VOLUME 4 • NUMBER 1 March 2014

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

Reconstructive REVIEW

OFFICIAL JOURNAL OF THE

Joint Implant Surgery and Research Foundation

Strategic Alliance with

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Reconstructive Review
Volume 4, Number 1, March 2014

Reconstructive Review

A Journal Published by the Joint Implant Surgery & Research Foundation

JISRF Founder

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

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- Clinical/Surgical
- Commentary
- Controversial Issues (i.e. modularity, tapers, MoM)
- Historical Reviews
- Letters to the Editor
- Surveys

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is Pleased to Announce a Strategic Alliance with the

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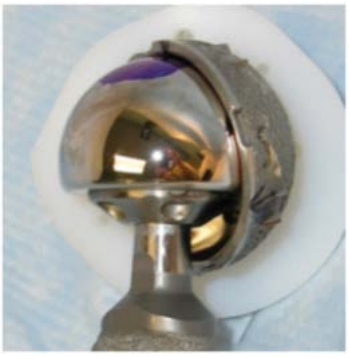
Ian Clarke, PhD & Thomas K. Donaldson, MD



Metal on metal retrieval

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

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- Original Articles
- Basic Science
- Case Reports
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- Historical Reviews
- Letters to the Editor
- Surveys

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

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

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For more information, please contact:

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Greenbrier Medical Institute, 330-697-6581
mekrohn@bmdllc.com

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CASE REPORT

Massive Pseudotumor in a 28mm Ceramic-Polyethylene Revision THA: A Case Report

Edward J. McPherson, M.D., FACS†, Matthew V. Dipane, B.A.†, Sherif M. Sherif, M.D.†

Abstract

This report reviews the findings of a massive pseudotumor detected pre-operatively in a 13-year-old revision total hip arthroplasty. The case is unique in that the bearing involved was a 28mm zirconia ceramic head on a polyethylene liner. We propose that the pseudotumor arose from ultrafine titanium particles liberated from the proximal porous coating of the femoral stem. We suspect that the osteolysis produced from polyethylene wear exposed the proximal porous coating and, via a process of mechanical abrasion with the surrounding soft tissues, liberated ultrafine titanium particles. We believe the pseudotumor formed because the patient was pre-sensitized to metal debris based upon a pre-operative lymphocyte T-cell proliferation test (LTT). Based upon this unique case, we feel that pseudotumors more likely form when there is a high rate of ultrafine metal particles generated in a pre-sensitized patient. Finally, we introduce what we believe are the main biologic wear responses in THA. Further research is needed to validate this proposed model.

Keywords*: pseudotumor, ceramic, polyethylene, osteolysis, THA, bearing wear eesponse, titanium debris*

Level of Evidence*: AAOS Therapeutic Study Level IV*

Introduction

Over the last decade, pseudotumor has become a rising complication of total hip arthroplasty (THA). It was first described by Griffiths in 1987 in a series of 15 patients with metal-on-polyethylene THA. [8] The presentation of pseudotumor varies, ranging from asymptomatic cases accidentally observed during routine follow-up, to a patient with well-fixed implants having pain, to severe osteolysis with implant failure requiring complex revision arthroplasty. Although the pseudotumor response was first described in metal-polyethylene implants, the more recent literature of the last 10 years impugns metal debris as the pro-inflammatory nidus for pseudotumor formation. [1,5,6,7]

We report a case of a massive pseudotumor that arose in a revision THA with a ceramic-polyethylene bearing. Based on intra-operative observation and review of histologic tissue, we propose a mechanism of pseudotumor formation in this case.

Case Review

HISTORY

This case involves a 59-year-old female suffering from avascular necrosis of the hips. She has idiopathic thrombocytopenia and has no other risk factors for avascular necrosis. She had a spleenectomy at age 27. For the right hip, she had a core decompression at age 30. Her right hip condition still remains stable with only mild intermittent pain.

The left hip was treated with primary THA at age 30 (May 1984). Her reconstruction provided a good functional lifestyle, allowing her to enjoy life as a mother. At 15 years post-op she began having pain and a limp. She

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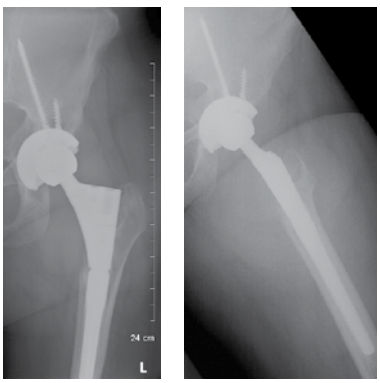
underwent revision THA in June 2000 (16 years post-op) for osteolysis and mechanical loosening of her implants. On the acetabular side, the patient was revised with a porous plasma spray modular titanium cup (Vision™ , Biomet, Warsaw, IN) with 3 screws. The acetabular liner was a compression-molded polyethylene cup (Himont 1900 UHMWPE) with a 10 degree posterior hood placed inferiorly and posteriorly. Her stem was revised with a titanium alloy modular revision stem (Modular Reach™ , Biomet, Warsaw, IN). The head was a 28mm zirconia ceramic bearing (CeramTec, Plochingen, Germany). Post-operatively, she recovered with no problems and again enjoyed an active lifestyle as a mother of 3 children.

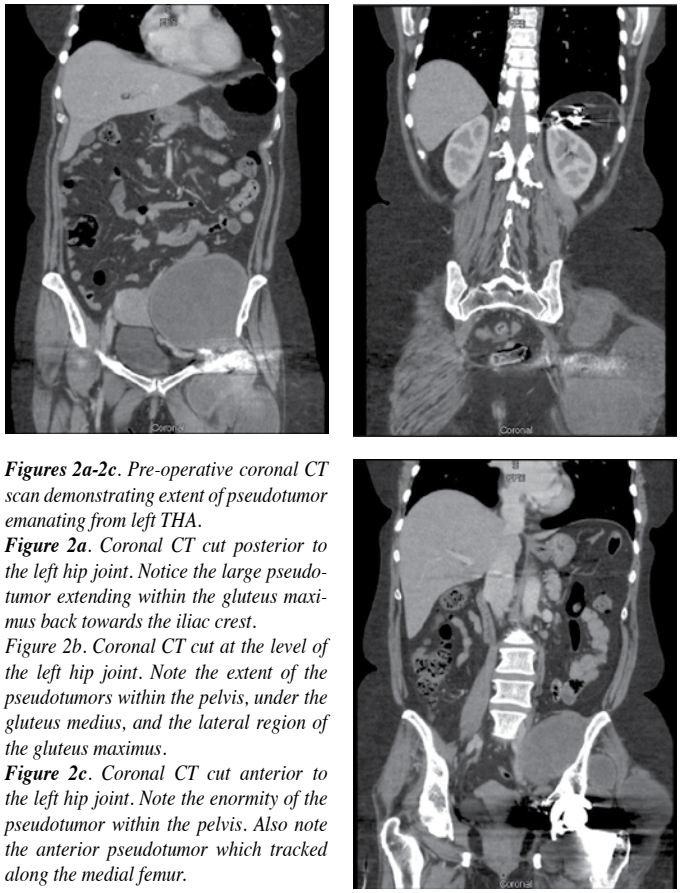
She suffered one late dislocation in 2007 which was treated with a closed reduction in the emergency room. She had no subsequent dislocations.

At 9 years post-op from her revision THA, the patient noted no pain or problems with her hip on annual review. The patient was then seen at 10.5 years post-op. She reported suffering from mechanical low back pain and mild left hip pain. At the time she started a weight loss program with daily exercise and had lost 30 pounds. Eccentric polyethylene wear was noted radiographically. Her hip exam showed no hip irritability. She was started on a lumbar trunk stabilization program and her hip was observed. The patient returned at 12 years post-op and was symptomatic in her left hip. She reported hip clicking with flexion and had activity-related pain and mild hip "fullness." Her hip range testing was comfortable with passive range, but her mid-thigh circumference at that time was 2cm greater on the left. Radiographs showed increased eccentric polyethylene wear. At that time a modular bearing exchange and debridement surgery of the hip was recommended. No other radiographic studies were ordered. The patient declined surgery to finish her teaching duties at an elementary school for the upcoming year.

At 13 years post-op the patient returned with increased pain and swelling (Figures 1a-1b). She had developed numbness and tingling in her left leg. An MRI of the lumbosacral and upper pelvis was performed to evaluate for sciatica. Two tumors were seen on this study which prompted further studies by her local physician. These included MRI's of the pelvis and thigh and a CT scan of the pelvis and chest. Loculated masses were identified within the pelvis, hip, and thigh; all appeared to emanate from the hip region (Figures 2a-2c). In addition, one mass was seen extending to the anterolateral distal thigh. Her hip exam revealed only mild irritability. Her mid-thigh circumference was now 6cm greater on the left.



Figures 1a-1b. *Preoperative radiographs of revision left THA. These are taken 13 years post-operative from the patient's revision THA.*
Figure 1a. *AP Radiograph. Note the significant swelling medial to the hip and superior to the greater trochanter. Notice the osteolytic bone loss of the medial femoral neck region.*
Figure 1b. *Lateral Radiograph. This image demonstrates the significant periarticular soft tissue swelling and peritrochanteric bone loss.*



Figures 2a-2c. *Pre-operative coronal CT scan demonstrating extent of pseudotumor emanating from left THA.*
Figure 2a. *Coronal CT cut posterior to the left hip joint. Notice the large pseudotumor extending within the gluteus maximus back towards the iliac crest.*
Figure 2b. Coronal CT cut at the level of the left hip joint. Note the extent of the pseudotumors within the pelvis, under the gluteus medius, and the lateral region of the gluteus maximus.
Figure 2c. *Coronal CT cut anterior to the left hip joint. Note the enormity of the pseudotumor within the pelvis. Also note the anterior pseudotumor which tracked along the medial femur.*

A hip aspiration was performed, drawing off 175cc of thick, dark fluid with a dark brown and maroon coloring. There was a normal string sign. All cultures were negative. These included aerobic, anaerobic, fungal, and mycobacterium cultures. Fluid analysis showed a red cell count of 840,000 and a white cell count of 1,000 with 58% neutrophils, 32% lymphocytes, and 10% monocytes. Serum C-reactive protein was mildly elevated at 1.6mg/dL (normal <0.3) and erythrocyte sedimentation rate was 32mm/hr (normal 0-15). Her CBC was normal. Serum blood was drawn for a metal lymphocyte T-cell proliferation test (LTT) which was sent to Orthopaedic Analysis. [10,11,19,39] Results showed moderate sensitivity to nickel metal particles (Figure 3).

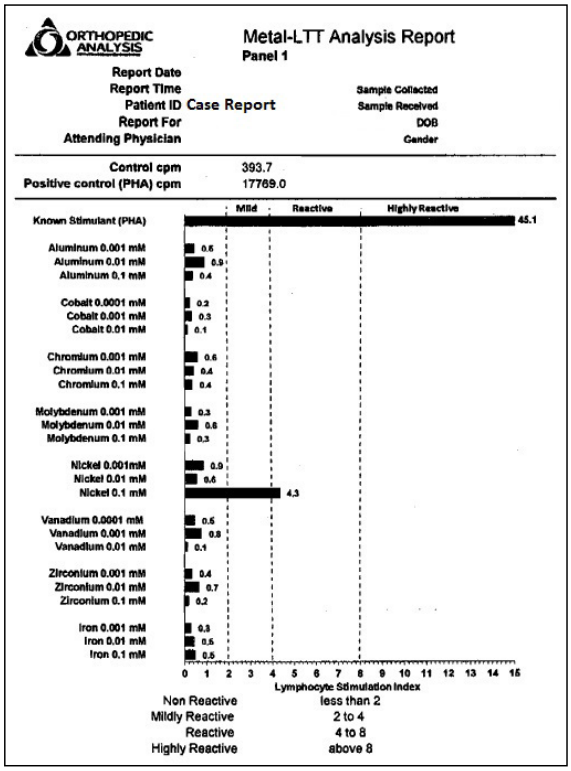


Figure 3. *Graphic display of Lymphocyte T-cell Proliferation Test (LTT) for metal sensitivity. This patient showed moderate reactivity to Nickel particles at 0.1mM concentration.*

INTRA-OPERATIVE FINDINGS

Intra-operative examination showed a large multiloculated mass that was extending in multiple directions surrounding the hip region. A large 8x14cm mass was lateral to the greater trochanter and extended superiorly within the gluteus maximus. Upon entering the mass, the fluid exited under considerable pressure, shooting out approximately 20cm in distance. The fluid was bloody with a coloration of dark brown and maroon (Figure 4).

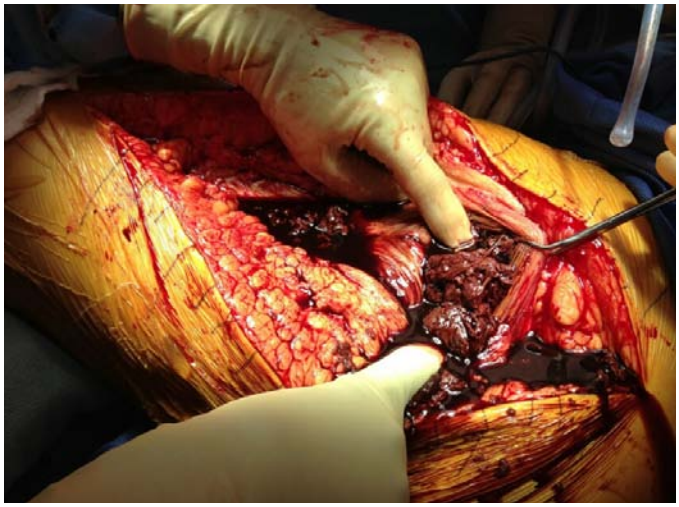


Figure 4. *Intra-operative photograph of left hip pseudotumor upon opening the iliotibial band and splitting the gluteus maximus muscle. Photograph is of the patient in lateral decubitus position with the head to the right of the photo. Note the bloody fibrinous material within the cyst.*

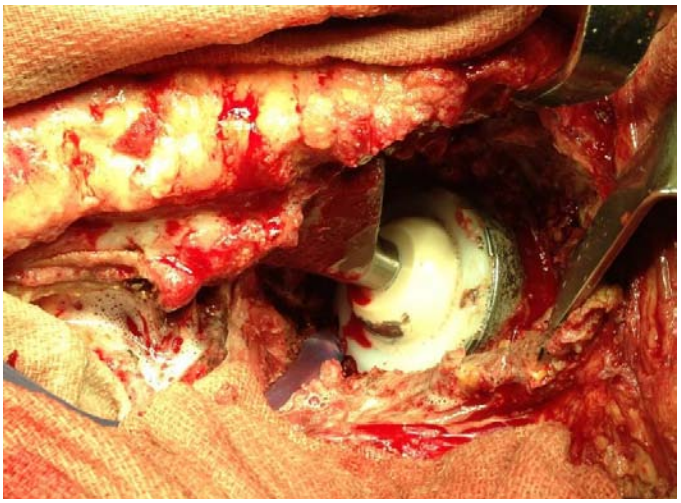


Figure 5. *Intra-operative photograph of left THA in-vivo after excision of posterior and lateral pseudotumors. Significant osteolytic bone loss is seen around acetabulum and proximal femoral stem. Also note the metal smear on the zirconia ceramic head located inferiorly. This was caused by the patient's single hip dislocation 6 years prior. Despite significant osteolysis, both implants were solidly fixed to bone.*

The hip showed implants that were well affixed to bone with porous coating (Figure 5). Severe osteolytic bone loss was noted in the proximal femur down to the metadiaphyseal region. The cup showed several osteolytic holes.

Five major pseudotumor masses were seen. One pseudotumor mass extended along the iliopsoas into the pelvis for a distance of 12cm (Figures 6a-6b). Another mass extended along the femur and under the vastus lateralis to the distal one-third of the thigh. The third mass extended in between the lateral ilium and gluteus medius up to the iliac crest. The lateral peritrochanteric mass extended posteriorly over the gluteus maximus. Finally, the fifth large mass extended down the medial adductor for a distance of 7cm.

The pseudotumors were excised and a modular bear-

Figures 6a-6b. *Intra-operative photographs showing delivery of pelvic pseudotumor into the hip. Photographs show the femur reflected anterior to the acetabulum. Views are of the left hip in the lateral decubitus position.*

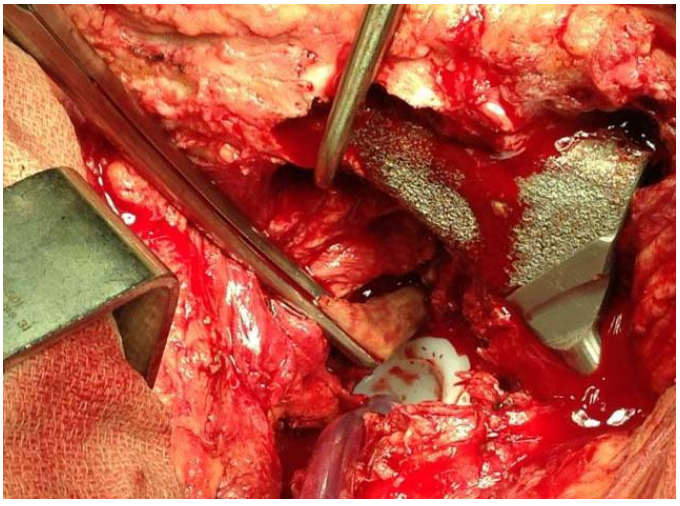


Figure 6a. *Intra-operative photograph. An aortic cross-clamp is seen curving into the pelvis along the iliopsoas. The clamp is grasping the inner wall of the intra-pelvic pseudotumor pulling it inferiorly.*

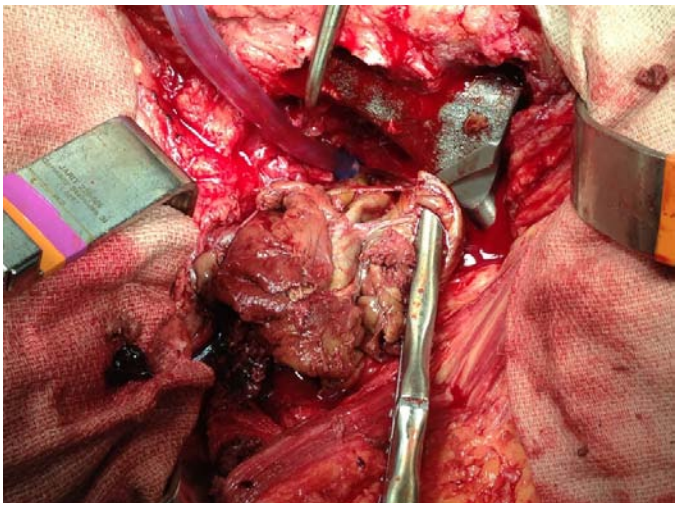


Figure 6b. *Intra-operative photograph. With the assistance of a long rongeur and the aortic cross-clamp, the intra-pelvic pseudotumor is dissected off the iliopsoas with Metzenbaum scissors and delivered into the hip region.*

ing exchange was performed (Figure 7). The femoral taper showed no corrosion or adverse wear (Figure 8). A highly cross-linked, vitamin E infused polyethylene cup (Biomet, Inc., Warsaw, IN) was used. The head was changed over

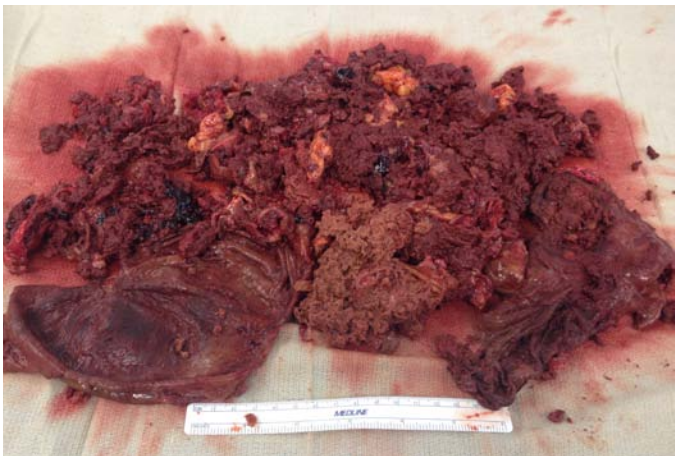


Figure 7. *Photograph of gross specimen recovery of all pseudotumors from the left pelvis, hip, and thigh. Ruler placed inferiorly is 15cm in length.*

Figure 8. *Intra-operative photograph of modular taper junction of the femoral stem. The ceramic head did not have an internal metal jacket. The taper junction shows no abnormal abrasion and is free of corrosion.*

to a 36mm Delta ceramic head with an internal titanium sleeve (CeramTec, Plochingen, Germany). At 1 year post-op the patient still has a mild gluteus medius lurch, but remains pain free.

