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

Reconstructive REVIEW

An Open Access Journal

OFFICIAL JOURNAL OF THE



Joint Implant Surgery and Research Foundation

Strategic Alliance with



Reconstructive REVIEW

OFFICIAL JOURNAL OF THE



Joint Implant Surgery and Research Foundation

Strategic Alliance with

Joint Implant Surgeons



Signature Orthopaedics France L'Arobase - 2 Rue Georges Charpak 81100 CASTRES FRANCE

T: +33 (0)5 63 73 51 83 F: +33 (0)5 63 73 51 84







000-000-000

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

Stratęgic Alliance



Joint Implant Surgery & Research Foundation

is Lleased to Continue a Strategic Alliance with the



Donaldson Arthritis Research Foundation

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

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

ANNOUNCEMENTS..

... from Timothy McTighe

Executive Director - JISRF Editor-In-Chief - Reconstructive Review

Reconstructive Review has made significant advances since its first issue in 2011. We published nine articles as a test to see if there was sufficient interest in a new Journal. Some asked why we decided to venture into this field? Part of our reasoning was that 2011 was the 40th anniversary of the Foundation, and our Founder Professor Charles O. Bechtol was all about continuing education. It seemed to be a natural extension of our mission and there appeared to be need to get articles in print faster than the historical journals were reacting.

We took it slow publishing one more journal in 2012 with 15 articles. Feedback was good and we were getting favorable results and started to put together the making of a reputable Editorial Board. We got a little more confident in 2013 and published three editions and made the decision that 2014 we would standardize on quarterly publications but with fewer articles. We were finding a pattern of readership that adjusted our thinking.

Most readers, including myself, when reading a journal that has ten to twenty articles scan the journal and focus on just the articles within their own interest or specialty. Rarely does one read a journal from "cover to cover". This is also the same trend at CME courses that have multiple specialty programs. Our focus changed to publish fewer articles within a fairly broad spectrum within total joint reconstructive surgery – covering clinical/surgical, basic science, oncology related arthroplasty, case reports and commentaries. We have been finding readership will read from cover to cover if we stay within 5 to 7 articles per publication. Additionally we try to encourage early publications that can highlight certain concerns on design, technique and material hope-fully reducing overall complications and revision surgery. Case reports have a high readership since they tend to provide sharp focus on a given problem.

Reconstructive Review has authors post their article as to the guidelines of the AAOS Level of Evidence and with this edition; JISRF has established a guideline as to the level of Educational Value & Significance. This will now become part of the Peer Review process with the following rating system:

JISRF Levels of Educational Value & Significance
A = Novel and extremely significant for all.
B = Novel and significant for many.
C = Novel and interesting for limited readership.

 \mathbf{D} = Novel and mild interest to readership.

McTighe maintains active memberships with these organizations in the field of medical publishing:

- World Association of Medical Editors (WAME)
- Society for Scholarly Publishing
- American Medical Writers Association (AMWA)

...from David Faroo

Director of Communications - JISRF Managing Editor - Reconstructive Review

August 18, 2017 • JISRF a Member of National Network of Libraries of Medicine



We are very please to announce that JISRF is now a member of the National Network of Libraries of

Medicine, a division of the U.S. National Library of Medicine, and dedicated to providing high quality information services and to improving the public's access to health information.



September 21, 2017 • Reconstructive Review a Member of Committee on Publication Ethics (COPE)

We are also very pleased to announce that Reconstructive Review has been accpeted for membership in COPE, an organization that provides advice to editors and publishers on all aspects of publication ethics.



Thanks to All Who Support Reconstructive Review

We want to thank our Board of Directors, our Editorial Board Members, our Journal Reviewers, Authors and Co-Authors who continue to support the educational and scientific activities of the Foundation and Reconstructive Review.

Faroo maintains active membership in:

• International Society of Medical Publication Professionals (ISMPP)

Reconstructive Review

A Journal Published by the Joint Implant Surgery & Research Foundation

Editor-in-Chief

Timothy McTighe, Dr. HS (hc) Executive Director, JISRF Chagrin Falls, OH, USA tmct@jisrf.org

Associate Editor-in-Chief USA

Keith R. Berend, MD Joint Implant Surgeons New Albany, OH, USA

Associate Editor-in-Chief UK

Evert J. Smith, MD

Associate Editor-in-Chief Pacific Rim

Rami M Sorial, FRACS FAOrthA

Editor Emeritus

M.A.R. Freeman, MD, FRCS London, UK (Deceased, 1931-2017)

Managing Editor

David Faroo Chagrin Falls, OH, USA dfaroo@jisrf.org

Associate Editor for Scientific Quality

Linda Walton, MLS, AHIP University of Iowa

Co-Directors of Research & Development, JISRF

Declan Brazil, PhD NSW, Australia, Branch

Professor Ian Clarke, PhD Orthopaedic Research at Loma Linda University & Co-Director, DARF Implant Retrieval Center

USA Editorial Board

Daniel C. Allison, MD Keith R. Berend, MD Harbinder S. Chadha, MD Edward Cheal, PhD Terry Clyburn, MD Douglas Dennis, MD Thomas K. Donaldson, MD Chris Drinkwater, MD Mark Froimson, MD Ron Hillock, MD Eric Hirsch, MD Riyaz Jinnah, MD Richard "Dickey" Jones, MD

Kristaps J. Keggi, MD John M. Keggi, MD Robert "Ted" Kennon, MD Louis Keppler, MD Stefan Kreuzer, MD James Kudrna, MD, PhD Richard Kyle, MD Jeremy Latham, MA MCh FRCS Audley Mackel, MD David Mauerhan, MD Michael B. Mayor, MD Joseph McCarthy, MD Ed McPherson, MD

Jon Minter, DO Russell Nevins, MD Lee Rubin, MD Frank Schmidt, MD H. Del Schutte, MD W. Norman Scott, MD David Stulberg, MD Sam Sydney, MD Robert L. Thornberry, MD Thomas Tkach, MD Bradley K. Vaughn, MD

International Editorial Board

Declan Brazil, PhD Warwick Bruce, MD Hugh U. Cameron, MB, ChB, FRCS David Campbell, MD Dermot Collopy, MD Dr. John M. Harrison AM Christian Kothny, MD

Lewis Samuels, MD Jasmeet Saren, MD Suresh Siva, MD, FRCS Evert Smith, Bsc, MBBCh, FRCS Rami M Sorial, MD Robert M. Streicher, PhD

Lafayette Lage, MD

Prof. Emer. Panayot Tanchev, MD Allen Turnbull, MD Adrian van der Rijt, MD Peter Walker, MD Duncan Whitwell, MD David Wood, MD Ian Woodgate, MD



JISRF Board Members

Charles O. Bechtol, MD (Founder 1971-1998)

Louise Bechtol, R.N. (Founding member)

Keith Berend, MD Hugh U. Cameron, MB, ChB Ian Clarke, PhD Jack Diamond, Esq. Thomas Donaldson, MD Kristaps J. Keggi, MD Dr. John M. Harrison AM Edward James McPherson, MD Richard E. Jones, MD Timothy McTighe, Dr. HS (hc) H. Del Schutte, MD

Members of the TSI[™] Study Group posted on www.jisrf.org.

Lifetime Achievement Honorees

1991 Charles O. Bechtol, MD
1992 Charles O. Townley, MD
1993 Irwin S. Leinbach, MD
1994 Bruce D. Shepherd, MB
1995 James E. Bateman, MD
1996 Roderick H. Turner, MD
1997 William R. Murray, MD
2003 Thomas H. Mallory, MD
2007 Ian Clarke, PhD
2010 Kristaps J. Keggie, MD
2014 John H. Harrison, PM, MD

Clinical/Surgical Research Advisors:

Warwick Bruce, MD Terry Clyburn, MD John Keggi, MD Louis Keppler, MD S. David Stulberg, MD Thomas Tkach, MD Allan Turnbull, MD Bradley K. Vaughn, MD

Regional Offices

California Division Director Edward J. McPherson, MD, FACS 1414 S. Grand Ave. Suite #123 Los Angeles, CA 90015

Co-Directors of Research

Declan Brazil, PhD, Sydney, Australia Professor Ian Clarke, PhD, Loma Linda, California

Reviewers

The goal of JISRF and Reconstructive Review is to provide peer-reviewed, open-access orthopaedic articles focusing on total joint arthroplasty. To achieve this goal we rely on those individuals who are willing to take on the responsibility, and privilege, to review articles written by their peers. The following is Reconstructive Review's current list of reviewers.

Charles Alexander	Mark Froimson	Michael Manley	W. Norman Scott
Daniel Allison	Jerry Gorski	David Mauerhan	Raj Sinha
Hani Alnakhli	Kenneth Greene	Michael Mayor	Evert Smith
Christopher Anderson	William Griffin	Joseph McCarthy	Rami Sorial
Asaad Asaad	Ronald Hillock	Lorcan McGonagle	Panayot Tanchev
Keith Berend	Kirby Hitt	Harry McKellop	Panayot Tanchev, Jr.
Declan Brazil	John Ireland	Edward McPherson	Richard Tarr
Warwick Bruce	Robert Jamieson	Timothy McTighe	Jeffery Taylor
Hugh Cameron	Riyaz Jinnah	Jon Minter	Robert Thornberry
David Campbell	Richard Jones	Russell Nevins	Patrick Treacy
Edward Cheal	Maurice Jove	Steven Nishiyama	Allen Turnbull
Michael Christie	Michael Kaplan	Philip Nobel	Anthony Unger
Ian Clarke	Stephen Kayiaros	Mary O'Connor	Adrian van der Rijt
Terry Clyburn	John Keggi	Julio Palacio	Bradley Walter
Simon Coffey	Kristaps Keggi	Christopher Peters	William Walter
Richard Cook	Robert Kennon	Derek Pupello	Bill Walter
Paul Della Torre	Louis Keppler	Lee Rubin	Andrew Wassef
Paul DiCesare	Stefan Kreuzer	Mark Sacaris	Richard Welch
Thomas Donaldson	Lafayette Lage	Lewis Samuels	Duncan Whitwell
Scott Dunitz	Jeremy Latham	Kent Samuelson	Sumesh Zingde
C. Anderson Engh	Audley Mackel	Frank Schmidt	



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, 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 <u>http://www.reconstructivereview.org</u>.

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 INFOR-

MATION. The manuscript is used in creating the file for peer review – a double blind process. Your submission should follow this structure:

- Title
- Structured Abstract (Introduction, Materials & Methods, Results, Discussion, and Conclusion)
- Introduction
- Materials & Methods
- Results
- Discussion
- Conclusion
- References (for styles please refer to the website <u>http://www.nlm.nih.gov/bsd/uniform_require-</u> ments.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 <u>Creative Commons Attribution-NonCommercial CC BY-NC</u>. 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

As part of the online submission process, corresponding authors are required to confirm whether they or their co-authors have any disclosures to declare, and to provide details of these. If the Corresponding author is unable to confirm this information on behalf of all co-authors, the authors in question will then be required to submit a completed <u>Disclosure Statement form</u> to the Editorial Office (<u>editors@reconstructivereview.org</u>). It is the Corresponding author's responsibility to ensure that all authors adhere to this policy.

There are three statements to choose from on the Disclosure Statement form, they are:

- No benefits or funds were received in direct or indirect support of this article.
- Benefits or funds were received in support of this article either directly or indirectly.
- Either family, institution I am associated with, or I have received benefits or funds either directly or indirectly regarding this article. (Examples include: Royalties, Consulting Fees, Stock Options, Equity, Institutional Funds)

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, 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.



Develop

rototype

ORTHOPAEDICS

Manufacture

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!









all on 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

Eliminate Cable-Generated Metal Debris

SuperCable[®] Polymer Cerclage System

This unique polymer cable eliminates one possible source of metal debris and metal ions in your patient's fracture or reconstructive procedure. Metal cables have been shown to suffer from significant rates of fatigue failure and to contribute to the generation of local and systemic metallic debris burden.^{1,2}

Laboratory testing demonstrates that the remarkably tough SuperCable withstands over one million load cycles while fully tensioned and abraded by a simulated bone plate, with negligible damage to the cable and metal plate.³

SuperCable has no sharp ends to irritate patient tissue, cut gloves, or create a "sharps injury" risk.

With over 50,000 cables used in cases worldwide since 2004, SuperCable has demonstrated its clinical effectiveness^{4,5,6} and offers significant benefit versus old technology metal cable and wire.

- 1. Callaghan et al (1997) Contribution of cable debris generation to accelerated polyethylene wear. Clin Orthop 344:20.
- Jacobs et al (2004). Accumulation in liver and spleen of metal particles generated at nonbearing surfaces in hip arthroplasty. J Arthroplasty 19:94.
- Sarin, Mattchen, Hack (2005) Novel iso-elastic cerclage cable for treatment of fractures. ORS. Washington, DC. 739.
- Della Valle et al (2010) Early experience with a novel nonmetallic cable. Clinical Orthop 468:2382.
 Edwards et al (2011) Utility of polymer cerclage cables in revision shoulder arthroplasty. Orthopedics
- Standors et al (2017) stand of polymer Cable/Grip-Plate System with Locking Screws for Stable
 Berend, Lombardi et al (2014) Polymer Cable/Grip-Plate System with Locking Screws for Stable
- b. berefind, Lonitadin et al (2014) Folyriner Gaussicarip-Flate System with Locking Screws for Stable Fixation to Promote Healing of Trochanteric Osteotomies or Fractures in Revision Total Hip Arthroplasty. Surg Tech Intl. 25:227.



For additional information or to schedule a product evaluation, please give us a call at 800-827-5775. To view a video demonstration, visit us on the Web at:

SuperCable® USA Patent Nos. 6,569,246; 7,207,090; 8,469,967. JAP Pat. No. 4,829,236. TUR Pat. No. TR201309922T4. EUR Pat Nos. 1,389,940; 1,781,961; 2,432,401. Additional US & International Patents Pending. ©2015 Kinamed® Inc. B00138F JBJS

Proven Performance

- In clinical use since 2004
- Over 50,000 implantations



Curved and straight plate options



Expect Innovation.

CE

CONTENTS

Reconstructive Review Volume 7, Number 3, September 2017

ORIGINAL ARTICLE

- 13 Native Patella Retention Versus Resurfacing in a Cohort of Staged Bilateral Total Knee Patients *Head J, Nelson R, Dyball M, Lawrence B*
- 19 Exploration of Serum 25-hydroxy Vitamin D in Total Joint Arthroplasty Within a Subtropical Climate Naylor B, King A, Voges S, Blackwell T, Huff R, Schutte H
- 23 Mid-Term Follow Up Results of Mini-Subvastus Approach for Total Knee Arthroplasty in Obese Patients *Kekatpure A, Shah N, Nistane P, Agrawal N*
- 29 The 16-Year Evolution of Proximal Modular Stem Design Eliminating Failure of Modular Junction *Tkach T, McTighe T*
- 35 Simulator Study of MOM using Steep-cup Flexion A Clinically Relevant Incorporation of Intermittent Edge-loading *Clarke I.C., Shelton J.C., Bowsher J.G., Savisaar C, Donaldson T*
- 41 Dissemination of Pathogens by Mobile Phones in a Single Hospital Canales M, Craig G, Boyd J, Markovic M, Chmielewski R

CASE REPORT

49 Successes and Failures of Freedom[™] Constrained Cups – A Case Report of Leg-salvage Using a Total-femur Replacement Donaldson T, Clarke I.C.

EULOGY

55 The Passing of A Renaissance Man By Hugh U. Cameron & Timothy McTighe







ORIGINAL ARTICLE

Check for updates

http://dx.doi.org/10.15438/rr.7.3.175

Native Patella Retention Versus Resurfacing in a Cohort of Staged Bilateral Total Knee Patients

Head J¹, Nelson R¹, Dyball M¹, Lawrence B¹

Abstract

Background: Patellar resurfacing in total knee arthroplasty remains a point of controversy within the literature and the generally followed paradigm varies among regions.

Methods: In effort to elucidate a difference following the change from universal patellar resurfacing to universal non-resurfacing, 32 patients with bilateral TKA that included one resurfaced and one native patella were retrospectively reviewed at average follow up 21.4 months from the most recent surgery.

Results: No difference was observed in patient satisfaction, KOOS-ADL score, and VAS scores. No complications or secondary patellar resurfacing occurred.

Conclusions: Therefore, patients perceive no difference between knees with native patella retention or a resurfaced patella in regards to pain and function.

Background

The first total knee arthroplasty (TKA) prosthesis designs essentially ignored the patellofemoral joint, as the tibia-femoral replacements were seen as an alternative to arthrodesis for severe axial deformities, with success gauged as any improvement in function and pain relief. [1,2] Subsequent prosthesis designs evolved to account for the increased reports of patellofemoral complications with specific implant designs for the patella, which became universally accepted as an integral part of TKA, providing an improved level of patient satisfaction. $[\underline{3}-\underline{6}]$

However, with new designs came new complications, which included: patellar fracture, disruption of the extensor mechanism, osteonecrosis, aseptic loosening, instability and dislocation, "overstuffing" of the patellofemoral joint, catastrophic failure, patellar polyethylene wear, and patellar clunk syndrome. [3,7-11] This gave rise to the re-thinking whether or not to resurface the native patella. While some studies and meta-analysis have shown patella resurfacing to be better in terms of cost-effectiveness, reduced revision rate for anterior knee pain, and produced less anterior knee pain, emerging evidence suggests that resurfacing has no influence on the clinical outcome of the patient. [12-17] Proponents of retention of the native patella claim that it has no affect on total healthcare cost, reoperation rate or functional outcome and has a lower complication rate. [18-21]

TKA is one of the most commonly performed operations in adult reconstructive surgery and there currently exists three different approaches among orthopedic surgeons regarding patellar resurfacing: resurfacing all patellae; not resurfacing all patellae; and selective resurfacing for patients with significant pre-operative patellofemoral arthritis-related symptoms and/or advanced patellofemoral arthritis on radiographs. Certain advantages and possible

Keywords: Total knee arthroplasty, patella resurfacing, native patella, bilateral total knee, anterior knee pain, patella retention Level of Evidence: AAOS Therapeutic Level III Educational Value & Significance: JISRF Level A complications reported in the literature can guide the surgeon toward establishing a practice paradigm.

In the present study, we aimed to retrospectively assess whether a difference exists in the function and pain relief after total knee arthroplasty in knees treated with patella resurfacing and knees with native patellae. Our patient population consisted of consecutively performed, staged bilateral TKA in which the first patella was resurfaced and the subsequent patella was left unresurfaced. Our hypothesis, was that there would be no measurable difference from the resurfacing side to the native side.

Methods

The two senior authors changed their practice from always resurfacing the patella up to 2012 to never resurfacing the patella, thereafter. Following this paradigm shift, the implant was not changed, nor any other part of the operative technique.

Patient population

We retrospectively reviewed patient records for consecutively performed, staged bilateral TKA in which the first patella was resurfaced and the subsequent patella was left unresurfaced. Our aim was to collect their Knee injury and Osteoarthritis Outcome Score for Activities of Daily Living (KOOS-ADL), VAS, and satisfaction of both knees and determine if there was a difference between resurfaced versus unresurfaced patella, within the same patient. After hospital Institutional Review Board approval was obtained, informed consent for record review and survey administration was obtained from all patients prior to voluntary participation in the study.

Included patients had minimum 12 months follow up and were recruited from 2007 to 2015. Of the available 34 patients, two were lost to follow up, leaving 32 patients participants in the study. Patients were contacted via phone and a single clinician administered a survey consisting of The Knee injury and Osteoarthritis Outcome Score for Activities of Daily Living (KOOS-ADL), visual analog score, and patient satisfaction. The survey administrator was blinded to all patient information and surgical records. Data from the above outcome measures were analyzed with Student's t-test.

Operative Technique

The surgical procedure was performed under spinal anesthesia or utilizing general anesthesia, when requested by the patient or indicated per the treating anesthesiologist. No peripheral nerve blocks were used. We employed a midline incision and a medial parapatellar arthrotomy. The patella was everted and the patellofemoral joint was inspected. During procedures performed prior to 2012, patellae were universally resurfaced and, after a paradigm shift in clinical practice in 2012, the two senior authors began leaving all patellae unresurfaced.

The DePuy Sigma fixed bearing cruciate-retaining knee system was utilized in all cases. The femoral component was externally rotated three degrees from the posterior condylar axis and implants were fixed with standard cementing technique.

Patellar osteophytes were excised and neurectomy performed in all cases. When the patella was resurfaced the composite patellar thickness was restored to within 2 mm of the pre-resection thickness. The patellar component was an all polyethylene dome-shaped implant with three fixation pegs and the patellar surface was prepared with standard cementing technique. A lateral retinacular release was performed when the patella was not centered in the trochlea with the knee flexed 45° and the medial capsular retinaculum approximated.

Results

The retrospective review gave us 32 patients with a mean age 68.4 (range 47-84) and BMI of 32.8 (range 25.7-46.1). The mean duration of follow up was 21.4 months (range 12-46) for the unresurfaced group and 51.3 months (range 16-97) for the resurfaced group. There were no intraoperative complications. One patient in the resurfaced group and two patients in the unresurface group had lateral release performed at time of index procedure. There were no revisions on resurfaced or native patella sides.

