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Reconstructive REVIEW

OFFICIAL JOURNAL OF THE

Joint Implant Surgery and Research Foundation

Strategic Alliance with

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

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

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

For more information, please contact:

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Reconstructive Review

A Journal Published by the Joint Implant Surgery & Research Foundation

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

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

Reconstructive Review *Volume 3, Number 2, September 2013*

JISRF Announcements

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

This edition makes our fourth full edition since our October 2011 flag ship introduction edition. This is also our second full edition for 2013. We are getting closer to our goal of quarterly publication, which we expect to hit in 2014. We will have one more full edition prior to years end providing three full editions for 2013.

In addition we have done three CME Abstract Supplements for ICJR with this October's highlight of From ICJR East (the Combined 14th Annual ISK and European Knee Associates Conference) October 4 - 6, 2013 • New York, NY

We announced in our last Journal the formation of the JISRF Institutional Review Board. I am please to further announce the approval of Osteointegration Implant (OI) for Transfemoral Amputation IRB application. We highlight within this Journal a case report "A Global Collaboration - Osteointegration Implant (OI) for Transfemoral Amputation on pages 50 to 54. This to our knowledge is the first case reported of this technique being preformed as a custom in the United States.

We are optimistic that (OI) for Transfemoral Amputation will provide an alternative treatment for patients for whom a traditional-socket type above-the-knee prosthesis presents difficulties. We will follow this patient as seen progress through her secondary procedure and healing process.

Timothy McTighe, Dr. HS (hc)
Executive Director, JISRF

JISRF Mission Statement

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

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

Strategic Alliance Announcement

Joint Implant Surgery & Research Foundation

is Pleased to Announce a Strategic Alliance with the

DARF
DONALDSON ARTHRITIS
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Donaldson Arthritis Research Foundation

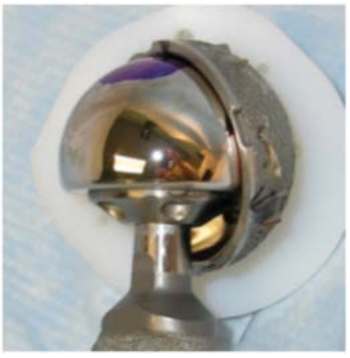
DARF, founded in 2005 by Dr. Thomas K. Donaldson, has a focus on outcome studies and basic science with major emphasis on implant retrievals. His ongoing collaboration with Ian Clarke, PhD provides a synergy between the laboratory and clinical surgical science. Both men are Board Members of JISRF and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

Ian Clarke, PhD & Thomas K. Donaldson, MD

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

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

Together both groups will provide unprecedented analysis of your Retrievals.



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JISRF Feature

One of the JISRF Board Members from Australia is receiving accolades from his country. Dr. John M. Harrison AM receives the 2013 Member of the Order of Australia.

Dr. John M. Harrison AM

In the Australian honours system appointments to the Order of Australia confer recognition for outstanding achievement and service.

How it is Awarded

The Order of Australia is the pre-eminent way Australians recognise the achievements and service of their fellow citizens.

Nominations to the Order of Australia come directly from the community: either individuals or groups. Anyone can nominate a fellow Australian for an award.

The 19-member Council for the Order of Australia then considers the nominations. The Council makes its recommendations, independent of government, direct to the Governor-General.

Awards in the Order of Australia are publicly announced on Australia Day (26 January) and the Queen's Birthday public holiday (June).

John, is a product of self determination and hard work. Educated in the public school systems in The English School, Cairo Egypt and finishing high school at North Sydney Boys High School in Sydney NSW, Australia. He went on to complete his medical degree at Sydney University achieving honours in both Science and Medicine. He then took a year off from study to represent Australia in water polo at the Mexico Olympics.

After a short Residency Program in Sydney, he travelled to the United Kingdom and worked and studied at St. Bartholomew's Hospital in London, graduating with his Fellowship in General Surgery in 1973. He returned to complete the Orthopaedic Training in Sydney, obtaining his Fellowship (FRACS Orthopaedics) in 1977.

He pursued his Post-Graduate studies, largely in joint replacement surgery of the hip and knee visiting most of the major centers of joint replacement worldwide, including Charles O. Bechtol, MD, the Founder of the Joint Implant Surgery and Research Foundation (JISRF).

He is a member of many specialty societies where he has held a number of leadership positions and is a past President of the Australian Orthopaedic Association and its political arm ASOS. He has been awarded Honorary Fellowships of the AMA and Australian College of Sports Physicians for services to those bodies.

In sport, he has had numerous ties with sporting teams including cricket, rugby union and rugby league and he still plays water polo. He has been the Team Doctor for the Australian Women's Water Polo Team in the World Titles in Rome in 1994 and was the Manager and Orthopaedic Surgeon for the Australian Men's Water Polo Team at the Athens Olympics in 2004. He was also a Reserve Manager for the Men's Water Polo Team for Beijing in 2008.

John has been a strong supporter of JISRF. His leadership and direction have been invaluable as both a Board of Trustee and as a Member of our International Editorial Board.

Memberships:

- Australian Orthopaedic Association
- Australian Doctors Fund
- Australian Academy of Orthopaedic Surgeons (International Affiliate)
- Australian Orthopaedic Foot and Ankle Society
- Royal Australian College of Surgeons
- American Academy of Orthopaedic Surgeons
- Australian Association of Surgeons
- Australian College of Sports Physicians
- Academy of Medicine
- Med-Law
- Australian Orthopaedic Medico-Legal Association

It is with a great sense of pride that I pass along the news that one of our Board Members receives the 2013 "Member of the Order (AM) by the Australian Government. He is ever deserving of this award, well done my friend!

Timothy McTighe, Dr. HS (hc)
Executive Director, JISRF

Submit Articles

Instructions to Authors

To submit an article to Reconstructive Review please review the instructions below. Once the article is ready for submission please send it to submitarticle@jisrf.org.

Please use the following criteria:

1. Title page: List the title and the names of the authors in order you want them to appearance. Provide complete contact information including both regular mail and email addresses.
2. Informed consent: Any manuscript dealing with human subjects must include a statement that proper disclosure was given and patient consent was received.
3. Copyright agreement: All articles published are the property of the authors. However, the journal gives blanket permission to copy as long as proper notification and recognition are provided to JISRF.
4. Disclosure statement: Disclosure by all authors as to any commercial interest must be submitted and signed by the corresponding author. It is the responsibility of the corresponding author to ensure compliance and full disclosure of all co-authors. The disclosure is simple: I have a financial interest in the following commercial companies: Financial interest being define as: royalties, consulting fees, stock or stock options and any direct or indirect instructional support. We do not need to know any detailed information other than you have a financial interest. If you are reluctant to disclose then you probably should not being doing what you are doing.
5. Suggested structure of articles:
   - Structured abstract Note: do not include abstract with case reports
   - Introduction
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6. Structure of endnotes (please refer to the website http://medlib.bu.edu/facts/faq2.cfm/content/citationsama.cfm)

Types of Articles Accepted

- Basic Science
- Case Reports
- Clinical/Surgical
- Commentary
- Controversial Issues (i.e. modularity, tapers, MoM, etc.
- Historical Reviews
- Letters to the Editor
  (We welcome letters to the editor and acceptance is at the sole discretion of the Editor.)
- Original Articles
- Surveys

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

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

Format

We can accept Word documents (.doc), text files (.txt), or PDF documents (.pdf) as e-mail attachments. Alternatively you may paste the whole text of the media release directly into your e-mail.

Acceptable Image Files

BMP, EPS, JPG, TIFF, PDF, (most anything)

All photographs and continuous tones should be at least 300 dpi (dots per inch), illustrations and line art should be at least 1200 dpi.

Reconstructive Review Specifications

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

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

Ad Specification

Full color or black and white - avaiable sizes:

- Full Page, 7.25" x 9.25"
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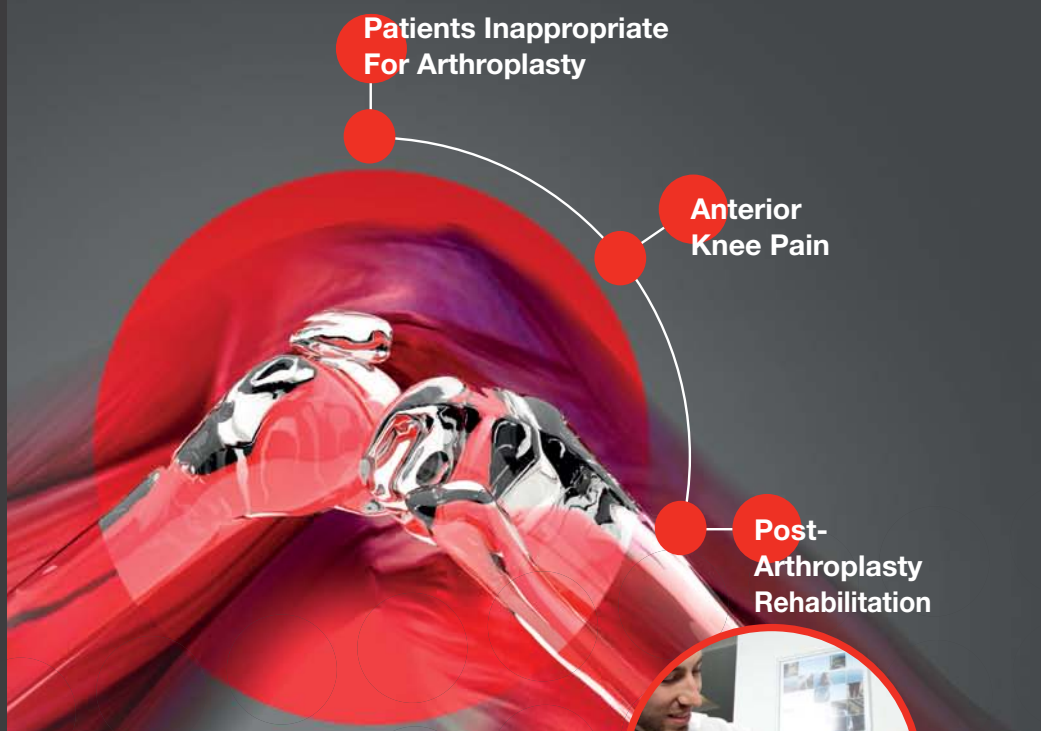

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Joint Implant Surgery & Research Foundation
Chagrin Falls, Ohio, USA

Delayed Administration of Risedronate Does Not Restore Bone Loss In Patients Following Total Hip Arthroplasty

A randomized, double blinded clinical study

David R. Lionberger, MD[1§], Joshua M. Liao[2], Mitchell D. Eggers, PhD[3], Sahar Bawkher, BS[3]

Abstract

Background: Periprosthetic bone loss after total hip arthroplasty (THA) increases the risk of serious post-operative complications. Previous studies have reported the beneficial effect of risedronate therapy to improve periprosthetic bone mineral density (BMD) around new implants. The current study is to evaluate the effect of risedronate treatment in enhancing mature well fixed THA implants one year or more after implantation.

Methods and Results: A total of 32 osteoarthritic patients received total hip replacement surgeries and were enrolled from the primary investigator's clinical practice between February and September 2007. All eligible patients who met the inclusion criteria underwent total hip arthroplasty for reasons other than low traumatic hip fracture due to osteoporosis with normal or osteopenic lumbar spine BMD scores. Subjects received oral risedronate or a placebo with daily calcium plus Vitamin D. DEXA BMD scanning and bone-specific biomarkers, NTx and ALK phosphatase were collected at 6 and 12 months post-surgery. The result showed that risedronate did not increase BMD values of operative femur nor levels in NTx or ALK phosphatase.

Conclusions: This study suggests that risedronate treatment is not effective in preventing periprosthetic bone loss nor enhancing existing density in well fixed osteointegrated following total hip arthroplasty.

Key words: *risedronate, bisphosphonate therapy, total hip arthroplasty*

Background

The most profound and dynamic changes in periprosthetic bone mineral density (BMD) have been observed in the first 6 to 12 months following total hip arthroplasty (THA). This early bone loss may have latent implications in implant loosening and mechanical failure as well as an increased risk of fracture due to general bone weakness. [1,2] Periprosthetic bone remodeling is a complex, multifunctional process caused by stress shielding and wear-induced osteolysis, among other factors. Stress shielding is regional and reproducible around the proximal femur. The reduction in weight-bearing stress leads to a significantly higher incidence of bone resorption, most prominently in Gruen zone 7, both in the early and late stages of recovery following THA.

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[3,4] Femoral stems have been developed and engineered to reduce bone resorption in the proximal part and enhance the long-term survival of the implant through specific design modifications. [5,6,7] In spite of these changes, osteolysis resulting from byproducts of wear is not a regional or design-specific process and may present a continuing concern. [8,9,10,11,12] In a typical osteoarthritic patient undergoing THA, the greatest bone loss from implants of wear and stress shielding occurs during the first 3-6 months post-surgery. The altered load conduction in the femoral bone, however, continues to cause periprosthetic bone resorption in the proximal femur well beyond 6 months. The effects of implanted byproducts of wear due to incomplete implant osteointegration and fixation are key factors impacting further periprosthetic bone remodeling. [1,13]

Several therapeutic options such as calcium and vitamin D supplements, oestrogen receptor agonists, parathyroid hormone (PTH), and calcitonin have been suggested to reduce the severity and duration of periprosthetic bone resorption as well as early remodeling post-THA by enhancing bone mineral density (BMD) systemically and bone tissues around the prosthesis. [2] Recently, bisphosphonates have emerged as an alternative to anti-osteoporosis treatments by increasing BMD. [14,15,16] Bisphosphonates are widely used in the treatment of Paget's disease, hypercalcemia of malignancy, corticosteroid induced osteopenia, and post-menopausal osteoporosis. [17,18] They have also been indicated in the treatment of fibrous dysplasia, osteogenesis imperfecta, osteoarthritis, and rheumatoid arthritis. Bisphosphonate treatment has recently been incorporated in the management of periprosthetic bone remodeling. Several studies have investigated the benefits of bisphosphonate therapy in the first 6 to 12 months following surgery, while bone resorption is most dramatic. However, clinical evidence suggests that the short-term gains of bisphosphonate therapy may not be sustained in the long term or reversed once they have occurred. [17,19,20,21]

Although the benefits of risedronate administration on enhancing periprosthetic BMD have been observed in the first year post-THA, currently, there is no evidence to show that the risedronate therapy may reverse the delayed periprosthetic bone loss occurring after the initial post-operative year. We hypothesized that oral risedronate may augment or prevent bone loss in well osteointegrated patients following THA, just as it has been demonstrated in recent post-operative THA patients. [2,5,17] To test our hypothesis, we designed a randomized, double-blinded clinical trial to observe the effects of risedronate therapy on periprosthetic BMD in the period of 1 to 10 years after surgery. We also monitored the systemic effects of risedronate treatment such as gastrointestinal intolerance, myalgias, or joint pain, in order to observe any adverse effects in this cohort of patients potentially resulting from long-term bisphosphonate administration. The primary endpoint of this pilot study was to evaluate the effects of risedronate prospectively on a group of patients one year or more after THA compared to a control cohort receiving no study medication. Secondary endpoints would include adverse events or medication intolerance.

Patients and Methods

A total of 32 osteoarthritic patients received total hip replacement surgeries were enrolled from the primary investigator's clinical practice between February and September 2007. All eligible patients who met the inclusion criteria underwent total hip arthroplasty for reasons other than low traumatic hip fracture due to osteoporosis with normal or osteopenic lumbar spine BMD scores. Recruited subjects were of the ages 30 – 80 (Mean age: 71.24, Range: 37, 10 Female, 22 Male) and able to understand and tolerate instructions for taking risedronate (Actonel, Proctor & Gamble Pharmaceuticals, Cincinnati, Ohio). Average BMI was 32 with gender distribution of 22 males and 10 females. No difference was found in demographics between groups with regards to age, BMI, or sex. Exclusion criteria included a history of prosthetic hip infection, retained hardware in the hip region, previous fracture induced-femur deformity, cancer, thyroid disease, debilitating psychiatric disease, alcohol dependence or substance abuse, coagulation disorders, or hepatic disorders. Subjects who had recently taken parathyroid hormone, bisphosphonates, estrogen receptor modulators, fluorides, calcitonin, calcitrol, corticosteroids, or any other osteoactive drugs were also excluded from this study. While tight entry level BMD's may identify at-risk or causal factors for higher incidence of post traumatic fractures, we felt a better representation of a real world variance of fracture incidence would be provided by not restricting patients to have either low or normal BMD. As such, all levels of risk factors would be provide more merit for the efficacy of proactive intervention of bisphosphonates similar to

what the original bisphosphonate literatures depicted. [7,16,19] Therefore, no control over BMD was used to represent a more real world cross section of what a typical trauma practice would see in an emergency room where BMD's are simply unavailable. The study protocol received full approval from Institutional Review Board, Patient Advocacy Council, Inc.

To determine the appropriate sample size of the study, several assumptions were made for the t-test employed to determine significance of the endpoint outcome in addition to a power assessment based on previous density response rates over the study period of one year. A-prior statistics were determined to compute the sample size from published literature. Based on a meta-analysis of bisphosphonate use following total joint arthroplasty that included 5 trials with a total 224 subjects, the baseline BMD standard deviation to mean ratio was chosen to be 14%. [17] The meaningful average BMD difference between the cohorts was selected to be at least 15%.

All enrolled subjects underwent the cementless THA fiber-coated metal taper femoral stem (Zimmer Company, Warsaw, Indiana). Enrolled patients were randomly assigned to either the study group or the control group. Patients and the primary investigator remained blinded throughout the trial. During the 52-week treatment period, subjects in the study group received a weekly dose of 35mg risedronate sodium (Actonel, Procter & Gamble Pharmaceuticals, Cincinnati, Ohio) and a twice-daily dose of 500mg calcium with 200 IU of vitamin D (Caltrate, a total of daily dose of 1000mg calcium with 400 IU of vitamin D). The rationale for the selective dosage of 35 mg weekly of risedronate originates from several previous studies. [22,23,24] Patients in the control group were placed on the placebo regimen with a twice-daily 500mg calcium plus 200 IU of vitamin D. The primary investigator gave each patient specific oral and written instruction for taking risedronate and Caltrate to ensure that the calcium did not interfere with the risedronate. Patients returned to the primary investigator's clinic at 6 and 12 months for evaluation. Measurements of BMD of the operative hip and spine, creatinine, NTx, and bone-specific alkaline phosphatase were performed at each follow-up visit in the same manner and location as the initial visit. If a dose failure of greater than 10% of the year's allotment of medication was witnessed, the patient was withdrawn from the study.

At the initial study visit, the baseline BMD measurement of the operative femur and spine were taken by using a dual energy x-ray absorptiometry (DEXA) BMD scanning system (GE Lunar Prodigy Bone Densitometer with enCORE software). In order to measure BMD, two X-ray beams that have differing energy levels, are aimed at the subject's bones. BMD is then determined by subtracting the soft tissue absorption and measuring the absorption of each beam by bone. Creatinine, collagen-type I N-telopeptides (NTx), and bone-specific alkaline phosphatase levels were assayed from blood serum and second morning void urine specimens were collected at the initial visit. [25,26] These critical biochemical markers were used to show homogeneity between cohorts. All bio-fluid samples were collected and performed at the Department of Laboratory Medicine at the Methodist Hospital, Houston, Texas.

Patient demographics, specifically age and months between their surgery and enrollment in the study, were evaluated using Welch's t-test to ensure homogeneity between the study and control groups. Mean periprosthetic BMD in the study and control groups were evaluated using Welch's t-test in each of the seven Gruen zones. The percentage profiles of initial BMD were determined in each zone by dividing the average measured BMD at 6 or 12 months when compared to the average initial BMD value. In order to assess the systemic effects of risedronate therapy, BMD, and t-scores of the lumbar spine and biochemical markers of bone metabolism at 6 and 12 months, specifically levels of collagen-type I N-telopeptides (NTx) and bone-specific alkaline phosphatase, were assessed by using Welch's t-test analysis.

Results

Initially, 66 patients were considered for the study and randomized, but only 32 subjects were eligible for the completion of the study. This was due to the exceedingly tight exclusion criteria of dose administration, bone scan, and follow-up visits to maintain consistency of endpoint sampling. Patients were monitored through a weekly diary that was overseen by the investigative team. If a 10% total deviation was found, the patient was excluded from the study. This guaranteed tight control on timeline changes that may have existed in the study while ensuring that the patients did not result in becoming a placebo rather than the study group. Patient demographics and biochemical assays were used to establish homogeneity between the two groups. The average age

of patients upon enrollment in study was 69 years in the control group and 71 years in the study group (p = 0.221). While age stratification was not controlled on entry, it was evaluated post-hoc. Risedronate carries no recommendation of onset institution of therapy guidelines for THR and therefore an unrestricted window of enrollment was intentionally allowed. Primary hip replacements took place between 1 and 10 years prior to enrollment in the study, with an average time-period from surgery to enrollment of 62.7 months in the control group and 76.2 months in the study group (p = 0.625). Finally, initial creatinine, NTx, and bone-specific alkaline phosphatase levels indicated no significant differences between the two groups (p = 0.288, 0.720, 0.254, respectively). Homogeneity in biochemical function was essential to ensure that no other osteoactive condition such as osteoporosis affected the outcome of the study.

No significant difference in periprosthetic BMD was observed between the control and study cohorts for any of the seven regions of interest (Table 1 and Figure 1). In zones 2, 3, and 5, both risedronate and the control agents yielded slightly higher, though not statistically significant at six months. In zone 4, the study and control groups yielded similar results. Finally, in zones 1, 6, and 7, the group taking Caltrate alone appeared to yield slightly better BMD, yet statistically insignificant when compared to the risedronate group (Table 1 and Figure 1). All the p-values detected are greater than 0.05. In Figures 2 and 3, the change in percent profiles of BMD over time for each Gruen zone is seen for the control and study groups. Neither group revealed a distinct, consistent pattern.