HISTOLOGY

The histologic examination of the pseudotumor was obtained near the base of the intragluteal pseudotumor, just superior to the acetabulum. It was a representative sample of all five pseudotumor masses resected. The histologic images are presented in figures 9a-9b. Within the cyst there contained old, decaying red blood cells and fibrin clots. The wall of the pseudotumor was thin, measuring 1.5 to

Figures 9a-9b. *Photomicrographs of histologic specimens of pseudotumor. Specimens were preserved in formalin and processed with Hematoxylin and Eosin (H&E).*

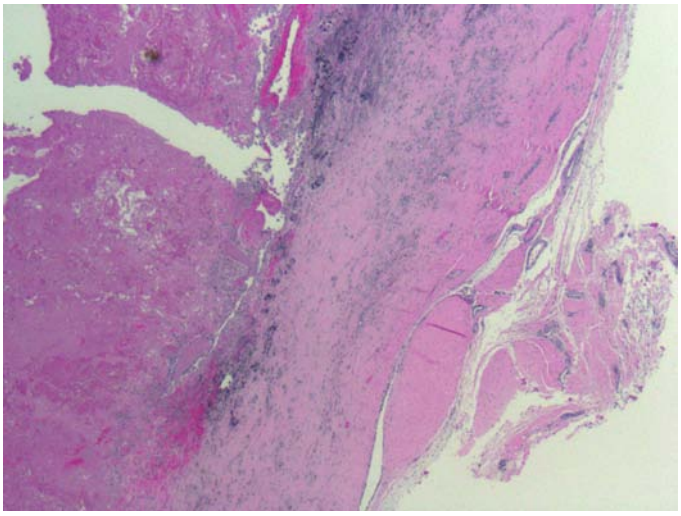


Figure 9a. *4x magnification of pseudotumor showing that the wall itself measures 1.5 to 3mm. Within the cyst there is decaying RBC's along with fibrin clots (left side). One can see the collagen matrix and fibroblasts that form the pseudotumor sac. The inner lining consists predominantly of monocytic histiocytes. There is no lymphocytic response seen within the pseudotumor or in the perivascular regions.*

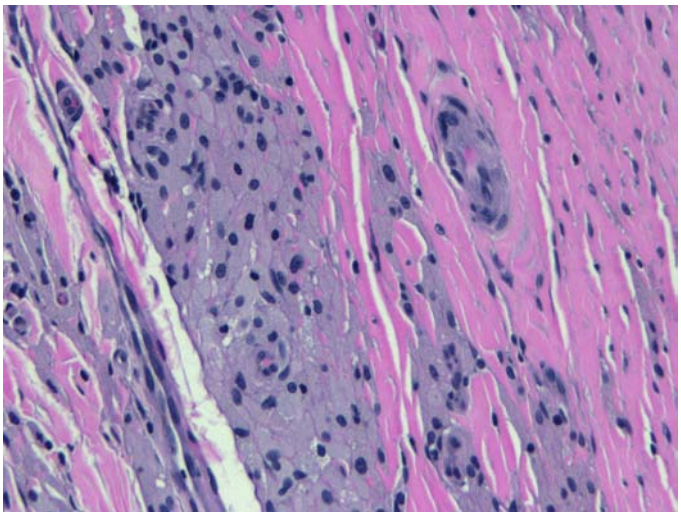


Figure 9b. *40x magnification of pseudotumor wall near its inner surface. Notice specifically the ultrafine light grey/bluish colored particles within the histiocytes. The particles do not refract, indicating that the particles are not polyethylene debris. Instead, these ultrafine particles are likely a titanium alloy particulate shed from the proximal porous coating of the femur.*

3mm, and consisted primarily of collagen fibers aligned haphazardly and interspersed with fibroblasts. The inner lining of the pseudotumor predominantly contained monocytic histiocytes. There was a paucity of giant cells. Furthermore, there was no lymphocytic response within the pseudotumor wall or perivascular vessels. [3,9,10,37] The histiocytes contained ultrafine titanium metal particles (there was no other metal alloy in the hip construct). [29] Some histiocytes contained hemosiderin pigments likely acquired from the decaying RBC's within the cyst. No particles were seen freely interspersed within the collagen matrix. Vascularity to the pseudotumor wall came from local connections from the outer wall to the surrounding muscle. [32,33]

Discussion

This case of pseudotumor formation is unique. The senior author (ejm) has an extensive history of treating metal-metal bearing associated pseudotumors and this case was by far the most extensive pseudotumor he has treated. In all, five large pseudotumor masses were excised in a 5-hour long operation. The bearing in this case was a small-diameter head (28mm) made of zirconia ceramic. The eccentric wear was visually evident, but could not be described as excessive. In addition, we carefully examined the head-taper junction and did not visually observe any taper corrosion reaction nor adverse metal wear. [13] We feel in this case that the osteolysis produced from polyethylene wear exposed the proximal porous coating and, via a process of mechanical abrasion with the surrounding soft tissues, liberated ultrafine titanium particles. Histologically, the histiocytes in the pseudotumor contained ultrafine metal particles. Since no other metal was used in the case, we must conclude that the metal debris derived from the titanium implants.

Most surgeons currently believe the metal debris causing pseudotumors derives from cobalt-chrome alloy bearings. [14,15,16,18,19] This is based upon the wear debris phenomenon seen with metal-metal bearings over the last decade. [20,22,24,27,28] The toxic reactive synovitis seen with this bearing can cause effusion, pain, and, in some cases, pseudotumor formation when the bearing couple is improperly designed or mated.

A pseudotumor reaction consists of an expanding extra-capsular inflammatory process consisting of collagen, fibroblasts, and, in this case, histiocytes. Anecdotal evidence provided by older arthroplasty surgeons described this phenomenon, verbally, as far back as 27 years ago and was associated with metal-polyethylene hip bearings. [8,35] Since polyethylene induced osteolysis is well described and consistent in presentation, the early and later descriptions suggest metal debris as the initiator of pseudotumor formation. The pseudotumor reaction, therefore, may reflect the interaction of an overactive immune system in combination with metallic particulate debris. [10,39]

In this case we call into question the effect of porous coating as a contributor to the particulate metallic load within the effective joint space. Many porous coatings on titanium alloy stems are known to shed debris. [20,38] Furthermore, exposed porous coated surfaces resulting from classic PE-induced osteolysis can release increasing amounts of metal as the area of exposed porous coating increases. In this case the sequence of pseudotumor formation followed an escalating course of periprosthetic osteolysis. We propose that the sequence of events forming the pseudotumor syndrome is the following: (1)PE-induced boney osteolysis eroded the proximal femoral metadiaphysis [4,17,23,25]; (2)the exposed prosthetic porous coated surface mechanically abraded with the soft tissues introducing ultrafine particulate debris into the effective joint space [21,26,30,36]; (3)the patient's pre-sensitization to metal (positive LTT results) triggered inflammatory cytokines to form the pseudotumor capsule. [19,28,31,34]

This case illustrates the point that a pseudotumor can form in the absence of cobalt-chrome implants. A majority of reports in the last decade have impugned cobalt and chrome metal particles of eliciting an immune response unique to that metallic alloy. [10] Based upon this case, we reject that concept outright. We believe that the biological response to particulate hip debris can be categorized into five main syndromes (Figure 10). These biologic responses are based upon particulate type and size, rate of particle formation, and pre-sensitization of the internal immune system to metal debris. [2,12,13,20]

In retrospect, to mitigate the recurrence of the pseudotumor, we advocate sealing off the exposed porous coating to minimize metal particle generation. We feel this would be best accomplished by covering the exposed porous coating with methyl methacrylate cement. In the future, based on the findings in this case, we intend to cover all exposed porous surfaces or, if possible, to replace modular porous segments with segments which have smooth surfaces (preferably polished).

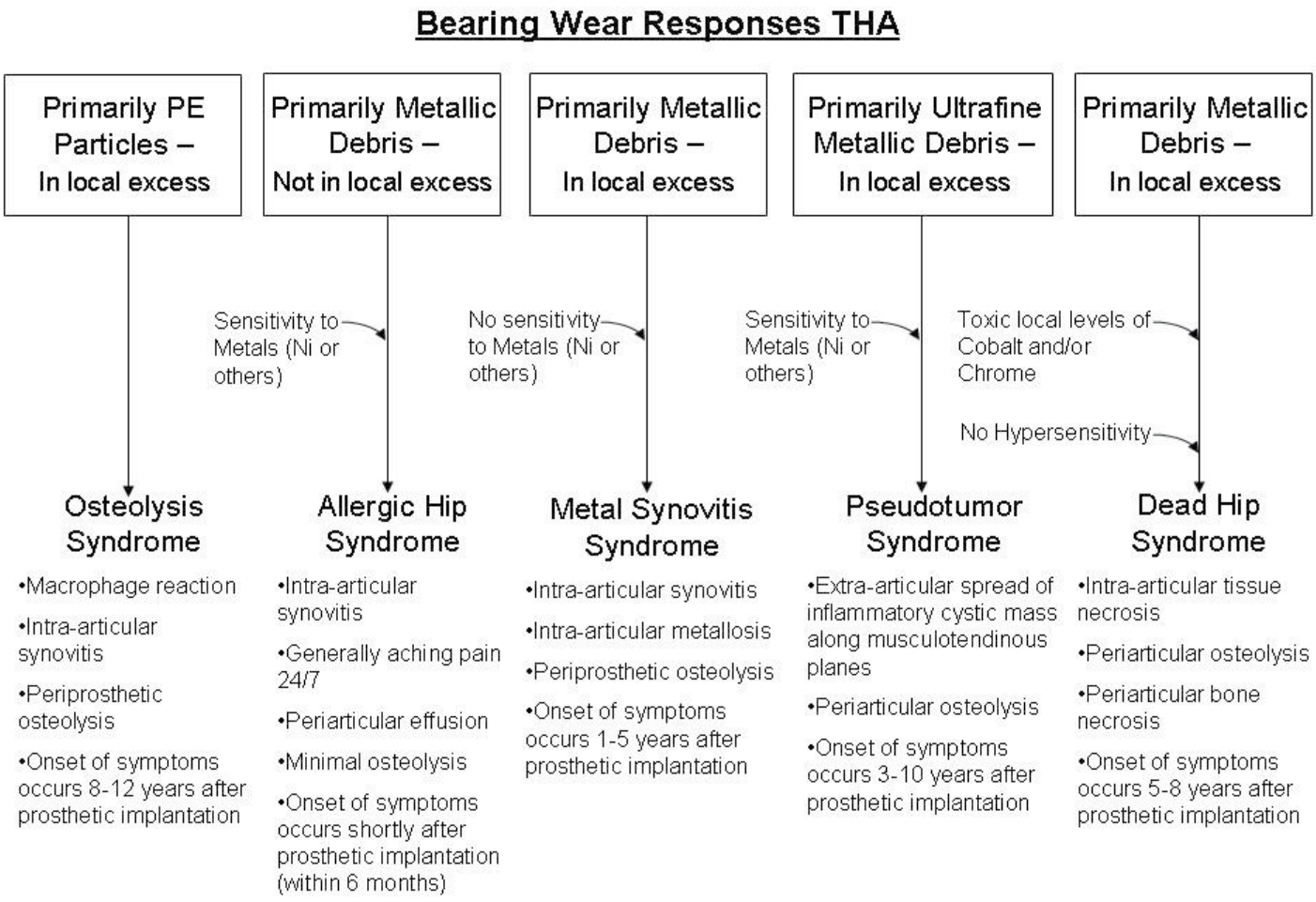


***Figure 10**. Diagram describing the proposed five major biologic wear responses in THA.*

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Reconstructive Review
Volume 4, Number 1, March 2014

ORIGINAL ARTICLE

Mechanical Performance of a Self-Unplugging Surgical Suction Instrument: A Randomized Controlled Trial

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Abstract

Introduction: Obstruction of the surgical suction instrument is a common problem in orthopaedic surgery. Previous attempts have tried to address this problem. The 'Super Sucker' has a screen compartment that can be unclogged upon disassembly. The Yankauer sucker has small holes in its tip that strain larger bits of debris. The aim of this study is to clinically evaluate a new gas-actuated suction instrument in which a special screen at its tip is cleared, as needed, by a rapid burst of pressurized carbon dioxide gas.

Methods: This IRB-approved, prospective, randomized study compared a gas-actuated suction instrument with the Super Sucker and Yankauer in 70 consecutive primary total joint arthroplasty cases. Outcome measures included: incidence of complete suction loss due to suction instrument obstruction; time lost while unplugging the suction instrument; number of additional suction instruments needed; and a subjective surgeon-assessed performance score (1 to 5, with 5 being most favorable) for type of suction instrument.

Results: There were no cases in which the gas-actuated suction instrument could not be rapidly cleared of debris. The Super Sucker completely plugged in 71% of cases, requiring 67 minutes total to unplug (3.9 minutes per case, range 0 to 12 minutes). In four cases, replacement Super Suckers were required to finish the case. The Yankauer completely plugged in 47% of cases, requiring 52 minutes total to unplug (2.8 minutes per case, range 0 to 10 minutes). In three cases, replacement Yankauers were required to finish the case. The average performance score was 2.7 for the Super Sucker, 3.6 for the Yankauer, and 5 for the gas-actuated suction instrument on a scale of 1 to 5, with 5 being most favorable.

Discussion: This study evaluated a suction instrument in which a screen tip prevents obstruction, and a burst of pressurized carbon dioxide gas clears debris from the tip. The new suction instrument was successful in 100% of cases, with considerably less time lost compared to the other suction instruments. The gas-actuated suction tool actively and rapidly cleared obstructive debris with minimal disruption to the surgical flow. Recent clinical experience has shown the gas-actuated suction tool to be particularly enabling in the settings of tourniquet-free total knee replacement, small incision total hip replacement, bipolar hemiarthroplasty, and revision total hip replacement.

Keywords: *suction, total joint arthroplasty, tourniquet-less, carbon dioxide gas*

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Introduction

For generations, modern surgical technique has utilized the ability of operating room vacuum systems to create suction as a method of evacuating fluids and debris from a surgical field. This problem is no more manifest than in orthopaedic surgery, where a fundamental principle in the treatment of surgical wounds is to flush the tissue with high volumes of sterile antibiotic-loaded fluid to reduce bacterial contamination. An important technical issue for the removal of fluids is the ability to maintain an unobstructed flow of suction. Plugging of the suction instrument is a source of irritation and delay for orthopaedic surgeons all over the world who deal with the typical suction instrument that becomes chronically plugged due to small fragments of bone and soft tissue. This debris is created during surgical manipulations and can become lodged in the tip, internal chamber, or tubing of the suction instrument (Figure 1). A number of systems have been designed over the years to deal with this problem. One such device, known as the 'Super Sucker' (Gateway Medical, Mooresville, NC, USA), utilizes a modular plastic device that has a tubular screen in the proximal part that, once plugged, allows the surgeon to disassemble the device, clean off the screen, reassemble the device, and resume the operation. [7] This maneuver can be required 4 to 5 times during a standard orthopaedic procedure. In addition, the suction tubing may become clogged by a chunk of bone that becomes lodged at one of its internal junctions.

This study evaluates the performance of a new surgical suction instrument that is designed to be self-unplugging via a mechanically activated jet of carbon dioxide (CO2) gas. The tip of the instrument contains a porous metal screen that is intended to capture solid and viscous material that has been liberated from a surgical wound. The pores in the screen tip are a fraction of the inner tubing diameter, thus preventing large chunks of bone from moving up the tube and becoming lodged. A porous metal screen was found to be more effective than a wire mesh screen, as the porous metal screen could easily be wiped of debris, much as a spaghetti strainer. The suction instrument also includes a long thin tube that is placed inside the suction conduit for delivery of a positive pressure carbon dioxide (CO2) gas jet to the back side of the screen. The effect of this internal gas jet is to 'blast' debris off of the tip as needed (Figures 2A and 2B). The hypothesis of this study was that the gas-actuated suction instrument would be less likely to plug during a typical orthopaedic procedure such as a total joint arthroplasty (TJA). A randomized control trial was designed to test the hypothesis against two commonly used suction instruments, the Yankauer and the Super Sucker. [7,10]

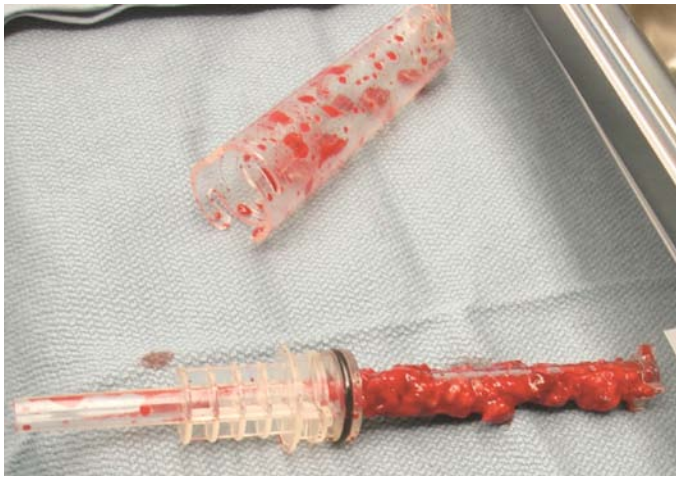

Figure 1. *Discarded 'Super Sucker' that clogged during primary TKA; Obstruction is a relatively common occurrence.*

Methods

This study is an IRB-approved, single-blinded, randomized controlled trial. Patients were recruited from the

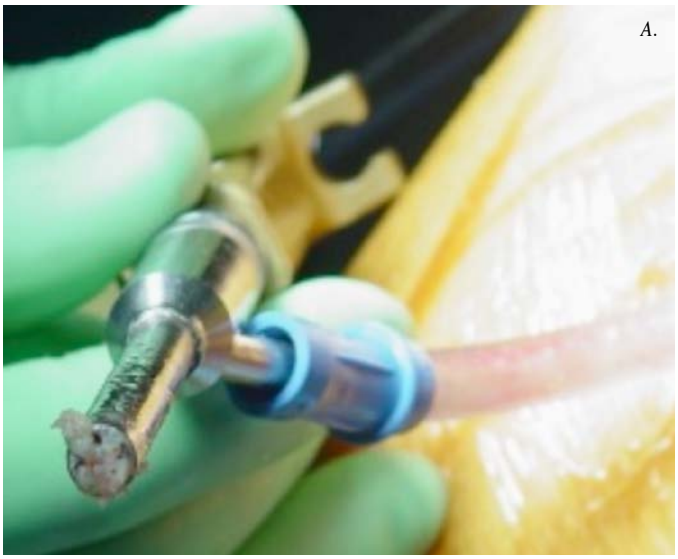

Figure 2. *(A) Clogged suction tip; blockage at screen prevents continuous flow of suction. (B) Same suction tip immediately after screen has been cleared by a rapid blast of pressurized medical-grade carbon dioxide gas.*

surgical practice of the author. During the study period, all consecutive patients requiring total knee (TKA) and total hip (THA) arthroplasty were asked to participate. Seventy patients (40 TKA and 30 THA) provided informed consent and were enrolled. Because this study evaluated a specific characteristic during the surgical procedure, the only patient contact was the original recruitment and consent process for the study. Using a computerized randomization scheme, the 70 patients were randomized into one of three study groups: TJA performed with either Super Sucker (n=17), Yankauer (n=19), or the gas-actuated (n=34) suction instrument. Patient characteristics are summarized in Table 1.

The CO2 gas-actuated suction instrument consists of a hand piece attached to two tube connections, one tube for the standard operating room vacuum suction line, and another tube for a pressure-regulated positive supply of CO2 gas through the suction tip (Figure 3). Carbon dioxide was the gas of choice as it is delivered sterile and has been used for decades for similar purposes, such as with the FDA-cleared CarboJet® lavage system (Kinamed Inc, Camarillo, CA, USA). [4,5,8,9] The CarboJet lavage system was connected to the new suction instrument for the current study. The suction tip includes an inner tube with a connector that attaches to the CarboJet lavage hand piece such that activation releases a jet of CO2 to the undersurface of the suction tip. The Yankauer, 'Super Sucker', and the gas-actuated suction instrument all used the standard vacuum hose tubing that connects to a typical operating room suction canister pulling 45 psi of negative pressure. Outcome measures included: incidence of complete suction loss due to suction instrument obstruction; time lost while unplugging the suction instrument; number of additional suction instruments needed; and a subjective surgeon assessed performance score (5 for the highest performance and 1 for the lowest performance).