A Student's t-test demonstrated no significant difference in the KOOS-ADL at time the of the interview with the mean in the resurfaced group 88.0 + 7.37 (95% CI 85.4 to 90.6) and 89.1 + 7.17 (95% CI 86.6 to 91.6) in the unresurfaced group (p=0.914). The questions were then analyzed for seven questions specifically pertaining to patellofemoral symptoms which showed no statistical significance on Student's t-test (p=0.975) (Table 1). There was also no significant difference in the VAS with a mean in the resurfaced group of 1.7 + 1.37 and 1.9+ 1.51 in the unresurfaced group (p=0.667). With regard to the patient satisfaction, again no significant difference was noted with a mean satisfaction in the resurfaced group of 9.4 + 1.21and 9.4+ 1.04 in the unresurfaced group (p=1).

	Mean±SD KOOS-ADL score, points				
Parameter	Resurfaced Patella	Unresurfaced Patella			
Grinding or grating	4.88±0.4	4.91±0.5			
Stair climbing	4.42±0.8	4.51±0.6			
Stair descent	4.15±0.3	4.18±0.4			
Kneeling	1.33±0.5	1.33±0.7			
Squatting	3.51±1.0	3.57±1.2			
Sitting with knee bent	4.90±0.3	4.87±0.5			
Up from chair	4.75±0.5	4.75±0.7			

Table 1. Patellofemoral-specific K	KOOS-ADL scores j	for the cohort.
------------------------------------	-------------------	-----------------

KOOS-ADL; The Knee injury and Osteoarthritis Outcome Score for Activities of Daily Living

Discussion

In current clinical practice a dichotomy exists regarding patellar resurfacing, owing in part to regional differences within the literature. Data from a 2009 Norway arthroplasty registry showed 2.4% of patients received a patellar component, while this number was 80% in a Danish Knee Arthroplasty Registry and over 90% in North American registries. [2,22] Literature supporting both clinical practices is immense and varies even within each country with the surgeon choice to resurface owing ultimately to a combination of education, clinical evidence, specific implant design, and cultural influence. Emerging data and meta analysis suggests maintaining the native patella in TKA has no influence on clinical outcome measures or patient satisfaction. [17, 23] This was the motivation for the senior authors' change from universal resurfacing to universal non-resurfacing.

The current study saw no revisions for secondary resurfacing, for patellar button related issues, or for any other reason. Patient satisfaction was equivalent between resurfaced and unresurfaced patellae (p=1). Further, only 4 patients rated their satisfaction with either knee under an 8 on a scale of 10 (2 resurfaced, 2 unresurfaced), for a dissatisfied rate of 6.2%. Utilizing the Swedish Knee Register, Robertson reviewed 27,372 patients outcomes. [24] Resurfaced patella reported a 15% dissatisfaction rate compared to 19% of unresurfaced patella. Although this significant difference appears to highlight the disparity among paradigms, the resurfaced group became less satisfied with their knee over time, while the unresurfaced group remained unchanged. Considering the current revision rate for causes attributable to the resurfaced patella is approximately 12% and secondary patella resurfacing is performed in 13% of cases, the benefit of the patellar button is time dependent

and the need for revision for secondary resurfacing may be balanced by the need for revision due to failed patellar components. [2] Further, revisions in unresurfaced patellae may be artificially increased as secondary resurfacing provides the only viable surgical option for this group of patients. [17]

While we found no difference in VAS scores between resurfaced and unresurfaced sides, numerous reports exist in the literature of a higher revision rate for TKA with unresurfaced patella related to anterior knee pain (AKP). [18,25] In a prospective, randomized study of 514 consecutive primary press-fit condylar total knee replacements, Waters and Bentley found an increased prevalence of anterior knee pain in the unresurfaced patellae cohort, 25.1%, compared to 3.5% in the resurfaced group. [26] Of note, 35 patients in their cohort had simultaneous bilateral TKA with one resurfaced and one unresurfaced patella. Subjectively, patients preferred the resurfaced side. However, in a small series, patients with well-tracking patella whom undergo secondary resurfacing for anterior knee pain have poor results, with only 30.7% improvement. The authors recommend appropriate patient counseling and conclude that revision for anterior knee pain in unresurfaced patella is not recommended. [27] Barrack et al. reported on patients whom elect for secondary resurfacing, any perceived improvement is accompanied by recurrence of symptoms in 55% of patients. [28] Appropriate consideration of physiotherapy for anterior knee pain may help elucidate the etiology of anterior knee pain and guide the decision for revision if patient anatomy is a cause of the anterior knee pain.

We specifically isolated KOS questions related to patellofemoral pain and function. While there was no statistical difference between resurfaced and unresurfaced knees (p=0.975), there was a universal lower score regarding patients' ability to tolerate kneeling on their TKA, with no difference from resurfaced versus native patella (p=1.0). These results mirror the results reported in a meta-analysis of 7,075 TKA's, no difference existed regarding the incidence of AKP between resurfacing and unresurfaced group. [17]

Several reports in the literature report bilateral TKA with resurfaced and unresurfaced patella. In a prospective study, Kwon reports on 17 patients with bilateral TKA in which the patella was resurfaced on one side. After a mean follow-up of 10.6 years, no difference was observed in HSS knee scores, radiological parameters including tibio-femoral angle, width of patella, length of patella, thickness of patella, tilt of patella and shift of patella. [29] Keblish et al. prospectively followed 30 patients and reported equal outcomes for modified Hospital for Special Surgery score for all categories, including: pain, range of motion, func-

tion, deformity, and strength. The authors concluded that with the appropriate prosthesis design and appropriate surgical technique, that retention of the patella is an acceptable option. [30] Burnett, et al. found no differences with regard to range of motion, Knee Society Clinical Rating Score, satisfaction, revision rate, or anterior knee pain in their single-stage bilateral TKA cohort of 32 patients. [31]

The influence of femoral and tibial component position on clinical outcomes warrants mention, as it may account for anterior knee pain unrelated to patellar resurfacing. It is well known that malrotation of TKA components adversely affects patella tracking and may contribute to increased patellofemoral contact pressures, thus predisposing a patient to anterior knee pain possibly leading to revision surgery. [32-34] One study showed a 30% incidence of AKP when implants were placed at a combined internal rotation of 3-17 degrees compared to external rotation of 0-10 degrees. [23] Therefore, patient reported AKP must be analyzed within the entire clinical picture and not just with regards to presence or absence of patellar resurfacing.

In regards to our specific implant, Roberts, et al. also used the Depuy Sigma prosthesis and reported on a cohort of 315 selectively resurfaced patellae at 2 years minimum mean follow up. While no difference was observed in KSS scores, patient reported satisfaction was statistically higher for resurfaced patellae. The authors concluded that the clinical significance of this outcome may be minimal. [25] Liu, et al. found similar results in their 133 patients randomized to receive either resurfacing with the modified dome implant or patellar reshaping; which included: resecting the partial lateral facet of the patella and the osteophytes surrounding the patella, trimming the patella to match the trochlea of the femoral component. They found no significant difference between the groups with regard to the Knee Society Scores, presence of anterior knee pain rate and radiographic differences. [35]

The present study had several strengths. The most notable being that the patient essentially acted as their own control, having one patella resurfaced and the other being left unresurfaced, which eliminated the possibility of cohort selection bias. Further, the style of patient self-reporting utilized in the KOOS-ADL survey allows for a clear delineation of a patients' preference from one knee versus the other and lends toward a definite consensus that our patient population truly had no preference between resurfaced or native patella. High patient retention and blinded survey administration by a single clinician also strengthen the study.

The main limitation of our study was that it was underpowered, which reduces the strength of our conclusion (power = 0.008). A larger sample size is desirable, but is precluded by the small population of patients in our practice that meet the indications. Further, an analysis of pre-operative patellofemoral symptoms and outcome differences in patients with advanced patellofemoral arthritis with resurfacing versus non-resurfacing would possibly delineate a role for selective resurfacing in this population of patients. Other limitations include the retrospective nature of the study and lack of pre-operative KOOS-ADL and VAS scores. For the observed difference in KOOS-ADL scores of 1 percentage point, the study was under powered to claim whether this minor difference was not statistically significant. However, the high satisfaction ratings and KOOS-ADL scores among both treatment groups suggest, if not equivocal, satisfaction that is acceptable regardless of the type of intervention. While this study was not sufficiently powered to prove non-inferiority for the surgeon, it is patient-based evidence suggesting that satisfaction with either resurface type may be similarly acceptable to patients. The choice to resurface is up to the surgeon, but our data provides patient-based evidence for the surgeon to discuss with his patient's when faced with questions regarding patella resurfacing.

To conclude, TKA technique may include patellar resurfacing or native patella retention without any demonstrable difference in patients' activity of daily living, overall pain, or satisfaction.

References:

- Walldius B. Arthroplasty of the knee joint using endoprosthesis. Acta Orthop Scand Suppl 1957;24:1–112.
- Schindler OS. The controversy of patellar resurfacing in total knee arthroplasty: Ibisne in medio tutissimus? Knee Surg Sports Traumatol Arthrosc 2013;20:1227– 44.
- Mochizuki RM, Schurman DJ. Patella complications following total knee arthroplasty. J Bone Jt Surg 1979;61A:879–83.
- Insall JN, Lachiewicz PF, Burstein AH. The posterior stabilised prosthesis. A modification of the total condylar design. A two to four year clinical experience. J Bone Jt Surg 1982; 64A:1317–23.
- Groeneveld HB.Total arthroplasty of the knee joint and the need for replacement of the patella. In: The medical engineering working party: total knee replacement. Mechanical Engineering Publications Limited, London, 1975 p.50–51.
- Insall JN, Ranawat CS, Aglietti P, et al. A comparison of four models of total kneereplacement prostheses. J Bone Joint Surg Am 1976;58(6):754.
- Clayton ML, Thirupathi R. Patellar complications after total condylar arthroplasty. Clin Orthop. 1982;170:152-5.
- Aglietti P, Buzzi R, Gaudenzi A. Patellofemoral functional results and complications with the posterior stabilized total condylar knee prosthesis. J Arthroplasty 1988;3:17-25.
- Goldberg VM, Figgie HE 3rd, Inglis AE, Figgie MP, Sobel M, Kelly M, Kraay M. Patellar fracture type and prognosis in condylar total knee arthroplasty. Clin Orthop 1988;236:115-22.
- Lombardi AV Jr, Engh GA, Volz RG, Albrigo JL, Brainard BJ. Fracture/dissociation of the polyethylene in metal-backed patellar components in total knee arthroplasty. J Bone Joint Surg Am. 1988;70:675-9.
- Lynch AF, Rorabeck CH, Bourne RB. Extensor mechanism complications following total knee arthroplasty. J Arthroplasty. 1987;2:135-40.
- Helmy N, Anglin C, Greidanus NV, Masri BA. To resurface or not to resurface the patella in total knee arthroplasty. Clin Orthop Relat Res 2008; 466 (11): 2775-83.
- Clements WJ, Miller L, Whitehouse SL, Graves SE, Ryan P, Crawford RW. Early outcomes of patella resurfacing in total knee arthroplasty. Acta Orthop 2010; 81 (1): 108-13.

- Murray DW, MacLennan GS, Breeman S, Dakin HA, Johnston L, Campbell MK, et al. A randomised controlled trial of the clinical effectiveness and cost-effectiveness of different knee prostheses: the Knee Arthroplasty Trial (KAT). Health Tech Ass 2014;18(19):1-235.
- Chen K, Li G, Fu D, Yuan C, Zhang Q, Cai Z. Patellar resurfacing versus nonresurfacing in total knee arthroplasty: a meta-analysis of randomised controlled trials. Int Orthop 2013; 37 (6): 1075-83.
- Pavlou G, Meyer C, Leonidou A, As-Sultany M, West R, Tsiridis E. Patellar resurfacing in total knee arthroplasty: does design matter? A meta-analysis of 7075 cases. J Bone Joint Surg Am 2011; 93 (14): 1301-9.
- Pavlou G, Meyer C, Leonidou A, As-Sultany M, West R, Tsiridis E. Patellar resurfacing in total knee arthroplasty: does design matter? A meta-analysis of 7,075 cases. J Bone Jt Surg 2011;93-A:1301–1309.
- Burnett RS, Boone JL, Rosenzweig SD, Steger-May K, Barrack R L. Patellar resurfacing compared with nonresurfacing in total knee arthroplasty. A concise follow-up of a randomized trial. J Bone Joint Surg Am 2009; 91(11):2562-7.
- Breeman S, Campbell M, Dakin H, Fiddian N, Fitzpatrick R, Grant A, et al. Patellar resurfacing in total knee replacement: five-year clinical and economic results of a large randomized controlled trial. J Bone Joint Surg Am 2011;93(16):1473-81.
- Group KATT, Johnston L, MacLennan G, McCormack K, Ramsay C, Walker A. The Knee Arthroplasty Trial (KAT) design features, baseline characteristics, and two-year functional outcomes after alternative approaches to knee replacement. J Bone Joint Surg Am 2009; 91 (1): 134-41.
- Ogon M, Hartig F, Bach C, Nogler M, Steingruber I, Biedermann R. Patella resurfacing: no benefit for the long-term outcome of total knee arthroplasty. A 10- to 16.3-year follow-up. Arch Orthop Trauma Surg 2002;122(4):229-34.
- Abdel MP. Parratte S, and Budhiparama NC. The Patella in Total Knee Arthroplasty: To Resurface or Not Is the Question. Current Reviews in Musculoskeletal Medicine 2014;7.2: 117-24.
- Figgie HE III, Goldberg VM, Heiple KG, Moller HS III, Gordon NH. The influence of tibial-patellofemoral location on function of the knee in patients with the posterior stabilized condylar knee prosthesis. J Bone Jt Surg 1986;68:1035–40.
- Robertsson O, Dunbar M, Phersson T, Knutson K, Lidgren L (2000) Patient satisfaction after knee arthroplasty: a report on 27,372 knees operated on between 1981 and 1995 in Sweden. Acta Orthop Scand 2000;71:262–7.
- Roberts DW, Hayes TD, Tate CT, Lesko JP. Selective Patellar Resurfacing in Total Knee Arthroplasty: A Prospective, Randomized, Double-Blind Study. J Arthroplasty 2015;30:216–22.
- Waters TS, Bentley G. Patellar Resurfacing in Total Knee Arthroplasty. J Bone Joint Surg. Am. 2003;85(2) 212-17.
- 27. Mockford BJ, Beverland DE. Secondary resurfacing of the patella in mobile-bearing total knee arthroplasty. J Arthroplasty 2005;20:898–902.
- Barrack RL, Bertot AJ, Wolfe MW, Waldman DA, Milicic M, Myers L. Patellar resurfacing in total knee arthroplasty: A prospective randomised double blinded study with five to seven years of follow-up. J Bone Jt Surg 2001;83-A:1376–81.
- Kwon OS, Bae DK. Comparative Analysis of Resurfaced and Unresurfaced Patella in Bilateral Total Knee Arthroplasty. J of Korean Northrop Assoc. 2003;38:478-483

- Keblish PA, Varma AK, Greenwald AS. Patellar resurfacing or retention in total knee arthroplasty. A prospective study of patients with bilateral replacements. Bone & Joint Journal 1994;76-B(6)930-93
- Burnett RS, Boone JL, McCarthy KP, Rosenzweig SD, Barrack RL. A prospective randomised clinical trial of patellar resurfacing and nonresurfacing in bilateral TKA. Clin Orthop Relat Res 2007;464:65–72.
- Berger RA, Crossett LS, Jacobs JJ, Rubash HE. Malrotation causing patellofemoral complications after total knee arthroplasty. Clin Orthop Relat Res 1998;356:144–53.
- Incavo SJ, Wild JJ, Coughlin KM, Beynnon BD. Early revision for component malrotation in total knee arthroplasty. Clin Orthop Relat Res 2007;458:131–136.
- Incavo SJ, Coughlin KM, Pappas C, Beynnon BD. Anatomic rotational relationship of the proximal tibia, distal femur, and patella. J Arthroplasty 2003;18:643– 648.
- Liu ZT, Fu PL, Wu HS, Zhu Y. Patellar reshaping versus resurfacing in total knee arthroplasty—results of a randomized prospective trial at a minimum of 7 years' follow-up. Knee. 2012 Jun;19(3):198-202.

SUBMISSION HISTORY

Submitted February 19, 2017 Reviewed June 1, 2017 Revised June 25, 2017 Accepted July 14, 2017 Published September 30, 2017

AUTHOR AFFILIATIONS

 Justin M Head, DO; Ryan Nelson, DO; Mark Dyball, DO; Bruce D Lawrence, DO Genesys Regional Medical Center, a Michigan State University Statewide Campus, One Genesys Parkway, Grand Blanc, MI 48439

(Direct inquires to Justin M Head, justin.head8@gmail.com)

AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

COPYRIGHT & OPEN ACCESS

© 2017 Head, Nelson, Dyball, Lawrence. All rights reserved. Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review is an open access publication and follows the <u>Creative Commons Attribution-NonCommercial CC BY-NC</u>. 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".





Attend any one of our live events, including Global Congresses, CME Courses and Resident Training Programs.



Interact with experts and colleagues on hot topics in orthopaedics, benefit from enhanced access to on-line content, practice marketing support, and discounted text books.



Access a wealth of educational content anytime, anywhere from your computer or mobile device.

JOIN ICJR AND HELP SHAPE THIS GROWING GLOBAL COMMUNITY GIVING BACK TO ORTHOPAEDICS!

www.icjr.net





"EXCELLENT COURSE! I LEARNED MANY NEW INNOVATIVE IDEAS THAT I WILL TAKE BACK TO MY PRACTICE"

9TH ANNUAL WINTER HIP & KNEE COURSE VAIL CASCADE | VAIL, CO JANUARY 12-16, 2017

Register at www.icjr.net/2017winter

Mark your calendar for the ICJR Winter Hip & Knee Course in beautiful Vail, Colorado! The 2016 course brought together more than 250 orthopaedic surgeons and allied healthcare professionals who learned about the latest trends in hip & knee surgery from our internationally renowned faculty. For 2017, we have planned an exciting, interactive program featuring didactic presentations, video vignetit











ORIGINAL ARTICLE

Check for updates

http://dx.doi.org/10.15438/rr.7.3.186

Exploration of Serum 25-hydroxy Vitamin D in Total Joint Arthroplasty Within a Subtropical Climate

Naylor B¹, King A², Voges S², Blackwell T², Huff R², Schutte H²

Abstract

Background: The importance of appropriate serum 25-hydroxy vitamin D [25(OH)D] for multiple health measures is widely described, however, the prevalence of vitamin D deficiency remains remarkably high. The goal of our study is to explore the distribution of vitamin D deficiency among an elective total joint arthroplasty (TJA) population within a lower latitude climate with relatively abundant sunshine. We hypothesize this group will demonstrate a high prevalence of vitamin D deficiency, thus exposing a potential opportunity to improve outcomes with proper identification and management.

Methods: From January to December, 2014, serum 25(OH)D levels were collected during a standard preoperative workup prior to primary or revision joint arthroplasty in South Carolina. Mean serum 25(OH)D, seasonal variation, and patient demographics were recorded. We defined Vitamin D deficiency consistent with the current Endocrine Society classification: serum 25(OH)D < 20 ng/ml, 21-29 ng/ml, and 30-100 ng/ml representing deficiency, insufficiency, and normal, respectively.

Results: A total of 308 patients underwent evaluation. 46.8% (144) of the participants were female, and 89.6% (276) identified as Caucasian. The mean patient age was 68.3 years ± 13.8 (32-88). The average serum 25(OH)D was 29.8 ng/ml ± 12.8 (5.1-79.9), with only 46.2% of patients having a normal serum 25(OH)D (p<0.0001). Caucasian and non-white patients averaged 33 ng/ml [56% normal 25(OH)D] and 25 ng/ml [36% normal 25(OH)D], respectively (p = 0.22). Patients over the age of 65 demonstrated lower serum 25(OH)D (28.5ng/ml) compared to those under 65 (30.7ng/ml)(p=.12). As expected, serum 25(OH)D demonstrated variation throughout the year: January to March, April to June, July to September, and October to December recorded 28.5 ng/ml, 31.73 ng/ml, 36.57 ng/ml, and 23.03 ng/ml 25(OH)D, respectively.

Conclusion: The majority (53.8%) of an otherwise classically low risk patient population present with vitamin D insufficiency or deficiency prior to undergoing elective total joint arthroplasty, with elderly non-white patients in the winter months at the highest risk. Appropriate vitamin D management is associated with favorable influences on both skeletal and non-skeletal outcomes. Potential complications of total joint arthroplasty (TJA), including periprosthetic joint infection and aseptic loosening, can possibly be decreased with proper identification and treatment, which can be elucidated by future high quality studies.