Mean BMD measurements in the lumbar spines (L-1 to L-4) also show no significant difference between the control and study cohorts (Table 2), indicating that risedronate did not produce a significant systemic effect on BMD value in our enrolled groups. BMD of the spine was maintained in both the control and study group with no significant difference between the cohorts in any lumbar region (Table 2). Statistical analysis did not show any significant difference between the two groups at 6 months

Table 1. Summary Statistics for Periprosthetic Bone Mineral Density in Gruen Zones 1 - 7

		Initial			6 Months			12 Months		
		Control	Study	t-test	Control	Study	t-test	Control	Study	t-test
Zone 1	Average	0.914839	0.958017		0.987171	0.969830		0.942382	0.966046	
	Stdev	0.205018	0.324272	**0.650**	0.268978	0.328247	**0.871**	0.203439	0.337999	**0.808**
	% Initial BMD	100%	100%		107.91%	101.23%		103.01%	100.84%	
Zone 2	Average	1.992605	1.965311		1.994915	1.985935		2.007402	1.982757	
	Stdev	0.369568	0.316124	**0.827**	0.391753	0.310239	**0.945**	0.385522	0.310908	**0.847**
	% Initial BMD	100%	100%		100.12%	101.05%		100.74%	100.89%	
Zone 3	Average	2.264854	2.108745		2.256865	2.152704		2.287772	2.134658	
	Stdev	0.253643	0.299067	**0.121**	0.263905	0.335177	**0.333**	0.274879	0.283805	**0.134**
	% Initial BMD	100%	100%		99.65%	102.08%		101.01%	101.23%	
Zone 4	Average	2.058250	1.985164		2.018321	1.948280		2.023194	1.948122	
	Stdev	0.411474	0.458377	**0.639**	0.348387	0.359368	**0.582**	0.335253	0.314298	**0.524**
	% Initial BMD	100%	100%		98.06%	98.14%		98.30%	98.13%	
Zone 5	Average	2.262189	2.146768		2.231091	2.190629		2.246679	2.185048	
	Stdev	0.245129	0.192242	**0.160**	0.221163	0.211757	**0.605**	0.257030	1.063623	**0.474**
	% Initial BMD	100%	100%		98.63%	102.04%		99.31%	101.78%	
Zone 6	Average	1.851831	1.781677		1.842337	1.768810		1.872155	1.754615	
	Stdev	0.397378	0.292214	**0.585**	0.409617	0.334000	**0.590**	0.423214	0.309608	**0.392**
	% Initial BMD	100%	100%		99.49%	99.28%		101.10%	98.48%	
Zone 7	Average	1.312915	1.174041		1.276148	1.134982		1.312177	1.088361	
	Stdev	0.454741	0.346348	**0.352**	0.432930	0.309008	**0.313**	0.463216	0.293162	**0.129**
	% Initial BMD	100%	100%		97.20%	96.67%		99.94%	92.70%	

Table 1. Measurements of perioperative Bone Mineral Density (BMD) show no significant difference between the control (n= 19) and study groups (n= 13) in any of Gruen Zones 1 through 7. Table 1a, baseline; Table 1b, six month time point; Table 1c, twelve month time point. Values are measured as gram per cm2 (Mean ± SD).

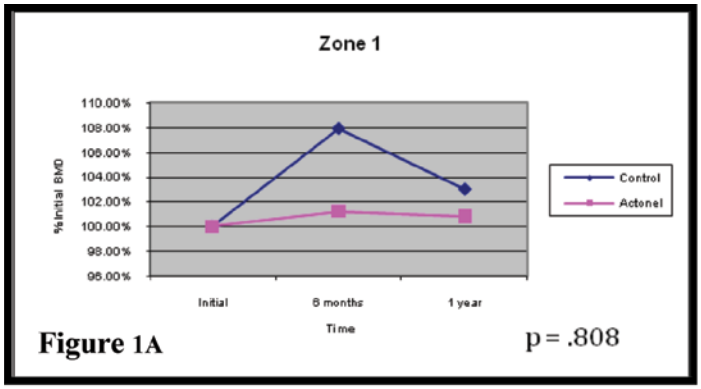

Figure 1A p = .808

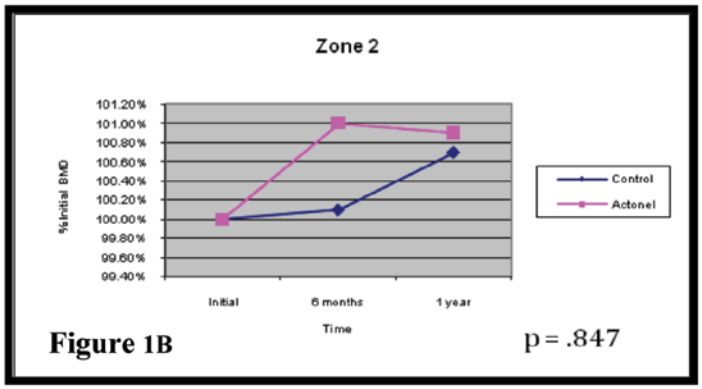

Figure 1B p = .847

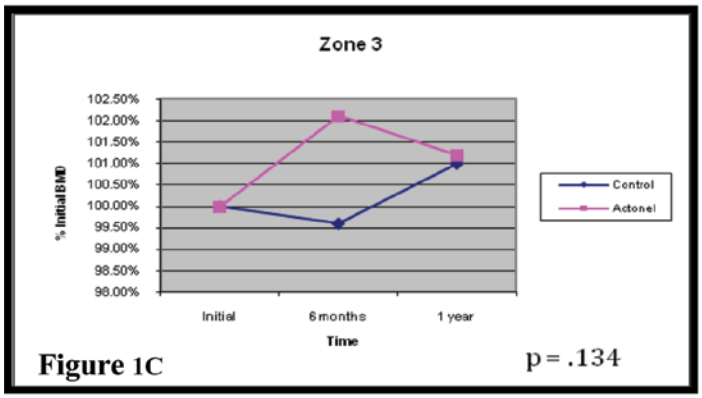

Figure 1C p = .134

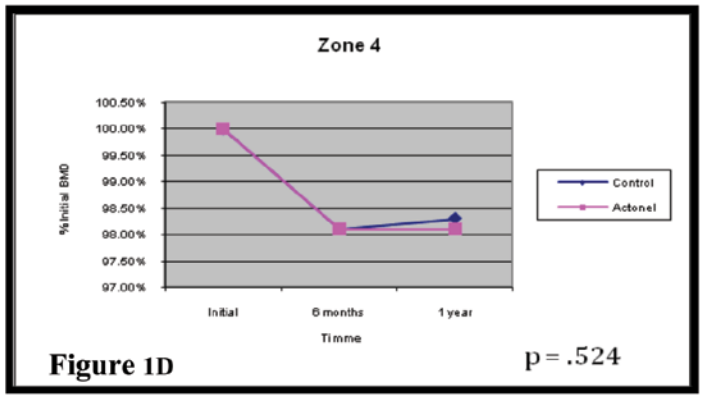

Figure 1D p = .524

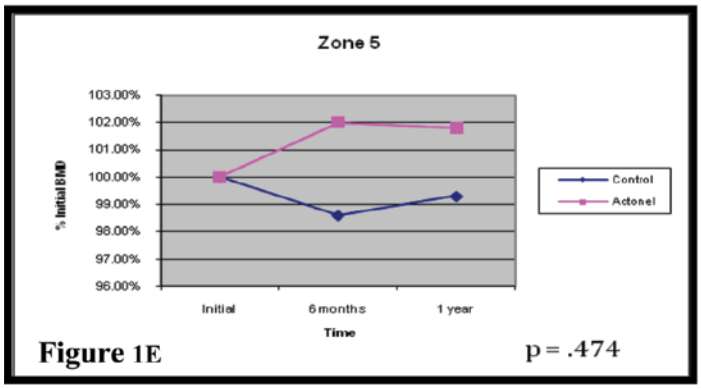

Figure 1E p = .474

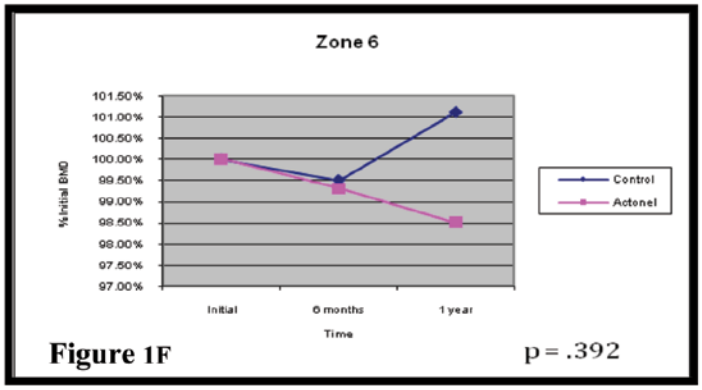

Figure 1F p = .392

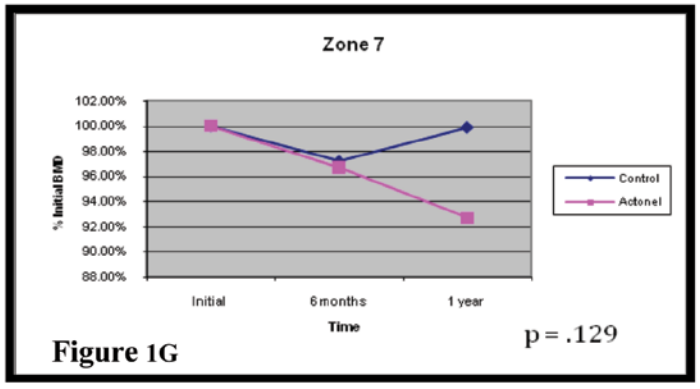

Figure 1G p = .129

Figure 1. The percentage profiles of measured BMD in each Gruen zone in the control (n=19) and study group (n=13) at 6 months and 12 months are assessed and no statistical significance was found between any time point. Blue lines, control group; orange lines, study group.

or 12 months post-surgery ($p > 0.05$).

Biochemical markers indicating bone resorption and turn-over from blood and urine samples were also evaluated to assess the systemic effect of risedronate and control therapy. The results showed that there are no significant differences in levels of collagen-type I N-telopeptides (NTx) or bone-specific alkaline phosphatase between the control and study groups at any point in the study (p=0.09; Figures 2 and 3). The detailed numbers of values of NTs and bone-specific alkaline phosphatase tested from subjects, as well as p-values are present in Table 2.

Table 2. Summary Statistics for Spine Bone Mineral Density in Lumbar Regions 1 - 4																
		Baseline BMD					6 month BMD					1 year BMD				
		L1	L2	L3	L4	L1-L4	L1	L2	L3	L4	L1-L4	L1	L2	L3	L4	L1-L4
Control	Mean	1.223	1.406	1.454	1.404	1.381	1.245	1.410	1.470	1.441	1.400	1.235	1.426	1.505	1.453	1.412
	St. Dev	0.215	0.259	0.260	0.248	0.214	0.208	0.258	0.282	0.241	0.217	0.239	0.288	0.279	0.231	0.232
	n=			10					10					10		
Study	Mean	1.105	1.239	1.327	1.303	1.249	1.094	1.239	1.321	1.287	1.238	1.110	1.237	1.314	1.313	1.253
	St. Dev	0.104	0.198	0.209	0.252	0.173	0.128	0.204	0.209	0.278	0.185	0.142	0.216	0.234	0.283	0.206
	n=			12					12					12		
	t test	0.140	0.113	0.228	0.353	0.134	0.065	0.108	0.185	0.178	0.080	0.168	0.106	0.104	0.216	0.108

Table 2. Assessments of Bone Mineral Density (BMD) of the lumbar spines show no systemic difference between groups treated with the control agent and with risedronate. Table 2a, baseline; Table 2b, six month time point; Table 2c, twelve month time point. Values are measured as gram per cm2 (Mean ± SD).

Discussion

This study investigated the potential benefits of bisphosphonate therapy for delayed periprosthetic bone remodeling and hypothesized that risedronate treatment would significantly reduce long-term bone loss in patients following THA. Previous studies have reported that bisphosphonate therapy reduced the dramatic loss in bone mineral density in the six months immediately following surgery, as well as potentially reducing the risk of post-operative fractures and implant loosening in the short-term. [3] The long-term sustainability of these benefits, however, has not been explored since wear-induced osteolysis appears to be related to a group of key factors not necessarily related to osteoporosis. These factors include the mevalonate pathway induced by osteoclastic stimulation; the differentiation of macrophages into osteoclastic bone reabsorbing cells with the involvement of macrophage colony stimulating factor (M-CSF), tumor necrosis factor-α, interleukin-Iβ, prostaglandin E2 (PGE2), synovial parathyroid hormone (PTH) and nuclear factor-κβ ligand (RANKL). [8,11,12,27] Any of these alone may be responsible for the destructive pathway inducing osteolysis around an implant and leading to loosening and other post-surgical complications. [9,10,17,28]

Risedronate, a synthetic analogue of pyrophosphate, is one of the clinically available bisphosphonates binding to hydroxyapatite crystals in the mineralized bone matrix to prevent the degradation of pyrophosphatase through its influence on the mevalonate pathway. It has been tested in the treatment of Paget's disease, heterotopic ossification, hypercalcaemia, and postmenopausal osteoporosis. [24] In a long term multi-center study, risedronate significantly reduced the risk of hip fracture among elderly female subjects. This was additionally shown to increase the BMD level as early as 6 months despite the extent of osteoporosis. [29] Several previous studies on bisphosphonate application for preventing bone loss reported that the administration of medication began immediately after surgery. Bhandari's group reported that cementless THAs can achieve greater gains from early bisphosphonate therapy than cemented THAs. [17] The outcome differences in cemented and uncemented THA have been well documented in another study less than one year after implantation with improvement in BMD suggesting again the anabolic effects on density are time limited. [30] With various numbers of enrolled subjects and different hip implants, other groups have definitely shown that an early treatment of bisphosphonate works well in preventing bone loss. [23,24,30,31,32,33] Those studies strongly suggest that oral bisphosphonate treatment may be one of the effective therapeutic options to improve bone strength in patients at an early administration following THA. They cannot however conclude effectiveness in the late administration following THA. [32,33]

In our study, patients represent a wide window of latent post-operative time frames consistent with a typical total joint practice where patients may develop loss at varying times after the initial implantation stabilization period of one year. Though late intervention may first seem unimportant, our results show that while other investigators show improvement earlier, late treatment will not be effective in preventing bone loss. Although the study was not powered to determine when the window opportunity ceases; it is clear that treatment after a year has elapsed will not help. As such, this study cannot make any conclusions other than late treatment will not reverse years of encapsulated established osteolysis after THR.

This compares to other work showing that the most dramatic changes in periprosthetic BMD are observed within the first 6 months. It may be reasonable to conclude that any of the years following the

initial 6-12 months of implantation will present similar patterns of bone loss in the femur as in the vertebral region. [1,17,29,30,31,34] Our results show that the risedronate treatment did not significantly improve the value of BMD in Gruen zones around the hip stem. Once the most dramatic changes in bone density subside and optimal window of therapeutic opportunity have passed, bisphosphonates have no effects. This may be due to the absence of the systemic rather than a regional mechanical or metabolic process. Given this scenario, bisphosphonates do not appear to reverse or suppress the local regional osteoporotic condition of a resorbing implant even though they work effectively in the global diseases state of an osteoporotic patient.

This study has several study limitations in this prospective pilot trial. The study is a small sample with tightly controlled medication and lab value time lines. The strict control of medication compliance in patients excluded virtually half of the enrolled patients. However, this tight control group validates strict adherence to dosimetry as well as the importance of early intervention. There is no stratification for new THR (< 5 years) versus older aging THA with more mechanical wear debris potentially creating osteolysis. We investigated implant age related to response to treatment in the study cohort and found no trends. While not powered to detect this, more research in this group should reveal a more distinct time for optimal to suboptimal treatment efficacy.

It has been accepted that stress shielding, byproducts of wear, and proximal periprosthetic bone loss lead to complications such as fracture or implant failure and reduce the quality of bone around the stem essential in revision surgeries. Furthermore, we performed a bioassay of two critical serum biomedical markers of bone resorption, N-telopeptides of Type I collagen (NTx) and bone-specific alkaline phosphatase. The results indicate that risedronate therapy does not have an impact on these two bone remodeling-related molecules in our investigative setting (Table 3; Figures 2-3). This supports the premise that there was no significant change in the metabolic osteoporotic systemic state. More prosthetic resorptive loss is not enough to trigger therapeutic effects from bisphosphonates. The p value of 0.09 for alkaline phosphatase may suggest more patients could eventually power a significant change in bone resorption response. However, this effect was very weak and not seen in the other marker or BMD which may not represent an adequate dose response to justify an extension study.

Conclusion

Our data demonstrates that risedronate treatment instituted in a latent setting of a fully ingrown THA provides no significant beneficial effects on periprosthetic or systemic BMD values when administered after the first postoperative year. While we cannot make conclusions on timing of earlier interventions, it suggests there may be a window of opportunity where intervention may retard loss. However, once the osteo-resorption is underway, treatments with bisphosphonates will not arrest or suspend the catabolic process. The lack of evidence supporting a long-term implemented therapy of combined risedronate with calcium suggests that novel therapeutic strategies should be developed to preserve periprosthetic BMD sustainably following total hip arthroplasty. This study shows that bisphosphonate treatment to enhance bone density is not effective in reversing osteolysis once bone loss is radiographically detected one year or more after implantation has occurred.

Table 3. Summary Statistics for Biochemical Bone Markers

		NTx (Resorption Marker)			Bone-specific Alk. Phosphatase		
		Baseline	6 mo	1yr	Baseline	6 mo	1 yr
Control (Caltrate)	Average	35.5556	25.7778	33.4444	12.1375	12.0000	11.8667
	StDev	31.7809	14.8894	25.1700	5.3452	6.3257	5.5066
	n=	9	9	9	8	9	9
Study (Actonel + Caltrate)	Average	35.7273	30.0000	25.7500	13.8000	10.5182	10.9417
	StDev	17.5162	16.4384	10.3408	3.2241	3.9217	3.0276
	n=	11	10	12	9	11	12
	p-value		0.8760526	0.4136380		0.2435755	0.0903372

Table 3. Analysis of bone-specific biochemical markers (NTx and alkaline phosphatase) showed no significant difference between the control (n=19) and residronate treated groups (n=13). Values are measured as nmol BCE/mmol cretinine in NTx analysis and µg/L in alkaline phosphatase, respectively (Mean ± SD).

Figure 2: BMD Change vs Time in each Gruen Zone in Caltrate Cohort

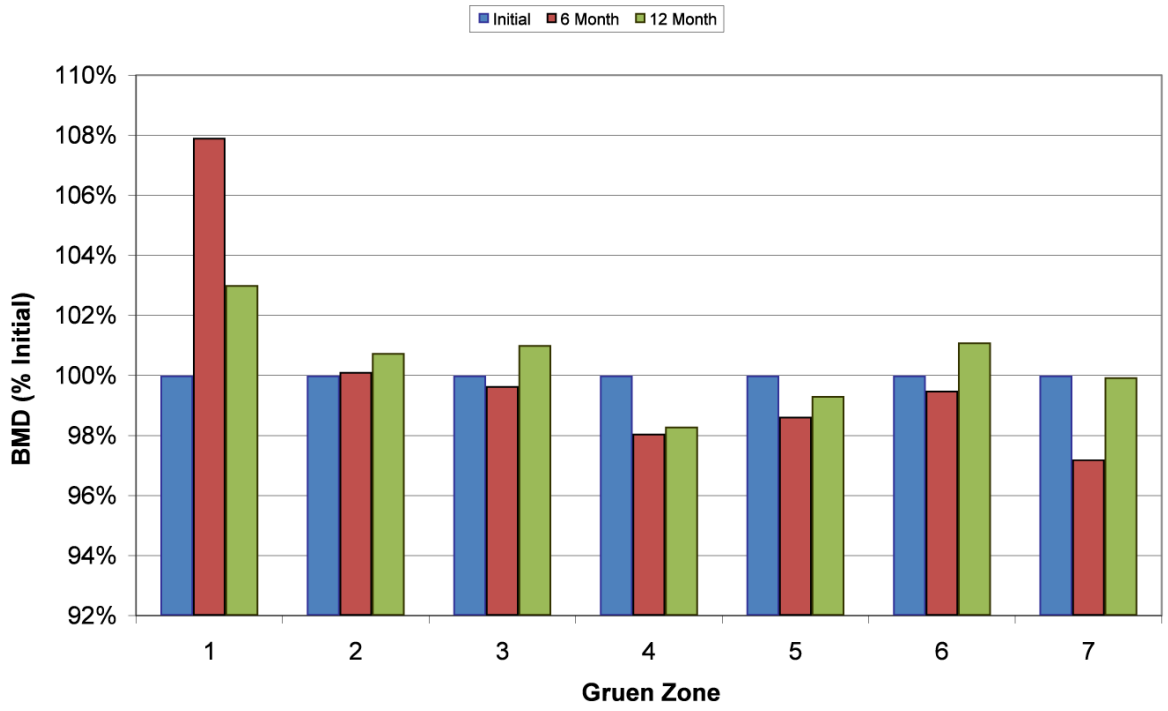

Figure 2. Measurement of a bone-specific biochemical marker, NTx showed no significant difference between the control (blue color, n=19) and residronate (orange color, n=13) treated groups. Values are expressed as Mean ± SD.

Figure 3: BMD Change vs Time for each Gruen Zone in Actonel + Caltrate Cohort

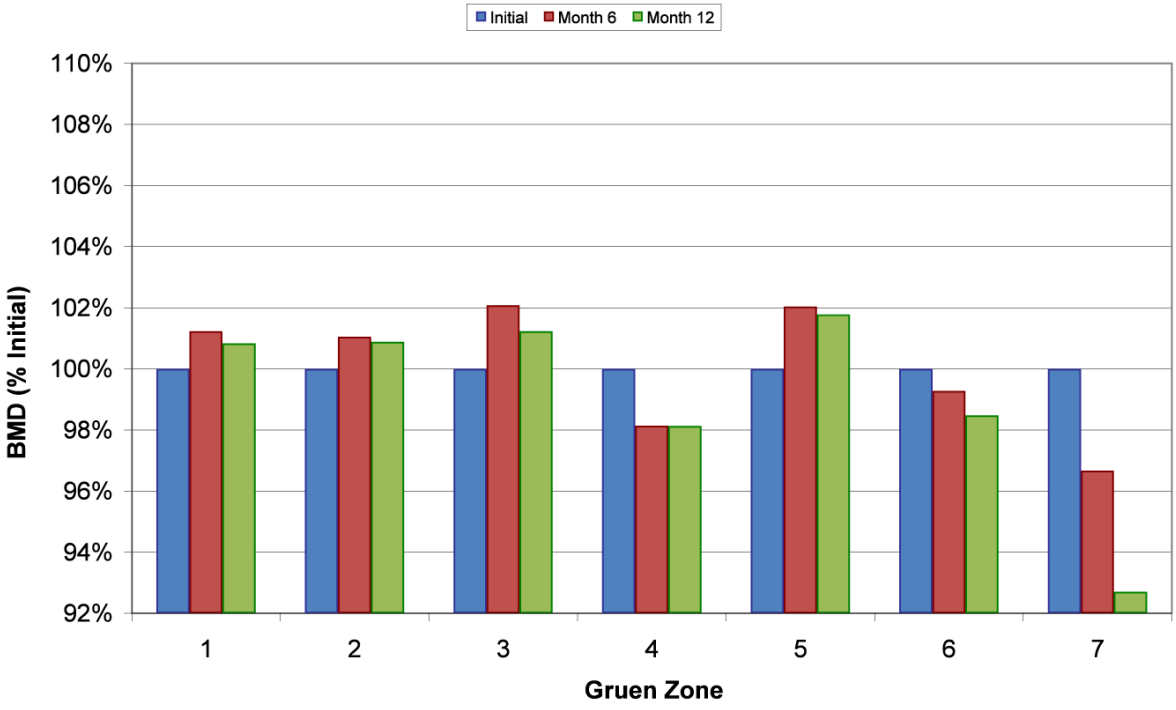

Figure 3. Analysis of a bone-specific alkaline phosphatase in specimen collected from groups of the control (blue color, n=19) and residronate (orange color, n=13) treatment. No significance was found between groups at the time points examined. Data shown as Mean ± SD.

