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Reconstructive REVIEW

OFFICIAL JOURNAL OF THE

Joint Implant Surgery and Research Foundation

Strategic Alliance with

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JISRF

Joint Implant Surgery and Research Foundation

Strategic Alliance with

An Announcement From:

Dr Rami M Sorial FRACS FAOrthA

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

&

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

Executive Director, JISRF,

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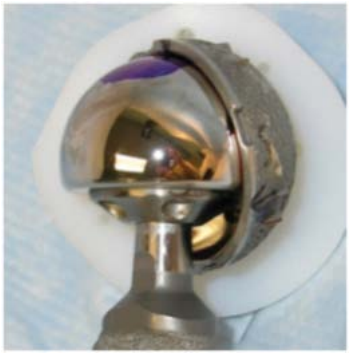

Metal on metal retrieval

Levels of Evidence

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

Levels of Evidence For Primary Research Question[1]

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

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

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Reconstructive Review

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Charles Bechtol, MD

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

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- Clinical/Surgical
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- Healthcare Policy/Economics
- Reviews
- Letters to the Editor
- Surveys

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  - Materials and Methods
  - Results
  - Discussion
  - References (for styles please refer to the website http://www.nlm.nih.gov/bsd/uniform_requirements.html)
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ORIGINAL ARTICLE
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Multimodal Venous Thromboembolism Prophylaxis with Preoperative Thrombophilia Screening Examinations for Total Hip and Knee Arthroplasties

Oshima Y [1], Fetto J [1]

Abstract

Objective: To evaluate the efficacy of a multimodal venous thromboembolism (VTE) prophylaxis including preoperative thrombophilia screening for total hip and knee arthroplasties (THAs and TKAs) and to consider the possibility of utilizing thrombophilic blood markers for preoperative identification of patients with high risk for VTE.

Method: The physical evaluation, involving the medical history of previous VTE, recent malignancy, and preoperative prolonged immobility status, and the existence of deep venous thrombosis (DVT) detected by duplex venous ultrasonography were assessed. Then, the patients with high risk of VTE were offered an inferior vena cava (IVC) filter preoperatively. The laboratory examination of complete blood count and standard biochemistry with factor VIII, activated protein C resistance (APCR), and prothrombin gene mutation were also measured. The operations were performed under regional anesthesia in most cases, and with venous foot pump (VFP), and early mobilization and aspirin (325 mg) daily were applied postoperatively.

Results: IVC filters were placed in 6, and acute DVT was detected in 5 of the total 99 cases. However, there was no critical bleeding or fatal VTE. In the blood markers, prothrombin mutation and factor VIII seemed to have a relation to DVT.

Conclusion: The efficacy of our multimodal protocol was confirmed. Further research is necessary to apply factor VIII and prothrombin gene mutation as thrombophilic blood markers.

Keywords*: total hip and knee arthroplasties, multimodal venous thromboembolism prophylaxis, thrombophilia screening examinations, factor VIII, prothrombin gene mutation*
Level of Evidence*: AAOS Therapeutic Level IV*

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***Abbreviations**: total hip and knee arthroplasties (THAs and TKAs); venous thromboembolism (VTE); deep venous thrombosis (DVT); pulmonary embolism (PE); inferior vena cava (IVC); intermittent pneumatic compression (IPC); venous foot pump (VFP); low molecular weight heparin (LMWH); activated protein C resistance (APCR)*

Introduction

Total hip and knee arthroplasties (THAs and TKAs) are highly successful treatments for severe arthritis to remove pain, increase functional ability, and improve the quality of life. [1] In 2009, there were an estimated 284,000 primary THAs, 45,000 revision THAs, 619,000 primary TKAs, and 59,500 revisions TKAs performed in the USA, and these numbers are expected to increase in the future. [2]

Generally, the factors related to surgery including the operative procedures, the use of pneumatic tourniquet, and the heat of bone cement, together with the patients' inherent factors and intra- and post-operative immobilization are thrombogenic stimuli, which are part of Virchow's triad of hypercoagulability, hemodynamic stasis, and endothelial injury. [3] The surgery is a traumatic event that increases the risk of venous thromboembolism (VTE) including deep venous thrombosis (DVT) and pulmonary embolism (PE). Especially THAs and TKAs have been reported to have high incidence of VTE in surgery. [4, 5]

The incidence of DVT without prophylaxis after THAs and TKAs has been reported to be 42 to 57 % and 41 to 85 %, and the incidence of fatal PE is 0.1 to 2.0 % and 0.1 to 1.7 %, respectively. [6] However, VTE is considered to be a preventable cause of hospital readmission and death. [7,8]

Traditional VTE prophylaxis is composed of mechanical and pharmacological categories. The mechanical treatments with early mobilization, the use of elastic stocking, intermittent pneumatic compression (IPC) and venous foot pump (VFP) devices work against the immobility status to prevent blood stagnation and promote blood circulation. [9] The pharmacological prophylaxis has been developed with many anticoagulant agents, i.e. aspirin, warfarin, unfractionated heparin, low molecular weight heparin (LMWH), factor Xa inhibitors, and thrombin inhibitors. However, the most effective or the gold standard treatment for VTE prophylaxis with the optimum outcome, minimum risk and acceptable expense after THAs and TKAs remains undecided. [10] This situation has been made more confusing by the assumption discussed by all of the published studies, that all patients undergoing THAs and TKAs present with an equal genetic potential for suffering of a VTE event. This is a wholly unsupported assumption which compromises the conclusions made regarding the benefits of one prophylaxis protocol or agent over another.

A multimodal thromboprophylaxis with regional anesthesia, VFP, early mobilization and aspirin has been applied at our institution, and the outcome was acceptable without any critical complications or fatal VTE. [11,12] However, the question remains of whether additional approaches are needed for preventively and objectively identifying patients with inherent or acquired thrombophilia condition. [13]

We hypothesized that a multimodal VTE prophylaxis with aspirin would be able to perform even better if we could identify and exclude patients with a demonstrated increased risk for VTE. Thus, the primary objective of the present study was to evaluate the efficacy of a multimodal VTE prophylaxis with preoperative thrombophilia screening examinations involving preoperative physical evaluations and duplex venous ultrasonography for THAs and TKAs. Moreover, many blood markers for thrombophilia screening have been reported, however, it is still debatable which markers are reliable and how to use these markers for patient selection before surgery. Therefore, the second objective was to consider the possibility of utilizing thrombophilic blood markers for preoperative identification of patients with high risk for VTE.

Patients and Methods

Between January 2011 and June 2014, 135 primary and revision THAs and TKAs were performed by a single surgeon with a multimodal VTE prophylaxis in 113 unselected, consecutive patients. Prior to the surgery, all patients received preoperative physical evaluations by their primary care physicians. Patients without all items of laboratory examinations were excluded.

1. *Preoperation*

   To detect thrombophilia as a high risk condition for VTE, physical evaluation, involving the medical history of previous VTE, recent malignancy, and preoperative prolonged immobility status, and the existence of DVT by duplex venous ultrasonography were assessed for all pre-surgical patients. Moreover, laboratory examination of complete blood count and standard biochemistry with factor VIII, activated protein C resistance (APCR), and prothrombin gene mutation were measured.

   Those patients with positive physical evaluations and a pre-existing DVT were regarded as having an increased thromboembolic risk. These patients were examined by hematologists at our institute, and treatments with a removable inferior vena cava

(IVC) filter and anticoagulants of warfarin, heparin, or LMWH, were applied to maintain blood coagulation level at international normalized ratio of 2.0, when necessary. IVC filters were usually removed 3 months after surgery.

2. *Intraoperation*

Regional anesthesia was undertaken, in which the physical conditions were stable and pain management was achieved. Otherwise, patients were operated under general anesthesia.

THAs were performed through a posterior approach with noncemented FMP Acetabular and Revelation Hip System (DJO Global, Vista, CA). TKAs were performed through a parapatellar approach with cemented 3DKnee System (DJO Global, Vista, CA). Patella was replaced in all cases. Pneumatic tourniquet was applied only during cementing process, usually 15 to 20 minutes.

VFP (Covidien, Mansfield, MA) were worn on the contralateral site foot from the beginning of surgery, and on the surgical site from just after surgery. This device consists of an anatomically shaped inflation pad and cushioned foot cover that can withstand a period of rapid inflation (0.4 seconds) followed by a 3 second impulse hold time to achieve a pressure of 130 mmHg and a 20 second deflation period.

3. *Postoperation*

VFP were worn on both feet throughout hospitalization, usually for two to three days after surgery. Ankle and toe mobilization was started with a physical therapist from the night of surgery. Full weight bearing ambulation with a walker, crutches, or a cane was started from the morning of the first postoperative day. Patients received two sessions of physical therapy per day during their hospitalization. Aspirin (acetylsalicylic acid) 325 mg daily was administrated for six weeks, started from the night of surgery. Celecoxib (COX-2 selective nonsteroidal anti-inflammatory drug) 400 mg per day and oral opioids were prescribed for breakthrough pain.

All patients were followed for three months after surgery, and none was lost to follow-up. Standardized clinical criteria were used to identify probable cases of DVT (tenderness or discomfort of the calf or thigh, a positive Homan's sign, edema of the leg and ankle, and increase in local temperature) or PE (pleuritic chest pain, dyspnea, arterial blood gas measurements, changes in the chest radiograph and/or changes in the electrocardiogram). [11] Routine venography or duplex venous ultrasonography was not performed.

This study was approved by Institution Review Board (IRB). All patients provided informed consent. No funding or financial benefits were provided to the authors for the project from any source.

Statistical Analysis

Descriptive statistics were used to describe the subject population and evaluate the incidence of VTE. Fisher's exact tests were used to compare the rates of VTE for each of the variables included. Logistic regression was used to identify factors related to the occurrence of VTE while controlling for all other variables. All statistical analyses were performed with SPSS version 19.0 software (SPSS Inc., Chicago, Il), and significance level was set at $p < 0.05$.

Results

Ninety-nine cases in 83 patients were enrolled. Sixteen patients had received 2 separated surgeries during this time periods (Table 1). Of 99 cases, 42 were male and 57 were female. The mean age was 68 years (range from 36 to 92 years). Fifty-two cases were primary THAs, 32 were primary TKAs, 11 were revision THAs, and 4 were revision TKAs. Six patients with 8 cases were severely obese (40 $kg/m^2 > BMI \geq 35\ kg/m^2$), and 5 patients with 6 cases were morbidly obese ($BMI \geq 40\ kg/m^2$). The procedures of anesthesia were regional in 81 cases (81.8%) (femoral nerve block : 1, epidural : 21, spinal : 59), and general in 18 cases (18.2%).

Table 1: Patients with 2 surgeries

Total number of patients:	16
Simultaneous bilateral THA:	5
Simultaneous bilateral TKA:	6
Two staged bilateral THA:	1
Two staged bilateral TKA:	1
Primary THA and revision THA:	2
Revision THA and contralateral primary THA:	1

One patient with a revision THA had already had a permanent IVC filter in place at the time of initial consultation, because of a prior history of PE and chronic distal DVT. No additional VTE treatment was performed for this patient, however, he did not have any further episode of VTE. IVC filters were placed for 6 cases in 5 additional patients, and thus, the total was 7 cases in 6 patients.

Acute DVT was detected postoperatively in 5 cases in 4 patients, all of which were distal. An IVC filter had been newly placed preoperatively in only one among these 5 cases in 4 patients with acute DVT, and this was the only case of acute DVT among the 6 newly placed filter cases.

Six patients had previous VTE histories, and 1 patient, as mentioned above, had already received a filter. Because 2 out of 5 patients had rejected treatments with a filter and additional anticoagulants, these patients received only the standard treatment with aspirin, and the other 3 patients received new filters and additional anticoagulant treatments. One patient with a newly placed filter had acute DVT after surgery, however, there was no fatal VTE.

All patients suffered from severe hip or knee pain preoperatively, however, none were categorized as critically immobilized.

For malignancy, 6 patients with 8 cases had histories, and 5 patients with 6 cases were in remission. One patient with 2 cases was suffering from an advanced stage breast cancer, however, that patient rejected any additional anticoagulant and/or filter treatment. She received only our standard treatment, however, there was no critical VTE after surgery. Thus, no filter nor additional anticoagulant treatment was applied for malignancy in any cases.

Ten patients with 15 cases had histories of cardiovascular diseases, and they consulted cardiologists. Most of these were treated with warfarin, started before surgery.

In the preoperative laboratory examinations, factor VIII was elevated in 40 patients with 49 cases, in which all the acute and chronic DVT cases were included (P=0.012). APCR was lower than normal in 2 patients with 2 cases, however, these cases did not involve any VTE episode. Heterozygosity of prothrombin gene was shown in 4 patients with 5 cases, in which one case had a prior VTE history, 1 case had prior VTE and chronic DVT, and 1 case had prior VTE and acute DVT (Table 2).

A 71-year-old male, who had suffered from hypertension, hypertrophic obstructive cardiomyopathy, aortic regurgitation, and diabetes, died 2 weeks after primary TKA under general anesthesia. However, autopsy determined cause of death to be acute myocardial infarction. Consequently, there was no patient readmitted or reoperated with critical bleeding, major wound complications, or critical VTE.

Table 2: Heterozygosity of prothrombin gene mutation

Age, Gender	Factor VII	APCR	Surgery	Anesthesia	VTE History	Filter	DVT
71-y-o, male	219	2.9	Revision THA	General	PE and chronic DVT	Prior filter	Chronic
70-y-o, female	207	3.05	Revision THA	Regional	None	Received a new filter	Acute
85-y-o, male	141	2.84	Revision THA	Regional	DVT	Received a new filter	None
91-y-o, male	106	2.59	Two staged TKAs	Regional	None	No filter	None

Discussion

VTE is a common multicausal disease affected by interaction of genetic, environmental and behavioral factors. [14] Many surgeons tend to focus on DVT prophylaxis to prevent VTE, however, low correlation has been found between DVT and PE. [9,15] Accordingly, we have been applying a multimodal VTE prophylaxis to manage each risk factor of VTE step by step.