Background

Genetic evolution has struggled to keep pace with the gradual decline in abundant sun exposure that cloaked our distant ancestors. Consequently, the ultraviolet dependent

Keywords: Adult reconstruction, basic science, osteoporosis, total joint arthroplasty Level of Evidence: AAOS Therapeutic Level III Educational Value & Significance: JISRF Level B metabolism of vitamin D, or "sunshine vitamin," has been challenged. [1,2] Historic vitamin D recommendations unfortunately reflect only the modern "normal" reference range for serum 25-hydroxy vitamin D [25(OH)D]. [3] Those who spend a significant amount of time outdoors, for example, farmers and construction workers, likely reflect a true physiologic normal reference range; a range humans evolved to optimally function within. Popular recommendations regarding sunscreen, skin coverage, and sun avoidance have further discouraged our natural vitamin D synthesis. Many experts now believe moderate sun exposure, or heliotherapy, should be sought rather than avoided, with beneficial influences on blood pressure, general well-being, and balancing the sleep-wake cycle. [1,4]However, controlled sun exposure is an unreliable means of generating adequate synthesis of this unique vitamin. Regional variations in climate and cultural practices can significantly impact serum 25(OH)D. Even in temperate climates like Honolulu, Hawaii, over half of otherwise healthy patients have demonstrated sub-optimal vitamin D indices. [5]

The importance of appropriate serum 25(OH)D on multiple health measures is widely described. Vitamin D supplementation reveals direct dose-response improvements in bone mineral density, fracture prevention, and lower extremity strength and function. [3,4,6,7] A serum 25(OH) D within normal limits is associated with a decreased risk of microbial infections, falls, numerous cancers, multiple sclerosis, cardiovascular disease, autoimmune diseases, and diabetes mellitus. [6-10] Standardized management of vitamin D deficiency could potentially have profound effects on health care costs and morbidity related to countless chronic diseases. [6,11]

The high prevalence of vitamin D deficiency in those undergoing orthopedic surgery is well described. [12] However, limited studies exist documenting vitamin D deficiency in the elective arthroplasty group, particularly in a subtropical climate. The goal of our study is to explore the prevalence and distribution of vitamin D deficiency among an elective total joint arthroplasty (TJA) population within a lower latitude climate with relatively abundant sunshine. We hypothesize a continued high prevalence of vitamin D deficiency within this population, exposing a potential opportunity to improve outcomes with proper management.

Materials and Methods

From January to December, 2014, serum 25(OH)D levels were collected during a standard preoperative workup prior to primary or revision joint arthroplasty by the senior author (H.D.S.) in South Carolina. Mean serum 25(OH)D, seasonal variation, and patient demographics were recorded. We defined Vitamin D deficiency consistent with the current Endocrine Society classification: serum 25(OH)D < 20 ng/ml, 21-29 ng/ml, and 30-100 ng/ml representing deficiency, insufficiency, and normal, respectively. Post-traumatic primary joint replacement and revision secondary to periprosthetic joint infection (PJI) were excluded to limit confounding variables. The association between vitamin D classification and study group was tested with Fisher's exact test. Non-parametric Mann Whitney Wilcoxon tests with t-approximation two-tailed tests were used for intergroup comparisons.

Results

A total of 308 patients underwent evaluation. 46.8% (144) of the participants were female, and 89.6% (276) identified as Caucasian. The mean patient age was 68.3 years (± 13.8 , 32-88). The average serum 25(OH)D was 29.8 ng/ml (± 12.8 , 5.1-79.9), with only 46.2% of patients having a normal serum 25(OH)D (p<0.0001). Caucasian and non-white patients averaged 33 ng/ml [56% normal 25(OH)D] and 25 ng/ml [36% normal 25(OH)D], respectively, however this was not significant (p = 0.22) (figure 1). Patients over the age of 65 demonstrated slightly lower



Serum 25-hydroxy vitamin D [25(OHD] recorded as "ng/ml."

serum 25(OH)D (28.5ng/ml) compared to those under 65 (30.7ng/ml)(p=.12). As expected, serum 25(OH)D demonstrated variation throughout the year: January to March, April to June, July to September, and October to December recorded 28.5 ng/ml, 31.73 ng/ml, 36.57 ng/ml, and 23.03 ng/ml 25(OH)D, respectively (figure 2). July recorded the highest monthly average serum 25(OH)D with 40.11 ng/ml, while February recorded the lowest reaching 25.2 ng/ml.

Discussion

Our results demonstrate the majority (53.8%) of an otherwise classically low risk population based on latitude [13] and race [14] present with at least vitamin D insufficiency prior to undergoing elective total joint arthroplasty. Our findings reinforce previous findings regarding seasonal variations in serum 25(OH)D. [15] Additionally, while not significant, our findings lend support to the well described natural physiologic age dependent decline in serum 25(OH)D. [16] Non-white patients over 65 years of age during the winter months were at the greatest risk of vitamin D deficiency.

A majority of patients undergoing elective orthopedic surgery have demonstrated vitamin D insufficiency, with orthopedic trauma patients at a higher risk. [9,12] One study reported 77.7% of hip fracture patients had sub-normal serum 25(OH)D versus 58.6% in normal controls. [17] Furthermore, periprosthetic joint infections (PJI) show a close association with vitamin D deficiency in the arthroplasty population. [9] Emerging evidence also suggests vitamin D plays a significant role in antimicrobial activity. [7,8,18,19] Numerous advantages of maintaining appropriate serum 25(OH)D continue to emerge, however, appropriate management remains controversial. [7,18,20,21] Multiple dosing protocols have been evaluated. [20,21] One study suggested daily requirements of at least 1,600 IU D3 for optimal serum levels. [21] This dose was further analyzed in a randomized placebo control trial, where the mean serum 25(OH)D increased from 20.6 ng/ml to 33.7 ng/ml in the treatment group, but declined to 18.5 ng/ ml in the control group. [20] However, while encouraging, these findings suggest that even 1,600 IU D3 daily may fail to achieve the optimal serum threshold. Load and maintenance dosing is recommended when deficiency is identified. [10,22] Bolus dosing as high as 500,000 IU D3 with maintenance doses of 50,000 IU D3 monthly have demonstrated safe and rapid serum 25(OH)D normalization. Many experts believe 30 ng/mL 25(OH)D reflects a minimum threshold for both skeletal and non-skeletal benefits,

with an optimal range between 36 and 40 ng/ml. [2-4,20-22] The Endocrine Society recommends 1500-2000 IU D3 daily to meet these goals, and 50,000 IU D2 or D3 weekly for 8 weeks is recommended when deficiency is identified. [10]

Surgical site infections (SSIs) in the setting of TJA can have catastrophic consequences. [23] The vitamin D pathway is intimately involved in antimicrobial activity through both the innate and acquired immune response. [8,19] For example, interferon-gamma (IFN-y), a key antimicrobial mediator, is only induced in vitamin D-sufficient sera, with vitamin D receptor (VDR) induction required for antimicrobial peptide expression. [8] Additionally, tolllike receptors (TLRs), a key mediator of the innate immune system, demonstrate a key interplay with the vitamin D pathway. [19] Human macrophages appear to up-regulate VDR and vitamin D-1-hydroxylase genes inducing antimicrobial peptides like cathelicidin to eradicate microbial infections. Compared to Caucasian sera, African-American sera demonstrate significantly lower cathelicidin induction and antimicrobial peptide expression. Vitamin D supplementation for one year in both African-Americans and Caucasians in one study corrected the serum 25(OH)D discrepancy (24.1 ng/ml versus 37.2 ng/ml) after just two months of treatment, reaching a final 67.7 ng/ml and 67.3 ng/ml at one year, respectively. [2] Furthermore, a significantly higher prevalence of vitamin D deficiency was found in patients undergoing revision TJA for PJI compared to both primary TJA and aseptic loosening revision groups, with 13.29 ng/ml versus 20.52 ng/ml, respectively. [9] Interestingly, serum 25(OH)D shows an inverse relationship with C-reactive protein, although the significance of this relationship is not completely understood. [12,24]

As a cross sectional analysis, this study has several inherent limitations. First, we are unable to assess specific trends in serum 25(OH)D. Therefore, perioperative and long term outcomes associated with specific serum 25(OH) D are not revealed. In a addition, specific comorbidities and preoperative vitamin supplementation were not recorded. Our population was also largely Caucasians, which may have substantial influences on the generalizability of our findings. Other modes of diagnosis and treatment including intact vitamin D [18] and 25(OH)D3 (HyD) [7] are on the horizon and show encouraging results. Further research is needed to investigate the association between vitamin D deficiency, appropriate treatment thresholds, and specific orthopedic outcomes. Current evidence supports normalizing Vitamin D levels in the perioperative period with potentially reduced patient length of stay and SSIs in the orthopedic population. [25] At our institution we have developed a perioperative protocol based on a preoperative serum 25(OH)D evaluation. Those with serum 25(OH)D under 35 ng/ml receive 5,000 IU D3 daily beginning 2 weeks prior to surgery, with re-evaluation the day of surgery. Patients with a serum 25(OH)D <30ng/ml the day of surgery receive 50,000 IU D2 weekly for 8 weeks, followed by 2000 IU D3 daily indefinitely. Endocrinology referral is warranted for continued vitamin D deficiency.

Conclusion

Our results demonstrate the majority (53.8%) of an otherwise classically low risk patient population present with at least vitamin D insufficiency prior to undergoing elective total joint arthroplasty, with elderly non-white patients in the winter months at the highest risk. Appropriate vitamin D management is associated with favorable influences on both skeletal and non-skeletal outcomes. Potential complications of TJA, including periprosthetic joint infection and aseptic loosening, can possibly be decreased with proper identification and treatment. Appropriately designed studies are needed to fully elucidate the importance of vitamin D in short and long term outcomes within the total joint arthroplasty population.

References:

- Baggerly CA, Cuomo RE, French CB, et al. Sunlight and Vitamin D: Necessary for Public Health. Journal of the American College of Nutrition. 2015; 34 (4): 359-365
- Garrett-Mayer E., Wagner CL, Hollis BW, et al. Vitamin D3 Supplementation (4000 IU/d for 1 y) eliminates differences in circulation 25-hodroxyvitamin D between African American and white men. The American Journal of Clinical Nutirition. 2012; 96: 332-336.
- Hollis BW.Circulating 25-Hydroxyvitamin D Levels Indicative of Vitamin D Sufficiency: Implications for Establishing a New Effective Dietary Intake Recommendation for Vitamin D. The Journal of Nutrition. 2005; 135: 317-322.
- 4. Vieth R. What is the optimal vitamin D status for health? Progress in Biophysics and Molecular Biology. 2006; 92: 26-32.
- Binkley N, Novotny R, Krueger D, et al. Low Vitamin D Status despite Abundant Sun Exposure. The Journal of Clinical Endocrinology & Metabolism. 2007; 92 (6):2130-2135.
- Bishcoff-Ferrari HA, Giovannucci E, Willett WC, et al. Estimation of optimal serum concentrations of 25-hydroxyvitamin D for multiple health outcomes. The Am Journal of Clinical Nutrition. 2006; 84: 18-28.
- Bischoff-Ferrari HA, Dawson-Hughes B, Stocklin E, et al. Oral Supplementation With 25 (OH) D3 Versus Vitamin D3: Effects on 25(OH) D Levels, Lower Extremity Function, Blood Pressure, and Markers of Innate Immunity. Journal of Bone and Mineral Research. 2012; 27(1): 160-169.
- Fabri M, Stenger S, Shin D, et al. Vitamin D is Required for IFN-Mediated Antimicrobial Activity of Human Macrophages. Science Translation Medicine. 2011; 3 (104): 1-10.
- Maier GS, Horas K, Seeger JB, et al. Is There an Association Between Periprosthetic Joint Infection and Low Vitamin D Levels. International Orthopaedics. 2014; 38 (7): 1499-1504.
- Holick MF, Binkley NC, Bischoff-Ferrari HA, et al. Evaluation, Treatment, and Prevention of Vitamin D Deficiency: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, 2011; 96 (7): 1911-1930.
- Grant W, Schuitemaker GE. Health benefits of higher serum 25-hydroxyvitamin D levels in The Netherlands. Journal of Steroid Biochemistry and Molecular Biology. 2012; 121: 456-458

- Waldron JL, Ashby HL, Cornes MP, et al. Vitamin D: A negative acute phase reactant. Journal of Clinical Pathology. 2013; 66: 620-622
- Leary PF, Zamfirova I, Au J, et al. Effect of Latitude on Vitamin D Levels. The journal of the American osteopathic association. 2017;117:433-439.
- Harris SS. Vitamin D and African Americans. Journal of Nutrition. 2006. 136, 4 1126-1129.
- Levis S, Gomez A, Jiminez C, et al. Vitamin D deficiency and seasonal variation in an adult South Florida population. The J. of Clin Endocin & Metabolism. 2005;90(3):1557-1562.
- Gallagher JC. Vitamin D and Aging. Endocrinology and metabolism clinics of North America. 2013;42(2):319-332.
- Wang X, Yang B, Wang Y, et al. Serum Levels of 25-hydroxyvitamin D and Functional Outcome in Older Patients with Hip Fracture. Journal of Arthroplasty. 2014; 30: 891-894.
- Hollis BW, Wagner CL. The Role of the Parent Compoud Vitamin D with Respect to Metabolism and Function: Why Clinical Dose Intervals Can Affect Clinical Outcomes. The Journal of Clinical Endocrinology & Metabolism. 2013; 98 (12): 4619-4628.
- (16)Liu PT, Stenger S, Li H, et al. Toll-Like Receptor Triggering of a Vitamin D-Mediated Human Antimicrobial Response. Science. 2006; 311: 1770-1773.
- Toss G. Is a daily supplementation with 40 microgram vitamin D3 sufficient? A randomized controlled trial. European Journal of Nutrition. 2012; 51: 939-945.
- Cashman D, Hill TR, Lucey AJ, et al. Estimation of the dietary requirement for vitamin D in healthy adults. The American Journal of Clinical Nutrition. 2008; 88: 1535-1542.
- Bacon CJ, Gamble GD, Horne AM, et al. High-dose oral Vitamin D3 supplementation in the elderly. Osteoporosis International. 2009; 20: 1407-1415.
- Pulido L, Ghanem E, Joshi A, Purtill JJ, Parvizi J. Periprosthetic Joint Infection: The Incidence, Timing, and Predisposing Factors. Clinical Orthopaedics and Related Research. 2008;466(7):1710-1715. doi:10.1007/s11999-008-0209-4.
- Chandler PD, Scott JB, Drake BF, et al. Impact of Vitamin D Supplementation on Inflammatory Markers in African Americans: Results of a Four-Arm Randomized, Placebo-Controlled Trial. American Association for Cancer Research. 2013; 7 (2): 218-225.
- Myint MW, Wu J, Wong E, Chan SP, et al. Clinical benefits of oral nutritional supplementation for elderly hip fracture patients: a single blind randomized controlled trial. Age and Aging. 2012; 42: 39-45.

SUBMISSION HISTORY

Submitted June 16, 2017 Reviewed August 21, 2017 Revised September 8, 2017 Accepted September 11, 2017 Published September 30, 2017

AUTHOR AFFILIATIONS

- 1 Brandon Naylor, DO
- Mercy Health Department of Orthopedics, 2213 Cherry St Toledo, OH 43608 2 Amy King, APRN,MSN; Sarah Voges, APRN,MSN; Terry Blackwell PA; Robin Huff,
- BS; Harold "Del" Schutte, Jr., MD East Cooper Medical Center, 2000 Hospital Drive, Mt Pleasant, SC 29464

(Direct inquires to Brandon Naylor, Naylor.brandon@gmail.com)

AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

COPYRIGHT & OPEN ACCESS

© 2017 Head, Nelson, Dyball, Lawrence. All rights reserved. Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review is an open access publication and follows the <u>Creative Commons Attribution</u>-

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".

OPEN ACCESS





Check for updates





ORIGINAL ARTICLE

http://dx.doi.org/10.15438/rr.7.3.174

Mid-Term Follow Up Results of Mini-Subvastus Approach for Total Knee Arthroplasty in Obese Patients

Kekatpure A¹, Shah N¹, Nistane P¹, Agrawal N¹

Abstract

Background: Use of mini-subvastus approach for total knee arthroplasty (TKA) in obese patients is still debated. We had hypothesized in our study published in July 2010, that obesity should not be considered as a problem for patients undergoing a TKA with the mini-subvastus approach as the anatomy of the quadriceps in the obese and the non-obese patient population is the same. We present a mid-term follow-up study of the same set of patients with an average follow up of 96 months.

Materials and Methods: There were 97 obese patients (109 knees), 81 females + 16 males with a mean age of 64 years that underwent TKA by mini-subvastus approach between January 2006 to July 2007. A total of 16 patients (18 knees) were morbidly obese. Out of the total number of patients, 8 were lost in follow up and one died because of unrelated causes. Out of these 9 patients, two were operated for bilateral TKR. Thus, we have a midterm follow up results of 98 knees in 88 patients. Knee society and functional scores were used for patient evaluation and compared to their pre-operative and earlier follow up scores.

Results: At our latest follow-up of 96 months the Knee Society Score and functional scores were 84 (range 64-90) and 58 (range 45-75) respectively. One morbidly obese lady had aseptic loosening of tibial component at 42 months that needed a revision.

Conclusion: Our mid-term results show that the minisubvastus approach can be considered for TKA in obese and morbidly obese patient population with outcomes comparable to standard surgical approach.

Background

Obesity is an increasing worldwide problem and the demand for Total knee arthroplasty (TKA) in this patient group is increasing. [1,2] There is a general consensus that excessive weight is a risk factor for TKA as obese patients have a higher incidence of intra-operative and post-operative complications such as wound healing problems, in-fections, higher incidence of damage to medial collateral or patellar tendon ligament, lower Knee society scores and higher revision rates due to aseptic loosening. [3-5] However, some studies have shown that obesity does not influence the clinical outcome and complication rates at five years following a TKA. [6] Alteration in technique for soft tissue closure and protection of medial collateral ligament can decrease the risk of perioperative complications in obese and morbidly obese patients. [5]

There is no consensus for the ideal surgical approach for TKA. In the subset of obese patients requiring a TKA

Keywords: Mini-subvastus approach, Total knee arthroplasty, Obesity Level of Evidence: AAOS Therapeutic Level II Educational Value & Significance: JISRF Level B a standard midline parapatellar approach is generally recommended. Subvastus approach has many advantages as preservation of extensor mechanism integrity, better patellar tracking and early quadriceps recovery thereby facilitating early post operative recovery [7-9] These advantages of the subvastus approach are particularly relevant for the obese with their limited pre-operative mobility. However, obesity is considered a relative contraindication for the subvastus approach in TKA as it is thought to lead to an inadequate exposure, difficulty in eversion of patella and increased risks of patellar tendon avulsion. [10,11] Some authors suggested that increasing obesity can cause greater difficulties in exposure due to higher thigh girths and if the thigh girth measurement is more than 55 cm, the incidence of peri-operative complications with the subvastus approach in TKA is higher. [12]

In our previous study published in July 2010, we had hypothesized that obesity should not be considered a contraindication for this approach for TKA as the anatomy of extensor mechanism does not differ in the obese and nonobese population. Initially we had presented a short term follow up of a group of obese population operated by mini subvastus approach for TKA. Here we present a mid term follow up results of the same group of patient population.

Materials and Methods

All obese (BMI>30) and morbidly obese (BMI>40) patients with a diagnosis of primary OA of knee who underwent a TKA with the mini-subvastus approach between January 2006 to July 2007 at our center were included in this study. Preoperative Anteroposterior (AP) and lateral radiographs (Lat) were taken in all patients (Figure 1) All



Figure 1. Showing Preoperative Anteroposterior and Lateral radiograph.

surgeries were performed by the senior author using Mini-Subvastus approach. $[\underline{13}]$

Surgical Technique

A skin incision was made slightly medial to the midline of the knee, extending from the superior pole of the patella to the tibial tubercle, with the knee in 90° of flexion. Dissection was carried out until the extensor apparatus was exposed. A medial flap was raised to identify the inferior margin of the vastus medialis. The vastus medialis was bluntly dissected off the intermuscular septum. An 'L' shaped capsulotomy was made with the horizontal limb of the L along the inferior margin of the vastus medialis up to the superior pole of the patella. The vertical limb of the L extended from here up to the tibial tubercle. At this stage it was possible to displace the patella laterally to expose the suprapatellar synovium, which was then divided medially keeping the suprapatellar pouch intact. This method allows patella to be subluxed in the lateral gutter further. If there were prominent osteophytes in the trochlear region, these were removed with the knee in extension. A Hohmann retractor was placed, retracting the subluxated patella. A preliminary soft tissue release was carried out from the medial tibia until the mid-coronal plane in the varus knees. The knee was then flexed, with the Hohmann retractor retracting the patella in the lateral gutter. This flexion of the knee with the patella retracted laterally could be easily achieved when the knee had a good range of movement. When the knee was stiff this manoeuver could be difficult. In these cases, (stiff knees) quadriceps muscle needed to be dissected off the medial internuscular septum more proximally. Also all hypertrophic osteophytes from the trochlear region and from the patella required meticulous removal so that the patella could be displaced laterally. Once the patella was displaced laterally satisfactorily the knee was gently flexed with a Hohmann retractor placed laterally to keep the patella laterally subluxed. Now another retractor was placed medially around the medial femoral condyle to expose the knee. The cruciate ligaments were excised and this allowed the knee to be flexed a little more. Care was taken to ensure that the patellar tendon insertion remained intact.