Competing interests

All research herein was conducted in accordance with ethical standards in compliance with privacy guidelines and in accordance with The Methodist Hospital Research Institute and Patient Advocacy Council, Inc. IRB. This study was funded in part by Proctor & Gamble Pharmaceuticals. None of the authors have any other financial or non-financial competing interests to disclose.

Authors' contributions

DRL, MDE designed the study and performed the clinical evaluation, JML collected the data. DRL, JML, MDE analyzed the data. DRL, MDE prepared and organized the manuscript. DRL, MDE ensured the accuracy of the data and analysis. All authors have read and approved the final manuscript.

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An Alternative Conservative Approach to Hip Reconstruction

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Abstract

Primary Total Hip Arthroplasty (THA) has been a very effective surgical procedure, with improvements in design and clinical outcomes since the days of Sir John Charnley. [1-4] However, many implant femoral hip designs and surgical approaches have not been considered conservative for bone preservation.

Insertion of a femoral stem in THA does alter the physiological loading of the femur. Often these altered loading conditions can and do lead to bone reaction (stress shielding) and loss of proximal bone. Proximal stress shielding occurs regardless of fixation method (cement, cementless). [5,6]

This stress shielding and bone loss can lead to implant loosening and or breakage of the implant. In an attempt to reduce these boney changes some designers have advocated the conservative concept of "Neck Replacement" THA. [7-9]

This paper is a review of past, present and future development within this narrow classification of Neck Replacement Arthroplasty with highlighted focus on the Silent™ Implant.

Key Words: *total hip arthroplasty, tissue-sparing, neck-preserving, and conservative approach.*

Introduction

There has been significant focus on the development of short stems over the past twenty years with most implant companies now offering a selection of designs. Many of these designs range from just shorter versions of current conventional length stems to a broad range of novel new design concepts including neck replacement only designs.

The Joint Implant Surgery and Research Foundation (JISRF) has developed and advocated for a femoral implant classification system based on primary fixation (stabilization) contact region. This classification system has been presented at a number of continuing medical educational (CME) seminars and has been well received.

The basic categories of classification include the following: head stabilized, neck stabilized, metaphyseal stabilized, and conventional metaphyseal/diaphyseal stabilized. This classification system should help clarify the design principles inherent with each type and provide some guidance when researchers and other investigators are reporting on the outcomes of the various implant styles.

The structurer of the Classification System is as

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

follows:

1. Head Stabilized
   A. Hip Resurfacing
   B. Mid-Head Stem
2. Neck Stabilized
   A. Short Curved Stems
   B. Short Lateral Engaging Stem
   C. Neck Plugs or Neck Only
3. Metaphyseal Stabilized
   A. Taper Stems
   B. Bulky/Fit and Fill Stems
4. Conventional Metaphyseal/Diaphyseal Stabilized

This paper will only review 2 C. Neck Only Replacements.

Review (JISRF Classification 2 c.)

This is a narrow classification of devices with just a limited quantity of implants in the market. However, interest appears to be increasing, in part, with the significant decline of hip resurfacing (HR).

Models of neck plugs in development or currently on the market include the Silent Hip from DePuy, launched in 2009; the Primoris Neck Replacement from Biomet; the Spiron™ Hip by ARGE Medical Technics; the CUT™ Stem by Orthodynamics; and the TSI™ Hip by Concept Design & Development, LLC. All of these devices have a common theme: engagement in the femoral neck and a 12/14 modular head neck taper. As many of these models are still in development, details on precise specifications and early clinical results are available for only three models of neck replacements: the Spiron™ Hip, the CUT™ Stem, and the Silent™ Hip.

The Spiron™ Hip

This hip has a conical, self-cutting screw that is inserted without cement into the prepared subcapital femoral neck.

ARGE Medical Technics, Hannover, Germany

The CUT™ Stem

The implant is made from a cobalt-chromium-molybdenum (CoCrMo) alloy and has a macroporous structure. The stem is curved at the distal tip designed to rest against the lateral cortex of the femur.

Orthodynamics, Lübeck, Germany

The TSI™ Neck Implant

Designed to load the medial calcar with a novel conical flare with a multiplanar implant body for enhanced rotational stability and surface area for fixation.

Concept, Design & Development, LLC (CDD™) Chagrin Falls, Ohio

The Primoris™ Neck Replacement

It has a collared lip for abutment on the resected femoral neck and may reduce the risk of subsidence. Cross section is trapezoidal for rotational stability and optimizes fit and fill of the neck.

Biomet, Warsaw Indiana

The Silent™ Hip

Optimizes soft-tissue preservation that may enable earlier recovery and rehabilitation. The original design concept was by Dr. Mathhius Honl in Germany 1997.

DePuy International Leeds, England

Three reviews will be discussed on this device the first is short to mid-term results from two clinical studies across eight centers and was presented as a poster at the British Orthopaedic Association Annual Meeting in 2009 and the senior author"s personal series with a 6-7 year follow-up. In addition, we are reviewing the Australian experience of three surgeons.

Methods for BOA Poster [11]

A pilot clinical study used Radiostereometric Analysis (RSA) to demonstrate the implant stability. Following satisfactory results over the early post operative period, a larger, second phase study was initiated with a wider group of surgeons, to demonstrate the transferability of the surgical technique in a larger group of patients. No design changes were made to the Silent™ Hip throughout the clinical evaluation period.

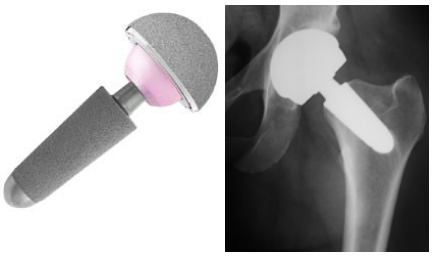
41 hips were recruited in two centers (Australia, Germany) throughout 2003 in the RSA pilot study. 100 hips were recruited in second phase clinical study by eight surgeons in seven centers (Australia, France, Germany, Italy, UK) between May 2005 and

October 2008. Surgical approaches including posterior, direct anterior and anterolateral were used across the two studies according to each surgeon's standard practice.

Methods for Waller Series [12]

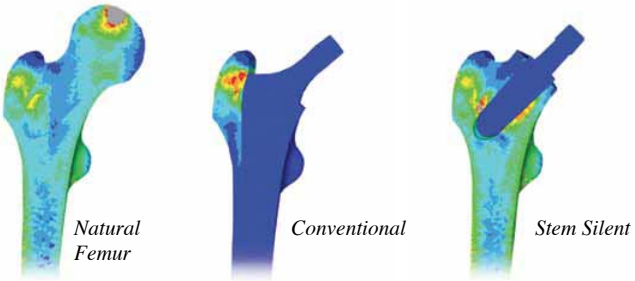
15 Hips in 14 patients (13 males, 1 female), average age 56 (49-66). BMI range 23-35 (mean 27.4) all bone stock Dorr type A, with OA in all cases. ASR cementess cup and XL metal heads used in all cases with a 6-7 year follow up.

Implant



A neck only replacement that features a taper style shape of titanium alloy with a fully DuoFix™ cementless coating for long-term fixation. It features a 12/14 head neck modular taper. The hip is available in five cross-sectional sizes at 2 mm increments measured at 3 mm below the shoulder of the implant. A variety of implant lengths are available depending on stem cross sectional size.

Finite Element Analysis



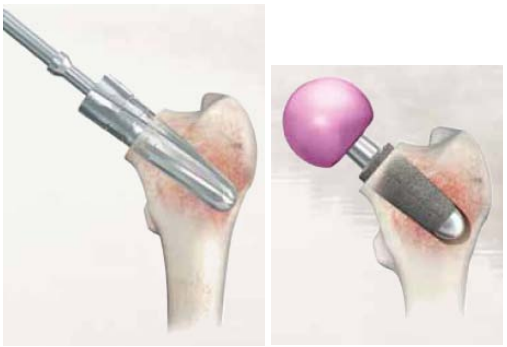
FEA shows that the Silent Hip loads the bone in a more physiological manner transfers load, via the neck, to the femoral shaft.

Surgical Technique [13]

The Silent Hip lends itself to implantation with any surgical approach, however, is very user friendly in smaller tissue sparring approach including the direct anterior approach.

Powered reaming of the femoral neck, as opposed to broaching, ensures precise cavity preparation, optimizing positioning and press fit for optimum in-growth and fixation.

A void is created at the tip of the prosthesis, which allows the sides of Silent™ Hip to lock in place and prevents contact with the lateral cortex. This prevents contact with the lateral cortex which could cause the taper to disengage.



Results of RSA Studies [11]

Results show that the Silent™ Hip achieves stability and does not exhibit continuing patterns of movement over time.

X-Rays of 54 year old female pilot study patient, operated for osteoarthritis.

Immediate Post-Operative

5 Year X-Ray

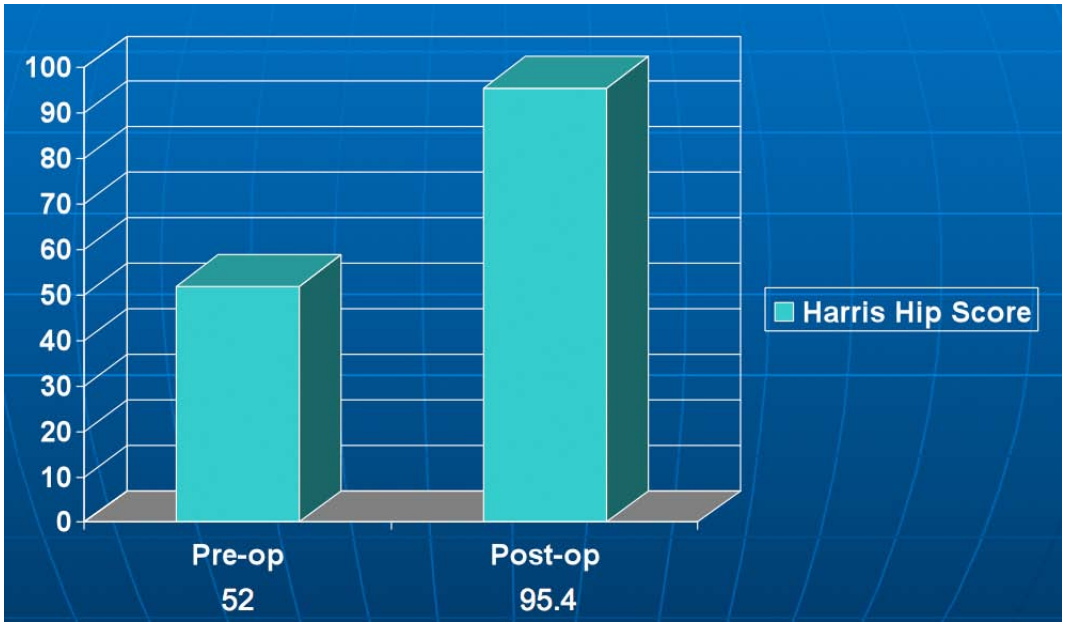
Only one hip in the RSA pilot study exhibited movement of more than 1mm in any direction, which can be explained by proximal bone resorption following a deep infection. Despite this loss of bone, this subject remains unrevised at five years and is clinically asymptomatic, with maximum reported values for HHS and OHS.

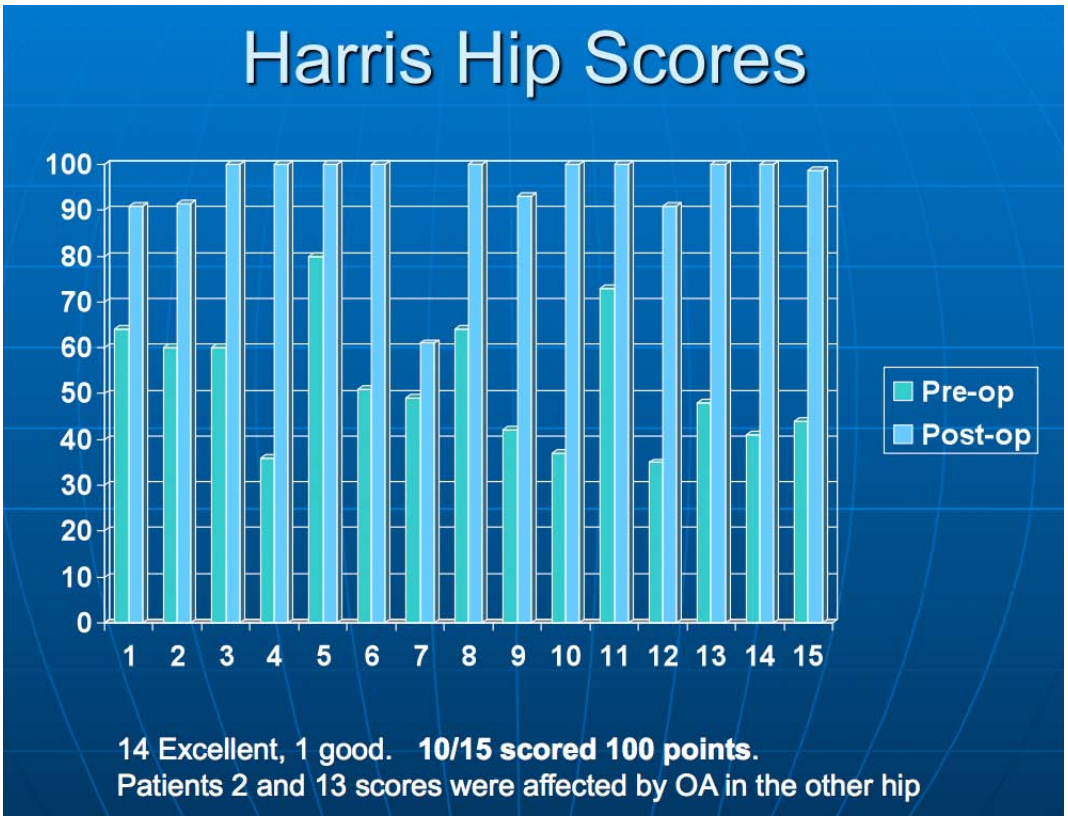
In a total of 141 hips, four revisions of the Silent™ Hip have been necessary. Three were following periprosthetic femoral neck fractures in the first

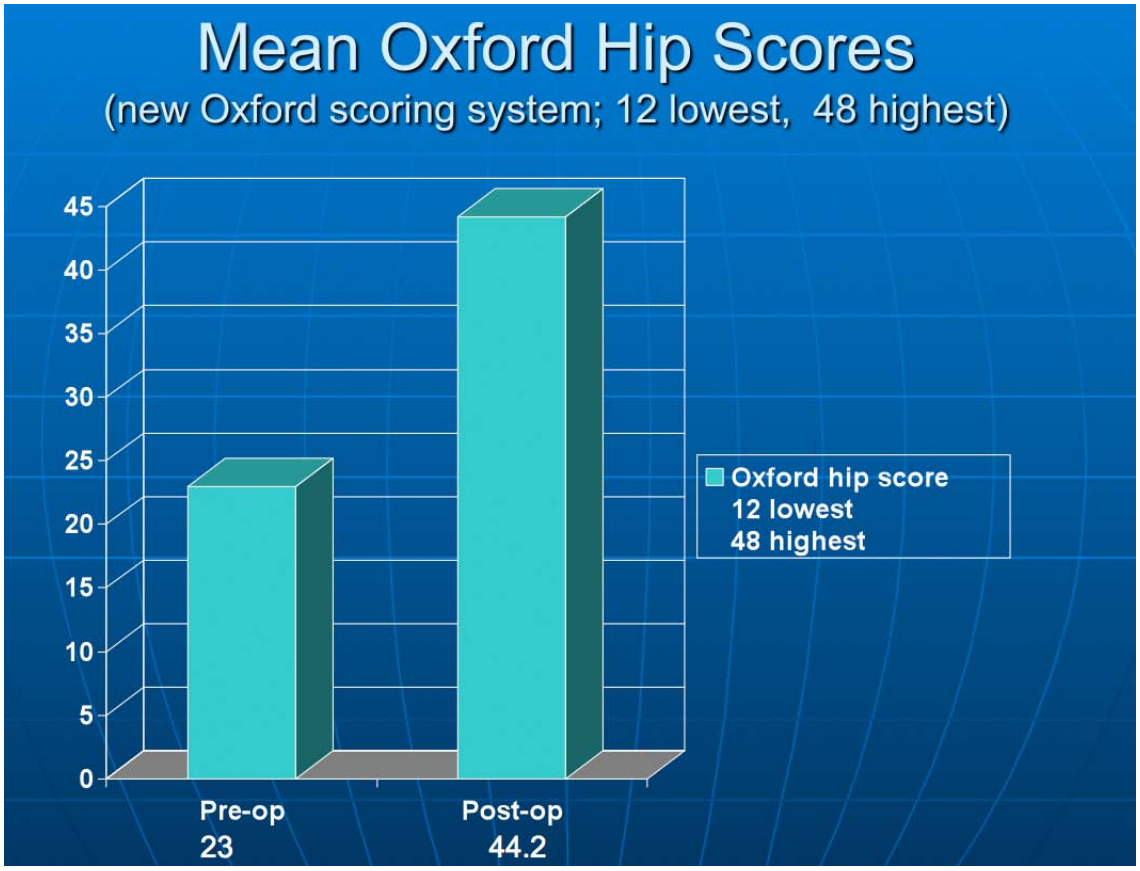
month post-operatively. An independent review of the fracture cases concluded that these failures were further to a combination of sub-optimal patient selection and surgical technique, and none were directly related to the Silent™ Hip. The fourth patient had their Silent™ Hip revised following an early post-operative deep infection.

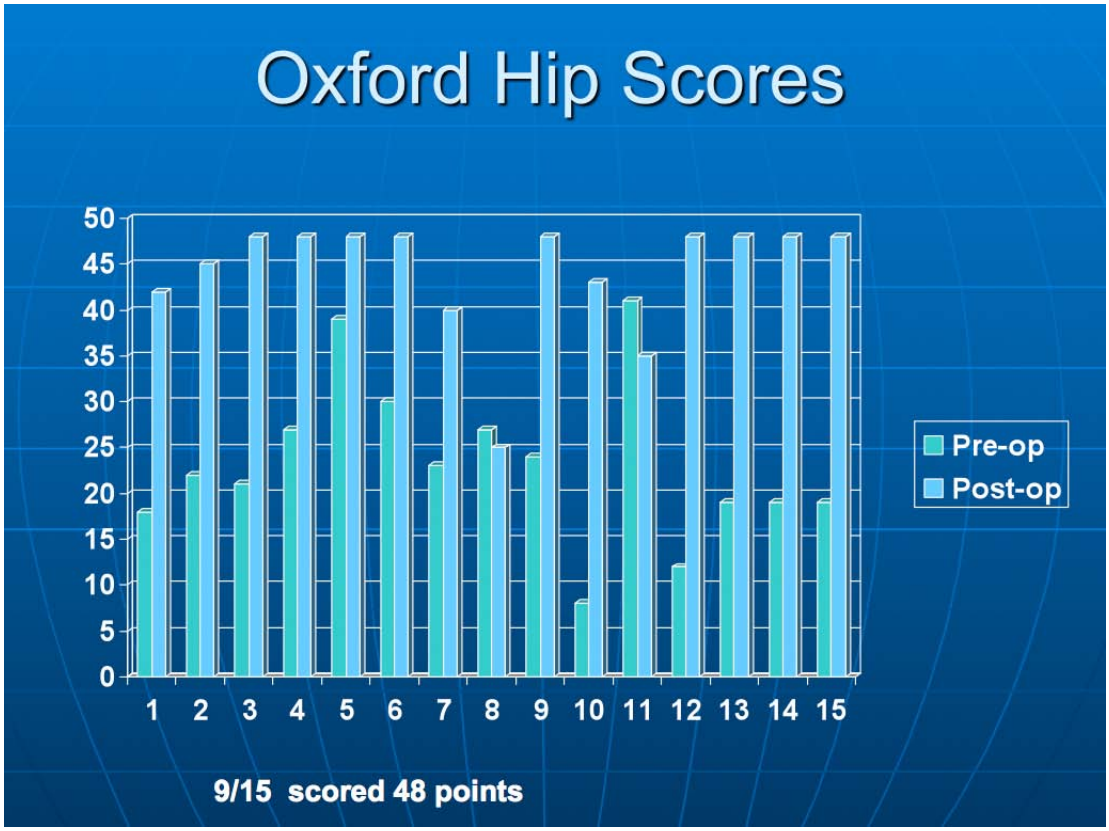
The combined Kaplan-Meier survivorship of the Silent™ Hip based on revision of the stem for both studies is 97% (95% CI of 94–100%) at three years.

