this publication. Publication of advertisement does not indicate an endorsement of product or service by the publisher or editor of JISRF. The publisher and editor assume no responsibility for any injury or damage resulting out of any publication of material within the Reconstructive Review. The reader is advised to review and regard with balance any information published within this publication with regard to any medical claim, surgical technique, product features or indications and contraindications. It is the responsibility of the professional treating medical physician to review any and all information before undertaking any change of treatment for their patients.

# CONTENTS

Reconstructive Review
*Volume 6, Number 1, April 2016*

Reconstructive REVIEW
ISSN 2331-2262 (print) • ISSN 2331-2270 (online)
Volume 6, Number 1
April 2016
ORIGINAL ARTICLE http://dx.doi.org/10.15438/rr.6.1.131

# Trunnion Corrosion Causing Failure in Metal-on-Polyethylene Total Hip Arthroplasty with Monolithic Femoral Components

*Manthe M[1], Blasser K[1], Beauchamp C[2], O'Connor M.I.[3]*

## Abstract

We describe nine patients who had total hip arthroplasty failure [titanium alloy monolithic stem, cobalt-chromium head (32 mm or 36 mm), highly cross-linked polyethylene liner, metal socket] related to metal wear debris generated at the trunnion. Symptoms included pain with onset 2.9 years after THA. Preoperative serum cobalt metal ion levels were elevated [mean 8.8 ng/ml (normal < 0.9 ng/ml)] and were higher than chromium levels [mean 1.2 ng/ml (normal < 0.3 ng/ml)]. All patients had debridement of the periarticular soft tissues, stem retention, revision to ceramic head and new liner; two patients had acetabular revision. At early follow-up, 7 of 8 available patients did well, with improved cobalt (0.6 ng/ml) and little change in chromium levels. We recommend heightened awareness regarding this mode of failure.

***Keywords***: *hip arthroplasty, corrosion, revision procedures*
***Level of Evidence***: *AAOS Therapeutic Level IV*

## Introduction

Corrosion at the head-neck taper may be emerging as an unusual and early mode of failure in conventional metal-on-polyethylene total hip arthroplasty (MoP THA; monolithic uncemented titanium alloy femoral component with narrower trunnion, modular cobalt alloy head, highly cross-linked polyethylene liner and uncemented acetabular component). The common use of different metals for the modular femoral head (cobalt-chromium alloy) and monolithic femoral stem (titanium alloy) in modern hip arthroplasty creates the potential for galvanic corrosion. Fretting and micromotion at the head neck junction

1 Megan Manthe, MD; Kurt Blasser, MD
Mayo Clinic, 4500 San Pablo Road South, Jacksonville, FL
2 Christopher Beauchamp, MD
Mayo Clinic, 13400 East Shea Boulevard, Scottsdale, AZ
3 Mary I O'Connor, MD
Yale School of Medicine, 800 Howard Avenue #133, New Haven, CT 06519 (Direct reprint requests to Mary I O'Connor)

can also result in the release of metal ions. Adaptation of narrower neck tapers to lower the risk of impingement may increase such micromotion. While failure of metal-on-metal THA due to metal wear debris has been well documented [1-3] and corrosion at the head-neck junction is known to contribute to the adverse local tissue reaction in these patients [4], failure of conventional MoP THA due to trunnion corrosion is now being reported [5]. The purpose of our study was to report our experience with early failure of conventional MoP THA related to corrosion at the modular head-neck junction.

## Materials and Methods

This is a retrospective case series of patients treated at two tertiary care, academic medical centers. Inclusion criteria were arbitrarily set to include patients who had undergone conventional primary total hip arthroplasty between January 2006 and December 2010. There were 2,703 primary arthroplasties performed at our two centers during this time frame. Revision procedures on these patients were performed between December 8, 2011 and May 13, 2013. Data was collected from review of the electronic medical record and radiographic images. Approval was obtained from the local Institutional Review Board.

Patients who presented with either clinical symptoms or radiographic abnormalities (or both) were identified for this study. The demographics of the study population are detailed in Table 1. Of the nine patients that comprised the cohort group, six had their primary arthroplasty at our institution. Eight of the nine patients presented for evaluation of pain (Figures 1 and 2). The final patient was asymp-

*Table 1: Patient Demographics*

| Patient | Age (yrs) | Comorbidities | Date of Primary THA | Sex | Femoral Component | Acetabular Size (mm) | Stem Size | Head Size/Neck Length (mm) | Taper |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 72 | OSA, DMII (metformin), OA, Depression, Nodular thyroid disease | 11/3/2008 | F | Stryker Accolade | 50 | 3 | 32, -4 | V40 |
| 2 | 63 | CAD, HLD, HTN, Hypothyroid, Tinnitus | 10/27/2009 | M | Stryker Accolade | 54 | 3 | 36, -5 | V40 |
| 3 | 63 | HTN, HLD, OSA, | 11/20/2006 | M | Zimmer M/L taper | 56 | 11 | 32, -3.5 | 12/14 |
| 4 | 68 | HTN, HLD, OA | 6/12/2007 | F | Stryker Accolade | 50 | 2 | 32, +0 | V40 |
| 5 | 53 | Metastatic seminoma, CAD, Peripheral neuropathy | 10/27/2007 | M | Stryker Accolade | 52 | 3.5 | 32, +0 | V40 |
| 6 | 74 | Hx Breast Ca, HLD, Hypothyroid, Osteopenia | 5/30/2006 | F | Stryker Accolade | 54 | 4 | 36, +0 | V40 |
| 7 | 67 | OA, PAC | 4/2/2007 | F | Stryker Accolade | 52 | 3 | 32, -4 | V40 |
|  | *** | " " | 11/8/2010 | F | Stryker Accolade | 54 | 4 | 36, -4 | V40 |
| 8 | 59 | DMII (Metformin), HTN, GERD, Hypothyroidism, Atrial arrhythmia | 3/3/2006 | F | Zimmer M/L taper | 52 | 12 | 32, +0 | 12/14 |
| 9 | 78 | HTN, Glaucoma | 5/12/2008 | M | Zimmer M/L taper | 56 | 12.5 | 36, +3.5 | 12/14 |

| | | Pre-operative Serum Levels | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Liner** | **Time to pain (After index op)(yr)** | **Cr (ng/ml) (nml < 0.3)** | **Co (ng/ml) (nml < 0.9)** | **ESR (nml<22mm/hr)** | **CRP (nml < 8mg/L)** | **Advanced Imaging (CT/MRI)** | **Aspiration** | **Time to Revision (after index THA) (yr)** | **Time to Revision (after symptoms) (yr)** |
| 10° elevated | 2 | 0.5 | 15 | * | * | Abnormal enhancement soft tissues, Psoas impingement | Negative Cx, turbid; unable to perform cell count (too viscous) | 3.7 | 1.7 |
| 10° elevated | 2 | 0.2 | 2.1 | 8 | * | Abnormal enhancement soft tissues | Negative Cx, turbid; cell count 2,512 | 2.1 | 0.1 |
| 20° elevated | 3.4 | 1.3 | 9 | 40 | 76.3 | Abnormal enhancement soft tissues | Negative Cx, turbid; cell count 7,000 | 5.4 | 2 |
| 10° elevated | 4.5 | 0.7 | 4.6 | 30 | 9.4 | Lytic focus at acetabulum | Negative Cx, turbid; cell count 1 | 4.7 | 0.2 |
| 10° elevated | No Pain | 0.2 | 11 | 33 | 7.1 | Abnormal enhancement soft tissues | Negative Cx; unable to perform cell count (limited fluid) | 5.3 | No Pain |
| Neutral | 2 | 2 | 8.9 | 11 | 2.5 | Abnormal enhancement soft tissues; Pelvic pseudotumor | Negative Cx, brown; cell count 20,966 | 6.3 | 4.3 |
| 10° elevated | 3.8 | 0.3 | 11 | 40 | 16.4 | Abnormal enhancement soft tissues | Negative Cx, cloudy; cell count 1,001 | 5.7 | 1.9 |
| 10° elevated | 0 | 0.3 | 11 | 40 | 16.4 | Abnormal enhancement soft tissues | Negative Cx, cloudy; cell count 1,001 | 2.5 | 2.5 |
| * | 0.1 | 3.1 | 1.2 | 17 | 9.6 | Abnormal fluid collection | Negative Cx; cell count 50 | 6.5 | 6.4 |
| Neutral | 4.5 | 2.2 | 16 | * | * | Abnormal fluid collection with metal debris present | Negative Cx; opaque; unable to perform cell count | 4.9 | 0.4 |

** Stryker components (Mahwah, New Jersey) consist of Trident hemispherical acetabular component with X3 polyethylene liner, Accolade TMZF stem manufactured from beta titanium alloy (TMZF) and cobalt-chromium alloy femoral head.*
*# Zimmer components (Warsaw, Indiana) consist of Trilogy acetabular component with Longevity polyethylene liner, M/L taper femoral stem manufactured from titanium alloy (Ti-6Al-4V) and cobalt-chromium alloy femoral head.*

*Figure 1: Patient #7 was a 67-year-old female who had revision surgery 5.7 years following the index procedure.*

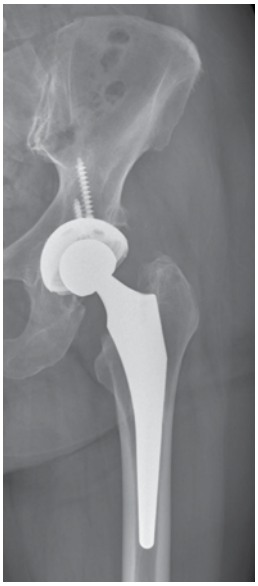


*Figure 1a. Pre-revision Anteroposterior radiograph of the left hip showing mild osteolysis at the periphery of the acetabular component (zone 1) and a mild resorption of the medial femoral calcar (zone 7).*

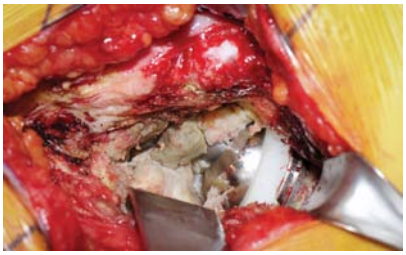


*Figure 1b. Intraoperative photo showing necrotic debris and fibrosis within the hip joint. Notice that there is no visible abnormality at the junction of head and stem.*

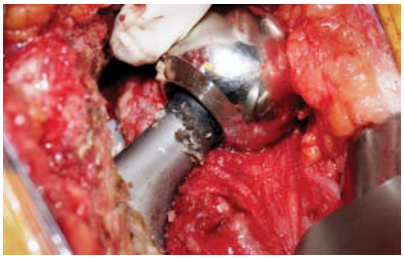


*Figure 1c. With removal of head, extensive corrosive debris can be seen at trunnion/neck region.*

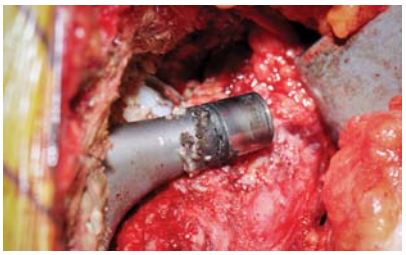


*Figure 1d. Corrosive debris at base of trunnion; trunnion damage visible.*

*Figure 1e. Corrosion and debris within femoral head.*

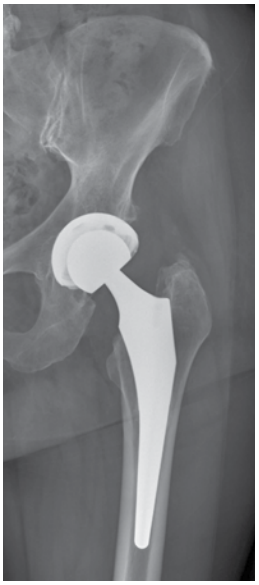


*Figure 1f. Anteroposterior view of the left hip two months following revision polyethylene liner and conversion of the cobalt-chromium to a ceramic femoral head.*

*Figure 2: Patient #4 was a 68-year-old woman.*

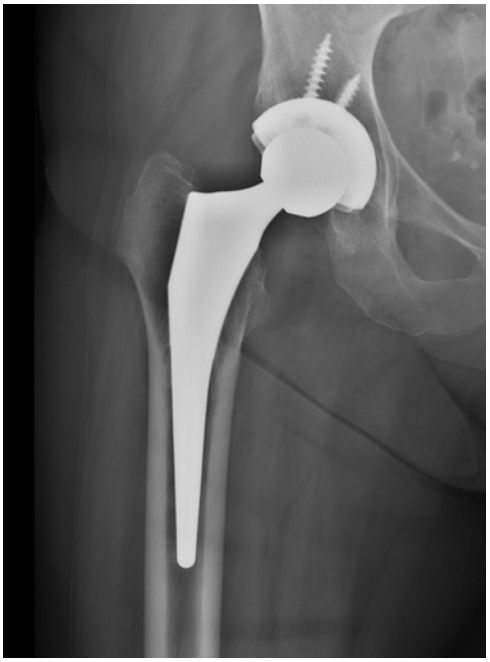


*Figure 2a. Anteroposterior radiograph of the right THA three years following the index procedure. The patient is asymptomatic.*

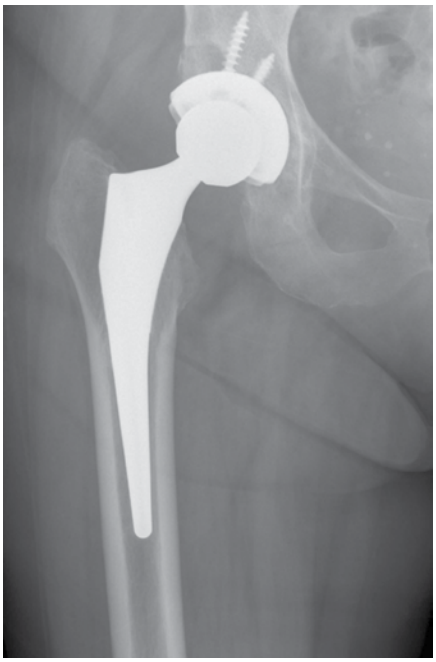


*Figure 2b. Anteroposterior radiograph of the right THA 4.5 years following the index procedure showing interval development of acetabular bone loss in zone 1. Patient then developed hip pain.*

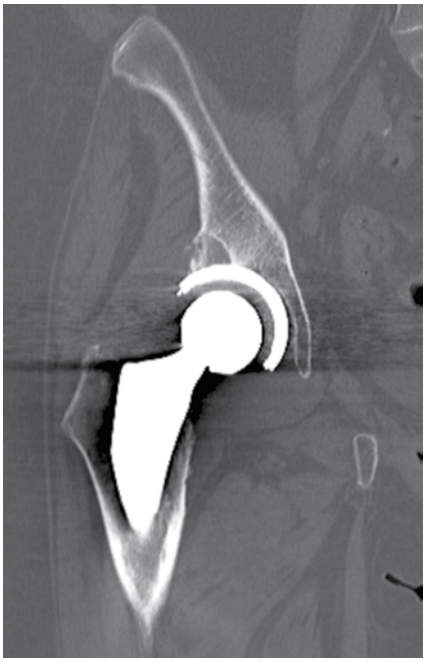


*Figure 2c. Computed tomography scan of the right hip showing a fairly localized area of bone destruction with some surrounding sclerosis. Neoplasm (particularly metastatic disease) was included in the differential diagnosis.*

*Figure 3: Patient #5 was a 53-year-old male who underwent revision surgery 5.3 years after the index procedure.*

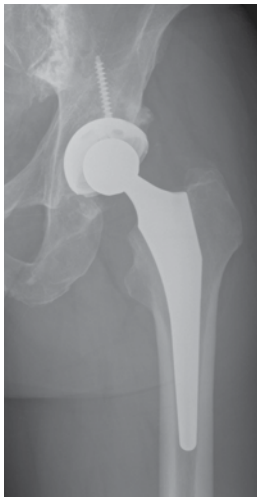


*Figure 3a. Anteroposterior radiograph of the left hip three months after primary THA. Note the presence of the medial femoral calcar bone.*

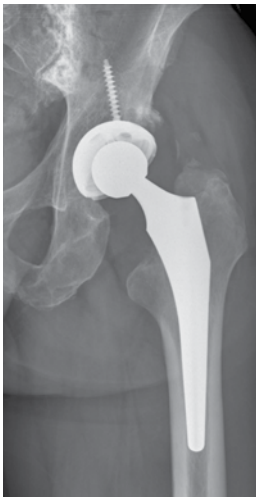


*Figure 3b. Anteroposterior radiograph of the left hip prior to revision showing mild osteolysis at the periphery of acetabular component (zone 1) and a marked resorption of the medial femoral calcar (zone 7).*

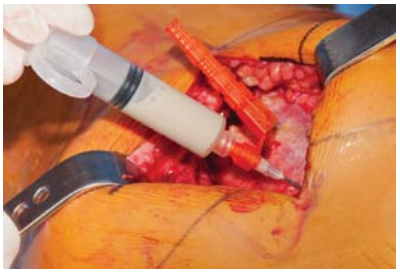
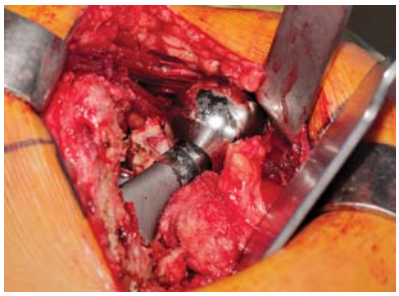


*Figure 3c. Intraoperative aspiration of left hip joint showing grayish tinted white fluid.*



*Figrue 3d. Intraoperative photograph of the femoral head being removed showing underlying debris due to trunnion corrosion.*

*Figure 3e. Trunnion with debris and corrosion*

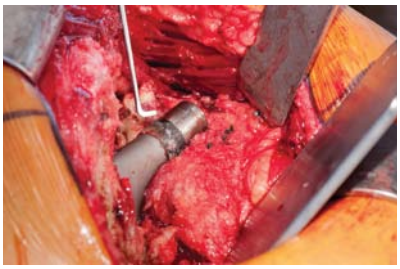


*Figure 3f. Corrosion and debris within femoral head*

tomatic patient and had presented for routine follow-up and had an abnormality identified on radiographs (Figure 3). The variables studied included preoperative serum chromium and cobalt levels, preoperative hip-joint fluid analysis, and advanced imaging of the hip joint with computed tomography or magnetic resonance imaging with metal artifact reduction sequencing. As available, postoperative serum metal ion levels were documented as well as clinical status at most recent follow-up.

Ten revision procedures were performed in 9 patients; one patient underwent bilateral revisions (Table 2). In one patient, the preoperative diagnosis was psoas impingement, and serum metal ion levels were drawn immediately following revision after noting intraoperative findings consistent with metal debris generated at the trunnion. In the remaining patients, failure related to trunnion corrosion was suspected prior to revision. The average time between conventional THA and revision surgery was 4.7 years (range 2.1-6.5 years).

The surgical hip approach during revision surgery was dictated by surgeon preference and included 8 posterior approaches and 2 anterior approaches. All femoral stems were determined to be well-fixed and retained. Black flaky material at the head-neck junction was identified in all patients and was easily removed with either a damp lap pad, fresh blade, or bovie scratch pad. A titanium-alloy adapter sleeve was used in seven of ten constructs prior to ceramic head impaction on the taper. In the three cases where an adapter sleeve was not used, we employed an off label application based on the decision of the treating surgeon that the integrity of the trunnion was satisfactory. One well-fixed acetabular shell was revised in the patient who had the preoperative diagnosis of psoas impingement, and another acetabular shell was revised due to lack of ingrowth. All acetabular liners were revised with highly cross-linked polyethylene liners. All cobalt-chrome femoral heads were revised to ceramic heads.