Overhanging osteophytes were removed from the femur and the tibia. The distal femoral cut was made first using a downsized intramedullary jig. Remnants of the cruciate ligaments were further excised. (Only Posterior stabilized implants were utilized) The knee was then extended. The lateral tibial plateau was exposed in extension by sharp dissection, taking care to avoid injury to the patellar ligament. The fat pad was not excised. A retractor was placed around the lateral tibial metaphysis and another was placed around the medial tibial metaphysis. The knee was flexed again and the third Hohmann retractor was used posteriorly to subluxate the tibia forward. An extramedullary jig was utilized to cut the proximal tibia at an adequate depth and angle. In some cases, the cut tibial bone was removed in piecemeal. The knee was now extended and the menisci were excised in extension. Care was taken whilst removing the medial meniscus, not to damage the medial collateral ligament. Overhanging osteophytes were removed from the posteromedial tibia if present. A spacer block was utilized to check the extension space. If necessary, further medial or lateral release was done to establish a proper extension space and to check the alignment. Thereafter, the femur was sized and the appropriate AP cutting jig was placed on the femur such that the flexion space equaled the extension space. Due care was taken to avoid notching of the anterior cortex of the femur by the anterior cut. Champher and the notch cuts were made next. In case of the high-flex (n=90) variety of knee prosthesis, the posterior femur was recut appropriately. The highflex implant was used whenever the knee which was operated had an excellent pre-operative ROM i.e. > 120 degrees). The patella was everted only after the femoral and tibial cuts had been made. Hypertrophic suprapatellar synovium and overhanging osteophytes from the patella were easily removed after everting the patella. The jig was utilized to size and resect the patella if patellar resurfacing was to be carried out (n=3). The patellar resurfacing was carried out when there were prominent arthritic trochlear and patellar lesions. Trial components were inserted and a careful check was made regarding the range of movement, stability, and patellar tracking. If posterior femoral osteophytes were present, they were removed using a curved osteotome. If required, posterior capsular release was carried out. The bony surfaces were washed with pulsatile lavage, dried, and the appropriate components were cemented and the trial insert was placed into the tray. The knee was brought to full extension to pressurize the bone-cement interface during polymerization. After the cement had cured, the trial insert was removed and the entire periphery of both the femoral and tibial implants was checked for any extruded cement, which was removed if present. The definitive tibial insert was placed after adequately cleaning and drying the tibial implant. Thorough lavage was given.

An apical stitch at the angle of the 'L' was first taken to ensure that the capsule was neither advanced nor recessed. The rest of the closure was routine. The knee was infiltrated with 20 ml of mixture containing 0.25% bupivacaine, cefuroxime, and normal saline. A bulky dressing was applied for the first 24 hours. A femoral nerve catheter was inserted with the help of a nerve stimulator (Stimuplex, Braun) and 10 ml of a mixture containing 2% lignocaine and 0.25% bupivacaine was injected at 4-hourly intervals for 1 day. For 24-48 hours postoperatively a cryocuff was utilized on the operated knee.

The knee implants utilized included Zimmer NexGen Legacy PS in 18 knees, Zimmer NexGen Highflex in 39 knees, Zimmer NexGen Gender solution in 51 knees and PFC Sigma (Cruciate substituting) in 1 knee to give a total of 109 knees.

There were total 97 patients comprising of 81 females and 16 males with a mean age of 64 years (Range 49-80 years), with none of them having history of previous knee surgery. Out of the total, 12 were operated for staged bilateral knee arthroplasty, within the above study period. The patient demographics were as shown in Table 1. The knees were evaluated pre- and postoperatively by the American Knee Society (KSS) clinical and functional score. [14] Standard anteroposterior and lateral view radiographs were obtained post-operatively (Figure 2 & Figure 3). At 6 weeks post-operatively, an additional merchant view (skyline view) radiograph was taken. The postoperative follow-up was at 6 weeks, 3 months, 6 months, and yearly thereafter. At each yearly follow up radiographs were taken to identify linear radiolucent lines around implants and where compared with previous radiographs to determine whether they were progressive or non-progressive. (Figure 4) The final evaluation has been done at a minimum of 90 months with an average follow up of 96 months (Range 90 to 108 months).

	Obese Group	Morbid Obese Group
Total no. of patients (n=97)	81	16
Total no. Knees (n=109)	91	18
Varus knees		
- Mild Deformity (<150)	79	12
- Severe Deformity (>150)	10	05
Valgus Knee	02	01
Average height (cm)	153.75	149.69
Average Weight (kg)	75.36	97.30
Average BMI (kg/m2)*	33.52	43.29
Average thigh girth (cm)	50.17	61.01
Gender		
- Male	16	0
- Female	65	16

*Thigh girth was measured 15cm proximal to adductor tubercle. [13]



Figure 2. Showing Postoperative day 1 Anteroposterior and Lateral radiograph.



Figure 3. Showing Anteroposterior and Lateral radiograph at 2 months followup.



Figure 4. Showing Anteroposterior and Lateral radiograph at 8 years followup.

Results

The mini-subvastus approach was used in all cases in the study group. Out of the total number of patients, 08 were lost in follow up and 01 died because of unrelated cause. Out of these 09 patients, two were operated for bilateral TKR. Thus, we had midterm follow up results of 98 knees in 88 patients. Mean age of the patients at the last follow-up was 69.5 years.

As in our previous study, the Knee Society score (KSS) had shown improvement from the preoperative average of 42 (range: 17-62) to 89 (range: 72-95) and Knee Society functional score had improved from the preoperative average of 48 (range: 15-60) to 65 (range 50-80) postoperatively. At our latest follow-up of 96 months the Knee Society Score and functional scores were 84(range 64-90) and 58 (range 45-75) respectively. Patellar tracking was excellent in all patients, with none of them requiring lateral release during surgery. Overall the mechanical alignment of the lower limb remained satisfactory with an average valgus angle of 6 degrees (range 30-90).

We had complications in the form of intraoperative Medial collateral ligament (MCL) injury in one case and complete avulsion of patellar tendon in an obese patient with stiff knee. Both were managed surgically. No wound complications and infection were noted in any case.

At the latest follow-up, patient with MCL injury had KSS and functional score of 83 and 70 and the other patient with repaired patellar tendon avulsion had a KSS of 68 and functional score of 55. A young (48yrs) morbidly obese patient had aseptic loosening of the tibial component 42 months post surgery. It was managed with revision arthroplasty again using subvastus approach, with recent follow up KSS and FS of 76 and 65 respectively.

Discussion

The mini-subvastus is a minimally invasive approach for TKA which preserves quadriceps integrity thus allowing a faster and a less painful recovery as compared to medial parapatellar approach. [7,8] Obesity has been considered a relative contraindication for mini-subvastus approach, because of the difficulty in exposure of the knee and eversion of the patella. [11] Our earlier publication with short term follow up showed good functional outcome. In immediate postoperative period, quadriceps recovery in our patients was early and 95% of the patients (103 knees in 87 patients) were able to do an active SLR by day 2 without any lag. The KSS and Knee society functional score had improved from the preoperative average of 42 (Range 17-62)

& 48 (range:15-60) respectively to 89 (Range 72-95) and 65 (range:50-80) respectively in the post operative period during the initial follow up of 1 year. These scores were comparable to those in studies with non-obese patients and obese patients operated upon with conventional approaches. At midterm average follow up of 96 months the mean Knee Society Score and Functional scores were 84 and 58 respectively. We did a literature study to compare our results with previously published studies. (Table 2) As per a results of Foran et al the implant failure rate, as defined either clinically (Knee Society Score- KSS) or radiographically, is significantly higher in the obese population. [4] Kerkhoffs et al did a meta analysis to study the influence of obesity on the complication rate and outcome of total knee arthroplasty, and found that the overall revision rate is 1.79 times higher in an obese group of patients compared to patients with a normal BMI after five years follow up. [15]In our study, one morbidly obese young patient (age at index operation 48 years) with BMI > 50, had failure due to aseptic loosening of tibial component 42 months post surgery. This was treated with a revision TKA using constrained condylar prosthesis with tibial and femoral rods, again using Subvastus approach. We have been successfully using Subvastus approach for revision TKR as well.

There has been a concern over the issue of component malalignment with minimally invasive TKA especially in obese patients. In our study at latest follow up,all knees had valgus anatomical alignment with average valgus angle maintained at 60 (range 30 - 90), which was measured with standing long leg film as seen in other series. We be-

Study	Year	Patients (knees)	Mean Age in years	Mean Follow-up in years	Mean operative at last fol	Post e scores llow-up
					KSS	FS
Winiarsky et al [24]	1998	40 (50)	64.6 (45.6- 76.5)	4.8 (2-13)	84	53
Spicer et al [25]	2001	285 (326)	66 (35-83)	6.4 (4-12)	77.9	65.8
Foran et al [4]	2004	27 (30)	62 (36-78)	6.7 (5-10.3)	81	NR
Krushell R.J. et al [26]	2007	NR (39)	67.4 (48-81)	7.5 (5-14)	91	44
Dewan et al [27]	2009	102 (135)	64 (NR)	5.4 (2.2-14.6)	88	69
Current study	2015	72(83)	64 (49-80)	8 (7.5-9)	84	58

Table 2. Comparison of Reported results of Total Knee Arthroplasty in Obeseand Morbidly Obese patients with current Study [23]

KSS= Knee Society Score, FS =Functional score

lieve that component malalignment in Mini-subvastus approach can be avoided by proper use of mobile skin window and careful identification of anatomical. On the knee society roentgenographic evaluation and scoring system, the scores remained less than 10 in all of our patients. As per a recent study by Chalidis BE et al, minimally invasive surgery is a reliable and safe option in obese patients undergoing TKR regardless the level of BMI. [22] It is associated with improved early clinical outcome with optimum radiographic positioning of the implants. An interesting observation in our study was that in comparison to obese patients with age less than 60 years (n=31), obese patients with age more than 60 years (n=52) performed better, with an average KSS of 77 and functional score of 52 in first group as compared to 86 and 63 in the elderly group (p value < 0.05). The explanation for this may be related to lesser physical activity and patient demands in elderly population. Thus it is safe to assume that while elderly obese patients with knee OA are ideal candidates for TKA, caution must be exercised while considering TKA in the young obese especially if morbidly obese BMI >40 or if super obese BMI > 50 and they should be advised to lose weight prior to surgery or be counseled regarding the inferior results before proceeding with surgery. [3]

In the recent years, there has been an increase in the need for TKA performed in younger population for various reasons, obesity being one of them. In a recent study, Kurtz et al. projected that patients younger than 65 years will become the majority treated with TKAs during the next two decades and that up to one million TKAs may be per-

> formed for patients younger than 55 years by 2030. [16] Recent studies reporting data from community, academic, and national registries have suggested higher TKA revision rates occur in the younger patient group. [17-19] Out of the young patients in our series, one morbidly obese patient required revision as stated earlier, although the others are being routinely followed to detect early signs of loosening.

> Many groups report that post-operative KSS is significantly lower in an obese population, however, the level of improvement is similar to the non-obese group. [5,20,21]

The limitation of this study is that we do not have a control group of non obese patients or those operated by the medial parapatellar. Hence we have compared our results with previously published available literature (Table No. 02). Also we have not separately evaluated the results in Morbidly Obese patients since the number of morbidly obese patients in our study were less. We have not accounted for associated comorbities in the obese and morbidly obese group that may have affected the clinical outcome. A separate study involving multiple centres and larger number of patients may be considered to compare outcome of TKA in obese patients operated through minisubvastus and medial parapatellar approaches.

Conclusion

To conclude, the follow up evaluation results in our patient population operated by subvastus approach have been good till 96 months. This approach offers excellent intraoperative exposure even in obese and morbidly obese patients. It has not resulted in increased complication in our hands and our results have been comparable to TKA with conventional approach. It can be considered for obese and morbidly obese patients undergoing TKA.

References:

- Saif Salih and Paul Sutton. Obesity, knee osteoarthritis and knee arthroplasty: a review. BMC Sports Science, Medicine and Rehabilitation 2013, 5:25
- 2. Vasarhelyi EM, MacDonald SJ: The influence of obesity on total joint arthroplasty.
- 3. J Bone Joint Surg Br 2012, 94:100-102.
- Amin AK, Clayton RA, Patton JT, Gaston M, Cook RE, Brenkel IJ. Total knee replacement in morbidly obese patients. Results of a prospective, matched study. J Bone Joint Surg Br. 2006;88:1321–6. [PubMed]
- Foran JR, Mont MA, Etienne G, Jones LC, Hungerford DS. The outcome of total knee arthroplasty in obese patients. J Bone Joint Surg Am. 2004;86:1609–15. [PubMed]
- Winiarsky R, Barth P, Lotke P. Total knee arthroplasty in morbidly obese patients. J Bone Joint Surg Am. 1998;80:1770–4. [PubMed]
- Amin AK, Patton JT, Cook RE, Brenkel IJ: Does obesity influence the clinical outcome at five years following total knee replacement for osteoarthritis? J Bone Joint Surg Br 2006, 88:335-340. <u>PubMed Abstract | Publisher Full Text</u>
- Matsueda M, Gustilo RB. Subvastus and medial parapatellar approaches in total knee arthroplasty. Clin Orthop Relat Res. 2000;371:161–8. [PubMed]
- Scuderi GR, Tenholder M, Capeci C. Surgical approaches in mini-incision total knee arthroplasty. Clin Orthop Relat Res. 2004;428:61–7. [doi: 10.1097/01. blo.0000148574.79874.d0]
- Boerger TO, Aglietti P, Mondanelli N, Sensi L. Mini-subvastus versus medial parapatellar approach in total knee arthroplasty. Clin Orthop Relat Res. 2005; 440:82–7. [PubMed]
- Scuderi RG, Tria J A. 2006, Insall and Scott's Textbook of Knee Surgery, New York,1634p
- Engh GA. Midvastsus approach. In: Scuderi GR, Tria Aj Jr, editors. Surgical Techniques in Total Knee Arthroplasty. New York: Springer-Verlag; 2002. pp. 127–30.
- Kim JM, Choi NY, Kim SJ. Large thigh girth is a relative contraindication for the subvastus approach in primary total knee arthroplasty. J Arthroplast. 2007;22:4. [PubMed]
- Halder A, Beier A, Neumann W. Mini-subvastus approach for total knee replacement.Oper Orthop Traumatol. 2009 Mar;21(1):14-24. [doi: 10.1007/s00064-009-1602-1]

- Ewald FC. The Knee Society total knee arthroplasty roentgenographic valuation and scoring system. Clin Orthop Relat Res. 1989;284:9–12. [PubMed]
- Kerkhoffs GMMJ, Servien E, Dunn W, Dahm D, Bramer JAM, Haverkamp D: The influence of obesity on the complication rate and outcome of total knee arthroplasty: a meta-analysis and systematic literature review. J Bone Joint Surg Am 2012, 94:1839–1844.
- Kurtz SM, Lau E, Ong K, Zhao K, Kelly M, Bozic KJ. Future young patient demand for primary and revision joint replacement: national projections from 2010 to 2030. Clin Orthop Relat Res. 2009 Oct;467(10):2606–2612 [PubMed]
- Gioe TJ, Novak C, Sinner P, Ma W, Mehle S. Knee arthroplasty in the young patient: survival in a community registry. Clin Orthop Relat Res. 2007;464:83–87. [PubMed]
- Rand JA, Trousdale RT, Ilstrup DM, Harmsen WS. Factors affecting the durability of primary total knee prostheses. J Bone Joint Surg Am. 2003;85:259–265. [PubMed]
- W-Dahl A, Robertsson O, Lidgren L. Surgery for knee osteoarthritis in younger patients: a SwedishRegister Study. Acta Orthop. 2010;81:161–164 [PubMed]
- Jones CA, Cox V, Jhangri GS, Suarez-Almazor ME: Delineating the impact of obesity and its relationship on recovery after total joint arthroplasties. Osteoarthr Cartil OARS Osteoarthr Res Soc 2012, 20:511–518.
- Collins RA, Walmsley PJ, Amin AK, Brenkel IJ, Clayton RAE: Does obesity influence clinical outcome at nine years following total knee replacement? J Bone Joint Surg Br 2012, 94:1351–1355.
- Chalidis BE1, Petsatodis G, Christodoulou AG, Christoforidis J, Papadopoulos PP, Pournaras J. Is obesity a contraindication for minimal invasive total knee replacement? A prospective randomized control trial. Obes Surg. 2010 Dec;20(12):1633-41. Epub 2009 Sep 16. [PubMed]

SUBMISSION HISTORY

Submitted February 5, 2017 Reviewed April 24, 2017 Revised July 30, 2017 Accepted August 14, 2017 Published September 30, 2017

AUTHOR AFFILIATIONS

1 Aditya laxmikant Kekatpure, MBBS, D. Ortho, DNB, MNAMS; Nilen A Shah, D. Ortho, MS Ortho, MCh Ortho; Prithviraj Prabhakar Nistane, MBBS, MS Ortho, DNB Ortho; Pritam K Agrawal, MBBS, MS Ortho, DNB Ortho Bombay Hospital, 12 Marine Lines, Vitthaldas Thackersey Marg, New Marine Lines, Marine Lines, Mumbai, Maharashtra 400020, India

(Direct inquires to Nilen A Shah, drnilen@gmail.com)

AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

COPYRIGHT & OPEN ACCESS

© 2017 Kekatpure, Shah, Nistane, Agrawal. All rights reserved. Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review is an open access publication and follows the <u>Creative Commons Attribution-</u>



<u>NonCommercial CC BY-NC</u>. 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".







ORIGINAL ARTICLE

http://dx.doi.org/10.15438/rr.7.3.193

Check for updates

The 16-Year Evolution of Proximal Modular Stem Design – Eliminating Failure of Modular Junction

Tkach T¹, McTighe T²

Abstract

Background: The complexity of hip reconstruction has been and continues to be a perplexing problem with restoring leg length, femoral offset, joint stability and overall hip implant fixation. These were contributing factors that lead to the development of a novel proximal femoral component design "Apex Modular Stem" (Omni, Raynham, MA). The basic stem geometry features a straight stem with a metaphyseal fit and fill cone, a medial triangle and a modular neck junction that allows for version and offset adjustment.

In recent years, there has been great concern with the use of modularity in total hip arthroplasty. The goals of this study are (1) to identify complications with the use of a proximal modular design and (2) demonstrated factors that have eliminated those complications.

Methods: This is a retrospective study of a single surgeon series (Generation I and Generation II) of using the same cementless stem and proximal modular neck body (Apex Modular Stem and Omni Mod Hip Stem) from 2000 to 2016 totaling 2,125 stems (483 Generation I and 1,642 Generation II).

Results: Generation I, 483 stems were implanted between 2000 and 2004 of which 31 alignment pins sheared resulting in a revision rate of 6.4%. Generation II, 1,642 stems have been implanted between 2004 and 2016 all by the same surgeon with no failures of the modular junction.

Conclusion: All implant devices entail a multitude of risks and benefits. The Apex Modular Stem (Generation I), provided excellent fixation, minimal risk of modular junc-

tion corrosion, and simple control of anteversion and femoral offset. The limitation was found to be the risk of the alignment pin shearing (6.4%). The pin was enlarged to make it 225% stronger in torsional resistance, and in a subsequent series of over 1,600 femoral stems in a single surgeon series, there were no pin failures over a 12 year duration.

Background

Generation I (Apex Modular Stems) 483 were implanted between 2000 and 2004 on consecutive patients by the senior author. All were performed using the posterior approach. All cases used a mixture of different cementless acetabular components from a variety of manufactures.

Surgical stem and cup preparation and instrumentation has not changed between the two-generation stem designs.

The Dual Press modular junction employs two areas of cylindrical press-fit. To create this mechanical lock, the proximal and distal diameters of the peg are slightly larger than the corresponding holes in the stem, creating two bands of interference, or press-fit. Figure 1.

The proximal end of each stem includes an alignment pin that engages with a mating hole on the distal surface of each neck. This pin allows for anteversion position and for de-rotation of the modular neck on the stem. Figure 2.

Keywords: cementless stem; proximal modularity; modular junction Level of Evidence: AAOS Therapeutic Level II Educational Value & Significance: JISRF Level B



Methods

Generation I Design "Apex Modular Stem"

The Apex Modular $\stackrel{\text{TM}}{\longrightarrow}$ Hip Stem was developed as an evolutionally design based off the successful historical S-Rom[®] Modular Hip Stem [3,4]. The basic stem geometry was similar to the S-Rom in that both were straight stems with a proximal fit and fill cone and a medial triangle shape. Figure 3A & B.



Figures 3A, and B. A: Apex Modular Stem. Note: Proximal modular shoulder/neck not fully seated (Courtesy George Cipolletti). B: S-Rom® Stem (Courtesy JISRF Archives).

Stem features a novel proximal modular shoulder/neck design that is not a taper junction. This modular junction is a Dual Press. This attachment mechanism is new to or-

thopaedics but was derived from conventional mechanical tool designs. The entire shoulder of the neck sits flush onto the stem body thus shares load over a larger surface area vs. a taper junction. This provides fatigue values equal to that of a monoblock stem. Figure 4.



flush onto stem body.

An alignment pin engages with a mating hole on the distal surface of each modular neck. This provides additional torsional stability, as well as control of version angle. The diameter of the locating pin was 3.175 mm and would engage with one of three holes within the interface of the modular shoulder/neck. This provided 13° of version control. One of three positions could be picked, 13° of anteversion, neutral, or 13° of retroversion. Figure 5A & B.





Figure 5A. Picture of stem body showing location / derotational pin. (Courtesy JISRF Archives)

Figure 5B. Underside of neck showing 3 pin holes for version angle. (Courtesy JISRF Archives)

The original design included pre-clinical testing of the following worst-case scenario [5]:

- Six size 2, 9mm stems with medium 42.5 necks, +7 heads (for a total femoral offset of 47.5 mm).
- Assembly forces measured for three stems.
- All six stems fatigued tested as per ISO 7206-4 and 7206-8, under the direction of A. Seth Greenwald, D. Phil (Oxon)
- All six stems survived 5 million cycles at 2300 N.
- Same stems loaded to 81.3 kg of torsion, then axial tension to disassembly, or 1000 lb limit.
- Fretting wear measured.