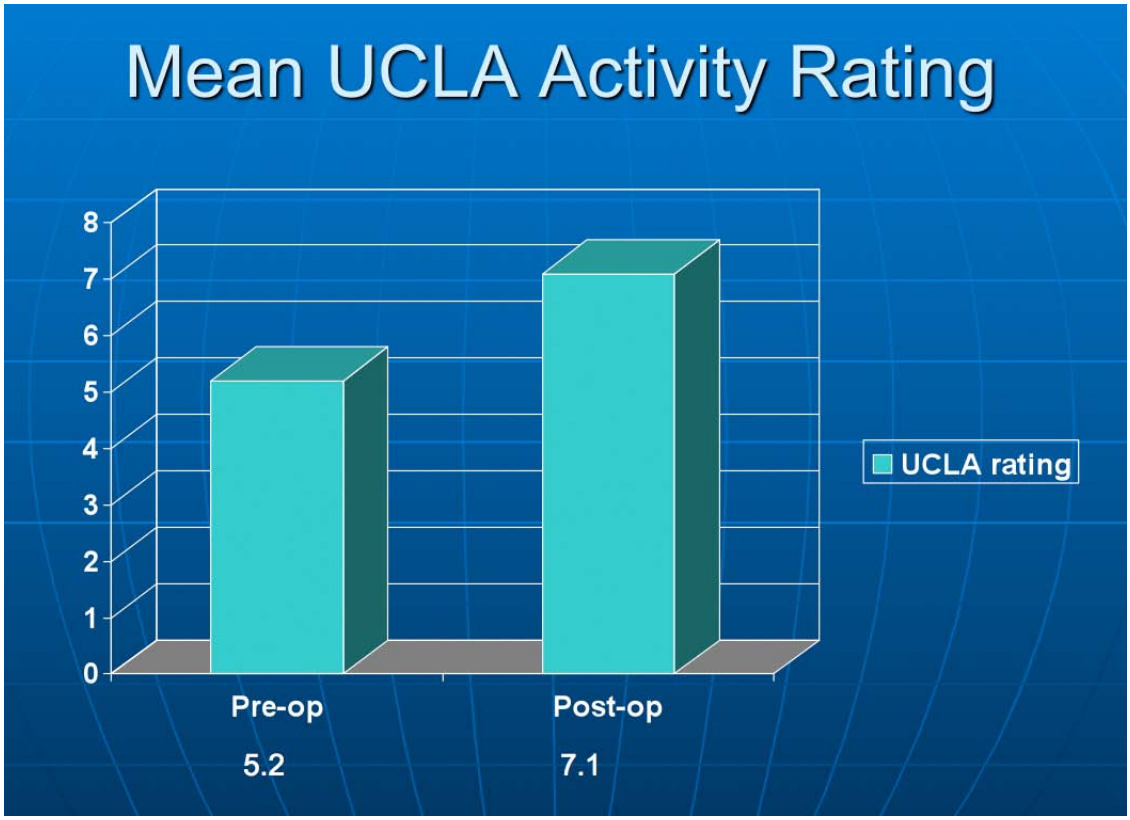
Results for Senior Author's Series

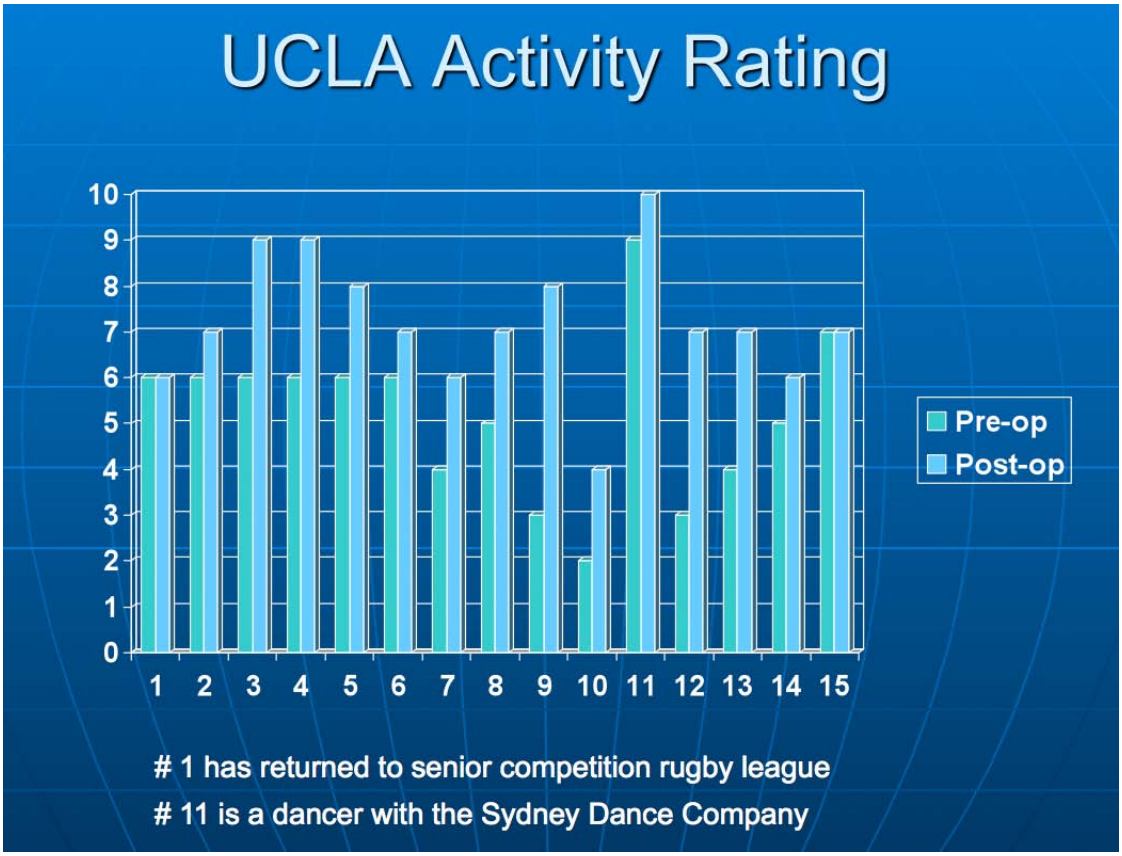





Mean Oxford Hip Scores
(new Oxford scoring system; 12 lowest, 48 highest)
45
40
35
30
25
20
15
10
5
0
Pre-op
23
Post-op
44.2
Oxford hip score
12 lowest
48 highest


Oxford Hip Scores
50
45
40
35
30
25
20
15
10
5
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
9/15 scored 48 points
Pre-op
Post-op

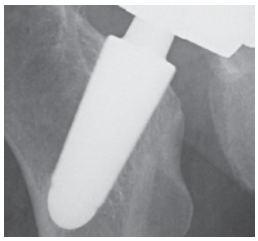

Mean UCLA Activity Rating
8
7
6
5
4
3
2
1
0
UCLA rating
Pre-op
5.2
Post-op
7.1


UCLA Activity Rating
10
9
8
7
6
5
4
3
2
1
0
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Pre-op
Post-op
1 has returned to senior competition rugby league
11 is a dancer with the Sydney Dance Company

Complications

Stem revisions = 0
ASR cup revisions for metallosis = 6
Note: All Silent Stems were solidly fixed at revision. 3 of the 6 stems scored lower after revision.
Thigh pain = 0
DVT non-occlusive = 1

Radiographic Review

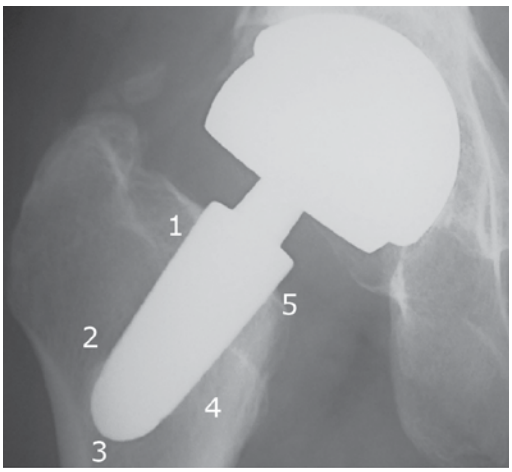


5 years n=15
- Loosening = 0
- Subsidence = 0
- Migration = 0
- Radiolucent lines = 0

Angle of Implantation

- Mean CCD angle 138º
- CCD range 125-155º
- All within 9º of native

The angle of implantation did not appear to have any effect on range of motion, thigh pain, hip scores or implant migration.



Preliminary FEA showed high Von Mises stresses in zones 2 & 5 if the implant made no contact with the lateral cortex.

Lateral Cortex Contact

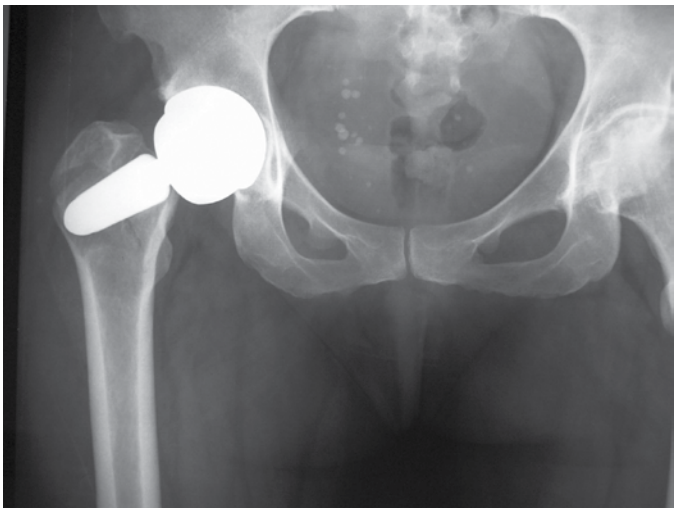
Other than distal pedestal formation lateral cortex contact did not appear to have any effect on range of motion, hip scores, thigh pain or implant migration.

The Combined Australian Experience

Forty cases from three surgeons (J. Sullivan, R. Verhuel and C. Waller.)
- 1 death from pancreatic cancer
- 1 early fracture due to technical error (short neck cut)
- Harris Hip Scores 52 pre to 97 post-op
- Oxford hip scores 23 pre to 46 post
- UCLA rating 5.2 pre to 7.8 post-op
- No other complications at 2-4 years

Observations on the Forty Australian Cases

Silent Stem provides stable initial fixation capable of immediate full weight bearing. Osteintegration remains stable at 6-7 years and short neck cut with a long implant is a risky combination.



One fracture.

Overall Conclusions

The Silent™ Hip successfully achieves the desired aims of a safe and effective femoral implant for use in primary hip replacement with the alleviation of pain, restoration of function, marked improvements in patient outcomes and a stable X-Ray appearance, whilst conserving bone stock. The major-

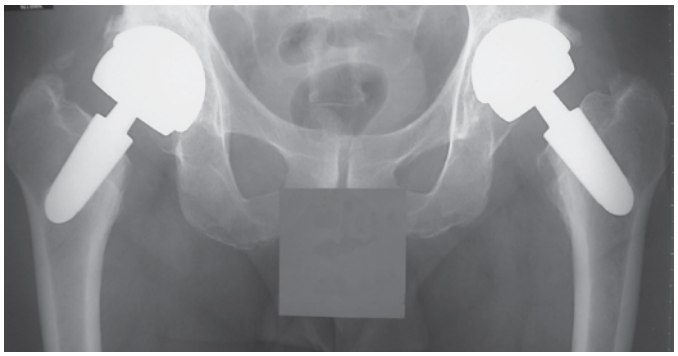
ity of problems have been associated with the ASR™ metal on metal bearing system for metallosis. We no longer recommend or use metal on metal bearings with the Silent Neck Replacement or for that matter any total hip replacement.

Initial and mid-term fixation has held up well even in the face of metallosis. Radiographic appearance demonstrates the calcar bone becomes stronger over time.

The Silent Hip has been used exclusively in Dorr type A bone, however, it would seem appropriate in selective type B bone in middle-aged males.

There is no question that this is a bone preserving surgical approach to hip arthroplasty and may be a reasonable surgical alternative to hip resurfacing and to conventional cementless stems for the younger more active patient.

The JISRF Stem Classification System should provide clarification and guidance when reporting on new novel femoral stem designs.



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

Lower Limb Joint Replacement in Patients with Rheumatoid Arthritis

Perioperative management considerations for patients with RA who need a total hip, knee, or ankle replacement

Nicholas D. Clement, Stephen J. Breusch**, and Leela C. Biant**

Introduction

Rheumatoid arthritis (RA) is a chronic systemic connective tissue disease, and it is the third most common indication for lower limb joint replacement in Northern Europe and North America. [1] The etiology of the disease remains unclear, but there are strong associations with human leukocyte antigens (DRB1). [2] The prognosis is poor, with 80% of patients being disabled 20 years from primary diagnosis. [3] The medical treatment of RA has improved during the last 25 years, which is reflected by a 40% decrease in the rate of hip and knee surgery since a peak that was observed in the mid 1990s. [4] Anemia, raised erythrocyte sedimentation rate, and a high disease activity score have all been identified as risk factors for the need for large joint arthroplasty. [5]

Seventeen percent of patients with RA undergo an orthopaedic intervention within 5 years of initial diagnosis. [5] More than one third of patients will need a major joint replacement, of which the majority will receive a total hip or knee replacement (THR, TKR). [4] This review article summarizes factors involved in the perioperative management of major lower limb arthroplasty surgery for patients with RA.

Methods of Literature Search

We searched the PubMed [6] electronic database for studies published in English between 1960 and 2011. Our defined search term was: “rheumatoid” “replacement” “arthroplasty” and “outcome.” This identified 669 eligible articles. All abstracts were reviewed and those matching the inclusion criteria were included; full papers were retrieved.

The inclusion criteria were:

- Articles reporting preoperative management of patients with RA receiving an orthopaedic intervention
- Articles reporting the survivorship and/or functional outcome and/or complications of primary total hip/knee/ankle replacements in patients with RA
- Articles reporting the survivorship and/or functional outcome and/or complications of revision total hip/knee/ankle replacements in patients with RA
- Articles reporting the rehabilitation of patients with RA after total hip/knee/ankle replacements
- Due to the insufficiency of published literature regarding arthroplasty in the patients with RA, further literature searches were executed. This was only performed when there were insufficient data to draw a conclusion about the question being addressed – for example, the use of tumor necrosis factor alpha (TNFα) drugs in patients with RA undergoing arthroplasty surgery.

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Table 1. Systemic Preoperative Assessment of the Rheumatoid Patient

History	Examinations	Investigations
Disease onset	Complete medical	Full blood count
Pattern and sequence	Joint inflammation	Urea & creatinine
Presences and persistent joint swelling	Joint damage and range of motion	Electrolytes
Pain (site, severity, duration)	Soft tissue integrity	Liver function tests
Morning stiffness	Extra-articular features	Chest radiograph
Functional limitations	Grip strength	Cervical spine radiograph
Non-articular features	General health	Electrocardiogram
Psychological features	Dental inspection	Urine dipstick +/– culture
Systemic features	Neurological assessment	Pulmonary function tests
Review of all systems		Echocardiogram (limiting cardiac pathology)
Drugs and allergies		Airway assessment
Prior anaesthetic and surgery		

Preoperative Assessment

In the preoperative assessment, the history, examination, and investigations need to be comprehensive, as described in Table 1. [7]

Eighty percent of RA patients have cervical spine involvement. Thirty percent have instability of the cervical spine, half of whom are asymptomatic. [8,9] Subluxation of the atlanto-axial joint, due to the destruction of the transverse ligament by inflammatory pannus, is defined as a distance of >3 mm between the anterior aspect of the atlas and dens on a plain lateral cervical spine radiograph. [7] Clinical symptoms of occipital headache, weakness of limbs, bladder and bowel dysfunction, and long track signs should alert the clinician to such pathology. Computed tomography (CT) may be helpful to assess the extent of subluxation. [10]

Immunosuppressants

Steroids are used as a therapeutic bridge to control symptoms until the disease-modifying anti-rheumatic drugs (DMARDs) take effect. If a patient has used long-term steroids, an increased dose should be given in times of stress to prevent an Addisionian crisis. Use of steroids in the perioperative period for general surgical procedures increases the infection rate and impedes wound healing. [11] There is, however, no published literature regarding the risk of steroid use in the perioperative period for arthroplasty surgery

Methotrexate is a commonly used DMARD and has been shown to improve symptoms and slow radiographic progression of joint destruction. [12] There is a single prospective randomized control trial: 388 patients undergoing elective surgery were randomized to either cease or continue with methotrexate. [13] A 2% infection rate occurred in those who continued methotrexate, with a decreased complication rate and number of flares of their rheumatoid disease. Those who stopped the methotrexate had a 15% infection rate. Hence, it would seem safe and beneficial for the patient to continue methotrexate perioperatively, and it may aid their postoperative recovery.

Newer targeted immunotherapy such as TNFα antagonists are more effective in disease control, with slowing of radiographic joint destruction. [14] The evidence as to whether these drugs should be continued or stopped during orthopaedic procedures is limited. One study of 31 patients undergoing foot and ankle surgery demonstrated no difference in the infection rate if patients continued with their TNFα prescription. [15] A larger retrospective study of 128 patients undergoing major orthopaedic surgery revealed an increased infection risk in those who remained on TNFα antagonists (odds ratio 21.8), and an associated increased risk of deep vein thrombosis (odds ratio 2.8). [16]

Surgical Sequence

Wilkinson et al suggest addressing lower limb arthropathy before the upper limb. Their hypothesis is that prior fragile upper limb interventions may be damaged by mobilization on crutches after lower limb surgery. [7] The surgical sequence they recommended is forefoot, hip, knee, hindfoot, and then ankle, which they deemed the order of "reliability" of the procedures. Constructing a base on which to build would be logical; the "reliability" of different procedures is arguable and individual patient assessment may dictate a different protocol. Hindfoot fusion may necessitate plaster immobilization, and could be considered at an earlier stage. Restoration of the correct femoral alignment and length

with a THR precedes the TKR to allow correct implant alignment and rotation. Significant joint stiffness and/or contracture at adjacent or bilateral joints may be optimally addressed by simultaneous arthroplasty. Preoperative long leg standing alignment radiographs and a CT scan for assessment of soft tissue integrity and bone loss can help plan surgery.

Total Hip Replacement

Technical challenges of performing THR in patients with RA are mainly due to bone loss, osteopenia, and protrusio acetabuli. These patients are not suitable for hip resurfacing because of the risk of secondary osteoporosis. [17]

Until recently, there was little evidence to support the use of cemented over uncemented THR. Chmell et al reviewed 39 patients with juvenile rheumatoid disease (66 hips) who received a cemented THR with a mean follow of 15.1 years. [18] They report a stem survival of 85% and a cup survival of 70% for various implant designs. Creighton et al reviewed 75 patients (106 hips), all of whom received a cemented prosthesis. Stem survival was 98% and cup survival was 92% at 10 years. [19] They also demonstrated an association of cup loosening with younger patients. Jana et al, using an uncemented stem in 64 patients (82 hips) for juvenile RA, reported a survival of 98.1% at 11 years. However, various cemented and uncemented cups were used.

Analysis of 2,557 primary THRs using various implants for patients with RA from the Finnish arthroplasty register found the best survival to be with uncemented proximally circumferentially porous-coated stems (89% survival at 15 years) and cemented all-polyethylene cups (80% survival at 15 years). [20] However, more recent data from the Norwegian arthroplasty register suggested that cemented THR was superior to uncemented THR, with a 10 year survival of 89% and 81% respectively. [21]

Protrusio acetabuli is a common occurrence in the rheumatoid hip, and technical difficulties can be encountered due to medial wall deficiency. Two grading systems are used: that of Charnley, [22] relative to the ilio-pectineal line, and more commonly, Hirst et al, [23] relative to the ilio-ischial line (Table 2).

Table 2. Grading of Protrusio Acetabuli

Grading of protrusio acetabuli according to the distance between the acetabular line (medial wall of acetabulum) and the ilio-ischial line

Grade	Men	Women
I	3-8 mm	6-11 mm
II	8-13 mm	12-17 mm
III	>13 mm with fragmentation	>17 mm with fragmentation

Figure 1. *Grade II protrusio acetabuli (A) in a female who underwent total hip replacement with medial bone graft and restoration of the center of rotation (B).*

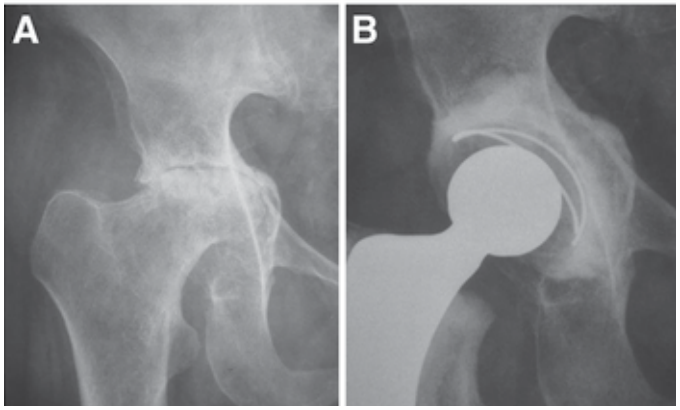
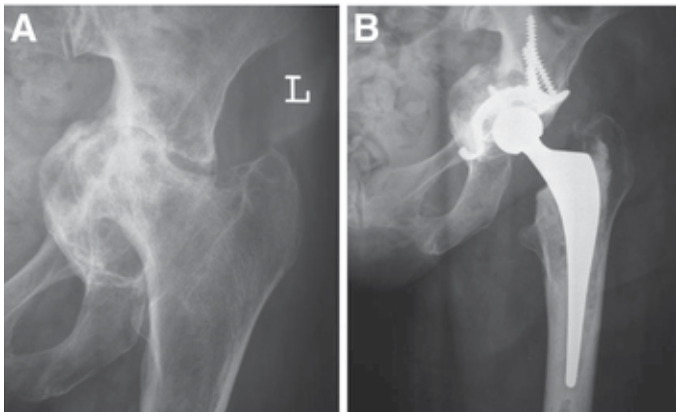
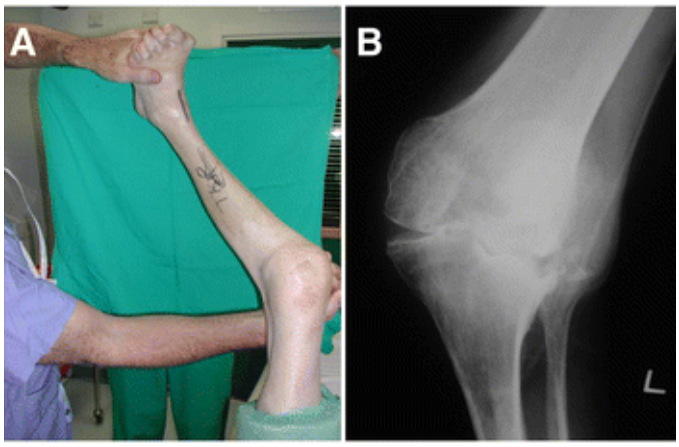


Figure 2. *Grade III protrusio acetabuli (A) with cage augmentation and medial bone graft (B).*



Hirst also described the Wrightington technique for bone grafting the acetabular floor, using 2-mm discs cut from the dislocated femoral head, which are molded using a dome pusher to conform to the acetabular floor. Restoration of the center of rotation lateral to Köhler's teardrop is essential (Figure 1). To further improve cement fixation, 6-mm holes may be drilled around the periphery of the acetabulum. The cement is placed directly onto the floor graft with insertion of the cup. More extensive acetabular destruction in Grade III protrusio may require a cage and additional bone grafting to prevent early failure (Figure 2).

Figure 3. *Valgus deformity of knee (A) due to avascular necrosis and bone destruction (B).*

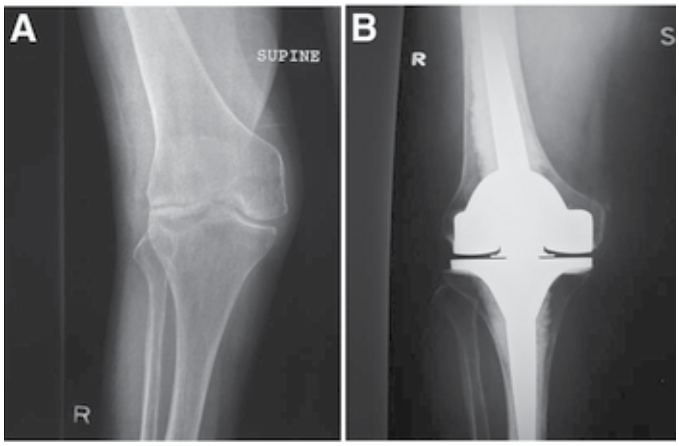


Total Knee Replacement

Poor bone stock, avascular necrosis, deformity, and contracture (Figure 3) can present technical challenges. Implant augmentation and bone grafting may be required. An implant that retains the posterior cruciate ligament (PCL) is favored by many surgeons for osteoarthritis of the knee. In rheumatoid disease, however, there is soft tissue destruction resulting in joint instability. Even if the PCL is intact intraoperatively, it may subsequently be eroded by inflammatory pannus postoperatively, resulting in an unstable prosthetic joint. Laskin reviewed 178 rheumatoid patients at an average of 8.2 years of follow up and demonstrated a 50% instability rate with PCL-retaining implants, in contrast to a 1% instability rate with the PCL-sacrificing implants. [24]

Longer-term results in rheumatoid disease are limited. Goldberg et al [25] and Kristensen et al [26] demonstrated a 0% to 14% instability rate for PCL-sacrificing implants, respectively. Gill et al [27] and Meding et al [28] have shown similar rates of instability for PCL-retaining implants (1.5% and 9.9%, respectively). The differences between the reported instability rates may relate to disease severity and medical treatment, with more recent studies having the advantage of modern pharmacokinetics and preservation of soft tissues.