## Results

*Clinical Presentation:* In our small cohort, eight patients presented with or reported symptoms of groin, buttock, or thigh pain at an average of 2.9 years after initial THA (range 0.1-4.5 years). One asymptomatic patient returned for routine surveillance 1.9 years following his index procedure and radiographs revealed abnormal bone resorption (Patient 5). The average time between symptom presentation and revision surgery was 2.4 years (range 0.2-6.4 years), and the time between index arthroplasty and revision surgery was 4.7 years (range 2.1-6.5 years). Of the index arthroplasties, 7 were composed of Stryker compo-

*Table 2: Revision Procedures and Findings*

| Patient | Revision Procedure | Head size | Head Type | Liner | Shell | Stem | Titanium adapter sleeve | Intraop histology description |
|---|---|---|---|---|---|---|---|---|
| 1 | Shell, liner, head exchange | 36, +5 | Ceramic | Neutral | Stryker Trident Hemispherical | Retained | No | NA |
| 2 | Liner + head exchange | 36, +0 | Ceramic | Elevated rim | Retained | Retained | Yes | "Fibrosis with focal perivascular lymphocytic inflammation; compatible with ALVAL" |
| 3 | Liner + head exchange | 32, +0 | Ceramic | Elevated rim | Retained | Retained | Yes | "Degenerative synovial tissue; bone with extensive necrosis' |
| 4 | Shell, liner, head exchange | 36, +0 | Ceramic | Elevated rim | Zimmer Continuum Trabecular metal | Retained | Yes | "Necrotic debris with fibrous soft tissue" |
| 5 | Liner + head exchange | 36, +0 | Ceramic | Elevated rim | Retained | Retained | Yes | "Necrotic tissue & patchy chronic inflammation" |
| 6 | Liner + head exchange | 36, +0 | Ceramic | Elevated rim | Retained | Retained | No | "Infarcted tissue & hyalinization" |
| 7 | Liner + head exchange | 36, +0 | Ceramic | Elevated rim | Retained | Retained | Yes | "Patchy chronic inflammation & lymphoid aggregates" |
|  | Liner + head exchange | 36, -2.5 | Ceramic | Elevated rim | Retained | Retained | Yes | "Fibrinous degeneration" |
| 8 | Liner + head exchange | 36, +3.5 | Ceramic | Neutral | Retained | Retained | Yes | NA |
| 9 | Liner + head exchange | 32, -3 | Ceramic | Neutral, Constrained | Retained | Retained | No | "Fibrinous degeneration present" |

nents: Accolade TMZF stem with a V40 taper, a cobalt-chromium alloy femoral head, and a Trident hemispherical acetabular component with an X3 polyethelene liner (Mahwah, New Jersey); 3 index arthroplasties were composed of Zimmer components: M/L taper femoral stem (Ti-6Al-4V) with a 12/14 taper, a cobalt-chromium alloy femoral head, and a Trilogy acetabular component with a Longevity polyethylene liner (Warsaw, Indiana).

*Radiographic Findings:* All patients had pre-revision radiographs. Two patients had bone resorption at the medial calcar, and one had an area of well-defined acetabular osteolysis. All patients had radiographs interpreted as having well fixed components. Seven of nine patients had metal artifact reduction sequencing magnetic resonance imaging (MARS MRI), which showed abnormal enhancement around the hip capsule and/or iliacus muscle; two patients also had large pseudotumors. The remaining two patients had computed tomography (CT) imaging of the hip, one detailing the osteolytic acetabular lesion and the other suggesting debris (Table 1).

*Laboratory testing:* Laboratory test results are detailed in Table 1. In all patients, the cultures from fluid aspirated from the hip joint were negative. Serum metal ion levels were evaluated on all patients and demonstrated elevated

| | Post-Operative Serum Metal Ion Levels | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Cr (ng/ml) (nml < 0.3)** | **Co (ng/ml) (nml < 0.9)** | **Time of blood draw (post- revision) (mos)** | **Complications** | **NOTES** | **Time to Latest Clinical Follow-up after Revision (mos)** | **Patient comments at clinic follow-up** |
| | 0.6 | 2.1 | 3.7 | none | Revised shell due to intraop appearance of retroversion | 5.7 | "Doing better"; "Hip feels less prominent" |
| | * | 0.2 | 8.9 | none | * | 8.9 | "Hip definitely better" |
| | 2.1 | 1.3 | 3.8 | Died from unrelated MI 5 mos after revision | * | 3.8 | "Recovery better after this than prior surgeries" (prior to unrelated MI) |
| | 0.7 | 0.9 | 3.4 | none | Revised shell because acetabular component found to not be ingrown | 7.7 | "No problems while walking" |
| | 0.2 | 1.8 | 3.2 | none | * | 3.2 | "Not much pain, patient already returned to gym" |
| | 1.1 | 2.7 | 1 | Infection, failed Prostalac, now with girdlestone | * | 6.6 | "Minimal discomfort, less swelling; awaiting ESR/CRP to normalize prior to reimplantation" |
| | 0.4 | 7.6 | 1.8 | none | Patient had bilateral primary THA with corrosion. Both hips were revised as described, with 5.1mos between revisions. | 0.7 | "Able to ambulate independently" |
| | 0.3 | 1 | 4.7 | none | " " | 4.7 | "Walking 2 miles a day now, prior to revisions couldn't walk 2 blocks" |
| | * | * | * | none | * | 1.9 | "Really well with respect to hip" |
| | * | * | * | none | Large pseudotumor | *** | *** |

cobalt levels, with a mean of 8.8 ng/ml (range 1.2-16 ng/ml; normal <0.9 ng/ml) and elevated chromium level of a mean of 1.2 ng/ml (range 0.2-3.1 ng/ml; normal < 0.3 ng/ml).

*Intraoperative Findings:* At the time of revision, each modular head appeared fully engaged on the taper, based on intraoperative manual testing. Black debris at the head-neck junction was identified in all patients. Our retrospective review of the operative reports did not detail if visible damage to acetabular liner was observed. Material analysis of the removed components was not performed. The structural integrity of each trunnion was inspected and found to be maintained. Synovial tissue hypertrophy and necrotic periarticular debris were seen in all patients, and a pseudotumor was identified in two patients. These abnormal tissues were debrided, as possible. Operative histology in seven cases showed fibrinous degeneration, chronic inflammation, and necrotic tissue, but no acute inflammation. Descriptions of intraoperative histology as dictated by pathology are shown in Table 2. A variable degree of abductor muscle necrosis was also seen. We could not correlate the severity of tissue damage and preoperative metal ion level or time delay to revision procedure in this small series. Intraoperative cultures were negative in all patients.

Descriptions of intraoperative histology as dictated by pathology are shown in Table 2.

*Early clinical follow-up:* Early results following revision surgery have been favorable in seven of eight patients with clinical follow-up. One patient has been lost to follow-up. These seven patients report significant improvement in hip pain and function (Table 2). In seven patients with postoperative metal ion levels, serum cobalt ion levels decreased from a preoperative mean of 8.8 ng/ml to 0.6 ng/ml (range 0.2-1.3) at a mean time of 11 months after revision. There was little change in chromium levels from a preoperative mean of 1.2 ng/ml to a postoperative mean of 0.6 ng/ml (range 0.1-2.1 ng/ml).

*Complications:* One patient died months following revision surgery from an unassociated myocardial infarction. He reported clear improvement in hip pain at 4 month follow-up (Patient 3). Another patient with a large pseudotumor developed an acute postoperative infection and currently has a girdlestone (Patient 6). No postoperative dislocations have been reported.

## Discussion

Corrosion at the tapered head-neck junction of a monolithic titanium alloy femoral component and modular cobalt-chromium femoral head can result in elevated serum metal ion levels and adverse local tissue reaction, leading to failure of the MoP THA (Table 3). Although an uncommon finding, trunnion corrosion can result in significant pain and debilitation for patients. Most recently, Cooper et al. reported on a cohort of 10 patients with failed MoP THA due to trunnion corrosion [5]. Although case reports have documented MoP trunnion corrosion and pseudotumor development throughout recent years [14,21-22,25-27], our report of nine patients is the second series, to our knowledge, of early failure in MoP THA due to corrosion at the head-neck junction.

In our series, nearly all patients had pain that prompted advanced imaging and subsequent metal ion level testing. All patients had abnormal MRI or CT findings and elevated metal ion levels. In eight of nine patients, serum cobalt levels were dramatically elevated compared to serum chromium levels; a finding that was also reported by Cooper et al [5]. While Cooper et al. [5] did not report changes on radiographs of bone resorption, we identified osteolytic lesions in two of our patients. While we cannot conclude that there is a consistent clinical presentation for patients with failure of MoP THA due to trunnion corrosion, our experience suggests that metallosis due to trunnion corrosion should be considered in patients with pain within the first few years after MoP THA.

Revision of patients in our series to a ceramic-on-polyethylene bearing THA resulted in clinical improvement in all patients except one who developed a postoperative infection. Postoperative cobalt metal ion levels returned to normal levels at an average of 11 months from revision. Cooper et al. also reported reduction in postoperative serum metal cobalt levels in 6 of their patients in whom testing was performed [5]. While patients will require longer follow-up to assure clinical success, our early experience suggests that revision to a ceramic-on-polyethylene bearing surface will effectively treat the metallosis associated with trunnion corrosion in these patients.

The etiology of trunnion corrosion at the head-neck junction in the patients in our series remains unclear. Implant design features, size selection of the femoral head component, surgical technique, and even patient factors may play a role in the development of trunnion corrosion. Reports from the field of implant dentistry have shown that titanium implant failure via corrosion is more likely to occur under conditions of increased serum glucose as well as increased acidity, as seen in conditions of inflammation and infection [6-8]. While our cohort had two patients with diabetes mellitus, our numbers are too small to comment on the role of elevated blood glucose and inflammatory conditions on the development of trunnion corrosion. Future research reviewing a larger cohort of patients could potentially identify patient comorbidities, which may increase the risk of subsequent trunnion corrosion in THA.

*Table 3: Trunnion Corrosion with Monoli*

| Previous Study | Patient demographics |
|---|---|
| Walsh et.al. [21] 2011 | 79-year-old male |
| Lindgren et. al. [22] 2011 | 70-year-old male |
| Bonnaig et. al. [23] 2011 (Titanium morse taper with Ceramic-Ceramic articulation) | 46-year-old male |
| Cooper et al. [5] 2012 | 10pts (8 female, 2 male) |
| Khair et al. [24] 2013 | Unknown age, male, modular fixed-head unipolar hemiarthroplasty |
| Mao et. al. [25] 2012 | 64-year-old female |
| Clyburn [26] 2013 | 52-year-old female |
| Scully et. al. [27] 2013 | 80-year-old male |
| Cook et. al. [13] 2013 | 2pts (69-year-old female, 79-year-old male) |

*ithic Femoral Components with Metal Femoral Head and Polyethylene Acetabular Liner*

| | Time to pain after index op (yr) | Presenting symptoms | Laboratory workup | Pre-revision imaging | Revision procedure | Notes |
|---|---|---|---|---|---|---|
| | 1.8 | Enlarging mass over gluteus maximus | ESR: elevated CRP: elevated; Metal ions: not drawn; Aspiration: negative culture | MRI: well defined soft tissue mass near greater trochanter | Head: ceramic Acetabular shell: retained Liner: ceramic Femoral stem: retained | Excessive fibrotic soft tissue at time of revision |
| | 1 | Buttock and groin pain | ESR: normal CRP: elevated; Cobalt: 0.5bbp (nml<0.007); Chromium: 0.09ppb (nml<0.006); Aspiration: negative culture | X-ray: unremarkable CT: increased volume of iliopsoas MRA: cystic lesion anteromedially in iliopsoas | Head: stainless steel Acetabular shell: retained Liner: polyethylene Femoral stem: Stainless steel | Surface corrosion at head-neck; disrupted abductor insertion; necrotic appearance of tissue |
| | 2 | Groin swelling; painless medial thigh mass | Blood work: not described; Metal ions: not described; Aspiration: negative cultures | CT: subcutaneous fluid collection extending from iliopsoas to hip joint; MRA: communication between hip joint and medial thigh sinus | Head: cobalt-chrome alloy Acetabular shell: revised, not specified Liner: polyethylene Femoral stem: revised, not specified | Foreign body granuloma thigh mass; black debris on morse taper neck; metallic fragments embedded in ceramic |
| | 0.7-8.7 | 7-Pain (groin, thigh, buttock, trochanteric); 1-weakness; 1- fluid collection; 1-swelling | ESR: mean 47.3 (range 4-108) CRP: mean 2.6 (range 0.5-5.7) Cobalt: mean 9.55 (range 1.6-42.45) Chromium: mean 1.39 (range 0.18-3.28) Aspiration: negative cultures | Radiographs (10): all interpreted as normal MRI (3): large fluid collection CT (2): abnormal fluid collection | Ceramic head + liner exchange (8); Ceramic head, liner exchange, acetabular revision (2) | All patients with black corrosion at trunnion; abductor muscle necrosis (2) |
| | 2 | Groin pain | ESR: not reported CRP: not reported; Cobalt: 1.8ppb (nml <1ppb); Chromium: 2.4ppb (nml < 1.4ppb); Aspiration: not reported | X-ray: osteolysis surrounding acetabulum | Head: cobalt-chrome alloy Acetabular shell: cage reconstruction Liner: polyethylene Femoral stem: retained | Surface corrosion at trunnion; necrotic appearance of tissue |
| | 4 | Greater trochanteric pain | ESR: normal CRP: normal; Cobalt: 11.2ng/ml (nml < 0.9); Chromium: 13ng/ml (nml < 0.3); Aspiration: negative culture | X-ray: well-fixed components without signs of polyethylene wear | Head: ceramic Acetabular shell: retained Liner: ceramic Femoral stem: retained | Surface corrosion at trunnion; metal debris in tissue |
| | 5 | Buttock and groin pain; difficulty ambulating | ESR: elevated CRP elevated; Aspiration: purulent, negative culture | X-ray: stable implant with ischial osteolysis | First stage: Prostalac Second stage: Head: ceramic Acetabular shell: revised, not specified Liner: polyethylene Femoral stem: revised, not specified | Pseudotumor lateral to greater trochanter; damage to abductor insertion; metallic staining of tissue; black debris at headneck interface |
| | 5 | Mass anterolateral to greater trochanter, pain, difficulty ambulating | ESR: normal CRP: normal; WBC: normal | MRI: well defined cystic mass deep to IT band expanding out from hip joint | Head: ceramic | Scully et. al. [17] 2013 |
| | 1-4 | Groin and lateral thigh pain | ESR/CRP: not described; Cobalt: mean 6.6ng/ml (range 6.3-6.9); Chromium: mean 1.56ng/ml (range 0.47-2.65); Aspiration: negative culture | US: large fluid collection anterior to greater trochanter in continuity with hip joint | Finite material analysis performed, revision not specified | Deep pseudotumor (x2) adherent to capsule; 3D metrology reveals mechanical damage at taper-trunnion overlap |

While we nor Cooper et al. [5] could correlate femoral head diameter with trunnion corrosion in our small series, femoral head size and trunnion design features may be factors influencing the risk of corrosion [9-12]. Failure due to trunnion corrosion in MoP THA has been reported in two patients with large femoral heads (40 mm and 44 mm diameter) [13]. A significant elevation in serum cobalt levels in MoP THA has been reported when comparing a 36 mm femoral head to a 28 mm femoral head [14]. The Australian Registry 2011 annual report demonstrated increased revision rates at 10 years when head size in metal-on-metal THAs was greater than 32 mm compared to those constructs in which the head size was equal to 32 mm or less [15]. This increase in failure was believed to be related to the larger head diameter increasing the load, torque, and micromotion at the trunnion interface. Trunnion design may be a factor as Jani et al. reported the lowest metal ion release, with a 12/14 trunnion taper with a proximal taper locking location as compared to a 10/12 taper with either distal or proximal locking location[16]. Furthermore, the amount of debris generated at the trunnion interface may be underappreciated; recent data shows that in metal-on-metal THA, approximately one-third of the total volumetric wear is generated at the tapered head-stem junction, and it is unknown if such debris may be more biologically active than debris generated at the femoral head-acetabular liner interface [17]. With our small numbers we cannot comment on the length of the neck extension as a factor in failure in these patients. Based on correspondence with implant manufacturers, we did not identify any change in trunnion design or metal composition of the implants in the last decade.

Limitations of this study include a small cohort of patients, short duration of follow-up and lack of titanium metal ion levels in these patients. We do not know if the damage present on the trunnions of the retained femoral components will be problematic with longer follow-up. Titanium metal ion levels were not measured in our patients and could be factor in failure and a source of debris particularly as a recent ten-year study showed titanium levels peaked at 36 months in patients with similar constructs [20]. Furthermore we do not have a sense of the prevalence of corrosion causing failure in MoP THA in monolithic femoral components. A search of the FDA MAUDE database showed 18 reports of Accolade MoP THA stem failures and 15 M/L taper MoP THA stem failures due to metallosis, corrosion, pseudotumor, metallic debris, or elevated serum metal ion levels resulting in pain and/or loosening [18]. Interestingly, the Australian Registry 2012 annual report stated that metal sensitivity as a reason for revision increased from 1.2% to 5.9% over the past year, although the exact source of metal sensitivity was not specified [19].

Early failure in conventional MoP THA can occur due to corrosion at the head-neck interface. As radiographs and physical examination findings may be unremarkable, the diagnosis may be elusive early in the clinical course. In patients with unexplained pain after conventional THA, we will now frequently proceed with advance imaging and serum metal ion level testing. We recommend a heightened awareness of this mode of failure.

## *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.

### References


1. Klapperich C, Graham J, Pruitt L, Ries MD. Failure of a metal-on-metal total hip arthroplasty from progressive osteolysis. J Arthroplasty. 1999 Oct;14(7):877-81.
2. Park YS, Moon YW, Lim SJ, Yang JM, Ahn G, Choi YL. Early osteolysis following second-generation metal-on-metal hip replacement. J Bone Joint Surg Am. 2005 Jul;87(7):1515-21.
3. Willert HG, Buchhorn GH, Fayyazi A, Flury R, Windler M, Koster G, Lohmann CH. Metal-on-metal bearings and hypersensitivity in patients with artificial hip joints. A clinical and histomorphological study. J Bone Joint Surg Am. 2005 Jan;87(1):28-36.
4. Fricka KB, Ho H, Peace WJ, Engh CA, Jr. Metal-on-metal local tissue reaction is associated with corrosion of the head taper junction. J Arthroplasty. 2012 Sep;27(8 Suppl):26-31 e1.
5. Cooper HJ, Della Valle CJ, Berger RA, Tetreault M, Paprosky WG, Sporer SM, Jacobs JJ. Corrosion at the head-neck taper as a cause for adverse local tissue reactions after total hip arthroplasty. J Bone Joint Surg Am. 2012 Sep 19;94(18):1655-61.
6. Messer RL, Tackas G, Mickalonis J, Brown Y, Lewis JB, Wataha JC. Corrosion of machined titanium dental implants under inflammatory conditions. J Biomed Mater Res B. 2009 Feb;88(2):474-81.
7. Souza ME, Lima L, Lima CR, Zavaglia CA, Freire CM. Effects of ph on the electrochemical behaviour of titanium alloys for implant applications. J Mater Sci Mater Med. 2009 Feb;20(2):549-52.
8. Tamam E, Turkyilmaz I. Effects of ph and elevated glucose levels on the electrochemical behaviour of dental implants. J Oral Implantol. 2012 Feb 29.
9. Brown SA, Flemming CA, Kawalec JS, Placko HE, Vassaux C, Merritt K, Payer JH, Kraay MJ. Fretting corrosion accelerates crevice corrosion of modular hip tapers. J Appl Biomater. 1995 Spring;6(1):19-26.
10. Evans EM, Freeman MA, Miller AJ, Vernon-Roberts B. Metal sensitivity as a cause of bone necrosis and loosening of the prosthesis in total joint replacement. J Bone Joint Surg Br. 1974 Nov;56-B(4):626-42.
11. Gilbert JL, Buckley CA, Jacobs JJ. In vivo corrosion of modular hip prosthesis components in mixed and similar metal combinations. The effect of crevice, stress, motion, and alloy coupling. J Biomed Mater Res. 1993 Dec;27(12):1533-44.
12. Jacobs JJ, Skipor AK, Patterson LM, Hallab NJ, Paprosky WG, Black J, Galante JO. Metal release in patients who have had a primary total hip arthroplasty. A prospective, controlled, longitudinal study. J Bone Joint Surg Am. 1998 Oct;80(10):1447-58.
13. Cook RB, Bolland BJ, Wharton JA, Tilley S, Latham JM, Wood RJ. Pseudotumour formation due to tribocorrosion at the taper interface of large diameter metal on polymer modular total hip replacements. J Arthroplasty. 2013 Sep;28(8):1430-6.
14. Craig P, Bancroft G, Burton A, Collier S, Shaylor P, Sinha A. Raised levels of metal ions in the blood in patients who have undergone uncemented metal-on-polyethylene trident-accolade total hip replacement. Bone Joint J. 2014 Jan;96-B(1):43-7.
15. Australian orthopaedic association (aoa). Australia 2011 joint registry annual report. 2011 [08/2013]; Available from: https://aoanjrr.dmac.adelaide.edu.au/en
16. Jani SC, Sauer WL, McLean TW, Lambert RD, Kovacs P. Fretting corrosion mechanisms at modular implant interfaces. In: Marlowe DE, Parr JE, Mayor MB, editors. Modularity of orthopedic implants, astm stp 1301: American Society for Testing and Materials; 1997.
17. Matthies AK, Racasan R, Bills P, Blunt L, Cro S, Panagiotidou A, Blunn G, Skinner J, Hart AJ. Material loss at the taper junction of retrieved large head metal-on-metal total hip replacements. J Orthop Res. 2013 Nov;31(11):1677-85.
18. U.S. Food and drug administration. Maude - manufacturer and user facility device experience database. 2013 [08/2013]; Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.
19. Australian orthopaedic association (aoa). Australia 2012 joint registry annual report. 2012 [Accessed 08/2013]; Available from: https://aoanjrr.dmac.adelaide.edu.au/en.
20. Levine BR, Hsu AR, Skipor AK, Hallab NJ, Paprosky WG, Galante JO, Jacobs JJ. Ten-year outcome of serum metal ion levels after primary total hip arthroplasty: A concise follow-up of a previous report*. J Bone Joint Surg Am. 2013 Mar 20;95(6):512-8.
21. Walsh AJ, Nikolaou VS, Antoniou J. Inflammatory pseudotumor complicating metal-on-highly cross-linked polyethylene total hip arthroplasty. J Arthroplasty. 2012 Feb;27(2):324 e5-8.
22. Lindgren JU, Brismar BH, Wikstrom AC. Adverse reaction to metal release from a modular metal-on-polyethylene hip prosthesis. J Bone Joint Surg Br. 2011 Oct;93(10):1427-30.
23. Bonnaig NS, Freiberg RA, Freiberg AA. Total hip arthroplasty with ceramic-on-ceramic bearing failure from third-body wear. Orthopedics. 2011 Feb;34(2):132.
24. Khair MM, Nam D, DiCarlo E, Su E. Aseptic lymphocyte dominated vasculitis-associated lesion resulting from trunnion corrosion in a cobalt-chrome unipolar hemiarthroplasty. J Arthroplasty. 2013 Jan;28(1):196 e11-4.
25. Mao X, Tay GH, Godbolt DB, Crawford RW. Pseudotumor in a well-fixed metal-on-polyethylene uncemented hip arthroplasty. The Journal of arthroplasty. 2012 Mar;27(3):493 e13-7.
26. Clyburn T. Pseudotumor in metal-on-polyethylene total hip arthroplasty. Reconstructive Rev. 2013;3(1):18-22.
27. Scully WF, Teeny SM. Pseudotumor associated with metal-on-polyethylene total hip arthroplasty. Orthopedics. 2013 May;36(5):e666-70.