Additional testing of high cycle fatigue testing was performed [5].

- Size 6, 14.5 mm stem with medium 47.5 neck, + 7 head (for a total femoral offset of 52.5mm).
- Fatigue tested as per ISO 7206-4, with incrementally increased cyclic loads.
- Stem survived 48.5 million cycles, test halted due to failure of embedding material. Maximum load reached 6xBW, for an 81.6 kg individual (492.6 kg).
- Titanium debris average less than 0.001 mm3 per million cycles (less than 0.1 % of wear of MOM hips)

Failure Mode for Generation I "Apex Modular Stem"

The failure of the Apex Modular Junction was primarily limited to the locating/ de-rotational pin. The pin fractured allowing the proximal shoulder/neck piece to rotate back and forth against the proximal portion of the modular stem. This resulted in micro to macro motion, joint instability, pain and excess generation of titanium debris [2,8]. Figure 6.

Patients often heard an initial snapping sound and a

sense of hip instability, progressing to a painful hip. Lateral X-Ray views would demonstrate the implants to be rotated out of position and on rare occasion totally disengage from the Dual Press modular junction. Revision of the failed implant is not overly difficult. The proximal neck can be removed by hand provid-



Figure 6. Illustration showing crosssection of Generation I and locating pin that was the point of failure. Pin diameter 3.175 mm. (Courtesy Anna Farad)

ing direct access to the stem body. Retrieval instruments allowed for firm attachment and with the help of flexible ostetomes or a small high-speed burr you can break the bony attachment with minimal bone destruction. Often femoral replacement can be done with a primary length stem. Figures 7A, B, & C.

Since the two modular pieces are titanium there often would be considerable black debris and staining of the tissues making one think of corrosion. This was not the case. Titanium is a relatively soft material and abrasion debris



Figures 7A, B, and C. A: Post-op A/P X-ray of a fractured locating/ de-rotational pin. Note: is difficult to appreciate the pin has been broken on this view. B: Lateral X-Ray demonstrating modular should/ neck component has rotated out of position of function. C: A/P x-ray showing bi-lateral hips with Apex Modular stem on the left side, and a S-Rom (primary stem-length) that replaced the fractured locating/ de-rotational pin on the right. (Courtesy T. Tkach)

is easily generated. You might also think the fractured location/ de-rotation pin was a fatigue failure problem. This was also not the case. Figures 8, 9A, B, & C.



Figure 8. Retrieved Apex Modular Stem showing broken locating pin with no other apparent damage to Dual Press Modular Junction. Note: Good bone attachment to porous surface. (Courtesy JISRF Archives)



Figures 9A, B, and C. A: Picture showing proximal modular shoulder/neck with femoral head attached. B: Showing stem removed with significant bone attached to proximal porous area with retrieval instrument attached C: Showing stem removed with black titanium debris. Note: this is not corrosion (Courtesy JISRF Archives).

Metallic fatigue failures clearly demonstrate upon examination a surface fingerprint. There will be a fatigue source or crack initiation then a crack propagation resulting in fatigue failure. Although fatigue has been thought of as a function of time it has been shown that it is the number of repetitions of stress rather than mere duration of time.

So it is important to realize that fatigue cycles are accumulative and this has been the historical failure mode of fractured total hip stems [9,10] (Figure 10).



Figure 10. Typical cross-sectional image of a metal fatigued failure showing source, propagation and fracture. (Courtesy JISRF Archives source unknown.)

Upon inspection of the retrieved fractured pins (c.c.) there was no evidence of a fatigue failure [11]. So what was the cause of the fracture? The hypothesis is a dynamic high impact torsional shear failure marked by a vigorous physical force applying a load well beyond the shear strength of the material. Another way of expressing this would be a moment of momentum that produces a load beyond the shear strength of the material. Example jumping off the bed of a pick-up truck landing with your foot internally rotated or possibly stumbling could generate a high dynamic impact torsional load resulting in a shear failure of the locating/de-rotational pin.

It was further thought that the Dual Press plug would have additional property values that would contribute to the overall integrity of the composite design, which in hindsight had little torsional resistance value.

Results for Generation I "Apex Modular Stem"

Generation I, 483 stems were implanted between 2000 and 2004. 31 alignment pins sheared resulting in a revision rate 6.4%.

The stem system was voluntary withdrawn from the market and redesigned to a more robust design.

cubic 1. Generation 1 Results

Total Im	483	
Revisions	Pin Shear	31
	Infection	2
	Dislocation	1
	Total	34
% Revisions	Pin Shear	6.4%
	Infection	0.4%
	Dislocation	0.2%
	Periprosthetic Fracture	0.0%
	Total	7.0%

Generation II Design "Omni Mod Stem"

The Omni Mod Stem design is the exact same features of the proximal shoulder / neck and the stem body from Gen I with changes to the structures within the Dual Modular junction (plug to bolt and diameter of locating pin from 3.175 mm to 4.775 mm). The dimensions for the two bands of interference fit remained the same.

The increase in pin diameter resulted in creating two different shoulder / neck configurations. One style has a single engagement hole for neutral version and a second style that has two holes for selection of anteversion or retroversion at 13°. (Figure 11A, B, & C)

Figures 11A, B & C.A: Larger diameter pin (c.c. 4.775 mm) within the stem body of the Dual Press Modular junction. B: A single engagement hole that provides a neutral neck position. C: Two holes that provide 13° of version angle. (anteversion or retroversion)





This corrective action resulted in 225% increase in torsional strength. It serves as an example that changes and improvements are possible once there is a full understanding of the problem. There have been no reported mechanical failures of its modular junction since 2004 with the improved design "Omni MOD Stem" (Figure 12). [13]



Results for Generation II "Omni Mod Stem"

1,642 stems have been implanted since

2004 and 2016 utilizing the same stem surgical technique. There have been no pin shear failures since this more robust design has been introduced.

There have been no reported complications with the improved "Dual Press" Modular Junction.

Note: There have been two reported fractured necks from Australia, not the modular junction, as with conventional monoblock stem designs.

Discussion

The knowledge of implant failure and implant testing is continuing to grow but often as we solve one mode of failure we create another failure that has not been anticipated. Historical review and preclinical testing might meet the required standards set by regulatory bodies to achieve market release, but often these standards do not consider the ever-increasing physical activity and loads that these devices are encountering [10].

It was further thought that the Dual Press plug would have additional property values that would contribute to the overall integrity of the composite design, which in hindsight had little torsional resistance value.

Historical torque levels in our opinion have been underestimated in today's patient life styles that demonstrate increased physical activity. Previous studies have demonstrated torque values ranging between 15 Nm (11 ft-lbs) and 37 Nm (27 ft-lbs) depending on the physical activity (rising from chair to single-limb stance) [5].

The trends over the past ten years have been the use of large femoral heads, increased femoral offset, metal on metal bearings along with increased patient activity. All of these factors increase torque [8]. On average, a 1-mm true lateral increase to the ball center offset will increase torque values by 8%. A 1-mm increase in vertical height (leg length) will increase torque by 6% [8]. Torque is a force applied over a distance (lever arm) that causes rotation about a fulcrum (axis of rotation) (Torque=Force

<i>Tuble 2.</i> Ocheranon II Results	Table	2: (Gener	ation	Π	Results
--------------------------------------	-------	------	-------	-------	---	---------

Total Im	plants from 2004 - 2016	1642
Revisions	Pin Shear	0
	Infection	4
	Dislocation	1
	Periprosthetic Fracture	1
	Total	6
% Revisions	Pin Shear	0.0%
	Infection	0.2%
	Dislocation	0.1%
	Periprosthetic Fracture	0.1%
	Total	0.4%

(Fm) x Moment Arm). The greater the torque a muscle can produce, the greater the movement it will produce on the body's levers.

We now know by experience that the hip sees torque values over (128.8 Nm), as demonstrated in our mechanical failures of the Apex Modular hip stems [10,12] (Figure 13).

This paper follows on previous publications of this unique modular junction and demonstrates that design and materials can be improved upon once there is clear understanding of the failure mode. It is important to remember all devices are subject to failure. It is also necessary to recognize design and material limits and not to over-indicate in high-risk patients. Patient activities are higher and generate higher mechanical loads than historical references.

A number of modular junctions have come and gone from clinical use. Nevertheless, the endeavor to improve clinical outcomes should be continued.

Modularity can be designed and fabricated to provide safe, reliable, and reproducible clinical results. Because there are no laboratory tests allowing accurate prediction of the service life and performance of implant parts, clinical experience with a large number of cases over a period of several years is the only reliable indicator. However, clinical evaluations should only begin after conducting aggressive basic science material and mechanical testing to anticipate potential failure modes. Individual patient physical activities should be considered when deciding on stem modularity features. Since there are no standards established for modular junctions the overall performance of modular junctions are not equal. Careful review of basic engineering principles is necessary and recognizing design limits will reduce the indication of overuse [2,4,8,9,10].

We encourage early publication of all devices (good, bad & ugly) and continuation of those publications as clinical experience and outcomes become available.



Figure 13. Chart Showing Torque Loads Generated by Femoral Offset and Neck Length

Conclusion

All implant devices entail a multitude of risks and benefits. The Apex Modular Stem (Generation I), provided excellent fixation, minimal risk of modular junction corrosion, and simple control of anteversion and femoral offset. The limitation was found to be the risk of the alignment pin shearing (6.4%). The pin was enlarged to make it 225% stronger in torsional resistance, and in a subsequent series of over 1,600 femoral stems in a single surgeon series, there were no pin failures over a 12 year duration.

Improvements in this modular junction design have eliminated the mechanical failures of the first Generation design.

References:

- Cameron H.U. The Technique of Total Hip Arthroplasty. ISBN 0-8016-0825-2 1992 by Mosby-Year Book.
- Tkach T, Low W, Cipolletti G.B., McTighe T. Target Restoration of Hip Mechanics in THA. AAOS Scientific Exhibit 2006, DOI: <u>10.13140/RG.2.1.1084.0167</u>
- Cameron H.U., Yung-Bok, J., Noiles, D.G., McTighe, T. Design Features and Early Clinical Results with a Modular Proximally Fixed Low Bending Stiffness Uncemented Total Hip Replacement. DOI: <u>10.13140/RG.2.1.4714.7040</u> Conference: AAOS 1988 Annual Meeting, Scientific Exhibit

- Keppler, L., McTighe, T., The Role of Stem Modularity for THA in a Community Based Practice. Reconstructive Review Volume 2(Number 2): 16 · August 2012 DOI: 10.15438/rr.v2i2.10
- 5. Sales Training Slide Presentation by Omni (On file)
- G. M. Kotzar, D. T. Davy, J. Berilla, and V. M. Goldberg. Torsional Loads in the Early Postoperative Period Following Total Hip Replacement. JBJS 13:945-955
- T. W. Phillips, * L. T. Nguyen and S. D. Munro. Loosening of Cementless Femoral Stems: A Biomechanical Analysis of Immediate Fixation with Loading Vertical, Femur Horizontal. J. Biomechanics Vol. 24, No 1, pp. 37 48, 1991. 9,10
- Keggii K, Keggi J, Kennon R, Tkach T, Low W, et al., Within Any Important Issue, There are Always Aspects No One Wishes to Discuss- Femoral Component Failure. Poster Exhibit ISTA, Oct. 2006
- Jameel A, Majeed W, Razzaq A, Fatigue Analysis of Hip Prosthesis. Number 10, Vol 18, October 2012 Journal of Engineering p: 1100 to 1114.
- Mierzejewska Z, Case Study and Failure Analysis of a Total Hip Stem Fracture. Advances In Materials Science, Vol. 15, No. 2 (44), June 2015 DOI: <u>10.1515/</u> <u>adms-2015-0007</u>
- T. McTighe, D. Brazil, W. Bruce. Metallic Alloys in Total Hip Arthroplasty. Mc-Tighe T, Brazil D, Bruce W. Metallic Alloys in Total Hip Arthroplasty. In: Cashman J, Goyal N, Parvizi J, eds. The Hip: Preservation, Replacement and Revision. Baltimore, MD: Data Trace Publishing Company; 2015:14-1-14-12
- McTighe T, Brazil D, Clarke I, Keppler L, Keggi J, Tkach T, McPherson E. Metallic Modular Taper Junctions in Total Hip Arthroplasty. RR Vol 5, Number 2, July 2015 DOI:<u>10.15438/rr.5.2.108</u>
- 13. White paper published by Omni 2004

SUBMISSION HISTORY

Submitted August 30, 2017 Reviewed September 16, 2017 Revised September 24, 2017 Accepted September 27, 2017 Published September 30, 2017

AUTHOR AFFILIATIONS

- 1 Thomas Tkach, MD McBride Orthopedic Hospital, 1110 N Lee Ave, Oklahoma City, OK 73103
- 2 Timothy McTighe, Dr HS (hc) Joint Implant Surgery & Research Foundation, 46 Chagrin Shopping Plaza, #117, Chagrin Falls, OH 44022 US (Direct inquires to Timothy McTighe, tmct@jisrf.org)

(Direct inquires to finiotity with tight, thete)isi

AUTHOR DISCLOSURES

Tkach royalty and equity (Omni); McTighe equity (Omni)

COPYRIGHT & OPEN ACCESS

© 2017 Tkach, McTighe. All rights reserved. Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review is an open access publication and follows the <u>Creative Commons Attributic</u>



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".







ORIGINAL ARTICLE

http://dx.doi.org/10.15438/rr.7.3.190

Check for updates

Simulator Study of MOM using Steep-cup Flexion - A Clinically Relevant Incorporation of Intermittent Edge-loading

Clarke I.C.¹, Shelton J.C.², Bowsher J.G.³, Savisaar C⁴, Donaldson T⁵

Abstract

Background: Adverse-wear phenomenon in metal-onmetal (MOM) arthroplasty has been attributed to "edgeloading" of the CoCr cups. Simulator studies of steeplyinclined cups run in the 'Anatomic-cup' model represented many variations in design and test parameters with no coherent rationale. We created an algorithm to synthesize MOM test parameters and noted that wear areas typically averaged only 10-15% of cup surface. In contrast, retrievals showed wear areas extending to 60% of cup surface. We hypothesized that MOM wear studies run in the orbital hip simulator with the 'Inverted-cup' model would, (i) differentiate normal-loading versus edge-loading, (ii) demonstrate cup wear areas x3.8-times larger than on femoral heads, cover 30% of cup surface, and (iii) double the wearrates measured in prior Anatomic-cup study.

Methods: Edge-loading occurs when the cup rim is allowed to truncate the habitual wear area that provides optimal tribological conditions. A MOM algorithm was developed to synthesize relevant test parameters. The 60mm MOM bearings donated for this study were run in an orbital hip simulator using the Inverted-cup model. Tests #1 and #2 to one million cycles (1-Mc) duration assessed wear at peak cup inclinations 40° and 50°. Test #3 evaluated edge-loading with peak cup inclinations achieving 70° (5-Mc duration).

Results: Wear areas in Inverted-cups averaged 1663mm2 in tests #1 and 2, were fully contained within cup rims, and covered 30% of cup surface as predicted by

algorithm. Test-3 with 70° cup inclination produced the predicted edge-loading with volumetric wear-rates averaging 2mm3/Mc, approximately 5-fold greater wear than prior Anatomic-cup study.

Discussion and Conclusions: Simulator studies of steep-cup mechanisms necessitate production of clinically-relevant wear-patterns such that the biomechanical and tribological functionality is respected. As an aid to steeply-inclined cup analyses, the MOM algorithm allowed integration of confounding test parameters. The algorithm successfully differentiated between "normal" and "edge loaded" cups and the MOM wear areas were as predicted for three cup inclinations. Also as predicted, wear-patterns in Inverted-cup model exactly reversed those of the Anatomic-cup model. Even with only intermittent edge-loading, Test-3 produced 5-fold greater wear than our prior Anatomic study.

Clinical Significance: The Inverted-cup simulator model successfully mobilized the cup to produce larger wear areas that were more representative of those in-vivo and therefore reproduced more realistic test conditions for studies of edge-loaded cups.

Keywords: hip arthroplasty, MOM bearings, edge loading, simulator, wear Level of Evidence: AAOS Therapeutic Level II Educational Value & Significance: JISRF Level B

Background

Laboratory wear predictions of total hip arthroplasty (THA) have come under frequent criticism, partially because they present only a limited simulation of many possible clinical conditions (Fig. 1A). For example, international guidelines [1] only specify one inclination for the acetabular cup (30°) in the hip simulator [Fig. 1B], this believed analogous to a 45° cup inclination in patients (Fig. 1A). This test configuration, referred to as the 'Anatomic' mode (Fig. 1B), represents an ideal wear model and has been the standard simulator test for almost 2 decades. Various studies demonstrated MOM wear to be satisfactorily low over the specified 5-million cycle test (Fig. 2A: 5-Mc test, cup inclination 35°). [2,3,4]

The revival of large MOM hip bearings began in the mid 1990's [5,6] and the first warnings of adverse wear with CoCr cups started appearing between 2006 and 2008 [7,8,9]. Subsequent clinical and retrieval studies demonstrated that steeply-inclined CoCr cups were particularly at risk for adverse wear, believed due to "edge loading" of the head against the rim of the acetabular cup [10,11]. Simulator studies then explored the effects of steeply-inclined cups. In one study of 38.5mm MOM run with 35° and 50° cup inclinations, wear-rates averaged 3.3 and 11mm³/Mc, respectively [12]. In this 2-Mc test, the steeper cups demonstrated a 3.3-fold wear increase over-

all. In a similar study comparing 48mm MOM run with 35° and 65° cup inclinations, wear-rates averaged 2.5 and 19.5mm3/Mc, respectively [13]. Here the steeper cups presented a 7.8-fold increase over controls. However notable in two 5-Mc studies was that the wear with steeper cups appeared only double that of controls (Fig. 2B). [2,14] These exploratory studies included many confounding cup designs, diameters, metallurgy, and test parameters. Thus, no coherent theory was developed to explain such variations in wear performance of MOM bearings.

Using data from our prior 60mm MOM retrieval study [15], we developed an algorithm to integrate variations included in cup design, head diameter, and cup inclination. The key to the algorithm was an equation that defined size of wear-patterns on CoCr heads and cups. [16] In our prior Anatomic study, wear-patterns averaged 1668mm² on heads and 442mm² on cups, these data providing an experimental ratio of 3.77 for wear areas [17]. The theoretical wear-pattern ratio (x3.87) calculated using the cam design of the orbital simulator validated these data. It was also noted that the Anatomic simulator test produced cup wear-patterns that represented only 10-15% of the nominal



In vivo hip anatomy Figures 1A & B.





Figures 2A & B.

hemispherical surface, defined here as the hemi-cup ratio (Table 1). [15] In contrast, retrieval studies showed hemicup ratios extended 50-60% in-vivo, i.e. were much larger than produced in contemporary simulator studies [15,18]. This difference would not be readily apparent in the standard simulator test (Fig. 1B) but would clearly be an important parameter when simulating edge-wear in steeplyinclined cups.

Table 1. Cup wear areas in simulators at 5-Mc (ISO-14242), ranked by MOM diameter.

Study	Diameter (mm)	Clearance (µm)	Hemi- area (mm ²)	Wear area (mm²)	Hemi%
Leslie 2008	38.5	126	2328	429	18%
Lee 2008	40	400	2513	364	14%
Lee 2008	40	150	2513	383	15%
Leslie 2008	54.5	111	4666	474	10%
Lee 2008	56	400	4926	419	9%
Lee 2008	56	150	4926	416	8%
Bowsher 2009	60	245	5655	442	8%

Edge-loading occurs when the cup rim truncates what would be the normal, habitually worn area. Thus, a clinically relevant simulation of edge-wear effects necessitates a realistic wear pattern for the cup. Simulator mechanics creates the larger 'distributed' wear-pattern on the mobile bearing, this being the femoral head in the Anatomic test mode (Fig. 1B). The alternative 'Inverted cup' strategy would make the cup oscillate such that the larger wear-pattern would have a hemi-cup ratio of approximately 30% [15]. The first published studies of wear in 2nd generation MOM were run in this 'Inverted' test mode (Fig. 3) using MOM bearings of 28mm and 45mm diameter. [19,20] Although not measured in these early studies, distributed wear-patterns would have been produced in the cups. [21] The goal in this MOM simulator study was to demonstrate that steeply-inclined cups could be run successfully in "Inverted" test mode (Fig. 3). The hypotheses were that, (i) the MOS-algorithm would differentiate between "normal" and "edge-loading" conditions, (ii) wear patterns in 60mm cups run Inverted to 1Mc duration with no risk of edge-loading would be 3.8 times larger than on their mating heads, and (iii) cups run Inverted under edge-loading conditions to 5-Mc would double the wear-rates measured in the Anatomic study.



Figures 3A & B.

Methods

The hip simulator was identical to that used in our prior Anatomic study (Shore Western, Monrovia, CA) and our test methods duplicated that work. [17] Three tests were conducted with 60mm MOM bearings (*donated for research, DJO-Global, Austin TX*) with 1-Mc tests #1 and #2 run to



Figure 4.

to assess the wear-pattern shifting with steeper cup inclinations but with no edge-loading (Table 2). Test #3 (N=4 MOM) was run to 5-million cycles with cup mounting-angle (L) set to 47° such that the cam mechanism created minimum/maximum cup inclinations of 24° and 70° (Fig. 3). Our prediction was that the cup wear-pattern would be truncated by 7.8°, this representing an edge-wear condition of 9% in test #3 (Appendix A).