Figure 4. *Significant valgus deformity and concomitant medial collateral attenuation (A) managed with a rotating hinge TKR (B).*



For patients with significant valgus deformity and concomitant medial collateral attenuation, a rotating hinge (Figure 4) may be the treatment of choice, [29] as an extensive lateral release may result in "overstuffing" of the joint, with an increased risk of mid-flexion instability. Furthermore, if the patient has a marked fixed flexion contracture of >30 degrees, then threshold for a constrained design should be low, particularly in older patients. [30]

The 15-year survival, excluding infection, for cemented total knee arthroplasty in patients with RA is 96.5% and 91% for PCL-retaining and PCL-sacrificing implants, respectively. [28,31] However, it could be argued that the increased failure rate in those who received a PCL-sacrificing implant had a higher grade of rheumatoid disease with severe joint destruction and, hence, the indication of a stabilized implant. Cemented implants may be the preferred option in poor bone stock and osteoporosis. Vigano et al described a 10-year survival rate of 98.4% using an uncemented TKR for RA patients. The average age of their cohort was 49.5 years. It could be argued that these patients had a better bone stock than older patients, facilitating osteointegration.

Shoji et al conducted a retrospective comparison of rheumatoid patients undergoing TKR with and without patella resurfacing, and they found no difference in pain or functional outcome. [32] In contrast, Kajino et al conducted a prospective randomized controlled trial of rheumatoid patients undergoing TKR, and they found improved pain relief and functional outcomes for patients receiving patella resurfacing. [33]

Total Ankle Replacement

The survival of total ankle replacement (TAR) does not parallel that of THR and TKR. The reported success rate of TAR in RA ranges from 40% to 100%. [34] Mechanical loosening of the components is the major cause of revision surgery. [35] A recent long-term follow up of 33 TARs for RA reported an 85% survival rate at 10 years when failure was defined as removal of the prosthesis. The survival rate

decreased to 64% if signs of radiographic loosening were included. [35]

Failure after TAR has been shown to be much higher in patients with greater than 15° of varus or valgus deformity. [36,37] When a concomitant planovalgus forefoot abductus deformity exists, arthroplasty is a more difficult and less predictable procedure. Success will require a simultaneous or two-stage triple arthrodesis to correct the deformity, which is generally too severe to be corrected with a simple subtalar fusion. Patients are often frail or have poor soft tissues, making two-stage operations unattractive and a simultaneous triple arthrodesis a high-risk venture.

Revision Arthroplasty Surgery

Data regarding revision THR in rheumatoid patients are limited. The outcome of cemented cup revision for RA is inferior to patients without RA, with a 64% radiographic failure rate at 7 years. [38] This survival rate falls further at 9 years to 44% when an uncemented cup is used at revision. [39] Schreurs et al improved survival with the application of morselised bone graft in combination with a cemented cup at revision, reporting an 80% survival at 12 years. [40]

High failure rates have been reported for revision TKR in patients with RA. Garcia et al report a survival for all knees (27 mechanical failures and 18 infected revisions) of 76% at 5 years. They also, more worryingly, report a 34 % mortality rate at 6 months for RA patients revised for infection. [41]

Rehabilitation

Patients with RA have a longer length of hospital stay, with slower functional improvement, than patients undergoing joint replacement surgery for primary osteoarthritis. A study of 1,361 rheumatoid patients and 26,096 osteoarthritic patients undergoing lower limb arthroplasty found the length of stay to be only 1 day longer, but it did show a slower, more gradual improvement of their functional independence score. [42] Stanley et al demonstrated that RA patients undergoing bilateral TKR had a similar functional outcome and complication rate as those undergoing staged procedures, but they had the benefit of a more rapid recovery relative to staged procedures. [43]

Complications

Evidence from the Swedish joint registry suggests that periprosthetic fractures are more common among patients with rheumatoid disease compared to osteoarthritis patients, with a hazard ratio (HR) of 1.56. [44] Similar figures have been reported from the Finnish registry (HR 2.1). [45] This predisposition to fracture may to be secondary to poor bone quality. [45] The management of periprosthetic fractures can be challenging and associated with high morbidity and mortality. [43]

The risk of arthroplasty infection is greater for patients with RA. Bongartz et al conducted a retrospective review of 462 patients (657 implants) who received either a TKR or THR. They compared infection rates for RA patients with a matched cohort of patients with osteoarthritis. [46] They found RA patients to be at an increased risk of prosthetic joint infections for both primary (HR 4.08, 95% CI 1.35-12.33) and revision surgery (HR 2.99, 95% 1.02-8.75).

Conflicting evidence exists regarding the risk of venous thromboembolism (VTE) post-arthroplasty surgery in patients with RA, with Chotanaphuti et al. [47] declaring RA to be a risk factor and Guan et al [48] claiming RA to be protective for VTE. A retrospective review of nearly 5 million patients with RA showed that RA was an independent risk factor for pulmonary embolism and deep vein thrombosis in hospital patients who did not undergo surgery, with a relative risk of 2.25 and 1.9, respectively. [49]

Patient Outcomes

Patients with active disease, raised rheumatoid titer, or clinical depression do not improve to the same extent as patients without. [50] Ethgen et al performed a cost/outcome analysis of arthroplasty for patients with RA, finding good pain relief that was equal to that of patients with primary osteoarthritis, but there was only a minor improvement in the functional outcome. [51] They also demonstrated reduced use of DMARDS, with cost savings, which may relieve the patient of drug-related adverse effects. Sledge proposed the key to a successful surgical outcome for patients with RA is for the surgeon to be familiar with the technical challenges of patients with polyarthritis and to work as part of a multidisciplinary team. [1]

Summary

RA is a systemic disease, and as with any other medical co-morbidity, the patient should be optimized preoperatively using a multidisciplinary approach. The continued use of methotrexate does not increase infection risk, and aids an early recovery with control of the disease during the perioperative period. Biologic agents (TNFα antagonists) should be stopped preoperatively due to the increased infection rate. Patients should be made aware preoperatively of the increased risk of infection and periprosthetic fracture rates associated with their disease.

The surgical sequence is commonly hip, knee, and then ankle. Cemented THR and TKR have superior survival rates over uncemented components in RA patients. The need for bone grafting for protrusio acetabuli should be identified during preoperative planning. The evidence is not clear regarding a PCL-sacrificing versus a PCL-retaining implant in TKR, but a PCL-sacrificing component limits the risk of early instability and potential revision. Patella resurfacing as part of a TKR is associated with improved outcomes and should be considered in the rheumatoid patient. The results of TAR remain inferior to THR and TKR. RA patients achieve equivalent pain relief, but their rehabilitation is slower and their functional outcome is not as good. However, the key to managing these complicated patients is to work as part of a multidisciplinary team to optimize their outcome.

Competing interests

The authors declare that they have no competing interests.

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Source

Clement ND, Breusch SJ, Biant LC. Lower limb joint replacement in rheumatoid arthritis. Journal of Orthopaedic Surgery and Research 2012, 7:27 doi:10.1186/1749-799X-7-27. http://www.josr-online.com/content/7/1/27 Accessed 12/13/12.

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Joint Implant Surgery & Research Foundation
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Revision of Hip Resurfacing Arthroplasty with a Bone-conserving Short-stem Implant

Florian Schmidutz, Lorenz Wanke-Jellinek*, Volkmar Jansson*, Andreas Fottner*, and Farhad Mazoochian**

As this case report demonstrates, revision of hip resurfacing arthroplasty can be performed not only with a conventional hip implant, but also with a bone-conserving short-stem hip implant, providing a long-term solution to younger patients with a high risk of further revisions.

Introduction

The good clinical results in hip arthroplasty have led to an increasing number of joint replacements in younger patients. Regardless, it is well known that this patient group faces an increased risk of early implant failure, [1] which is probably related to their higher activity level. Revision surgeries often go along with loss of bone substance, [2] resulting in more difficult procedures and an impaired functional outcome. [3] To facilitate potential revision surgeries, bone-preserving implants, such as hip resurfacing arthroplasty (HRA) and short-stem arthroplasty (SHA) implants, have been developed and recently have gained increasing popularity.

However, data are lacking on how much bone stock is conserved – and whether revision procedures are actually facilitated by the use of bone-preserving implants. So far, only a few studies have reported on the revision of failed HRA implants, and all revisions have exclusively been performed by the use of a conventional stem. [4,5]

In this report, we describe a woman with early failure of HRA. Revision was performed with a bone-conserving short-stem hip implant, which minimizes the bone loss on the femoral side in order to facilitate potential revision surgery.

Case Presentation

A 56-year-old Caucasian woman presented to the outpatient clinic of our department with osteoarthritis of the left hip of approximately 6 years. As conservative treatment had failed, she requested hip replacement arthroplasty. Due to her comparatively younger age and activity level, HRA (Cormet, Corin Group, Cirencester, UK) was performed.

Her postoperative course was unremarkable, and the final radiologic assessment showed an implant position with a cup inclination of 50° and a stem-shaft angle of 132°. Our patient fully recovered, and the follow-up investigation revealed a stable implant. The patient did not report any pain or problems related to the implant.

Three years later, the patient presented outside the normal follow-up with severe pain in the replaced hip joint. She reported a falling incident that had occurred 2 months earlier, followed by an increasing pain over the subsequent weeks.

Clinical and radiologic evaluation revealed a failure of the acetabular component, which was already dislocated, and additionally showed a narrowing of the femoral neck (Figure 1). For those reasons, the patient underwent revision surgery.

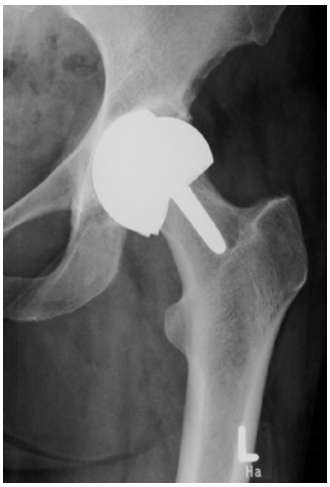

Figure 1. *Early failure of hip resurfacing arthroplasty three years after implantation.*

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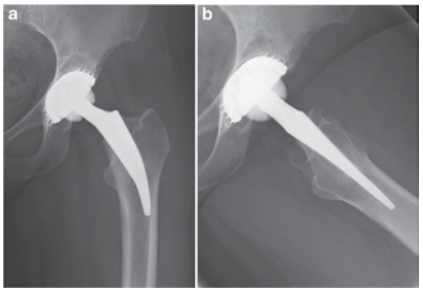
Management

Intraoperatively, a massive metallosis of the periprosthetic tissue was found, and the femoral and acetabular components were already damaged. Therefore, removal of the whole implant became necessary.

As the femoral bone was found to be intact, osteotomy could be performed directly below the femoral component. By doing this, preservation of the femoral neck was possible, which allowed a revision with a metaphyseal-anchored short-stem hip implant (Metha, B. Braun AesculapOrthopedics, Tuttlingen, Germany).

Postoperatively, our patient recovered well and was subsequently referred to a rehabilitation facility. Mobilization was performed by default with half body weight until soft tissue healing was accomplished (2 weeks), followed by a rapid and pain-adapted increase to full weight-bearing. The follow-up visits at 1, 3, 6, 12, and 24 months postoperatively were normal. The radiographs at the 2-year follow-up showed a stable implant position (Figures 2a-b).



Figures 2 a-b. *Short-stem hip implant two years after revision surgery in (a) anterior-posterior and (b) lateral views.*

Clinical function 2 years after revision was good, with a Harris Hip Score of 86, a University of California Los Angeles(UCLA) score of six, and a Western Ontario and McMaster Universities Arthritis Index (WOMAC) score of 12.6, with 3.8 in the category "pain," 1.7 in the category "stiffness," and 7.1 in the category "function."

Discussion

Preservation of bone stock in younger patients requiring hip replacement is important because those patients will most likely experience at least one implant revision during their remaining lifetime. [1] Our patient was provided with HRA, as the implant design had shown good clinical function and dislocation rates as well as high sports activity levels. [6,7] Furthermore, several studies have demonstrated a satisfying mid-term and long-term outcome. [6] However, it has recently become apparent that HRA also compromises the risk of early failure in certain patients, especially in women with small implants, as seen in our patient. [8]

Although we are not able to state what finally caused the early implant failure in our patient's case, HRA preserved femoral bone stock and thereby facilitated revision surgery. This is of major importance as, beside damage of the soft tissue, bone loss represents one of the main reasons leading to an impaired function after revision surgery. [3] Because many patients with a failed HRA are less than 60 years of age, [4,5] it is necessary to devise a long-term strategy.

Up until now, published data have described revision of HRA with a conventional hip stem. [4,5,9] Moreover, SHA has so far only been used for primary hip replacement. [10-12] Sanguesa-Nebot et al reported the case of a patient with a broken cementless conventional stem that was revised with SHA. [13] As the tip of the implant was broken and stuck in the distal femur, removal would have caused considerable bone and soft tissue damage. Therefore, they used a Proxima short-stem, which is shorter compared to a conventional stem, but has a resection level similar to standard implants and also has a size which, at least at the proximal part, is as large as conventional stems.

In our patient's case, we used a metaphyseally anchored short-stem design, which clearly preserves more bone stock at the proximal femur but requires a resection level closely under the femoral head. By doing this, the femoral neck ring is preserved, which is needed for a firm anchorage of the implant. If those prerequisites are met, good primary stability of the SHA implant can be achieved. [14]

So far, good functional results and good short-term and mid-term survival rates have been reported for various short-stem hip designs. [10-12] Advantages of SHA include a more physiologic load transfer at the metaphyseal part of the femur and reduced soft tissue trauma, as the small and curved designs facilitate the preparation of the femoral cavity and the insertion of the stem. [12] As a result, faster postoperative mobilization with a reduced hospital stay has been reported. [15]

A further advantage of SHA is the preservation of the femoral bone stock. This allows the use of a conventional stem should revision become necessary, thus avoiding revision implants with an inferior outcome. All acetabular cups, bearing surfaces, and head sizes that are used for conventional total hip arthroplasty can also be applied for SHA. For those reasons, SHA offers an attractive alternative

for younger patients requiring hip replacement and, as shown in this report, can also be used to revise a HRA implant.

Regardless, it should be noted that to date, only short-term and mid-term results are available for SHA, and these results still have to be confirmed by long-term studies.

Conclusion

This case report demonstrates that revision of hip resurfacing arthroplasty can be performed not only with a conventional hip implant, but also with a bone-conserving short-stem hip implant. This is of particular importance, as it allows further preservation of the femoral bone stock and helps to provide a long-term solution to younger patients with a high risk of further revisions.

Consent

Written informed consent was obtained from the patient for publication of this case report and any accompanying images.

Competing interests

The authors declare that they have no competing interests.

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Source

Schmidutz F, Wanke-Jellinek L, Jansson V, Fottner V, Mazoochian F. Revision of hip resurfacing arthroplasty with a bone-conserving short-stem implant. Journal of Medical Case Reports 2012, 6:249 doi:10.1186/1752-1947-6-249. http://www.jmedicalcasereports.com/content/6/1/249

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Physician Payment Sunshine Act: Orthopedic Surgeons What You Should Know

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Despite the overwhelming benefits that physician-industry collaboration and innovation have created over the last century, politicians, members of academia, and other public citizen groups have increasingly expressed their concern that physician-industry relationships may raise ethical issues, such as potential conflicts of interest. As a result of these concerns, Congress passed the Physician Payments Sunshine Act ("Sunshine Act"), section 6002 of the Affordable Care Act, in 2009.

The Sunshine Act, now called Open Payments, does not directly change or prohibit relationships between manufacturer's, physicians or teaching hospitals. Rather, the legislation and regulations require applicable pharmaceutical, biological and device manufacturers and group purchasing organizations (GPO), to report certain payments such entities make to physicians or teaching hospitals.

The definition of "physician" includes all licensed MDs, DOs, Dentists, Dental Surgeons, Podiatrists, Optometrists, or Chiropractors, regardless of whether they are currently practicing or whether they are enrolled with CMS. Non-U.S. physicians are excluded, but several countries have enacted similar legislation (e.g., France, U.K., Slovakia, Russia and the Netherlands). The Sunshine Act does not apply to pharmacists, physician's assistants, nurses, or nurse practitioners, though indirect payments meant paid to these individuals meant to pass through to a physician are reportable. The Sunshine Act also does not apply to medical residents, however, CMS recently clarified in its Frequently Asked Questions (FAQ) that payments to "fellows" are reportable.

Manufacturers must begin reporting their payments to physicians and teaching hospitals on August 1, 2013. The first "payment reports" will collect data through December 31, 2013 (with the first report due March 31, 2014). Reporting is required annually thereafter. A manufacturer or GPO that fails to report or reports inaccurately may face annual fines up to $1.15 million dollars. However, physicians face no fines or penalties under this law.

Once manufacturers collect, record and report the required information, the Center for Program Integrity at the Centers for Medicare & Medicaid Services (CMS), which issued the final regulations and is responsible for the oversight and implementation of this program, will aggregate payments to all physicians and teaching hospitals and post them on a searchable, public website sometime after September 30, 2014.

Manufacturers and GPOs will have to report certain payments or transfers of value to physicians and teaching hospitals for categories including, but not limited to meals, travel, clinical research, honorarium, charitable contributions, consulting, speaking at promotional events, gifts, royalties or licenses and grants. For each of these categories, manufacturers and GPOs will also have to report the form of payment: 1) cash; 2) in-kind items or services; 3) stock, stock option or other ownership interest; and 4) dividend, profit or other return on investment.

Importantly, if a payment or transfer of value is related to marketing, education or research, including compensation for speaking, the manufacturer or GPO must also report the associated covered drug, device, biological or medical supply associated with that transaction.

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Impact on Orthopedic Surgeons

First, as a reminder, all physicians should locate the National Plan and Provider Enumeration System (NPPES) website, and ensure that the following information is up-to-date and accurate: 1) name (first, last and middle); 2) mailing address; 3) primary practice address (and secondary if applicable); 4) specialty, including any subspecialty (particularly those in general practice, e.g., internal medicine); 5) National Provider Identifier (NPI) number; and 6) state license number(s).

Second, physicians should register with the CMS Open Payments website to receive updates and notifications. More importantly, registration will allow CMS to notify doctors when they have aggregated all payments in a reporting year and such payments are ready for review by the physician. Specifically, once physicians receive notice, they will have 45 days to review them. If the physician believes there is an inaccuracy, they may notify CMS of the problem. The agency will notify the manufacturer. However, CMS will not be responsible for resolving the dispute. An additional 15 days will be provided to resolve the dispute. If it is unresolved after 60 days, CMS will publish the payment as the manufacturer has reported it, indicating that it is "disputed."

Next, orthopedic surgeons must be aware of certain reporting requirements that are unique to this specialty. Orthopedic surgeons likely use a combination of both drugs, devices, biological, and medical supplies—all of which reporting is required.

With respect to devices, there are a number of categories of payments or transfers of values that a medical device manufacturer may give to a surgeon that do not require reporting or tracking. For example, CMS excluded from reporting short-term loans of a covered device between 1-90 days. In the final rule, CMS expanded this exclusion to include covered devices "under development" including "a supply of disposable or single use devices (including medical supplies) intended to last for no more than 90 days." [1] In addition, CMS clarified that once a short-term loan exceeds the 90-day exclusion period, "regardless of whether the days were consecutive," the manufacturer must begin reporting from the 91st day. [2] Further, if a covered recipient purchases the device within the 90 days, manufacturers do not need to report the loan. Thus, surgeons will need to be aware of the timing of any loans and purchasing

In addition, CMS clarified that certain medical devices may be excluded from reporting as "product samples" while others may fall under the "short-term loan" exclusion. Specifically, CMS reasoned that "single use or disposable devices, demonstration devices or evaluation equipment" are excluded from reporting as samples as long as they "are intended for use by patients"; otherwise, such items "may be excluded from reporting … [as] short term loans." [3] Thus, surgeons should ask whether a manufacturer classifies the product as a sample or short term loan and have staff record such information so a surgeon is not later surprised when a payment appears on the Open Payment website.

Surgeons will also need to pay close attention to contractual warranties offered by manufacturers or GPOs. CMS finalized that contractual warranty exclusions may extend to items and services provided "outside the expiration period" "as long as the contractual warranty specified in the terms prior to expiration." [4] In addition, CMS finalized that "items or services provided under a contractual service or maintenance agreement" are also subject to the contractual warranty exclusion because they are "so similar to warranty agreements." [5]

There are also unique challenges for reporting research and consulting arrangements. Specifically, surgeons must understand that only payments included in a written research agreement or protocol are eligible for delayed publication as "research payments." Because of the frequent interactions medical device manufacturers must have with surgeons to develop medical technologies, manufacturers will not always be able to capture in a written agreement or research protocol each interaction necessary for the research and development of a medical device or technology—before, during and after FDA clearance.

As a result, meals, travel, education, consulting, honoraria or training associated with the R&D of a medical device or technology will likely become separately reportable in their respective categories, even though they are associated with the research. Accordingly, surgeons must be aware of these special rules to understand that some payments will not be delayed in publication even though they are related to research.

Similarly, because CMS finalized that clinical investigations of new applications of existing products are not eligible for delayed publication, surgeons will need to ask manufacturers about when certain products are not eligible for delayed payment, and

thus, payments related to the 'non-delayable' research (e.g., travel, meals, etc.) will also have to be reported separately. Surgeons conducting clinical research and trials should also work with manufacturers to determine who is responsible for reporting the costs of medical devices and supplies in the "total amount of research payment" that is eligible for publication delay.

Another area is ownership interests, if an orthopedic surgeon is receiving royalty, stock or options in return for work in developing innovative medical products those payments will be reported. In addition if a surgeon owns stock or options in a medical products or GPO company not being traded in a public exchange the value of that stock will be reported each calendar year. This includes private stock held by immediate family members including spouse, children, grandparents, grandchildren, siblings and their spouses if their relationship is known to the company.

Surgeons and Patients

Finally, surgeons should begin checking all of their current or near future contracts with GPOs and manufacturers to ensure that reporting requirements and obligations are met. Importantly, surgeons that are members of guidelines committees or professional medical associations, or who work working at academic institutions will need to ensure that any relationships with industry do not exceed what are permitted by the policies governing these institutions or groups.