Firstly, to minimize the immobilization period, VFP and early mobilization are applied. However, additional chemoprophylaxis is still thought to be necessary, especially for patients at high risk for VTE. [9]

Recently, many anticoagulant agents have been developed and applied to target different steps of the coagulation cascade, in which fibrin becomes blood clot at the end. The balancing of clotting and bleeding is essential, however, some of the recent anticoagulants are costly and may increase such wound complications as hematoma, delayed wound healing, surgical site infection, and uncontrolled bleeding. [13,15] Thus, the routine use of these agents for all patients has been questioned. [16]

Aspirin, an antiplatelet drug, does not directly affect the coagulation cascade, and thus results in much less bleeding complication than aggressive anticoagulants. [15] Recently, the two most commonly applied guidelines, published by the American College of Chest Physicians (ACCP) and the American Academy of Orthopaedic Surgeons (AAOS) in the USA, have accepted aspirin as a VTE prophylaxis agent. [17]

The use of regional anesthesia has been shown to decrease the incidence of VTE and to attain the rehabilitative goals more rapidly compared to general anesthesia. [18] Consequently, regional anesthesia was applied for most of our cases, other than the physically morbid and some bilateral and revision cases. Because of its low risk for bleeding complication, aspirin could be applied safely even after spinal and epidural anesthesia. [15]

The efficacy and safety of VTE pro-

phylaxis using regional anesthesia, VFP, early mobilization and aspirin for THAs and TKAs had been confirmed. [4,11,12,15,16,19] However, it is still debatable whether aspirin is adequate for high risk patients of VTE. [13] Thus, preoperative screening examinations were used to detect and eliminate high risk patients, rather than applying the potent anticoagulants routinely to all. Obesity is commonly considered to be a risk factor of VTE. [4,16] However, while obesity has been reported to be a risk for peripheral edema, wound inflammation, and wound infection, [20,21] at least, no critical VTE was detected in the severe and morbid obese patients in the present study. Cardiovascular disease is a high risk for arterial complications, and actually one patient in this study died of acute myocardial infarction. However, cardiovascular disease, itself, is not directly linked to high risk of VTE. [14]

Blood markers have also been examined to detect thrombophilia conditions. [14,22] D-dimer rises during an acute event of VTE, however, it has been reported not to be an adequate marker for VTE risk screening, because the value easily varies depending upon the conditions and timing of taking blood samples. [23]

Elevated factor VIII has been reported to increase the risk of VTE. [22,23] Forty-nine among our 99 cases (49.5%), i.e. 40 among 83 patients showed elevated factor VIII levels, and all acute and chronic DVT cases in our study were included among this group with statistical significance. However, further research for the threshold of this marker for VTE risk screening is necessary. Factor V Leiden is a common genetic risk factor for VTE, and over 80% of the APCR phenotype can be explained by the factor V Leiden mutation. [24] Thus, we examined APCR levels, and 2 patients with 2 cases showed lower than normal, however, they had no episode of VTE before or after surgery. Prothrombin gene mutation has been shown to be associated with a high risk of VTE. [24] In the present study, prothrombin mutation seemed to have a relation to VTE. However, the benefit and accuracy of routine blood marker examinations for thrombophilia screening could not be proven even in our results. [24-26] Thus, blood markers have been used only as a reference at our institute.

After preoperative thrombophilia screening, we placed new filters and administered additional anticoagulants for 5 patients, and one among those 5 patients developed acute DVT. The remaining 4 patients did not have any VTE episodes after surgery. However, we do not know whether these were over treated or if VTE had actually been prevented in some patients by the multimodal prophylaxis.

This study has several limitations. It was a retrospective analysis based on a data source. It was not designed to investigate the incidence of VTE, nor did it include a control group. DVT evaluation was performed only for symptomatic patients, and thus asymptomatic DVT was not elucidated. Although we had never had any case of critical VTE with our multimodal VTE prophylaxis before introducing the VTE risk screening, we thought the screening to be beneficial for detecting high risk patients preoperatively. [11,12] Therefore, we applied the preoperative thrombophilia screening examinations, and tried to evaluate their usefulness in this study. Unfortunately, many patients had to be excluded from this study because of lack of blood marker data from primary care physicians.

The costs of blood screening examinations, duplex venous ultrasonography evaluation and IVC filter placement are much less than those associated with the use of recent anticoagulants or the cost for readmission, reoperation, or critical PE treatment. Therefore, our multimodal prophylaxis with preoperative thrombophilia screening is thought to be beneficial for THAs and TKAs, as it reduces the need for aggressive anticoagulants.

Conclusions

As there was neither critical bleeding nor fatal VTE when applied for THAs and TKAs, the efficacy of our multimodal VTE prophylaxis with preoperative thrombophilia screening examinations and mechanical and pharmacological prophylaxis has been confirmed. Further research, however, is necessary to discuss factor VIII and prothrombin gene mutation as useful markers for preoperative VTE risk assessment.

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New Instrumentation Reduces Operative Time in Medial Unicompartmental Knee Arthroplasty Using the Oxford Mobile Bearing Design

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Abstract

Redesigned instrumentation has become available for implantation of the Oxford Mobile Bearing Medial unicompartmental knee arthroplasty. To assess the benefit of these changes, we compared operative time of 200 Phase III and 176 Microplasty UKA done 2008-2011. An average time savings of 8.6 minutes was seen with the Microplasty design. Additionally, the standard deviation in operative times, minimum and maximum operatives were lower in knees in which Microplasty instrumentation was utilized. A 15% savings in operative time was seen with the new Microplasty instrumentation.

Keywords: *unicompartmental knee arthroplasty, surgical technique, instrumentation, mobile-bearing, operative time*
Level of Evidence: *AAOS Therapeutic Level III – Retrospective comparative therapeutic study*

Introduction

Multiple publications cite excellent results in terms of survivorship and functional outcomes with a medial-mobile bearing unicompartmental partial knee arthroplasty design utilizing the Phase III minimally invasive instrumentation platform (Zimmer Biomet, Warsaw, IN) (Figure 1A-D) [1-13]. The most recent modifications to the mobile-bearing Oxford Partial Knee Arthroplasty (Zimmer Biomet) were intended to enhance the stability and mechanics of the femoral component and improve the process of implantation and reproducibility of implant positioning. Previous reports have demonstrated good early outcomes and more accurate and reproducible femoral component alignment and implantation using this newer design and improved instrumentation [14,15]. Specific design changes to the instrumentation platform include sizing spoon-stylus system to decrease the need to recut the tibial plateau (Figure 2A-B), an intramedullary based femoral alignment guide (Figure 3A-B) and an accurate and efficient guide for reducing impingement (Figure 4A-B) (Microplasty Instrumentation; Zimmer Biomet). In addition to improved accuracy, the Microplasty instrumenta-

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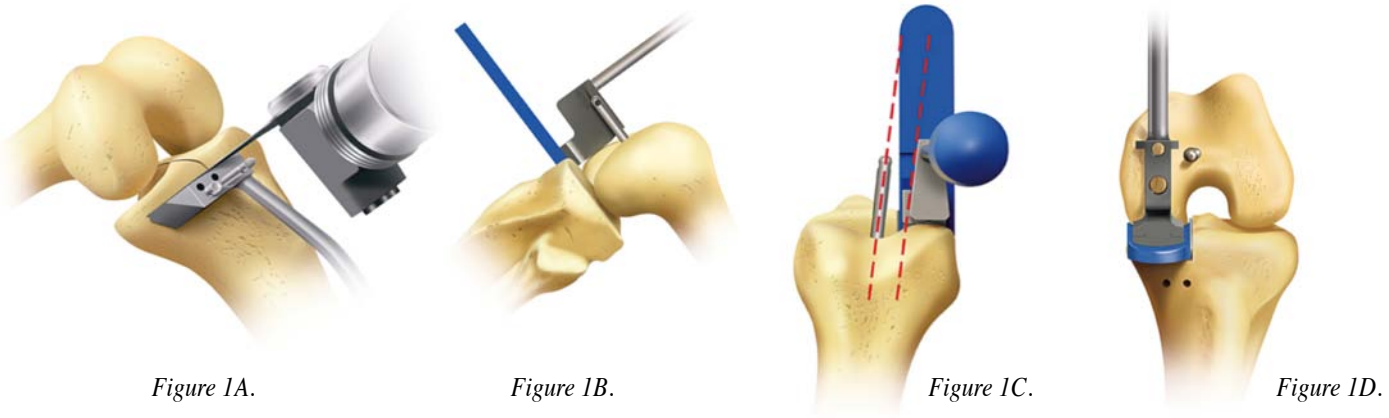

Figure 1A. *Figure 1B.* *Figure 1C.* *Figure 1D.*

Figure 1. The Phase III instrumentation: Tibial resection (1A), femoral alignment lateral view (1B), femoral alignment A/P view (1C), femoral alignment distal femoral view (1D) (Reproduced courtesy of Zimmer Biomet, Inc.)

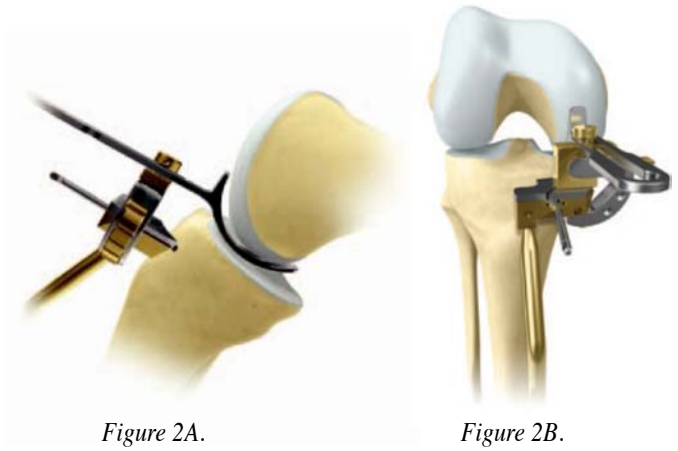

Figure 2A. *Figure 2B.*

Figure 2. Microplasty instrumentation tibial resection guide with spoon/stylus and "G-clamp" for setting resection depth: lateral view (2A), A/P view (2B). (Reproduced courtesy of Zimmer Biomet, Inc.)

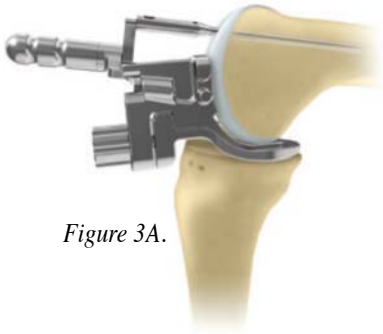

Figure 3A.

Figure 3. Microplasty intramedullary linked femoral alignment guide: lateral view (3A), A/P view (3B). (Reproduced courtesy of Zimmer Biomet, Inc.)

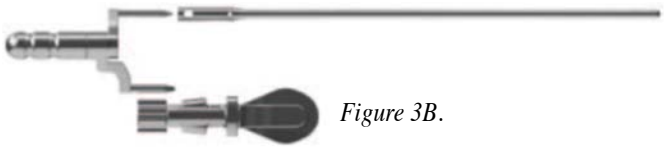

Figure 3B.

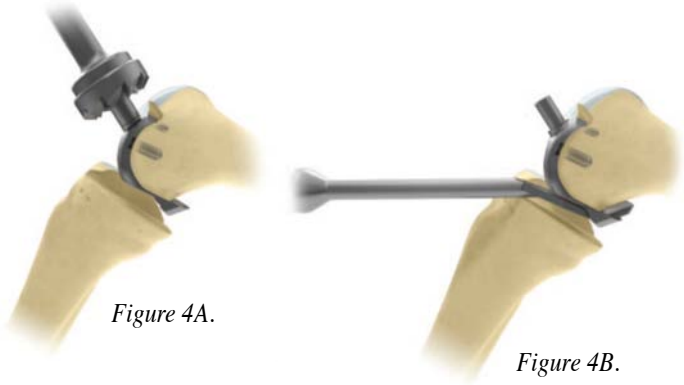

Figure 4A. *Figure 4B.*

Figure 4 Microplasty impingement removal device: Removal of anterior impingement (4A), removal of posterior impingement (4B). (Reproduced courtesy of Zimmer Biomet, Inc.)

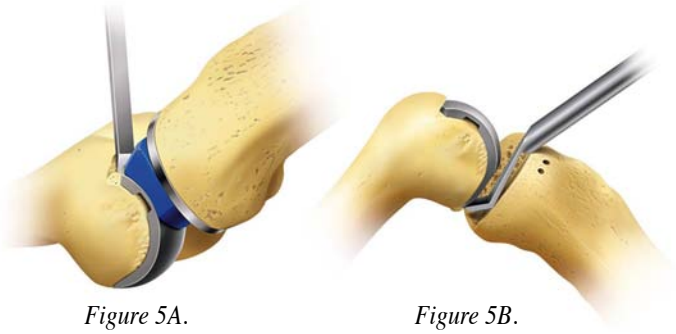

Figure 5A. *Figure 5B.*

Figure 5. For the Phase III instrumentation, anterior osteophytes and potential impinging bone were removed with the use of an osteotome: Removal of anterior impingement (5A), removal of posterior impingement (5B). (Reproduced courtesy of Zimmer Biomet, Inc.)

tion platform was intended to streamline the surgical procedure making it more efficient. The purpose of this study is to determine if the new Microplasty instrumentation allows for a more efficient surgical procedure that would translate into reduced operative time.

Materials and Methods

A query of our practice's arthroplasty registry revealed 176 knees in patients who signed an institutional review board-approved general research consent allowing retrospective review, and underwent medial unicompartmental knee arthroplasty (UKA) performed with the Microplasty instrumentation between July 2011 and December 2011. A matched group of 200 UKA in patients who signed an IRB-approved general research consent allowing retrospective review, implanted using the Phase III instrumentation and the single-peg femoral component from 2008 to 2011, was selected. Only procedures in which unilateral UKA were performed were examined; 38 simultaneous bilateral procedures were excluded (Table 1). The surgeons (KRB, AVL, JMH, MJM) begin using the Phase III instrumentation in July of 2004, and thus the Phase III group represents procedures that are well beyond the initial learning curve.

The preoperative diagnosis was avascular necrosis in 1 knee (enhanced twin-peg group) and osteoarthritis in all others. The groups were well matched in terms of gender, age, body mass index, preoperative ROM, and Knee Society pain and clinical scores. Forty-six percent of patients were males and 54% were females. Mean patient age at surgery was 63.7 years overall (stdev 9.1; range 29-88 years), mean BMI was 32.3 kg/m^2 (stdev 6.6, range 17-57 kg/ m^2), and mean ROM was 116.3° (stdev 7.7, range 90°-135°).

Operative time was recorded for each procedure. Operative time was defined as the time from initial incision until the final dressing was applied. Operative time between the Microplasty group and the Phase III group was compared using the Satterthwaite method and the Folded F test. Statistical significance was defined as $p<0.05$.

Results

The mean operative time was significantly shorter with the Microplasty instrumentation (49 minutes) compared with the Phase III (58 minutes). This difference was significant (t value 5.23; $p<0.0001$ and F value 1.41; $p=0.02$). Additionally, the standard deviation was significantly lower in the Microplasty group (14 minutes) versus the Phase III (17 minutes). The minimum and maximum operative times were also less in the Microplasty group compared with the Phase III (24-88 minutes versus 30-126 minutes).