#	Parameter	Test-1	Test-2	Test-3
1	Cup rim profile angle (P)	5.6	5.6	5.6
2	Angle subtending wear area (A)	90.4	90.4	90.4
4	angle $(P + A/2)$	50.8	50.8	50.8
5	Inclination angles (L)	17.0	27	47
6	Angle (L+P+A/2)	67.8	77.8	97.8
7	MOS angle	22.2	12.2	-7.8
8	Edge wear (EW%)	none	none	-9%

Table 2. Algorithm parameters for 60mm MOM.

Cup adaptors were machined from Polyacetal with locking rings added to secure the steeply-inclined cups (Fig. 6). Each assembly was attached to a steel baseplate that housed a Plexiglas cylinder acting as lubricant chamber (450ml). Wear-patterns and weight-loss data were measured at 0.5-million cycle intervals to 5Mc duration. Areas of wear on heads and cups were identified visually and by light microscopy, stained red, and taped where necessary to minimize reflections during photography.

Results

Cup wear patterns in tests #1 and 2 were fully contained within cup rims as predicted by the MOS-algorithm and averaged 1663mm² and 1571mm² areas, respectively with < 3% variation about these means. The small MOS-angle in test-2 was difficult to measure, approximately 5.3° (Fig. 5B). The wear-patterns in study-1 (Fig. 5A) were selected as controls and demonstrated a 15.4° margin of safety (Table 3). Cup wear patterns were distinct and described by an included-angle of 90.2° (angle-A) subtended by a



Figures 5A & B.

Test-1	Cup-1	Cup-2	Averages
NWZ angle (N)	55.6	55.6	55.6
MWZ angle (A)	91.6	88.9	90.2
MOS angle (MOS)	14.0	16.7	15.4
Calculated MWZ area			1663
Hemi-area (60mm cup)			5655
Hemi-area ratio (%)			29.4%

Table 3. Cup wear areas using 40° peak inclination (test-1: 1Mc).

wear area of 1663mm² with corresponding hemi-area ratio 29.4%. The femoral-head wear patterns at 1Mc duration were too indistinct to measure.

Cup weight-loss from wear over 5-Mc trended fairly linearly to beyond 50mg. Transient weight-gains were evident at 0.25Mc duration (Fig. 6A: flag-1, 15mg) and at 2.5-3Mc (flag 2). These fluctuations were due to build-up of protein contaminants inside the cups and were disregarded. Also noted was that cup #4 sustained damage at 0.75Mc and was not included in the analysis (flag-4: malfunction of simulator cam-bearing).

Head weight-loss trends showed run-in variations up





to 0.75Mc (Fig. 6B: flags-1, 2). Transient weight-gains were also evident on heads (Fig. 6B: flags 3-4). Statistical analysis over 0.75 to 5Mc for heads favored a steady-state weight-loss averaging 0.9 mg/Mc. The corresponding steady-state cup trend averaging 10.5 mg/Mc was 11.7-fold greater than for heads. By 5-million cycles duration, the total weight-loss in heads and cups amounted to 11.2 and 71.1mg, respectively, i.e. 6.4-fold greater in cups (Fig. 7). The corresponding volumetric wear-rates for run-in and steady-state phases averaged 6mm3/Mc and 1.4mm3/Mc, respectively. These represented an overall wear-rate of approximately 2mm3/Mc.

Steep-cup test-3 (70° inclination) was predicated on truncating the normal wear-pattern by 7.8° to produce edge-loading in the cup. The main wear pattern (MWZ) clearly showed the effects of edge-loading produced (Fig. 8). Wear-patterns on femoral heads were faint, difficult to characterize and quite variable. Heads 1 and 4 were selected as the best representation at 2.5Mc duration, providing wear-pattern areas of 330mm² and 588mm² (approximated to 460mm²).

Discussion

This appears to be the first simulator study using a mathematical approach to define edge-loading in cups. The MOS-algorithm predicted that 60mm cups would have a 'critical' inclination angle of 62° (Appendix A). Tests 1 and 2 at 1Mc duration (peak inclinations $40^{\circ} / 50^{\circ}$) showed wear patterns did not extend to the cup rims. In contrast, test-3 with 70° peak inclination produced edge loading as confirmed by the truncation of the wear patterns (Fig. 8). These data satisfied the first hypothesis that the MOS-algorithm would differentiate between "ideal" and "edge-loading" conditions.

There was no precedent for this simulator edge-loading study in 'Inverted' mode. The test validity was established by comparing areas worn in Inverted cups to those on heads run in 'Anatomic' test mode. Inverted cup areas (wear pattern =1663mm²) corresponded almost exactly



Figure 8.

to Anatomic head areas (wear pattern =1668mm²). This established our overall thesis, that running hip bearings in an Inverted test simply reversed the wear patterns produced in the Anatomic test. A governing criterion for steep-cup simulations is the cup wear-patterns should be representative of those in MOM retrieval studies. This study increased cup wear-patterns from a low of 8% in Anatomic mode to 29% in Inverted mode but this was still not as high as measured in retrieved cups. Possibly this reflects patients having much greater gait complexity compared to simulators using a fixed 45-46° flexion arc.

MOM bearings typically show high wear during initial run-in phase, and then generally transition to a lower wearrate within 1-million cycles. This occurs when head and cup wear-patterns enlarge enough to support optimal tribological conditions. Edge-loading produces truncation of normal wear patterns (compare Figs. 5 and 8) such that optimal conditions cannot be met and thus higher wear results. Even with Inverted cups experiencing edge-loading only intermittently in each cycle, test-3 produced 5-fold greater wear than our prior Anatomic study. This more than satisfied our 3rd hypothesis that MOM wear rates would be doubled under edge-loading.

Our 60mm MOM wear-rates (Inverted cups) averaged 2mm³/Mc over 5-Mc test with a ratio of 86% cup to total MOM wear. The prior Anatomic test produced a cup wear ratio that varied from 68% in normal trending to 85% during "breakaway" wear trends [17]. The latter value was virtually identical to that in our edge-loaded test-3, likely signifying a trigger such as partial lubrication failure. There was also a dramatic correspondence of wear trends with 60mm Inverted cups run dynamically inclined over 5-Mc with 40mm cups in Anatomical mode and run at fixed 60° inclination. [14]. Clearly this could be coincidental due to the many experimental differences. However, our observation was that MOM bearings run under such edge-loading conditions did not provoke adverse wear as reported by others. Our data represented stable trends with wearrates that did not turn lubricants black. These data suggest that additional conditions need to be present to provoke adverse wear, such as surgical and patient-related risks that may contribute to joint laxity, impingement, head subluxation, release of large metal particles, etc.

Appendix A

The size of head and cup wear patterns is produced by the simulator mechanics and this ratio is x3.87 for the orbital machines. Thus, in our prior 60mm Anatomic test, cup and head wear-patterns averaged 442mm² and 1668mm², respectively, giving the experimentally derived ratio x3.77. Knowing the angle subtended by the cup wearpattern (45.6°) and cup flexion-angle (46° arc), the summated angle (91.6°) can be shown by spherical geometry to to be subtended by a head wear-pattern of 1712mm² area. The measured and calculated wear-areas on heads agreed within 44mm² (< 3% difference), revealing that wear patterns on hip bearings were predictable.

In our previous study, a MOS-algorithm was created to define sizes of cup wear-patterns and clinical risks of edgeloading. Equations governing edge loading in Anatomic test mode (Fig. A1) were presented as,

Equation-1: $L + P + MOS + A/2 = 90^{\circ}$ Equation-2: $2*P + F = 180^{\circ}$

Where,

Angle (A) =wear-pattern angle from simulator data. [16]Angle (F) =cup-face angle in sub-hemispherical cup.Angle (L) =cup inclination in horizontal plane of simu-

lator Angle (MOS) = angle between cup rim and wear pattern Angle (P) = rim-profile angle of sub-hemispherical cup



The critical cup angle (*L) can be defined as that inclination where the edge of the wear pattern becomes juxtaposed to cup rim, i.e. MOS angle = zero and given by,

Equation-3: $*L = 90^{\circ} - (P + A/2)$

Degree of edge-wear (Figure 3) can be defined as

Equation-4: EW% = 100*(A - B)/A

The notable difference between Inverted and Anatomic test modes is that in the former the cup inclination angle varies dynamically whereas in the latter the cup inclination is held fixed. However, analysis for edge-loading condition is essentially the same for both Inverted and Anatomic modes.

Acknowledgements

This project was supported by FDA contracts on preclinical (simulator) validation studies of Metal-on-Metal (MOM) Bearings (FDA-1090372 and 1119682).

SUBMISSION HISTORY

Submitted August 16, 2017 Reviewed September 14, 2017 Revised September 21, 2017 Accepted September 22, 2017 Published September 30, 2017

AUTHOR AFFILIATIONS

- Ian Clarke, PhD Professor in Research, Dept. Orthop., Loma Linda University Medical Center, 11406 Loma Linda Drive, Loma Linda University, Loma Linda, CA 92354 US
- 2 Julia Shelton, PhD School of Engineering and Materials Science, Queen Mary University of London, London, UK
- 3 John Bowsher, PhD
- Anterior Spine Devices Branch, FDA , Silver Springs, Washington, DC 4 Christina Savisaar, PhD
- Orthopedic Joints Devices Branch, FDA, Silver Springs, Washington DC 5 Thomas Donaldson, MD
- Donaldson Arthritis Research Foundation, 900 E. Washington Street, Suite 200 Colton, CA 92324 US

(Direct inquires to Ian Clarke, ithipgeek15@yahoo.com)

AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

COPYRIGHTS

© 2017 Clarke, Shelton, Bowsher, Savisaar, Donaldson. All rights reserved. Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review is an open **OPEN**



access publication and follows the <u>Creative Commons Attribution-</u> <u>NonCommercial CC BY-NC</u>. 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".

References

- ISO 14242-1 (2002) Implants for surgery -- Wear of total hip-joint prostheses --Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test.
- Williams S, Leslie I, Isaac G, Jin Z, Ingham E, Fisher J. Tribology and wear of metal-on-metal hip prostheses: influence of cup angle and head position. J Bone Joint Surg Am. 2008;90 Suppl 3:111-117.
- Leslie I, Williams S, Brown C, Isaac G, Jin Z, Ingham E, Fisher J. Effect of bearing size on the long-term wear, wear debris, and ion levels of large diameter metal-on-metal hip replacements-An in vitro study. J Biomed Mater Res B Appl Biomater. 2008;87:163-172.
- Lee R, Essner A, Wang A. Tribological considerations in primary and revision metal-on-metal arthroplasty. J Bone Joint Surg Am. 2008;90 Suppl 3:118-124.
- McMinn, D. Treacy, R. Lin, K. Pynsent, P. (1996). Metal on metal surface replacement of the hip. Experience of the McMinn prosthesis. Clin. Orthop. 329 Suppl., pgs S89-98.
- Amstutz, H. C. Campbell, P. McKellop, H. Schmalzreid, T. P. Gillespie, W. J. Howie, D. Jacobs, J. Medley, J. Merritt, K. Metal on metal total hip replacement workshop consensus document. Clin. Orthop. 329 Suppl., pgs S297-303.
- Hart, A. J. Hester, T. Sinclair, K. Powell, J. J. Goodship, A. E. Pele, L. Fersht, N. L. Skinner, J. The association between metal ions from hip resurfacing and reduced T-cell counts (2006). JBJS-Br. 88(4), 449-54.
- McLardy-Smith, P. Steffen, R. T. Pandit, H. Murray, D. W. Gill, H. S (2006). Metal-on-metal hip resurfacing: America, where are you? Orthopedics 29:795-6.
- Langton DJ, Jameson SS, Joyce TJ, Webb J, Nargol AV. The effect of component size and orientation on the concentrations of metal ions after resurfacing arthroplasty of the hip. J Bone Joint Surg Br. 2008;90:1143-1151.
- Glyn-Jones, S., Roques, A., Gill, R.Taylor, A., Whitwell, D., Esposito, C., Walter, W., Tuke, M., Murray, D.Metal on metal hip resurfacing arthroplasty-related pseudotumours are associated with increased bearing surface wear, caused by impingement and edge-loading. In 56th Annual Meeting of the ORS, poster #2164, 2010.
- Morlock, M. M., Bishop, N. E., Zustin, J., Hahn, M., Ruther, W. Amling, M. Modes of Implant Failure After Hip Resurfacing: Morphological and Wear Analysis of 267 Retrieval Specimens. J Bone Joint Surg (Am):90;89-95, 2008.
- Leslie, I. J. Williams, S. Isaac, G. Ingham, E. Fisher, J. (2009). High cup angle and microseparation increase the wear of hip surface replacements. Clin. Ortho. 467(9), 2259-65.
- Hu, XQ Jeffers, J Roques, A Taylor, A Tuke, M.(2011). In vitro wear study of MOM and COM Hip Prostheses with High Cup Angle. In Orthop Res. Soc, poster 1163.
- Angadji A, Royle M, Collins SN, Shelton JC. Influence of cup orientation on the wear performance of metal-on-metal hip replacements. Proc Inst Mech Eng H. 2009;223:449-457.
- Clarke IC, Donaldson TK, Burgett MD, Smith EJ, Bowsher J, Savisaar C, John A, Lazennec JY, McPherson E, Peters CL. Normal and Adverse Wear Patterns Created In-vivo on MOM Surfaces - a retrieval study representing four vendors. In: Kurtz SM, Greenwald SA, Mihalko WM, Lemons JA, ed. Metal-on-Metal Total Hip Replacement Devices. West Conshohocken, PA: ASTM International; 2013:157-192.
- Clarke IC, Lazennec JY. Margin-of-safety Algorithm used with EOS imaging to Interpret MHRA Warning for Small-diameter MOM Hip Arthroplasty. Reconstructive Review. 2015;5:13-21.
- Bowsher JG, Clarke IC, Williams PA, Donaldson TK. What is a "normal" wear pattern for metal-on-metal hip bearings? J Biomed Mater Res B Appl Biomater. 2009;91:297-308.
- Koper MC, Mathijssen NMC, Claasen HHR, Witt F, M MM, Vehmeijer SBW. Pseudotumor after bilateral ceramic-on-metal total hip arthroplasty. J Bone Joint Surg: JBIS Case connect; 2014.
- Chan, F. W. Bobyn, J. D. Medley, J. B. Krygier, J. J. Yue, S. Tanzer, M.(1996). Engineering issues and wear performance of metal on metal hip implants. Clin. Ortho. 333:96-107.
- Anissian, H. L. Stark, A. Gustafson, A. Good, V. Clarke, I. C. (2009). Metal-onmetal bearing in hip prosthesis generates 100-fold less wear debris than metal-onpolyethylene. Acta Orthop. Scand. 70(6): 578-82.
- Park, S. H. McKellop, H. Lu, B. Chan, F. W. Chiesa, R.(1999). Wear morphology of metal-metal implants: Hip simulator tests compared with clinical retrievals. In "Metasul, A Metal-on-Metal Bearing", Eds. Rieker, Claude Windler, Markus and Wyss, Urs, Pub: Hans Huber, Berne Switzerland.



Check for updates





ORIGINAL ARTICLE

http://dx.doi.org/10.15438/rr.7.3.192

Dissemination of Pathogens by Mobile Phones in a Single Hospital

Canales M¹, Craig G¹, Boyd J¹, Markovic M¹, Chmielewski R¹

Abstract

Background: Superficial wound complications are among the most prevalent problems associated with any surgical procedures. Infection rates of the primary hip and knee joint arthroplasty have been reduced with modern aseptic techniques but this rate may reach 20% in some revision procedures. Mobile phones are frequently used in the hospital and operating room settings, regardless of their microbial load. This study aimed to: 1) determine the level of bacterial contamination of mobile phones from resident physicians at Saint Vincent Charity Medical Center (SVCMC) in Cleveland, Ohio; 2) determine the effectiveness of quaternary ammonium compound (QAC) wipes; and 3) heighten awareness of potential dissemination of pathogens by mobile phones in the hospital setting.

Materials & Methods: A total of fifty mobile phones were randomly sampled from podiatric surgical resident physicians and internal medicine resident physicians at SVCMC. For each mobile phone, a swab was collected from the touch screen prior to use of QAC wipes and following use of QAC wipes.

Results: The results demonstrated that 82% (41/50) of mobile phone touch screens possessed polymicrobial organisms and 30% (15/50) of mobile phones possessed pathogenic organisms. The vast majority of residents, 98% (49/50) used their phones within the hospital and 37% (18/49) used their phones inside patients' room. Most of the residents, 86% (43/50), did not clean their phones on a daily basis and of the residents who did, a majority of them, 71% (5/7) used either dry wipes or alcohol wipes.

Discussion: Sanitizing mobile phones with QAC dis-

posable wipes was shown to be an effective infection control intervention as mobile phone touch screens showed no growth after two minutes of sanitization. QAC could potentially decrease the transmission of microorganisms that cause diseases and reduce the risk of cross contamination infections from mobile phones.

Background

Today mobile phones have become one of the most essential accessories to both personal and professional life. Mobile phones are frequently handled throughout the day and are held close to the face and mouth. They are placed on various surfaces in a variety of rooms (i.e. bedroom, bathroom, floor, and kitchen) and are used during various activities (i.e. driving, showering, breastfeeding, bathroom use, and cooking) [1-6] (Figure 1). Mobile phones are a health hazard and have been identified as one of the carriers of bacterial pathogens [7]. Research has demonstrated that a square inch of a mobile phone contains ten thousand microbes, which is significantly more than the sole of a shoe or a door handle [8]. The consistent heat generated by phones creates a breeding ground for colonization of microorganisms. The regular use of mobile phones makes them a potential source for transmission of microorganisms that cause disease [9,10].

Keywords: Mobile Phones, Cell Phones, Hospital Infections, Prosthetic Joint Infection, Total Knee Arthroplasty Level of Evidence: AAOS Therapeutic Level III Educational Value & Significance: JISRF Level A



Figure 1: Various locations of mobile phone use in the hospital setting.

Hospital-acquired infections in United State (U.S.) hospitals cause 1.7 million infections per year and are associated with approximately 100,000 deaths each year. It is estimated that one third of these infections could be prevented by adhering to standard infection control guidelines [11]. The Center for Disease Control and Prevention (CDC) and World Health Organization (WHO) guidelines on hand hygiene in health care require decontamination of hands with preferentially alcohol-based hand rub or alternatively soap and water before and after direct patient contact, after removing gloves, and after contact with inanimate objects in the patients' immediate environment [12]. Rusin, et al. documented both gram- positive and gram-negative bacteria in hand- to-mouth transfer during casual activities. This implies that mobile phones may serve as vehicle of transmission for diseases such as diarrhea, pneumonia, boils, and abscesses [13]. Mobile phones are often used in hospitals by patients, visitors, and health care workers. Unlike hands, which are more readily sterilized with hand sanitizers, mobile phones are cumbersome to clean and users rarely make the effort to sanitize them.

Superficial wound complications are among of the most prevalent problems associated with any surgical procedure [14]. Such complications following total knee arthroplasty have been reported to occur in 10% of cases [15]. Literature has correlated superficial wound complications following total knee arthroplasty (TKA) to the eventual development of periprosthetic joint infection (PJI) [16-18]. Infection rates of primary hip and knee joint arthroplasty have been reduced to 0.3% to 2% with modern aseptic techniques, but this rate may reach 20% in some revision procedures [19,20]. Mobile phones are commonly used in the operating room by staff, vendors, residents, and physicians and have been found to possess a high rate of pathogenic bacterial contamination and organic material such as food, human secretions, and excretions [21].

The first study of bacterial load on mobile phones was conducted in a teaching hospital in Turkey with a bed capacity of 200 and one intensive care unit. One-fifth of the mobile phones examined in a study conducted in New York were found to harbor pathogenic microorganisms. Health care workers' mobile phones provided a reservoir of bacteria known to cause nosocomial infection [22]. Cleaning of mobile phones throughout the day has been shown to decrease the bacterial load, but it requires effort from health-care workers [23]. Other studies have shown that health-care workers do not often comply with cleaning protocols [24-26].

The CDC guidelines for cleaning and disinfecting environmental surfaces in healthcare facilities suggests to disinfect noncritical medical devices such as bedpans, blood pressure cuffs, crutches, and computers with an Environmental Protection Agency (EPA)-registered hospital disinfectant [27]. High-touch environmental surfaces (HTES) (i.e. bed rails, bedside tables, call buttons, telephones, chairs, wall-mounted vital signs equipment, intravenous medication stands, door knobs and handles, bathroom hand rails, and toilet seats) require appropriate decontamination to reduce the risk of contamination of hands of healthcare personal [28]. Disinfectant pre-soaked wipe (DPW) utilize the microbicidal action of disinfectant coupled with physical removal by way of wiping the HTES [29].