Statistical analysis. Pilot testing demonstrated that traditional suction instruments become completely obstructed at least once during more than half of TJA cases. It was determined that, at a 95% confidence level and with 80% power, a sample size of 14 patients per group were required to detect a statistically significance difference between an instrument that plugs in 60% of cases versus one that plugs in 10% of cases. Student's t-tests and analysis of variance (ANOVA) tests were used to assess differences in continuous variables (e.g. patient characteristics, time lost due to obstruction) and chi-squared tests were used to compare proportional differences in categorical variables (e.g. gender, presence or not of obstruction). [2] A p-value of 0.05 was considered statistically significant.

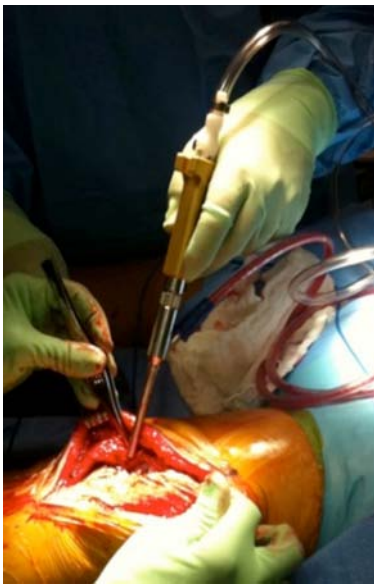

Figure 3. Gas-actuated suction instrument in use during primary TKA.

Results

There were no cases in which the gas-actuated suction instrument could not be rapidly cleared of debris. The Super Sucker completely plugged in 71% of cases, requiring 67 minutes total to unplug (3.9 minutes per case, range 0 to 12 minutes). In four cases, replacement Super Suckers were required to finish the case. The Yankauer completely plugged in 47% of cases, requiring 52 minutes total to unplug (2.8 minutes per case, range 0 to 10 minutes). In three

Table 1. Patient characteristics.
Height and weight data reported as average ± standard deviation (range).

	Group 1 (Super Sucker)	Group 2 (Yankauer)	Group 3 (Gas-Actuated)	Comparing all 3 Groups
n (Patients)	17 (12 TKA, 5 THA)	19 (9 TKA, 10 THA)	34 (19 TKA, 15 THA)	
Height (inches)	66 ± 3 (61 to 71)	67 ± 5 (60 to 74)	65 ± 4 (60 to 72)	Not Significant (p=0.57)
Weight (lbs)	192 ± 43 (112 to 240)	191 ± 56 (76 to 288)	177 ± 50 (83 to 281)	Not Significant (p=0.48)
BMI	31 ± 6.5 (20 to 43)	30 ± 8 (13 to 47)	29 ± 6.5 (15 to 40)	Not Significant (p=0.47)
Age (years)	72 ± 9.7 (54 to 88)	70 ± 11 (49 to 88)	74 ± 11 (51 to 100)	Not Significant (p=0.43)
Males:Females	7:10	7:12	8:26	Not Significant (p>0.19)

cases, replacement Yankauers were required to finish the case. The average performance score was 2.7 for the Super Sucker, 3.6 for the Yankauer, and 5 for the gas-actuated sucker on a scale of 1 to 5, with 5 being most favorable. These results, including the statistical analyses, are summarized in Table 2.

Discussion

This study evaluated a suction instrument in which a screen tip prevents obstruction, and a burst of pressurized carbon dioxide gas clears debris from the tip. The new suction instrument was successful in 100% of cases, with considerably less time lost compared to the traditional suction instruments. The traditional suction instruments demonstrated a high tendency to plug. The Yankauer suction instrument could be unplugged by inserting a narrow probe, such as a Bovie tip, into its tip to dislodge the obstruction. The Super Sucker plugged more frequently as the screen in the mid-portion of the device captured the debris. The Super Sucker required the most time for unplugging and it was noted that suction was not always restored to the original state. The gas-actuated suction tool actively and rapidly cleared obstructive debris with minimal disruption to the surgical flow.

The primary limitation of this study is the fact that all cases were done by the developer of the gas-actuated suction instrument who had considerable prior experience in developing the screen tip and the methods to easily clear it. One of these methods is related to the finding that debris and viscous fluid, as is often found in the hip joint after a femoral neck fracture, can congeal in the tube of the gas-actuated suction instrument if not completely cleared. Experience has shown that occasionally suctioning irrigation fluid will eliminate this plugging. In addition, on occasion collagenous soft tissue will collect on the screen tip surface and cannot be blown away by the CO2 jet. Because the metal tip functions like a spaghetti strainer, simple brushing of the tip with a finger will dislodge the debris and allow it to be suctioned away. With attention to these details, no examples of complete plugging of the gas-actuated suction instrument were noted in this study.

Clinical studies on actuated suction instruments are rare. The patent literature, however, describes other types of actuated suction instruments. The author has filed several such examples, but all lacked the simplicity and efficiency of the gas-actuated system studied here. Most of these ideas attempt to combine the function of suction and irrigation with a mechanism to redirect flow. Prusmack [11] described a concept developed for spine surgery with a thumb-valve mechanism for activating the flow of air or fluid irrigant into a common neurosurgical sucker conduit and designed a simple stop-cock mechanism to control the suction outflow from this conduit. Unfortunately, the Prusmack idea ignores fluid mechanics as the negative pressure created by the suction outflow will compromise the flow of air into the suction conduit. To counteract this problem, the user of such a system would need to secondarily turn off the stop-cock for suction outflow to create a 'closed' non-suctioning system. The gas-actuated instrument described in this paper uses the high air inflow created by the Venturi effect of a narrow conduit over the distance of the suction instrument in order to create a blast of CO2 of sufficient force to dispel debris from its tip. The system is 'open' and the countereffect of suction is minimal at the tip of the instrument. Efficiency is optimized as the entire unplugging maneuver occurs rapidly with activation of the CO2 gas jet via a trigger valve.

Several surgical techniques may benefit from a more efficient suction instrument. Recent clinical experience has shown the gas-actuated suction tool to be particularly enabling in the settings of tourniquet-free total knee replacement, which continues to gain interest, "small incision" total hip replacement, bipolar hemiarthroplasty, and revision total hip replacement. Tourniquet-less total knee arthroplasty has been shown to reduce the risk of nerve injury, acute phlebothrombosis, and postoperative hematoma compared to cases where a tourniquet is used. [3,6] The gas-actuated suction instrument also functions as an excellent retractor when not in use, which can be advantageous during minimally invasive procedures. Considering the

Table 2. Summary of results.

	Group 1 (Super Sucker)	Group 2 (Yankauer)	Group 3 (Gas-Actuated)	Comparing all 3 Groups	Comparing Groups 1 and 2 only
n (Patients)	17	19	34		
Obstruction Rate	71% (12/17)	47% (9/19)	0% (0/34)	p<0.001	Not Significant (p=0.16)
Average time to unplug (minutes)	3.9 ± 3.5 (0 to 12)	2.8 ± 3.0 (0 to 10)	0	p<0.001	Not Significant (p=0.28)
Average Score	2.7± 1.5 (1 to 5)	3.6 ± 1.3 (2 to 5)	5	p<0.001	p=0.03

nontrivial cost of operating room time [1,12], the gas-actuated system offers the benefit of reduced operative time. In conclusion, the new gas-actuated suction instrument has been shown to be effective for eliminating the problem of clogged surgical suction.

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Reconstructive Review
Volume 4, Number 1, March 2014

HISTORICAL REVIEW

Utility of Carbon Fiber Implants in Orthopedic Surgery: Literature Review

Ronald Hillock, MD§, Shain Howard, BS†

Abstract

Carbon fiber (CF) consists of a multitude of unique physical, chemical and biological characteristics that can be utilized and exploited for a number of diverse applications. Found in aerospace systems, structural elements, energy storage and other products, the most recent application of CF has expanded into the realm of surgical implants. The material properties of CF, historical development and applications and methods of manufacturing are illustrated upon. The various surgical applications of CF are defined, from biocompatibility within the human body and wound healing products to numerous surgical implantations.

Keywords: carbon fiber; orthopedics; historical review

Introduction

Carbon fiber (CF) offers many unique physical, chemical and biological characteristics that can be exploited for many diverse applications. CF components can be found in aerospace systems, structural elements in civil engineering projects, automotive components, lighting filaments, energy production systems, power transmission systems, energy storage, sporting goods and recently, their use has expanded into the surgical implant space.

Material Properties of CF

CF offers many unique physical and chemical properties to include high heat tolerance, high strength to weight ratio, resistance to corrosion, & conductivity.

One measure of stiffness is modulus of elasticity

Elastic modulus = stress/strain

Modulus is measured in units of pressure such as Pascal or pounds per square inch (PSI). It is typical for large measurements to be listed as thousands or millions KSI and MSI respectively. The modulus of carbon fiber is normally 20 MSI, significantly greater than comparable materials such as 2024-T3 aluminum or steel, which have moduli of 10 and 30 MSI respectively. [1]

The tensile strength of CF is greater than comparable metallic materials. The ultimate tensile strength of CF is 500 KSI, significantly stronger than 2024-T3 aluminum 65 KSI or steel 125 KSI. The added advantage of a lower density than comparable materials is responsible for the increased strength to weight ratio. The strength of CF devices is further augmented by the layout and orientation of the carbon fibers and the ratio of CF to polymer, like carbon fiber reinforced polymer (CFRP), which is comprised of a combination of CF and polyethylene. CF materials generally have an increase in tensile strength and stiffness when layers of CF fibers embedded in polymer are oriented at different angles. [2]

Of note it is difficult to compare CF to metallic devices for endurance limits, as CF does not have a definable endurance limit. A lack of a predictable stress cycle failure makes engineering calculations more difficult. This is overcome by allowing a greater margin than would typically be used with non-CF structural materials. [2]

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Historical Development and Industrial Application of CF

The first commercial application of CF was in the filaments of the light bulb in 1879. The first industrial enterprise dedicated to the use and manufacture of CF materials was the National Carbon Company in Cleveland, Ohio, established 1886. The physical and chemical properties of CF were studied in detail and published in 1956 by R Bacon of the Parma Technical Center [3]. Bacon later went on the develop CF nanotubules, small segments of CF filament that resume their original shape and orientation in the face of mechanical deformation. Nanotubules have been shown to be the strongest material per mass ever fabricated by humans.

Later developments in CF applications came in the 1960s with the development of the process known as "hot stretching." [4] When heated to extremely high temperatures, CF could be molded and pulled into a carbon yarn that could be formed into heat resistant components. The aerospace industry was then able to exploit this feature in the fabrication rocket nozzles, missile protective tip covers, heat resistant gaskets, heat-resistant aircraft structural members and spacecraft heat shields. When compared to metallic devices, CF offered reduced mass, increased strength and increased heat resistance. CF materials were ideal for aerospace applications allowing for the creation of more novel vehicles with increased performance characteristics as well as savings in fuel consumption.

Further advances in CF materials came out via the addition of polyacrylonitirel (PAN). [5] The combination of PAN with CF created a material with a higher modulus of elasticity and heat resistance. PAN-based CF materials have further expanded applications in aerospace, civil engineering and electric storage lithium batteries.

The next wave of CF production technology came by taking advantage of petroleum and coal based starting materials that were heated to produce "pitch.. While heating the precursor material purifies its carbon content and gives the structure order, precursors differ in their ability to approach perfect graphite structure on heating. Pitch approaches a level of order closer to perfect graphite crystal than either PAN or rayon. With higher carbon content and the ability to align and layer the molecules, pitch based CF had a higher elastic modulus and became the first carbon fibers to have very high thermal conductivity. With more perfect CF filaments, the material could then be used in electronic circuits and high performance aircraft brake pads.

Other teams also working with PAN-based CF in the 1960s developed a low modulus PAN fiber with a very high tensile strength that went on to become the material widely used in sporting goods applications, golf clubs, snow and water skis, as well as baseball bats (2013).

Industrial Corporate Evolution of CF Applications

Union Carbides main CF division was eventually sold to Amoco, later then acquired by Cytec Industries. With its headquarters in New Jersey and 5,800 employees worldwide, Cytec continues to deliver both pitch and PAN based CF products. Its earnings are up 64% compared to the prior year quarter; second quarter 2013 sales are $514 million, and the significant increase in earnings per share (EPS) are largely attributed to their aerospace materials division. [6] The United States Department of Energy (DOE) has also been seeking to develop CF applications. Oak Ridge National Laboratory in Tennessee, the largest science and energy laboratory in the DOE, has been working toward a lower cost CF production and application project with the goal of making CF more accessible for the benefit of industry and the economy. [7]

In Japan, Toray Industries focused on synthetic chemistry and biochemistry in order to expand its scope of business to include fibers, textiles, plastics, and pharmaceuticals. It is currently the world's largest producer of CF. Among the many customers of Toray Industries, the Boeing Company has taken advantage of the properties of CF in the production of lighter more efficient aircraft. The Boeing 787 Dreamliner is the company's latest and most fuel-efficient airliner. This twin engine, 210–330 passenger jet airliner is mostly composite material, with CFRP accounting for 50% of its material. [8]

Another aircraft whose design takes advantage of the unique features of CF is the United States Air Force F-22A Raptor air superiority jet fighter. [9] The Raptor was designed to be a more agile, stealthy, and longer range replacement for the aging fleet of F-15's. The Raptor can cruise at speeds over Mach 1.5 without using an afterburner. The Raptor is built from 24% composite other than metal materials, with CF composite components used in the fuselage frame, doors, and wing structural elements.

CF has also led the revolution of speed and performance on the ground. The McLaren Formula One racecar was the first to use a CF composite monocoque, which describes a system where a vehicle is supported by its external surfaces. [10] Since then, CF has become widely used in automotive monocoque assemblies. CF elements can be found in NASCAR vehicle exterior components, and both the interior and exterior of many of the world's finest supercars.

Ferrari's latest offering, the F70, has a body and frame that is largely fabricated from CF materials as a weight reduction measure, greatly enhancing performance while reducing mass. [11]

A less exotic use of CF technology that is becoming increasingly common can be found in civil engineering applications for both new structures and reinforcement of existing structures. One example is CFRP used in the reinforcement of bridges for both flexural and shear applications. The mechanism of flexural improvement has been shown to be through increasing fatigue life by reducing the magnitude of steel stress when used to reinforce girders, which are structural beams. [1]

Published studies have investigated the effects of CFRP on shear resistance. One such study investigated the use of L-shaped CFRP plates on a shear deficient concrete structure. The L-shaped CFRP plates used were not damaged after 5 million cycles at a load equal to 59% of failure load. The eventual mode of failure was crushing of the concrete after the internal flexural reinforcement gave way. [12]

The Oregon Department of Transportation has put a significant amount of research into shear stress strengthening as it relates to CF. Their results show a significant increase in load capacity and stiffness in CFRP repaired beams. This improvement was maintained, even after being exposed to the equivalent of twenty years of traffic induced fatigue. These findings have lead to many US States and Canadian Provinces adopting CFRP members in bridge reinforcement projects. [1]

Manufacturing

Although historically rayon had been used in the production of CF, two main precursors are used today. One is based on pitch while the other is based on PAN; with each having it's own unique set of properties.

Pitch fibers have larger crystal size, higher modulus/stiffness, and higher electrical & thermal conductivity. The University of Tennessee Space Institute (UTSI) is currently researching and producing pitch-based CF production. The process involves selecting a pitch with adequate softening point temperature then passing it through a spinning device. After being cooled from liquid to solid, the fibers undergo the rate-limiting (cost and time) step of oxidative stabilization. The final step is carbonization or graphitization, where the product is heated in a solution to dissolve and remove any residual non-CF contamination.

PAN fibers are the most commonly used CF. They are expensive to produce, have small crystals, high tensile strength, good flexibility, and good electrical conductivity. PAN fibers are made by stretching, heating, and oxidizing PAN precursor filaments. Carbonization at very high temperatures (1200°C) in a nitrogen atmosphere purifies the carbon content.

There are a few different ways of making CF reinforced products (molding, compression molding, filament winding, & vacuum bagging) from these precursors. With each of these methods, the directional CF are layered perpendicular to one another and some type of resin is added. The resin/reinforcement used determines the name and the properties of each carbon fiber type. [13]

A few examples are:

- CFRP – carbon fiber reinforced plastic
- CRP – carbon reinforced plastic
- CFRTP - carbon fiber reinforced thermoplastic
- CF-PEEK – carbon fiber polyether ether ketone

Hybrid fabrics such as carbon-Kevlar can also be produced. [14] This protects and enhances the properties of carbon fiber leading to a very high tensile strength, high impact, and abrasive resistant product. This has been used the fabrication of combat helmets, composite armor reinforcement, penetration resistant body armor garments, ropes, and cables.

Manufacturers such as FiberForge™ have reduced the explanation of the process to 4 simple steps: layup, consolidation, forming, & trimming. [15] The process and machinery allows for reduced production time, while allowing customization of CF products and forms.

CF materials are expensive when compared to similar metallic elements on a unit mass basis. Excess CF materials can't be recycled and simply melted down, as is the standard in metal device manufacturing. Recycled CF material leads to reduced fiber lengths. Some applications do not need long CF strands such as laptop computers and other electronic devices. This can be done when the waste CF materials do not contain toxins such as halogenated polymers (e.g., PVC).

Medical Application of CF Materials

Advances in the manufacture of carbon fiber have allowed large-scale production of a more diverse array of carbon fiber composites. As in other industries, its physical properties have lead to many innovations in medical implants and devices. CF medical applications range from dental orthodontics to medical limb prosthetic fabrication; literally from head to toe examples are now found on the market.

WOUND HEALING PRODUCTS

A bilayer wound dressing developed in 2012 has shown to accelerate wound healing. An oxidized PAN-CF cloth has been used as the starting base material in wound dressings. This PAN-CF cloth was treated with phosphoric acid and steamed at high temperatures to activate it before adding a gentamycin gelatin membrane. Follow up examination of wounds treated with this device at days 2, 4, 8, and 12 after surgery in 24 specimens showed the bilayer dressing acted as a scaffold in wound healing. This scaffold promoted fibroblast growth and migration, leading to up-regulation of fibronectin and type I collagen, which was theorized to have allowed for accelerated wound healing and closure. [16]

BIOCOMPATIBILITY

Carbon fiber reinforced PEEK (CF-PEEK) has good mechanical properties, high resistance to ionizing radiation, and lower wear than comparable materials like ultra high molecular weight polyethylene (UHMWPE). A 2010 study compared the inflammatory response of CF-PEEK pitch, CF-PEEK PAN, and UHMWPE. Wear particles from each of these materials were injected into the left knee of 50 rats. Fluorescence microscopy and subsequent (7 days later) histological analysis were used to assess synovial microcirculation and leukocyte-endothelial cell interaction as measures of inflammatory reaction. Results indicated no significant difference in inflammatory response generated by each of the particle types, therefore both types of carbon fiber are theorized to be potential alternatives to UHMWPE as bearing materials in arthroplasty. [17]

CF has increased strength and stiffness with better fatigue and wear resistance than comparable metal alloys such as titanium. It also has an elastic modulus much closer to that of bone and is radiolucent, all of which make it a favorable implant biomaterial. Establishment of these strengths has allowed research to focus on its few biocompatibility limitations, which include its bio-inert and hydrophobic properties. A 2010 study examined the use of Diamond-like carbon (DLC) as a coating for PEEK. Plasma immersion ion implantation and deposition was used to coat 5x3 mm samples of PEEK. The structure and surface were then analyzed with atomic force microscopy, X-ray photoelectron spectroscopy, and Raman spectroscopy. The hydrophilic nature of CF was assessed with static contact angle measurement by the sessile drop method on a ramé-hart instrument. Hardness and elastic modulus were measured by nanoindentation. Finally, human fetal osteoblast cell lines and rat calvaria-derived osteoblast were used to assess the DLC-coated PEEK. Cell viability, scanning electron microscopy, and real-time PCR showed that osteoblast attachment, proliferation, and differentiation were better on DLC-PEEK. [18]

A review of the published literature will show that no cases of allergic reaction to CF implants have ever been reported in animal models or clinical applications in human subjects. No known hypersensitivity response has ever been documented in CF implant application.