Table 1. Demographics and results

Characteristic	Phase III Instrumentation	Microplasty Instrumentation	P value
Knees	200	176	
Patients	177	164	
Gender by patients			
Male patients	76 (43%)	81 (49%)	0.322
Female patients	101 (57%)	83 (51%)	
Gender by knees			
Knees in male patients	84 (42%)	86 (49%)	0.182
Knees in female patients	116 (58%)	90 (51%)	
Mean age (years)	62.9 (±9.6, 29-88)	64.5 (±8.5, 44-81)	0.086
Mean height (inches)	66.7 (±4.0, 59-76)	66.8 (±4.0, 59-75)	0.759
Mean weight (pounds)	202.0 (±42.0, 120-330)	207.6 (±47.0, 116-375)	0.227
Mean body mass index (kg/m2)	31.9 (±6.0, 17-52)	32.7 (±7.3, 17-57)	0.235
Mean preoperative range of motion (degrees)	116.5 (±7.8, 90-135)	116.1 (±7.6, 90-130)	0.640
Mean preoperative Knee Society pain score (0-50 possible)	9.8 (±11.8, 0-50)	9.5 (±10.6, 0-45)	0.834
Mean preoperative Knee Society clinical score (0-100 possible)	41.0 (±14.1, 18-83)	40.4 (±12.7, 23-94)	0.637
Mean operative time (minutes)	58.0 (±17.1, 30-126)	49.4 (±14.4, 24-88)	<0.001

Discussion

Unicompartmental knee arthroplasty (UKA) using the Oxford Phase III medial mobile-bearing knee has enjoyed excellent results [1-13]. Price and Svard reported 91.0% all cause cumulative survival rate at 20 years in a series of 543 patients (682 knees) [12]. Our center previously reported 95.2% survival at a mean of 3.7 years in 688 patients with 839 medial Oxford III UKA [1]. We have also previously reported that use of the new Microplasty instrumentation results in more accurate and reproducible femoral component placement [15]. White et al reported 100% survival and 97% patient satisfaction at 2 years postoperative utilizing the Microplasty instrumentation and twin-peg femoral design [14]. An additional goal of the new instrumentation was to allow for a more efficient procedure. The current study demonstrates that this new instrumentation platform reduces operative time.

Specifically, the three steps of the procedure in which we believe this improved efficiency and decreased operative time are gained include the tibial resection, femoral alignment, and removal of impingement. The spoon-based Microplasty instrumentation (Figure 2) references the posterior femoral condyle and acts as a stylus to accurately remove 6.5 (3 "G-clamp") or 7.5mm (4 "G-clamp) of tibial resection. This accuracy reduces the number of time the tibial plateau requires re-resection. Further, in our previous study, we noted that this bone-conserving approach to tibial preparation resulted in a greater number of thinner 3 and 4 mm bearings utilized in the Microplasty group [15]. This provides the added benefit of not only less operative time, but a more conservative tibial resection and less bone removal.

With Phase III instrumentation, femoral alignment required visualization and adjustment of 6 separate variables or alignment measurements (Figure 1A-D). This individual adjustment required checking each alignment position while manually holding the other 5 positions. With the intramedullary alignment guide, not only is the alignment more accurate and reproducible, but this step requires less operative time (Figure 3A-B). With Phase III instrumentation, anterior osteophytes and potential impinging bone were removed with the use of an osteotome (Figure 5A-B). This was inaccurate and frequently required checking the bearing in extension multiple times to ensure an appropriate amount of bone was removed. The Microplasty guide for removing impingement (Figure 4A-B) allows for this step to be performed once with no need to recheck impingement-free range of motion, thus reducing operative time. These efficiencies resulted in an average of almost 9 minutes less operative time or a 15% reduction.

Microplasty instrumentation decreases operative time for implanting the Oxford mobile-bearing medial unicompartmental knee. A 15% reduction in operative time could translate into the ability to perform more surgeries, decreased risk of infection, and decreased length of tourniquet use, all of which would have positive benefits to surgeon and patient.

Disclosure Statement

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

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Early Experience with a Modern Generation Knee System: Average 2 Years' Follow-up

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Abstract

Arthritis in the knee is a leading cause of pain and disability with total knee arthroplasty (TKA) often the treatment of choice after failure of more conservative treatments. TKA has been demonstrated to be one of the most successful procedures performed. However, despite the good long-term survivorship rates, patient satisfaction is still an issue post TKA with over 20% of patients exhibiting patient dissatisfaction most commonly due to anterior knee pain (over 18-28% patients) and mediolateral or varus-valgus instability. Recent studies have demonstrated that collateral ligament strains are altered post TKA which may lead to laxity and/or tightness of the ligaments resulting in patient discomfort, pain, stiffness and/or instability post TKA. As a result, it may be beneficial to ensure ligamentous strains after TKA are similar or close to the native situation. The purpose of this study was to evaluate the clinical and radiographic results of the Unity Knee™ Total Knee System (Corin Ltd, Cirencester, UK), a modern generation, single-radius total knee replacement (TKR) and its accompanying instrumentation which is designed to help maintain proper ligament balance and restore the medial joint-line. A total of 89 knees (89 patients) were implanted with the device in a single surgeon series. All patients were assessed using the American Knee Society Score (AKSS), the Oxford Knee Score (OKS), and radiographs. There was 1 revision due to infection and Kaplan-Meier survivorship was 98.9% at 2 years. The mean AKSS knee score for the total cohort was 87.1 ± 7.98 and the mean Oxford Knee score was 45.89 + 3.69. Radiographic review found no signs of radiographic failure in any of the knees. This study demonstrates good survivorship, clinical, and radiographic results at 2 years for this TKR.

Unity Knee™ Total Knee System

Keywords*: total knee arthroplasty; total knee replacement; knee prosthesis; treatment outcome; single radius, joint line preservation*
Level of Evidence*: AAOS Therapeutic Level IV*

Introduction

Arthritis in the knee is a leading cause of pain and disability [1] and when non-surgical treatments like medications and walking supports are no longer effective, total knee arthroplasty (TKA) is frequently the treatment of choice. It has been demonstrated to be a safe and effective procedure and one of the most successful procedures per-

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formed [2].

Despite the good long-term survivorship rates, patient satisfaction is still an issue post TKA with over 20% of patients exhibiting patient dissatisfaction [3]. In particular anterior knee pain is a persistent issue post-surgery with over 18-28% patients demonstrating pain. [4] In addition mediolateral or varus-valgus instability is the most common cause of instability resulting in early clinical failure post total knee arthroplasty [5,6,7]. Recent studies [8] have demonstrated that collateral ligament strains alter post TKA which may lead to laxity and/or tightness of the ligaments and subsequent instability and loss of motion. In order to prevent patient discomfort, pain, stiffness and/or instability post TKA, it may be beneficial to ensure ligamentous strains after TKA are similar or close to the native situation. It has been shown that structural damage occurs in ligaments from 5.14% strain levels [9]. Therefore, as a minimum, attempts should be made to keep strain levels below this by ensuring medial collateral ligament (MCL) isometry post TKA.

Studies have highlighted that both the medial and lateral posterior femoral condyles, in the native knee, are a single radius in the sagittal plane between 10˚ and 120˚ of flexion [10,11]. Modern TKA femoral implants which mimic this geometry have demonstrated improved mid-flexion stability, preventing anterior movement of the femoral component during flexion [13]. The cohort studies published on these designs have demonstrated faster rehabilitation, reduction in anterior knee pain and improved range of motion over traditional knee designs [13,14,15]. However, there have also been studies which do not demonstrate an improvement in function over traditional knee systems [16,17,18]. Hall et al [16] found comparable knee extensor mechanism function after TKA with either a single-radius or multi-radius implant. Jo et al [17] found no differences in Hospital for Special Surgery (HSS) knee scores, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and visual analog scale (VAS) of anterior knee pain during stair climbing in a single-radius knee design compared to a multi-radius knee design.

Biomechanically, the MCL is significant in maintaining knee stability post TKA. Unlike the lateral collateral ligament (LCL), the MCL remains near isometric with length changes less than 2% throughout the range of motion of the knee [19]. The MCL contributes 78% of the restraining force against valgus injuries in mid-flexion [20,21]. Given this significance of the MCL in maintaining knee stability post TKA, knee implant systems that focus on the optimization of MCL isometry through the range of motion may lead to improved outcomes.

The purpose of this study is to evaluate the early clinical and radiographic results of a modern, single-radius total knee replacement system that uses a unique instrumentation system to maintain balance throughout the range of motion. This study reports on 2 year post-operative outcomes of a modern knee system in a single surgeon series and compares this to published literature on more established traditional knee implants.

Materials and Methods

This retrospective/prospective study analyzes 2 year clinical and radiographic outcomes of patients in a consecutive single surgeon series who received the Unity™ Total Knee System (Corin Ltd., Cirencester, UK). The design of this total knee system utilizes a single radius implant geometry with an instrument platform which aims to maintain the medial joint-line throughout range of motion in order to optimize MCL isometry post TKA. In addition, the patellofemoral track in this design has a lower profile and an early lateralized anatomic patellar track compared with traditional knee systems, with the aim to reduce constraint on the patellofemoral mechanism and therefore minimize anterior knee pain [22]. The goal of this TKR system is to maintain balance throughout the range of motion, resulting in improved patient outcomes.

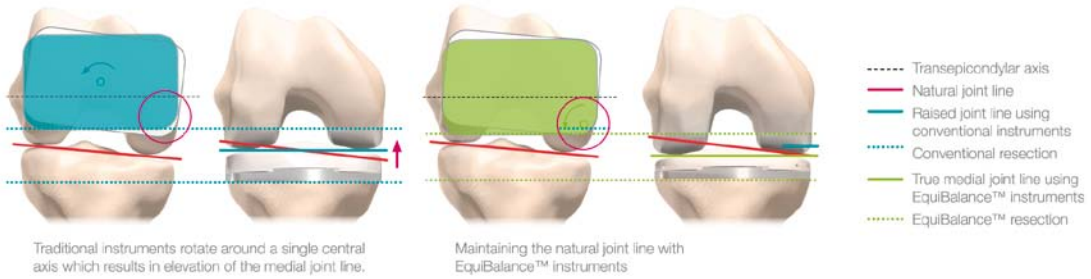
Eligibility criteria included skeletally mature male and female patients diagnosed as having severe osteoarthritis with clinical and radiological symptoms. The study was ethics approved and patients were properly consented to participate in the study. Retrospective data included pre-operative, operative, and early post-operative data obtained from clinic records and prospective data was collected during a clinic visit at the 2 year post-operative interval.

A total of 89 patients (31 males and 58 females) were implanted with the Unity knee system between March 2012 and January 2014 with an average of 68 years of age (SD = 8.49; range 45 – 87) and average BMI of 28.6 (SD = 5.33; range 19.8 – 45.5) at time of surgery. All patients had a primary diagnosis of osteoarthritis (Table 1).

All surgeries were conducted after extensive pre-operative planning which used long leg radiographs to assess the degree of deformity. All surgeries used the implant specific surgical technique and unique instrumentation to confirm rotation and ligament balance intra-operatively. All patients were implanted with posterior-stabilized (PS) implants using a minimally invasive approach under general anaesthesia. The patella was resurfaced on all patients using a domed patellar implant.

Survivorship, clinical outcomes and radiographic review were assessed at 2 years post-operative. Clinical out-

comes included the American Knee Society Score (AKSS), AKSS pain score, AKSS function score, and range of motion (ROM). The Oxford Knee Score (OKS) was also collected since it is a patient reported assessment of post-operative results. Weight-bearing anteroposterior (AP), lateral, skyline patella and long-leg x-rays were completed. Pre-operative x-rays were evaluated by each surgeon and post-operative x-rays were evaluated by an independent reviewer. Radiographs were assessed for signs of aseptic loosening including radiolucent lines >2mm in 50% or more of zones around a single component, measurable changes of tibial vertical migration and/or subsidence >2mm, measurable changes in angular orientation of any component >2 degrees, and progressive radiolucent lines, extending into one or more contiguous zones or expanding in width >2mm. Post-operative adverse events (AEs) were also reported.



Demographic and baseline characteristics were tabulated and descriptive analysis of patient outcomes (frequency, mean, standard deviation, minimum & maximum values) were completed. Additional analysis included Student t-tests for difference in means of outcomes scores for comparisons based upon on gender and Pearson correlation for analysis of interval data age and BMI.

Table 1
Patient Demographics and Surgical Details

	All		Male		Female	
	n		n		n	
Number of procedures	89		31	34.83%	58	65.17%
Number of patients	89		31	34.83%	58	65.17%
AGE & BMI	**mean**	**SD (R)**	**mean**	**SD (R)**	**mean**	**SD (R)**
Age at surgery (yrs)	68	8.49 (45.0-87.0)	67	9.73 (45.0-84.0)	69	7.66 (53.0-87.0)
BMI[1] at surgery	28.6	5.33 (19.8-45.5)	26.8*	3.21 (21.0-34.4)	29.5*	5.99 (19.8-45.5)
Primary Diagnosis	**n**	**%**	**n**	**%**	**n**	**%**
Osteoarthritis	89	100	31	100	58	100
Side	**n**	**%**	**n**	**%**	**n**	**%**
Left	34	38.2	9	29.03	25	43.1
Right	55	61.8	22	70.97	33	56.9
Implant Type	**n**	**%**	**n**	**%**	**n**	**%**
Cruciate Retaining (CR)	0	0	0	0	0	0
Posterior Stabilized (PS)	89	100	31	100	58	100
Patellar Resurfacing	**n**	**%**	**n**	**%**	**n**	**%**
Patella Resurfaced[2]	89	100	31	100	58	100
Patella Not Resurfaced	0	0	0	0	0	0
Approach	**n**	**%**	**n**	**%**	**n**	**%**
Minimally invasive (MIS)	89	100	31	100	58	100
Anaesthesia	**n**	**%**	**n**	**%**	**n**	**%**
General	89	100	31	100	58	100

**Significant difference $p < 0.05$*
[1]Due to missing height and weight some BMI are incalculable
[2]All patellar implants were domed.

Results

The mean follow-up for all subjects (n=89) was 1.95 years (SD 0.301; range 1.1 – 2.9 years). There was 1 revision for infection in a 72 year old male which occurred at 1.1 years post-operative. Kaplan-Meier survivorship at 2 years was 98.9%. There have been no deaths.

Female patients were on average 69 years of age with an average BMI of 29.5 at time of surgery with their male counterparts respectively 67 years of age and a BMI of 26.8. There was a significant difference between female and male patients on BMI ($p<.05$). See Table 1.

The mean AKSS knee score at 2 years post-operative for the total study group of 89 patients was 87.10 ± 7.98 (range 36 - 100), mean AKSS pain score of 48.64 ± 4.27 (range 20 – 50), AKSS function score of 96.42 ± 8.84 (range 60 – 100), and a mean ROM score of 24.63 ± 1.44 (range 16 – 25). The mean patient reported OKS was 45.89 ± 3.69 (range 23 – 48) out of a possible score of 48 (best outcome). This is consistent with the good AKSS results.

On examination, all patients had excellent anteroposterior and mediolateral stability in the knee. Three patients had a fixed flexion deformity (2 of 5° and 1 of 10°) and for one patient this was associated with quadriceps weakness (<10 degree lag). Average flexion was 136.31 ± 12.09 degrees (range 90 - 155).