Touchscreen phones have been found to harbor fewer microbes than equivalent keypad devices due to the irregular surfaces of keypad phones, but data are limited regarding effective disinfecting protocols [30]. Apple, Inc. forbids the use of wet cleaning wipes citing possible screen damage as the reason [31]. However, in order for mobile phones to be successfully used in a clinical setting, appropriate and effective cleaning must be demonstrated. Disinfectants with quaternary ammonium compounds are commonly used in hospitals for surface decontamination. Sani-Cloth ® has not only shown that a single disinfection prevents further contamination, it has also shown it could be effective for up to 12 hours despite the opportunity for repeated contamination [32]. The active ingredient in Sani-Cloth® (Professional Disposables International Ltd, Flint, UK) wipes are quaternary ammonium compounds (QAC) [33,34] which chemically consist of nitrogen cations covalently bonded to alkyl groups some of which contain long carbon chains.

In this study, investigation was performed to determine 1) the microbiological flora (qualitative and quantitative) of Saint Vincent Charity Medical Center (SVCMC) residents' mobile phones, 2) the effectiveness of QAC disposable wipes on disinfecting mobile phones, and 3) increase awareness and concern of mobile phones as potential vehicle of transmission of pathogenic microorganisms among hospital settings.

Materials and Methods

Samples Collection

The study was conducted at Saint Vincent Charity Medical Center in Cleveland, Ohio. SVCMC has 450 inpatient beds, 20 intensive care unit beds, and 24 emergency department beds. A total of fifty mobile phones were randomly selected from internal medicine and podiatric medicine and surgery residents during the hours of 8 o'clock a.m. to 4 o'clock p.m. After cleaning of hands with an alcohol based instant hand sanitizer, powder-free disposable nitrile gloves were worn. A moistened sterile cotton swab with normal sterile saline was used to swab the touch screen surface across an approximate 28cm2 area (Figure 2) after which the swab was immediately placed into a sterile container and sealed with the cotton end soaked in 1 milliliter of sterile normal saline. The phone surface was then cleaned thoroughly with QAC wipes (Figure 3) and remained wet for two minutes and air- dried as recommended by the manufacturer's technique. After the surface was allowed to dry for five minutes, the phone was re-swabbed in the same fashion. The same technique was employed for each of the fifty samples.





Figure 2: Moistened sterile cotton swab used to culture the touch screens of fifty mobile phones.

Figure 3: Surface of mobile phones cleaned post culture with QAC wipes.

Questionnaire

A questionnaire was distributed and completed by all participants pertaining to mobile phone use (Table 1).

Organisms Identification

Swabs collected from mobile phones were vortexed for

	-	- ·		-			~ ~
Table	1.	Augation	a anna fa	m agal	mantioinato	at time a	of anala
Tame	1.:	Quesiloni	iaire ic	n eacn	Darnendale	ai time.	oi swab
10000	••	2			pen neupene		0,0,0,00

	Res	ults		
1. Do you use your mobile phone within the hospital?				
Yes	98%	49		
No	2%	1		
2. How many hours per day do you use your mobile phone?				
>12h	18%	9		
8-12h	26%	13		
4-8h	26%	13		
1-4h	30%	15		
3. Which locations do you use your pho	one?			
Hospital	98%	49		
Patient's Room	37%	18		
Restroom	40%	20		
Home	90%	45		
4. How frequently do you clean your pl	none?			
1x/day	14%	7		
Occasionally	38%	19		
Rarely	36%	18		
Never	10%	5		
5. What cleaning agent do you use? (Cl	heck all that	apply)		
Dry Wipe	42%	21		
Alcohol	34%	17		
Purple Sani-Cloth	10%	5		
Orange Sani-Cloth	2%	1		
Other (Clorox, Lens Cleaning Solution, Soap Water)	16%	8		
6. How long ago did you last clean your	6. How long ago did you last clean your phone? 19.74 days			
7. Do you wash your hands				
a. Before using your phone				
Yes	10%	5		
No	90%	45		
b. After using your phone				
Yes	6%	3		
No	94%	47		
8. Do you use your phone to check the time?				
Yes	82%	41		
No	18%	9		

60 seconds to elute the microbes. Samples were then plated onto 5% TrypticaseTM Soy Agar and incubated in a CO2 incubator for 48 hours. Identification was performed by standard microbiological methods.

Results

Of the fifty mobile phones sampled, only 18% (9/50) revealed no growth. Polymicrobial growth was detected in 88% (44/50) of the mobile phones. Pathogens isolated from the phone samples included: coagulase negative staphylococcus (CoNS), Staphylococcus aureus (S. aureus), Bacillus species (sp.), Diphtheroides, Micrococcus sp., Proteus sp., Pseudomonas sp., Alpha Streptococcus (Strep) sp., Enterobacter sp., Strep sp., Aspergillus, Penicillium, Mold sp., and Dematiacious (Table 2). After cleaning the mobiles phones with QAC wipes, mobile phones were swabbed in an identical fashion and all phones revealed no growth.

Among the organisms isolated, CoNS was most prevalent and harvested from thirty-two phones with an average of 12 colony-forming units (CFU)/ml. Microorganisms known to be pathogenic (S. aureus, Proteus sp., Pseudomonas sp., Enterobacter sp., Strep sp.,) were isolated from 30% (15/50) of mobile phones.

The vast majority of residents, 98% (49/50) used their phone within the hospital and 37% (18/49) used their phones inside patients' rooms. 40% (20/50) of residents used their phones in the restroom. 82% (41/50) of residents used their phone regularly to check the time (Table 2).

10% (5/50) of residents never cleaned their phones and 74% (37/50) occasionally or rarely cleaned their phones. On average, residents had not cleaned their phones for 19.74 days at the time of the initial random swab. Only 14% (7/50) of the residents cleaned their phones daily; however, a majority of the residents

71% (5/7) used either dry wipes or alcohol and all residents had organisms isolated from their mobile phones. A total of 42% (21/50) of residents used dry wipes to clean their phone and only 10% (5/50) of the residents used QAC disposable wipes. Only 10% (5/50) of the residents washed their hands before using their phones and

6% (3/50) washed their hands after using their mobile phones. None of the residents washed their hands before and after using their mobile phones.

Discussion

Mobile phones are multipurpose, non-medical devices used in health care facilities. Health care facilities have few restrictions on mobile phone use even in sensitive areas such as intensive care units and operating rooms.

Greater than five CFU/cm2 of microorganisms is considered unacceptable in health care environments [35]. This study demonstrated 88% of mobile phones had polymi-

Table 2: Number of isolates and types of microorganisms from touch screen mobile phone devices of residents

Total number of cultivated swab samples	50				
Positive Culture	41 (82%)				
Type of Microorganisms	Total Colonies (CFU/ml)	Average Total Colonies (CFU/ml)	# of Phones with Isolate		
Non-Pathogenic					
CoNS	385	12	32		
Diphtheroides sp.	163	6	26		
Dematicaious	1	1	1		
Penicillium	4	1	4		
Bacillus sp.	89	11	8		
Microcci sp.	21	5	4		
Alpha Strep sp.	63	6	10		
Aspergillus sp.	5	3	2		
Mold sp.	11	6	2		
Pathogenic					
S. aureus	312	31	10		
Proteus sp.	6	3	2		
Pseudomonas sp.	5	3	2		
Enterobacter sp.	2	2	1		
Strep sp.	8	8	1		

crobial organisms isolated from residents' mobile phones and 30% of the mobile phones had pathogenic organisms. Of the pathogenic organisms isolated on mobile phones in this study, all had ≤ 1 CFU/cm2, which is still considered acceptable in health care environments; however, the vast majority of residents (98%) used their phones within the hospital, and 37% used their phones inside patients' rooms. This raises concern for potential spread of pathogenic bacteria to patients from microorganisms on the mobile phones.

Many of the residents 86% did not clean their phones on a daily basis and of the ones who did, a majority of them used either dry wipes or alcohol wipes. When wiping with 70% isopropanol, it has been shown to not adequately disinfect surfaces with high titers of pathogenic microorganisms [36]. A few of the residents (6%) used Clorox® Disinfecting Wipes (Clorox, Oakland, CA, USA) to clean their mobile phones. Although Clorox® reduced pathogenic counts, it has been shown to have a short-lived effect and immediate repeat contamination resulted in microbial growth when swabbed. In a clinical environment, repeated cleaning with Clorox® would be required after every potential contamination [32]. QAC wipes have shown that a single disinfection prevents further contamination and could be effective for up to 12 hours in spite of repeated opportunistic contamination [32]. Ammonium compounds within QAC is well known to have a wide spectrum of antimicrobial activity including some antifungal and antiviral properties, although it is ineffective against norovirus and Clostridium difficile (C. Difficile) [37]. In this study, QAC wipes were an effective method of disinfecting mobile phones with no microorganism growth approximately five minutes after cleaning mobile phones with them.

QAC wipes have demonstrated that repeated usage does not have long-term damaging effects on the Apple iPad®. Both the appearance and functionality of the touch screen on the iPad® are not affected [32]. One of the downsides of QAC wipes is the 'residual effect' causing a white residue

on the touch screen (Figure 4), which would require users to polish the device to remove the residue which would consequently reduce the efficacy of the QAC wipes [<u>32</u>].



Figure 4: Post QAC wipe mobile phone was left wet for two minutes and air dried per manufactures instructions. Post wipe residue present.

None of the dry wipes, alcohol wipes, Clorox® wipes, or QAC wipes have the ability to eradicate C. difficile. Tristel (Tristel Solutions Ltd., Snailwell CB8 7NY) wipes system has been shown to be effective in reducing C. difficile colony counts. Tristel is a chlorine-based cleaning wipe system, which includes a sporicidal component. There is evidence that sodium hypochlorite may be effective against C. difficile, but its safety for use on iPads® has yet to be established [<u>38</u>].

The use of mobile phones is a concern within the operating room setting. Mobile phones are commonly used in the operating room by staff, vendors, residents, and physicians and have been found to possess a high rate of pathogenic bacterial contamination and organic material such as food, human secretions, and excretions [29]. The bacterial and organic material load was decreased after a single disinfecting process with commercially available cleaning wipes safe for mobile phone use.

The use of mobile phones by inpatients is also a concern. 1) Demographics, 2) characteristics of mobile phones, and 3) phone surface microbial contamination used by inpatients were examined by Brady, et al [39]. A majority of the inpatients (70.3%) completed a questionnaire about the utilization of mobile phones and also provided their mobile phones for bacteriological analysis and comparative bacteriological swabs from their nasal cavities. The majority of the patients, 94% supported utilization of mobile phones by inpatients and 24.5% of patients stated that mobile phones were vital to their inpatient stay.

In addition to mobile phones as potential vehicles of pathogenic bacterial dissemination, multiple studies have shown that white coats, neckties, keyboards, and stethoscopes [40-43] are also potential vectors. White coats' sides, collars, and pockets were the most highly contaminated areas [40]. Neckties are 'poor practice' (other than bowties) when in contact with patients as they 'serve no beneficial function' in patient care, they are rarely laundered, and they have colonized pathogens in healthcare settings [41]. More than half of the keyboards in hospitals had isolated pathogens [42]. Lastly, stethoscopes have been shown to have significant bacterial contamination resistant to multiple classes of antibiotics [43]. Disinfections before and after each patient contact of any potential vector is recommended to avoid the spread of pathogenic microorganisms.

Creating a Policy

The results of this study and others suggest a feasible policy of mobile phone usage among patients, visitors, and health care workers could be formulated for hospital settings. Mobile phones are essential devices for professional and social lives of users and restrictions on the use of mobile phones is difficult and not a practical solution.

Mobile phone users need to be regularly advised on the use of effective sanitizer wipes in order to decrease the bacterial load of mobile phones. Sanitizing mobile phones regularly will reduce the risk of recontamination while allowing the use of mobile phones in the hospital setting. Specific software applications have been developed to remind users to regularly disinfect their devices. Using the wipes is economical and not time consuming [44].

In addition, a standard infection guideline should be implemented for before and after mobile phone use such as hand washing and sound hygienic practice in order to prevent mobile phones as vehicles of transmission of both hospital and community acquired diseases. Furthermore, possible abstinence from use of mobile phones within a patient's room and operating room or use of a protective sleeve (Figure 5) could be helpful in preventing the transmission of pathogens.



Figure 5: Protective sleeves for use in operating room setting with no interference of talk and touch function. The principle drawback is the cumbersome nature of the sleeve.

Conclusion

Mobile phones have become a part of personal and professional life and accompany patients and healthcare providers everywhere. Furthermore, they are a principle source of communication among health care providers within the hospital. The regular use of mobile phones within the hospital setting may serve as a vehicle of transmission of microorganisms that can cause disease in human beings. Consequently, it is important to regularly disinfect mobile phones, especially health care professionals whose hygiene can directly impact patients' wellbeing.

Further research including phenotyping and genotyping organisms may discover a direct link between mobile phones and hospital acquired infections. Awareness and concern among health care providers of mobile phones use can help control infection and avoid transmission of diseases. Possible solutions include guidelines for curtailing mobile phone use among patients and health care providers.

References

- https://finance.yahoo.com/blogs/the-exchange/americans-t-put-phones-downeven-shower-135304962.html
- http://nypost.com/2013/07/24/new-study-finds-that-62-of-women-check-phonesduring-sex/
- https://www.scpr.org/news/2015/09/24/54595/brexting-impacts-baby-bondingduring-breastfeeding/
- https://www.cnet.com/news/study-19-percent-of-people-drop-phones-down-toilet/
- 5. <u>http://www.nytimes.com/2009/01/21/dining/21tele.html?_r=1</u>
- 6. http://www.refinery29.com/2015/06/89986/smartphone-sleep-habits
- Prescott, L.M., J.P. Harley and D.A. Klein, 2005. Microbiology. 6 Ed. Tim McGraw-Hill Co., New Delhi, India, pp: 675.
- Daud M, Saadullah, Hidayatullah, Khan H, Khan I, Ullah N, Ahmad H, Rehman G, Ahmed S. Antibiotic Susceptibility Patterns of Various Bacteria Associated with Cell Phone in a Khyber Teaching Hospital Peshawar (Pakistan). World Appl. Sci. J., 30 (12): 1712-1714, 2014
- Yusha'u, M., M. Bello and H. Sule, 2010. Isolation of bacteria and fungi from personal and public cell phones: A case study of Bayero University, Kano (old campus). Intl. J. Biomed and Health Sci.,
- Glodblatt, J.G., I. Krief, T.D. Haller, V. Milloul, cellular telephones and transmission of pathogens by medical staff in New York and Israel. Infec Con Hosp and Epi., 28: 500-503. 6(1): 97-102. D.M. SixSmith, I. Srugo and I. Potasman, 2007.
- 11. Washington (2011). Study finds dangerous bacteria on cell phones of hospital based patients. Available from Elsevier
- Katherine Ellingson, Janet P. Haas, Allison E. Aiello, Linda Kusek, Lisa L. Maragakis, Russell N. Olmsted, Eli Perencevich, Philip M. Polgreen, Marin L. Schweizer, Polly Trexler, Margaret VanAmringe and Deborah S. Yokoe (2014). Strategies to Prevent Healthcare-Associated Infections through Hand Hygiene. Infection Control & Hospital Epidemiology, 35, pp S155-S178 <u>https://doi.org/10.1017/S0899823X00193900</u>
- Rusin P, Maxwell S, Gerba C (2002) Comparative surface-to-hand fingertip tomouth transfer efficiency of gram-positive bacteria, gram negative bacteria and phage. J ApplMicrobiol93: 585-592.
- Kurz A, Sessler DI, Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. Study of wound infection and temperature group. N Engl J Med 1996;334(19):1209.
- Gaine WJ, Ramamohan NA, Hussein NA, Hullin MG, McCreath SW. Wound infection in hip and knee arthroplasty. J Bone Joint Surg Br 2000;82-B:561–5
- Parvizi J, Ghanem E, Joshi A, et al. Does "excessive" anticoagulation predispose to periprosthetic infection? J Arthroplasty 2007;22:24–8 [Suppl]
- 17. Berbari EF, Hanssen AD, Duffy MC, et al. Risk factors for prosthetic joint infection: case-control study. Clin Infect Dis 1998;27:1247-54.
- Warwick D, Harrison J, Glew D, et al. Comparison of the use of a foot pump with the use of low- molecular-weight heparin for the prevention of deep-vein thrombosis after total hip re- placement: a prospective, randomized trial. J Bone Joint Surg Am 1998;80-A:1158–66.
- Joseph TN, Chen AL, Di Cesare PE. Use of antibiotic-impregnated cement in total joint arthroplasty. J Am Acad Orthop Surg 2003;11:38–47.
- Lentino JR. Prosthetic joint infections: bane of orthopedists, challenge for infectious disease specialists. Clin Infect Dis 2003;36:1157–61.
- Shakir I, Patel N, Chamberland R, Kaar S. Investigation of Cell Phones as a Potential Source of Bacterial Contamination in the Operating Room. The Journal of Bone and Joint Surgery. 2015. 97(3).
- Karabay O, Kocoglu E, Tahtaci M (2007) The role of mobile phone in the spread of bacteria associated with nosocomial infections. J. Infect. Develop. Countries. 1: 72-73.
- Kampf G, Löffler, H., Gastmeier, P. Hand hygiene for the prevention of nosocomial infections. DeutschesÄrzteblatt International. 2009;106(40):649-55.
- Khan B.A., Hui K.Y., Hu, S. et al. Time-motion analysis of health care workers' contact with patients and workers' hand hygiene: Open vs closed units. American Association of Critical-Care Nurses. 2011;20(3):e75-e9.
- Karaaslan A., Kepenekli K.E., Atuci S., et al Compliance of healthcare workers with hand hygiene practices in neonatal and pediatric intensive care units overt observation. Interdisciplinary Perspectives on Infectious Diseases. 2014;2014:306478
- Chang J.C., Ossoff S.F., Lobe D.C., et al. UV inactivation of pathogenic and indicator microorganisms. Applied and Environmental Microbiology. 1985;49(6):1361-65.

- Rutala W, Weber D, Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.
- Kundrapu S, Sunkesula V, Jury LA, Sitzlar BM, Donskey CJ. Daily disinfection of high-touch surfaces in isolation rooms to reduce contamination of healthcare workers' hands. Infect Control HospEpidemiol 2012;33:1039e1042.
- Sattar SA, Maillard J-Y. The crucial role of wiping in decontamination of hightouch environmental surfaces: review of current status and directions for the future. Am J Infect Control 2013;41:S97eS104.
- Pal P, Roy A, Moore G, et al. Keypad mobile phones are associated with a significant increased risk of microbial contamination compared to touch screen phones. J Infect Prev 2013;14:65e68.
- Apple, Inc. iPad User Guide for iOS 6.1 software. Cupertino, CA:Apple, Inc.; 2013. http://dx.doi.org/019-2528/2013-01.
- Howell V Thoppil A, Mariyaselvam M, Jones R, Young H, Sharma S, Young P. Disinfecting the iPad: evaluating effective methods. Journal of Hospital Infection 87 (2014) 77-83.
- Environmental Protection Agency. Office of Pesticide Programs. List E: EPA's Registered Antimicrobial Products Effective Against Mycobacterium tuberculosis, Human HIV-1 and Hepatitis B Virus. Available at: <u>https://archive.epa.gov/pesticides/oppad001/web/pdf/list e_mycobact_hiv_hepatitis.pdf</u>. Accessed December 10, 2011
- PDI FAQ. Sani-Cloth. Available at: www.pdipdi.com/healthcare/faq.aspx.Accessed December 10, 2011
- Sadat-Ali M, Al-Omran K, Azam Q, et al. Bacterial flora on cell phones of health care providers in a teaching institution. American Journal of Infect Control 2010; 38(5): 404-405. <u>http://dx.doi.org/10.1016/j.ajic.2009.08.007</u>
- Nandy P, Lucas A, Gonzalez E, Hitchins V. Efficacy of commercially available wipes for disinfection of pulse oximeter sensors. American Journal of Infection Control 44(2016) 304-10.
- McDonnell G, Russell AD. Antiseptics and disinfectants: activity, action and resistance. ClinMicrobiol Rev 1999;12:147e149
- Kiedrowski LM, Perisetti A, Loock MH, Khaitsa ML, Guerrero DM. Disinfection of iPad to reduce contamination with Clostridium difficile and methicillin- resistant Staphylococcus aureus. Am J Infect Control 2013;41:1136e1137.
- Brady RR, Wasson A, Stirling I, McAllister C, Damani NN (2006). Is your phone bugged? The incidence of bacteria known to cause nosocomial infection in healthcare workers mobile phones. J Hosp Infect 62: 123-125
- Banu A, Anand M, Nagi N. White caots as a vehicle for bacterial dissemination. J ClinDiagn Res. 2012. Oct;6(8)1381-4
- 41. McGovern B, Doyle E, Fenelon L, FitzGerald S. The necktie as a potential vector of infection: are doctors happy to do without?
- Rutala W, White M, Gergen M, Weber D. Bacterial contamination of keyboards: efficacy and functional impact of disinfectants. Infect Control HospEpidemiol. 2006. Apr:27(4):372-7
- Shiferaw T, Beyene G, Kassa T, Sewunet T. Bacterial contamination, bacterial profile and antimicrobial susceptibility pattern of isolates from stethoscopes at Jimma University Specalized Hospital. Ann ClinMicrobiolAntimicrob. 2013. Dec 13;12(39).
- Albrecht U-V, von Jan U, Sedlacek L, Groos S, Suerbaum S, Vonberg R-P. Standardized, app-based disinfection of iPads in a clinical and nonclinical setting: comparative analysis. J Med Internet Res 2013;15:e176.