Reconstructive REVIEW
ISSN 2331-2262 (print) • ISSN 2331-2270 (online)
Volume 6, Number 1
April 2016
CLINICAL / SURGICAL
http://dx.doi.org/10.15438/rr.6.1.133

# Bone Preservation in a Novel Patient Specific Total Knee Replacement

*Kurtz W [1], Slamin J [2], Doody S [2]*

## Abstract

***Background:*** The volume of total knee arthroplasty procedures is growing rapidly and, correspondingly, it is expected that the volume of revision procedures will grow rapidly as well. Revision surgery is most successful when adequate bone remains on both the tibia and femur to allow for the least invasive revision.

We hypothesized that total knee arthroplasty with a patient-specific implant would result in significant bone preservation as compared to standard total knee arthroplasty with "off-the-shelf" implants.

***Methods:*** We evaluated 100 total knee arthroplasties which utilized patient-specific implants, versus 37 standard posterior stabilized and 32 standard posterior cruciate retaining total knee arthroplasties. Bone resection was quantified utilizing intra-operative measurements of actual resected bone. Additionally we performed a virtual, CAD-based analysis of resections via CT imaging on 15 knees.

***Findings:*** We found that patients had significantly less bone resected in all zones measured, on both the femur and tibia, when patient-specific implants with patient-specific jigs were used. When assessed volumetrically with CAD imaging, standard implants resected 12-49% more bone than did patient-specific implants, depending on the size of the implant utilized.

***Interpretations:*** Utilizing patient-specific implants in total knee arthroplasty results in significant bone sparing as compared to standard total knee arthroplasty. This has the potential for less invasive revision surgery in the future, possibly obviating the need for dedicated revision implants or augments and other bone substituting devices.

***Keywords****: total knee arthroplasty, bone resection, bone preservation, patient-specific implant*
***Level of Evidence****: AAOS Therapeutic Level II*

## Introduction

In 2013 approximately 800,000 knee replacement surgeries were conducted, including partial knee, primary total knee, and revision knee surgeries. Kurtz et al. have predicted that revision knee surgeries will grow to over 250,000 procedures by 2030 [1].

Because of the anticipated increase in revision surgeries in the future, it is important to be mindful of the poten-

1 William. B. Kurtz, MD
Tennessee Orthopedic Alliance, 301 21st Ave N, Nashville, TN 37203 USA
2. John E. Slamin; Scott W. Doody
ConforMIS Inc., 28 Crosby Dr, Bedford, MA 01730 USA
(Direct reprint requests to John E. Slamin)

tial for a revision during the performance of the primary surgery. Maximizing bone preservation during a primary knee replacement is especially important as substantial bone loss during a subsequent revision surgery can complicate surgical techniques and compromise outcomes of the revision.

A typical primary total knee femoral component has distal condylar thicknesses that range between 8.5mm and 10mm. Posterior condylar thicknesses can range from 8mm to 11 mm in standard flexion implant systems. The 'high flexion' femoral components can have posterior condyles that are as thick as 13mm. The thickness of the implant correlates directly to the amount of bone resection that is required to implant the prosthesis, as most implant systems attempt to restore the amount of bone that is removed as closely as possible.

It remains unknown if, as is seen with hip resurfacing, bone preservation leads to improved proprioception [2]. It is clear that improved bone preservation means less chance for dramatically altering the articular surface geometry.

In this study, we hypothesized that a total knee replacement (TKR) system with a patient-specific design would result in substantial preservation of bone compared to a standard off the shelf implant system. This in turn would preserve more native bone in the event of a revision.

### *Patient-Specific Total Knee Replacement Design Concept*

Designing a TKR that will fit the patient's geometry requires detailed information on the patient's bone that can only be provided by computed tomography (CT) scanning or other 3D imaging scans. Utilizing proprietary software, the CT data, required to manufacture an iTotal®(ConforMIS, Bedford, MA) patient-specific implant, is post processed and converted into a computer assisted design(CAD) solid model. A secondary proprietary software system is then used to analyze the bone geometry and design the femoral component. Predefined design rules that are embedded into the software are applied in the design process. The predefined design rules include the coronal radii for the trochlear groove and condyles, which are designed with low polyethylene wear in mind, employing radii that have been shown to produce low contact stress [3]. The embedded design rules include recreation of the patient's natural sagittal 'J' curves for the medial condyle, the trochlear groove, and the lateral condyle.

This patient-specific implant design requires thinner cross sections of the component, which should require less bone removal in the implantation procedure. Traditional TKR femoral components employ a multifaceted bone side geometry. Typical thicknesses for these components can be 9mm for the distal condyles and 8mm for the posterior condyles. Contemporary femoral components have 5 facets: the anterior flange, the anterior chamfer, the distal surface, the posterior chamfer, and the posterior condyle surface. All of these surfaces are coplanar between the medial and lateral condyles on the traditional TKR.

In the iTotal, each facet is placed where maximum bone preservation can be achieved while still maintaining adequate fatigue strength. Furthermore, the iTotal employs six facets rather than the traditional 5 faceted cuts. The rationale for choosing six bone cuts, and their thickness, was determined based on the results of finite element modeling and subsequent fatigue testing. There are also embedded design rules within the proprietary software that control the thickness of the femoral component. This 6-cut design concept has been shown to provide adequate fatigue strength and, for the same component thickness, to be stronger than a 5-cut design [4].

Frequently, a patient's femur, when viewed in the coronal plane, displays an asymmetry between the lateral and medial condyles. This natural condylar offset is defined as the coronal offset. The iTotal femoral component respects these patient specific differences and is designed with the patient's exact coronal offset. The coronal offset is defined as the height difference between the medial and lateral femoral condyles as viewed in the coronal extension plane. This typically creates an asymmetry of the extension gap that must be accounted for at the tibial articular surface, much in the same manner that the natural human knee does. The same is true for the posterior condyles of the femur. Typically, the lateral posterior condyle is shorter than the medial condyle creating a unique asymmetry in the flexion space as well. These are the patient-specific design elements along with the patient's unique 'J' curvatures that are incorporated into the femoral component of the iTotal Cruciate Retaining Knee System. Figure 1 shows a typical post processed bone model in CAD with the pre-

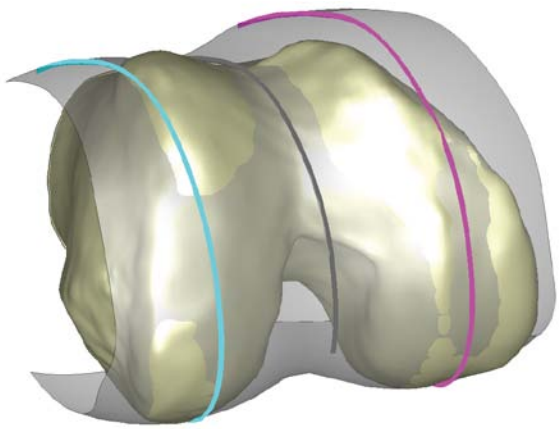


*Figure 1. Showing in process stage of patient-specific 'J' curves on a CAD model of the distal femur.*

liminary patient specific 'J' curves in the early stages of design within the proprietary implant software program. Figure 2 shows a typical iTotal complete implant system. The patient-specific condylar widths and asymmetry, the trochlear shape, coronal center to center, and the distal offset are clearly evident in this image.

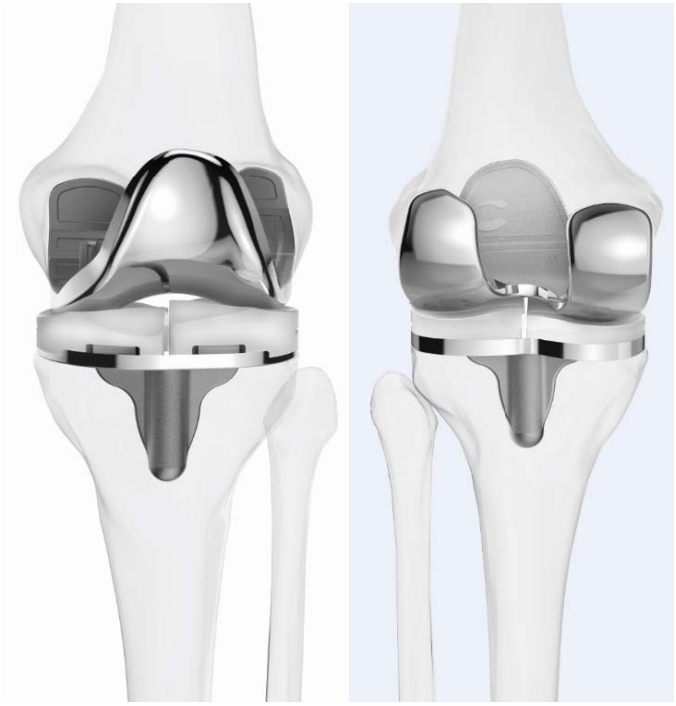


*Figure 2. The patient-specific iTotal implant.*

The tibial plateau system is also patient-specific, though there is less opportunity to preserve bone stock on the tibial plateau side. This is primarily due to the strength requirements for the metal base plate and a minimum polyethylene thickness requirement of 6mm. The shape of the tibial base plate is derived from the patient's natural geometry at the level of the planned tibial resection. The tray profile is 1.5mm smaller than the planned tibial cut to allow for minor rotational adjustments of the implant at the time of surgery. Separate medial and lateral inserts are provided, creating the opportunity to balance each compartment individually and correct any potential coronal leg malalignment. The articular geometry is derived from the femoral component. The medial insert geometry is slightly more conforming than the lateral insert. The coronal geometry utilizes a broad radius on both condyles, thus employing the round on round principle that has been shown to reduce contact stress. The coronal conformity is extremely high, yet yields a relatively low constraint design, bridging the best of both worlds. The coronal center to center of the condyles is individualized based on the patient's natural dimension. This individualization of the condyle center to center allows the contact geometry to be optimized for each patient and thus not suffer from compromises that 'off the shelf' implant have.

## Methods

In order to determine the amount of bone preservation the iTotal femoral component can yield when compared to conventional TKR, two different approaches were taken, ultimately producing a similar result. The first approach used real world data to conduct a comparative analysis of actual bone cuts made during implantation of both iTotal and competitive systems. The second approach used CAD software to prepare the patient for implantation and the prescribed resections were recorded.

### *Intraoperative Bone Resection Method*

Between June of 2011 to January of 2013, the thickness of bone removed from the distal medial femoral condyle, distal lateral femoral condyle, posterior medial femoral condyle, posterior lateral femoral condyle, the medial tibial plateau, and the lateral tibial plateau were recorded for every knee replacement performed by one surgeon. The combined thickness of the medial extension gaps was recorded by placing the distal medial femoral condyle on top of the medial tibial plateau and measuring the combined thickness of the two pieces of bone together as described by Hodge [5]. The thickness of the lateral extension gap, and the medial and lateral flexion gap were recorded in the same fashion. This data collection was part of an IRB approved study looking at bone resection and range of motion. The implant selection included 37 Zimmer posterior stabilized NexGen high flex TKRs, 32 Zimmer cruciate retaining NexGen high flex TKAs, and 100 ConforMIS cruciate retaining ITotal TKAs. The saw blade thickness was included in the reported bone measurements.

### *Virtual Bone Resection Method*

The second approach involved a virtual CAD simulation comparing standard off the shelf knee designs to a patient-specific implant system of a similar size. 15 CT scans were utilized from the ConforMIS database that had undergone the design process for the iTotal cruciate retaining knee system. The CT scan contains detailed data for the femoral head, 60mm of the knee joint, and the center of the ankle. The CT scans are converted to a point cloud for the hip, knee, and ankle and then converted into a CAD models. The CAD models were divided into three size groups. A knee with a femoral A-P length between 53 & 56mm was considered a small size, a knee with a femoral A-P length between 61 & 63mm was a medium size, and a knee

with a femoral A-P length between 74 & 76mm was considered a large size. The CT scans were selected so that there were 5 knees falling into each size group.

Radiographic sizing templates were obtained for 5 contemporary total knee systems that are in widespread use today. The radiographic templates include the Zimmer NexGen, the J&J DePuy Sigma, the Smith & Nephew Legion, the Smith & Nephew Journey, and the Stryker Triathlon implants.

The sagittal view of the radiographic template was traced using CAD software and the image was then scaled down to represent a 100% sized profile based on the scale factor provided on the radiographic template. The process was repeated on each size radiographic template. Verification that the scaling was accurate was determined by comparing the advertised anterior to posterior dimension of the particular implant to the generated image. All dimensions were confirmed to within 0.1mm.

The 15 CAD knee models were then processed through the proprietary design software that generates a patient-specific total knee femoral component, which has all of the bone cuts placed for optimal bone preservation; thus, every femoral component is different. A component of the design process includes resection of the bone model where the implant will be placed.

Once the patient-matched implant was designed, the implant and bone model were converted back into a CAD program to conduct the volumetric analysis. The bone resection for each patient-matched implant was then measured utilizing the volume function within the CAD program. The volume for each knee model was then recorded for the patient-specific implant. Figure 3 shows a typical CAD image of the bone resection removed from the bone model. The volume analysis CAD tool was used to determine the volume of bone removed.

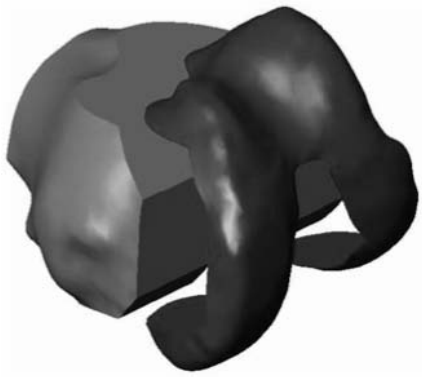


*Figure 3. Showing the bone resection removed during the CAD bone removal process.*

We then used a copy of the same CAD bone model that was used to produce the patient-specific knee component to conduct an analysis of the off-the-shelf knee components. Since the radiographic templates are 2-dimensional images, this analysis was conducted in the sagittal plane. Using the established size ranges and standard orthopedic guidelines, the competitive implants were best fit to the bone model. When choosing the correct location and size for competitive implants, the following rules were established for repeatability and to ensure simulation of proper placement was consistently established:

1. The posterior condylar surface of the competitive template aligns to the posterior surface of the bone.
2. No anterior notching of the femoral cortex occurs.
3. The anterior to posterior dimension of the radiographic image should be within 2mm of the bone model in the sagittal view.
4. The distal medial condylar surface of the competitive template image aligns to the distal surface of the bone.

When the best size and placement of the competitive implant was determined, the surfaces of the 2-dimensional implant overlay were used to remove the bone virtually from the bone model. This was repeated for each competitive implant using the volume tool to record the required resection value for each virtual surgery.

## Results

### *Results of Intraoperative Resection Analysis*

The results for the intraoperative bone resection method are tabulated in Tables 1, 2 and 3 below. Table 1 provides the results for the calculated average bone resections for all cases in the intraoperative bone resection method. P-values were determined using a two tailed student t-test. In all cases, the ConforMIS iTotal showed statistically significant less bone resection compared to both Zimmer NexGen products.

Table 2 provides the implant thicknesses for all of the implants used in the intraoperative bone resection method. The thickness for the Zimmer implants was obtained from technical literature provided by the manufacturer. The ConforMIS iTotal thickness was obtained from a pre-surgical planning guide provided by the manufacturer. With the exception of the lateral tibial thickness for the ConforMIS iTotal, all other implant thickness was greater for the Zimmer NeGen implants.

The amount of bone resected from the posterior medial femoral condyle more closely matched the amount of bone resected from lateral femoral condyles with the iTotal, as shown in Table 3. The lower values in the ConforMIS knees indicate that the femoral components in the iTotal knees more closely matched the femoral curvature, which is possible with the iTotal due to the differing heights of the medial and lateral polyethylene, along with the inbuilt distal and posterior femoral off-sets.

*Table 1: Average Thickness of Bone Resection in mm*

| Implant | # OF CASES | DISTAL MEDIAL FEMORAL RESECTION | DISTAL LATERAL FEMUR RESECTION | POSTERIOR MEDIAL FEMORAL RESECTION | POSTERIOR LATERAL FEMORAL RESECTION | MEDIAL TIBIAL RESECTION | LATERAL TIBIAL RESECTION | Medial Extension Gap Resection | Lateral Extension Gap Resection | Medial Flexion Gap Resection | Lateral Flexion Gap Resection |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Zimmer PS | 37 | 7.76 | 7.37 | 10.58 | 8.24 | 6.13 | 9.47 | 14.53 | 17.08 | 17.03 | 17.89 |
| Zimmer CR | 32 | 7.79 | 7.88 | 11.36 | 9.36 | 6.64 | 8.64 | 14.82 | 16.30 | 17.73 | 17.70 |
| Conformis CR | 100 | 6.43 | 6.40 | 6.99 | 5.87 | 3.03 | 7.41 | 9.78 | 13.29 | 10.17 | 12.66 |
| **Difference between Zimmer and Conformis** | | | | | | | | | | | |
| Zimmer – Conformis in mm | | 1.35 | 1.21 | 3.95 | 2.89 | 3.33 | 1.68 | 4.88 | 3.43 | 7.18 | 5.14 |
| Zimmer – Conformis in % | | 17.4% | 15.9% | 36.1% | 33.0% | 52.4% | 18.5% | 33.3% | 20.5% | 41.4% | 28.9% |
| Zimmer – Conformis p value | | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 |

*Table 2: Average Implant thickness in mm*

| Implant | DISTAL MEDIAL FEMORAL THICKNESS | DISTAL LATERAL FEMUR THICKNESS | POSTERIOR MEDIAL FEMORAL THICKNESS | POSTERIOR LATERAL FEMORAL THICKNESS | MEDIAL TIBIAL THICKNESS | LATERAL TIBIAL THICKNESS |
|---|---|---|---|---|---|---|
| Zimmer PS | 10 | 10 | 12 | 12 | 10.44 | 10.44 |
| Zimmer CR | 9 | 9 | 11 | 11 | 10.21 | 10.21 |
| Conformis CR | 7.93 | 7.78 | 6.39 | 6.27 | 8.4 | 10.68 |
| **Difference between Zimmer and Conformis** | | | | | | |
| Zimmer – Conformis in mm | 1.60 | 1.76 | 5.14 | 5.27 | 1.91 | -0.37 |
| Zimmer – Conformis in % | 16.8% | 18.4% | 44.6% | 45.7% | 18.5% | -3.6% |
| Zimmer – Conformis p value | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 | P<0.0001 | P=0.227 |

*Table 3: Difference in Posterior Femoral Resection in mm*

| | Posterior Medial femur – Posterior Lateral femur Resection | P value compared to Conformis |
|---|---|---|
| Zimmer PS | 2.34 | (p = 0.006) |
| Zimmer CR | 2.00 | (p = 0.044) |
| Conformis CR | 1.13 | |

### *Results of Virtual Analysis*

The tabulated results are reported in mm3. The size reported is the size of the competitive implant as defined by each manufacturer. The iTotal size is described by the serial number since each implant is unique and patient-specific. The data is tabulated and referenced by a serial number, which is a unique identifier for each original CT scan. Each serial number scan has bone resection data for the iTotal femoral component as well as the resection data for each of the competitive off-the-shelf femoral components from Zimmer, Smith & Nephew, DePuy, and Stryker.