Analysis examined the comparison of the AKSS outcomes scores by gender, which showed no significant difference between male and female patients (Table 2).

Analysis also demonstrated that age was significantly correlated to AKSS pain score ($p=0.01$) (Table 3). However, age and BMI are not predictive of any of the other AKSS scores or the OKS. The results demonstrated that older patients experienced less pain at 2 year follow-up than younger patients. The coefficient of determination ($R^2 = 0.0648$) demonstrated that 6% of the variation in the AKSS pain score is predicted by age.

Radiographic review by an independent reviewer found no signs of aseptic loosening, no radiolucent lines >2mm in 50% or more of zones around a single component, no measurable changes of tibial vertical migration and/or subsidence >2mm, measurable changes in angular orientation of any component >2 degrees, or progressive radiolucent lines. One patient had a stable lucency around the tibial keel at 6 months which had not progressed at the 2 year radiograph. Myositis Ossificans was identified in one patient at 3 months post-operative.

Discussion

This paper reports the early clinical outcomes and radiological results for a single surgeon series using a modern total knee implant system which includes a single sagittal femoral radius in the active flexion arc and unique instrumentation designed to optimize MCL isometry by maintaining the medial joint-line throughout the range of motion. The short-term results reported in this study demonstrate good survivorship and patient outcomes using the PS prosthesis.

In comparison to the published literature on more established traditional knee implants, total knee implants with a single sagittal femoral radius have demonstrated good to excellent results. Mahoney et al. [13] reported mean AKSS

Table 2
Comparison of 2 Year AKSS Scores by Gender

	GENDER			
	All (89)	Female (n=58)	Male (n=31)	
	Mean (SD, range)	Mean (SD, range)	Mean (SD, range)	Sig*
AKSS knee score	87.10 (7.98, 36 -100)	87.02 (8.81; 36 - 100)	87.27 (6.21; 71 - 100)	NS
AKSS pain score	48.64 (4.27, 20 - 50)	48.53 (4.49; 20 - 50)	48.83 (3.87; 30 - 50)	NS
AKSS function	96.42 (8.84, 60 – 100)	97.33 (6.89, 70 – 100)	94.67 (11.67, 60 – 100)	NS
AKSS ROM	24.63 (1.44, 0 - 25)	24.53 (1.65; 16 - 25)	24.80 (0.93; 0 - 25)	NS
OKS	45.89 (3.69, 23 - 48)	45.74 (4.09, 23 – 48)	46.17 (2.82, 34 – 48)	NS
	**t-test difference in means between female and male patients*			

Table 3
Correlation of Age & BMI on 2 Year AKSS scores

	AGE	BMI
AKSS knee score	r = 0.1238 NS	r = -0.0434 NS
AKSS pain score	**r = 0.2546 p = 0.0167 R2 = 0.0648**	r = -0.0697 NS
AKSS function	r = 0.1741 NS	r = -0.0327 NS
AKSS ROM	r = 0.0609 NS	r = -0.148 NS
OKS	r = 0.1098 NS	r = -0.1565 NS
	*Pearson correlation N=70 due to missing BMI	

knee scores improving from an average 44.0 (range: 30 – 59) pre-operatively to 95.3 (range: 85 – 100) at 2 years. Molt and Toksvig-Larsen [23] also reported significant improvements in Knee injury and Osteoarthritis Outcomes Score (KOOS) and AKSS scores from pre-operative to 2 years post-operative. Similarly, Cook et al. [15] reported a mean pre-operative AKSS score of 57.5 ± 14.9 and a mean post-operative AKSS score of 90.1 ± 18.0 at a minimum of 2 years follow-up. Dixon et al. [14] reported significant improvements in WOMAC pain scores (mean score: 75; SD = 17.5), WOMAC function scores (mean score: 71; SD = 17.1) and Knee Related Quality of Life (KRQoL) (mean: 57; SD = 20.8) at one year. Martin et al. [29] reported a mean OKS and WOMAC score at final follow-up of 30.64 (range 12-48 and 74 (range 18.9-100) respectively for a cohort of 456 consecutive patients who underwent a primary Scorpio TKR.

Molt and Toksvig-Larsen [23] reported no significant difference in AKSS or AKSS range of motion between Triathlon CR and PS implants at 2 years post-operative. Sur et al. [24] reported no significant difference in ROM between Triathlon CR and PS implants at final follow-up (mean 5.2 years; range 5.0 - 5.5 years) with mean ROMs of 135.8˚ ± 9.0˚ (range: 120˚ – 145˚) and 133.6˚ ± 12.2˚ (range: 100˚ – 145˚), respectively. However, they did find a significant difference between CR and PS for AKSS scores ($p = 0.017$) due to a significant difference in anteroposterior stability scores with the CR implants having a mean score of 4.1 ± 3.3 (0 – 10) and PS having a mean score of 9.2 ± 1.7 (0 – 10) ($p = 0.000$). There was no significant difference in mean AKSS pain, mediolateral stability, flexion contracture, extension lag, alignment, or functional scoring at final follow-up.

The literature reports discussion on the clinical benefit of resurfacing the patella. Baker et al. [25] looked at Patient Reported Outcome Measures (PROMS) data for 23,393 patients to compare results for patellar resurfacing versus non-resurfacing and found no significant difference in post-operative Oxford Knee Scores (OKS) ($p = 0.96$). Chen et al [26] found that the rate of re-operation was lower in total knee replacements with resurfacing, but resurfacing did not have any effect on anterior knee pain. They did find that the patellar resurfacing group had better AKSS scores in studies with 5 years or more of follow-up. Certain traditional knee implants have been designed with a constrained patellar articulation and tend to function best when the patella is resurfaced. Snir et al. [27] reported a significantly higher ($p < 0.001$) incidence of patellar clunk syndrome in patients that received a mobile-bearing, high-flex, PFC Sigma implant (DePuy) as compared with a fixed-bearing, single-radius, Scorpio implant (Stryker) with 22 knees (11.7%) and 4 knees (1.8%) reporting patellar clunk, respectively.

While this is a single surgeon series, comparison to the most recent Registry data for the total knee system used in this study has also demonstrated excellent survivorship. The Implant Summary report produced for the manufacturer by the National Joint Registry England, Wales and Northern Ireland (NJR) [28] comprising primary total knees implanted up to 4 June 2015 showed 1 revision in 165 implantations (158 patients) since the first recorded usage of this knee in the NJR (maximum implant time 3.1 years; mean: 0.9 years). This is a revision rate of 0.61%. Cumulative revision rate KM 1.3% (range: 0.2% - 4.35%) in comparison to the combined revision rates for all other TKAs listed on the NJR were 0.4% (range: 0.4% - 0.4%) at 1 year, 1.0% (range: 1.0% - 1.0%) at 2 years and 1.5% (range: 1.5% - 1.5%) at 3 years. The implant cohort in the NJR had a mean age of 73.8 years; a median BMI of 29 (90.9% of BMIs available); 46.1% male and 53.9% female; and primary diagnoses of osteoarthritis (98.18%), rheumatoid arthritis (0.61%), other inflammatory arthropathy (1.21%), previous trauma (1.21%) and Other (0.615) (NOTE: More than one indication can be listed per case). The NJR cohort is similar to the cohort in this study with the exception of patient sex which was more skewed towards females in the study cohort (65.17% female).

This cohort follow-up study utilized a surgical procedure to facilitate restoration of native knee kinematics. All patients were implanted with a PS implant, the system was designed to restore femoral rollback, maintain the joint line, and cam post engagement at 50-55 degrees of flexion with the expectation that anterior knee pain will be minimized and knee kinematics facilitated throughout the range of movement [30]. The patella was resurfaced in all subjects. Long leg radiographs to assess the degree of deformity were used pre-operatively as part of the extensive pre-surgical planning and, unique to this system, the intra-operative procedure combined both measured resection and ligament balancing to preserve the postero-medial joint line and balancing of the MCL. Post-operative patient management included intensive physiotherapy, CPM and pain management.

Survivorship and patient outcomes were excellent in these short term results. Age was significantly correlated with AKSS pain scores such that older patients in this group had less pain than younger patients. It is interesting to note that the mean age at time of surgery was 68 years which is younger than those reported in the NJR data. Mean BMI in this single surgeon series was comparable to the NJR data. There were no significant differences on patient outcomes between males and females.

Conclusion

This paper reports on the early clinical and radiological outcomes using a modern generation total knee system. All clinical and radiological 2 year post-operative results were excellent, including the patient reported Oxford Knee Score. Patients reported an Oxford score of 46 out of a possible 48 which is the very best possible outcome. Anteroposterior and mediolateral stability and flexion also demonstrated good results which may suggest optimized quad function and posterior condylar offset and balance.

Further research is needed to evaluate these clinical and radiological outcomes including a randomized controlled study comparing the results of this total knee system and its unique instrumentation and surgical philosophy to other total knee systems in orthopaedic use. Multi-center studies with larger patient cohorts and longer-term follow up are needed. Specific functional assessments such as knee stability across a range of activities would provide data more sensitive to variations across knee systems. A comparison of the PS to CR variants in this system, patella resurfacing vs non- resurfacing, and a comparison of post-operative treatment programs are also areas for further investigation.

Whilst this study is short-term and patients in this cohort were younger than reported in the NJR and more skewed towards females, the results published in this cohort highlight that this modern knee design performs equally well when compared to the literature on other traditional knee implants available today.

Disclosure Statement

The author has disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

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CASE REPORT
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Modular Head Mismatch in THA

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Acknowledgement:

This is a case report of two cases from JISRF's Tissue Sparing Study Group. We are grateful for their willingness to share these case examples of femoral head mismatch.

Abstract

Modular femoral heads have been used successfully since the mid-1980s in total hip arthroplasty. The use of metallic modular junctions presents a unique set of advantages and problems for use in total hip arthroplasty (THA). The separation of the head from the stem by a Morse taper has provided many benefits on the precision and balancing the reconstructed joint. Historically few complications have been reported for the modular Morse taper connection between the femoral head and trunnion of the stem in metal-on-polyethylene bearings. However, the risks or concerns are a little harder to identify and deal with. Certainly corrosion, and fatigue failure are the two most prevalent concerns but now the specifics of fretting wear and corrosive wear increasing particulate debris and the potential biological response is having an impact on the design and potential longevity of the reconstructed hip. This paper is dealing with a simpler consequence of head/stem modularity. Modular head mismatch to the socket bearing articulation.

Two patients by two different surgeons at two different hospitals underwent cementless THA. Both patients were female and both presented with degenerative changes to the hip articulation. Both patients underwent hip replacement via a direct anterior approach using a standard hemispherical porous coated shell. One patient had a ceramic on ceramic bearing and the other had a ceramic head on a polyethylene liner. One patient had a 32 mm inside diameter liner and a 36 mm ceramic femoral head implanted. The other patient had a 36 mm inside diameter liner and a 40 mm ceramic femoral head implanted. The ceramic on ceramic mismatch was not recognized until the second office visit at eight weeks. The ceramic poly mismatch was not recognized until first office visit at six weeks. Both underwent correction surgery.

These two cases demonstrate human mistakes can be made and steps need to be established to prevent future mistakes of this nature.

Keywords*: modular head, mismatch, total hip arthroplasty*
Level of Evidence*: AAOS Therapeutic Level IV*

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Introduction

In dealing with the complex problems of THA the use of metallic and ceramic modular heads has proven to be a significant benefit. [1,2] To-date, all current cementless stem designs have one feature in common – a modular head. However not all modular taper junctions are designed equally.

The success of a self-locking taper is influenced by the design of the taper, particularly the taper angle, the roughness, and the mating materials between the "male" and "female" components. This results in co-integration (locking), with material transfer across the zone of contact (cold welds). Figure 1.

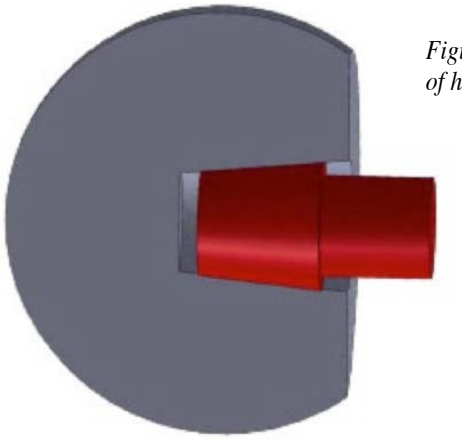

Figure 1. Schematic of head/neck taper

In the last two decades, manufactures have been altering femoral stem trunnions from various tapers such as 14/16 to 12/14 to 11/13. Figure 2. A range of different Morse taper angles, component tolerances and sizes, and surface finishes exist within commercially available hip systems. While manufacturers do not recommend mixing and matching of component brands, a number of surgeons have been mixing and matching without complications, provided the products used have the same manufacturing tolerances.

Figure 2. Illustration Showing Different Taper Designs by Manufacturers. (Courtesy Chris Burgess, Signature Orthopaedics Ltd.)

It is important to remember that early introduction of stem modularity did present problems, including disassociation of modular heads, incorrect head diameters implanted, and trunnion fatigue fractures. Figure 3.

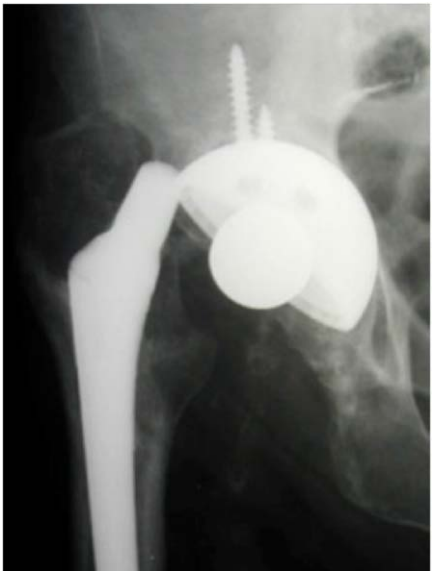

Figure 3. Detachment of modular head can damage stem trunnion. (Curtsey JISRF Archives)

This paper will review two separate case reports of mismatch articulation bearing diameters, one ceramic on ceramic and one ceramic on polyethylene.

Case Reports

CASE 1

The patient presented for initial evaluation in her sixth decade with a recent history of progressive right hip pain, stiffness and difficulty with daily activities unresponsive to non-operative measures. On exam she had hip irritability with attempted range of motion and walked with a moderate limp. She had moderate hip stiffness. She had generalized ligamentous laxity. Radiographs showed advanced degenerative changes of the right hip with underlying right hip acetabular dysplasia. Figure 4.

She underwent right hip replacement via a direct anterior approach using a standard porous coated 52 mm shell with an alumina ceramic liner of 32 mm inside diameter (S&N FS05 shell and liner, S&N ceramic alumina head). Augmentation of the acetabulum was not required, nor was additional screw fixation. On the femoral side a titanium neck-sparing, proximally porous coated small curved stem (ARC® by OmniLife) was implanted securely. This stem allowed modular options for hip reconstruction. A short, 8° varus cobalt chrome modular neck component was selected and impacted in place. The alumina ceramic femoral head component was impacted securely in place. The hip demonstrated good stability and limb length. She had an uneventful postoperative course with rapid mobilization and return of function.