Specific Clinical Applications of CF Implants

CRANIUM

CF-PEEK reinforced implants made by stereolithography have shown to be effective in cranioplasty. Between 1996 and 2002, 41 CF-PEEK implants created by stereolithography from helical CT were performed on 37 patients with large/complex cranial defects. 21 of these cases had frontal sinus involvement, a recognized risk factor for complications. Excellent results were attained in 87.8% of these cases. [19]

MAXILLOFACIAL

In the field of orthodontics, CF has recently been compared to other commonly used materials. In 2011, fifty human incisors were cut and prepared with each of the following types of posts: serrated titanium, CF reinforced, individually formed glass fiber reinforced (GFR), and individually formed split-GFR. Intact human incisors were used as the control. Stiffness was measured by microstrain, using the strain gage technique. Load bearing capacity was measured using a static load applied at forty-five degrees on the palatal side. Fractures that extended from the load-bearing site, across the incisor, and below the margin of stimulated bone were considered unfavorable. The intact group had the highest initial fracture load, while the titanium group had the highest number of unfavorable fractures. The composite groups showed a comparable load bearing capacity with a lower number of unfavorable fractures. The favorable fractures of the composite group have the advantage of being clinically repairable. [20]

CERVICAL SPINE

Multiple studies have shown the use of CF cages at the cervical spine. One study followed 97 patients suffering from myeloradiculopathy caused by spondylodiscarthrosis, simple disc herniation, or posttraumatic disc herniation. These 52 males & 45 females received microdiscectomy followed by inter-body fusion with CF cage stabilization, with only 10 cases requiring anterior plates. Of

the 91 patients that were followed to end state, there were no cases of spontaneous implant displacement, persistence of nerve compression symptoms, or change in intervertebral height. [21]

The use of cervical CF cages has also been compared to the Smith-Robinson technique. The traditional method of a Smith-Robinson cervical fusion is through the use of autologous tricortical iliac crest placed into the disc space. One study divided 40 patients with degenerative disc disease or refractory cervicalgia with radiculopathy into two groups. Half of the patients received a CF cage with iliac crest cancellous autograft. 19 patients of the second group received DePuy hardware and the last patient received CF-PEEK, all with unicortical locking expansion screws. After randomization, there was no significant difference between the two groups, indicating that in addition to the reducing graft site pain, the CF cages were an acceptable alternative to the classically performed Smith-Robinson technique. [22]

LUMBAR SPINE

CF has also proven to be a very effective material in the lumbar spine implant applications. A two-year prospective study of 46 patients with isthmic or degenerative spondylolisthesis helped establish its use. This group of 21-75 year old patients had symptomatic spondylolisthesis at a single level below L4 with greater than 3 mm translational misalignment. The results of increased fusion, increased function, decreased pain, and decreased complications are extremely positive. [23]

SPINE IMAGING

The strength of CF in spinal procedures is further bolstered by studies highlighting the radiological advantages as compared to the metal products that have been classically used. One of such studies compared carbon, titanium, and cobalt-chrome with the control of human cortical bone. This cadaveric study used a 1.5T MRI, focusing on 12 regions of interest, which were used to create a twenty-four point scoring system to evaluate the "distinguishability" of each sample. Cobalt-chromium ranked 50%, titanium ranked 62.5%, and carbon ranked the highest with 83.3%. Carbon allowed superior evaluation of local implant situation and pathological process while maintaining a lower susceptibility to cause image artifact. [24]

HUMERUS

Although many of the previously discussed properties of CF products have been characterized in studies since the early eighties, a 2012 study of CF-PEEK Optima (Piccolo™ system) further validated their use in orthopedic traum. [25] Among the CF-PEEK products evaluated was a proximal humeral plate (PHP), which was tested for four-point bending, static torsion, bending fatigue, and wear. Results showed the PHP to be sufficient for humeral fracture fixation. [26]

The Piccolo™ system is Manufactured and Marketed by Carbo-Fix™ , in Herzeliya, Israel. [25] The low profile PHP has suture holes on the proximal end of the plate, allowing for the use of K-wires for provisional fixation or suture eyelets for use of suture stabilization in osteoporotic bone. The Carbo-Fix™ PHP takes advantage of 3.5 mm proximal humeral head fixed angle threaded locking holes

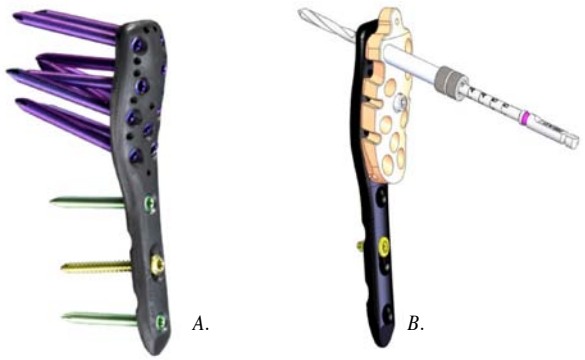


Figure 1: *CarboFix™ proximal humerus plating system with aiming guide attached (A) and with locking and nonlocking screw options in place (B). Images reproduced with the expressed permission of CarboFix Orthopedics Ltd. 11 Ha'hoshlim St., Herzeliya 46724, Israel.*

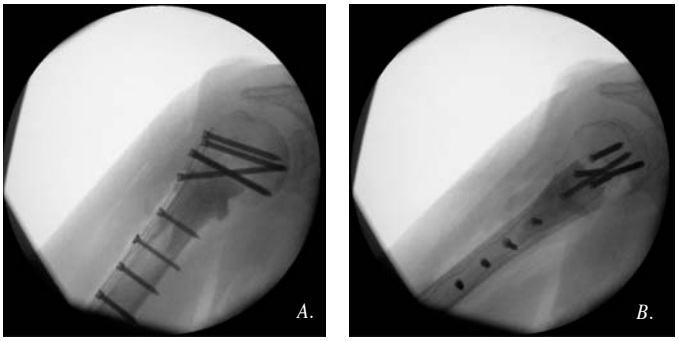


Figure 2: *Anterior to posterior (A) and lateral (B) intra-operative fluoroscopic images of a CarboFix™ proximal humerus plate used to stabilize a lytic bone lesion caused by multiple myeloma. Radio-opaque bone cement is used to fill the void from which the lesion was removed through an intralesional excision. The CF-PEEK plate is radiolucent with a metallic marker delineating its edges.*

for use with 3.5 mm titanium locking screws. There are 3 different sizes currently marketed in both left and right configurations. The shaft screw holes can be used in either a locking or non-locking mode. The radiolucent design allows for radiographic visualization of the fracture reduction while a thin embedded metallic/radiopaque outline at delineating the implant's edges for visualization during insertion and later follow up images. The PHP has been used successfully in trauma as well as oncologic applications since its introduction. [26]

A large fragment 4.5 mm CF-PEEK plate system is

now manufactured and marketed by Carbo-Fix™. [25] The large fragment plates come in both narrow and broad locking plate designs, analogous to the metallic large fragment systems produced by many implant vendors. The CF-PEEK large fragment screws are available in both threaded 4.5 mm locking and 4.5 mm nonlocking titanium options. Molding and contouring of these plates requires the use of a heating device, partially melting the CF-PEEK plate to melting point and then holding the plate while it cools and hardens. No studies have been published on the use of large fragment CF-PEEK plates as of this publication. An example of a pathologic fracture treated with a CF-PEEK large fragment narrow plate is shown in figure 3.

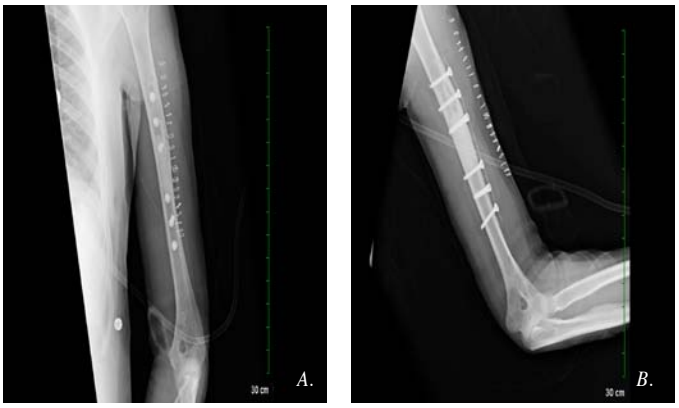


Figure 3: *Anterior to posterior (A) and lateral (B) post operative plane film radiographs of a humerus treated with a CarboFix™ CF-PEEK larger fragment plate. The large fragment plate was used to prophylactically stabilize the humerus after an open bone biopsy at the diaphysis of the humerus. The void created by the lesion's removal is filled with radio-opaque bone cement.*

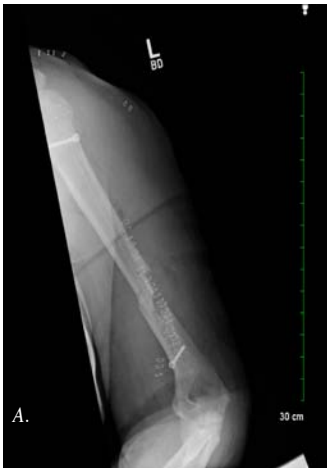
This CF-PEEK large fragment system can obviously be employed in any scenario in which a traditional metallic large fragment plate would have been used.

Humeral intramedullary (IM) Nails made of CF-PEEK are also available from Carbo-Fix™. [27] The Carbo-Fix™ humeral IM Nail has a five-degree proximal bend with 4-way proximal locking screw options. The Carbo-Fix™ humerus IM nail is not cannulated due to the small diameter of the implant, therefore guide wire insertion is not possible. Each interlocking screw hole is aligned with metallic orientation markers, parallel to the axis of each hole. The metallic markers allow the proximal interlocks to be placed either through an aiming gig or by free hand using fluoroscopy (see figure). Many case reports of fractures successfully treated with the CF-PEEK humeral IM nail have been published. A pathologic Fracture treated with a Carbo-Fix IM Nail is shown in figure 4.

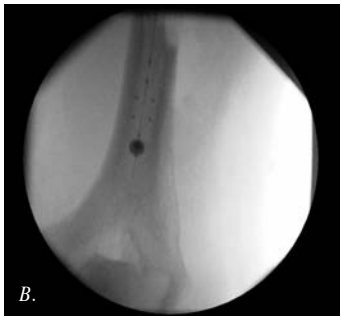
DISTAL RADIUS AND FOREARM

A 2012 comparison of CF-PEEK Optima distal volar radial plate with the DePuy™ anatomic volar plate showed the bending structural stiffness of the Optima to be superior. [26] These plates are similar to the previously discussed

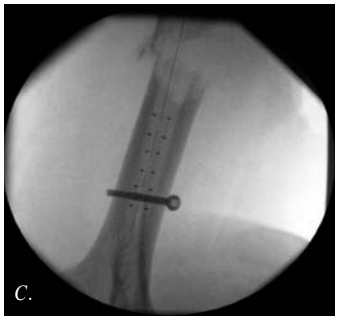
Figure 4:



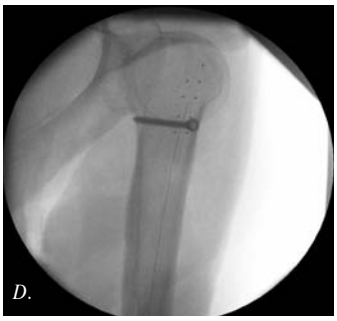
A) Postoperative plane film radiograph of humerus treated with a CarboFix™ CF-PEEK intramedullary nail (IM), locked proximally and distally. A lytic metastatic lesion created the pathologic fracture; primary tumor was proven to be adenocarcinoma of the lung.



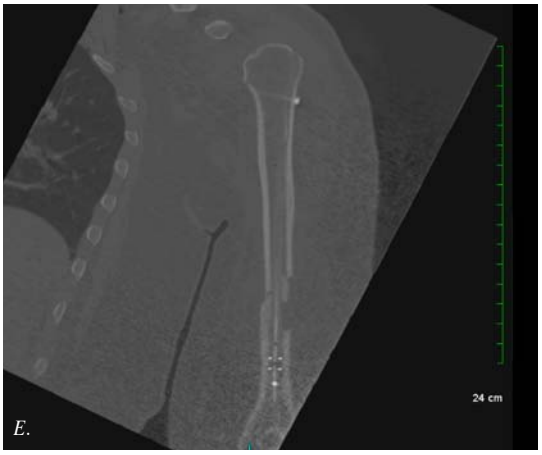
B) Intra-operative fluoroscopic image of the distal humerus interlock engaging the IM nail anterior to posterior (A/P) projection.



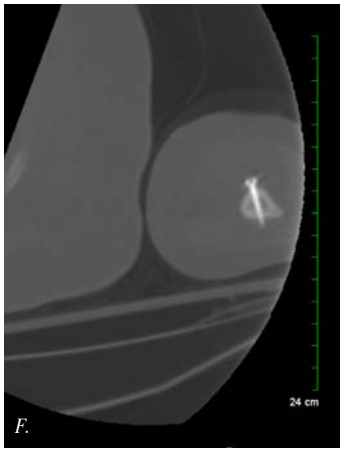
C) Intra-operative fluoroscopic image of the distal interlock engaging the IM nail in the lateral projection.



D) Intra-operative fluoroscopic image of the proximal interlock engaging the IM nail in the A/P projection.



E) Post-operative CT scan with coronal reconstruction with a metal subtraction protocol of the humerus IM nail bridging the pathologic fracture of the humerus. The lack of artifact generated by the CF-PEEK device allows for precise imaging of the pathologic fracture and lesion during follow up evaluations.



F) Post-operative CT scan transaxial image with metal subtraction protocol of the distal interlocking screw engaging the IM nail and the cortex of the humerus.

PHP, but even lower profile (2.4 mm vs. 3.7 mm). They have the same characteristics of increased fatigue strength, increased tensile strength, superior imaging, and elastic modulus closer to that of bone. There are five different hole patterns available in either standard width or as a narrow plate [28], see figure 5. See figure 5 for an example of a Carbo-Fix™ CF-PEEK Optima distal radius plate clinical application.

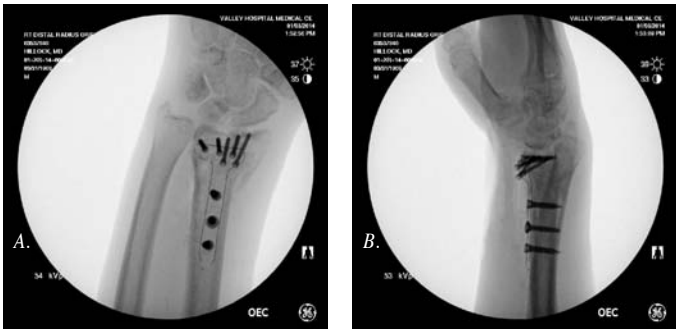


Figure 5: *Application of a CarboFix™ distal radius plate for stabilization of a pathologic fracture through the distal radius, benign lesion was curetted, and then allograft bone tissue was packed into the void. Figure (A) is an A/P intra-operative image, (B) is an intra-operative lateral image of the plate and screw construct stabilizing the fracture after curettage, reduction and bone grafting.*

Carbo-Fix™ has recently introduced a CF-PEEK small fragment system using 3.5 mm plates of varying lengths. [29] The fixation screws can be applied in a locking or nonlocking configuration depending on the clinical indication. As in the large fragment system molding and contouring of the CF-PEEK small fragment plates requires the use of a heating and bending device, partially melting the CF-PEEK plate to melting point and then holding the plate while it cools and hardens. No clinical studies on the CF small fragment system have been published to date.

HIP JOINT

Some of the newest advances in carbon fiber research and development are in the hip arthritis treatment implants. A recent study has been published based on the use of a CFR-PEEK hip prosthesis in a sheep model. [30] Total hip arthroplasty (THA) was performed on sixteen sheep to evaluate both cemented and press fit fixation of a CFR-PEEK hip prostheses. Five sheep experienced periprosthetic femoral fracture, were euthanized, and not included in the study. All other stems implanted, both cemented and press fit designs were well fixed, five out of six cemented cups showed micro motion and one easily dislodged. Of the hydroxyapatite-coated press-fit hips, two cups were well fixed, two easily dislodged, and one showed micro motion. While deformation of the bearing surface and sclerotic acetabular bone may have contributed to the lack of cup fixation, all press-fit stems were well fixed. This was among the first studies to show in vivo CF-PEEK prosthetic fixation for both cemented and press-fit designs under physiologic load bearing conditions. [31]

As CF has become more established in orthopedics, research has responded by analyzing its compatibility with other biomaterials. The combination of Biolox (zirconia toughened alumina) and CF-PEEK with a 40 mm bearing component diameter was tested with a Durham hip wear simulator at 60, 55, and 45 degrees. Although the angle didn't have a significant effect on the friction, the ceramic-on-CF-PEEK combo showed lower wear than either ceramic-on-polymer or metal-on-polymer combinations. [32]

FEMUR

A retrospective study of 12 patients with an average age of 78 years yielded good results even though the plates used were designed for supracondylar periprosthetic femoral fractures. 11 of these patients went on to full union with average time of 4 months, while the 12th patient died of pneumonia on post-operative day 18 after a repeat fracture of her opposite femur. This study highlighted some of the strengths of CF plates, including elastic modulus half that of bone, decreased stress shielding, and high strain and strength in bending – resulting in higher fatigue strength. [33]

The treatment of periprosthetic femoral fractures with CF plates has also proven successful in elderly patients with significant osteoporosis, restricted mobility, and in the setting of rheumatoid arthritis. A small study of 5 patients treated with supracondylar femoral fractures from low energy trauma over 2 years after a total knee arthroplasty used the lateral approach with carbon fiber plates to repair them. Although 1 patient died of pulmonary embolism 4 weeks post-surgery, all surviving participants showed full clinical and radiological union. [34]

Carbo-Fix™ markets a femoral intramedullary nail made of CF-PEEK. These femoral nails have many of the same features found in traditional metallic IM Nails; anatomic bow representing a radian of 1.5 meters, interlocking screw holes that are threaded, cannulated for insertion over a 2.4 mm guide wire, nail cap for the proximal end, implantation technique is the same as a typical priformis fosa entry point used in other femoral IM nail. [35]

As with all the Carbo-Fix™ CF-PEEK IM Nails, radiopaque markers are embedded about the interlocking screw holes to facilitate positioning during insertion and while drilling under fluoroscopic guidance. The CF-PEEK femoral nails come in lengths of 200 mm to 420 mm with a proximal diameter of 11.5 mm to 12.0 mm and distal diameters of 10, 11 and 12 mm. Static Proximal interlocking screws perpendicular to the shaft of the nail are placed

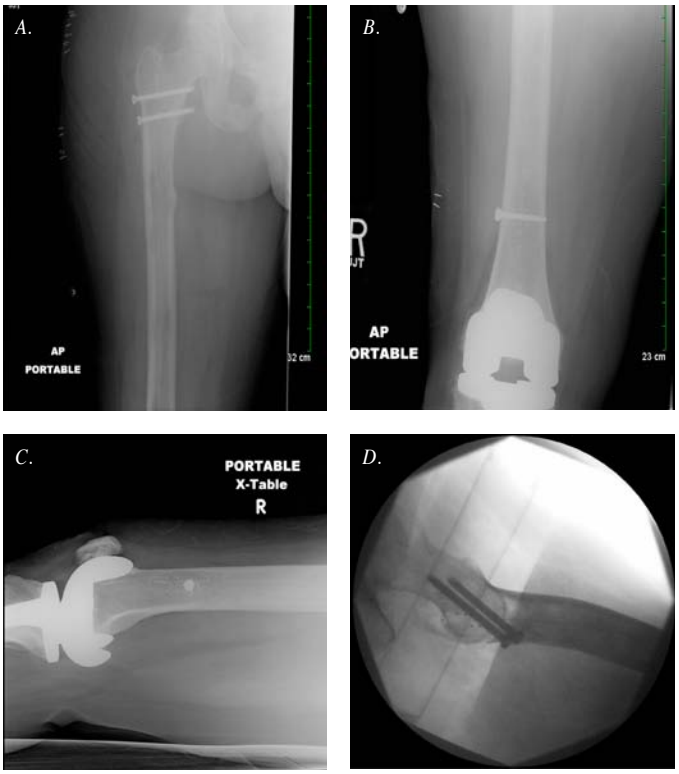


Figure 6: *CF-PEEK femoral IM nail by CarboFix™ used to treat a pathologic fracture of the right femur in a patient with widely metastatic adenocarcinoma of the breast. The device was employed in the same manner a conventional metallic IM nail would have been used, through percutaneous incisions, using a standard fracture table and intra-operative fluoroscopic images. The fixation was stabile and the patient was pain free within a few days of surgery, bearing full weight by 14 days after surgery.*

with an assembly handle-aiming device. Distal interlocking screws are placed using the free hand technique in either static or dynamic options in medial to lateral and/or anterior to posterior orientations. Locking screws are titanium. [35]

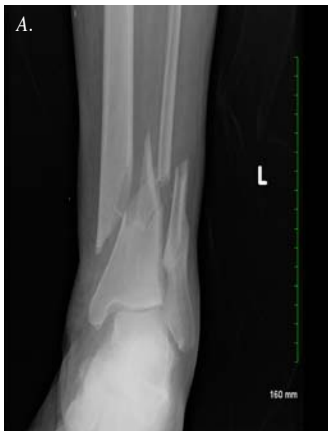
The CF-PEEK femoral nail offers many advantages over traditional metallic devices of similar design. The CF-PEEK nails are radiolucent on both fluoroscopy and regular radiographic imaging allowing for more precise fracture visualization at the time of insertion and during subsequent follow up. The CF-PEEK has been shown to cause no artifact on CT and MRI imaging, only minor distortion is found about the titanium screws, making these devices ideal for evaluation of fracture healing or tumor progression during follow up. They have a modulus of elasticity closer to that of native bone. They demonstrate unparalleled fatigue strength. [25]

TIBIA

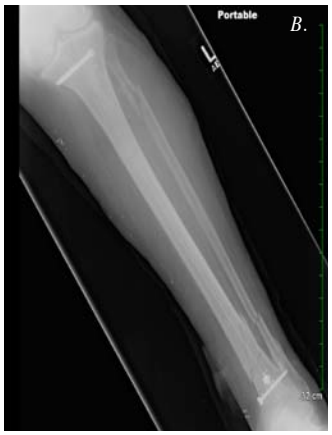
Carbo-Fix™ also makes CF-PEEK IM nails for the treatment of tibia pathology. [36] Like the humeral and Femoral IM Nails they made from continuous CF. The tibial IM nail has a 9-degree proximal bend. Screw holes are threaded for more rigid fixation. The proximal interlocks are placed through an aiming assembly handle, and can be placed in either static or dynamic configurations. Distal interlocking screws are placed using free hand fluoroscopic guided technique. A radiopaque marker is oriented along the nails' axis and about each of the screw holes to facilitate insertion; screw placement and subsequent imaging during follow up. The tibial nail is inserted over a 2.4 mm smooth tipped guide wire. A nail cap made of CF-PEEK is available if needed (See figure 7).