- Results for all measurements are tabulated in Table 4. The average bone resection increase for all tested competitive implants compared to the iTotal, regardless of size, is 28%.
- For the small sized implant group, the sampled iTotal implants required less bone resection volumetrically compared to the 5 implant systems tested. The average bone resection increase for the competitive implants was 49%. The increase in bone resection ranged from 30% to 77%.
- For the medium sized implant group, the sampled iTotal implants required less bone resection volumetrically compared to the 5 implant systems tested. The average bone resection increase for the competitive implants was 25%. The increase in bone resection ranged from 11% to 46%.
- For the large sized implant group, the sampled iTotal implants required less bone resection volumetrically compared to the 5 implant systems tested. The average bone resection increase for the competitive implants was 12%. The increase in bone resection ranged from 7% to 18%.

*Table 4: Comparison of resected bone thicknesses obtained during CAD analysis. (mm)*

| **Small Size** | | | | | | |
|---|---|---|---|---|---|---|
| | **Size** | **A-P Length** | **Distal Medial Thickness** | **Distal Lateral Thickness** | **Posterior Medial Thickness** | **Posterior Lateral Thickness** |
| Zimmer NexGen | C | 54 | 9 | 9 | 9 | 9 |
| Johnson & Johnson PFC Sigma | 1.5 | 53 | 9 | 9 | 8 | 8 |
| Smith & Nephew Legion | 3 | 54.5 | 9.4 | 9.4 | 9.3 | 9.3 |
| Stryker Triathlon PS | 1 | 53 | 8.5 | 8.5 | 8.2 | 8.2 |
| Smith & Nephew Journey | 2 | 53 | 7.5 | 5.3 | 7.5 | 5.6 |
| Average for Standard Sample | - | 53.5 | 8.7 | 8.2 | 8.4 | 8.0 |
| ConforMIS: Serial #10768 | - | 55 | 6.0 | 6.0 | 6.3 | 6.6 |
| ConforMIS: Serial #3017 | - | 55 | 6.6 | 6.6 | 5.0 | 5.2 |
| ConforMIS: Serial #12601 | - | 56 | 7.0 | 7.0 | 6.5 | 5.6 |
| Average for ConforMIS Sample | - | 55.3 | 6.5 | 6.5 | 5.9 | 5.8 |
| Delta (Standard vs. ConforMIS) | | | -2.2 | -1.7 | -2.5 | -2.2 |
| **Medium Size** | | | | | | |
| | **Size** | **A-P Length** | **Distal Medial Thickness** | **Distal Lateral Thickness** | **Posterior Medial Thickness** | **Posterior Lateral Thickness** |
| Zimmer NexGen | E | 62 | 9 | 9 | 9.3 | 9.3 |
| Johnson & Johnson PFC Sigma | 3 | 61 | 9 | 9 | 8 | 8 |
| Smith & Nephew Legion | 5 | 62 | 9.5 | 9.5 | 9.3 | 9.3 |
| Stryker Triathlon PS | 4 | 62 | 8.5 | 8.5 | 8.5 | 8.5 |
| Smith & Nephew Journey | 5 | 62 | 9.5 | 7.0 | 9.5 | 7.4 |
| Average for Standard Sample | - | 61.8 | 9.1 | 8.6 | 8.9 | 8.5 |
| ConforMIS: Serial #10535 | - | 62 | 6.3 | 6.9 | 5.9 | 5.7 |
| ConforMIS: Serial #11399 | - | 62 | 6.9 | 7.7 | 5.9 | 5.6 |
| ConforMIS: Serial #11675 | - | 62 | 7.5 | 5.9 | 5.5 | 6.1 |
| Average for ConforMIS Sample | - | 62 | 6.9 | 6.8 | 5.8 | 5.8 |
| Delta (Standard vs. ConforMIS) | | | -2.2 | -1.8 | -3.1 | -2.7 |
| **Large Size** | | | | | | |
| | **Size** | **A-P Length** | **Distal Medial Thickness** | **Distal Lateral Thickness** | **Posterior Medial Thickness** | **Posterior Lateral Thickness** |
| Zimmer NexGen | H | 76 | 9 | 9 | 9 | 9 |
| Johnson & Johnson PFC Sigma | 6 | 74 | 10 | 10 | 9 | 9 |
| Smith & Nephew Legion | 8 | 75 | 9.5 | 9.5 | 11.3 | 11.3 |
| Stryker Triathlon PS | 8 | 75 | 8.5 | 8.5 | 8.6 | 8.6 |
| Smith & Nephew Journey | 9 | 75 | 11.5 | 9.0 | 11.5 | 9.4 |
| Average for Standard Sample | - | 75 | 9.7 | 9.2 | 9.9 | 9.5 |
| ConforMIS - Serial #7837 | - | 75 | 7.9 | 7.6 | 7.0 | 6.9 |
| ConforMIS: Serial #11863 | - | 75 | 6.7 | 8.9 | 7.6 | 6.3 |
| ConforMIS: Serial #12108 | - | 74 | 8.1 | 8.0 | 7.2 | 6.6 |
| Average for ConforMIS Sample | - | 74.7 | 7.6 | 8.2 | 7.3 | 6.6 |
| Delta (Standard vs ConforMIS) | | | -2.1 | -1.0 | -2.6 | -2.9 |

## Discussion

We hypothesized that a patient-specific implant would preserve more bone as compared to a standard off-the-shelf design, which we tested in actual practice through a measured resection technique. We then further tested this hypothesis volumetrically with a virtual application utilizing CAD imaging. Both methods of testing bone resection yielded similar results demonstrating that the patient-specific design preserved a significantly greater amount of bone during implantation.

There are limitations to this study. In the actual resection group, measurements include remaining cartilage, which is variable in each patient dependent on disease status. Given that these are all patients with significant disease requiring TKA and that the measurement methodology was consistent, the effect across groups is believed to be minimal. In the virtual resection group, access to actual CAD models of the standard implants would be the most precise method to measure volumetric bone resection. However, obtaining CAD models of these implants is not possible as all of the manufacturers consider this information proprietary. Utilizing the radiographic templates provided the most accurate secondary method.

The bone preserving aspect of the ConforMIS iTotal can be explained by four unique design features:

1. Each bone cut is individualized for each patient, meaning every single femoral cut is moved to the most peripheral location possible for a patient's unique geometry.
2. The 6th facet of the femoral component affords more peripheral resection and a stronger implant design, which in turn enables a thinner femoral component.
3. A stepped distal femoral cut preserves bone on the medial femoral condyle.
4. The restoration of the patient's own 'J' curve seems to allow the surgeon to resect less bone and still balance the knee joint accordingly.

Comparing the implant thickness of the ConforMIS iTotal to the high flex Zimmer Nexgen, the Zimmer implant demonstrates a substantially thicker posterior femoral implant in the high flex implant and, subsequently, a thicker posterior femoral bone resection.

The iTotal preserves more of the medial tibial plateau bone based on a tibial resection that is 2mm below the medial subcondural surface. The intraoperative bone resection method data shows that the ConforMIS iTotal has a slightly thicker lateral tibial implant thickness compared to the Zimmer NexGen. This is caused by the anatomically thicker lateral insert of the iTotal system that is dictated by preservation of the patient's natural 'J' curves and natural offset between the medial and the lateral femoral condyle of the patient. The iTotal femoral component relies on the elevated lateral polyethylene to tighten up the lateral flexion gap instead of externally rotating the femoral component as is often required in standard implants. This allows the femoral component to be better situated along the epicondylar axis.

## Conclusions

The ConforMIS iTotal patient-specific implants preserve significantly more bone than standard total knee replacements due to both the thickness of the required bone resections as well as the implant thickness being tailored to each patient's individual knee. This will translate to having more native bone available in the event that a patient requires a revision. The hope is that this patient-specific approach may enable revision to a standard primary total knee in the future rather than a revision implant. Alternately, in the event extensive osteolysis has developed, a patient-specific primary implantation may at least obviate the need for spacer and augments when the time comes for revision surgery.

The amount of bone resected from the posterior medial femoral condyle more closely matched the amount of bone resected from lateral femoral condyles with the iTotal as shown in Table 3. The lower values in the ConforMIS knees indicate that the femoral components in the iTotal knees more closely matched the femoral curvature, which is possible with the iTotal due to the differing heights of the medial and lateral polyethylene.

### *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.

**References**


1. S. Kurtz, K. Ong, E. Lau, F. Mowat, M. Halpern, Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030, J. Bone Joint Surg. Am. 89 (2007) 780-785.
2. M.A. Mont, T.M. Seyler, P.S. Ragland, R. Starr, J. Erhart, A. Bhave, Gait analysis of patients with resurfacing hip arthroplasty compared with hip osteoarthritis and standard total hip arthroplasty, J Arthroplasty 22 (2007) 100-108
3. D.L. Bartel, V.L. Bicknell, T.M. Wright, The effect of conformity, thickness, and material on stresses in ultra-high molecular weight components for total joint replacement, J. Bone Joint Surg. Am. 68 (1986) 1041-1051
4. R.A. Bojarski, R. Ketelholn, B.S. Parsley, J.E. Slamin, Optimizing knee femoral component strength and bone preservation with finite element analysis, 58th Annual Meeting of the Orthopedic Research Society (2012) Poster No. 1042
5. W.A. Hodge, Intraoperative assessment of bone cuts to guide surgical technique during total knee arthroplasty, J. Bone Joint Surg. Am. 89 (2007) 137-43

Reconstructive REVIEW
ISSN 2331-2262 (print) • ISSN 2331-2270 (online)
Volume 6, Number 1
April 2016
ORIGINAL ARTICLE http://dx.doi.org/10.15438/rr.6.1.132

# Experience with Modular Necks for Cemented Total Hip Arthroplasty

*Cameron H [1], McTighe T [2]*

## Abstract

This is a retrospective review of the senior surgeons series ( Model I and II) of using the same-cemented stem and modular neck design (R-120™ ) with the exception that the second series had an improved modular neck construct. Model I, 145 stems implanted between 2002 and 2005. Taper neck problems consisted of two neck trunnion fractures at the neck-stem junction and one modular neck dissociation at the modular junction. The stem was voluntary withdrawn from the market and redesigned to a more robust structure.

Model II, 188 cemented-stems were implanted between 2007 and 2011 by the senior author utilizing the same surgical technique. There have been no modular neck taper problems in this series. This paper will demonstrate that once a modular junction problem has been identified corrective action can be taken to resolve the problem. We believe that there is a benefit to a modular neck-stem junction cemented stem design, and that all modular junctions are not equal in design or function.

***Keywords****: cemented stem, modular neck, trunnion, taper junction*
***Level of Evidence****: AAOS Therapeutic Level III*

## Introduction

Cemented stems are still widely used in total hip arthroplasty (THA) especially in Europe, [1,2] however there are still concerns with adverse effects of bone cement in that biomaterial properties of the cement contribute to the pathologic state that separates this disease from other modes of mechanical loosening. This leads inevitably to the conclusion that Cement Disease does exist [3]. The senior author still uses cement in 15 to 20 percent of cases in Dorr type C bone.

Dislocations continue to be a significant problem in THA regardless of stem fixation method (cement or cementless) and in theory modular necks provide features to adjust both femoral offset and version orientation. The causes of dislocations, can be multi-factorial, and include: soft tissue laxity, malpositioned components resulting in mechanical impingement of component on component or component on fixed obstructions such as osteophytes. Encountering these factors, stability is often achieved at the expense of limb lengthening. [2,4,5]

Leg-length discrepancy after THA can present consid-

1 Hugh U. Cameron, MB, ChB, FRCSC
Sunnybrook, Health Science Centre, Holland Orthopaedic & Arthritic Centre, 43 Wellesley St. East, Toronto, ON Canada M4Y 1H1
2 Timothy McTighe, Dr. HS (hc), Joint Implant Surgery & Research Foundation, 46 Chagrin Shopping Plaza, #117, Chagrin Falls, OH 44022 US
(Direct reprint requests to Timothy McTighe)

erable difficulty for the patient, such as nerve palsy, low back pain, abnormal gait and dislocation with leg shortening. Patient dissatisfaction with leg-length discrepancy after THA is the most common reason for litigation against orthopaedic surgeons. [6]

Reconstruction of the joint mechanics (combined anteversion) to prevent impingement of the stem on the cup and avoidance of bone-on-bone requires correct restoration of hip neck length and femoral offset regardless of cement or cementless fixation [7,11]. The senior author's cement technique uses a broad stem design with a smaller cement mantel as compared to other European style stems (Exceter) so intraoperative version adjustment is limited.

Traditional cemented and cementless stems since the 1980s have had one common denominator that being a modular head neck taper junction. The success of a self-locking taper is influenced by the design of the taper, particularly the taper angle, the roughness, and the mating materials between the "male" and "female" components. The major advantage of modularity at this junction was to provide some level of adjustment of leg length or vertical height to reduce leg length discrepancy. Version and femoral offset were still difficult to adjust or fine-tune and as a result of growing acceptance of modularity the neck-stem junction seemed to be the next logical area of product development. [8].

Individual modular design parameters can offer significant advantages for both fit and fill of implant to bony structures while providing more options for intraoperative customization of joint mechanics and provide significant economic value in reducing levels of finished goods inventory. Now, amid reports of clinical incidents in which metal modular junctions have demonstrated fretting, corrosion, and pseudotumors, there is renewed interest as to what causes these junctions to fail. The recent fall in the use of modularity can be contributed primarily to concerns with inflammatory reactions to metal debris. Can failures be predicted or avoided? When a failure does occur what can be done about it? [9]

This paper will highlight one specific modular neck-stem junction that encountered mechanical failure with a first generation product. With observation and analysis of these failures, the manufacturer identified the problem and reintroduced an improved second-generation design. Since this second-generation prosthesis was introduced, there have been no failures in our cohort of patients since 2007. A 9-year follow up. (Figure 1)

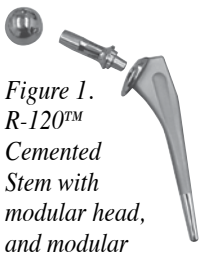


*Figure 1. R-120™ Cemented Stem with modular head, and modular indexable neck. (OTI, Encore, DJO Orthopaedics) (Courtesy JISRF archives)*

## Material and Methods

### *MODEL I*

Original cemented stem R-120™ by Osteoimplant Technology Inc. (OTI) Hunt Valley, Maryland, USA. Stem and modular necks are manufactured from CoCr alloy. The shape of the stem is trapezoidal with a large collar that provides for impaction and compression of the cement. The stem collar is made with a cavity where a self-locking taper and a positive indexing mechanism provide 12 different positions to ensure proper restoration of joint mechanics (Figure 2).

*Figure 2. Patented 12 indexable modular neck-stem junction allows for fine-tuning joint mechanics.*

145 stems were implanted between 2002 and 2005 in 50 males and 95 females. Mean age 72 with 2 patients under the age of 60. CoCr heads 28 or 32 mm were used and all cups were cemented polyethylene sockets. Surgical incision for both cohort of patients (Model I & Model II) was a Modified Anterolateral Watson-Jones Approach.

### *Neck Positions: (Figure 3, Tables 1, 2, 3)*

*Table 1.*

| Positions Varus/Valgus | Number of Cases | Percentage of Cases |
|---|---|---|
| 8º | 82 | 56% |
| 12º | 63 | 44% |

*Table 2.*

| Neck Length in mm | Number of Patients |
|---|---|
| 32 | 74 |
| 35 | 68 |
| 38 | 3 |

*Table 3.*

| Positions | Number of Cases | Percentage of Cases |
|---|---|---|
| Anteverted | 2 | 2% |
| Neutral | 57 | 39% |
| Retroverted | 86 | 59% |

*Figure 3. Modular Neck (CoCr), available in both 8º & 12º versions, 3 neck lengths 32mm, 35mm, & 38mm*

*• If the neck was not modular 61% would not have been in the optimal position resulting in increased risk for mechanical impingement as determined by intraoperative trial range of motion.*

### *MODEL II*

Maintained the same stem shape and dimensions with the exception of the modular neck stem junction. The failure mode of the model I design was basic fatigue failure caused by an under-designed modular junction.

188 stems implanted between 2007 and 2011 in 79 males and 109 females. Mean age 75 with 14 being younger than 65 years of age. All stem were cemented and all cups were non-cemented with porous press fit hemispherical components.

### *Neck Positions:*

*Table 2.*

| Neck Length in mm | Number of Patients |
|---|---|
| 32 | 104 |
| 35 | 37 |
| 38 | 2 |

*Table 3.*

| Positions | Number of Cases | Percentage of Cases |
|---|---|---|
| Anteverted | 3 | 2% |
| Neutral | 48 | 26% |
| Retroverted | 137 | 73% |

*• All femoral heads for both series were 28 mm or 32 mm diameter. 32 mm diameter is preferred head size with improved highly cross-linked polyethylene.*

### *Fatigue Failure*

Repeated cycling of the load causes metal fatigue. It is a progressive localized damage due to fluctuating stresses and strains on the material. Metal fatigue cracks initiate and propagate in regions where the strain is most severe. The process of fatigue failure consists of three stages [9,10]:

- Initial crack initiation
- Progressive crack growth across the part
- Final sudden fracture of the remaining cross section of the material

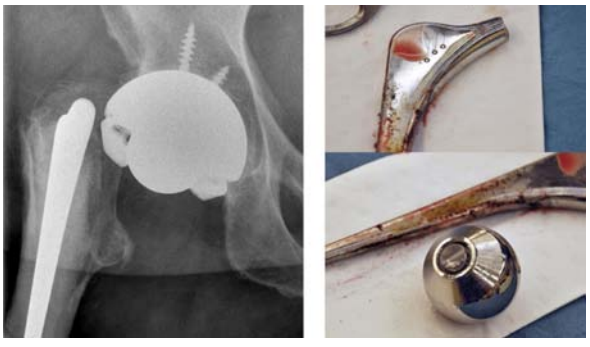


*Figure 4. Fractured Monoblock Femoral Neck in a Cemented Exeter Stem. (Source Unknown)*

*Figure 5. Pictures showing a fatigue failure of Model I in explanted OTI Co-Cr modular neck and close up of broken neck within the stem cone body. Stem, neck and head are Co-Cr. (Courtesy JISRF archives)*

All devices are subject to fatigue failure especially with the increased patient activity we are seeing today. There are reports of device failure regardless of material, and regardless of design style (monoblock, modular) (Figures 4, 5) [10].

### *Design Improvements*

Improvements made to this novel neck design, which increased surface contact by 40%, included specific size increases of the taper trunnion that improved mechanical strength from 520-700 lbs. to greater than 1,200 lbs. [9,10] (Figure 6)

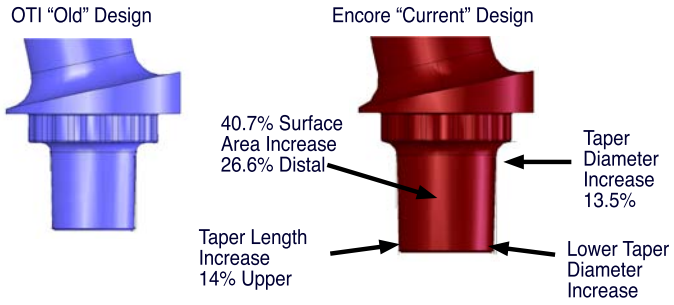



*Figure 6. Illustration showing modular taper improvements from the original OTI™ design to the Encore improvement design. (Courtesy JISRF Archives)*

## Results

### *MODEL I*

In our cohort of 145 patients with Model I of the R-120 modular neck cemented stem all femoral components, modular head, modular neck and stem were Co-Cr material. Five patients presented with sudden symptoms of generalized hip, groin and buttock pain and inability to ambulate. Evaluation demonstrated 3 patients with modular neck stem junction failures. 2 modular neck fatigue fractures as depicted in figure 5 and figure 7. One fractured neck was revised to a long cementless S-Rom® stem (Figures 7a, 7b).

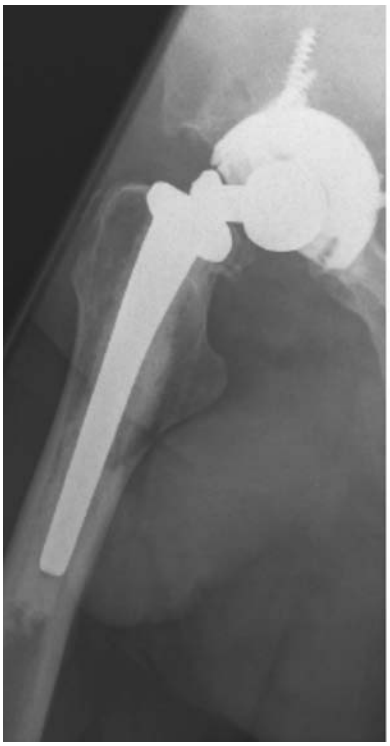


*Figure 7a. Fatigue failure of Model I R-120 modular neck cemented stem. (Courtesy Cameron)*

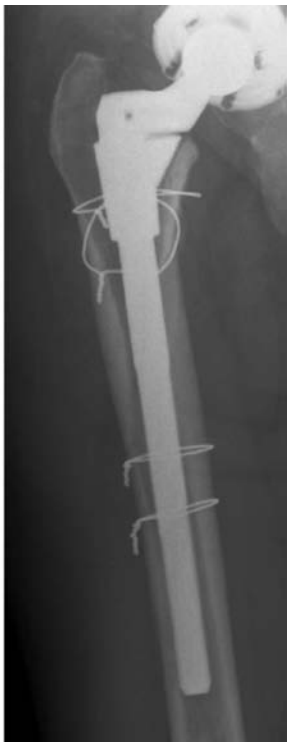


*Figure 7b. Revised Model I R-120 modular neck cemented stem with a long cementless S-Rom® stem. (Courtesy Cameron)*

Second fractured neck was revised with tap-out, tap-in technique as the Model II stem was identical in size and shape but had the improved modular neck-stem junction (Figures 8a, 8b).