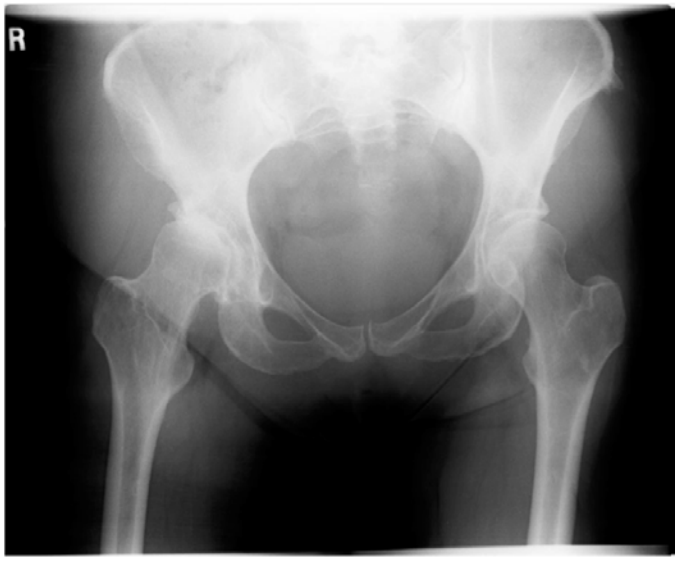

Figure 4. Radiographs showed advanced degenerative changes of the right hip with underlying right hip acetabular dysplasia.

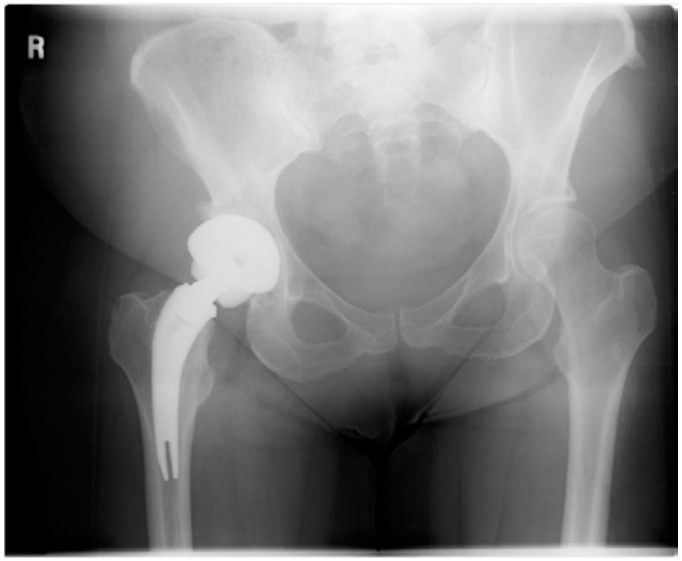

Figure 5. Mismatch head bearing diameter (36 mm ceramic head & 32 mm ceramic bearing liner)

She presented to the office for follow-up at three weeks with no difficulties. At eight weeks she reported a new grating sensation in the right hip without trauma. She had no significant pain and no complaints of a neurovascular nature. Radiograph revealed no evidence of ceramic fracture but a diameter mismatch of the femoral head and acetabular liner components. Review of the implant log revealed implantation of a 36 mm outside diameter had component with a 32 mm inside diameter acetabular liner. Figure 5.

She returned to the operating room for revision surgery which included acetabular liner exchange and exchange of the modular neck and femoral head component. The neck was replaced with identically sized implant. The femoral head component was changed to a 32 mm outside diameter medium length alumina ceramic head. This combination maintained leg length and provided good stability. Again, she had an uneventful postoperative course. Acetabular shell and femoral stem components were noted to be well fixed and well positioned.

CASE 2

The patient presented for initial evaluation at the beginning of her 6th decade with a several year history of progressive right hip pain, stiffness. She had failed conservative measures including injections, oral anti-inflammatories, and activity modifications. On exam she had hip pain with attempted range of motion, a 10 degree hip flexion contracture and walked with a moderate antalgic gait. Radiographs showed advanced degenerative changes of the right hip with cystic degeneration on both sides of the joint.

She underwent right hip replacement via a direct anterior approach using a standard porous coated plasma spray 52 mm shell (Biomet RingLoc+) with a neutral offset highly cross-linked vitamin E polyethylene liner of 36 mm inside diameter. Augmentation of the acetabulum was not required, nor was additional screw fixation. On the femoral side titanium neck sparing, proximally porous coated small curved stem (#2 Omni-ARC), was implanted securely. This stem allowed modular options for hip reconstruction. A short, 12° varus cobalt chrome modular neck component was selected and impacted in place. An alumina ceramic femoral head component was impacted in place. The hip demonstrated excellent stability with excellent restoration of limb length and offset as assessed both clinically and with intraoperative fluoroscopy (fluoroscopy used at trial component stage only). She had a normal postoperative course.

She presented to the office at 2 weeks having transitioned to a cane at one week. She presented at 6 weeks complaining of mild persistent pain. Radiograph revealed no evidence of ceramic fracture. Component position was felt to be excellent but a diameter mismatch of the femoral head and acetabular liner was suspected due to subtle asymmetry of the head and acetabula shell. Review of the implant log revealed implantation of a 40 mm outside diameter head component with a 36 mm inside diameter acetabula liner. Figure 6.

She returned to the operating room for revision. Acetabular shell and femoral stem components were noted to be well fixed and well positioned. The femoral head component was changed to a 36-+4-alumina ceramic. The modular neck and polyethylene liner were retained. This combination maintained good leg length and provided good stability. Again, she had an uneventful postoperative course.

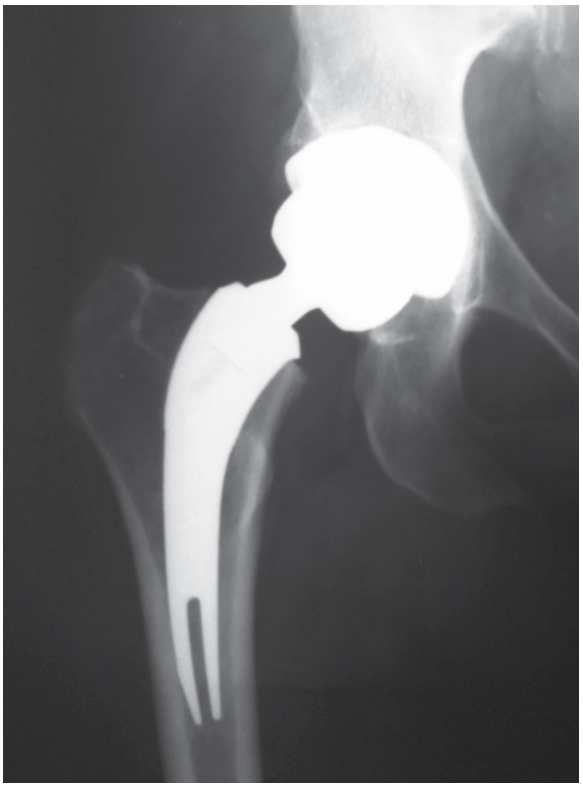

Figure 6. Mismatch head bearing diameter (40 mm head & 36 mm bearing liner)

Conclusion

These two separate case reports dealing with the same intraoperative errors clearly demonstrated that the best high technology devices are only as good as the surgical technique and surgical skills of the operating surgeon at the time of implantation. "Technique, Technique, Technique is more important than design or material" an old quote by David Hungerford, MD.

We have seen time out established prior to surgical incision to reduce errors and the surgeons along with their institutions recommend a formal implant time out at each stage of the procedure.

Both surgeons should be commended for as soon as they recognized the error they informed their patients and re-operated to correct the problem while it was still a minor situation.

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Third-body Wear Damage Produced in CoCr Surfaces by Hydroxyapatite and Alumina Ceramic Debris: A 10-cycle Metal-on-Metal Simulator Study

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Abstract

Ceramic particles are believed to be particularly abrasive due to their extreme hardness. Ceramic debris has been reported in retrieved total hip arthroplasty (THA) due to chipping and fracture of alumina components or by flaking of hydroxyapatite from implant coatings. However there appears to be no abrasion ranking of such particle behavior. The hypotheses in this study were, i) alumina particles would create large scratches in CoCr surfaces and ii) hydroxyapatite would produce very mild scratching comparable to bone-cement particles. Hydroxyapatite beads came in two types of commercial powders while the flakes were scraped from retrieved femoral stems. Alumina beads came in two commercial powders and flakes were retrieved from a fractured ceramic head. Particle morphologies were determined by SEM and CoCr surface damage by interferometry and SEM. Six 38-mm MOM were mounted inverted in a hip simulator and run with ceramic particles inserted for a 10-second test. Surface-roughness ranking after 10-second abrasion test revealed that bone cement and hydroxyapatite produced least damage to CoCr surfaces while alumina produced the most. Alumina increased surface roughness 19-fold greater than either hydroxyapatite or bone-cement particles. The alumina debris produced numerous scratches typically 20-80 μm wide with some up to 140μm wide. Surprisingly the alumina beads and flakes were pulverized within the 10-second test interval and remained adherent to the CoCr surfaces. Additionally, the hydroxyapatite although also a ceramic had no more effect on CoCr than the bone-cement debris. Use of well-characterized and commercially available alumina and hydroxyapatite powders appeared advantageous for abrasion tests. These new data indicated that such ceramic powders have merit.

Keywords: *ceramic hydroxyapatite alumina debris CoCr, 3rd-body abrasive wear, MOM hip arthroplasty, simulator*
Level of Evidence: *AAOS Therapeutic Level III*

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Introduction

There are many risks in total hip arthroplasty (THA) that may trigger adverse wear, including; impingement, [1,2] subluxation, [3,4] dislocation, [5,6] "edge wear", [7-9] and micro-separation. [10-12] Unfortunately there is little understanding with regard to which patients may be at risk [5,6,13-21] and uncertainty as to which events may trigger a major particle release. [22,23] Acetabular cups combined with metal and ceramic liners may incur additional risks due to, (a) the cup rim plastically deforming the femoral head, [24] (b) 3rd-body abrasion created by liberated metal particles, [25,26] and (c) smearing of metal alloy contaminants onto CoCr bearings. [6,27] There are also varying opinions on how hard a particle has to be to damage metallic bearings (Fig.1). These data are important for understanding material interactions between hard particles, [28,29] designing laboratory wear studies, [30-34] and understanding the implications of 3rd-body wear in vivo. [3,12,25,26,35]

Abrasion models have included a) particles inserted between bearing surfaces, [29,30] b) particles added to lubricants to produce abrasive slurries, [31,32,34,36-38] and c) mathematical modeling of debris interactions. [28,29] A MOM simulator study introduced titanium (Ti) particulates [30] that dramatically increased wear rates. Another study used a high concentration of hydroxyapatite powder (HA) in the test lubricant but this had no measurable effect on MOM wear. [31] Our prior simulator study contrasted abrasion potential of large particles of CoCr and Ti6Al4V versus bone-cement flakes (PMMA) in a 10-second simulator test. [39] The large PMMA particles had no visible effect on CoCr surfaces whereas the metal debris increased surface roughness by approximately 20-fold. The resulting scratch profiles ranging 20-108 μm wide and 0.5-2.8 μm deep. The scratch aspect ratio (Fig. 2) averaged 0.3, indicating that the large metal particles had plastically deformed to create wide but shallow scratches in CoCr surfaces. Such abrasion tracks appeared identical to those reported on retrieved MOM bearings. [25] Ti6Al4V particles produced abrasion tracks similar to CoCr particles but also clearly demonstrated an ability to fragment and adhere to CoCr surfaces. [39] Such varied debris interactions in MOM bearings illustrated that we have little understanding of the life history of debris that circulates in the human hip joint.

The aim of this study was to characterize 3rd-body abrasion effects of ceramic particulates in MOM bearings. Ceramic debris has been reported in retrieved THA, either from implant coatings such as hydroxyapatite [40-46] or following chipping or fracture of alumina components. [47-50] However there appears to be no ranking of ceramic particles in hip simulator models. Our two hypotheses in this study were that i) alumina particles would plow into CoCr surfaces creating scratches > 40μm wide, comparable to damage created by large CoCr particles [39], and ii) hydroxyapatite particles would produce very mild scratching on CoCr surfaces, comparable to the results with PMMA particles. [39,51]

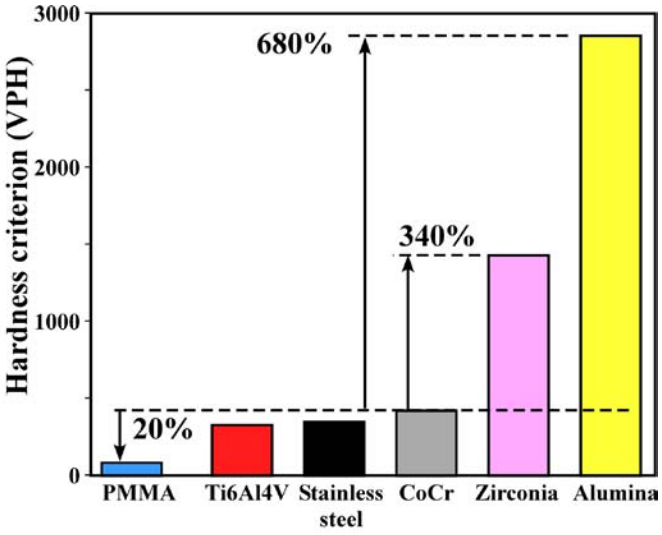

Figure 1. Ranking of material hardness for bone cement, metal alloys and ceramics.

Methods

Hydroxyapatite particles for our study were provided in powder form by two orthopedic vendors (Table 1). The flakes were scraped from retrieved Ti6Al4V femoral stems archived in the DARF Center. A ceramic vendor provided two alumina powders and we retrieved alumina flakes from a THA case that featured a fractured ceramic head. Size and shape distributions were determined by scanning electron microscopy (SEM: EVO MA15; Zeiss, Thornwood, NY). Energy dispersive x-ray imaging was used to characterize material types and to detect contaminants (EDS: X-flash detector 4010, Bruker AXS, Madison, WI). Particle numbers per 5mg allotments were determined mathematically using volume approximations and material densities (Table 1). Control data (PMMA and CoCr particles) were taken from a prior simulator study run under identical conditions.