In addition, doctors should update any and all conflict of interest disclosure forms or slides they may use in teaching and educational activities and with their institution, as well as any authorship or journal publications. Doctors will also need to pay close attention to past, present, and future filings with the IRS and any potential tax implications payment reporting may have, particularly with respect to royalties and licenses.

Lastly, it will be critical to ensure that doctors inform patients about any relevant relationships they may have with manufacturers prior to beginning a new course of treatment or recommending surgery. Some states have strong consumer protection laws and physicians may be held liable for failing to inform patients regarding certain relationships, which may raise lack of informed consent issues.

Accordingly, surgeons must be ready to discuss such payments with patients in a neutral way to ensure that patients understand the nature of the relationship and why these interactions are essential to lifesaving medical breakthroughs, the development of new medicines, and improvements in the care we all receive.

References:

1. Final Sunshine Rule at 9487.
2. Id.
3. Id. at 9487.
4. Id. at 9488.
5. Id.

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

Broach Handle Offset and Impact Acceleration During Femoral Preparation for Total Hip Arthroplasty

Stephen Kayiaros MD, Lee Eric Rubin MD*, Alison Biercevicz PhD*, Richard Limbird MD*, David Paller PhD**

Investigation was performed at the Rhode Island Hospital Orthopedic Foundation Laboratory, Providence, Rhode Island. At the time of the investigation, all authors were members of the Department of Orthopaedic Surgery within the Warren Alpert Medical School of Brown University.

Introduction

The direct anterior approach for minimally invasive total hip arthroplasty has become increasingly popular. [1] Preparation of the femoral canal using this approach can be technically challenging. Instrumentation of the femur involves a posteromedial capsular release, extension and external rotation of the operative leg and elevation of the femur anteriorly. Curved offset femoral broaches have been specifically designed to safely prepare the femoral canal through this single incision. [2,3] The objective of this study was to evaluate the amount of impact force generated and thus transferred to the proximal femur using a variety of curved single-offset broach handles compared to a traditional straight handled broach handle. The amount of acceleration transmitted through the femur could then be correlated to the number of impacts on the broach handle and thus operative time as well as trauma to the surrounding tissue.

Methods

A total of four Corail (DePuy, Raynham, MA) broach handles were tested for impact acceleration magnitude; solid straight handle (SS), medium curved single-offset with cannulated handle (MC), extended curved single-offset with solid handle (ES) and extended curved single-offset with cannulated handle (EC) (Figure 1). Broach insertions were simulated with the aid of a custom hinged impact assembly. For each trial a 1.1 kg mallet impacted the head

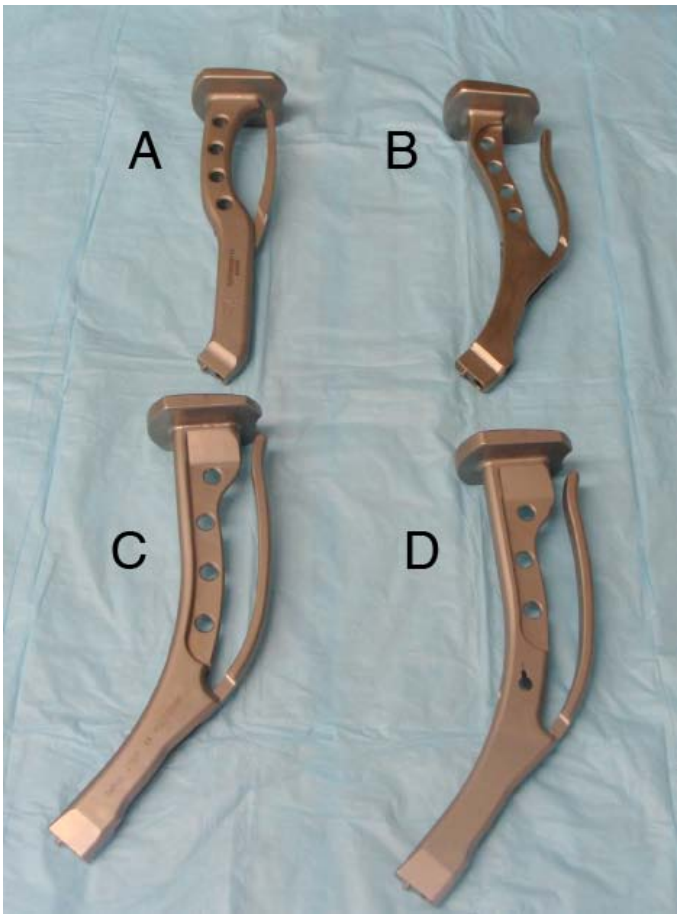

Figure 1: Schematic of four broach handles used during impact testing: A: SS, B: MC, C: EC and D: ES

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of the broach handle from a height of 75mm. The impact assembly allowed investigators to strike the broach handle at a constant velocity for each trial. A Sawbones (Pacific Research Lab, Vashon, WA) proximal femur was embedded in a Shore A 10 hardness Silicon Rubber (Smooth On Easton, PA). The silicon rubber simulated the soft tissue surrounding the femur. A PCB tri-axial accelerometer was rigidly mounted on the base of the Sawbones femur to record impact acceleration (g). Data was collected digitally using custom LabView software at an acquisition rate of 20 kilohertz.

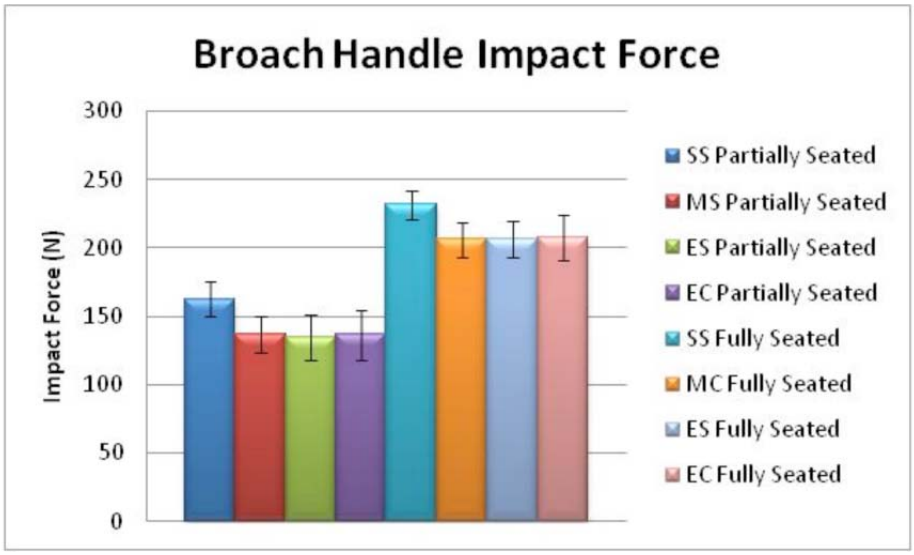

Figure 2: Summary of impact test results.

A total of two conditions were tested for each broach handle; partially and fully seated. For the partially seated condition, a size 13 broach was initially inserted into the proximal femur to simulate preparation of the femoral canal. A total of 40 impacts were recorded for each broach handle. The impact order was randomized into four trials of ten impacts for each broach handle. Following the completion of the initial tests, a size 14 broach was inserted to simulate a fully seated trial implant. Similar to the first test condition a total of 40 impacts were recorded for each handle in random order. Impact force was calculated using Newton's second law: F = m*a. In this case, acceleration was the maximum recorded value from the accelerometer and the mass was the total mass of the impact hammer and broach handle.

A one-way ANOVA with the Tukey method for post-hoc analysis was used to determine if the mean impact force was significantly different between different broach handles. Additionally, a two way ANOVA was performed to determine if significant differences existed between impact force and condition (partially seated versus fully) seated. A P-value of 0.05 was defined a priori and adjusted for multiple comparisons.

Results

For the experiments with the fully seated broach, the mean impact force in the SS was 231.4 ± 10.4 N. The mean impact force in the MC, ES and EC was 206.3 ± 12.8 N, 206.2 ± 13.4 N and 207.2 ± 16.5 N respectively. The mean acceleration of the SS was significantly higher than the ES ($p < 0.001$), EC ($p < 0.001$) and MC ($p < 0.001$). Figure 2 shows a summary of test results.

For the partially seated experiments, the mean impact force in the SS was 162.4 ± 12.6 N. The mean impact force in the MC, ES, and EC was 135.6 ± 13.4 N, 134.3 ± 16.5 N and 136.6 ± 18.4 N respectively. Results from the partially seated testing failed an equal variance test. Therefore, a Kruskal-Wallis one way ANOVA on ranks was performed. The mean impact force of the SS was significantly higher than the ES ($p < 0.05$), EC ($p < 0.05$) and MC ($p < 0.05$). Within all broaches, the impacted force in the seated condition was significantly higher compared to the impact force of the partially seated broaches, 212.8 ± 17.1 N verses 140.5 ± 19.8 N ($p < 0.001$).

Discussion

Clinical experience with the direct anterior approach for total hip arthroplasty suggests the curved offset broach handle may not allow the surgeon to properly seat the final femoral trial. This is most likely due to the large moment arm created by the bend in the offset handle. It can sometimes be necessary to switch to the straight handle to fully broach the femur, or utilize a straight impactor to seat the final prosthesis.

For all tests performed, the mean impact acceleration was highest using the traditional straight handle broach. Mean impact accelerations for all single-offset broach handles (including the MC, ES, and

EC) were significantly lower than the solid straight handle (SS). As expected, the mean impact acceleration for the MC was significantly higher than both extended curved offset broaches. It may be concluded that while curved offset broach handles may help to facilitate femoral preparation while utilizing a small direct anterior incision, the surgeon must be critical to assess that final implant position is correct and should employ a straight handle broach or seating impactor when appropriate.

There were several limitations to this study. A Sawbones model was used to approximate bone and soft tissue properties. The setup for generating impact strikes with the mallet on the broaches did not exactly replicate intraoperative conditions of proximal femoral preparation. However the results did provide data for each broach that was directly comparable and statistically significant. Further studies using a cadaveric model and an impact load cell would provide more information.

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Joint Implant Surgery & Research Foundation
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Total Knee Arthroplasty Using a Hybrid Navigation Technique

Alvin Ong, Kwang Am Jung, Fabio Orozco, Lawrence Delasotta, Dong Won Lee

The authors describe a novel technique for total knee arthroplasty that combines computer navigation and conventional TKA.

Introduction

The use of computer navigation for primary total knee arthroplasty (TKA) provides the benefits of accurate bone resection, low outlier frequencies, and the restoration of overall mechanical alignment. However, its use also involves the disadvantage of change in technique and workflow that have been associated with steep learning curve and increased surgical time.

Furthermore, several investigators have described the potential risks associated with the use of navigation, which include registration errors, notching of the anterior femoral cortex, oversizing of the femoral component, and overresection. [1-4] These risks mean that surgical plans provided by navigation software might require modification intraoperatively, based on the surgeon's experience and knowledge.

On the other hand, conventional TKA has the advantages of familiarity and simplicity. Furthermore, decisions regarding bony resection level are based on measurements taken using a traditional jig and rod, and thus, anterior notching and femoral component oversizing can be avoided. Unfortunately, the conventional technique is more inaccurate and inconsistent in terms of component alignment ability than computer navigation. [5,6]

In this article, we describe a hybrid technique that combines the benefits of computer navigation and conventional TKA. This hybrid navigation technique was developed to allow TKA to be performed in-line with accepted conventional TKA practice, but with the accuracy of computer navigation.

Indications & Contraindications

The devised hybrid navigation technique was indicated for all 3,500 knees that underwent TKA at our institution between January 2007 and April 2010. In no case was the hybrid navigation technique deemed to be contraindicated, and the procedure was not aborted intraoperatively in any case. With regard to contraindication, in theory, hardware in the distal femoral metaphysis and diaphysis that might interfere with intramedullary rod placement would pose the only potential contraindication to the use of the technique.

Preoperative Planning

No special preoperative planning was performed before hybrid navigation. In our practice, we routinely obtain standing anteroposterior (AP), posteroanterior (PA), and lateral radiographs for all patients scheduled for TKA. These images provide an overall picture of deformities present and of the corrections necessary. In addition, they provide information on the presence of hardware, extra-articular deformity, and bone loss.

The goal of surgery is to achieve a final mechanical axis of 0°, but we accept up to 3° of overall varus or valgus malalignment.

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Surgical Steps

The Stryker image-free knee navigation system (Stryker Navigation, Kalamazoo, Michigan) was used in all cases; however, any commercially available navigation system can be modified for use with the hybrid technique (described below.)

All patients received a posterior-stabilized knee system, and all patellae were resurfaced. The implants used were the Triathlon implant (Stryker; Mahwah, NJ, USA) and the Genesis II total knee implant (Smith & Nephew; Memphis, USA). A medial parapatellar approach and an anterior-referencing technique were used in all cases, and all implants were cemented.

The navigation computer is best positioned opposite the surgeon, approximately 4 feet away from the patient. The camera was located over the patient's knee and directed downward at 45°. Prior to exsanguination of the limb and incision, navigation trackers (light emitting diodes) were fixed to the distal femur and the proximal tibia. Two 3-mm Apex pins were utilized on the distal femoral metaphysis and proximal tibial metaphysis in conjunction with the Stryker OrthoLock System (Stryker, Kalamazoo, Michigan, USA).

We recommend that these pin clusters be placed approximately 10 cm distal to the joint line in the proximal tibia, such that they do not interfere with the surgical incision or the operative field. Likewise, we recommend that pin clusters be placed approximately 10-15 cm proximal to the joint line in the distal femur, such that they do not interfere with the trajectory of the intramedullary rod.

We do not recommend placement of pins in the diaphysis, due to the risks of thermal necrosis and stress fracture. Furthermore, we recommend that the pins be placed in different planes to avoid the creation of a stress riser in bone; alternatively, a single pin technique can be utilized using a Stryker Anti-rotation pin (Stryker, Kalamazoo, Michigan, USA) (Figure 1). One pin is placed in the metaphysis either medial to or lateral to midline (beyond the trajectory of the intramedullary rod.)

Care must be taken to ensure that the femoral and tibial trackers are positioned in direct view of the navigation camera. In all cases, a standard extramedullary tibial cutting guide, an intramedullary distal femur alignment guide, a femoral rotation cutting guide, and a navigation-enhanced distal femoral cutting block (Stryker, Mahwah, NJ, USA) were uti-

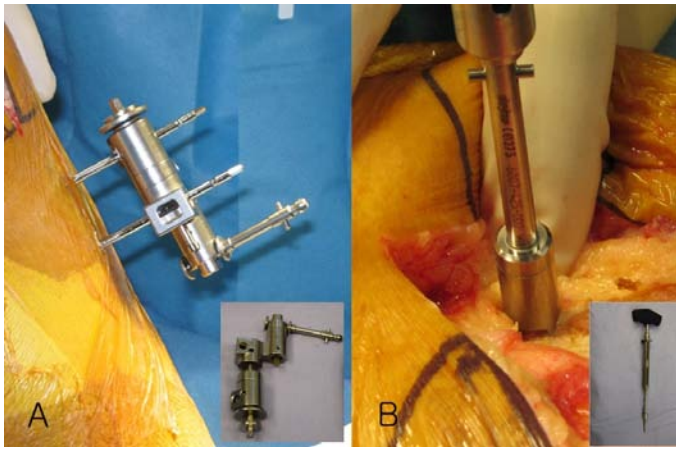

Figure 1. Two 3-mm Apex pins (A) were positioned in the proximal tibia 10 cm below the tibial joint and a single anti-rotation pin (B) was placed off center in the metaphysis approximately 4 cm above the trochlear articular surface

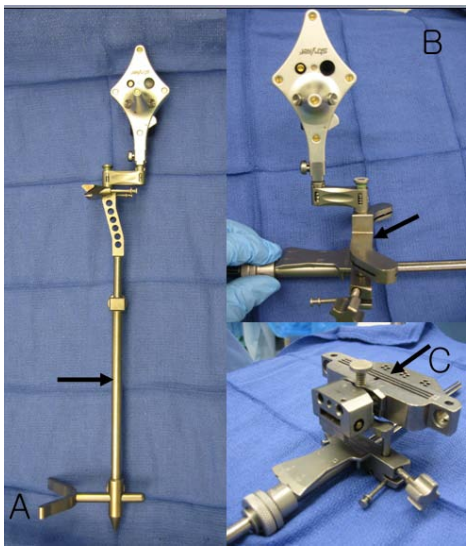

Figure 2. Standard extramedullary tibial cutting guide (A, arrow), intramedullary distal femur alignment guide with a femoral rotation cutting guide (B, arrow), and a distal femoral cutting block (C, arrow) were modified to accommodate a navigation tracker.

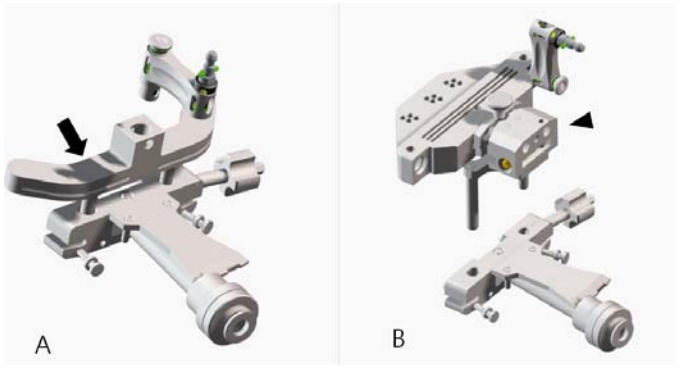

Figure 3. Navigation enhanced femoral rotation cutting guide (arrow) and a navigation enhanced conventional distal alignment guide with a distal femoral resection pivotal cutting block (arrowhead) were attached to the conventional distal alignment guide as shown (A,B).

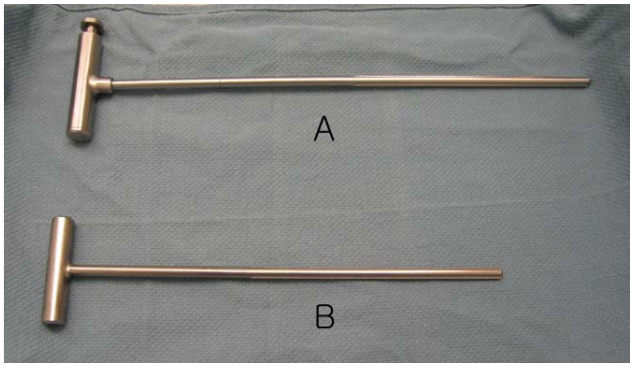

Figure 4. Conventional femoral intramedullary rods (A) were shortened by 25 cm (B).

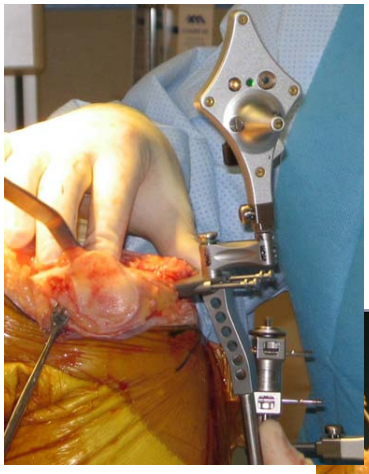

Figure 5. The modified conventional tibial guide with a tracker was first fixed to the tibia. Resection height and tibial slope were controlled manually under navigation guidance.

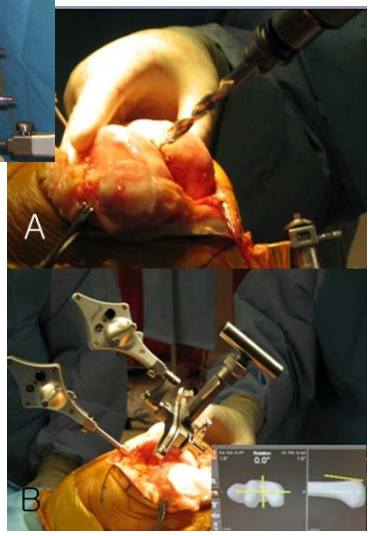

Figure 6. A "starting" hole was created in the distal femur for intramedullary rod insertion (A). The femoral component rotational axis was controlled under navigation guidance using a tracker connected to the anterior femoral cutting jig (B).

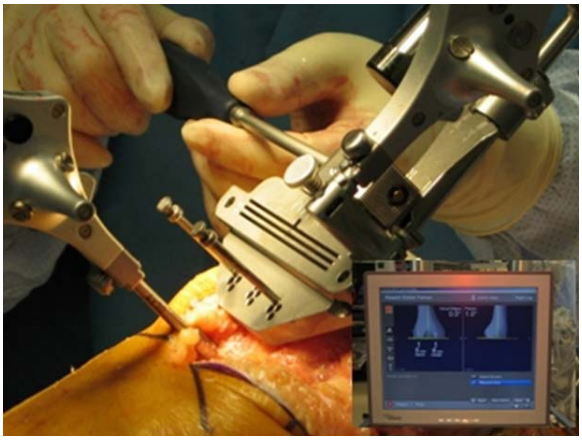

Figure 7. Resection level and its precise position were controlled and "fine-tuned" using a screwdriver to distal femoral resection pivotal cutting block.

lized; each of these instruments was modified to allow them to accommodate a navigation tracker.

A tracker was attached to a navigation-enhanced femoral rotation cutting guide and a navigation-enhanced conventional distal alignment guide with distal femoral resection pivotal cutting block (Figures 2-3) The conventional femoral intramedullary rod (Figure 4) was shortened by 25 cm to avoid interference with the tracker pin on the femoral side.

In terms of surgical steps, the centers of the femoral head, knee joint, and ankle joint were identified, and then surface mapping of anatomic landmarks of the knee was performed. After the anatomic survey, navigation of the femoral and tibial bone resection was performed using Stryker software (eNact Knee Navigation Software 3.1). The navigation system had axis and alignment incremental changes of 0.5 degree and the resection level and height in millimeter increments.

The modified conventional tibial guide with a tracker was first fixed to the tibia; resection height and tibial slope were controlled manually under navigation guidance (Figure 5). After completing the tibial resection, a "starting" hole was created in the distal femur for intramedullary rod insertion (Figure 6). This "starting" hole was made just above the notch centered between the lateral and medial condyle. A modified short intramedullary rod with a conventional distal alignment guide and tracker was then inserted into the opening.

The femoral component rotational axis was controlled under navigation guidance using a tracker connected to the anterior femoral cutting jig (Figure 6). Rotation is based off the transepicondylar axis.

After determining femoral component rotation, an anterior rough cut was performed using the conventional jig-based technique. Subsequently, the distal femoral resection pivotal cutting block was connected to the conventional distal femur alignment guide. The resection level and the exact position of distal femoral resection were controlled and "fine-tuned" using a screwdriver (Figure 7). Flexion of the distal femur was set at approximately 3-5° using the intramedullary rod to accommodate femoral bow.