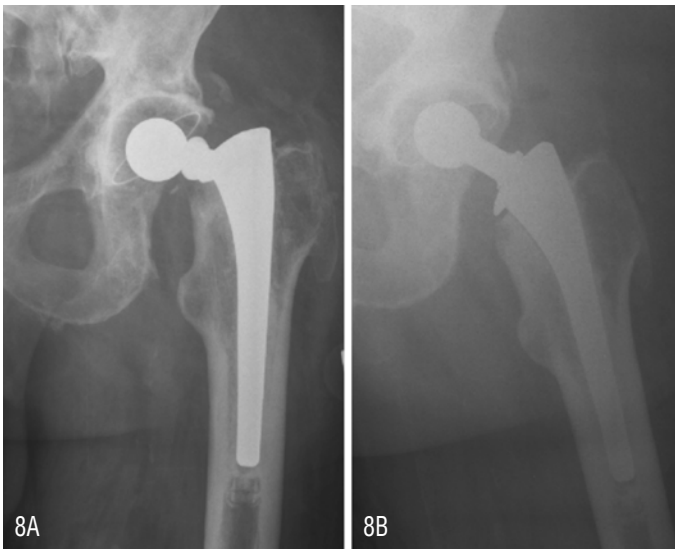



*Figure 8A & B. Fatigue failure on Model I R-120 modular neck revised to a improved Model II R-120 modular neck. Implanted with tap out tap in technique. (Courtesy Cameron)*

- Both modular neck fatigue failures had 35mm neck lengths with a long modular Co-Cr femoral head.
- 1 modular neck disassociation was revised to a cementless S-Rom stem.
- 1 stem removed during cup revision (stem was well fixed however senior author wanted more intraoperative options so stem was replaced with a S-Rom stem.)
- 1 late sepsis
- 2 bisphosphonate fractures (both were revised to a S-Rom stem)

Three modular neck-stem failures resulting in explantation represents a 2% revision rate. A total of 7 revisions out of our cohort of 145 represents an overall revision rate of 4%.

### *MODEL II*

In our cohort of 188 implanted stems with the Model II R-120 modular neck cemented stem there were no issues with the modular junction.

- Intraoperative complications, 6 calcar fractures all cerclaged
- 1 case of late infection (7 years)
- 1 dislocation at two years (closed reduction)
- 0 modular neck problems

## Discussion

The initial series of Model I had a modular neck complication in three cases out of 145 implanted stems, for a 2% complication rate of the modular neck-stem junction. The manufacture (OTI / Encore) based on additional reports voluntarily withdrew Model I from the market (2006). After additional testing and development an improved modular junction (Model II) was reintroduced (2007) with the same overall design features of the original R-120 cemented stem.

In our Model II series there has been no complications with the modular neck-stem junction out of 188 stems implanted.

Combined results on 333 stems implanted for modular neck-stem junction problems were three or a 1 % complication rate. Further in this combined series of using this novel modular junction design fabricated with the same material as the stem (CoCr) there have been no cases of delayed hypersensitivity and no cases of pseudo tumors.

The novel finding of indexing the neck orientation into a position of retroversion was 223 stems out of a combined total of 333 or 66.9%. This figure is similar to results of the usage of angled modular necks used with the ARC™ cementless neck-sparing stem in a review series of 1,790 stems implanted with 64% being positioned other than

neutral. [12]

Combined anteversion (CA) is the sum of cup anteversion and stem antetorsion (AT) that provides a parameter to asses the overall cup and stem alignment. However, there are a variety of studies published that recommend different implant orientation positions. [13] Lewinnek recommends 40º ± 10º of inclination and 15º ± 10º of Anteversion (AV). Biederman reported that AV of 15º and inclinations of 45º were associated with the lowest risk for dislocation. Wixson proposed cup positioning with inclination of 40-45º and AV of 17-23º with the posterior approach. [13]

So is there a definitive set of numbers for CV to reduce mechanical impingement and dislocation? Obtaining optimal implant positioning is critical for reducing these complications. Our experience with modular necks demonstrate that the best mechanism available is trial range of motion with trial implants. Modularity at the neck-stem junction provides for fine-tuning implant orientation prior to final implantation of definitive components. Often the final orientation of the femoral neck as determined by trial range of motion indicates a head-neck position of retroversion.

Modular neck design aids in fine-tuning joint mechanics after stem insertion, and allows for ease and access in case of revisions (Figure 9). [14]

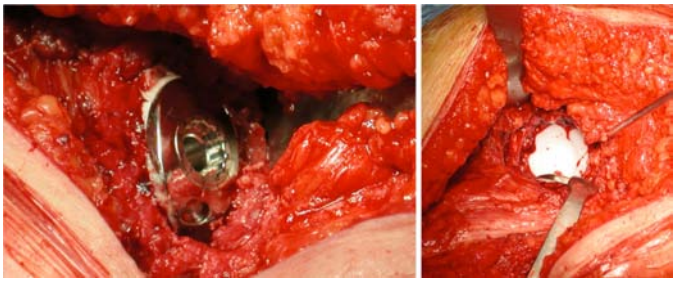


*Figure 9. Stem cemented in place without neck showing access to socket. (Courtesy Cameron)*

In our combined series of 333 stems implanted we had one postoperative dislocation for a dislocation rate of 0.3%. Two fatigue failures and one modular junction disassociation in Model I cohort of 145 stems implanted represent a failure rate of the modular junction of 2%. Combined series total of 333 stems implanted had a 0.9% complication rate of the modular neck-stem junction.

Manufacturers have all but discontinued modular neck-stem designs because of first generation failures. This, in our opinion, is a mistake. Fatigue failures of this first generation design have been identified and the redesigned modular junction (Model II) with 188 stems implanted between 2007 and 2011 have not demonstrated any modular junction complications. To give up on design concepts that have viable contributions to improve clinical outcomes is a failure in itself.

Our early pioneer surgeons (Sir John Charnley, Maurice Muller, Charles O. Bechtol, Charles Townley and others) did not surrender to early failures. They reviewed, learned and improved clinical surgical results for Total Hip Arthroplasty.

Product and surgical techniques need to be tightly controlled during the early stage of development and fully evaluated before general market release.

This improved model II R-120 cemented modular neck-stem junction has proven to be safe and efficient in our series and we encourage the manufacture not to give up on it (Figure 10).

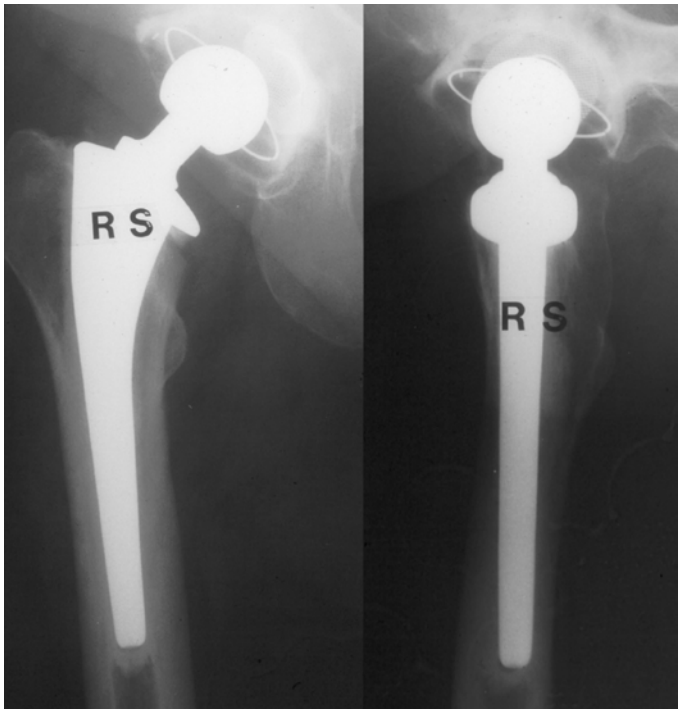



*Figure 10. Post-op of R-120 A/P X-rays cemented in place, neck in position one slightly retroverted. (Courtesy Cameron)*

## Conclusion

Modular neck-stem junctions have been under criticism as a result of fatigue failure and trunnion corrosion. Our experience with this novel modular junction has the benefit of being fabricated using the same material (Co-Cr) for the stem, neck and femoral head. Failures in the first generation demonstrated that the modular junction was under designed with regard to overall fatigue strength. This has been correct by increasing male taper diameter by 13.5%, taper length increase by 14% resulting in a 40.7% increase in surface area.

Further in this combined series of using this novel mod-

ular junction design fabricated with the same material as the stem (Co Cr) there have been no cases of delayed hypersensitivity and no cases of pseudo tumors.

The senior surgeon still uses this modular neck-stem cemented stem and will continue to follow these cases.

### *Disclosure Statement*

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.

**References**


1. Guerin S, and Jones C. Cemented Femur. In: Cashman J, Goyal N, Parvizi J, eds. The Hip: Preservation, Replacement and Revision. Baltimore, MD: Data Trace Publishing Company; 2015: 71-1 to 71-10.
2. Cameron H, Leslie, C, McTighe T. Design Considerations and Results for a Modular Neck in Cemented THA. Conference: The 21st Annual Conference of the International Society for Technology in Arthroplasty, At Seoul, Korea. Poster Exhibit DOI: http://dx.doi.org/10.13140/RG.2.1.1893.6082
3. Jones LC, Hungerford DS. Clin Orthop Relat Res. Cement disease. 1987 Dec;(225):192
4. McTighe T, Keggi K, Reynolds HM, Smit M, Keggi J, Cameron HU, Stulberg B. Design Considerations for a Modular Neck in Total Hip Arthroplasty. Conference: OARSI Annual Meeting 2003, Volume: Poster Exhibit DOI: http://dx.doi.org/10.13140 / RG.2.1.1346.1606
5. Benedetti MG, Catani F, Benedetti E, Berti L, Di Gioia A, and Giannini S. To what extent does leg length discrepancy impair motor activity in patients after total hip arthroplasty? International Orthopaedics (SICOT) (2010) 34:1115 –1121 / DOI http://dx.doi.org/10.1007/s00264-009-0855-5
6. Clark CR, Huddleston HD, Schoch EP, and Thomas BJ. Leg-Length Discrepancy After Total Hip Arthroplasty. J Am Acad Orthop Surg 2006; 14: 38-45
7. Clark CR, Huddleston HD, Schoch EP, and Thomas BJ. Leg-Length Discrepancy After Total Hip Arthroplasty. J Am Acad Orthop Surg 2006; 14: 38-45
8. McTighe T, Trick L, and Koeneman JB. Design Considerations for Cementless Total Hip Arthroplasty. In book: ENCYCLOPEDIC HANDBOOK OF BIOMATERIALS AND BIOENGINEERING, Edition: Part B: Applications Volume I 1995, Publisher: Marcel Dekker, Inc., pp. 3 to 43. DOI: http://dx.doi.org/10.13140/RG.2.1.2919.0240
9. McTighe T, Brazil D, Clarke I, Keppler L, Keggi J, Tkach T, and McPherson E. Metallic Modular Taper Junctions in Total Hip Arthroplasty. JISRF • Reconstructive Review • Vol. 5, No. 2, July 2015. DOI: http://dx.doi.org/10.15438/rr.5.2.108
10. Keggi K, Keggi J, Kennon R, Tkach T, et. al. Within Any Important Issue, There are Always Aspects No One Wishes to Discuss" – Femoral Component Failure. Conference Poster, ISTA, September 2006. DOI: http://dx.doi.org/10.13140/RG.2.1.4779.6329
11. Lawrence D. Dorr, Aarner Malik, Manish Dastane and Zhinian Wan, Combined Anteversion Technique for Total Hip Arthroplasty. Clin Orthop Relat Res. 2009 Jan; 467(1): 119–127. Published online 2008 Nov 1.doi: http://dx.doi.org/10.1007/s11999-008-0598-4
12. Timothy McTighe, John Keggi, Louis Keppler et al. The First 1,200 (1,790) U.S. Short Curved Neck Stabilized Stems. ISTA Annual Conference, October 2012, Sydney, Australia. DOI: http://dx.doi.org/10.13140/RG.2.1.4431.0168
13. Shigeo Fukunishi, Tomokazu Fukui, Shoji Nishio et. al. Combined Anteversion of the Total Hip Arthroplasty Implanted with Image-Free Cup Navigation and without Stem Navigation. Orthopedic Reviews 2012; volume 4:e33 doi: http://dx.doi.org/10.4081/or.2012.e33
14. McTighe T, and Tkach T. Design Considerations for Modular Junctions. Conference: Research on Modularity Hip Scientific Meeting sponsored by Global Orthopaedic Technology Oct. 9-10, 2009, At Gold Coast, Australia, Volume: Oral Paper. DOI: http://dx.doi.org/10.13140/RG.2.1.2957.5441

Reconstructive REVIEW
ISSN 2331-2262 (print) • ISSN 2331-2270 (online)
Volume 6, Number 1
April 2016
CASE REPORT
http://dx.doi.org/10.15438/rr.6.1.141

# Stress Analysis of a Burch-Schneider Cage in an Acetabular Bone Defect: A Case Study

*Plessers K [1], Mau H [2]*

## Abstract

Burch-Schneider cages are often used for the treatment of acetabular bone defects. In several clinical studies these cages have shown good mid- to long-term results. However, a higher failure rate has been reported in large Paprosky IIIB defects compared with smaller Paprosky II-IIIA defects. This study aims to investigate the effect of cage support on cage failure by means of finite element analysis. The Von Mises stresses in both the implant and the bone are analyzed for a Burch-Schneider cage used in the following scenarios: (1) a large acetabular bone defect, (2) a small acetabular bone defect and (3) a large acetabular bone defect in combination with a reinforcement plate. The results show that implant and bone stresses are higher in the large defect (99th percentile of 146.6 and 73.5 MPa respectively) than in the small defect (99th percentile of 43.9 and 47.9 MPa respectively). Adding a reinforcement plate to posteriorly support the cage decreases the stresses but not fully compensates for the missing bone support (99th percentile of 93.1 and 55.3 MPa respectively). Since high stresses cause an increased risk for fatigue failure and implant loosening, sufficient implant support is required to reduce the risk of cage failure.

***Keywords**: Burch-Schneider cage, finite element analysis, Von Mises stresses, acetabular defect, bone support*
***Level of Evidence**: AAOS Therapeutic Level IV*

## Introduction

Implant fracture and aseptic loosening are common failure modes in hip arthroplasty. They can be caused by screw breakage, bone resorption, fractures and infections [1,2]. Besides pain, implant failure often leads to an enlargement of the bone defect. To restore the function of the hip, a complex revision surgery is required. Removing the old components and reconstructing the enlarged bone defect may involve a high complication risk for the patient and a high financial cost for the medical institution. Therefore, a durable surgical treatment should be selected for

1 Katrien Plessers, MSc
Materialise N.V., Leuven, Belgium
(Direct reprint requests to Katrien Plessers)
2 Dr. Hans Mau
Helios Endo-Klinik Hamburg, Hamburg, Germany

each patient from the beginning.

In the last 30 years, the Burch-Schneider cage has been widely used to reconstruct acetabular bone defects [2]. This type of anti-protrusio cage is often used to bridge bone defects with a perforation of the medial wall. The Burch-Schneider cage is made of pure titanium (Protasul Ti) [1] and consists of a hemispherical shell with an inferior and a superior flange. The inferior flange is impacted into a prepared slot in the ischial bone while the superior flange is fixed with screws to the iliac bone. The impaction into the ischium assures a rotationally stable implant. For a better bone contact of the implant, the flanges of the cage can be preoperatively bent according to the anatomical shape of the bone. After insertion, a cup insert is cemented into the hemispherical shell of the cage [1,2].

The Burch-Schneider cage has shown good results at mid- and long-term in the treatment of acetabular bone defects. Regis et al. [3] reported a survival rate of 80% (52/65) for an average of 14.9 years follow-up. Sembrano et al. [4] demonstrated a 5-year loosening-free survival rate of 80.7% for 72 cage reconstructions. Lamo-Espinosa et al. [5] showed a 79% survival rate at 10 years after implantation in 16 hips. The study of Hsu et al. [6] indicated a 5-year survival rate of 76% in 31 cage reconstructions. However, these studies do not separately report results for defects of different Paprosky classification [7]. Other clinical studies on the contrary show a higher failure rate in bone defects of class Paprosky IIIB compared to smaller bone defects: Perka et al. [8] found a direct correlation between Burch-Schneider cage migration and posterior column defects in increasing Paprosky stages. Udomkiat et al. [9] determined that Burch-Schneider cage migration also correlated with the amount of superior support from the ilium. Paprosky et al. [10] reported a failure of 7/11 (63.6 %) ilioischial acetabular systems in type IIIB defects, because insufficient host bone was available to support a cage.

To improve cage stability in large and uncontained bone defects, surgeons may use a defect-filling structure that provides additional support to a Burch-Schneider cage. Structural allografts are commonly used in defects with severely degraded acetabular bone stock [6,11,12,13]. A disadvantage of allografts is the complex surgical procedure they require to shape and fit the allograft to the bone defect. Moreover, without sufficient host bone, allografts may degrade or collapse due to a change in mechanical stimuli [3,9,10,13]. Another commonly used defect-filling structure is trabecular metal [13,14]. Trabecular metal augments are made of porous tantalum and are available in different shapes. However, additional reaming of the bone defect may be required to achieve a good fit of the augment. As an alternative to the Burch-Schneider cage and the required support structures, patient-specific implants are increasingly used for the treatment of large acetabular bone defects. Patient-specific implants have already proven their added-value in short-term patient outcome [15]. These implants can be designed as a cup with two or three flanges and a porous defect-filling scaffold. The personalized fit between the scaffold and the bone provides a large contact area for enhanced support and stability of the implant [16]. However, patient-specific implants are more expensive than standard available implants and are therefore limited to patients with few other options.

In general, implant stresses are known to have an impact on the implant's fatigue lifetime [17]. If the Von Mises stresses in an implant exceed the fatigue limit, the implant has an increased risk for breakage or fatigue failure after consecutive loading and unloading. Bone stresses on the other hand play a role in the bone remodeling process which subsequently may induce implant loosening [18,19]. If the stress distribution in the bone deviates from the natural and healthy mechanical conditions, the bone has an increased risk for bone degradation [20,21]. To evaluate implant designs and analyze implant performance under different loading conditions, finite element (FE) methods have been widely used [22,23,24].

The goal of this study is to analyze if the effect of Burch-Schneider cage support on the implant and bone stresses can be demonstrated by means of finite element analysis (FEA). Therefore, four scenarios are evaluated: first of all, the cage behavior is analyzed in a clinical case of a patient having a large acetabular bone defect of type Paprosky IIIB. Secondly, the Burch-Schneider cage is evaluated in a smaller acetabular bone defect which provides more bone support to the cage. Thirdly, a scenario is analyzed in which the large acetabular bone defect is treated with a cage in combination with a reinforcement plate. Surgeons may add such a reinforcement plate to provide some additional support to the cage. Reinforcement plates are mainly used in large uncontained bone defects or dissociations in order to avoid cage instability [11,12,25]. Finally, a healthy pelvis is evaluated as a reference model.

## Materials and methods

The following finite element models were created in Abaqus (Simulia, 3DS, Paris, France):

1. Large defect model: a Burch-Schneider cage used in a large acetabular bone defect. The large bone defect only provides support to the flange regions of the cage and to a small part of the cup.
2. Small defect model: a Burch-Schneider cage used

in a small acetabular bone defect. Additional bone behind the cup enlarges the contact region between cage and bone.

3. Plate model: a Burch-Schneider cage used in a large bone defect, but in combination with a reinforcement plate. Except for the plate, this model is exactly the same as the large defect model. The added reinforcement plate provides support to the posterior rim of the cage.
4. Healthy model: a model of a healthy hemi-pelvis that acts as a reference model.