The six 38-mm MOM bearings were wrought high-carbon, CoCr alloy, identical to those used in the prior study (DJO Global Company, Austin, TX). [39] Cups were mounted inverted in an orbital hip simulator (Shore Western Manufacturing, Monrovia, CA). [39,52] The simulator

Particle type	Range (dia)	Average (dia)	Ratio	Particle model (#)
HA powder-2	5-55	21	0.17	370,000
HA flakes	10-65	23	0.19	NA
HA powder-1	5-60	26	0.21	189,700
Al_2O_3 powder-1	5-80	33	0.27	65,600
Al_2O_3 powder-2	5-170	48	0.39	22,300
Al_2O_3 flakes	5-330	87	0.71	3,600
CoCr control	45-180	103	0.84	900
PMMA control	30-250	122	1.00	6,800

Table 1. Ceramic particles ranked in order of size and compared to PMMA and CoCr controls

test mode used dynamic loading of 0.3–3 kN for 10 simulator cycles (10-second test). Cleaning protocols were same as previous study. Only the femoral heads were characterized for roughness using white-light interferometry (WLI; NewView 600; Zygo, Middlefield, CT). Head roughness was compared using standard indices (Ra, PV) with 12 fields measured at each site. SEM and EDS imaging were used to study surface topography and detect contaminating elements. Surface scratches were characterized by their cross-sectional profiles (N=12 per site), noting widths and overall depth (Fig. 2: W, Z). Data analysis was performed by statistical review using one-way ANOVA and Dunn's multiple comparisons.

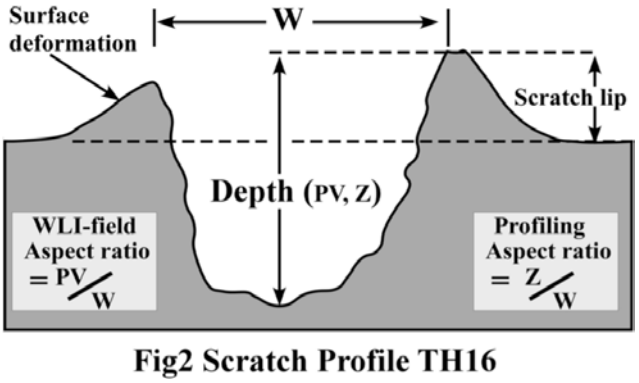

Figure 2. Profile showing scratch width (W) and depth. For field data on scratch depths, roughness assessment used the peak-to-valley parameter (PV) while profiles of individual scratches provided measurement-Z. The aspect-ratio comparisons used PV/W and Z/W.

Results

Size range of the ceramic particles averaged smaller than either PMMA or CoCr controls (Fig. 3). Both types of HA powders presented spherical beads of size range 5-65μm (Figs. 4a, b). The beaded morphology of alumina powder-1 (Fig. 5a: 5-80μm) appeared quite similar to the HA powders whereas alumina powder-2 contained more irregular globular shapes with double the size range (Fig. 5b). The particles collected from a retrieved ceramic case ranged still greater in size with some irregular fragments

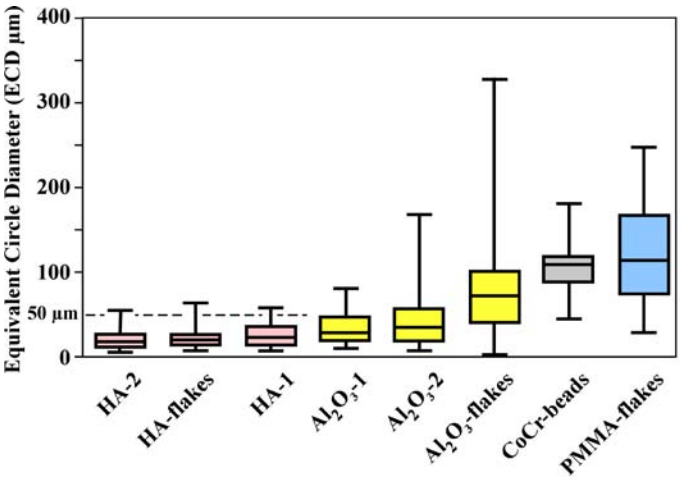

Figure 3. Ranking of particle sizes by equivalent circle diameter (ECD).

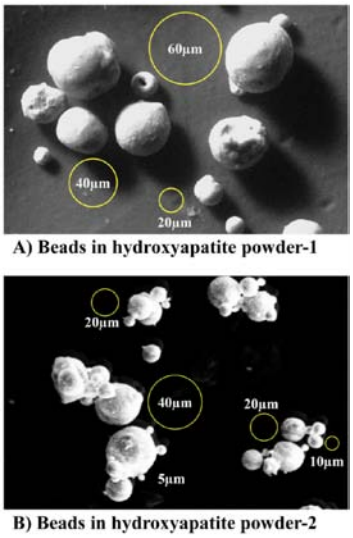

Figure 4. SEM imaging of hydroxyapatite beads in (A) powder-1 and (B) powder-2.

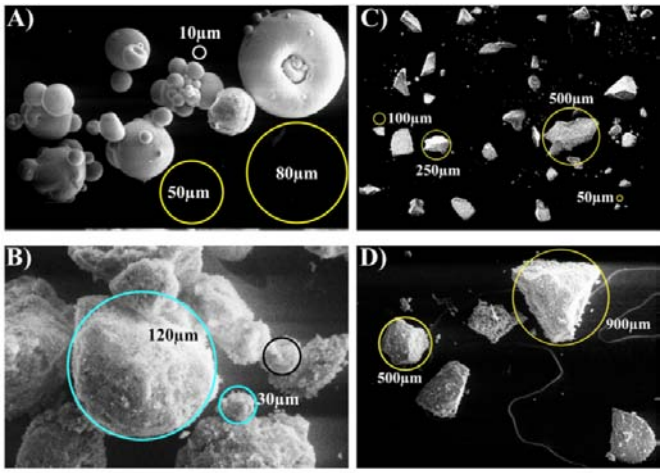

Figure 5. SEM imaging of alumina particles, (A) alumina powder-1, (B) alumina powder-2, (C) low magnification of alumina fragments, and (B) alumina fragments of size 500-900μm.

(Figs. 5c) having with well-defined edges (Fig. 5d).

Surface-roughness ranking after the 10-second abrasion test revealed that bone cement and hydroxyapatite ceramics produced least damage on CoCr surfaces while the alumina ceramics produced most (Table 2: Ra). Hydroxyapatite and bone-cement particles provided minimal damage to CoCr surfaces, average (Ra) indices being typically less than 0.01μm (Fig. 6). The hydroxyapatite flakes created 5-fold greater roughness than PMMA particles. Although suspected, particle imaging by SEM and EDS did not identify any metal contaminants (Ti, Al, V). Alumina and CoCr particles raised surface roughness to greater than 0.2μm on average (Ra), 19-fold greater than produced by bone-cement particles. Maximum peak-to-valley roughness indices (PV) provided similar damage ranking but with higher magnitudes (Fig. 7).

Debris	Ra (nm)	Ra ratio	PV (nm)	PV ratio
PMMA control	11 (7-19)	1.0	340 (131-725)	1.0
HA powder-1	14 (10-20)	1.3	362 (256-453)	1.1
HA powder-2	17 (9-30)	1.5	551 (244-994)	1.6
HA flakes	54 (34-89)	4.9	1287 (613-1805)	3.8
CoCr control	203 (38-628)	19	2003 (823-3721)	5.9
Al_2O_3 powder-1	365 (143-630)	33	2720 (1378-4278)	8
Al_2O_3 powder-2	475 (236-870)	43	3291 (1971-4635)	10
Al_2O_3 flakes	532 (127-1234)	48	5897 (3199-8034)	17

Table 2: Roughness indices measured on CoCr surfaces

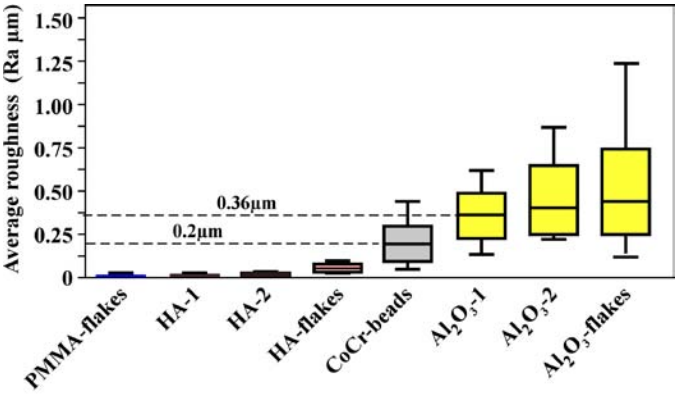

Figure 6. Ranking of CoCr surface damage (Ra: average roughness parameter) produced by particle types.

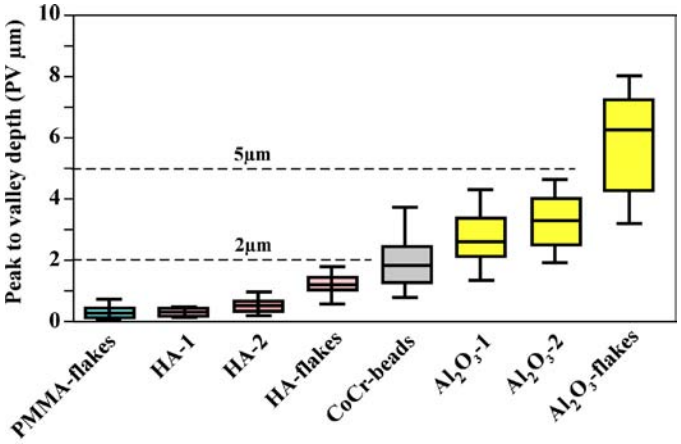

Figure 7. Ranking of CoCr surface damage (PV: peak-to-valley parameter) produced by particle types.

SEM imaging after 10-seconds of abrasive wear with hydroxyapatite particles revealed CoCr surfaces that were typically featureless (background scratches ± 0.1 μm) with an occasional scratch 0.25 μm deep in some fields of view (Fig. 8). In contrast alumina beads produced numerous scratches typically 20-80 μm wide (Figs. 9a, b) with occasional scratches up to 140μm wide by 3μm deep (Figs. 9c, d). These scratches averaged aspect ratios of 0.03. Thus a 50μm wide scratch would typically have 1.5μm depth in the CoCr surface (Table 3). Equally conspicuous were 100-500μm size areas of surface contamination. These as verified by EDS were layers of pulverized alumina particles, ranging 1.2-1.9μm thick on CoCr surfaces. Alumina flakes produced the greatest surface damage, with numerous large scratches 80 – 100μm wide surrounded by numerous pits (Fig. 10). There was also abundant evidence of pulverized alumina layers, typically adjacent to the larger scratches (Fig. 10b).

Sampling of individual scratches to characterize width

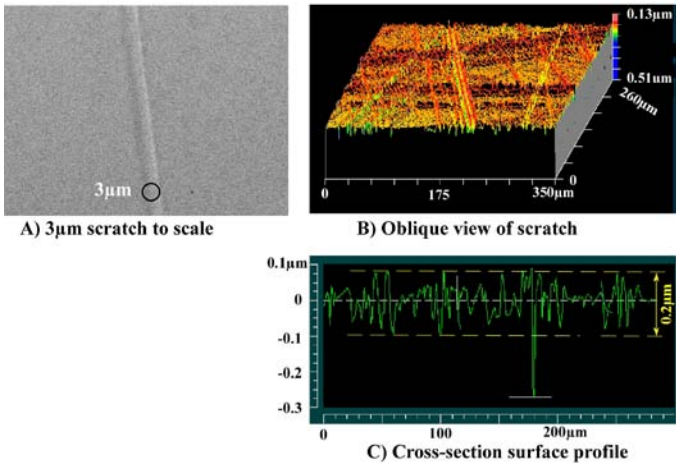

Figure 8. SEM and Zygo imaging of CoCr surface scratched during hydroxyapatite test, (A) surface scratch, (B) oblique image of scratched surface, and (C) profile of surface scratches.

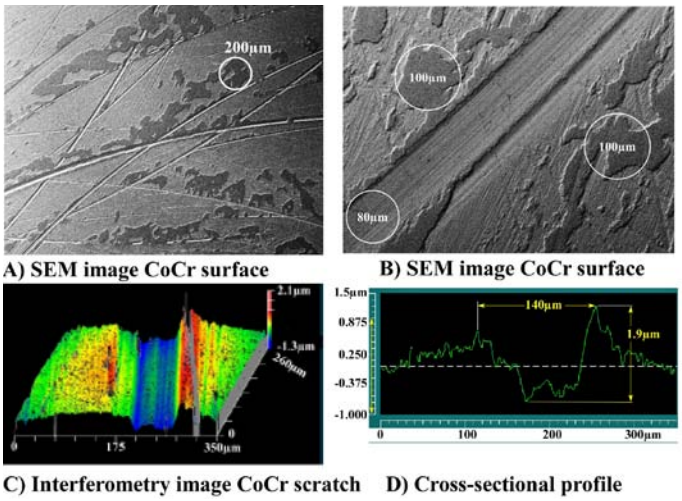

Figure 9 SEM and Zygo imaging of CoCr surface scratched during alumina bead test, (A) SEM image of 20-200µm size plaques of alumina contamination, (B) 80um wide scratch with 20-200µm size plaques of alumina contamination, (C) oblique Zygo image of scratched CoCr surface, and (D) large scratch profile.

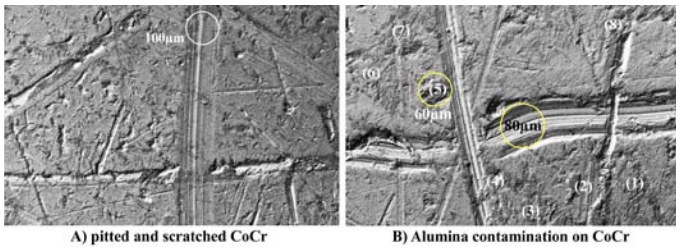

Figure 10. SEM imaging of CoCr surface scratched during alumina flake test, (A) 100µm wide scratch in pitted surface and (B) 30µm and 80µm wide scratches surrounded by plaques of alumina contamination (numbered 1-8).

Measurements	Debris	Lip width (W µm)	Scratch depth (PV µm)	Aspect ratio (PV/W)
N=24	PMMA control	8 (3-23)	0.12 (0.04-0.32)	0.02
N=12	HA powder-1	3 (2-5)	0.16 (0.13-0.20)	0.05
N=12	HA powder-2	4 (2-6)	0.18 (0.06-0.28)	0.04
N=12	HA flakes	12 (5-28)	0.73 (0.14-1.37)	0.06
N=24	CoCr control	54 (26-108)	1.44 (0.48-2.62)	0.03
N=12	Al_2O_3 powder-1	59 (16-92)	1.59 (0.67-2.17)	0.03
N=12	Al_2O_3 powder-2	75 (39-134)	1.99 (0.64-3.6)	0.03
N=18	Al_2O_3 flakes	54 (13-98)	4.97 (1.58-11.21)	0.09

Table 3: Profile measurements of scratches in surfaces of CoCr heads.

and depth (Fig. 2. W, Z) revealed virtually the same ranking as the roughness indices provided by the interferometry assessment (Ra, PV). Scratch widths produced by bone cement and hydroxyapatite particles were the smallest and those produced by CoCr and alumina particles were the largest (Fig. 11). Similarly with scratch depths, bone cement and hydroxyapatite particles produced the shallowest scratches while CoCr and alumina particles produced the deepest damage (Fig. 12). Aspect ratio of profiled scratches (Fig. 2: ratio Z/W) produced by alumina and CoCr beads averaged 0.03. The alumina flakes were noticeably different from the rest of the particles, producing a higher aspect ratio averaging 0.09 (Table 3).