SUBMISSION HISTORY

Submitted August 21, 2017 Reviewed September 12, 2017 Revised September 21, 2017 Accepted September 22, 2017 Published September 30, 2017

AUTHOR AFFILIATIONS

- Michael B Canales, DPM, FACFAS; John Boyd Jr., DPM; Mario Markovic, MS, SM(ASCP)MT; Richard A Chmielewski, MD
- Saint Vincent Charity Medical Center, 2351 E 22nd St, Cleveland, OH 44115 US 2 Grace C Craig, DPM
- Cleveland Clinic Fairview Hospital, 18101 Lorain Ave, Cleveland, OH 44111 US (Direct inquires to Grace C Craig, gracecraigdpm@gmail.com)

AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

COPYRIGHT & OPEN ACCESS

© 2017 Canales, Craig, Boyd, Markovic, Chmielewski. All rights reserved. Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review is an open

access publication and follows the <u>Creative Commons Attribution-</u>

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".



Tissue Sparing Total Hip Arthroplasty Study Group

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

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

Joint Implant Surgery and Research Foundation 46 Chagrin Shopping Plaza, #117 • Chagrin Falls, OH 44022





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



Check for updates





CASE REPORT

http://dx.doi.org/10.15438/rr.7.3.191

Successes and Failures of a Freedom™ Constrained Cup Used in a Major Salvage Procedure

Donaldson T¹, Clarke I.C.²

Abstract

Background: This is a case report of a 36mm constrained cup (Freedom[™], Biomet IN) that performed successfully for 7-years in a salvage case involving a totalfemur implanted in a leg already short by 3-4 inches. The goal was to enhance hip motion and stability using a 36mm head instead of the usual 32mm size. Templating indications were for a 50mm cup (Freedom[™]; Arcom[™] liner). The proximal femur inserted in 2008 incorporated the 36mm constrained THA and was anchored distally to bone using the Compress[™] fixator. By 2012 the fixator loosened and was replaced by hinged total-knee arthroplasty (TKA). The THA was retained at revision and patient's clinical follow-up was satisfactory for 4 years. As indicated by Martel radiographic method, the Arcom[™] liner showed minimal wear over this period. Radiographs in Feb-2016 showed the cup's constraint ring had rotated slightly but the patient had no symptoms. By Dec-2016, the patient had experienced three falls and also had heard a popping sound in her hip. At Dec-2016 office visit, radiographs indicated additional rotation of the constraint ring and CT scans showed an eccentric head position contacting the metal shell. At revision, 50% of the Arcom rim was ablated and the remainder present as a loose fragment. Following insertion of new Freedom liner and 36mm head, her follow-up appears satisfactory 10-months later. Her leg shortening remains but she walks to office visits using a cane and doesn't need the cane at home.

Methods: Retrieved Arcom liner and detached rim fragment were reconstructed, photographed, and then bi-

valved for comparison to similarly prepared exemplar liners, one identical to our revision and one with a thicker wall. Details of liner sections were taken from photographs and reconstructed by computer graphics (Canvas Draw- 3^{TM}). Wear performance over the first 7 years was assessed using the Martel x-ray method.

Results: Inspection of retrieved liner showed a large oval depression in the ablated rim. The contra-rim featured the large Arcom fragment and the underlying liner wall was less than 1mm thick. Comparison to exemplar liners showed that the large fragment had separated along the lower edge of the constraint groove. Exemplars demonstrated a substantial rim buttress spanning 13mm, which had been ablated in our retrieval.

Discussion and Conclusion: Although this was not a high-demand patient, the considerable hip-impingement forces in a flail limb likely levered the head repeatedly against the liner's constrained rim. Neck impingement was clearly evident in the damaged liner. A subluxing femoral head would also thin the contra-wall, as would backside wear. We do not know if the eccentric ring image in Feb-2016 radiographs depicted failure. The liner may have escaped from the shell's locking-ring and with activity, ablated the Arcom contours and led to rim fracture. It is also possible that the liner constraint was damaged when the patient fell, thereby allowing the liner to mobilize.

Keywords: Constrained Cup, mechanical impingement, salvage, complex revision Level of Evidence: AAOS Therapeutic Level III Educational Value & Significance: JISRF Level C

Background

Failed total hip arthroplasty (THA) may necessitate novel designs of revision implants that present unique risks as well as special salvage benefits. Use of constrained cups to enhance joint stability is offset by a reduction in the range of motion with concomittantly higher risk of impingement. [1-3] The patient in this case report had a total hip arthroplasty (THA, left leg) In her early thirties that subsequently became infected. This was revised to a Girdlestone hip and she had to walk with crutches for 19 years (1989-2008). Now in her early 50's, she had an attempted THA re-implantation but that immediately became infected. Following multiple debridements, an antibiotic bonecement spacer and two nails were inserted (Fig. 1A). Now in her early fifties (2008) she desired a more functional result and talked her surgeon into implanting a revision THA. With 3-4 inches of leg shortening, and lacking hip musculature, this patient was clearly at risk for dislocation. Therefore, a constrained-cup design with as large a femoral head as possible was essential.

In 2008, the patient's left femur was salvaged with a proximal femoral replacement (Fig. 1B). The choice of cup provided for a 36mm head with enhanced stability and improved range-of-motion (Freedom[™], Biomet, Warsaw, IN). The polyethylene insert (Arcom[™]) did not appear as motion restrictive as other designs and the external clamping ring came pre-installed from the factory. In addition, this design incorporated a unique method for inserting the 36mm femoral head into the cup. Three bone screws were added or additional security. The shaft of the femoral-implant was anchored distally using the Compress[™] fixator system (Biomet, Warsaw, IN). With a leg 3-4 inches short and with limited hip muscles, this patient's activity was considered low demand. Nevertheless, this reconstruction of her left femur represented a major salvage operation with success depending on fixation in the small segment of distal cortex and cancellous bone of the condyles.

At the 2011 office visit (2.5 years follow-up), the distal fixation was satisfactory with no signs of loosening (Fig. 2A). However, she presented at the 2012 office visit with distal-fixation failure at the level of connecting pin (Fig. 2B). This was revised to a hinge-knee arthroplasty while the original Freedom cup was retained . Her post-op results were satisfactory and follow-up continued satisfactorily from 2012 into 2014 (Fig. 3B).

Radiographs taken during office visit of February 2016 indicated that the external clamping ring had a rotational migration of 8° in the AP view (Fig. 4A) and 2.6° in the lateral view (Fig. 4B). This suggested that the cup's lock-ing-mechanism may have failed but the patient offered no



Figure 1. Patient radiographs illustrating (A) Girdlestone hip that the patient walked on for 19 years, and (B) her 2008 revision with the THA incorporating a Freedom constrained cup, a large femoral replacement, and distal Compress knee fixator.



Figure 2. Patient radiographs illustrating success of Compress distal fixation at 2.5 years (2011) but loose and disassociating at 3.5 years.



Figure 3. Radiographs illustrating, (A) hinge total knee replacement in 2012, and (B) retention of original Freedom cup, noting the clamp ring aligned with the acetabular cup.



Figure 4. Imaging showing clamp-ring eccentric to Freedom cup, (A) 8° rotation in AP view, and (B) 2.6° rotation in lateral view.



Figure 5. Martell x-ray method indicating very low wear.

complaints. Multiple radiographic assessments using the Martell software provided 0.4mm and 323mm3 estimates for linear and volumetric wear averages, respectively (Fig. 5). Over her 7-year follow-up (8/6/08 to 6/20/15) this would indicate linear wear was as low as 0.06mm/year. Thus, cup wear did not appear to be a problem. Repeat of radiographic wear assessments over the following 8-month period (6/20/15 - 2/16/16) revealed linear-wear measurement had increased from 0.4 to 1.1mm.

Unfortunately, this patient had a fall in December 2016 and presented in the office two days later. She also claimed two prior falls and had heard a "popping" sound from her hip. Radiographs revealed that the external clamping ring now had a rotational shift of 14.3° (Fig. 6A). This indicated that the cup's locking-mechanism had failed. CT scans showed the femoral head was in contact with the metal acetabular shell (Fig. 6B). Small cystic areas were also visible behind the acetabular shell (arrowed).

At revision operation, fully 50% of the liner's polyethylene rim had been abraded and a large loose fragment represented the other 50% (Fig. 7A). The rim-clamping ring and the cup-locking ring were also recovered. While the femoral head had been making some contact with the metal acetabular shell, there was no tissue-staining. A new Freedom liner and femoral head were installed following the recommended procedure. The patient's left leg remains 3-4 inches short but she walks in for office visits using a cane and doesn't use the cane at home. Her follow-up appears satisfactory to date.

Methods

Damage on the retrieved 36mm femoral head was analyzed by scanning electron microcopy (Zeiss, SEM), energy dispersive x-rays (Bruker, EDS) and interferometry for roughness assessment (ZYGO, NewView600). The retrieved liner was photographed and sectioned through the thin wall section located under the detached rim fragment (Fig. 7B). The components and sections were photographed for dimensional comparison with exemplar liners using computer graphics (Canvas Draw-3, ACDsee, Inc.)

Results of Failure Analysis

There were four striking aspects to this retrieved liner. These were, (i) 50% of the liner's rim missing, (ii) a large rim fragment loose, (iii) liner thickness under the loose fragment reduced to less than 1mm thick, and (iv) large oval depression on contra liner-rim. The average dome



Figure 6. Images showing, (a) clamp ring rotated 14.3°, and (B) femoral head contacting metal shell and cystic changes indicated by arrows.



Figure 7. Retrieved Freedom liner with its detached rim fragment, (A) opposite side of liner to the fragment showed large indent typical of impaction by the femoral neck, (B) liner was cut into two sections in the plane through the thinnest region that lay under the fragment.



Figure 8. Comparison of liner contours, (A) rim fragment superimposed on sectioned retrieval showed thinned wall, and (B) section of exemplar Freedom liner.



Figure 9. Matching sections retrieved and exemplar liners, comparing details of (1) cup rim, (2) groove for clamp ring, (3) sub-rim, (4) anti-rotation scalloping, and (5) groove for liner locking-ring to metal shell.

thickness of the retrieved liner approximated 7.5-7.7mm (Fig. 7). Two exemplar liners were compared, one similar to our patient's and one with a thicker wall. This design has a substantial rim buttress and scalloped contours measured 13.4mm high (Fig. 8B). Comparison of the sections confirmed a major loss of circumferential contours (Fig. 7A, 8A, 9).

Two exemplar liners were compared, one similar to our patient's and one of a thicker wall design. The average dome thickness of the retrieved liner approximated 7.5-7.7mm (Fig. 7). Comparison of the sectioned retrieval to the new liners confirmed there was a major loss of circumferential polyethylene (Fig. 7A, 8A, 9). This liner design has a substantial buttressed rim and scalloped contours av-

eraging 13.4mm high (Fig. 8B).

The groove for the locking ring had approximately a 3mm polyethylene thickness in this design (Fig. 8B: detail 'B'). However, this (Fig. 9A: contour '5') was not where rim fracture occurred. Rim separation occurred at the level of the clamping-ring groove (Fig. 9A: contours '2' and '3'). Equally remarkable was that the intermediate rim contour ('3') and scalloping detail ('4') had also been ablated (Fig. 9). In addition, the liner wall was paper thin under the loose fragment, (Fig. 8A).

Discussion

This is the first detailed report of a Freedom constrained cup performing over 8-years in a complex salvage case. Prior to this reconstruction, our patient had coped with a Girdlestone hip on the left side for 19 years before demanding a more functional outcome. Her subsequent Freedom cup and femoral construct did well for four years until the distal fixator failed. Revision to a hinged TKA gave her another four years before the Freedom cup failed.

As in other revisions of this nature, our planning was more focused giving our patient adequate mobility and stability by using a large head in a constrained liner, thereby reducing risk of multiple dislocations. It appeared very unlikely that this Arcom liner would show minimal wear for 8-years and then suddenly produce high wear in the last 8 months of follow-up. It was a retrospective analysis of the radiographs that showed an 80 rotation of the liner's clamp ring, suggesting the liner was loose as of February of 2016. At revision, \gross abrasion of the liner's external surface confirmed that the liner had been loose and free to piston inside the shell. We had not anticipated the degree of polyethylene destruction that could result from a flail limb habitually impinging on a polyethylene liner. At revision, the typical deformation pattern of the femoral neck was still visible on the ablated polyethylene rim (Fig. 7A). In addition, the polyethylene wall under the fractured rim was paper thin (Fig. 8A). We surmised that the resulting contact with the repeatedly subluxing femoral-head produced cold-flow and back-side wear in the polyethylene, thereby facilitating rim fracture. The patient confirmed she had 3 falls in the 9-months prior to revision, one accompanied by a "popping" sound. It was therefore likely that the patient's falls were contributory to the final fracture of the liner with release of the clamp ring. We noted that rim fracture had occurred around the lower edge of the clamp groove (Fig. 8B: 'A') and not at the site of the cup-locking ring (Fig. 8B: groove 'B')

Our learning experience in this educational case was six fold, (i) monitoring rotation of the clamping ring relative to the cup face may be a key indicator of liner failure, (ii) habitual impingement can be anticipated even when using a large head, (iii) we were impressed by the severity of polyethylene damage created over 9-months, (iv) wear of the Arcom liner was anticipated but did not materialize, and (v) Freedom liners with thicker polyethylene are available for the 36mm head. This may be a consideration in the future for patients with suitably large hip joints.

Conclusion

In conclusion, it was notable that this constrained liner functioned very well for 7 years in our complex case and was easily revised at 8 years to another Freedom liner. The unique method for inserting the 36mm femoral head into the Freedom cup greatly facilitated the revision operation.

References

- Berend KR, Lombardi AV, Mallory TH (2005) The long-term outcome of 755 consecutive constrained acetabular components in total hip arthroplasty examining the successes and failures. J Arthroplasty 20: 93–102.
- Widmer KH (2007) Containment versus impingement: finding a compromise for cup placement in total hip arthroplasty. Int Orthop 31 Suppl 1: 29–33.
- Noble PC, Durrani SK, Usrey MM (2012) Constrained cups appear incapable of meeting the demands of revision THA. Clin Orthop 470: 1907–1916.

SUBMISSION HISTORY

Submitted June 16, 2017 Reviewed August 21, 2017 Revised September 8, 2017 Accepted September 11, 2017 Published September 30, 2017

AUTHOR AFFILIATIONS

- 1 Thomas Donaldson, MD Donaldson Arthritis Research Foundation, 900 E. Washington Street, Suite 200 Colton. CA 92324 US
- 2 Ian Clarke, BSc, PhD Department of Orthopedics, Loma Linda University Medical Center, 11406 Loma Linda Drive, Loma Linda University, Loma Linda, CA 92354 US

(Direct inquires to Ian Clarke, ithipgeek15@yahoo.com)

AUTHOR DISCLOSURES

The authors declare that there are no disclosures regarding the publication of this paper.

COPYRIGHT & OPEN ACCESS

© 2017 Donaldson, Clarke. All rights reserved. Authors retain copyright and grant the journal right of first publication with the work. Reconstructive Review is an open access publication and follows the <u>Creative Commons Attribution-NonCommercial CC BY-NC</u>. 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". JOASIN



WHAT IS IRRISEPT?

Irrisept is jet lavage containing low concentration chlorhexidine gluconate (CHG*) 0.05% in sterile water for irrigation



HOW IRRISEPT WORKS

Irrisept's bottle design allows users to control the pressure of the solution through manual bottle compression.

The mechanical action of Irrisept helps remove bacteria, particulate and debris in wounds without harming underlying tissues.

Irrisept is a FDA-Cleared (K080779), Class II Medical Device

Irrisept is sterile packaged, contents include:

- Irrisept, Step 1, 450 mL bottle 0.05% CHG in sterile water, USP (99.95%)
- Irririnse, Step 2, 450 mL bottle, 0.9% sodium chloride, (USP)
 - Set of 3 applicators fitting both
 Irrisept and Irririnse bottles

www.irrisept.com

EULOGY •

Our sincere



The Passing of A Renaissance Man Michael A R Freeman (1931 - 2017)

With sadness we record the passing of Michael A R Freeman (MARF) surgeon, scientist, inventor, writer and raconteur. I met Michael Freeman in the 70s when he asked me to become one of his fellows and develop further the concept of porous implant fixation. However, one of his assistants, Bill Day, had just developed an interlocking plastic peg for non-cemented fixation which was so successful in the short term that MARF never actually did anything with porous coating.

In the 70s John Insall and MARF pioneered knee replacement. The prior results were not good but following the principles developed by MARF of ligament balancing, ACL sacrifice, area resurfacing etc. the operation became very reliable. These were immense contributions.

MARF also pioneered hip resurfacing, but long-term results were not good due to acetabular failure. In later years he developed a neck sparing hip stem. While vertical load transfer was sub optimal, rotational load transfer was excellent at least in the crucial first year or so.

MARF insisted on publishing his failures, which even today, is not easily done. This meant that others did not need to go down the same dead end roads he had already explored, or if they did knew what the problem was. This I think was the greatest gift of a great man to posterity.

- Hugh Cameron

y experience during the 1970s was from afar reading Freeman's books and articles and enjoying his presentations from the podium. He was a polished speaker with a romantic way with the English language. By 1986 I was intrigued with his concept on saving the femoral neck for total hip arthroplasty. "Why Save the Neck?" (Freeman 1986 JBJS) Over the years I got to interact with him and discuss his concept of preserving the femoral neck along with Professor Pipino who had the same concept although a slightly different implant design.

I was presenting a paper on "Short Curved Neck Retaining Stem Design" and quoting both Freeman and Pipino at the Hip Toulouse Meeting in France last week when I heard of Michael's passing. He was encouraging when I started this journal and agreed to lend his name as Editor Emeritus and was always encouraging in my own development work especially around neck retention hip designs. He was a true pioneer and I hope his history is not lost to our new generation of surgeons and industry. It was my pleasure in getting to know him and regret that I did not have more opportunity to interact with him.

- Timothy McTighe

*T*ith the passing of Michael Freeman, the world has lost one of the greatest men of our time. Not only was he brilliant, but he was very ethical and always a total gentleman. He developed and implanted the first condylar type knee prosthesis, which was fully cemented, (The Freeman/Swanson) in 1968. Afcondolences to ter spending a year with him as a felhis family and low, we developed a close professional and personal relationship. We collabfriends. He will be orated over the past forty years on biomechanics of the knee and various knee sorely missed. implant designs, including a new prosthesis, which facilitates full flexion. It was

always very interesting and stimulating to lis-

ten to his impressions and various anatomical and kinematic concepts.

My situation over the years has been such that I have been able to travel to London two to three times a year. Even though Michael and I kept in touch by phone and email, we had the opportunity during these visits to meet face to face, which was always very interesting. Our relationship was such that he would tell me when he thought I was wrong, but he could also take criticism from me, which made for a very healthy relationship.

My wife and three sons got to know Michael and his wife, Pat, very well. We would sometimes visit with them at their country home in Wiltshire, and would always go to dinner with them when they were in London.

Michael is one of the few people who during their lifetime have made life better for millions of people. I will very much miss my close association with this great man.

- Kent Samuelson



GLOBAL | PERSONAL | PORTABLE Make ICJR Your Source for Orthopaedic Education





Attend our live events, including Global Congresses, CME Courses, Resident & Fellow Programs, and our International Affiliate meetings.



JOIN our Global ICJR Community!

Become a member of ICJR and enjoy the benefits of our global orthopaedic community. Receive discounts on meeting registrations, access premium content on ICJR.net, and help support resident & fellow education.



INSTALL the ICJR App and visit ICJR.net!

Access a wealth of educational content anytime, anywhere from your computer or mobile device.





ReconstructiveReview.org • JISRF.org • Joint Implant Surgery & Research Foundation

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 Question¹

	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 Systematic Review² of Level I RCTs (and study results were homogenous³) 	 High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥ 80% follow- up of enrolled patients) Systematic review² of Level I studies 	 Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review² of Level I studies 	 Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review² of Level I studies 	
Level II	 Lesser quality RCT (e.g. < 80% follow- up, no blinding, or improper randomization) Prospective⁴ comparative study⁵ Systematic review² of Level II studies or Level 1 studies with inconsistent results 	 Retrospective⁶ study Untreated controls from an RCT Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) Systematic review² of Level II studies 	 Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review² of Level II studies 	 Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review² of Level II studies 	
Level III	 Case control study⁷ Retrospective⁶ comparative study⁵ Systematic review² of Level III studies 	• Case control study ⁷	 Study of non- consecutive patients; without consistently applied reference "gold" standard Systematic review² of Level III studies 	 Analyses based on limited alternatives and costs; and poor estimates Systematic review² of Level III studies 	
Level IV	Case Series ⁸	Case series	 Case-control study 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.

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.

JISRF Mission Statement

he 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.

BRENNAN, MANNA & DIAMOND

From physicians to hospital medical staff, from home healthcare providers to allied health professionals and everything in between, BMD can develop and implement strategic plans specifically designed to help you meet and navigate the ever changing healthcare environment.

We serve as legal counsel <u>AND</u> as business and strategic advisors to our healthcare clients.

We give our clients peace of mind so they can get back to the business of caring for their patients.

For more information contact our Health Law Department 75 E. Market Street, Akron, OH 44308 • (330) 253-5060 • www.bmdllc.com

Joint Implant Surgery & Research Foundation • JISRF.org • ReconstructiveReview.org

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

Future Site Selected For This Cutting-Edge Medical Initiative

S ince 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 firstin-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 • www.reconstructivereview.org