### *1. Geometry models*

The bone geometry of a 60-year old female patient (70 kg) was used in the finite element models. The left hemi-pelvis of the patient was dissociated and the acetabulum was completely degraded [26]. The defect was classified as Paprosky IIIB by the patient's surgeon. The 3D geometry of the bone (Figure 1a) was segmented from the CT scan by the image processing software Mimics (Materialise N.V., Leuven, Belgium) [27]. In addition to the severely defected hemipelvis, a bone model with a small defect was artificially created. The artificial bone model was generated by manually decreasing the bone defect of the patient (Figure 1b) in the 3d modeling software 3-matic (Materialise N.V., Leuven, Belgium). The acetabular cup was partially reconstructed by focusing on the geometry of a healthy pelvis. Furthermore, a healthy bone model was generated by reconstructing the severe bone defect of the patient with a statistical shape model (Figure 1c). Thus, three different bone models were developed, including a hemi pelvis with a large defect, a hemi-pelvis with a small defect and a hemi-pelvis with no defect.

In order to model the implant geometry, a Burch-Schneider cage of size 62mm (Zimmer Biomet, Warsaw, Indiana) and a 3.5mm dynamic compression plate (DePuy Synthes, Warsaw, Indiana) were optically scanned and processed by the software program 3-matic (Materialise N.V., Leuven, Belgium). The position of the Burch-Schneider cage on the bone was indicated by an experienced surgeon and was the same in the three models. The reinforcement plate was only present in the plate model. The surgeon positioned the plate on the posterior bone so that it provided support to the posterior rim of the cage (Figure 2).

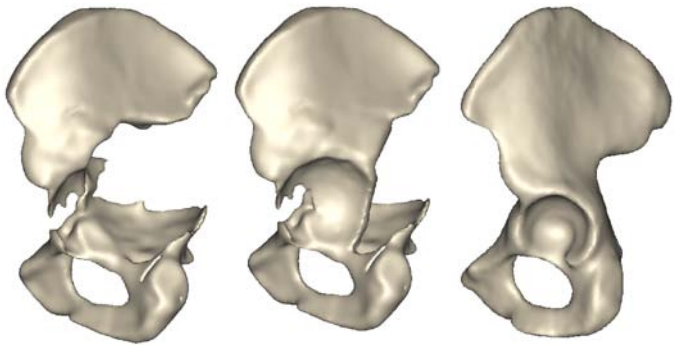



*Figure 1. (a) Hemi-pelvis of a patient with a Paprosky IIIB defect, (b) hemi-pelvis with an artificial defect derived from (a), and (c) healthy hemi-pelvis which is the reconstruction of (a).*

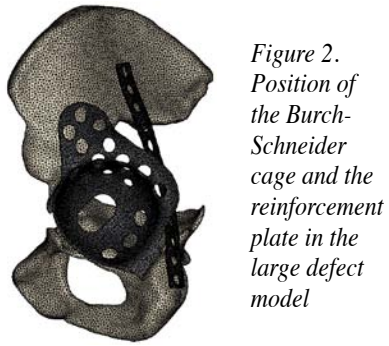


*Figure 2. Position of the Burch-Schneider cage and the reinforcement plate in the large defect model*

### *2. FE model*

The finite element modeling approach was based on studies in literature [28,29,30,31]. As in these studies, a linear and static approach was applied. The bone geometries were meshed with linear tetrahedral elements of 2mm average edge length [28]. Each bone was modeled as a trabecular inner region (volume elements) with an E-modulus of 300MPa and a 1mm cortical outer shell (shell elements) with an E-modulus of 17GPa [28]. The Burch-Schneider cage and the reinforcement plate were both modeled with linear tetrahedral elements of 1 mm average edge length and an E-modulus of 110GPa (titanium). The contacts between plate and bone, and cage and bone were modeled as bonding contacts. In bonded contacts, no displacements are allowed in axial and tangential directions. This way of modeling the implant-bone interface is a simplification of the actual screw connection between bone and both implants. The screws on the cage and the plate only partially inhibit the tangential motions, mostly in the regions of the screws. However, since a compressive force is acting on the cage, the tangential motions will be limited and the connection can be approximated by a bonding contact.

All models were rigidly fixed at the pubic symphysis and the sacroiliac joint of the hemi-pelvis, indicated in Figure 3 [28,32,33]. According to Bergmann et al. [34], an average hip joint experiences a peak load of 238% of body weight during normal walking. Therefore in all models a static load of

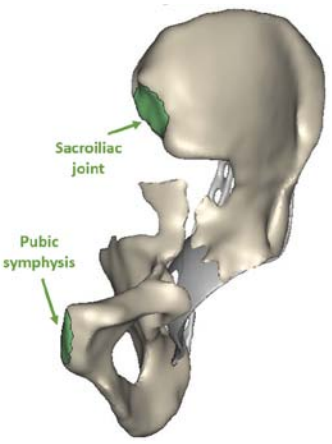



*Figure 3. Illustration of the fixed boundary regions*

1800N (≈ 2.5 times body weight) was applied in the cup of the Burch-Schneider cage or in the acetabulum. The force was applied along the vector (0.13, -0.12, 0.98) in the pelvic coordinate system, which is in accordance with Bergmann et al. [34]

### *3. FE stress analysis*

To evaluate the failure risk of the Burch-Schneider cage, the Von Mises stresses in the cage and in the cortex were calculated. The fatigue strength of pure titanium for 10^7 cycles is 350-450MPa [35,36,37,38], depending on the precise material characteristics and the production process of the implant. If the maximum Von Mises stress in the cage approximates this fatigue stress, the cage has a higher risk for fatigue failure. The risk for bone degradation on the other hand increases when the stress distribution in the cortex deviates from the natural and healthy mechanical conditions [20,21]. The Von Mises stresses in the healthy model were analyzed as a reference value.

## Results

Figures 4 and 5 show the stress distributions by color plots and cumulative graphs for the four models. The Von Mises stresses are highest in the large defect model and lowest in the small defect model. To exclude high peak stresses caused by modeling errors, the 99th percentile value is reported for each model instead of the maximum value (Table 1). The large defect model results in a 99th percentile value of 146.6 MPa in the cage and 73.5 MPa in the cortex. The small defect model shows a 99th percentile value of 43.9 MPa and 47.9 MPa in the cage and the cortex respectively. Adding a reinforcement plate to the large acetabular bone defect in the plate model gives a 99th percentile value of 93.1 MPa in the cage and 55.3 MPa in the cortex. In the healthy model, only the cortex stresses are assessed leading to a 99th percentile value of 37.6 MPa. The latter is used as a reference value for the stress distribution in a healthy pelvis.

The stresses in the cage are highest in the rim and the

*Table 1: 99th percentile values of the Von Mises stress in the cage and the cortex*

| Model | Cage stresses [MPa] | Cortex stresses [MPa] |
|---|---|---|
| Large defect | 146.6 | 73.5 |
| Small defect | 43.9 | 47.9 |
| Plate | 93.1 | 55.3 |
| Healthy | - | 37.6 |

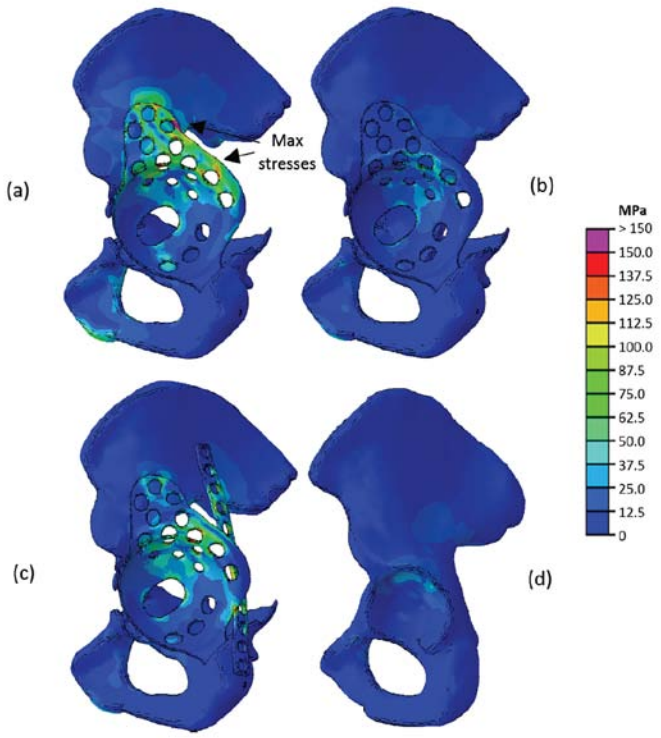



*Figure 4: Stress distribution plots of (a) a Burch-Schneider cage in a large acetabular bone defect, (b) a Burch-Schneider cage in a small acetabular bone defect, (c) a Burch-Schneider cage in a large acetabular bone defect in combination with a reinforcement plate and (d) a healthy pelvis*

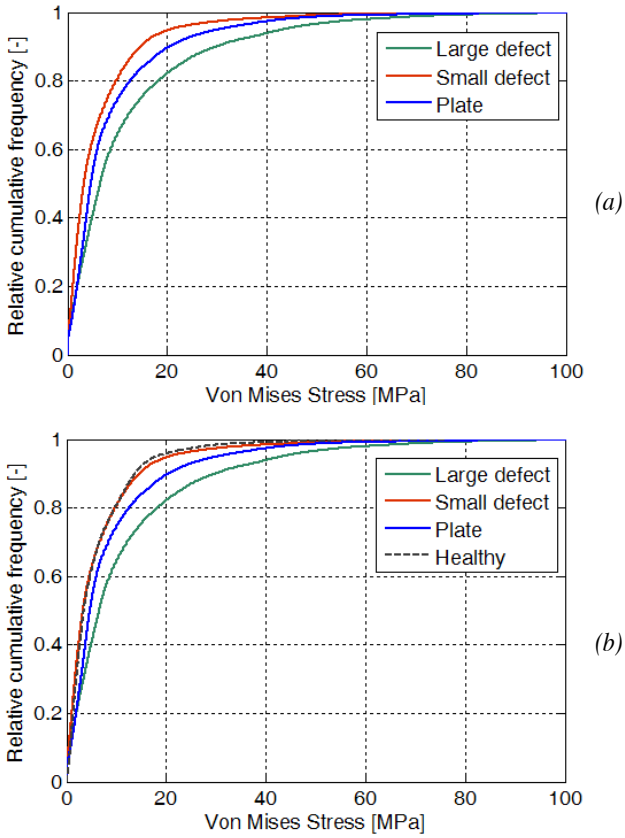



*Figure 5: Cumulative stress distribution plots in (a) the cage and (b) the cortex.*

iliac flange (indicated on Figure 4a). However, for all models the 99th percentile stresses in the cage are still within the fatigue limit of pure titanium. The large defect model shows the highest stress values. The 99th percentile cage stress in the large defect model is respectively 234% higher than the small defect model, and 58% higher than the plate model. Adding a reinforcement plate in the large bone defect reduces the 99th percentile stress in the cage by 37%. Furthermore, the cortex stresses in the large defect model, the small defect model and the plate model show a deviation of respectively 95%, 27% and 47% with respect to the healthy scenario. The small defect model thus most closely approaches the healthy pelvis.

## Discussion

Selecting a suitable treatment option for each patient is essential in order to avoid implant failure in hip arthroplasty. Clinical studies have reported that support beneath a Burch-Schneider cage has a large effect on the implant survival rate [6,8,9,10]. This study investigated if the effect of Burch-Schneider cage support on the implant and bone stresses can be demonstrated by means of finite element analysis.

The FEA results indicated that support beneath the cage has a large effect on the stresses in the implant and the bone. A large support area beneath the cage limited the presence of peak stresses and resulted in a more equal stress distribution. The large bone defect in this study only provided support to the flange regions of the cage and to a small part of the cup. This limited support resulted in high stresses in both the implant and the bone. In the small defect model, the additional bone behind the cup enlarged the support region and so improved the force distribution. As a consequence, stress concentrations and peak stresses were reduced. In the plate model, little host bone was available to support the cage, but an extra reinforcement plate provided support to the posterior rim of the cage. This extra support protected the cage from excessive bending moment and reduced the high stress concentrations that were present in the large defect model. However, the additional support of the reinforcement plate did not fully compensate for the missing bone support.

Although the Von Mises stresses in the cage were below the fatigue limit for all models, some additional aspects should be considered. First of all, the current FE analyses only calculated the peak stresses during normal walking with a patient weight of 70kg. For heavier patients and more demanding activities, like running or stumbling, the loads on the pelvis can be 3-6 times as high [34]. Since this is a linear analysis, the stresses in the implant and the bone would increase in proportion with the applied force. Secondly, the fatigue performance of the cage also worsens when the surgeon preoperatively bends the flanges of the cage to fit the shape of the patient's bone. Plastic deformation in the flanges decreases the fatigue strength and therefore additionally reduces the fatigue lifetime of the cage. So despite the acceptable Von Mises stresses, the simplicity of the current FE models makes it difficult to make conclusions about the actual fatigue lifetime. However, the FE analysis does indicate that the large defect model has a higher risk for fatigue failure than the other two models. A cage should thus be sufficiently supported in order to avoid fatigue failure.

Besides implant stresses, cage failure was investigated by evaluating bone stresses. A change in mechanical loading of the bone with respect to the healthy situation affects the bone remodeling process [20,21]. The bone surrounding the implant may degrade which subsequently leads to implant loosening. The deviation from the healthy scenario was largest for the large defect model. This indicates that the large defect model has the highest risk for bone degradation and implant loosening.

The outcome of this study corresponds with the findings in literature: sufficient support should be available for long-term stability of a Burch-Schneider cage [6,8,9,10]. These findings were based on the relatively high failure rates of cages in Paprosky IIIB defects compared to smaller defects. Therefore, in large and uncontained bone defects defect-filling structures such as bone allografts and trabecular metal can be used to improve the cage support. Besides, patient-specific implants have already shown successful results in the treatment of large and challenging bone defects and should be considered as a potential alternative to the Burch-Schneider cage.

The main limitation of the current study is that it only involves a numerical analysis. Although some assumptions have been made regarding material properties, loading conditions and boundary conditions, the finite element results are in good agreement with other FEA results in literature. Philips et al. [30] describes an FE model of a healthy pelvis with loading and boundary conditions similar to the ones used in our models. The authors observe high stress concentrations at the superior rim of the acetabulum and towards the sacro-iliac joint with a maximum around 70MPa. Anderson et al. [28] reported a subject-specific finite element analysis of a healthy pelvis resulting in Von Mises stresses in the range of 0-44MPa for the cortex. The Von Mises stress distribution in our healthy model agrees with the results described in these previous stud-

ies. Future finite element studies are required to investigate the effect of patient-specific modeling parameters and to improve the current modeling approach, specifically the boundary conditions, loading scenario and material properties. Moreover, experimental tests should be performed as a validation of the final simulation results.

## Conclusion

The FEA results showed that support beneath the Burch-Schneider cage has a large effect on the stresses in both the implant and the bone. A large support area beneath the cage limits the presence of peak stresses and results in a more equal stress distribution. Specifically, in a large Paprosky IIIB acetabular bone defect the stresses in implant and bone were higher than in a small bone defect. Adding a reinforcement plate to posteriorly support the cage in the large bone defect decreased the stresses but did not fully compensate for the missing bone support. The high implant and bone stresses that occurred due to limited support regions caused an increased risk for fatigue failure and implant loosening. Hence to reduce the risk of implant failure, the surgeon should strive for optimal support.

### *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.

**References**


1. J. Gallo and A. V. Florchutz, "Burch-Schneider cage fracture: a case report," Biomed. Pap.-PALACKY Univ. OLOMOUC, vol. 149, no. 2, p. 281, 2005.
2. Y. Kosashvili, O. Safir, D. Backstein, D. Lakstein, and A. E. Gross, "Salvage of Failed Acetabular Cages by Nonbuttressed Trabecular Metal Cups," Clin. Orthop. Relat. Res., vol. 468, no. 2, pp. 466–471, Feb. 2010.
3. D. Regis, A. Sandri, and I. Bonetti, "Acetabular Reconstruction with the Burch-Schneider Antiprotrusio Cage and Bulk Allografts: Minimum 10-Year Follow-Up Results," BioMed Res. Int., vol. 2014, pp. 1–9, 2014.
4. J. N. Sembrano and E. Y. Cheng, "Acetabular Cage Survival and Analysis of Factors Related to Failure," Clin. Orthop., vol. 466, no. 7, pp. 1657–65, Jul. 2008.
5. J. Lamo-Espinosa, J. D. Clemente, P. Díaz-Rada, J. Pons-Villanueva, and J. R. Valentí-Nín, "The Burch-Schneider antiprotrusio cage: medium follow-up results," Musculoskelet. Surg., vol. 97, no. 1, pp. 31–37, Dec. 2012.
6. C.-C. Hsu, C.-H. Hsu, S.-H. Yen, and J.-W. Wang, "Use of the Burch–Schneider cage and structural allografts in complex acetabular deficiency: 3- to 10-year follow up," Kaohsiung J. Med. Sci., 2015.
7. W. G. Paprosky, P. G. Perona, and J. M. Lawrence, "Acetabular defect classification and surgical reconstruction in revision arthroplasty: A 6-year follow-up evaluation," J. Arthroplasty, vol. 9, no. 1, pp. 33–44, Feb. 1994.
8. C. Perka and R. Ludwig, "Reconstruction of segmental defects during revision procedures of the acetabulum with the Burch-Schneider anti-protrusio cage," J. Arthroplasty, vol. 16, no. 5, pp. 568–574, Aug. 2001.
9. P. Udomkiat, L. D. Dorr, Y.-Y. Won, D. Longjohn, and Z. Wan, "Technical factors for success with metal ring acetabular reconstruction," J. Arthroplasty, vol. 16, no. 8, pp. 961–969, Dec. 2001.
10. W. G. Paprosky, S. S. Sporer, and B. P. Murphy, "Addressing Severe Bone Deficiency: What a Cage Will Not Do," J. Arthroplasty, vol. 22, no. 4, Supplement, pp. 111–115, Jun. 2007.
11. D. J. Berry, D. G. Lewallen, A. D. Hanssen, and M. E. Cabanela, "Pelvic Discontinuity in Revision Total Hip Arthroplasty*," J Bone Jt. Surg Am, vol. 81, no. 12, pp. 1692–1702, Dec. 1999.
12. J. B. Stiehl, R. Saluja, and T. Diener, "Reconstruction of major column defects and pelvic discontinuity in revision total hip arthroplasty," J. Arthroplasty, vol. 15, no. 7, pp. 849–857, oktober 2000.
13. T. J. Mäkinen, S. G. Fichman, E. Watts, P. R. T. Kuzyk, O. A. Safir, and A. E. Gross, "The role of cages in the management of severe acetabular bone defects at revision arthroplasty," Bone Jt. J, vol. 98-B, no. 1 Supple A, pp. 73–77, Jan. 2016.
14. S. M. Sporer and W. G. Paprosky, "The Use of a Trabecular Metal Acetabular Component and Trabecular Metal Augment for Severe Acetabular Defects," J. Arthroplasty, vol. 21, no. 6, Supplement, pp. 83–86, Sep. 2006.
15. M. Baauw, G. G. van Hellemondt, M. L. van Hooff, and M. Spruit, "The accuracy of positioning of a custom-made implant within a large acetabular defect at revision arthroplasty of the hip," Bone Jt. J., vol. 97, no. 6, pp. 780–785, 2015.
16. D. K. DeBoer, M. J. Christie, M. F. Brinson, and J. C. Morrison, "Revision Total Hip Arthroplasty for Pelvic Discontinuity," J. Bone Jt. Surg., vol. 89, no. 4, pp. 835–840, Apr. 2007.
17. T. Villa, F. Migliavacca, D. Gastaldi, M. Colombo, and R. Pietrabissa, "Contact stresses and fatigue life in a knee prosthesis: comparison between in vitro measurements and computational simulations," J. Biomech., vol. 37, no. 1, pp. 45–53, Jan. 2004.
18. D. Lacroix, A. Chateau, M.-P. Ginebra, and J. A. Planell, "Micro-finite element models of bone tissue-engineering scaffolds," Biomaterials, vol. 27, no. 30, pp. 5326–5334, Oct. 2006.
19. C. Boyle and I. Y. Kim, "Comparison of different hip prosthesis shapes considering micro-level bone remodeling and stress-shielding criteria using three-dimensional design space topology optimization," J. Biomech., vol. 44, no. 9, pp. 1722–1728, Jun. 2011.
20. F. Schmidutz, Y. Agarwal, P. E. Müller, B. Gueorguiev, R. G. Richards, and C. M. Sprecher, "Stress-shielding induced bone remodeling in cementless shoulder resurfacing arthroplasty: a finite element analysis and in vivo results," J. Biomech., vol. 47, no. 14, pp. 3509–3516, Nov. 2014.
21. J. H. Kuiper and R. Huiskes, "The predictive value of stress shielding for quantification of adaptive bone resorption around hip replacements," J. Biomech. Eng., vol. 119, no. 3, pp. 228–231, 1997.
22. M. Rabbani and H. Saidpour, "Stress Analysis of a Total Hip Replacement Subjected to Realistic Loading Conditions," J Robot Mech Eng Resr, vol. 1, no. 1, pp. 18–23, 2015.
23. Y. Hirata, Y. Inaba, N. Kobayashi, H. Ike, H. Fujimaki, and T. Saito, "Comparison of Mechanical Stress and Change in Bone Mineral Density Between Two Types of Femoral Implant Using Finite Element Analysis," J. Arthroplasty, vol. 28, no. 10, pp. 1731–1735, Dec. 2013.
24. J. M. F. K. Takahashi, A. C. Dayrell, R. L. X. Consani, M. A. de A. Nóbilo, G. E. P. Henriques, and M. F. Mesquita, "Stress Evaluation of Implant-Abutment Connections Under Different Loading Conditions: A 3D Finite Element Study," J. Oral Implantol., vol. 41, no. 2, pp. 133–137, 2015.
25. I. Ilyas, H. A. Alrumaih, S. Kashif, S. A. Rabbani, and A. H. Faqihi, "Revision of Type III and Type IVB Acetabular Defects With Burch–Schneider Anti-Protrusio Cages," J. Arthroplasty, vol. 30, no. 2, pp. 259–264, Feb. 2015.
26. F. Gelaude, T. Clijmans, and H. Delport, "Quantitative Computerized Assessment of the Degree of Acetabular Bone Deficiency: Total radial Acetabular Bone Loss (TrABL)," Adv. Orthop., vol. 2011, p. e494382, Oct. 2011.
27. F. Gelaude, T. Clijmans, P. L. Broos, B. Lauwers, and J. V. Sloten, "Computer-aided planning of reconstructive surgery of the innominate bone: Automated correction proposals," Comput. Aided Surg., vol. 12, no. 5, pp. 286–294, Jan. 2007.
28. A. E. Anderson, C. L. Peters, B. D. Tuttle, and J. A. Weiss, "Subject-Specific Finite Element Model of the Pelvis: Development, Validation and Sensitivity Studies," J. Biomech. Eng., vol. 127, no. 3, pp. 364–373, Feb. 2005.
29. M. Dalstra and R. Huiskes, "Load transfer across the pelvic bone," J. Biomech., vol. 28, no. 6, pp. 715–724, Jun. 1995.
30. A. T. M. Phillips, P. Pankaj, C. R. Howie, A. S. Usmani, and A. H. R. W. Simpson, "Finite element modelling of the pelvis: Inclusion of muscular and ligamentous boundary conditions," Med. Eng. Phys., vol. 29, no. 7, pp. 739–748, Sep. 2007.
31. Y. Zhou, L. Min, Y. Liu, R. Shi, W. Zhang, H. Zhang, H. Duan, and C. Tu, "Finite element analysis of the pelvis after modular hemipelvic endoprosthesis reconstruction," Int. Orthop., vol. 37, no. 4, pp. 653–658, Jan. 2013.
32. N. Kaku, H. Tsumura, H. Taira, T. Sawatari, and T. Torisu, "Biomechanical study of load transfer of the pubic ramus due to pelvic inclination after hip joint surgery using a three-dimensional finite element model," J. Orthop. Sci., vol. 9, no. 3, pp. 264–269, May 2004.
33. F. Bachtar, X. Chen, and T. Hisada, "Finite element contact analysis of the hip joint," Med. Biol. Eng. Comput., vol. 44, no. 8, pp. 643–651, Aug. 2006.
34. G. Bergmann, G. Deuretzbacher, M. Heller, F. Graichen, A. Rohlmann, J. Strauss, and G. Duda, Eds., "Hip contact forces and gait patterns from routine activities," 2001.
35. S. Bauer, P. Schmuki, K. von der Mark, and J. Park, "Engineering biocompatible implant surfaces," Prog. Mater. Sci., vol. 58, no. 3, pp. 261–326, Apr. 2013.
36. L. Pazos, P. Corengia, and H. Svoboda, "Effect of surface treatments on the fatigue life of titanium for biomedical applications," J. Mech. Behav. Biomed. Mater., vol. 3, no. 6, pp. 416–424, Aug. 2010.
37. I. P. Semenova, G. K. Salimgareeva, V. V. Latysh, T. Lowe, and R. Z. Valiev, "Enhanced fatigue strength of commercially pure Ti processed by severe plastic deformation," Mater. Sci. Eng. A, vol. 503, no. 1–2, pp. 92–95, Mar. 2009.
38. R. B. Figueiredo, E. R. de C. Barbosa, X. Zhao, X. Yang, X. Liu, P. R. Cetlin, and T. G. Langdon, "Improving the fatigue behavior of dental implants through processing commercial purity titanium by equal-channel angular pressing," Mater. Sci. Eng. A, vol. 619, pp. 312–318, Dec. 2014.