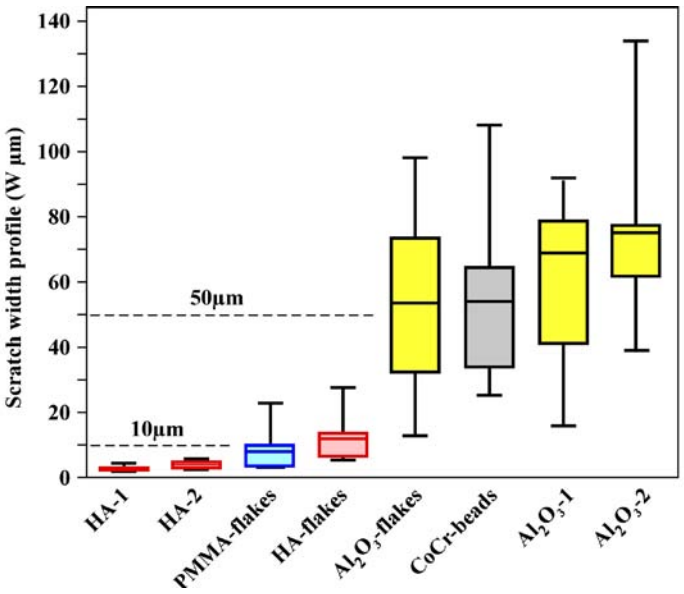

Figure 11. Ranking of scratch widths (W) profiled individually at selected damage sites.

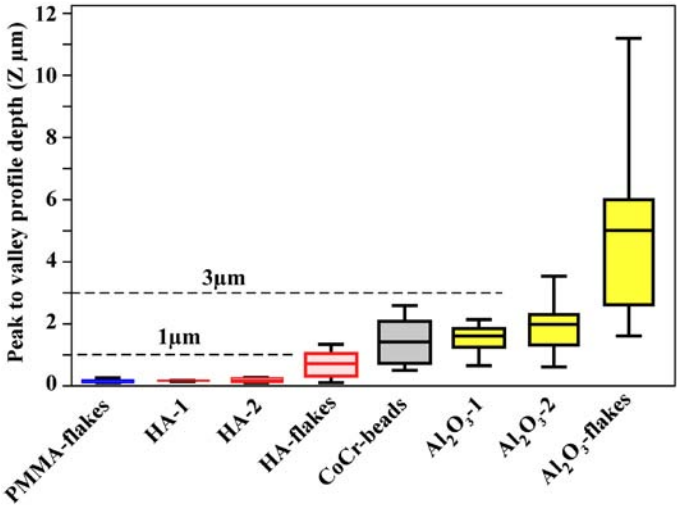

Figure 12. Ranking of scratch depths (Z) profiled individually at selected damage sites.

Discussion

The risk of alumina particles scratching CoCr surfaces was clearly an anticipatable result. The new evidence was that such scratches typically had an aspect ratio averaging 0.03, duplicating that created by metal particles. [39]. This conformity in surface damage supported our first hypothesis. The SEM data indicated that alumina beads typically 30-50μm in size were flattened massively within a 10-second test to produce 1-2μm thick ceramic layers on CoCr femoral heads. The larger alumina flakes reacted similarly, but with scratches having a somewhat higher aspect ratio (0.09). SEM imaging of these wide but shallow scratches indicated they were made by compressed plaques of alumina plowing across CoCr surfaces (Fig. 9). These data further illustrated the complexity of abrasion studies. The interaction of hip joint motion and applied contact stresses is a dynamic process that induces unpredictable fragmentation and wear mechanisms to circulating particles, even in alumina as the hardest biomaterial (Fig. 1). Thus the interaction of bearing type and debris compressive-strength adds additional complexity.

The hydroxyapatite beads did not damage CoCr surfaces due to a combination of low compressive-strength and hardness. This was not due to particle size or shape because a similar beaded morphology in alumina powder-1 produced dramatic CoCr scratches. This surprising result for hydroxyapatite particle revealed that this ceramic had no more effect than the large plastic particles that comprise bone cement. This result was in accordance with MOM simulator wear data. Liao et al (2010) ran a 5-million cycle study using a high concentration of hydroxyapatite particles and found no adverse effects. [31] Similarly it has been suggested that some commercial bone cements may be abrasive because they contain barium sulphate ($BaSO_4$) or zirconia ceramic (ZrO_2), such micron-size additives having three times the hardness of CoCr (Fig.1). [55,56] Nevertheless several MPE simulator studies demonstrated that bone cement does not damage CoCr surfaces. [34,36,37,57] We used a bone-cement slurry as the lubricant in a MOM simulator study and similarly found no adverse effect. [52] Therefore, these ceramic supported our second hypothesis, that hydroxyapatite debris would be no more damaging to CoCr surfaces than bone cement.

Prior abrasion models have primarily used metal-on-polyethylene (MPE) bearings. [13,36] Clinical studies indicated that, following revision of a fractured bearing, retained alumina debris could produce adverse wear of MPE. [54] Retrieval studies also indicated hydroxyapatite debris liberated from implant surfaces may accelerate polyethylene wear. [43,44] However, use of MPE bearings in this 3rd-body wear study would have added additional complexity, the soft polyethylene surface allowing the particles to imbed in an unpredictable manner. Thus, use of MOM hip joints simplified the task of ranking ceramic damage to CoCr surfaces. Such laboratory models are further challenging due to uncertainties regarding choice of particulate morphology, dosage, and test methods. The major limitation in this study was that use of commercial ceramic powders lacked clinical relevance. It may be argued that the hydroxyapatite beads in powders-1 and 2 differed in chemical and physical composition from hydroxyapatite particles released from implanted prostheses. It was also possible that the hydroxyapatite flakes scraped from the two retrieved femoral stems were contaminated by metal particles. This was not detected in samples scrutinized by SEM/EDS but could not be ruled out for debris allotments used in the simulator studies. A further limitation in this study was that the fields of study could not be precisely duplicated between microscopic mapping with SEM and by interferometry. Thus quantitative results were presented only by the latter method.

Use of well-characterized and commercially available alumina and hydroxyapatite powders would appear advantageous in development of standardized abrasion tests. This 10-second simulator test established that alumina powders and fracture flakes damaged CoCr surfaces equally, indicating that such ceramic powders represent a valid test model. This may also be true for hydroxyapatite powders and flakes. However the evidence in this study was not considered conclusive.

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Disclosure Statement

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

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The Power of One Publication

McTighe T [1]

Acknowledgements:
Michael T. Selch, MD, John Breneman, MD, Mohamed Samy A. Elhammady, MD, Roberto Heros, MD and Mark D. Jacobson, MD

Abstract

A simple definition of Peer Review: A process by which a scholarly work (such as a paper or a research proposal) is checked by a group of experts in the same field to make sure it meets the necessary standards before it is published or accepted. [1] There has been considerable debate over the years as to the value of publications. This commentary is going to highlight my experience with publications and how the power of one scientific report of two cases has significantly impacted my life and the life of my family.

My career of forty-five years in the orthopaedic field with over one hundred and eight publications, 69 citations, sixteen medical device patents, membership in nine professional medical societies prepared me for one significant effort in my personal life "the discipline and experience" to spend nearly two years researching a treatment modality for lymphocytic hypophysitis.

Conclusion: This experience demonstrates how the power of one specific paper can influence and play a positive effective role in the direction, treatment and outcome in a rare and uncommon medical condition.

Keywords*: peer review, publication, research, lymphocytic hypophysitis*

Introduction

Publications have a variety of value from setting you apart from hundreds, perhaps thousands of individuals in any given field, taking your curriculum vitae to a higher level and adding credibility to your career. Certainly publishing has enhanced my professional career in orthopaedics, in addition to the pleasure of collaborating with some of the worlds most acclaimed orthopaedic surgeons and scientist in the past forty-five years. All this has contributed to one of the most significant actions in my life, the ability and discipline to search for a reasonable treatment for my wife's health care condition "lymphocytic hypophysitis". This is a follow up to a commentary published last March "*Commentary on Grateful For Medical Advancements*". [2]

Background

My wife Catherine has been a significant part of my professional life and has many great friends worldwide as a result of our opportunity to travel and socialize brought about by the many activities generated by orthopaedics.

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Those close to Catherine (a retired nurse) know that she has had a significant struggle over the past two years with a rare cranial suprasellar lesion "lymphocytic hypophysitis". This was first reported in 1962, and the condition is rare, accounting for 0.38% to 1.1% of sellar lesions excised during transsphenoidal surgery.

In February 2014 she underwent emergency endoscopic endonasal cranial surgery as a result of compression of her optic apparatus. She presented on MRI as a pituitary adenoma, which on final pathology came back as a lymphocytic infiltration without any neoplastic cells, suggestive of lymphocytic hypophysitis. Her neurosurgical team in Miami was Mohamed Samy A. Elhammady, MD, guided by Professor Roberto Heros, MD.

Surgery was very successful, Cathy's postoperative scan showed excellent decompression of her optic apparatus and decompression of her cyst. Her visual fields completely recovered and we thought she was on her way to full recovery. However within three months the clinical symptoms of blurred vision, and disabling headaches had returned. New MRI demonstrated regrowth of the cyst (sellar and suprasellar mass). Her Miami medical team reviewed all pathology and reconfirmed diagnosis of lymphocytic hypophysitis. This is an unusual inflammatory disorder of the pituitary gland [4] with standard therapy being high-dose steroid medication. Steroid therapy has been effective in some patients however recurrent disease and morbid states have been reported. So now the medical condition was changing from a neurosurgical condition to an endocrinology situation.

Her Miami team started her on high does prednisone (40 mg per day) and recommended she see additional endocrinology consult upon returning to Cleveland.

So appointments were made at Case Western University Hospital in Cleveland, Ohio and both the head of Neurosurgical Oncology and Bahauddin Arafah, MD saw her:

- Division Chief, Clinical and Molecular Endocrinology, UH Case Medical Center
- Program Director, Endocrinology, UH Case Medical Center
- Professor, Medicine, CWRU School of Medicine

I mention the name of her consult with the Division Chief of Endocrinology because his behavior and attitude stand out way beyond the experience Cathy and I have encountered over her treatment period or for that matter over both of our careers in medicine.

Dr. Arafah disagreed with the diagnosis from Miami of lymphocytic hypophysitis and believes she has a Rathke's cleft cyst and prednisone treatment will not be effective. He was very insistent that only additional surgery, removing all traces of the cyst would effectively cure this problem. His only review of her medical condition was review of her MRI scans. We asked him to talk to her Miami team since they felt it was not a Rathke's cleft cyst. He said he did not need to since he could tell by her MRI scan and he was the expert in this area.

His attitude in refusing to talk to the medical team that operated and performed the pathology on Cathy was in our opinion less than professional and was arrogant beyond an acceptable standard.

A Rathke's cleft cyst is a benign pituitary cyst, which typically occurs in the area of the pituitary gland. It is thought to be remnants of an embryologic structure called Rathke's pouch, hence the name. If left over after development, the cyst can slowly expand and eventually cause symptoms. Rathke's cyst also does not respond to cortisone treatment.

Cathy decided to stay with the more conservative treatment proposed by her Miami team. Since she has begun the steroid treatment her clinical symptoms have improved and the latest MRI has demonstrated a decrease in size of the mass and resolution of the effect the mass has had on her optic chiasm (sight restored).

The high does prednisone (40mg) was doing the job of decompression however we were very concerned with the mid to long-term effect of such high dose treatment. This also confirmed the diagnosis of lymphocytic hypophysitis versus that of Rathke's cleft cyst. The Miami endocrinologist also suggested that Cathy see a rheumatologist and possibly receive additional chemical treatment with one of the new autoimmune drugs.

So this started out as a neurosurgical problem, then it became an endocrinology problem, and now a rheumatology problem. So she was put on to Cellcept in addition to the prednisone. Cellcept (mycophenolate mofetil) is used to prevent rejection of a kidney, liver, or heart transplant.

After almost ten months of treatment Cathy's overall health and medical condition were getting worse. As she would reduce the dose of prednisone her clinical symptoms would resume and there appeared to be no benefit of the Cellcept medication so that was discontinued. During all this time I was reaching out to all my medical contacts on a global basis seeking any suggestions for treatment. In addition I was searching all index databases looking for any published literature on the treatment of lymphocytic hypophysitis.

I eventually found one paper on ResearchGate "Stereotactic Radiotherapy for the Treatment of Lymphocytic Hypophysitis" published in 2003 in Journal of Neurosurgery senior author by Michael T. Selch, MD. [3] The article was a report on two cases, one a 58-year-old man, the other a 75-year-old man.

The role of surgery is to decompress and for tissue diagnosis. It is typically treated medically with steroids. Resection is often incomplete due to suprasellar extension or firm adherence to adjacent Dura matter. Recurrence has been reported and validated by Cathy's recent events. Surgery may result in diabetes insipidus or worsening of the anterior pituitary function. Cathy experienced both of these conditions.

High-dose steroid therapy has been advocated in an effort to avoid invasive procedures. The clinical response to corticosteroid medications, however, may be poor or transient and symptoms frequently return after cessation of therapy. Steroid therapy treatment after many months can result in serious side effects such as Cushing syndrome, avascular necrosis, and diabetes mellitus.

Until this paper there had been no reports of radiotherapy for lymphocytic hypophysitis, although its use has proven to be successful for histopathologically similar condition elsewhere in the body. The results of this report of two cases were that stereotactic radiotherapy represents a minimally invasive treatment option for patients with lymphocytic hypophysitis.

Needless to say, this was the first research that demonstrated a potential for not just treating my wife's condition but a realistic outlook on curing her disease. Now I was faced with the prospect of finding a new experimental treatment and presenting this option to my wife without over stating, or raising expectations beyond a reasonable level. This, after all, was just a case result of two patients.

So I reached out to contact Michael Selch from UCLA only to find that he had retired and his contact information was not readily available. After about three months I was successful and Michael gave me a call. We discussed Cathy's case and Michael did feel that Cathy could possibly benefit from radiation therapy.

Since this was a new treatment modality and Michael was retired Michael suggested that we contact Dr. John Breneman, MD from Cincinnati Ohio. Michael was kind enough to reach out on our behalf and contact John.

Dr. John Breneman is a Radiation Oncologist in West Chester, Ohio and is affiliated with multiple hospitals in the area, including Christ Hospital and Cincinnati Children's Hospital Medical Center. He received his medical degree from University of Iowa Carver College of Medicine and has been in practice for 34 years.