As found in all other CF-PEEK implants the tibial IM

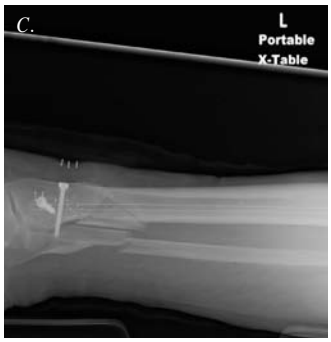
Figure 7:



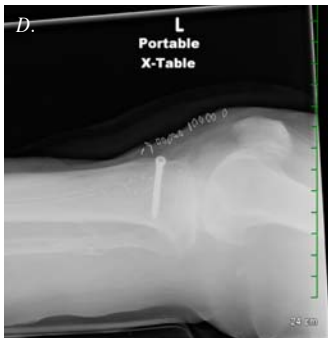
A) Closed distal 1/3rd tibia and fibula fracture, prior healed fibula fracture is also present.



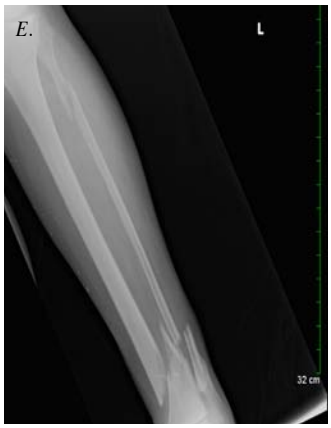
B) Anterior to posterior post reduction and stabilization with a CF-PEEK CarboFix™ intramedullary nail locked proximally and distally.

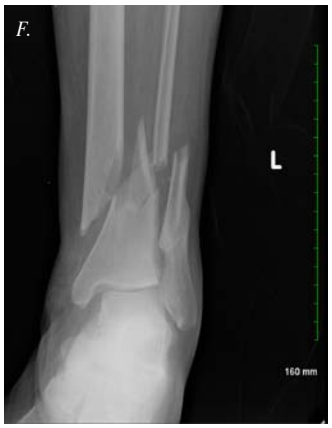


C) Lateral radiograph post reduction and stabilization with a CF-PEEK CarboFix™ intramedullary nail, distal interlock position demonstrated.



D) Lateral radiograph post reduction and stabilization with a CF-PEEK CarboFix™ intramedullary nail, proximal interlock demonstrated.





nail offers many advantages over comparable metallic Tibial IM Nails. The CF-PEEK nails are radiolucent on both fluoroscopy and regular radiographic imaging allowing for more precise fracture visualization at the time of insertion and during subsequent follow up. The CF-PEEK has been shown to cause no artifact on CT and MRI imaging, only minor distortion is found about the titanium screws, making these devices ideal for evaluation of fracture healing or tumor progression during follow up. They have a modulus of elasticity closer to that of native bone. They demonstrate unparalleled fatigue strength. [25]

FIBULA

There are currently 2 types of CF-PEEK fibular plates. [29] One is a 1/3 tubular plate that comes in several sizes and offers both non-locking and locking screw options. The CF-PEEK 1/3 tubular plate is offered in 4, 6, 7, 9 and 11-hole options. The other CF-PEEK fibula plate is an anatomical plate that comes in right or left side options with locking screws that can be given up to 10 degrees of variation in trajectory. It comes in 4 lengths, has guide holes for the use of K-wire, and has the same properties and benefits as discussed in prior sections.

ANKLE

One of the most recent CF-PEEK implants to enter the market is the Carbo-Fix™ ankle arthrodesis nail. Ankle arthrodesis is a commonly performed procedure for post-traumatic osteoarthritis; it's also used in complex fractures of the hindfoot that require reconstruction. The CF-PEEK ankle arthrodesis IM nail has shown to be associated with a lower rate of major revision at 5 years. [37] The Fibers in this nail are arranged both longitudinally and diagonally, allowing for multidirectional strength. [25]

As found in all other CF-PEEK implants the ankle arthrodesis IM nail offers many advantages over comparable metallic devices. The CF-PEEK are radiolucent on both fluoroscopy and regular radiographic imaging allowing for more precise fracture visualization at the time of insertion and during subsequent follow up. The CF-PEEK has been shown to cause no artifact on CT and MRI imaging, only minor distortion is found about the titanium screws, making these devices ideal for evaluation of fracture healing or tumor progression during follow up. They have a modulus of elasticity closer to that of native bone. They demonstrate unparalleled fatigue strength. [25]

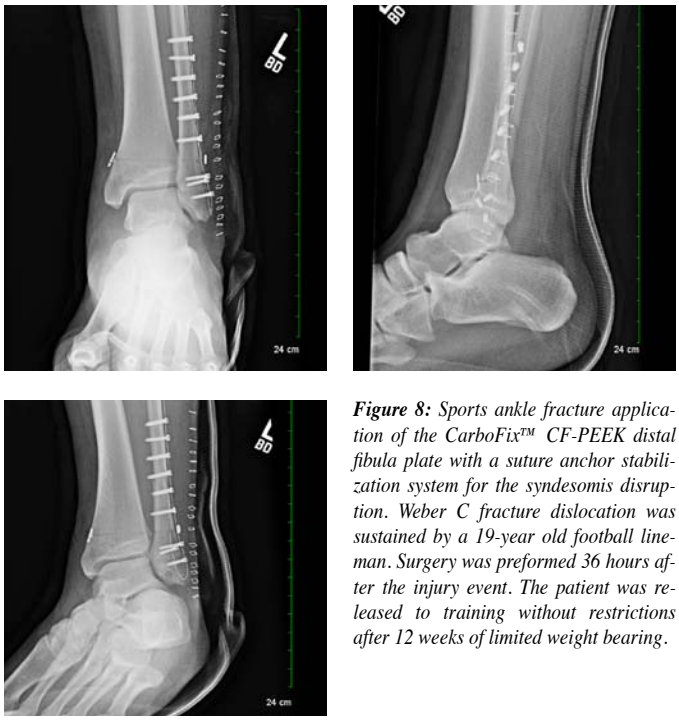


Figure 8: *Sports ankle fracture application of the CarboFix™ CF-PEEK distal fibula plate with a suture anchor stabilization system for the syndesomis disruption. Weber C fracture dislocation was sustained by a 19-year old football lineman. Surgery was preformed 36 hours after the injury event. The patient was released to training without restrictions after 12 weeks of limited weight bearing.*

CF-PEEK Implant Imaging Long Bones

As reported in spine imaging CF-PEEK implants in long bone applications offer superior imaging characteristics over similar metallic implants. Though no study to date has been published quantifying the clarity of imaging features of CF-PEEK implants in long bone settings, the imaging benefits are obvious. Fracture reduction is clearly seen in the preceding clinical cases reviewed in this publication. Experience has shown that MRI's and CT scans obtained in after implantation of a CF-PEEK device have virtually no artifact or image distortion. Fractures stabilized with CF-PEEK devices can be evaluated for healing more precisely. Oncologic lesions treated with CF-PEEK devices can be imaged for progression or regression with higher acuity due to the lack artifact as well, see figure 9 related to images.

Conclusion

CF implants has advanced a very broad and far reaching collection of industries. Its main limitation of cost is being slowly whittled down by its increased demand. In the field of orthopedics, it has provided innovative internal fixation to a wide variety of indications, fractures, joint arthrodesis and neoplastic lesion treatments. As in other industries, its physical properties of superior tensile strength, fatigue strength, and strength to weight ratio have challenged conventional materials and conferred novel advantages. Its elastic modulus has lessened the degree of stress shielding, allowing better callous formation and stronger union. Its radiolucency quickly brought it to the forefront of successful spine procedures. Radiolucency has also been par-

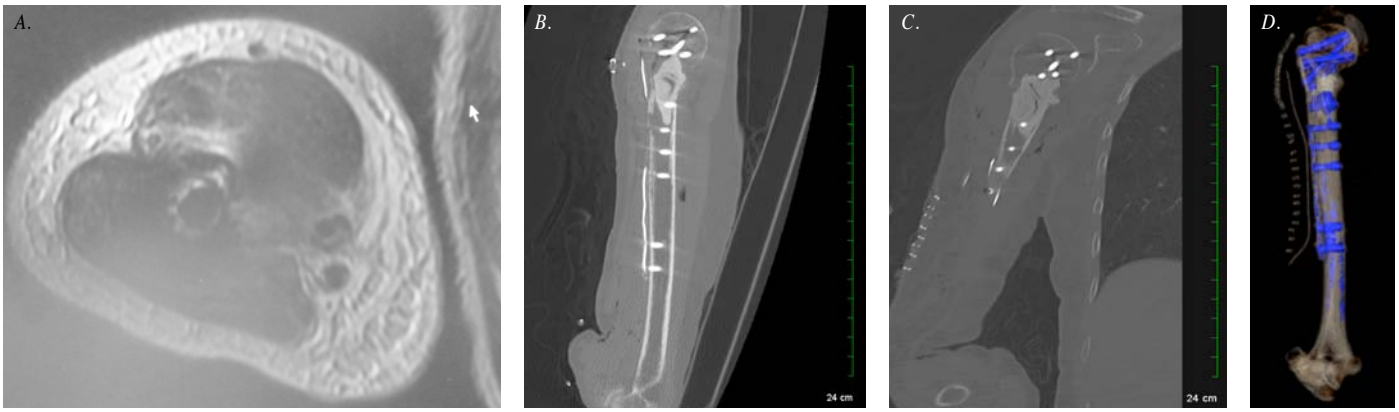


Figure 9:
A) Transaxial MRI of a humerus with a CF-PEEK CarboFix™ IM nail in position without artifact distortion typically associated with metallic IM nails.
B) Sagittal reconstruction of CT scan, images processed with a metal subtraction protocol, of a humerus with a pathologic fracture treated with a CF-PEEK CarboFix™ proximal humerus plate. The bone defect created by the tumor excision is filled with PMMA cement.
C) Coronal reconstruction of the humerus lesion demonstrated in figure (B).
D) Three dimensional reconstruction of the humerus lesion demonstrated in figure (B).

ticularly advantageous in the subspecialty of orthopedic oncology, where it has allowed superior monitoring of pathological fracture and the progression or regression of bone malignant lesions. Finally CF implants have no allergic reaction, an advantage when one considers the reported cases of nickel hypersensitivity related to some metallic implants. The use of CF implants in orthopedics will continue to improve current procedures and confer new advantages as it continues to be researched and employed in new applications.

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Reconstructive Review
Volume 4, Number 1, March 2014

ORIGINAL ARTICLE

MOM Failure Modes: An In-Depth Look at Metal Ions and Implant Wear

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Introduction

Contemporary MOM bearings (large-diameter heads) offered the perceived benefits of much greater range of motion and greater stability with reduced risk of impingement and dislocation. A variety of design and Both positive [1-3] and negative reports [4-8] have now emerged with regard to total hip arthroplasty (THA) and resurfacing arthroplasty. As a result, there has been an avalanche of studies focused on critical issues such as: surgical positioning, shallow cups (face angles 144-170°) [9-11] and "edge loading". [5,7,12-17] However, there are several, possibly synergistic, risk scenarios that could trigger adverse MOM wear and very little progress has been made in understanding such interacting parameters. In an effort to understand the role of metal ion analysis and how it relates to revision surgery and implant wear, selected MOM revised cases were reviewed [28]. Retrieval data was included in conjunction with metal ion analyses and intraoperative observations to determine various failure modes. We suggest MOM devices that are well fixed but fail after 2 years can be classified into one of six modes: (i) normal, (ii) allergic reaction, (iii) 3rd body wear, (iv) repetitive subluxation with metal impingement, (v) multi-directional subluxation with soft tissue impingement, and (vi) repetitive subluxation with soft tissue impingement.

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Methods

Six cases were selected based on their clinical history, imaging and retrieval analyses (Table 1). Times to revision varied from 3 to 8 years for cases with MOM diameters 28-55mm and listed causes for revision included: pain, high concentrations of metal ions, and cystic images viewed by MRI. X-ray imaging showed 3 cases with cup orientations in the so-called "safe zone" and three outside this zone (Fig. 1).

Table 1: *Patient demographics, implant sizes, and clinical findings.*

Mode	Age	Sex	Years in vivo	Size		Clinical Findings
				Ball	Cup	
1	76	F	7.8	38	NA	Infection
2	45	F	5.7	55	NA	Pain, effusion, ions
3	55	F	3.25	38	50	Pain, snapping, catching
4	63	F	3.5	28		Pain, clicking, ions
5	33	M	8.3	38	50	Pain, ions, lytic cyst, squeaking
6	77	F	6	42	48	Pain, lytic cysts, ions

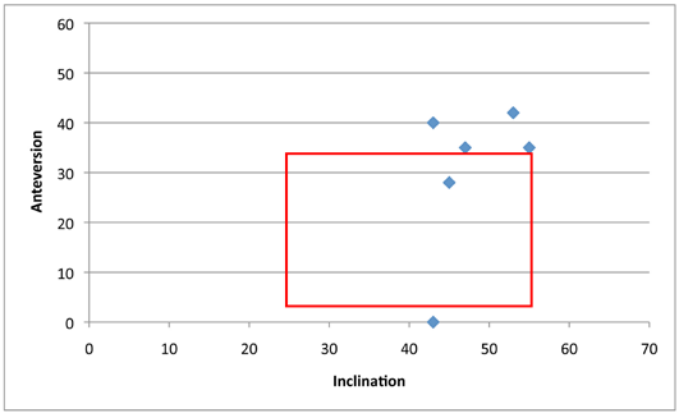

Figure 1: *Scatter plot of inclination and anteversion angles for all 6 THA cases.*

All MOM bearings were cleaned using a standard mild alkaline detergent and ultrasonic bath with ethyl alcohol. Strongly adherent protein films and rainbow colored hues were frequently evident [18] on retrieved bearings. The retrieved MOM bearings were then analyzed microscopically and by laser interferometry to document wear patterns. [19] Measurements of sphericity (form factor) and diameter-mismatch were included.

All implants were studied by the contour measurement method (CMM: Legex 322, Mitotoyo Inc., NJ) to provide an indication of wear magnitudes. Out of round measurements < 20μm were considered within the range of manufacturing tolerances (grade-1). Form factors were graded as; minimal wear (grade-2 =20-50μm), mild wear (grade-3 =50-100μm), moderate wear (grade-4 =100-250μm), and severe wear (grade-5 > 250μm).

The femoral stripe patterns were identified and being very difficult to photograph were first marked with ink. [20-23] Each femoral neck and cup rim was inspected for signs of impingement. In each case, the cup was positioned to check alignment with stripe wear patterns on femoral heads. Surface damage was imaged by scanning electron microscopy (SEM: MA 13, Zeiss, Cambridge UK) and by energy dispersive spectroscopy (EDS: Bruker Inc.). Variations in surface roughness were analyzed both by SEM (magnifications x100-1,000) and white-light interferometry (WLI: NewView 600, lens x5 and x25, Zygo, AZ).

Results

NORMAL

a. No measurable wear/minimal wear (CMM)
b. Defined MWZ, possible stripe wear
c. Low metal ion concentrations
d. No stained tissue

CASE-1 (R611)
A 76 y/o female with bilateral MOM replacements was revised at approximately 8 years due to infection (only the femoral head was retrieved). This patient had moderately elevated ions at the time of revision (Co=5, Cr=2.3). Retrieval analysis identified a well-defined main-wear zone with one polar stripe (Fig. 2). The CMM study indicated there was minimal wear overall (form factor = 11μm; grade 1).

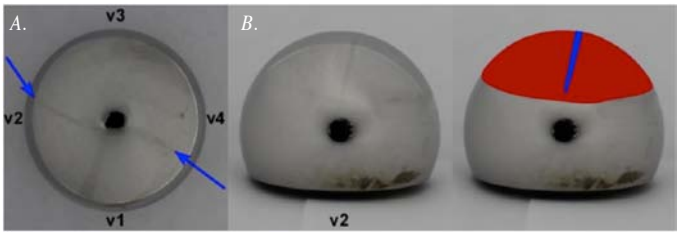

Figure 2: *Views of head showing main-wear zone (MWZ) with arrows indicating stripe wear*
A) Aerial view with arrows indicating the long polar stripe
B) Side view of femoral head showing MWZ (colored red) and polar stripe (colored blue).

ALLERGIC REACTION

a. Minimal wear (CMM)
b. Defined MWZ, possible stripe wear
c. Low-mild metal ion concentrations
d. Possible effusion, but no stained tissue

CASE-2 (R789)
This 45 y/o female was revised at approximately 6 years due to pain, reactive response effusion, and moderately elevated ions (Co=5, Cr=6). Retrieval analysis identified a well defined main-wear zone and one polar stripe (Fig. 3: only head retrieved). Minimal wear was indicated by CMM (form factor = 21, grade-2).

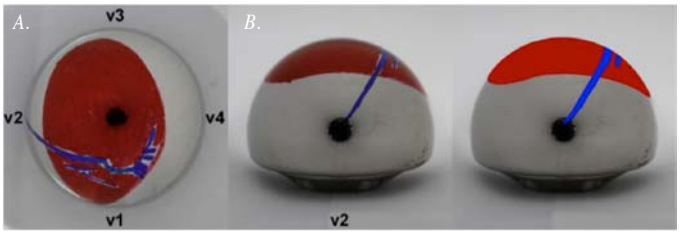

Figure 3: *Views of head showing MWZ with arrows indicating stripe wear:*
A) Aerial view of head with arrows indicating the long polar stripe
B) Side view of head showing MWZ (colored red) and long polar stripe (colored blue).