Following the distal femoral cut, the anterior/posterior and chamfer cuts were completed using a selected system-specific 6-in-1 or 4-in-1 femoral cutting block. Depending on the balance of flexion and extension gaps, minimal bone adjustment was carried out under navigation guidance.

After trial reduction, tibio-femoral mechanical

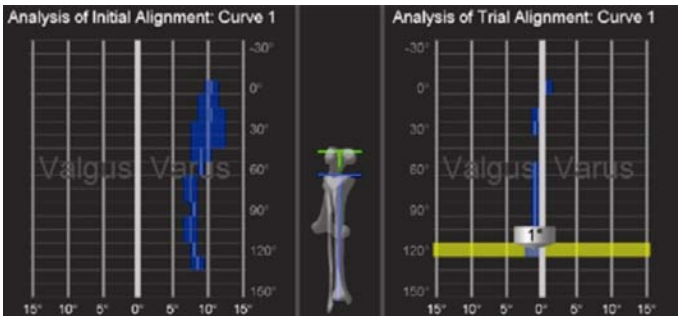

Figure 8. After trial reduction, tibio-femoral mechanical alignment was recorded and compared with preoperative tibio-femoral mechanical alignment.

alignment in knee extension and flexion were recorded and their kinematic curves were compared with preoperative tibio-femoral mechanical alignment (Figure 8). The accuracies of bone cuts were assessed after every surgical step with the aid of the navigation system and a resection plane probe. Cuts were corrected as necessary if they were deemed to be outside the acceptable range.

Once the accuracies of the bone cuts and soft tissue balance were confirmed, the real components were implanted with cement using the standard technique.

Brief Results

More than 3,500 knees underwent primary total knee replacement from January 2007 to April 2010. The first 50 knees treated (mean age 65.2 years) and the last 50 knees treated (mean age 64.3 years) were compared with respect to surgical time and component alignment to assess the effects of the learning process. Coronal and sagittal alignments of femoral components for the first 50 knees were mean valgus 0.5°and mean flexion 3.5°; these values were similar for the last 50 knees (mean valgus 0.2° and mean flexion 3.6°).

For tibial components of the first 50 knees, mean coronal and sagittal alignments were valgus 0. 3° and flexion 2.5°, and these were also similar for the last 50 knees (mean valgus 0.3° and mean flexion 2.7°). Overall mechanical alignments for the first and last knee groups were mean varus 1.5° and 1°, respectively, and mean operation times (skin incision to skin closure) were 61 and 50 minutes, respectively.

There were three cases of tibial fracture attributed to a tracker pin, but these fractures were considered to be related to general concerns of navigation TKA, and not to a system-specific problem. Ten cases developed a superficial infection at a tracker pin site, but no case of fat embolism occurred.

Discussion

Computer navigation is becoming a well-recognized technical alternative to conventional total knee replacement, but its merits and demerits continue to be widely debated. [7-11]

Computer navigation has the disadvantages of a protracted learning curve and increased surgical time. [11] In addition, several investigators have suggested that navigation might increase the risks of notching of the anterior femoral cortex and oversizing of the femoral component.

In particular, Minoda et al [3] found that 40-85% of males and 65-100% of older females treated with navigation showed anterior notching. Matsumoto et al [2] suggested that surgeons should be aware of the potential for oversizing when determining the size of the femoral component, particularly when the femoral bone is anteriorly bowed. Kim et al [10] also reported a higher incidence of anterior femoral notching in navigation treated knees than in conventionally treated knees.

However, these problems might be due to discrepancies between the anterior bow of the femur and its straight mechanical. More specifically, computer navigation calculates the sagittal axis of the femur by drawing a straight line between the center of the femoral head and the center of the knee. Thus, femoral bow is not taken into consideration, and therefore, cannot be determined from anatomic registration points.

Furthermore, decision making regarding resection level using navigation might be difficult, especially in knees with a deformed articular surface, such as, severe varus or valgus knees, as compared with decision making using the conventional technique. Kim et al [10] reported overresection of proximal tibial bone as a complication of navigation, and thus, the surgical planning provided by the navigation software might require modification based on surgeon's experience and knowledge of the surgical procedures.

The hybrid navigation system described in this article was devised to combine the ease of use of classic conventional resection instruments and the accuracy of the navigation technique. Furthermore, the use of an intramedullary rod in conjunction with navigation allows femoral bow to be taken into consideration. In theory and practice, the rod is deflected by femoral bow, which allows flexion of the femoral component to accommodate femoral bow, which

facilitates appropriate flexion of the femoral component and prevents inadvertent notching of the anterior femoral cortex. This use of an intramedullary rod in conjunction with navigation represents an advantage of the hybrid technique over the pure navigation technique, wherein femoral bow is not taken in account when determining femoral component position.

Although it has been reported that the use of a femoral intramedullary rod might increase the possibility of a fat embolism, [12,13] it appears that the use of a smaller diameter, shorter intramedullary rod may reduce this risk. On the other hand, Kim et al [14] found that the use of an intramedullary rod did not increase the risk of fat embolism or increase perioperative blood loss.

The present study shows that the hybrid navigation technique increases the accuracy of component alignment versus the conventional technique and requires less time than navigation technique. Furthermore, our findings indicate that hybrid technique does not require a protracted learning process. In addition, no case of fat embolism was encountered.

Accordingly, we believe that the described hybrid navigation technique enables TKA to be conducted safely and precisely without femoral notching or femoral component oversizing.

Conclusion

Considering several manufactures' navigation systems with their own successful benefits, we do not present the devised hybrid navigation technique as a definitive method for navigation TKA. Nevertheless, we believe that this technique should be considered as an alternative means of conducting navigation TKA.

Consent

All authors certify that the human research protocol used during this investigation was approved by our institution and that all investigations conducted during this study conformed with ethical research principles.

Competing interests

Alvin Ong is a consultant for Stryker Orthopaedics (Mahwah, NJ). All the other authors have no competing interests.

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Source

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

A Global Collaboration - Osteointegration Implant (OI) for Transfemoral Amputation

Case Report

(First Reported Case in U.S.)

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John Keggi, MD+, Robert Kennon, MD*+, Edward McPherson, MD*§, Terry Clyburn, MD*π, Declan Brazil, PhD*β, and Timothy McTighe, Dr. H.S. (hc)*§*

Acknowledgement: Design concept by Concept Design & Development, LLC (CDD,LLC); Development and Manufacturing by Signature Orthopaedics, LTD; Centennial Hills Hospital Medical Center, Las Vegas, NV; and Institutional Review Board (IRB) by Joint Implant Surgery & Research Foundation.

Background

Most investigators credit Branemark (1965) in Sweden with the idea of a percutaneous, osteointegrated prosthesis which has been successful in dental implantation. [1] In 1997, R. Branemark reported on the first femoral intramedullary percutaneous device using a 12 cm screw-type device for a patient with an above-knee amputation. [2] In 1999, ESKA produced the Endo-Exo Femurprosthesis (EEFP) which was first implanted into the femoral canal of a young motorcyclist who lost his leg in an accident and subsequently used for a number of patients in Germany. There have been variations in the design, including some types to allow proximal fixation to other devices such as a hip replacement, but commonly the device is a modular, noncemented device that fits within the intramedullary canal of the femur and has a hardpoint attachment that exits through the skin. [3]

Three of our co-authors (JK,RK, & TC) have been to Germany, studied this procedure and reviewed historical outcomes. The original device utilized a spongiosa surface of casted cobalt chrome that allows for a porous surface for bone ingrowth.

Challenges

The clinical challenges of an OI-style implant are twofold. First, the device must have a stable and secure fixation within the femur shaft for the forces to be transmitted from the subject's hip and thigh musculature to the distal prosthesis. Sec-

Figure 1. A transcutaneous, cementless porous coated press-fit distal femoral intramedullary device whose distal external aspect serves as a hard point for AKA prosthesis attachment. Courtesy R. Kennon, MD

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ond, the issue of the skin implant junction must be managed to prevent infection from traveling up from the skin to the bone of the femur.

Since the original device was made of cast Co-Cr our team felt a forged titanium alloy rod with a more contemporary porous coating of commercially pure (CP) titanium would provide for a better osteointegration.

Figure 2. Titanium forged IM Rod with a sintered CP porous coating.

The reported clinical experience has shown that the implant can be securely fixed into the medullary canal of the distal residual femur. This stable fixation is achieved by preparation of the femur with reamers and precision cutting instruments prior-to implantation.

Preoperative Considerations

Preoperative planning requires consideration of the local stump, including scars or burns as well as radiographic determination of the length and diameter of the prosthesis. A CT scan is helpful for determining the necessary implant size and limb length. Typically at least 12 to 15 cm of femoral shaft is needed for stable fixation.

3 D and Finite Element Modeling are done to provide for customization of the device for the individual bony parameters of the patient.

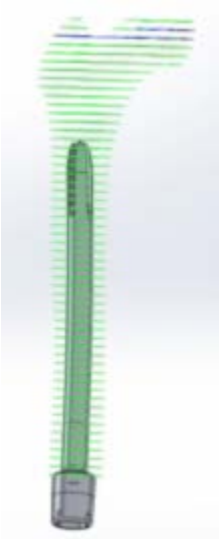


Figure 3. Modeling for custom implant.

Potential Benefits

Benefits include the patient having a more normal gait pattern with little to no pain via the use of prosthesis for transfemoral-level amputations. In essence, this would lead to a higher quality of life, such as higher levels of independence in daily living, physical activity levels, self-care and employment opportunities that would not be possible with the continued use of a socket-style prosthesis that joins the residual stump to a prosthesis.

Material and Methods

Patient Profile

Index patient is a 63-year-old African American Female. She is 170cm tall and weighed 75kg.

Primary amputation completed 78 days prior to this procedure.

Revision amputation was preformed 32 days prior-to index surgery due to wound healing problems and pain at the medial aspect of the residual limb scar.

The patient is a medical professional with more than 40 years of critical care experience. She did not want to accept permanent disability and has a strong desire to return to clinical practice.

She is married. A Nonsmoker. No illegal or recreational drug usage. She had no other co-morbidities. She takes no medications on a regular basis other than pain medications following the amputation. She has multiple medication allergies to include penicillins, cephalosporins, and a contact skin anaphylactic reaction to latex based products.

Diagnosis

Indication for amputation was a multiple recurrent low-grade chondrosarcoma of the right distal femur. The lesions did not fit the typical classification and could be described as juxtacortical. The classification of the lesion as a malignant cartilage tumor was based on it clinical behavior as well as its histology. Microscopic examination demonstrated bland appearing cartilage with minimal atypia and one mitotic figure per high-powered field of microscopic view.

The patient's first surgery for this was at the age of 16. She had undergone a total of 14 prior surgeries for this issue with incomplete resection and local recurrence. Prior-to amputation the tumor was found to have extended into the popliteal fossa and was clearly encasing the neurovascular bundle. The patient was experiencing vascular claudication symptoms on ambulation prior-to the amputation.

Preoperative Counseling

The patient had been counseled by experienced prosthatists on the design and function that was anticipated with a conventional suction suspension system prosthesis for the transfemoral level. She was

not satisfied with the level of function this was anticipated to afford after final fitting.

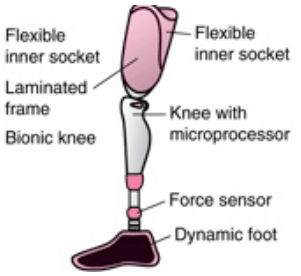


Figure 4. Traditional socket style prosthesis

The patient was counseled at length on the details of the staged Osseointegration implant system designed by a private orthopaedic device team and manufactured by Signature Orthopedics LTD, in Sydney Australia. She was shown YouTube videos of patients who had undergone similar surgery in Europe with a similar device. She preformed her own extensive literature review on the topic of osseointegration implant systems.

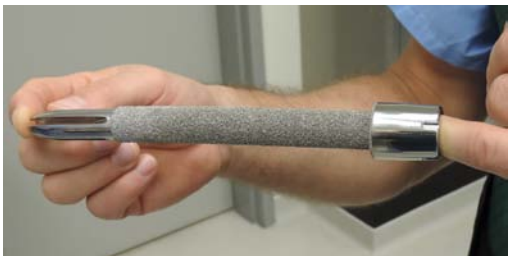


Figure 5. A custom titanium IM rod with a sintered porous coating for long-term fixation with a connector housing for the prosthetic limb.

She was consented per the IRB approved protocol. She was given a copy of the PI's financial disclosure statement prior-to completion of the consent documents.

Global Effort & Collaboration

A high lever of experienced orthopaedic surgeons, implant designers and device manufactures (CDD,LLC) have been collaborating on the refinement of pre-existing European technology (Eska) Orthodynamics "Intregral Leg Prosthesis (Endo-Exo). The Integral Leg Prosthesis incorporates Spongiosa Metal™ II technology for secure primary fixation and provides a 3 dimensional structure for subsequent osseointegration of the implant. Results have been very encouraging with this device, however this has not been available in the United States. So our team took on the project of designing an updated device with material (titanium alloy & CP porous coating) that was felt would provide for more precision in fabricating a custom device and a more contemporary porous structure to enhance bony fixation.

Our senior author has significant training with battlefield wounds from his military experience from 1993 to 2005 including being part of the 67th Forward Surgical Team, Operation Iraqi Freedom in 2003. His Orthopaedic Oncology Fellowship at UCLA, Department of Orthopaedic Surgery in 2005 provided additional training and interest in the field of limb amputation and resection arthroplasty. Three other members of our team (JK, RK, TC) have all been to Europe and received training on the Eska Endo-Exo device. Another member (EM) has significant experience and expertise in treating joint infections. Our remaining team members (DB, TM) have significant experience in design and fabrication of orthopaedic devices.

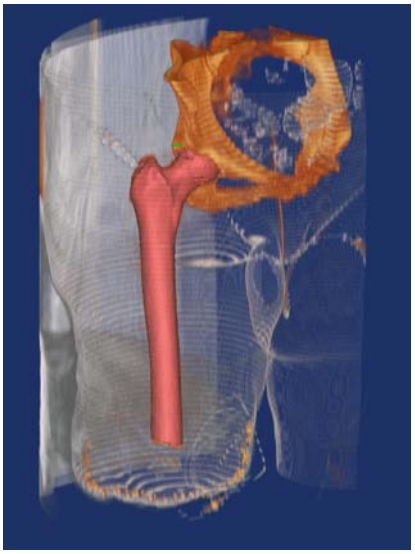


Figure 6. Specialized software "mAterialise" from Materialise HQ, Belgium

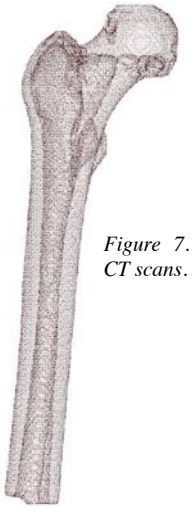


Figure 7. Modeling from CT scans.

Surgeons are experts at making the most of conventional 2D image data to prepare for their surgeries. However, even the best planners can struggle with limited information that is available in 2D images and with the inability to try out multiple approaches before entering the OR. Fortu-

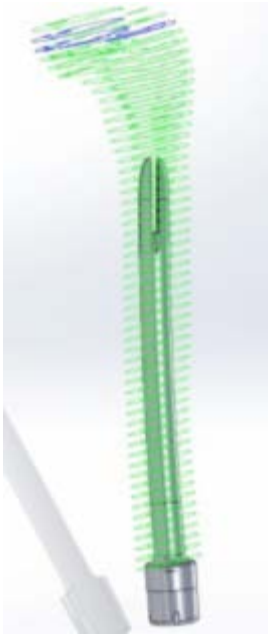


Figure 8. Modeling with IM rod checking length, diameter and curvature.

nately, 3D virtual surgical planning is available to remove many of the hurdles involved in determining the best plan and transferring it to reality.

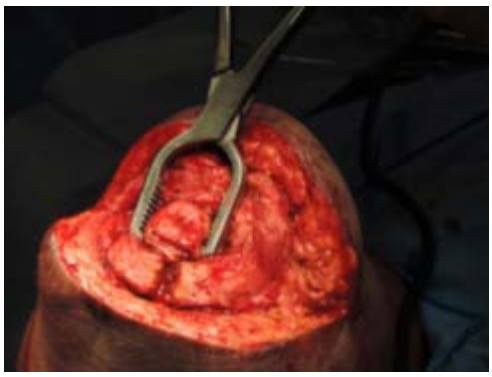
Current software is now available to aid in preparation, planning while guiding the production of your custom device, along with planning your surgery.

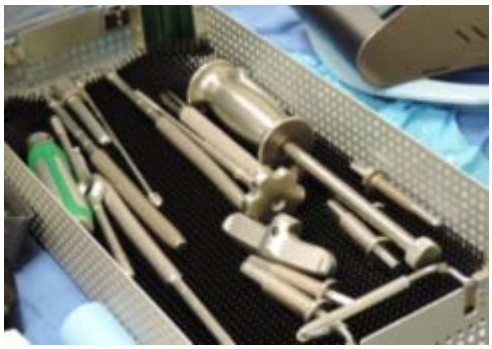
Custom fabrication can then be on sound scientific demonstration of fit and fill of the required parameters to ensure proper fit of the device.

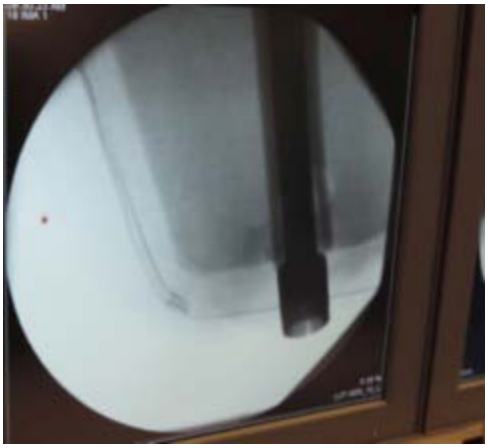
Surgical Technique

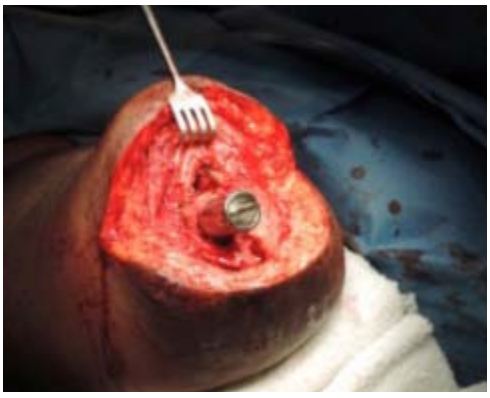
Primary amputation completed 78 days prior to this procedure. The patient's amputation was preformed with a clear surgical margin of more than 4 cm with no residual tumor was present. The amputation was carried out at the distal 1/3 of the diaphysis. The amputation was completed in the classic fish mouth style of equal anterior and posterior flaps of skin and muscle. The femur was transected 5 cm proximal to the skin incision. The closure was preformed with suture myodesis of the major muscles to the transected femur. The posterior fascia was sutured to the anterior fascia. The skin was approximated with simple surgical staples.

Surgical Case









Approximately six to eight weeks after the implantation of the endoprosthesis, when the wounds are well healed, the second procedure is done to create the stoma and attach the transdermal coupler. This is usually done as an outpatient procedure.

The secondary procedure will be reported on as a follow-up to this case report. We are excited that this Osteointegration implant (OI) for Transfemoral Amputation will provide an alternative treatment for patients for whom a traditional-socket-type above-the-knee prosthesis presents difficulties.

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

Revenue Enhancement Strategies For Orthopedic Surgeons

Jack T. Diamond, Esq., Jeana M. Singleton, Esq.* and Samantha L. Prokop, Esq.**

As payers continue to reduce payments, and as quality monitoring, reporting, performance, and other expectations rise, savvy surgeons are looking for ways to increase revenue and ensure that their businesses are in a position to thrive financially. This article is intended as an overview for orthopedic surgeons regarding various revenue enhancement strategies. In this ever-changing reimbursement environment, a penny saved is a penny earned.

There exist within current federal regulations several opportunities for surgeons to increase efficiency, quality, and patient satisfaction while simultaneously increasing revenue. If not structured in a compliant manner, however, these arrangements can prove to be fatal in a strict regulatory environment including violations of the Stark law, anti-kickback statute, False Claims Act, and imposition of civil monetary penalties as well as the risk of criminal conviction.

In determining which strategy might be best for your practice, it is first important to determine your appetite for risk. The proposed strategies below must be carefully arranged to meet statutory and regulatory requirements. As such, it is crucial that in order to take advantage of these strategies, you consult experienced healthcare legal counsel, and stay informed about ever-changing healthcare laws and regulations.

Accountable Care Organizations

Accountable Care Organizations (ACOs) are entities that are created with two main goals: (1) improve the quality of care provided to patients, and (2) reduce healthcare costs. ACOs can participate in both commercial and government healthcare programs. High-performing healthcare providers receive higher reimbursement based on meeting or exceeding set quality metrics or demonstrating their contributions to cost-savings within the ACO and sharing in that savings. Orthopedic surgeons wishing to participate in generating savings for ACOs should identify ACOs in their region and begin developing cost-saving strategies and negotiating increased reimbursement for demonstrated savings.

Gainsharing Arrangements

Gainsharing is a method in which hospital and physician incentives are aligned to encourage sur-

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geons to produce cost-savings by allowing hospitals to share the cost-savings recognized by physicians' efforts with physicians. The program includes an independent third party review to monitor cost-savings and establish a floor that cost-savings cannot fall below to avoid limiting the quantity or quality of services provided to patients. Gainsharing arrangements are highly regulated, but when structured properly, can generate significant cost-savings for hospitals and significant revenue for surgeons.

Hospital Outpatient Department ("HOPD") Model

Hospital-based reimbursement is significantly higher than that of free-standing or physician owned facilities. Hospitals often receive as much as twice the reimbursement for the same procedures performed in a hospital-based setting than in other settings. In order to operate as an HOPD, the department must meet Medicare requirements for hospital departments. The benefits of becoming an HOPD are significant. Surgeons will automatically increase reimbursement on average 40% to 80% depending on the payer mix and service line. Further, there is increased operational flexibility and the opportunity to receive additional fees under a management agreement where the physician practice agrees to manage the department. Further, the model typically results in increased efficiency and convenience for patients.

Split-Billing and Ancillary Services

The HOPD model allows surgeons and hospitals to take advantage of split-billing arrangements. Split-billing arrangements allow the hospital to bill the technical component and the physician to bill the professional component of procedures versus billing globally. The facility fee (technical component) in a hospital setting is typically higher than that allocated to procedures performed in a physician office setting. This is due to the higher overhead that hospitals incur. Further, patients can be referred for ancillary services, which are also reimbursed at the higher, HOPD price.

Sale-Leaseback Arrangement

Under this model, surgeons sell their group practice to a hospital, which leases the practice back to the surgeons for fair market value. The result is lower overhead, substantially reduced personal liability, and favorable tax treatment. The arrangement operates as a financing tool for surgeons. The surgeons still retain control of their practice and recognize increased revenue.