After being contacted by Michael, John called me and we discussed Cathy's case. John requested that I send her medical files so he could review them and present them to his department at the University of Cincinnati. In the meantime we kept Cathy's neurosurgeon, Samy (Mohamed Samy A. Elhammady, MD), abreast of our discussions. Samy has been our key contact since the surgery discussing every step of treatment along this challenging path. Both Cathy and I cannot express the immense respect that we have for this young gifted surgeon. He has grown into a friend making himself available day or night to help us with decisions that are very scary and experimental in nature. He has made himself available to all of Cathy's medical team even to the point of allowing us to give out his personal mobile telephone number. He made sure all of Cathy's medical files including the pathology slides were sent to John for his team to review.

John, the tumor board and the pathology department at the University of Cincinnati agreed and confirmed Miami's diagnosis of lymphocytic hypophysitis. After confirmation of the diagnosis upon meeting with John he was upfront with the fact that he and his department had no experience with treating this disease. After consultation with Michael Selch, John felt he and his team could develop a radiation therapy protocol that would benefit Cathy's condition. We were very impressed with John's open honest approach and had the confidence that we found the right man to help us at this junction.

Treatment and Results

Radiation therapy: Definitive
Image Guidance: Daily
RT Dose per Fraction (GY): 2 Gy
RT Total Fraction Count: 15
RT Total Dose (Gy): 30 Gy
Elapsed Days: 20

A sixty-eight-year-old Caucasian woman completed definitive radiotherapy as instructed without unintended treatment breaks. She tolerated radiotherapy well with expected acute treatment related toxicity including fatigue. Her HA's were moderately improved during radiation.

RTOG Acute Radiation Morbidity Scoring Criteria

General: grade 1 fatigue

Conclusion of MRI:

MARKED IMPROVEMENT IN THE MASS IN THE PITUITARY WHEN COMPARED TO THE PREVIOUS EXAMINATION OF 5/13/2015. THE CAVERNOUS SINUSES ARE NORMAL WITH NO MASS EFFECT ON THE PITUITARY STALK (Figure 1).

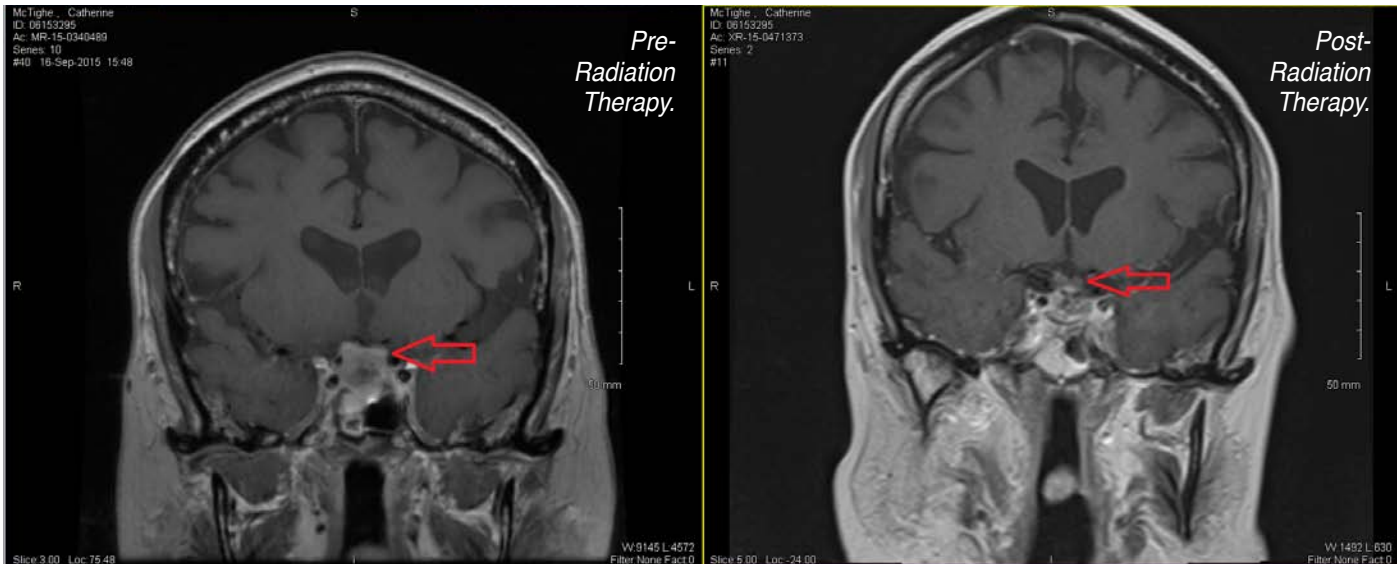

Figure 1. The new scan on the right shows a much smaller, residual area of contrast uptake in the area of the pituitary, which could represent resolving hypophysitis versus effects of radiation treatment.

Summary

Although this is a summary of a case report on an initial neuro-surgical problem the medical situation transformed itself to a multifocal problem involving four defined medical subspecialties:

1. Neuro-surgical
2. Endocrinology
3. Rheumatology
4. Radiation Oncology

The purpose of this paper is to highlight how one publication of a case report can lead to ongoing treatment and research that has effectively improved the quality and life expectancy of one patient. In addition to the benefit of this one individual patient the improvement in the quality of life that this one patient touches: husband, children, grandchildren, friends and the real possibility of this treatment benefiting additional patients and all the people that patients touch.

I want to encourage all medical professionals to publish. Publish the good and the bad, your work is a benefit and I want to thank all, that take the time to publish their work.

In addition this experience has demonstrated that almost all the health care team Cathy and I encountered were highly professional and extremely kind. It makes you proud to be part of this profession.

Our team that deserves high praise :

Roberto Heros, MD, Professor & Co-Chairman of Neurological Surgery, University of Miami Health System.

Mohamed Samy A. Elhammady, MD, Neurosurgeon, University of Miami and St. Joseph Hospital, Tampa, Florida

Michael T. Selch, MD, Radiation Oncologist, UCLA, Los Angles, CA

John Breneman, MD, Radiation Oncologist, University of Cincinnati, OH

Mark D. Jacobson, MD, Interventional Radiologist, Lady Lake, FL

Special note of interest:

On a personal note of interest shared by both Catherine and myself: two of Cathy's medical team are foreign born surgeons - Roberto Heros from Cuba and Mohamed Samy A. Elhammady from Egypt.

We are very grateful that these two professionals have chosen to settle in the United States and practice here. We consider them both to be friends and highly recommend them in their professions. People need to be judge based on their merit, nothing more, nothing less.

Cathy and I hope this radiation therapy protocol will benefit the increasing number of individuals that are inflicted with this disease.

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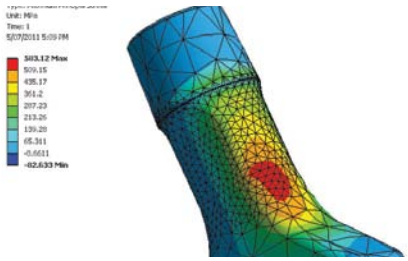

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The Institute's facility, designed by Willie Stokes, will feature Georgian architecture similar to the resort's façade, a replica of the Springhouse, the site of the famous sulphur springs and special guests suites for patients and their families. 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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JISRF and the Reconstructive Review take disclosure very serious and often readers don't appreciate the indirect benefit writers receive in publications. Many of our contributors are officially associated with JISRF by the membership on study groups, editorial committee and or clinical / surgical advisors. JISRF is dependent on donations and commercial funding. The overall success of this funding benefits indirectly all that are associated with activities produced by JISRF.

Disclosure for Authors

Article 1, page 13.
Oshima [1]; Fetto [1]

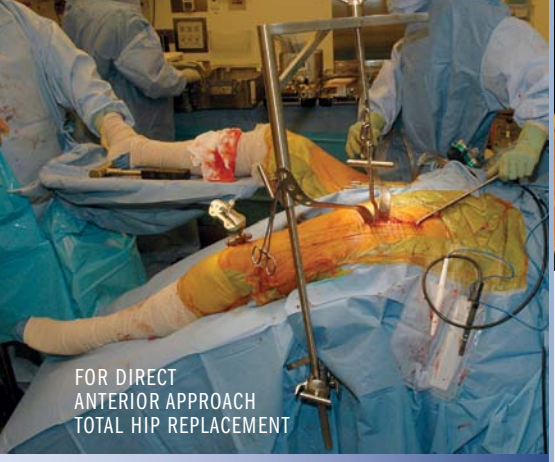
Article 2, page 19.
Berend [3]; Hurst [1]; Morris [1]; Adams [1]; Lombardi [3] - Direct institutional support of this study was received from Biomet, Inc. Warsaw, IN. Additionally, Berend and Lombardi receive royalties for intellectual property directly related to the devices in this study.

Article 3, page 23.
Paszicsnyek [4] - The author of this paper is a member of the design group and receives royalties from the manufacturer, Corin Ltd.

Article 4, page 29.
McTighe [1]

Article 5, page 33.
Halim [1], Burgett [1], Donaldson [1], Clarke [4] - Clarke received funding from J&J, Stryker, and WMT, none of which was related to this article.

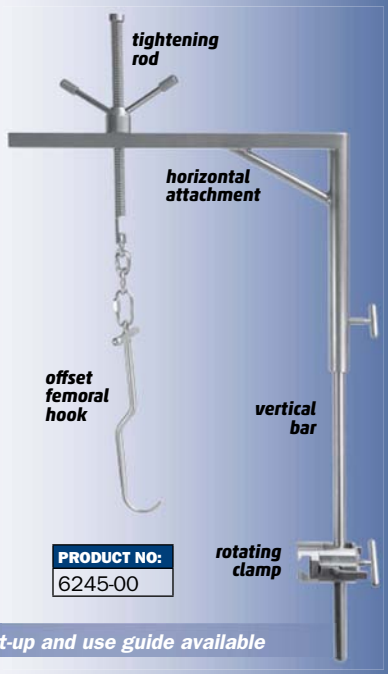
Article 6, page 41.
McTighe [1]



Wixson Anterior Suspension Hook System

Designed by Richard L. Wixson, MD

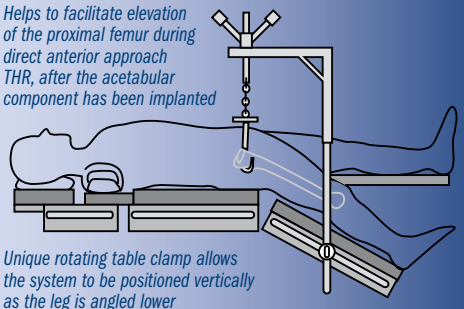
Designed for use with a standard operating room table



PRODUCT NO:
6245-00

Set-up and use guide available

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

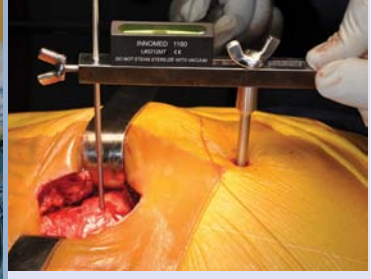


Unique rotating table clamp allows the system to be positioned vertically as the leg is angled lower

PRODUCT NO:
6245-00 [Complete Unit]

PROUDLY MADE IN THE USA

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



Used intra-operatively to establish measurements of both leg length and lateral hip offset. The measurements can then be used for verification, after femoral stem and head implantation but before final fixation, to help determine what adjustments (if any) are necessary.

PRODUCT NO'S:
1133-00 [Set]
Also available individually:
1133-01 [Llinas Length and Lateral Offset Gauge] *Slider Bar Length: 5"* *Cannulated Tube Length: 3.95"*
1180 [Sterilizable Level] *Dimensions: 2" x .5" x .75"*
1025 [Sterilizable Case]

Usage guide available at: www.innomed.net/instructions_innomed.htm

Llinas Leg Length & Lateral Offset Gauge

Designed by Adolfo Llinás, MD

Designed to help equalize the pre- and post-operative leg length/lateral hip offset

New!

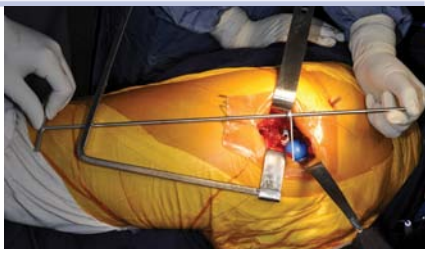
PROUDLY MADE IN THE USA

Llinas Vertical Offset Gauge

Designed by Adolfo Llinás, MD

New!

Designed to help equalize the pre- and post-operative vertical hip offset



Used intra-operatively to help determine the vertical distance of offset (if any) between the rotational center of the femoral head and the top of the greater trochanter. The measurement can then be used for verification, after femoral stem and head implantation but before final fixation, to help determine what adjustments (if any) are necessary to equalize the pre- and post-operative rotational center-trochanteric offset.

PRODUCT NO:
1133-02 *Overall Length: 17.25"* *Sliding Bevel Arm Lengths: 2.4" and 3.15"*

PROUDLY MADE IN THE USA

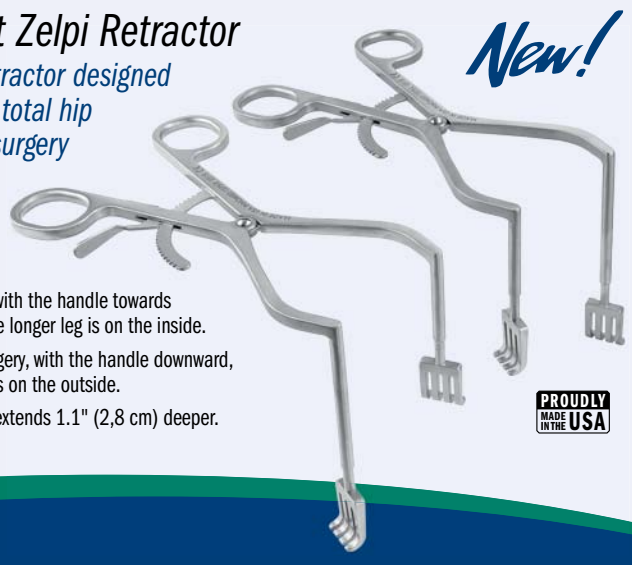
Usage guide available at: www.innomed.net/instructions_innomed.htm

Durham Offset Zelpi Retractor

New!

Staggered depth retractor designed for exposure during total hip and total shoulder surgery

Designed by Alfred Durham, MD



PRODUCT NO'S:
1573-L [Left] *Overall Length: 8.5"* *Leg Depths: 3.1" & 4.2"*
1573-R [Right] *Overall Length: 8.5"* *Leg Depths: 3.1" & 4.2"*

- In hip surgery, with the handle towards the surgeon, the longer leg is on the inside.
- In shoulder surgery, with the handle downward, the longer leg is on the outside.
- The longer leg extends 1.1" (2,8 cm) deeper.

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