3RD BODY WEAR

a. Minimal-moderate wear (CMM)
b. Defined MWZ, multi-directional stripe wear
c. Mild-moderate metal ion concentrations
d. Frequently presents with stained tissue

CASE-3 (Sorim)
This 55 y/o female was revised at approximately 3 years due to a hip "snapping" pain during flexion. CT scan showed that the antero-inferior aspect of the cup rim was uncovered 1.5cm and exposed to the illiopsoas tendon. Intraoperatively, there was evidence of wear represented by the darkly stained tissue. Retrieval analysis identified wear on the antero-inferior cup rim (Fig. 4). Both bearing surfaces had evidence of 3rd body wear seen as deep multidirectional scratching and measuring

3μm wide and 0.4μm deep (Fig. 5). Two novel features point to the 'snapping' illiopsoas tendon as the wear trigger; a) abrasion of the Ti6Al4V cup rim by the illiopsoas and b) accelerated 3rd-body wear of the bearings surfaces by titanium oxide particles released from the cup. Note: This case pre-dated metal ion studies and was returned to the referring center before CMM analysis was performed.

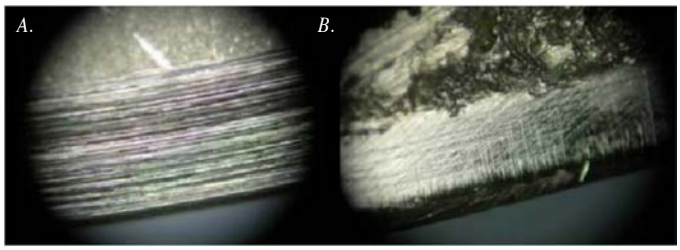

Figure 4: *Comparison of new and worn cup rims:*
A) Normal cup rim with manufacturing grooves evident.
B) Worn cup rim showing wear tracks perpendicular to the manufacturing grooves and loss of some titanium backing.

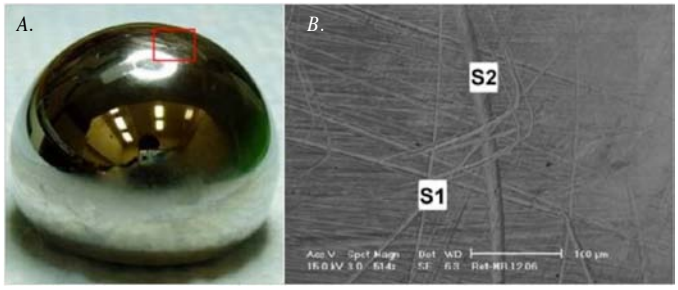

Figure 5: *Severely abraded head:*
A) Side view of head with square marked to indicate area examined by SEM
B) SEM image of microgrooves formed via 3rd body wear.

REPETITIVE SUBLUXATION WITH METAL IMPINGEMENT (ANTERIOR, POSTERIOR)

a. Moderate-high wear (CMM)
b. Defined MWZ, two polar stripes with offset, one or two notches on femoral stem
c. Moderate-high metal ion concentrations
d. Frequently presents with stained tissue

CASE-4 (R879)

This 63 y/o female was revised at approximately 3.5 years due to pain, clicking sensations and elevated ions (Co=47, Cr=41). Intraoperatively, there was evidence of femoral neck impingement on the posterior cup rim and stained tissue. The femoral head, acetabular cup and stem were retrieved, the latter featuring two notches on its postero-inferior aspect. Retrieval analysis identified a well defined main-wear zone and several polar stripes. One pronounced stripe traversed the MWZ, while several shorter stripes rand the length of the MWZ and corresponded to the cup rim-stem impingement (Fig. 6). CMM indicated moderate wear of the bearing couple (head form factor > 30μm grade-2, cup form factor >70μm grade-3).

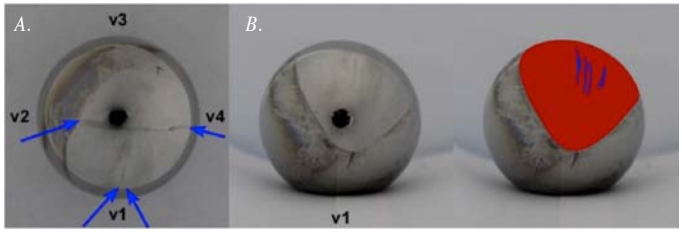

Figure 6: *Femoral head with multiple stripe wear:*
A) Aerial view of femoral head with arrows indicating polar stripe wear
B) Side view of femoral head and cartoon showing MWZ and polar stripes.

MULTI-DIRECTIONAL SUBLUXATION WITH SOFT TISSUE IMPINGEMENT (ANTERIOR OR POSTERIOR)

a. Moderate-severe wear (CMM)
b. Defined MWZ, multi-directional stripes
c. Moderate-high metal ion concentrations
d. Frequently presents with stained tissue

CASE-5 (R770)

This 33 y/o male (bilateral MOM hip replacements) had a left THA revision at approximately 8 years due to pain, popping/catching sensations, and elevated ions (Co=33, Cr=17). At surgery the implant was observed subluxing superiorly from the acetabular cup with anterior rotation of the leg. Both the femoral head and acetabular cup were retrieved. Retrieval analysis identified a well defined main-wear zone and multi-directional polar stripe formations (Fig. 7) similar to those reported on dislocated implants. CMM indicated severe wear of the bearing couple (head and cup form factor > 120μm, grade-4).

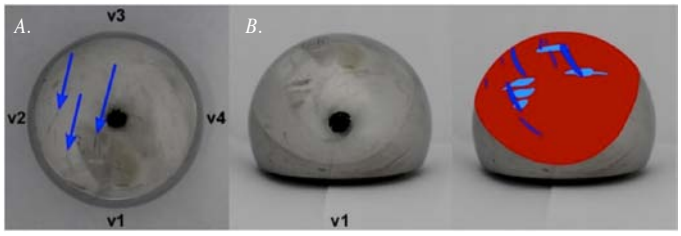

Figure 7: *Femoral head with multiple stripe wear:*
A) Aerial view of femoral head with arrows indicating polar stripe wear.
B) Side view of femoral head and cartoon showing MWZ and polar stripes.

REPETITIVE SUBLUXATION WITH SOFT TISSUE IMPINGEMENT (ANTERIOR OR POSTERIOR)

a. Moderate-severe wear (CMM)
b. Defined MWZ, one broad polar stripe
c. Moderate-high metal ion concentrations
d. Frequently presents with stained tissue

CASE-6 (R751)

This 77 y/o female was revised at approximately 6 years due to pain, suspected implant loosening, osteolytic cysts determined by CT, and highly elevated ions (Co=164, Cr=45). Intraoperatively, there was evidence of wear including darkly stained tissue and osteolytic cysts. Both the femoral head and acetabular cup were retrieved. Retrieval analysis identified a well defined main-wear zone and one polar stripe (Fig. 8). CMM indicated severe wear of the bearing couple (head form factor > 200 grade-4, cup form factor >300 grade-5).

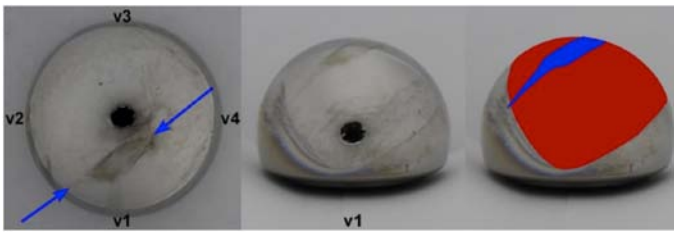

Figure 8: *Femoral head with multiple stripe wear*
A) Aerial view of femoral head with arrows indicating polar stripe wear
B) Side view of femoral head and cartoon showing MWZ and polar stripe.

Discussion

This study reviewed several unique failure modes using patient complaints, metal ion analysis, intraoperative findings, and retrieval analysis. It can be appreciated that descriptive studies such as this have multiple limitations. First, this study analyzed failed implants and these results may not reflect the overall population of MOM implants. Secondly, in the first two cases the stem and cups were found to be stable with good bony in-growth and therefore were left in the patient during revision surgery. Thus the wear in those two cases was based on data obtained from the femoral head only. Thirdly, some cases used to highlight unique modes of failure were (a) revised prior to our metal-ion studies and (b) no longer available for CMM measurements. Lastly, the pathways by which each case has come to failure classifications are based on the opinion of one experienced hip surgeon and may be considered subjective and speculative.

CMM measurements of sphericity and diameter-mismatch provided some clues about the overall volumetric wear of the MOM bearings. As the form factor (asphericty measurement) increased in most cases, so did the metal ion levels and the degree of stained tissue (Table 2). This suggested that CMM indicated the degree of material lost from the MOM bearing, which then goes on to stain local tissues and seep into the blood as metal ions.

It is the understanding of this group that MWZ areas and stripe wear may be a normal component of MOM bearing wear. However, dramatic changes in MWZ area and multiple or significantly larger stripe wear may warrant a closer scrutiny. The MWZ area appears to be consistent across multiple bearing types and patients and appears to increase with respect to diameter but maintains approximately 55% hemisphere. [24] Stripe wear is consistently observed as well, with the polar stripe being the most prominent but having the lowest surface roughness due to polishing effects in the MWZ. It is considered that polar stripes form at the terminal point in a patient's ROM and as the patient pushes beyond that point, subluxation may occur and form a larger polar stripe or additional polar stripes.

Given that 5 of 6 cases were greater than 38mm diameter, such large heads were expected to be stable and have a high range of motion and be free of impingement problems seen in 28mm MOM. [19] However, we concluded that this is not the case. Despite the use of large diameter implants, most of the cases showed evidence of patients exceeding their 'design' range of motion leading to stripe wear during either subluxation or impingement. [19,24-27]

Mode	F/U (y)	Metal Ion Analysis		Stained Tissue	IntraOperative Observations	Ball FF (μm)	Cup FF (μm)	MWZ	Stripes
		Co	Cr						
1	7.8	5	2	N		11	NA	Y	Y
2	5.7	5	6	N	Discoloration	21	NA	Y	Y
3	3.25	NA	NA	Y		NA	NA	Y	Y
4	3.5	47	21	Y	Stem impingement	31	71	Y	Y
5	8.3	34	17	Y	Superior subluxation	158	127	Y	Y
6	6	164	45	Y	Osteolytic cysts	214	324	Y	Y

Table 2: *Summary of results including: metal ion analysis, intraoperative observation, and retrieval analysis.*

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Reconstructive Review
Volume 4, Number 1, March 2014

ORIGINAL ARTICLE

Post-operative Weight Gain After Total Knee Arthroplasty: Prevalence and Its Possible Attenuation Using Intraoperative Sensors

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Abstract

As the proportion of adults with obesity continues to climb, so too does the need for total knee arthroplasty. Unfortunately, total knee replacement patients often experience post-operative weight gain, despite improved joint function. The purposes of this study were: 1) To execute a literature meta-analysis in order quantify the changes in body mass that are typically observed following TKA, and 2) Evaluate data from a prospective, multicenter study to assess any trends towards weight loss in a group of "balanced", sensor-assisted TKA patients. The literature review found that average proportion of patients who had weight gain after TKA is 47% to 66%. In literature, the average post-operative weight gain was 9.5 lbs. (1.6 kg/m^2 BMI increase), up to 14 lbs. (2.3 kg/m^2). In the multicenter study, only 30.4% of patients and 36.9% of patients exhibited weight gain at 6 months and 1 year, respectively. At the 1-year interval, this indicates an 11% decrease from reported averages ($p=0.049$), up to 29% as reported by the NIH ($p<0.001$). The average weight gain in the multicenter patient group was 4.3 lbs. (0.72 kg/m^2 BMI increase) at 6 months, and 3.5 lbs. (0.58 kg/m^2) at 1 year, both of which are non-clinically meaningful. The average weight loss of those in the non-gaining group was 7.8 lbs. (1.3 kg/m^2) at 6 months and 9.6 lbs. (1.6 kg/m^2) at 1 year. Both of these values are clinically meaningful. This evaluation demonstrates that weight gain after TKA is prevalent, but ensuring soft-tissue balance (via technologies such as intraoperative sensing) may help mitigate this expected increase in body mass.

***Keywords**: total knee arthroplasty, increased BMI, intraoperative sensors, weight gain, obesity*

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Introduction

The obesity epidemic has gone unchecked since its inception in the early 1980s. [3] As a result, over 35% of adults in the United States are now classified as "obese" by the standards set forth by the Centers for Disease Control and Prevention. [4] This rapid increase in the BMI of Americans also results in a costly increase in medical spending. Per capita, the obese patient incurs an additional $1,429 in annual health care expenditures beyond the medical costs of a patient with a normal BMI. [5] Nationally,

these additional costs culminate in a 147 billion dollar financial burden every year. [5]

An elevated BMI is implicated in atherosclerosis, hypertension, cardiovascular disease, acute pancreatitis, ovarian and colon cancers, and steatohepatitis. [1,9] The musculoskeletal system is also adversely affected by obesity. Increased and asymmetric loading across bearing surfaces, in heavy patients, contributes to acceleration of lower limb osteoarthritis (Figure 1). As such, an unprecedented influx of younger patients are undergoing total knee arthroplasty (TKA), partly as a result of joint damage sustained from excess body mass. [2,6]

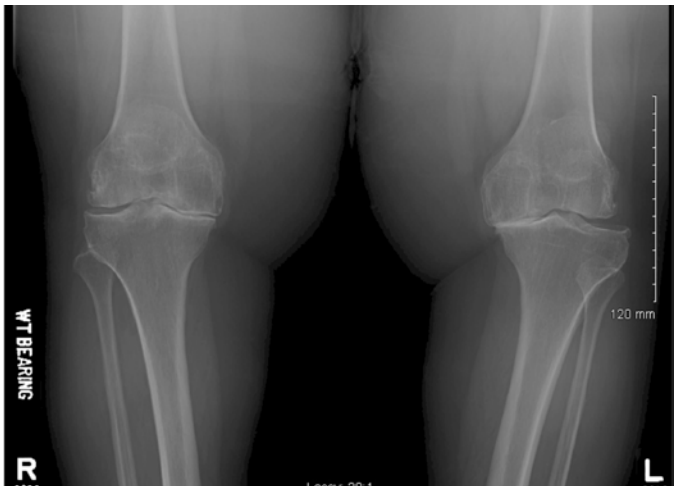

Figure 1*. From the multicentric study, a 59-year old osteoarthritic patient with a BMI of 40 kg/m2.*

Although many patients with advanced osteoarthritis report that reduced activity as a result of joint pain and dysfunction is responsible for their obesity, the majority of TKA patients have been shown to gain weight post-operatively, despite the restoration of joint function. [10-14] Unfortunately, these arthroplasty procedures intended to facilitate a return to an active lifestyle have done little to reduce the prevalence of adulthood obesity, contrary to what might be expected. With no foreseeable reduction in the national obesity rate anticipated, it has become important to explore options that may mitigate weight gain and its associated risk factors. [7]

New technology, incorporating intraoperative sensing into knee replacement trials, has been developed to quantify intercompartmental balance in TKA. A recent publication showed that TKA patients with quantifiably balanced soft-tissue (intercompartmental load difference ≤ 15lbs) had significantly higher activity levels, Knee Society and WOMAC scores at 6 months than patients with unbalanced soft-tissue. [15] We hypothesized that this increase in activity level and function would result in decreased incidence of weight gain, or even weight loss, when compared to historical controls. The purpose of this study was to evaluate changes in the body mass of patients with a quantifiably balanced TKA at 6 and 12 months, compared to an analysis of literature reporting weight change after primary TKA.

Patients and Methods

In order to quantify any changes in body mass that are typically observed after TKA, a blinded literature search and meta-analysis was performed by two contributing authors. Using PubMed, combinations of the following keywords were queried: "weight gain", "weight increase", "weight decrease", "TKA", "BMI increase", "obesity", "change in obesity", "change in BMI", "total knee arthroplasty", "total knee replacement," and "post-operative BMI".

Studies selected for inclusion in this analysis met the following criteria: all patients in the study had primary TKA; BMI data was collected pre-operatively and, at least, within 1-year of the surgical date; and the proportion of patients who gained or lost weight post-operatively was statistically described. All aforementioned criteria must have been met, and agreed upon by two participating authors, before subsequent inclusion in the data analysis.

In order to evaluate any trends toward weight loss, an analysis of 138 patients who had undergone sensor-assisted primary TKA was conducted. These patients were included as part of a U.S.-based, prospective, multicenter evaluation on soft-tissue balance using intraoperative sensors (Orthosensor Inc., Dania Beach, FL). The reason for reporting on this particular group of patients is due to its previously published findings, demonstrating statistically higher post-operative activity levels. [15] All patients in this analysis exhibited, as verified by the intraoperative sensors, soft-tissue balance (medial-lateral loading difference ≤ 15 lbs.) [15]

Pre- and post-operative (6-month and 1-year) BMI data was collected and evaluated. The resultant change in BMI (if any) was grouped into one of the following categories: "Group A" (weight loss/static weight), and "Group B" (weight gain).

All statistical evaluations were performed using SPSS - Version 21 (SPSS Inc., Chicago, IL). For the meta-analysis, Levene's homogeneity tests and I^2 index analyses were executed. For the prospective portion, analysis of variance (ANOVA) was used to assess any statistical significance between the proportion of patients in Groups A, and B. For the purposes of this evaluation significance was defined as a p-value <0.05, and heterogeneity was defined as a p-value <0.1.

Results

POST-TKA WEIGHT CHANGE IN LITERATURE

The blinded literature search yielded a total of 82 results. Of those, 5 publications met all inclusion criteria required for the meta-analysis. [10-14] In total, 1,740 patients were included.

The average proportion of patients with reported weight gain following TKA was 47%, with a maximum of 66%, at their respective one-year intervals. The test for homogeneity of weight gain prevalence between all 5 publications yielded a Levene's statistic of 9.002 with a p-value <0.001. The I^2 index was 94%.

The publications by Zeni, et al., Riddle, et al., Abu-Rejab, et al., and Heisel, et al. reported the average weight gain of their patient cohorts as 14 lbs., 11 lbs., 10 lbs., and 3 lbs., respectively. Odds ratios reported by the Riddle, et al. group indicated that patients with total knee arthroplasty are 1.6 times more likely to experience a "clinically important" weight gain (≥5% of their baseline body weight), when compared with a non-TKA control group. [12]

SENSOR-ASSISTED TKA PATIENTS EXHIBITING WEIGHT LOSS

Of the patients enrolled in the multicenter evaluation, 138 had 6-month BMI data; 87 had 1-year BMI data.

At 6 months, 30.4% gained weight; at 1 year, 36.9% gained weight. Thus, at 6-months Groups A and B represented 69.6% and 30.4%, respectively; at 1-year Groups A and B represented 63.1% and 36.9%, respectively.

An ANOVA analysis of the two time intervals showed that the proportion of patients that did not gain weight (Group A) was significantly higher than those that gained weight (Group B) ($p < 0.001$ at 6-months; $p<0.001$ at 1-year). The average weight gain at 6 months was 4.3 lbs. (0.72 kg/m^2 BMI); the average weight gain at 1 year was 3.5 lbs. (0.58 kg/m^2 BMI). The average weight loss at 6-months was 7.8 lbs. (1.3 kg/m^2 BMI), and the average weight loss at 1-year was 9.6 lbs. (1.6 kg/m^2 BMI) (Figure 2).

Of those patients who underwent surgery, classified as "morbidly obese" (BMI>35), 25.3% dropped to a lower BMI classification by the 1-year follow-up interval. Of those patients who began surgery, classified as "obese" (30<BMI<35), 15.1% dropped to a lower BMI classification by the 6-month interval.

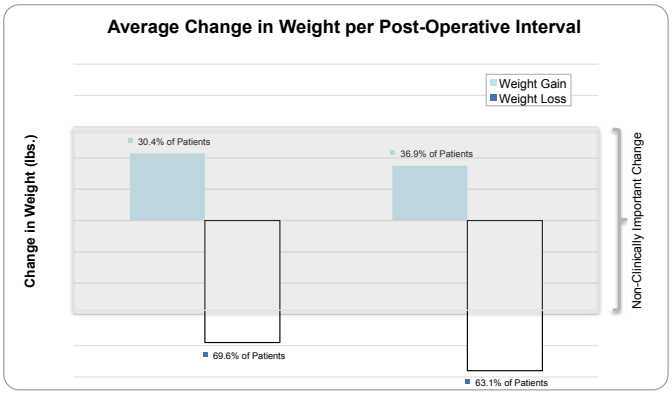

Figure 2.

Discussion

In the United States, the rate of obesity among adults has reached epidemic proportions. [3,4] Statistical projections predict that this increasing rate of obesity will continue through 2030. [7] Thus, it will be necessary for the orthopaedic surgeon to contend with the risks and complications associated with performing total knee arthroplasty on a younger, heavier population. However, it has been reported in literature that knee replacement patients commonly gain weight in the first year after surgery.