Reconstructive REVIEW
ISSN 2331-2262 (print) • ISSN 2331-2270 (online)
Volume 6, Number 1
April 2016
ORIGINAL ARTICLE http://dx.doi.org/10.15438/rr.6.1.134

# Comparison of Functional Outcomes of Total Knee Arthroplasty Using Two Different Single Radius Implants

*Pourmoghaddam A[1], Dettmer M[1], Malanka S[1], Kreuzer S[1]*

## Abstract

Total knee arthroplasty is used as the treatment plan for patients with end-stage osteoarthrosis associated with severely affected function. Although TKA has been used for many years, some patients have reported overall dissatisfaction regarding the outcome. This may be due to the complexity of the joint design. In recent years, the concept of single-radius knee prosthetics is gaining more popularity as many studies have discussed biomechanical and clinical benefits of such design compared to traditionally used multi-radius implants. In this study, we report the outcome of 78 patients who were treated by TKA utilizing a relatively new single-radius implant, Unity. Results showed that all subjects reported good outcomes as expressed by significant improvement in their Knee Injury and Osteoarthritis Outcome Scores at 1-year post-operative. The symptom, pain, and ADL subscores demonstrated significant improvement in patients with scores twice the pre-operative value, while the average improvement in sport and quality of life subscores showed even greater improvement with scores three times the pre-operative value.

***Keywords***: *total knee arthroplasty, Unity implant, single radius*
***Level of Evidence***: *AAOS Therapeutic Level III*

## Introduction

Total Knee arthroplasty (TKA) is the ultimate treatment to alleviate the symptoms of the knee osteoarthritis (OA) after alternative treatments are exhausted. TKA is used to relieve the pain and to restore normal function of the knee. However, different implants and surgical approaches have shown inconsistent results with achieving normal function of the knee. The limitations in performing normal activities such as limited range of motion, less stability of the knee compared to normal knee, and the loss of proprioception may be factors affecting the outcome of the

1 Amir Pourmoghaddam, PhD; Marius Dettmer, PhD; Stefany JK Malanka BSc.; Stefan W. Kreuzer, MD MSc.
The University of Texas Health Science Center at Houston, 7000 Fannin, Suite 1200, Houston, Texas 77030 USA
(Direct reprint requests to Marius Dettmer)

surgery. Therefore, design of knee implants has been the center of attention for TKA. While most common knee designs on the market are based on multiple centers of rotation, a new concept was proposed in 1993 based on a single-radius design to achieve more natural knee kinematics [1]. Since then, many studies have demonstrated that during a flexion-extension activity, knee rotation follows a single radius curvature path over the femoral condyles by rotating around a fixed transepicondylar axis [2-6]. A single-radius design concept provides a longer extensor moment arm and retains the movement isometry throughout the full range of motion [7,8]. Therefore, single radius design knees are expected to retain more natural kinematics of movement during daily activities [9-11]. Previous studies have reported superior functional outcomes in patients who received single-radius knee implants. These outcomes include a better rehabilitation process, faster recovery and return- to-work-time, and significant reduction in knee pain. In theory, the aforementioned benefits would result in superior patient satisfaction level [9-11]. The Unity Total Knee System, like other single radius knee designs, has been designed to reduce the muscular activities of the knee extensors and to provide better ligament stability, which may ultimately result in reduced and more normal patellar load [12,13]. This implant maintains the medial joint axis throughout full range of motion. This design concept helps with isometry of MCL loading and movement after TKA [14].

In a very recent study by Paszicsnyek, clinical outcomes of 89 patients treated by TKA using Unity knee implants with a posterior stabilizing approach (PS) were evaluated [14]. The authors indicated positive survivorship, clinical and performance improvements, and no radiographic failure. The Posterior cruciate ligament (PCL) is known to stabilize the knee during flexion, particularly by constraining the femoral and tibia relative translation, and in high flexion by constraining the mediolateral translation of tibia. Therefore, it has been suggested that PCL preservation might retain the natural knee movement after TKA [15]. In this study we aimed to add more clinical data to the body of the literature and to analyze the functional improvements in patients with Unity Knee TKA by using a cruciate retaining (CR) method. We hypothesized that the functional outcomes measured by the Knee Injury and Osteoarthritis Outcome Score (KOOS) evaluation would demonstrate significant improvement in patients during the postoperative period. In addition, we aimed to report revision and negative cases and to discuss the potential effects of patients' demographics on the outcome of TKA using the Unity TKA system.

## Materials and Methods

A retrospective review of preoperative and postoperative data of 80 individuals (34 males/46 females) who received total knee arthroplasty treatment was conducted. All patients received the Unity single radius Total Knee System (Corin Ltd., Cirencester, UK). The demographics of patients are shown in Table 1. However, as the majority of the patients (total 78) were treated by using a cruciate retaining method (32 males/46 females) the demographics of the patients used in the study is reported in Table 2. The data were collected from January 2013 to May 2015 at a single institution from cases performed by one of the authors. The data were collected by using an online web-based data-entry software from an IRB-approved joint registry. Informed consent was obtained from all participants in the study prior to data collection.

*Table 1- Demographics of CR patients in the study.*

| | N | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|---|
| Height (cm) | 78 | 149.86 | 193.04 | 170.72 | 9.40 |
| Weight (kg) | 78 | 52 | 147.70 | 87.01 | 19.68 |
| BMI | 78 | 21 | 45.50 | 29.69 | 5.53 |
| Age (years) | 78 | 53 | 85 | 68.47 | 7.23 |

A standard medial parapatellar approach was performed and all patients received a cemented single-radius cruciate-retaining Unity™ Total Knee System (Corin Ltd., Cirencester, UK). The sequence of surgical steps included a distal cut using an intramedullary reference guide followed by the proximal tibial cut. The slope and the varus/valgus angle was adjusted to the natural tibial plateaus of the patient avoid to exceed the accepted range of +/- 3 degrees. The extension gap was then balanced by soft tissue release. Femoral rotation was adjusted using the EquiBalanceTM in 90 degrees of flexion as shown in Figure 1.

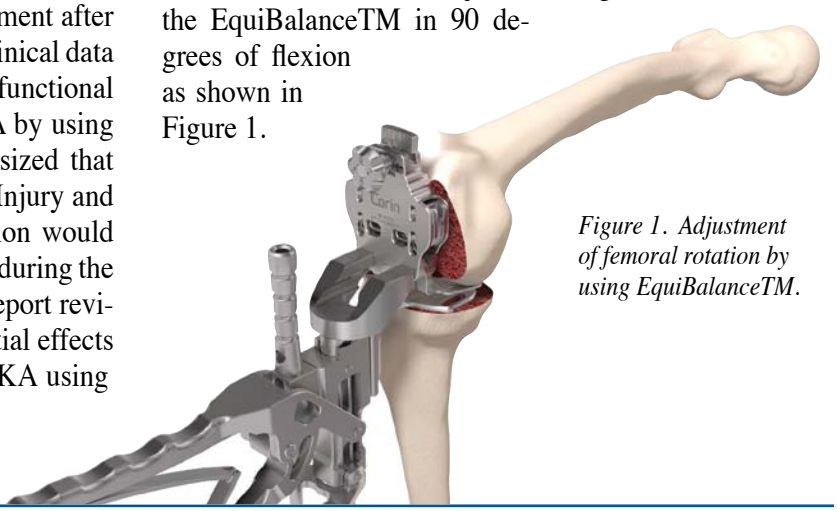



*Figure 1. Adjustment of femoral rotation by using EquiBalanceTM.*

The knee cap was measured pre-cut and was resurfaced to reestablish pre-operative thickness. Once adequate hemostasis was obtained, the joint was copiously irrigated followed by cementing of the tibia, patella and femoral component. All excess cement was removed and followed by irrigation and closure in layers. The design of this total knee system utilizes a single radius implant geometry with an instrument platform which aims to maintain the medial joint-line throughout range of motion in order to optimize MCL isometry post TKA. In addition, the patellofemoral track in this design has a lower profile and an early lateralized anatomic patellar track compared with traditional knee systems, which reduces constraint on the patellofemoral mechanism and therefore minimizes anterior knee pain [16]. The goal of this TKR system is to maintain balance throughout the range of motion, resulting in improved patient outcomes.

The underlying causes for a primary total knee arthroplasty were end-stage osteoarthritis (n=76; 97.43%), post-traumatic arthritis (n=1; 1.23%) or a failed implant (n=1; 1.13%). Each patient completed at least one postoperative questionnaire to calculate the clinical outcomes represented by KOOS. The KOOS represents five subscores which were compared for each group. These postoperative data were collected either during the follow-up clinic visits or by using an online questionnaire.

Patients in this study received an implant by Corin (Unity Knee, Corin, UK). The five subscores were Symptom, Pain, ADL, Sport, and Quality of Life (QOL). A postoperative radiograph was used in each case to check for fixation, component failure or malalignment, and progressive radiolucency around the implant.

## Statistical Model

A Multivariate mixed model was utilized to compare the postoperative outcome of each implant. A significance level of .05 was assumed in this study. Body Mass Index (BMI) and age (as covariates) and gender (as between group factor) were utilized in the model to evaluate potential changes in functional outcome in response to changes in these factors. All statistical analyses were conducted using SPSS 23.0.0 (SPSS Inc., Chicago, Illinois, USA).

## Results

All patients in the study completed at least one postoperative questionnaire to allow the calculation of KOOS for functional outcome measurement. The results of the overall multivariate mixed model indicated that the overall functional outcomes significantly improved between the pre-operative and post-operative survey with ($F(5,73)=77.34$, $p<0.001$)). This improvement in functional outcome was significant for all subscores, as summarized in Table 2. The post-surgery subscores were significantly higher in all patients demonstrating excellent clinical performance improvement.

*Table 2 – Comparison of pre and postoperative*

| KOOS | | Mean Square | F (1,78) | Significance |
|---|---|---|---|---|
| Pre vs. Post | Symptom | 47251.44 | 201.77 | <.001 |
| | Pain | 75372.06 | 375.36 | <.001 |
| | ADL | 61960.78 | 315.40 | <.001 |
| | Sport | 79470.78 | 230.49 | <.001 |
| | QOL | 81743.85 | 230.40 | <.001 |

*Table 3 – KOOS subscores assessed during preoperative and postoperative surveys.*

| | PreOp | | | |
|---|---|---|---|---|
| **KOOS** | **Minimum** | **Maximum** | **Mean** | **Std. Deviation** |
| Symptom | 0 | 97 | 47.78 | 20.91 |
| Pain | 0 | 84 | 42.26 | 16.75 |
| ADL | 5 | 95 | 46.31 | 17.56 |
| Sport | 0 | 95 | 19.67 | 18.02 |
| QOL | 0 | 57 | 22.19 | 15.51 |
| | **PostOp** | | | |
| **KOOS** | **Minimum** | **Maximum** | **Mean** | **Std. Deviation** |
| Symptom | 43 | 100 | 82.59 | 13.96 |
| Pain | 45 | 100 | 86.22 | 13.94 |
| ADL | 33 | 100 | 86.17 | 14.85 |
| Sport | 0 | 100 | 64.81 | 24.22 |
| QOL | 0 | 100 | 67.97 | 23.48 |

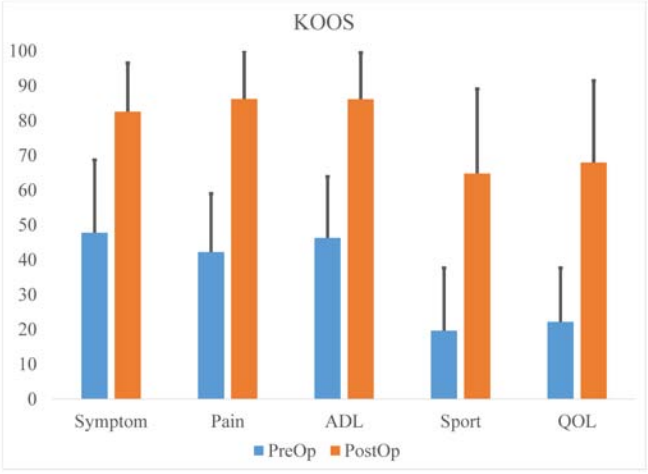



*Figure 2- The KOOS scores comparison between Preoperative and Postoperative period.*

*Table 4- KOOS subscores for categorized based on gender.*

| KOOS | Gender | Average | | | | | Standard Error | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Symptom | Pain | ADL | Sport | QOL | Symptom | Pain | ADL | Sport | QOL |
| **PreOp** | F | 43.39 | 37.43 | 40.84 | 15.23 | 19.34 | 3.16 | 2.41 | 2.28 | 2.47 | 2.33 |
| | M | 54.09 | 49.18 | 54.15 | 26.03 | 26.28 | 3.30 | 2.64 | 3.11 | 3.19 | 2.54 |
| **PostOp** | F | 80.06 | 84.28 | 85.58 | 62.04 | 66.52 | 2.15 | 2.16 | 2.27 | 4.55 | 3.39 |
| | M | 86.21 | 89.00 | 87.00 | 68.78 | 70.06 | 2.18 | 2.21 | 2.52 | 3.39 | 4.30 |

In addition, the results of the mixed model that was conducted to evaluate the differences between demographics data indicated that patients' demographics were not significant predictors of the functional outcome. For BMI ($F(5,70) = 1.06$, $p = 0.39$) and the KOOS subscores are summarized in Table 4, for age $F(5,70) = 0.565$, $p = 0.658$ and for gender effects $F(5,70) = 2.124$ $p = 0.073$.

## Discussion

Although TKA has been utilized as the ultimate treatment method for end-stage osteoarthritis and despite high survivorship of this procedure, for many patients it has not always resulted in satisfactory functional outcomes. Many studies indicated dissatisfaction of up to 20% of patients from the surgery [17-20] attributed mainly to the significant changes in knee kinematics that may result in abnormal gait and balance experience [21]. It has been proposed that prosthesis design is the primary factor altering the function of the knee following TKA [7,18,22-25]. As a result, implant manufacturers have focused on developing prosthetic knee devices that simulate the natural knee kinematics.

Traditionally, knee prosthetics with multi-radius design over the femoral component have been used; however, recent development of single-radius knee implants have shown improvements in both mechanical and clinical functions of the knee after TKA [8,13,14,18,26-30]. In these implants, the biomechanical functions are improved by lengthening the extensor moment arm, providing longer distal and posterior axis, and by maintaining the isometry of the rotation and force distribution throughout the range of motion resulting in less patellar load [7,8, 31,32]. The mechanical improvements of the prosthetic knee after TKA therefore may contribute to better functional outcomes, decreased knee pain, a shorter rehabilitation period, faster recovery and reduction in the time to return to work [18,29,30,33].

We report on the short term clinical outcome of a newly designed and recently released to the market single-radius implant, Unity Total Knee System. Our results indicated significant improvements in all clinical outcomes of the first 78 CR patients in a single surgeon series. Our results are similar to those recently reported by Paszicsnyek indicating good survivorship and positive clinical outcome of this implant [14]. In that study, the author investigated the functional outcome of the TKA by using Unity and indicated significant improvement in the outcomes measured by American Knee Society Score, Oxford Knee score and radiographic measurements. However, the authors had not reported KOOS subscores in that study.

Molt et. al have reported the clinical outcomes measured by KOOS in patients who received a traditional single radius implant, Triathlon TKA (Stryker, Mahwah, New Jersey, USA). In our study the average follow-up range was 361±228 days. Therefore, we descriptively compared our results with those 1-year results reported by Molt et. al., as summarized and reproduced in Table 4 and depicted in Figure 3. The scores in the current study are comparatively higher than those of patients who were treated by Triathlon CR in the earlier study [34]. Further research including a randomized controlled study is needed to compare the clinical outcomes of these single-radius implants.