Technology Partnerships

One of the biggest struggles hospitals face is being able to purchase new, innovative technology and equipment. On the other hand, physician practices may have funds on hand to purchase a piece of equipment or already purchased equipment that the practice is not using. These situations create a unique opportunity for surgeons to increase revenue by entering into arrangements with hospitals to lease or finance the equipment. In the alternative, if an orthopedic practice cannot afford a large, expensive surgical device, the hospital could purchase the equipment and partner with a specialist to promote a new procedure. These arrangements create mutually beneficial financing and revenue enhancement opportunities for both hospitals and orthopedic surgery practices.

Co-Management Arrangements and Commercial Under Arrangements

Commercial under arrangements involve a hospital contracting with a third party to provide services on behalf of the hospital. The contracted third party (i.e. surgery group) can benefit from higher reimbursement rates that typically exist under hospital contracts with commercial payers. It is important to note, however, that when parties utilize a commercial under arrangement structure, the arrangement only permits services to commercial and self-pay patients. The parties could not bill government payors for services rendered under this structure.

Additionally, the surgeons and hospitals can create a joint venture management company. The company will manage services in a specific hospital department on an at-risk basis. Under this arrangement, the surgeon group is typically responsible for clinical quality of care initiatives, care coordination, and supply chain management. The arrangement often results in increased operational efficiencies, increased patient satisfaction, and an expanded patient base and profile of the orthopedic surgeon group in the community.

Leadership Roles

Orthopedic surgeons have specific knowledge and expertise that can benefit entities such as hospitals, distributors, manufacturers, educational institutions, and other entities. These entities will often pay orthopedic surgeons as consultants or medical directors. The fees can be paid to the orthopedic surgeon's group practice or to the orthopedic surgeon individually. These leadership roles entail services such as attending meetings, participating in quality and other committees, developing and implementing new processes or procedures, and reviewing design and performance of surgical materials, among others. These relationships allow orthopedic surgeons to enrich the surrounding communities with their innovative ideas and expertise while allowing the orthopedic surgeon to gain more exposure in the community and establish a reputation for being a premier expert in his/her field.

Ownership Interests in Manufacturers and Distributors

Orthopedic surgeons can increase revenue through return on investments from ownership interests in manufacturers and distributors. Surgeons must be careful that their ownership interests do not result in over-utilization of products paid for under federal healthcare programs or interfere with independent medical judgment.

MSOs, GPOs, and IPAs

With overhead costs rising and reimbursement rates declining, independent physician practices can benefit from leveraging their services and purchasing power by creating an integrated physician association ("IPA"). IPAs can be structured for various levels of integration from a loose, contractual affiliation to complete integration including billing under one provider number. IPAs allow physician practices to leverage purchasing power through group purchasing and contract negotiation for products and services such as office supplies, cleaning services, group health plans, office staff, and insurance. The IPA can also benefit from volume discount purchases through group purchasing organizations ("GPOs"), which give discounts and rebates, which are often more significant for higher volume purchases. Through integration, the IPA can also operate as a management services organization ("MSO") to provide services for its physician members. These models allow surgeons to leverage purchasing power and make purchases from their own organizations, resulting in greater revenue.

Ownership in ASCs and Hospitals

Surgeons can recognize increased revenue by owning ASCs and hospitals. These models align surgeon incentives with that of the entity resulting in operational efficiencies, cost-savings, and increased revenue for the surgeon owners. Hospital ownership is more limited for surgeons than ownership in ASCs, but can be accomplished by owning the real estate, and creative financing models.

Medical Tourism

Surgeons can combine work and relaxation through participating in medical tourism opportunities. For instance, the Greenbrier Medical Institute offers a program where surgeons can participate in a timeshare and provide services to patients while simultaneously enjoying the amenities the resort has to offer. This opportunity allows surgeons to travel, provide services to patients in a state-of-the-art setting, and also attracts high profile patients and surgeons.

Other Ideas

There are endless opportunities for entrepreneurial surgeons to increase their revenue. Some additional ideas include the following:

- Call coverage arrangements;
- Ownership in imaging and physical therapy service lines;
- Real estate ownership and leases;
- Billing company ownership and operations;
- Expansion assistance and consulting (i.e. physician recruitment);
- Efficiency through leveraging the use of physician assistants, advanced practice nurses, and residents; and
- Private label/generic implants.

Conclusion

As payers tighten their belts resulting in reduced payments to providers, surgeons with an entrepreneurial spirit can embrace this ever-changing regulatory environment by entering into innovative business arrangements which improve the quality of healthcare for patients, reduce healthcare costs, and allow surgeons recognize increased revenue for their efforts. In such a highly regulated environment, it is imperative that these models are properly structured in accordance with federal, state, and local laws and regulations. As such, it is important that you consult experienced, healthcare legal counsel to assist you in taking advantage of these innovative business structures that can significantly enhance the revenue cycle of your practice.

For additional information on these opportunities, please contact Jack T. Diamond, Esq. (330) 253-1820, jtdiamond@bmdllc.com, Jeana Singleton, Esq. (330) 253-2001, jmsingleton@bmdllc.com, or Samantha L. Prokop, Esq. (330) 253-3766, slprokop@bmdllc.com.

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Knee replacement survival rates with all-polyethylene or metal-backed tibial components – what do the Registries say?

Arthur Turow BMBS, B Med Sci[¥], David Campbell BMBS, PhD, FRACS[§]

Abstractv

Background: With increasing numbers of primary total knee arthroplasty and ongoing economic pressure the use of all-polyethylene tibial components maybe an alternative option to achieve cost savings without an adverse impact on outcomes

Methods: A search of all publically available joint replacement registry data investigated the performance of all-polyethylene tibial components compared to metal backed modular tibial components.

Results: All-polyethylene tibial components were used in 0.47% of Australian and 1.2% of England and Wales national register reported knees. 2.6% of Norwegian fixed platform knees were all-polyethylene. Large institutional registers from the United States of America reported usage rates of 4%, 8.3% and 8.9%. Revision rates for all-polyethylene implants were comparable or better than modular components in all registries. Only one registry had sufficient data on patients aged less than 65 years who report a hazard ratio of 0.26.

Conclusion: In patients 65 years and older all polyethylene tibial components have similar rates of revision compared to metal backed. There is insufficient data in younger patients.

Introduction

Early total knee arthroplasty systems almost exclusively utilized all-polyethylene tibial components. When the tibial component was identified as a substantial source of implant failure [1-3], significant attention was directed towards improving these early systems. In-vitro biomechanical analyses that followed [4-6], demonstrated metal-backed components to have reduced stresses on the underlying cancellous bone and better distribution of symmetric loading forces when compared to the all-polyethylene designs. This lead to metal-backed tibial components to be more widely used, despite some metal-backed variants yielding highly unfavorable results [7]. Subsequently, further developments of metal-backed designs incorporated modularity, which allowed for intra-operative flexibility as well as the ability to apply a porous coating, and contributed further to the decline in the all-polyethylene tibial component use [7-9].

Concerns about implant deformity and subsidence raised by the biomechanical models, have not been echoed by long-term follow-up studies [10-14]. Failure rates of all-polyethylene tibial components are reported at rates of less than 10%, with even lower failure rates for patients aged 70 or older. A recent prospective study of 443 total knee arthroplasties reported survivorship of all-polyethylene tibial components of 99.4% at 14.3 years follow-up [15].

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Economic pressures have stimulated a revisit of all-polyethylene designs. With increasing volumes of total knee arthroplasties [7,16-19], cost savings can be substantial. Some studies report considerable cost reduction of 24-48% when all-polyethylene instead of metal-backed tibial implants are used [7,8, 15,17].

We examined currently available registry data in joint replacement registries from Australia, New Zealand, The United Kingdom, Norway, Sweden, and regional registries from the United States of America. We revisited the original design premise that metal-backed tibial components were superior to all polyethylene tibial components and performed a review of the current literature.

Registry Data

Currently, only two national joint registries specifically report on all-polyethylene tibial prostheses: the National Joint Registry (NJR) for England and Wales and the Australian Orthopaedic Association National

Joint Replacement Registry (AOANJRR). Most other registries do not provide publically available data on all-polyethylene tibial components or their survival [20-22]. The Register of Orthopaedic Prosthetic Implants [23] only reports on all-polyethylene implants in unicompartmental knees. The Swedish Knee Arthroplasty Register [24] remarks that all-polyethylene tibial components had been used, but fails to elaborate on their prevalence or outcomes. Minimal data is available from the Norwegian Arthroplasty Register [25]. The registry recorded an all-polyethylene tibial component in 65 out of 2494 (2.6%) fixed platform knees in 2009. All-polyethylene prostheses use in the previous years has been almost non-existent, with merely eleven all-polyethylene implants recorded since 1994. No outcome measures are provided.

The AOANJRR began data collection on September 1st in 1999 and data collection was implemented in a staged fashion, capturing all joint replacements on a national level in 2002. All Australian hospitals undertaking joint replacement surgery contribute data to the registry. As of December 2012, the registry recorded 342457 primary total knee replacements. 240983 were modular fixed bearing and in 1225 knees an all-polyethylene component was used, representing an overall uptake of merely 0.47%. Cumulative percent revision rates were similar for the first two years between metal backed and all-polyethylene components (HR 0.90; p=0.654) but after this time, all-polyethylene components had a higher rate of revision (HR 1.75; p<0.001). Rates of revision vary, depending on which implants had been used. The Stryker Scorpio Series 7000 and the Optitrack-PS performed worse than all other prostheses in this group and, when excluded, there was no observable difference (all-polyethylene excluding Optitack and Scorpio 3.1 [1.7, 5.6] compared to modular 5.2 [5.1, 5.4]). Furthermore, due to the low number of all-polyethylene tibial prostheses used, direct and meaningful comparison with modular fixed bearing knees becomes difficult.

The National Joint Registry of England and Wales was established in 2003 and data is contributed by NHS and privately funded operations. As of March 2013, 490939 cemented primary total knees were recorded [26]. All-polyethylene tibial implants were used in 6124 knees (1.2%). Uptake of all-polyethylene components has steadily increased from 0.3% in 2003 to 2.1% of yearly procedures. Kaplan Meier estimates of failure rates at 9 years are promising (2.64%; 1.96-3.55, 95% CI) and are, in fact, lower than those of unconstrained, fixed cemented total knee replacements (2.90%; 2.77-3.04, 95% CI).

Data from community registries is available via prospective studies. Rand and colleagues [27] examined 11606 primary joint replacements registered at the Mayo clinic between January 1978 and December 2000. All-polyethylene designs had been used in 464 knees (4%) with 97% (94-99, 95% CI) projected survivorship at 10 years; comparing favorably to metal-backed implants (90%; 89-91, 95% CI).

Another community registry showed similar results. Gioe and colleagues [15] examined 5420 primary total knee replacements. 443 knees (8.9%) received an all-polyethylene tibial implant. The authors reported a Kaplan-Meier survival at 14.3 years of 99.4% for revisions for any reason and of 99.7% for revisions where aseptic loosening or wear was used as the end-point.

In a recent prospective analysis [28] of the Kaiser Permanente Total Joint Replacement Registry 27657 primary total knee replacements were examined. All-polyethylene tibial component uptake was 8.3% (2306). The authors found lower revision rates for the all-polyethylene components (0.30 vs. 0.65 for modular implants per 100 observed year). They also demonstrated that, in age adjusted models, patients younger than 65 years had a decreased risk of

revision for any cause if all-polyethylene rather than modular components had been implanted (HR 0.26; 95% CI 0.35-0.99; p=0.045).

Discussion

Currently available registry data appears to be consistent with previously published data for elderly patients [12-15,29]. Pagnano and colleagues [12] followed 81 knees in 59 patients 75 years or older for 8.1 years. Only one patient required revision surgery for medial instability. Extrapolated survivorship at 14 years was 98% for any cause and 100% for symptomatic aseptic loosening. Similarly, an earlier study of 98 primary total knee replacements with an average patient age of 82 years [29] demonstrated that 97% of all-polyethylene tibial components did not require revision surgery at 12 years.

Two recent systematic reviews [30,31] showed similar results. All-polyethylene tibial components were shown to perform on par to their metal backed counterparts. In fact, Voigt and colleagues [31] demonstrated that this was independent of implant manufacturer and that the all-polyethylene tibial implants had a smaller probability of failing due to instability than the metal backed designs.

Data for younger patient cohorts has been limited. One small study examined all-polyethylene tibial components in 38 patients who were younger than 60 years of age [32,33]. After a mean follow-up of 12.4 years (range 12-18), the authors reported a survivorship of 95.5% as well as excellent performance in activities of daily living.

The study from Moham and colleagues [28] shows promising results for younger patients. However, a high prevalence of metal-backed implants and an overall poor uptake of the all-polyethylene alternatives render the survival data of tibial designs in this younger age group inconclusive. This appears to be reflected in the cumulative percent revision rates of the AONJRR. More than half of the all-polyethylene tibial implants in the AOANJRR were Stryker Scorpio Series 7000 or Optitrack-PS. These implants performed slightly worse than the other implant types and its predominance in the relatively small number of revisions skews the overall outcomes. It would be interesting to see if exclusion of these two implants from the AOANJRR data as well as a separate analysis for younger patients would yield different results.

Previously, several authors have ascribed the good outcomes of all-polyethylene designs to the inherently low activity levels in older patients [12,29]. However, the advantages that all-polyethylene implants offer, namely avoidance of mechanical interlocking and backside wear issues as well as higher resistance to wear due to thicker polyethylene, do not support that argument. Whether our results are due to different loading stresses on the tibial component in more active patients or are related to inherent differences in these two patient cohorts and their environmental exposures is unclear. Discrepancies in expectations of implant performance and surgical outcome might also results in a higher rate of revisions related to pain between these two age groups.

When revising a total knee arthroplasty for wear, the advantages of an isolated bearing exchange is appealing. The potential advantage of benign revision options with implant retention and polyethylene liner exchange has not performed as expected; there is a high rate of failure with isolated polyethylene exchange which has been attributed to deterioration of the polyethylene locking mechanism [34,35]. Modular metal-backed tibial implants may have a different mode of failure compared to non-modular implants. Backside wear is a unique consequence of tibial modularity [36] and may present with silent osteolysis that can be associated with dramatic bone

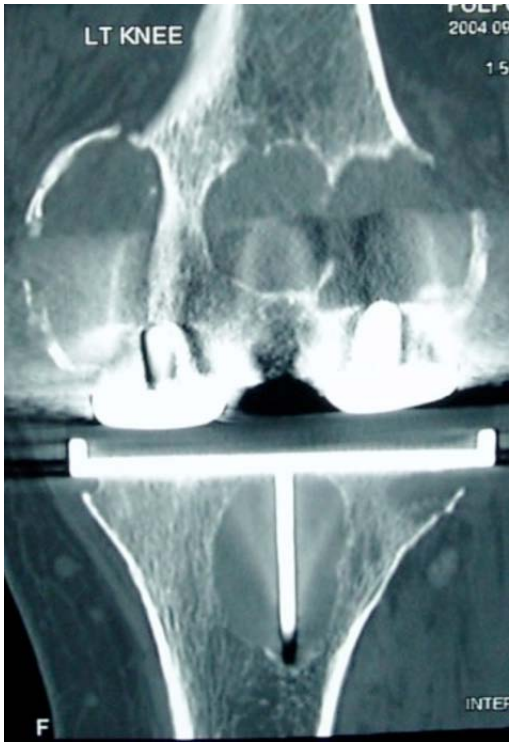

Figure 1. Modular metal-backed knee arthroplasty associated with asymptotic osteolysis at seven years. The knee was revised with implant exchange and extensive bone defect grafting.

deficiency (Figure 1). Further, the addition of metal-backed implants obscures imaging leading to poor detection and definition of osteolytic defects compared to a non-metal implant [37]. Conversely, revision for wear of an all-polyethylene implant is usually a simple procedure as the polyethylene implant is readily removed with a power saw without additional bone loss and the original cement mantle can occasionally be preserved (Figure 2).

Figure 2. Non-modular all-polyethylene knee arthroplasty in a 24 year old male with post traumatic arthritis. Revised for symptomatic wear-related instability and effusion at 30 years with a primary implant.

Radiostereophotogrammetric analysis (RSA) has been shown to be highly sensitive in predicting mechanical failure of the tibial component based on progressive implant migration at one to two years after operation [8,38,39]. Randomized RSA studies have not demonstrated metal-backed tibial components to be superior to their all-polyethylene counterparts [8,40-44]. In a randomized trial, Hyldahl and colleagues [42] prospectively examined 40 cemented low-conforming total knee arthroplasties (AGC, Biomet) using RSA. The authors found no difference in migration between twenty all-polyethylene tibial components and twenty identical, but metal-backed components at two years after surgery. The same authors [43] also examined 40 patients where tibial components (AGC, Biomet) were horizontally cemented, leaving the stem uncemented. Their results at two years follow-up showed that the metal backed components had sustained significantly more longitudinal rotation and had significantly higher maximal total point motions than the all-polyethylene implants.

There is a significant price differential between all-polyethylene and metal-backed tibial components. This is often justified by more intra- and postoperative advantages of the metal-backed designs: possibility for cementless fixation, polyethylene liner selection after tray insertion, liner exchange without removing the tibial component and excellent clinical outcomes [7,45-47]. Nevertheless, previous research has failed to show any significant superiority of the metal-backed systems [48-51]. For example, Bettinson and colleagues examined 293 patients in their prospective randomised controlled trial and concluded that, at ten years, there was no significant difference in survivorship between the all-polyethylene and metal-backed designs. With increasing volumes of total knee arthroplasties and a changing health-care environment, justification of an increased expense of metal-backed tibial components, in particular for an elderly patient cohort, becomes increasingly difficult.

In areas where all-polyethylene tibial components are actively promoted [15,28], their use is relatively high. Data from the UK and Norway shows increasing all-polyethylene prostheses uptake [25,26] and this could be related to increased awareness or costing pressures. In contrast, all-polyethylene tibial implant use in other regions is either stagnant [16,52] or so low that registries do not report on it. It is uncertain why this is the case.

Despite registry data being in line with previous research, fundamental limitations exist and these predominately reflect the nature of data collection. As the registry focuses on surgical outcomes of primary knee replacements, clinical and radiological outcomes are not recorded. Similarly, registry data can be adjusted for patient demographics, but not for the indication for implant selection by the operating surgeon for either the primary or subsequent revision, possibly resulting in a degree of selection bias between the two implant types.

Conclusion

Current registry data, together with previously published research, suggests that in patients 65 years and older all polyethylene tibial components have similar rates of revision as metal backed designs. This highlights the necessity to rethink indications for all-polyethylene tibial components in this patient cohort. Recent data for younger patients is promising, however, due to the high prevalence of metal backed options and an overall poor uptake of all-polyethylene implants, data for the use of all-polyethylene components in this cohort is inadequate.

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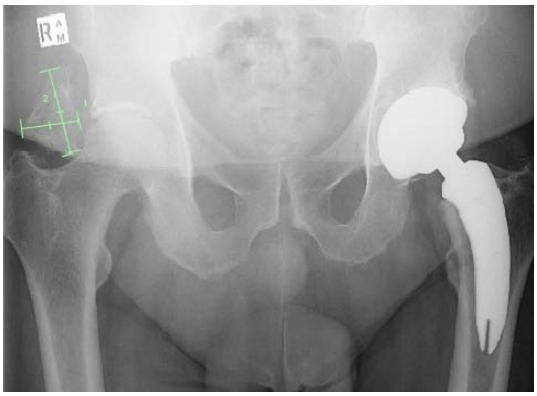
Letter to the Editor

Dear Tim,

I attach the three month x-rays of Mr TP, a 55 year old male. He previously suffered a bilateral fracture of the femoral shaft treated with open K nails and a crush injury to his ankle.



The patient reports, three months post operatively that he is "absolutely brilliant". Six weeks post op he returned to working ten hours a day five days a week as a kitchen hand. He can stand and lift and comments on how marvellous his function is and his pain is relieved.

This marked early improvement in function is noted in patients with MSA stems and it does differ from the function seen in total hip replacement patients. I am uncertain if this related to the lesser invasive procedure with retention of neck but it is a feature associated with the implant.

I think it would be a tragedy if the effectiveness of MSA and potentially other mini stems is lost in the background noise of trunions and metallosis associated with them. It is imperative we keep our focus on the excellent outcome patients can and do achieve with the MSA.

Regards,
Adrian van der Rijt

Dear Adrian,

Thank you for your letter with regard to your personal experience with the MSA™ Neck Persevering Stem. You have appreciated the biomechanical advantages of neck retention since our early discussions back in 1997. Past surgeon design leaders like Freeman and Pipino have been advocating saving the femoral neck since the late 1970s. The reduced axial and torsional moments provided by neck retention is a concept that we have actively advocated since 1997. The MSA™ Stem represents a refined design concept that incorporates a proximal conical flair that enhances proximal compressive load transfer to the medial calcar. Your personal experience matches that of our ARC™ Neck Persevering Stem here in the United States. Both the MSA and ARC feature a modular c.c. neck with this novel proximal conical flair.

You correctly raise the concern that recent results with certain modular devices have tainted the concept of neck modularity. First and foremost the MSA and ARC stems designs are short curved neck preserving designs with specific designs features unique to those individual stems. Conventional modular neck resection devices have a much harsher biomechanical effect on their modular junction as compared to neck preserving designs. This is proven by both biomechanical studies and clinical evidence as presented over the past couple of years. In close to 3,000 cases between the MSA and ARC stems I am aware of one reported pseudotumor in Australia (Metal on Metal bearing) and two reported pseudotumors in the States (Metal on Metal bearing) and one possible metal on poly bearing. The MSA has been implanted since 2007 and the ARC since April 2010.

Short curved neck preserving stems have started to dominate the European short stem market and are growing in awareness here in the States. There is no question that the surgical technique is slightly different and requires some expertise as compared to metaphyseal short stems but the benefits can be very impressive as you point out. I believe short stems are here to stay and short curved neck preserving stems will continue to survive and prosper. As for neck modularity there is no question that the recent results of the Stryker modular junction has raised concern about modularity in general. However as time moves on and the outcomes of enhanced modular neck junctions like the MSA and ARC will demonstrated that modular junctions can be designed and provide safe and effective outcomes. JISRF will continue to publish all results on modularity good, bad and ugly.

I thank you for your continued interest and please keep your observations and comments coming.

Sincerely,
Timothy McTighe

Suggested references can all be found on the JISRF TSI™ Study Group web site: www.jisrf.org

- September 2013 - Cementless Stem Selection and Options "JISRF Stem Classification System"
- October 2012 - Effect of Optimizing Bone-Implant Contact on Hip Offset and Anteversion with Three Contemporary Uncemented Short Metaphyseal-Engaging Implants
- October 2012 - Analysis of Neck Sparing (TSI) Versus Conventional Cementless Stem
- October 2012 - The First 1,200 U.S.A. (May 2010 - May 2012) Short Curved Neck Sparing Stems - Clinical Surgical Observations
- September 2012 - Early Experience with MSA™ Neck Sparing Stem Via Anterolateral Approach
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