In this evaluation, a meta-analysis of literature was performed to quantify the post-operative change in body mass typically observed after TKA. Amongst the 5 publications that met all criteria for the analysis (1,740 patients), the Levene's statistic showed 9.002, with a p-value <0.001. This indicates that there is a high level of heterogeneity in the literature that is currently available. The I^2 index specifies the heterogeneity with a 94% variance value. These numbers, together, indicate that power is lacking to make direct statistical comparisons; they explicate the need for an increase in similar studies to be published.

Even so, descriptive comparisons among the literature can still be made, and they are staggering. The average proportion of patients that exhibit post-operative weight gain, at a one-year interval, was 47%. This value was reported to be as high as 66% in a study sanctioned by the National Institute of Health. [11] Four of the five publications also specified the post-operative weight gain. The average reported was an increase of 9.5 lbs., which corresponds to a 1.6 kg/m^2 increase in BMI. This value was as high as 14 lbs., or a 2.3 kg/m^2 increase in BMI. [11] When odds ratios were calculated, it was found that patients receiving TKA are 1.6 times more likely to exhibit "clinically important" weight gain (≥5% of their baseline body weight) than a control group. [12] Thus, weight gain and BMI increase after TKA is something that is calculable, predictable, and prevalent.

Yet, the evidence from this prospective multicentrer study indicates that this does not necessarily need to be the case. For this evaluation, a group of sensor-assisted TKA patients—previously reported in literature to have exhibited statistically higher activity levels [15] —were evaluated for post-operative BMI changes at 6 months and 1 year. It was found that the majority of multicenter patients showed a trend towards no net weight gain (69.6% at 6 months; 63.1% at 1 year). As such, only 30.4% and 36.9% of patients gained weight at 6 months and 1 year, respectively. On average, at 1 year, this is an 11% decrease from what is reported in literature ($p=0.049$). When compared with data from the National Institute of health, this is a 29% decrease ($p<0.001$). [11]

Among patients who did gain weight after balanced TKA, the average weight gain at 6 months was only 4.3 lbs.; the average weight gain at 1 year was 3.5 lbs., neither of which were clinically meaningful. [8]

Most importantly, the average weight loss in this cohort, at 6-months, was 7.8 lbs. (1.3 kg/m^2), and the average weight loss at 1-year was 9.6 lbs. (1.6 kg/m^2). This decrease in BMI, at both time points, represents a clinically relevant interval for weight loss (Δ BMI > 1 kg/m^2) [8], and is most likely attributed to the increased activity levels of these patients, previously reported. [15]

What has made this group of patients so distinct is their verifiably-balanced soft-tissue envelopes. Published in the initial report, were the results of a multivariate logistic regression analysis which demonstrated that the most significant contributing variable to the observed increase in activity level and outcomes scores, was whether or not the medial-lateral loading on the bearing surface was "balanced" in the coronal plane. This balance was quantified using intraoperative sensors, and must have necessarily registered as a mediolateral loading difference ≤ 15 lbs. through the passive range of motion. All patients included in this analysis of change in weight and BMI were of the same "balanced" cohort previously published. [15]

There were weaknesses in this study. First, the number of publications which focus on post-operative weight gain after TKA is limited. While we can make descriptive comparisons between the publications used in our analysis, it would take more than the 5 that met inclusion criteria for the meta-analysis to provide statistically meaningful conclusions. However, the main argument is still clear: weight gain amongst TKA recipients occurs commonly and predictably. Second, not all of the centers in our multicenter evaluation were collecting post-operative BMI. While the numbers we were able to collect are strong, it is always preferable to collect as much data as possible for an analysis of this type. Third, we do not know how the balanced cohort of patients is performing kinematically. With a gait analysis, it may be better understood why these balanced patients are exhibiting higher activity levels and, consequently, losing weight when compared with non-sensor-assisted TKA patients.

In a society in which obesity levels continue to climb, every measure should be undertaken to mitigate risks for potential weight gain. Historically, total knee arthroplasty has not resulted in weight loss. In this study, patients with a quantifiably balanced TKA were less likely to gain weight and more likely to lose weight at 6 and 12 months versus those reported in the meta-analysis; those that gained weight did so in small increments that were not clinically meaningful. Sensor-balanced TKA results in higher activity levels that may be responsible for this improvement in postoperative weight and body mass change. Quantitative knee balancing using intraoperative sensing technology holds promise for improved outcomes. Longer-term follow-up and additional study of the kinematics of sensor-balanced TKA is warranted to understand the impact that this technology can have on patient outcomes.

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Reconstructive Review
Volume 4, Number 1, March 2014

Original Article

Does the Kinematch® Prosthesis Impair Knee Flexion in Patients with Trochlear Dysplasia?

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Abstract

Background: Patellofemoral replacements are used to treat isolated patellofemoral arthritis in carefully selected patients. The Kinematch® custom-designed implant is placed directly on subchondral bone, leading critics of the device to believe that this results in overstuffing and limitation of flexion in cases of trochlear dysplasia; the current study aims to evaluate this premise.

Methods: A retrospective analysis of a consecutive series of 24 patients (32 knees) was conducted. Trochlear dysplasia was evaluated using pre-operative axial CT scans, and knees were categorized as having minimal or moderate/severe dysplasia (moderate = flat trochlea, severe = convex trochlea). The primary outcome was post-operative knee flexion.

Results: There was no statistical or clinical difference in post-operative knee flexion between the minimal (120°+12) and the moderate/severe dysplasia (117°+9) groups (p=.34).

Conclusions: Use of the Kinematch® patient-specific custom trochlear component does not significantly limit flexion in cases of trochlear dysplasia, and although the surgeon has the ability to deepen the trochlea by way of the pre-operative model, this is not necessary.

Keywords: *Patellofemoral replacement; custom; flexion; trochlear dysplasia*
Level of Evidence: *III, Case-control study*

Introduction

Patellofemoral replacements are available in a number of formats: inlay, onlay, off-the-shelf, custom and combinations thereof. One implant, Kinematch® (Kinamed®, Camarilla, CA), features a custom trochlear component that is modeled on three-dimensional CT reconstructions to match the subchondral bone of the trochlea (Figure 1). No bone is removed from the trochlea unless the surgeon has chosen to do so prior to the creation of the implant. Sisto and Sarin [1] have reported promising results with no revisions at six years. However, some critics of the custom-designed implant believe that the anteriorization of the troch-

Figure 1. *A: Model of trochlea with custom-fit prosthesis with patient specific drill guide and marking template. B: Patient specific component and native bone model showing a precise fit.*

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lea results in overstuffing of the anterior compartment, leading to increased pain and limited flexion. [2]

It is widely agreed upon in the literature that appropriate patient selection is critical to the success of a patellofemoral replacement. [3,4,5] One of the principal indications for a patellofemoral replacement (PFR) is patellofemoral arthritis secondary to dysplasia [6,7] where, by definition, the trochlea is deficient and/or misshapen. In such cases, will a custom implant limit knee flexion due to over-stuffing of the patellofemoral compartment? This is the first study to evaluate post-operative flexion in patients with either normal or dysplastic trochlear architecture receiving this custom-fit PFR.

Methods

PATIENT SELECTION

The study retrospectively assessed a consecutive series of 25 patients (17 unilateral, eight bilateral) who underwent a PFR between 2007 and 2012. All patients received the custom-fit Kinematch® trochlear prosthesis with a standard round all-poly 3-pegged patellar button.

One patient was excluded from the study due to the post-operative diagnosis of subcutaneous malignancy leading to further surgery, resulting in a final study of 24 patients (16 unilateral, eight bilateral). Bilateral procedures were assessed independently of each other for a total of 32 knees. Out of the 32 knees assessed, 21 (66%) were female. The average age at the time of the surgery was 61.1 years (range 44-88 years), and average time to the most recent follow up evaluation was 21.6 months (range 12.5 - 46 months).

MEASUREMENT OF TROCHLEAR DYSPLASIA

Knees were subdivided into groups based on the degree of femoral trochlear dysplasia evaluated according to Dejour & Saggin's criteria [8] and validated by Lippacher et al. [9] (Table 1). First, a "two-grade" analysis of knees was conducted using pre-operative axial CT scans of patient knees. Briefly, knees were categorized as having either minimal dysplasia (Dejour grade A dysplasia; n=17) or moderate/severe dysplasia (Dejour grades B, C, or D dysplasia; n=15). Female patients made up a significantly higher percentage of the moderate/severe dysplasia group (87%) than the minimal dysplasia group (47%), p =.02. There was no difference in mean age or time to follow up between the groups (Table 2).

Knees were subsequently classified on a "three-grade" scale in which the moderate/severe dysplasia group from the previous analysis was broken into two groups: flat trochlea (Grade B dysplasia, n=7) and convex trochlea (Grade C/D dysplasia, n=8). The minimal dysplasia group remained the same. Again, female patients made up a significantly higher percentage of the flat trochlea (71%) and convex trochlea groups (100%) than the minimal dysplasia group (47%), p = .03. There was no difference in mean age or time to follow up between the groups (table 3).

OUTCOMES

The primary outcome measure was post-operative knee flexion measured by the surgeon at each post-operative visit (by way of a protractor). Measurements from the most recent follow up visit were used for the study.

ETHICS

The study was approved by the Institutional Review Board of the Mount Sinai School of Medicine.

STATISTICAL METHODS

Statistical analyses were conducted using SPSS version 20 (IBM 2011). Normally distributed continuous variables are presented as mean +/- standard deviation, while nominal data is shown as percentages. Student t-tests were used to compare means of groups in the 2-grade analysis; one-way ANOVAs were calculated to compare means of groups in the 3-grade analysis; similarly, nominal data in both the 2-grade and 3-grade analysis were evaluated via Pearson chi-squared analyses. A stepwise linear regression was performed to determine the interaction of all variables in the database on the prediction of knee flexion. P<.05 was considered statistically significant.

Results

"TWO-GRADE" ANALYSIS

The average post-operative flexion in the "minimal dysplasia" (A) group was 120˚ while the average flexion in the "moderate/sever dysplasia" (B and C-D) was 117˚; this is not a significant difference (p = .34) (Table 2). Linear regression demonstrated that age, female sex, and time to follow up were not independent predictors of post-operative flexion.

"THREE-GRADE" ANALYSIS OF KNEES

When the dysplastic group was further divided into the moderate (B) and severe (C-D) subdivisions a small, a non-significant difference was noted (120˚ vs. 115˚) (Table 3). Linear regression demonstrated that age, female sex, and time to follow up were not independent predictors of post-operative flexion.

Discussion

There has been a resurgence of interest in PFR surgery as evidenced by the growing number of implants. [10,11] With this increased interest comes the discussion of whether the trochlear groove should be sculpted into a pre-determined shape or left as is.

When the trochlea has a normal shape, the discussion is moot. However, since one of the principal indications for a PFR is arthritis secondary to dysplasia, a significant number of patients receiving a PFR will exhibit an abnormal trochlea. In such cases, if the surgeon does not deepen the trochlea, will flexion be limited?

Kinamed® manufactures the Kinematch® custom trochlea that offers two main advantages over off-the-shelf inlay prostheses requiring by definition bony cuts and/or milling of the trochlea:

1) diminished operative time and

2) an intact femur upon revision.

The diminished operative time is the result of the planning and the CT scan performed by the surgeon and the manufacturer pre-operatively. The intact femur upon revision results from no bone having been removed from the trochlea.

The limitation of flexion relates to the issue of "overstuffing" in total knee replacement surgery, except that in cases of trochlear dysplasia, it is the trochlea that is "thick" rather than the patella. Some studies have specifically listed this as a cause of failure in PFR surgeries. [12] However, it has been our suspicion that over-stuffing is not a factor in the custom-designed implant:

1) Even in total knee arthroplasty, the concept of overstuffing has now been challenged. [13] Indeed, a few extra millimeters of extra patellofemoral compartment thickness have not been found to significantly limit flexion, the compliance of the peri-patellar soft tissues being a more important parameter.

2) A lateral release most likely offsets increases in patellofemoral pressure that might be caused by an increased thickness of the patellofemoral compartment. (We routinely perform a partial lateral release up to but not including the geniculates.)

3) There are two surfaces to the trochlear implant: the one touching the trochlea (the "trochlear" surface) and the one facing the patella (the "patellar" surface). The topography of the "trochlear" surface will vary from patient to patient (size, shape and relief), but the patellar surface of the implant is always concave and always matches the patellar button.

4) Most significantly, trochlear dysplasia is by and large a condition affecting the proximal trochlea [14], and it is the distal trochlea that is in play during knee flexion.

In this study group, half the patients had a normal – or only slightly dysplastic- trochlea (DeJour A), while the other half exhibited dysplasia (B and C-D). The dysplasia group was also roughly equally divided between the flat trochleas (B) and the convex trochleas (C-D). Pre-operative and post-operative radiographic images of a patient with severe dysplasia are displayed in figure 2.

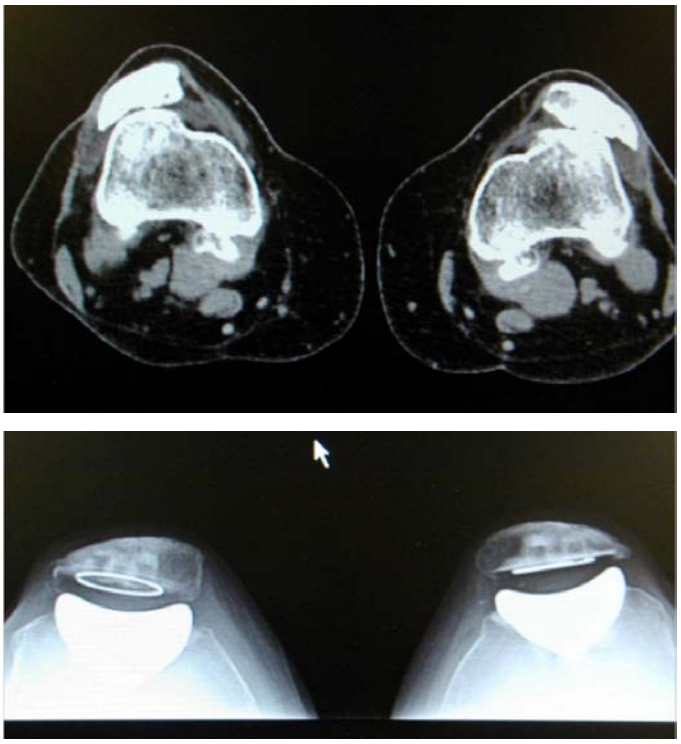

Figure 2. *Radiographic imaging of severely dysplastic trochlea (A) pre-operative and (B) post-operative.*

Incidentally, the dysplasia was always more impressive on the MRI than on both the plaster model and the prepared trochlear bed, as the cartilage contributes to the size of the prominence (when cartilage is still present).

The surgeon can eliminate the dysplasia pre-operatively by sculpting the plaster model to his/her specifications. The manufacturer will create an implant that matches this re-designed trochlea. (The surgeon then re-creates his sculpting intra-operatively). As this study suggests, these extra steps are not necessary.

A limitation of our study was the application of a protractor to the patients' leg to assess knee flexion. Application of the protractor to a perfect lateral radiograph would have been better and use of digital computation better yet. Obtaining x-rays for the purpose of measuring flexion, however, is not realistic. Fortunately, the variation in measurements from visit to visit was negligible, suggesting precision if not accuracy. As a measure of reference, the same investigator using the same measuring technique has found an average of 110˚ of flexion using the DePuy

LCS total knee replacement system (unpublished data). A more generous assessor might have found greater flexion for both the total knee replacements and the patellofemoral replacements.

The time from surgery to final measurement varied from patient to patient, and certainly some of the subjects measured soon after surgery might have continued to see increases in flexion. However, in our experience, a feature particular to patellofemoral replacements (and in contradistinction to total knee replacements) is the rapid progression to final flexion. Therefore the timing of our measurements relative to surgery was probably of little import.

While two years is a common follow-up minimum for studies relating to joint replacements, this would not seem to apply here as we are not looking at pain, function, wear, or loosening. Likewise, while imaging studies are routinely analyzed and published after joint replacement studies, imaging analysis does not apply to this study.

Will a prominent trochlea affect the stability of the extensor mechanism after surgery with the Kinematch prosthesis? We do not think so. This trochlear component features a normal groove that allows the patella to be captured as soon as the knee flexes. In fact, deepening the groove might lead to increased laxity of the soft tissue envelope and greater instability. We have not formally studied this.

In short, use of a patient-specific custom trochlear component does not significantly limit flexion in cases of trochlear dysplasia, and although the surgeon has the ability to deepen the trochlea on a pre-operative model, this is not necessary.

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Reconstructive Review
Volume 4, Number 1, March 2014

CASE REPORT

Osteolysis with Ceramic on Highly Cross-linked Polyethylene

Joseph Fetto, MD§

Abstract

A major reason for the longevity of native articular cartilage over that of materials used in arthroplasties is the former's ability to self-lubricate. The self-lubricating property of hyaline cartilage produces an extraordinarily low coefficient of friction between the joint surfaces. So long as shear stresses remain low or the architecture of the joint unchanged by trauma, native articular cartilage can provide for a lifetime of joint function, i.e. the ankle. Therefore, wear and the particulate debris created by surface wear presents a significant challenge to the arthroplasty community. [1,2] Over the past 100 years, many materials have been introduced to address this issue: ivory, wood, gold, bioglass, stainless steel, cobalt/chrome alloys, Teflon, polyethylene, ceramics, diamond. To date, although there has been significant improvement in the wear properties of bearing surfaces, no perfect surrogate for native articular cartilage has been found. Presently, ceramic on highly cross-linked polyethylene (COP) appears to be the best available option. However, although it has been demonstrated to produce less particulate debris than metal on polyethylene (MOP) articulations in the hip, it is not immune to the same osteolytic complication seen in MOP bearings.

Keywords*: osteolysis; ceramic on highly cross-linked polyethylene*

Case Report

R.P. is a 72 year old white female. She is 6 years S/P right THR with a MOP (chrome/cobalt on highly cross-linked polyethylene) articulation, for primary OA. Her BMI is 26. She is married, retired and engages in no regular exercise program. She had been independent in her ADL's. Over the past year, she experienced an insidious increase in right groin and buttock pain unrelated to any trauma. This was aggravated by weight bearing, stair climbing and transfer movements. Although she retained an unrestricted range of motion, sufficient to perform foot hygiene, shoes and socks, she failed to find pain relief with over the counter analgesics and NSAID's. Ultimately she became dependent on a walker in her home and a wheelchair out of doors.

The patient presented with the above complaints. Her physical exam demonstrated a slender female in moderate discomfort with attempts to ambulate. Her internal/external rotation and ab/adduction in a seated position were unrestricted but produced groin/buttock pain at the end of range. Neuro-vascular examination of the lower extremities was unremarkable. Her x-rays demonstrated well positioned non-cemented components with asymmetrical positioning of the femoral head within the acetabular shell. There was a large osteolytic lesion in zones 1 and 2 over the right acetabulum. (Fig.1).

At surgery, after placement of a prophylactic trochanteric plate to protect the integrity of the femur, the non-cemented femoral component was found to be a well fixed.