*Table 5 – KOOS subscores reported by Molt et. al versus those reported in the current study.*

| | | PreOp | | 1 year PostOp | |
|---|---|---|---|---|---|
| KOOS | | Mean | Std. Deviation | Mean | Std. Deviation |
| Pain | Unity | 42.26 | 16.75 | 86.22 | 13.94 |
| | Triathlon CR | 43 | 19 | 80 | 19 |
| | | | | | |
| Symptom | Unity | 47.78 | 20.91 | 82.59 | 13.96 |
| | Triathlon CR | 52 | 20 | 76 | 15 |
| | | | | | |
| ADL | Unity | 46.31 | 17.56 | 86.17 | 14.85 |
| | Triathlon CR | 45 | 15 | 79 | 20 |
| | | | | | |
| Sport | Unity | 19.67 | 18.02 | 64.81 | 24.22 |
| | Triathlon CR | 12 | 13 | 38 | 24 |
| | | | | | |
| QOL | Unity | 22.19 | 15.51 | 67.97 | 23.48 |
| | Triathlon CR | 25 | 15 | 68 | 25 |

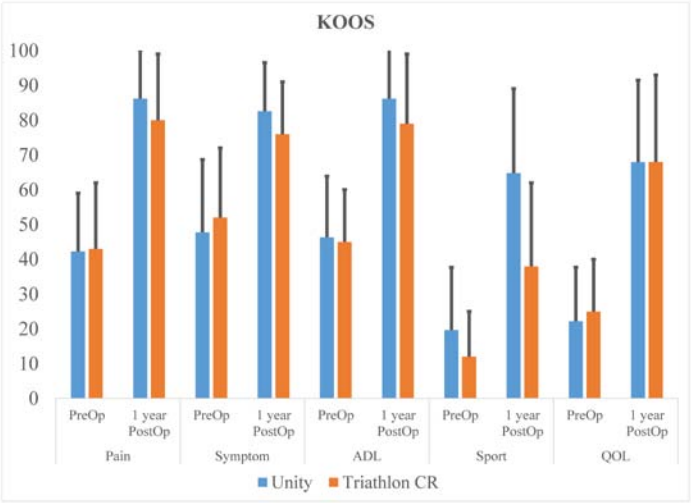



*Figure 3 – KOOS subscores reported by Molt et all for patients treated by two types of single-radius Knee (Triathlon CR) compared to the KOOS subscores reported in the current study for patients receiving Unity.*

There are several limitations to the current study. First, the study was conducted retrospectively on single design implants. The aim of the study was to evaluate the improvement in patients' functional scores; however, future studies may be needed to further evaluate the outcome of the Unity implant compared to other traditionally available single-radius prosthetics prospectively. The surgeries were conducted by one surgeon; thus, this might limit the scope and generalizability of the outcome. Future studies may be designed to use multiple investigational centers. In addition, we did not analyze the range of motion or conduct other biomechanical assessments of the performance, which should be considered for future studies; however, clinical assessments based upon patient- reported outcomes, as assessed by the application of KOOS, can be a reliable indicator of post-operative improvement and potentially overall patient satisfaction.

## Conclusion

In this study we reported the short term clinical outcome of a new single-radius knee prosthetic design. Patients in the study demonstrated excellent improvement in functional outcome indicating the short term success of this implant design. Future studies and longer-term data collection is needed to further generalize the outcome of this study.

### *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.

**References**


1. Hollister, A. M., Jatana, S., Singh, A. K., Sullivan, W. W., & Lupichuk, A. G. (1993). The axes of rotation of the knee. Clinical Orthopaedics and Related Research, (290), 259–68. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8472457
2. Blakeney, W. G., Khan, R. J. K., & Wall, S. J. (2011). Computer-assisted techniques versus conventional guides for component alignment in total knee arthroplasty: a randomized controlled trial. The Journal of Bone and Joint Surgery. American Volume, 93(15), 1377–84. http://dx.doi.org/10.2106/JBJS.I.01321
3. Churchill, D. L., Incavo, S. J., Johnson, C. C., & Beynnon, B. D. (1998). The transepicondylar axis approximates the optimal flexion axis of the knee. Clinical Orthopaedics and Related Research, (356), 111–8. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/9917674
4. Insall, J. N., Lachiewicz, P. F., & Burstein, A. H. (1982). The posterior stabilized condylar prosthesis: a modification of the total condylar design. Two to four-year clinical experience. The Journal of Bone and Joint Surgery. American Volume, 64(9), 1317–23. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/7142239
5. Mugnai, R., Digennaro, V., Ensini, A., Leardini, A., & Catani, F. (2014). Can TKA design affect the clinical outcome? Comparison between two guided-motion systems. Knee Surgery, Sports Traumatology, Arthroscopy : Official Journal of the ESSKA, 22(3), 581–9. http://doi.org/10.1007/s00167-013-2509-9
6. Tayot, O., Aït Si Selmi, T., & Neyret, P. (2001). Results at 11.5 years of a series of 376 posterior stabilized HLS1 total knee replacements. Survivorship analysis, and risk factors for failure. The Knee, 8(3), 195–205. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11706727
7. Ezechieli, M., Dietzek, J., Becher, C., Ettinger, M., Calliess, T., Ostermeier, S., & Windhagen, H. (2012). The influence of a single-radius-design on the knee stability. Technology and Health Care : Official Journal of the European Society for Engineering and Medicine, 20(6), 527–34. http://dx.doi.org/10.3233/THC-2012-0698
8. Jenny, J.-Y. Y., Miehlke, R., Saragaglia, D., Geyer, R., Mercier, N., Schoenahl, J.-Y. Y., & Thiel, B. (2013). Single-radius, multidirectional total knee replacement. Knee Surgery, Sports Traumatology, Arthroscopy : Official Journal of the ESSKA, 21(12), 2764–2769. http://dx.doi.org/10.1007/s00167-012-2178-0
9. Daniilidis, K., & Tibesku, C. O. (2013). Frontal plane alignment after total knee arthroplasty using patient-specific instruments. International Orthopaedics, 37(1), 45–50. http://dx.doi.org/10.1007/s00264-012-1732-1
10. Harvie, P., Sloan, K., & Beaver, R. J. (2011). Three-Dimensional Component Alignment and Functional Outcome in Computer-Navigated Total Knee Arthroplasty. The Journal of Arthroplasty, 26(8), 1285–1290. http://dx.doi.org/10.1016/j.arth.2010.12.022
11. Ng, V. Y., DeClaire, J. H., Berend, K. R., Gulick, B. C., & Lombardi, A. V. (2012). Improved accuracy of alignment with patient-specific positioning guides compared with manual instrumentation in TKA. Clinical Orthopaedics and Related Research, 470(1), 99–107. http://doi.org/10.1007/s11999-011-1996-6
12. Hall, J., Copp, S. N., Adelson, W. S., D'Lima, D. D., & Colwell, C. W. (2008). Extensor Mechanism Function in Single-Radius Vs Multiradius Femoral Components for Total Knee Arthroplasty. Journal of Arthroplasty, 23(2), 216–219. http://doi.org/10.1016/j.arth.2007.04.001
13. Wang, H., Simpson, K. J., Ferrara, M. S., Chamnongkich, S., Kinsey, T., & Mahoney, O. M. (2006). Biomechanical differences exhibited during sit-to-stand between total knee arthroplasty designs of varying radii. The Journal of Arthroplasty, 21(8), 1193–9. http://doi.org/10.1016/j.arth.2006.02.172
14. Paszicsnyek, T. (2015). Early Experience With a Modern Generation Knee System: Average 2 Years' Follow-Up. Reconstructive Review, 5(4), 23–28.
15. Mihalko, W. M., & Krackow, K. a. (1999). Posterior cruciate ligament effects on the flexion space in total knee arthroplasty. Clinical Orthopaedics and Related Research, (360), 243–250.
16. Abolghasemian, M., Samiezadeh, S., Sternheim, A., Bougherara, H., Barnes, C. L., & Backstein, D. J. (2014). Effect of patellar thickness on knee flexion in total knee arthroplasty: A biomechanical and experimental study. Journal of Arthroplasty, 29(1), 80–84. http://doi.org/10.1016/j.arth.2013.04.026
17. Bourne, R. B., Chesworth, B. M., Davis, A. M., Mahomed, N. N., & Charron, K. D. (2010). Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clinical Orthopaedics and Related Research, 468, 57–63. http://doi.org/10.1007/s11999-009-1119-9

18. Harwin, S. F., Issa, K., Given, K., Hitt, K. D., Greene, K. A., Pivec, R., … Mont, M. A. (2013). Clinical and patient-reported outcomes of primary TKA with a single-radius design. Orthopedics, 36(7), e877–82. http://doi.org/10.3928/01477447-20130624-17
19. Mahomed, N., Gandhi, R., Daltroy, L., & Katz, J. N. (2011). The Self-Administered Patient Satisfaction Scale for Primary Hip and Knee Arthroplasty. Arthritis, 2011, 1–6. http://doi.org/10.1155/2011/591253
20. Scott, C. E. H., Howie, C. R., MacDonald, D., & Biant, L. C. (2010). Predicting dissatisfaction following total knee replacement: a prospective study of 1217 patients. The Journal of Bone and Joint Surgery. British Volume, 92(9), 1253–8. http://doi.org/10.1302/0301-620X.92B9.24394
21. Bell, S. W., Young, P., Drury, C., Smith, J., Anthony, I., Jones, B., … McLean, A. (2014). Component rotational alignment in unexplained painful primary total knee arthroplasty. Knee, 21(1), 272–277. http://doi.org/10.1016/j.knee.2012.09.011
22. Cook, L. E., Klika, A. K., Szubski, C. R., Rosneck, J., Molloy, R., & Barsoum, W. K. (2012). Functional outcomes used to compare single radius and multiradius of curvature designs in total knee arthroplasty. The Journal of Knee Surgery, 25(3), 249–53. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/23057145
23. Harman, M. K., Banks, S. A., Kirschner, S., & Lützner, J. (2012). Prosthesis alignment affects axial rotation motion after total knee replacement: a prospective in vivo study combining computed tomography and fluoroscopic evaluations. BMC Musculoskeletal Disorders, 13, 206. http://doi.org/10.1186/1471-2474-13-206
24. Harvie, P., Larkin, J., Scaddan, M., Longstaff, L. M., Sloan, K., & Beaver, R. J. (2013). Stiffness after total knee arthroplasty: does component alignment differ in knees requiring manipulation? A retrospective cohort study of 281 patients. The Journal of Arthroplasty, 28(1), 14–9. http://doi.org/10.1016/j.arth.2012.03.003
25. Huang, N. F. R., Dowsey, M. M., Ee, E., Stoney, J. D., Babazadeh, S., Choong, P. F., … P.F., C. (2012). Coronal Alignment Correlates With Outcome After Total Knee Arthroplasty. Five-Year Follow-Up of a Randomized Controlled Trial. Journal of Arthroplasty, 27(9), 1737–1741. http://doi.org/10.1016/j.arth.2012.03.058
26. Kim, D.-H., Kim, D.-K., Lee, S.-H., Kim, K.-I., & Bae, D.-K. (2015). Is Single-Radius Design Better for Quadriceps Recovery in Total Knee Arthroplasty? Knee Surgery & Related Research, 27(4), 240–6. http://doi.org/10.5792/ksrr.2015.27.4.240
27. Liu, S., Long, H., Zhang, Y., Ma, B., & Li, Z. (2015). Meta-Analysis of Outcomes of a Single-Radius Versus Multi-Radius Femoral Design in Total Knee Arthroplasty. The Journal of Arthroplasty, 1–9. http://doi.org/10.1016/j.arth.2015.10.017
28. Mahoney, O. M., & Kinsey, T. L. (2008). 5- to 9-year survivorship of single-radius, posterior-stabilized TKA. Clin Orthop Relat Res, 466(2), 436–442. http://doi.org/10.1007/s11999-007-0070-x
29. Mahoney, O. M., McClung, C. D., dela Rosa, M. a., & Schmalzried, T. P. (2002). The effect of total knee arthroplasty design on extensor mechanism function. The Journal of Arthroplasty, 17(4), 416–421. http://doi.org/10.1054/arth.2002.32168
30. Wang, H., Simpson, K. J., Chamnongkich, S., Kinsey, T., & Mahoney, O. M. (2005). A biomechanical comparison between the single-axis and multi-axis total knee arthroplasty systems for the stand-to-sit movement. Clinical Biomechanics, 20(4), 428–433. http://doi.org/10.1016/j.clinbiomech.2004.12.003
31. D'Lima, D. D., Poole, C., Chadha, H., Hermida, J. C., Mahar, A., & Colwell, C. W. (2001). Quadriceps moment arm and quadriceps forces after total knee arthroplasty. Clinical Orthopaedics and Related Research, (392), 213–20. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/11716385
32. Ostermeier, S., & Stukenborg-Colsman, C. (2011). Quadriceps force after TKA with femoral single radius. Acta Orthopaedica, 82(3), 339–343. http://doi.org/10.3109/17453674.2011.574564
33. Harwin, S. F., Greene, K. A., & Hitt, K. (2008). Triathlon total knee arthroplasty: 4-year outcomes with a high-performance implant. The Journal of Knee Surgery, 21(4), 320–6. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/18979936
34. Molt, M., & Toksvig-Larsen, S. (2014). Similar early migration when comparing CR and PS in Triathlon™ TKA: A prospective randomised RSA trial. Knee, 21(5), 949–954. http://doi.org/10.1016/j.knee.2014.05.012

# JISRF Mission Statement

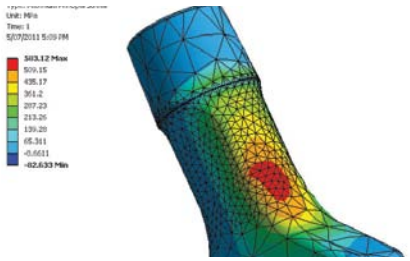
The specific and primary endeavors are to operate for scientific purposes by conducting medical research of potential improvements in medical surgical methods and materials for preserving and restoring the functions of the human body joints and associated structures which are threatened or impaired by defects, lesions or diseases.

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

# Signature ORTHOPAEDICS

*Design Develop Prototype Manufacture Certification*

Signature Orthopaedics is a design, development and manufacturing company for orthopaedic implants and instruments.
The head office located in Sydney Australia, with offices in Europe and North America.
We have years of experience in taking concepts right through design and development and into certification, whether it be the FDA, BSI or the TGA.



We are routinely supplying parts for the Hip, Knee, foot and ankle, spine, shoulder, both to the locally and international markets.
With the added capability of making custom implants for specific cases, using the latest software to guarantee the perfect fit.

We are happy to design and develop both instruments and prosthesis for your needs, or we can supply one of our many FDA approved solutions as an OEM vendor.
Our product, your box!

*Call or email to discuss which solution is right for you!*

**Signature Orthopaedics Europe**
88 Harcourt St Dublin Ireland
T+353 1 691 5293F+353 1 691 5010

**Signature Orthopaedics Australia**
7 Sirius Rd Lane Cove West NSW Australia
T+61 2 9428 5181 F+61 2 8456 6065
info@signatureortho.com.au
www.signatureortho.com.au

**Signature Orthopaedics USA**
Sunset Road Las Vegas NV United States
T+1 702 750 2600


MAKE ICJR YOUR SOURCE FOR ORTHOPAEDIC EDUCATION

# ICJR LIVE MEETINGS AROUND THE GLOBE

*MEMBERS RECEIVE A $100 DISCOUNT OFF REGISTRATION FEES!

| MEETING | DATES | LOCATION | COURSE CHAIRS & DIRECTORS |
|---|---|---|---|
| 4th Annual **Revision Hip & Knee Course*** | May 6 – 7 | Philadelphia, PA | Charles L. Nelson, MD<br>Craig L. Israelite, MD<br>Gwo-Chin Lee, MD |
| 4th Annual **South/RLO Spring Hip & Knee Course*** | May 19 – 21 | Charleston, SC | Walter B. Beaver Jr. MD<br>H. Del Schutte Jr., MD |
| ICJR Instructional Course at the 9th Congress of the Chinese Association of Orthopaedic Surgeons | May 20 | Chengdu, China | Henry D. Clarke, MD<br>Richard Kastenbaum, MD<br>Yan Wang, MD, |
| 3rd Annual **Pan Pacific Orthopaedic Congress*** | August 10 – 13 | Big Island, HI | Matthew S. Austin, MD<br>Kazuo Hirakawa, MD, PhD<br>Richard D. Komistek, MD<br>Rajesh N. Maniar, MS, MCh<br>Raj K. SInha, MD, PhD |
| 5th Annual **Direct Anterior Approach Hip Course*** | August 11 – 14 | Houston, TX | Stefan W. Kreuzer, MD<br>Joseph T. Moskal, MD, FACS<br>John L. Masonis, MD<br>Michael Nogler, MD |
| 3rd Annual **Transatlantic Orthopaedic Congress (17th Annual ISK Sports Medicine & Total Hip & Knee Course in collaboration wth EKS)*** | October 7 – 9 | New York, NY | Jean-Noël A. Argenson, MD, PhD<br>W. Norman Scott, MD, FACS<br>William J. Long, MD, FRCSC<br>Richard Iorio, MD<br>Emmanuel Thienpont, MD |
| 24th Annual **Perspectives in Joint Arthroplasty: Updates in Knee Replacement** | October 21 - 22 | Fall River, KS | J. Christopher Banwart, MD<br>Kenneth A. Greene, MD |
| ICJR Russia | October | St. Petersburg, Russia | Siegfried Hofmann, MD<br>Rashid Tikhilov, MD |
| ICJR/KOA Instructional Course | October | Seoul, Korea | Henry D. Clarke, MD<br>Dae Bae, MD |
| 5th Annual **Shoulder Course*** | November 3 – 5 | Las Vegas, NV | Richard J. Friedman, MD, FRCSC<br>John W. Sperling, MD, MBA<br>Joseph D. Zuckerman, MD |
| ICJR Middle East | November 3 – 5 | Dubai, UAE | Samih Tarabichi, MD |
| ICJR Instructional Course at the 11th International Congress of the COA | November | Beijing, China | TBD |
| 9th Annual **Winter Hip & Knee Course*** | January 12-15, 2017 | Vail, CO | Raymond H. Kim, MD<br>Fred D. Cushner, MD<br>Mark W. Pagnano, MD |

GO TO www.icjr.net FOR DETAILED INFORMATION ABOUT UPCOMING MEETINGS.


# *Play a Role in Our Ground Breaking Research*

Perhaps you were a patient and you were able to regain an important part of your life. Or, perhaps you are simply someone interested in medical research and seeking a new way to participate. Whatever the case, your generosity in helping to fund research is critical to our success - and much appreciated.

The Joint Implant Surgery & Research Foundation is a not-for-profit 501(c)(3) corporation. Your contributions enable scientific discoveries that will help future patients. Contributions over the years from people like you have helped to shape orthopaedics today.

**Contributions**
Donations of any amount will immediately be put to use to fund ongoing and future orthopaedic research projects.

**How to Give**
- Your gift of cash, securities or other negotiable assets is immediately put to use in our research.
- Your contributions are fully tax deductible as specified under Section 501(c)(3) regulations.

*For more information please visit our website at www.jisrf.org or contact us at:*

**Joint Implant Surgery & Research Foundation**
46 Chagrin Shopping Plaza, #117
Chagrin Falls, OH 44022
440.785.9154

# Reconstructive Review Disclosure Statement

*The following information will be published on each paper.*

Please check one or more if pertinent of the following:

☐ 1. No benefits or funds were received in support of this article.

☐ 2. Benefits or funds were received in support of this article either directly or indirectly.

☐ 3. Either family, institution I am associated with, or I have received benefits or funds either directly or indirectly regarding this article.

☐ 4. Describe:

Author's Signature: _____ *(Typed signature is valid for online submission.)*

Joint Implant Surgery & Research Foundation www.jisrf.org

## Conflict of Interest Statement JISRF Orthopaedic Industry Affiliations (Past & Present)

Many Authors, Co-Authors, JISRF, or its Members have had affiliations past or present with one or more of these organizations.

AAHKS
AAOS
American Society of Biomechanics
Apex Surgical
Australian Orthopaedic Association
Bactrin International, INC.
Concept Design & Development,
DePuy
Dow Coring Wright
Encore Medical
E.M. Warburg, Pincus & Co., LLC
Global Orthopaedic Technology
Harrington Arthritis Research Center
Howmedica
ISTA
Johnson & Johnson
Joint Medical Products Corp.
Kirschner
Kenesis Medical, Inc
Montreal General Hospital Orthopaedic Lab
NASA
ORS
OrthoDevelopment
OTI
Richards Manufacturing
Signature Orthopaedics
Smith & Nephew, Inc.
Society for Biomaterials
Zimmer

### *Disclosure Statement*

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.
Manthe [1]; Blasser [1]; Beauchamp [1]; O'Connor [1]

Article 2, page 23.
Kurtz [1] on ConforMIS surgical advisor board and receive roylaties; Slamin [2] an employee of ConforMIS, which the paper's content is about one of our products; Doody [2] an employee of ConforMIS Inc., has received stock options for ConforMIS Inc.

Article 3, page 31.
Cameron [1]; McTighe [1]

Article 4, page 37.
Plessers [1]; Mau [1]

Article 5, page 43.
Pourmoghaddam [1]; Dettmer [1]; Malanka [1]; Kreuzer [1]

# The Greenbrier Medical Institute

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


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

The Greenbrier
America's Resort

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

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

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

For more information, please contact:

Mark E. Krohn, Chief Operating Officer
Greenbrier Medical Institute, 330-697-6581
mekrohn@bmdllc.com


**Joint Implant Surgery and Research Foundation**
46 Chagrin Shopping Plaza, #117
Chagrin Falls, Ohio 44022
www.jisrf.org