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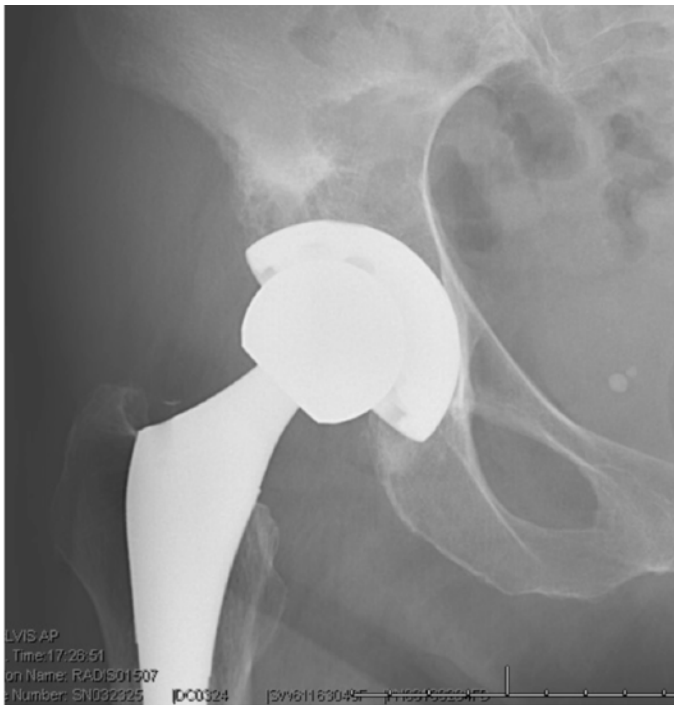

Figure 1. *Pre-operative pelvic x-ray, 6 years S/P a right non-cemented ceramic on polyethylene THA. There is a large area of pelvic osteolysis in zones 1 and 2; osteolysis is also seen in the greater trochanter and femoral zones 1 and 7. There is asymmetrical positioning of the femoral head within the acetabular shell, implying polyethylene wear.*

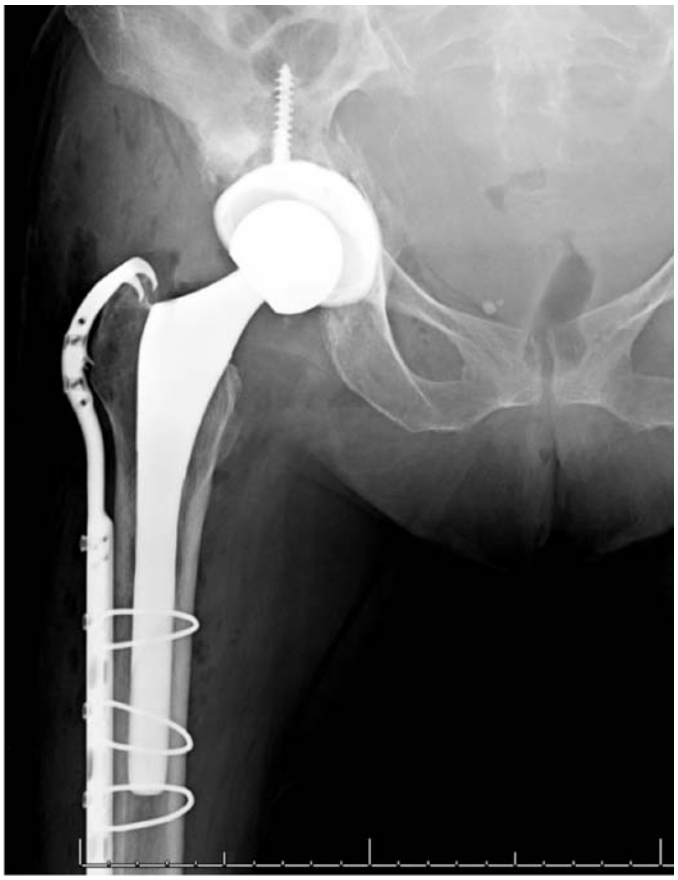

Figure 2. *Post-operatively, the patient has been permitted toe-touch-partial weight bearing with a walkerShe is now two months following her revision surgery, with resolved groin/buttock discomfort and no change in position of her acetabular component.*

There was osteolysis within the greater trochanter, extending circumferentially into Gruen zones 1 and 7 about the femoral component. The white casseous material was found peripherally about the posterior, superior and anterior aspects of the acetabular component, from 8 o'clock to 4 o'clock. The component appeared to be osseously integrated in the lower, medial quadrant but demonstrated a rocking motion when pressure was applied to the superior margin of the cup. After explant of the cup, a large cavitary defect was exposed measuring 2x43x3 centimeters extending into the ilium and pubis. There was no defect in the medial or posterior-inferior walls.

Fibrous tissue was gently curetted from the defect and the acetabulum reamed to accommodate a 54mm non-cemented component. Prior to implantation of the new acetabular component, the defect was filled with a mixture of ground cancellous chips and DBM paste. The acetabular preparation was completed by reverse reaming . Impaction of a flared rim cup provided modest "press-fit" fixation. This was supplemented with three 6.5mm cancellous screws. A non-hooded highly cross-linked, Vitamin E liner was gently impacted in place. With secure fixation of the acetabular component achieved, a 34mm ceramic head was fitted to the femoral component and the hip reduced without complication. (fig.2).

Conclusion

Although there has been a decrease in particulate debris production and resultant osteolysis with the introduction of COP bearing couples, wear remains an unmet challenge to hip arthroplasty.

Hopefully, promising developments in new "self-lubricating" materials which can be covalently bonded to a substrate will offer approximations of native articular cartilage, resulting in further reduction of wear and debris production.

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Reconstructive Review
Volume 4, Number 1, March 2014

COMMENTARY

Grateful for Medical Advancements

Timothy McTighe, Dr. H.S. (hc)§
Acknowledgement: Roberto Heros, MD†; Mohamed Samy A. Elhammady, MD†

"Grateful" has been described as warmly or deeply appreciative of kindness or benefits received.

This commentary will express my personal gratefulness for benefits received by recent Medical Advancements. Most readers are well aware of my orthopaedic career over the past forty-four years and the many benefits that my family and I have received. However, recent benefits received gives me reason to pause and reflect, and to acknowledge their receipt.

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 in the many varied activities brought about by orthopaedics. Catherine (a retired nurse) was diagnosed in 2006 with a small cranial suprasellar lesion that had been very stable over the years. However, early this past February her condition changed.

I was invited by my Dear Friend Professor Warwick Bruce, MD to present some of my research at the First Annual ICJR Meeting in Sydney Australia. In addition, during the ICJR Meeting I was to Award Dr. John Harrison, AM to be the 2014 Recipient of the JISRF Lifetime Achievement Award along with a $10,000 dollar donation made in his name to the Australian Orthopaedic Research Fund.

Upon my arriving in Sydney I was getting settled in for a ten-day trip full of CME and social activities when I receive a call from my wife. With stress in her voice she informs me that she had sudden loss of vision in the left eye and the right was degrading quickly. I remembered that vision loss was a sign that her mass could be growing, placing increase pressure on the optic nerves. This was also associated with increased thirst and increased urine output. There was no question the brain lesion had enlarged and was causing some additional cranial pressure – and my wife was going to wait for me to get home.

I have great friends in Australia and they all stepped up offering to present my data, and also stepped in for presenting our Lifetime Achievement Award to Dr. Harrison. My thanks go out to John Harrison our recipient, Drs. Bruce and Turnbull for handling the Lifetime Award Presentation, and Dr. Decal Brazil for hosting a small dinner party after the conference. This provided me with the opportunity to catch a return flight back to the United States.

Upon returning to central Florida (our winter location) on a Friday evening we were having difficulty reaching Cathy's Neuro Surgeon back in Cleveland. All we knew at this point was that surgical intervention was most likely going to be needed, and we didn't know of a Neuro Surgeon available to us in Central Florida.

My wife and I were not excited about the possibility of taking a chance with just any Neuro Surgeon on call so I started racking my brain to see if I could remember anyone who I knew in the orthopaedic world that might have some more direct contacts. That's when I thought of my long time friend Ricardo Heros.

Most total joint surgeons know Ricardo as Mr. Ceramic. Ricardo is American Manager at CeramTec Medical Products and my wife and I have known Ricardo since 1973. I remember Ricardo mentioning to me that his brother Roberto Heros was Professor of Neuro Surgery in Miami, Florida. So I give Ricardo a call at home only to find he was in Mexico. His lovely wife was kind enough to give me Roberto's home telephone number in Miami. I reached Roberto at home an explained I was an old friend of his brother along with a quick narrative summary of Cathy's condition.

There was no hesitation on his end and he advised me to bring Cathy down to see him Monday morning. Professor Heros had everything set from an MRI, to blood work and Neuro Ophthalmology. He also set up a meeting with Assistant Professor Mohamed Samy A. Elhammady, MD, a bright young surgeon who is Director of Minimally Invasive Crani-

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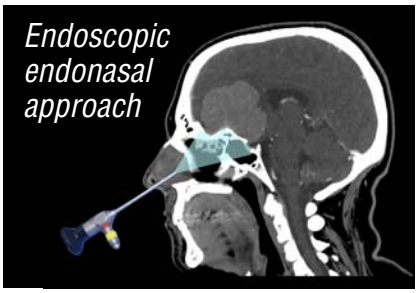
al Neurosurgery and Co-Director of Neuroendovascular and Skull Base Surgery at University of Miami Health System.

Dr. Elhammady likes to be called "Samy", so Samy is telling us he did a Clinical Fellowship in Minimally Invasive Neurosurgery at Prince of Wales Hospital, Sydney, Australia with Dr. Charles Teo, who is Director of the Centre for Minimally Invasive Neurosurgery. I have been visiting Australia since 1986 and have been pleased to be an International Affiliate of the Australia Orthopaedic Association. As a result I have many friends and relationships in Australia, so of course I am texting my mates down under to find out about Dr. Teo and his reputation. All reports came back as world class. Needless to say the feedback reassured both Cathy and I that Samy was the right guy to intervene and relieve the elevated cranial pressure that she was having.

NARRATIVE SUMMARY

New MRI images revealed growth of the sellar and suprasellar lesion with a large cystic component, as well as a solid component involving the hypothalamus and the pituitary stalk. Samy operated on my wife on February 19th, the day after her birthday, where she underwent an endoscopic endonasal transsphenoidal resection of her lesion. During the surgery Samy found that there was some yellowish firm tissue, distinct from the pituitary gland that was resected. Once the cystic cavity was entered Samy found a creamy yellowish fluid. Although the frozen section suggested a pituitary adenoma, the final pathology came back as a lymphocytic infiltration without any neoplastic cells, possibly suggestive of a lymphocytic hypophysitis.



Cathy's postoperative scan showed excellent decompression of her optic apparatus and decompression of her cyst. Samy did not attempt any resection of the solid enhancing lesion involving the hypothalamus and pituitary stalk to avoid any hypothalamic or pituitary dysfunction. We did discuss preoperatively with Samy just this situation as to operative goals and knowing when to get out before additional damage might be caused. I must say he impressed me with his confidence and description of his operative goal without any attempt to over sell. Both Dr. Heros and Samy provided myself, and more importantly Cathy, with the confidence she was in good hands.

I am pleased to say Cathy is doing well. Her visual acuity is 20/30 bilaterally, her visual fields have completely recovered, and she is on her way to full recovery. Samy has given us his personal cell number and email, and has been in direct contact with Cathy every few days checking on her.

Getting back to being grateful, over my 44 years in the orthopaedic health care field I have seen fracture treatment go from skeletal traction and body cast to surgical intervention. I have also seen arthritic treatment go from hip and knee fusions to the significant advantage of total joint reconstruction. I have been privileged to be part of that historical evolution and plan on being part of its future growth.

I am grateful that my 41-year relation with Ricardo led me to his brother Roberto who provided my wife the opportunity to receive excellent surgical treatment in a timely fashion with the best possible outcome. I am grateful for the technological advancement in neurosurgery that has provided my wife the ability to live a full and active life, thus enhancing my life.

Medicine has changed dramatically and is currently under significant change as I write this commentary. We must all do what we can to ensure the advancement of technology in medicine. I worry that the current climate of our health care system will negatively impact the desire of our brightest individuals to go into medicine, specifically into neurosurgery. The declining reimbursements for surgeons are well documented. The demand of the surgical specialties and especially a seven-year post doctorial education in neurosurgery requires the best of the best. I believe a high-end financial reward is just one of the requirements that must be available for us to attract the caliber of Master Surgeon that is needed in these specialties. As for our area of total joint reconstructive surgery, I do not accept the trend that total joint surgery should be considered a commodity. We can always improve design, surgical technique and delivery of the reconstructive surgical procedure.

As we improve the technical aspects of medical care, we must not forget the importance of nursing care that takes over after the surgical procedure. In my opinion, nursing care has and continues to suffer. This critical element of medical care is suffering because nurses are being used more and more for documentation and management, while more non-medical personnel are involved in making medical decisions. Unfortunately, I don't have any answers, but to say that we all need to stay involved with both our finical resources, and more importantly our energy, to ensure the best and brightest enter the medical field.

Finally, I am grateful to all my orthopaedic friends and colleagues all over the world for their continued support and prayers for Cathy and her recovery. My family and I have been very blessed.

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

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Pan Pacific Orthopaedic Congress | July 16 – 19, 2014 • Waikoloa, Hawaii • icjr.net/2014hawaii

The 2014 ICJR Pan Pacific Congress will bring together over 1,000 surgeons and researchers from the Pacific Rim and North America to expand our global understanding of key issues in orthopaedics. With a comprehensive focus on knee and hip arthroplasty, shoulder and elbow surgery, as well as sports medicine, this course will explore the areas of customized instrumentation, surgical navigation, imaging, clinical evaluations and outcomes, and long-term follow-up with a goal of translating research into practical medicine and better patient care.

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Transatlantic Orthopaedic Congress (15th Annual ISK Sports Medicine and Total Knee and Hip Course in Collaboration with EKA)
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Over the years, this meeting has enhanced its curriculum focusing on sports medicine as it relates to hip and knee arthroplasty by incorporating live surgeries, case reviews, scientific posters and more opportunities for surgeon-to-surgeon interaction. While maintaining an intimate setting, this course has also increased significantly in attendance and expanded its reach globally with the joining of forces between ISK and EKA. Our 2014 Congress promises to be better than ever as we continue to grow our International faculty and offer even more opportunities to interact with these orthopaedic experts from around the world.

COURSE CHAIRMEN: Jean-Noël Argenson, MD, PhD, Aix-Marseille University Hospital Sainte-Marguerite • W. Norman Scott, MD, FACS, Insall Scott Kelly Institute for Orthopaedics and Sports Medicine • Giles R. Scuderi, MD, Insall Scott Kelly Institute for Orthopedics and Sports Medicine

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JISRF Creates Institutional Review Board

JISRF's Board of Directors have approved the formation of an Institutional Review Board (IRB).

JISRF has a long rich history of conducting clinical/surgical research projects. There has been considerable interest in JISRF establishing a formal IRB Committee. The specific purpose of this IRB Committee is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. JISRF's IRB Committee will attempt to ensure protection of subjects by reviewing research protocols and related materials. IRB protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices and seeks to maximize the safety of subjects.

JISRF has lectured and published on ethics and full disclosure since 1993. The Board sees the IRB Committee as a next logical step in interdisciplinary research and education while protecting the individual patients rights on full disclosure with regard to decision making of new technologies and potential conflict of interest in an ever changing health care environment.

Research grants, charitable contributions and revenue from our general fund support the IRB's work.

ICJR Global

CREATING A GLOBAL ORTHOPAEDIC COMMUNITY

EKA EUROPEAN KNEE ASSOCIATES A SECTION OF ESSKA

WORLD ARTHROPLASTY CONGRESS

16 -18 APRIL 2015 | PARIS, FRANCE

COURSE CHAIRMEN: Jean-Noël Argenson, MD, PhD | Arlen D. Hanssen, MD
W. Norman Scott, MD, FACS | Jan Victor, MD, PhD

Partnering the European Knee Associates (EKA) with ICJR's global affiliates and in combination with the 3rd Best Current Practice in Europe of EKA, the World Arthroplasty Congress is the first-ever global meeting dedicated entirely to hip and knee arthroplasty.

PLAN FOR PARIS!

- Transcend societal, political and economic differences as well as variances in surgical environments for the benefit of learning from one another to advance the field of arthroplasty and improve patient care
- Develop a global understanding of key issues in orthopaedics, surgical innovation, cutting-edge science, and practical knowledge through a dynamic and engaging 3-day agenda
- Gain insight from and interact with a faculty of orthopaedic experts from around the world
- Submit your abstract for consideration for the scientific poster sessions featuring global advances in hip and knee arthroplasty
- Participate in a unique and exciting social program featuring the finest that French and Parisian culture has to offer

FOR REGISTRATION/INFO VISIT
www.icjr.net/2015paris

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The following information will be published on each paper.

Please check one or more if pertinent of the following:

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

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

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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

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Fetto [1]

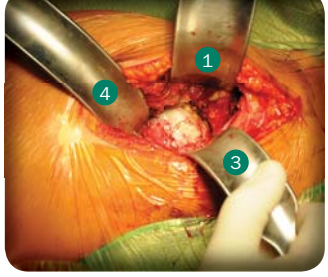
NOTES

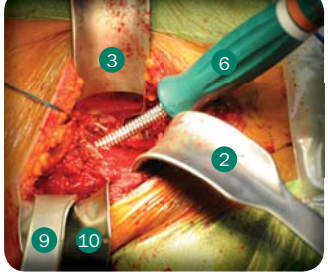
Unger Anterior Total Hip Instruments

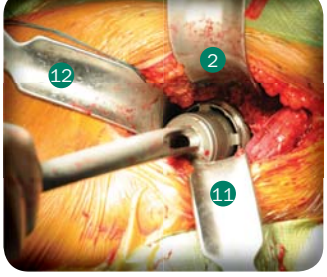
PROUDLY MADE IN THE USA

Designed by Anthony Unger, MD

PRODUCT NO'S:	
1	3001 [Unger Wide Hohmann–Single Prong] *Blade Width: 43.6mm* *Blade Depth: 5"* *Overall Length: 13.5"*
2	3008 [Unger Wide Hohmann–Double Prong] *Blade Width: 33.6mm* *Blade Depth: 5"* *Overall Length: 13.5"*
3	3002 [Unger Narrow Hohmann] *Blade Width: 24.5mm* *Blade Depth: 4"* *Overall Length: 13"*
4	3003 [Unger Blunt Narrow Cobra] *Blade Width: 22.5mm* *Blade Width at Tip: 12mm* *Blade Depth: 5.25"* *Overall Length: 14.5"*
5	3004 [Unger Canal Finder Rasp–Straight] *Overall Length: 11"* *Handle Length: 5"*
6	3004-01 [Unger Canal Finder Rasp–Curved] *Overall Length: 11"* *Handle Length: 5"*
7	3005-R [Unger Box Osteotome–Right] *Overall Length: 12"*
8	3005-L [Unger Box Osteotome–Left] *Overall Length: 12"*
9	3006 [Unger Femoral Neck Elevator] *Blade Width at Widest: 25mm* *Overall Length: 13"* *Handle Length: 9"*
10	3007 [Unger Soft Tissue Protector] *Blade Width: 50.5mm* *Blade Depth: 1.75"* *Overall Length: 10.125"*
11	3009-R [Unger Offset Narrow Hohmann–Right] *Blade Width: 24.5mm* *Blade Depth: 4"* *Overall Length: 13"*
12	3009-L [Unger Offset Narrow Hohmann–Left] *Blade Width: 24.5mm* *Blade Depth: 4"* *Overall Length: 13"*







Universal instrument system specifically designed for Direct Anterior approach THR

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

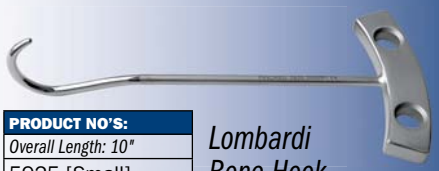
5 6 Canal Finder Rasp–Straight & Curved

9 Femoral Neck Elevator

10 Soft Tissue Protector

7 8 Box Osteotome

11 12 Offset Narrow Hohmann–Right & Left



PRODUCT NO'S:
Overall Length: 10"
5925 [Small] *Curve Diameter: 25mm*
5930 [Medium] *Curve Diameter: 35mm*
5935 [Large] *Curve Diameter: 55mm*

Lombardi Bone Hook

Designed by Adolph V. Lombardi, MD

Three sizes available

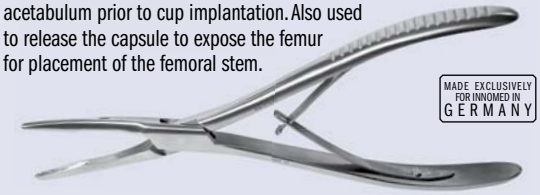
PROUDLY MADE IN THE USA

Hannum Grasper

Designed by Scott Hannum, MD

Teeth in jaw firmly holds bone and tissue

Used for dissection(to preserve)/or removal of the anterior capsule, removal of the labrum, or other soft tissue around the acetabulum prior to cup implantation. Also used to release the capsule to expose the femur for placement of the femoral stem.



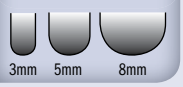
MADE EXCLUSIVELY FOR INNOMED IN GERMANY

Long, low profile helps facilitate working through a small incision without disrupting vision.

PRODUCT NO'S:
Overall Length: 9.25"
1775-01 [Short Jaw] *Jaw Width: 8mm*
1775-02 [Medium Jaw] *Jaw Width: 5mm*
1775-03 [Long Jaw] *Jaw Width: 3mm*

Available in three jaw sizes: short jaw for holding bone, medium jaw for smaller bones, and long jaw for tissue.

Jaw widths at actual size



3mm 5mm 8mm

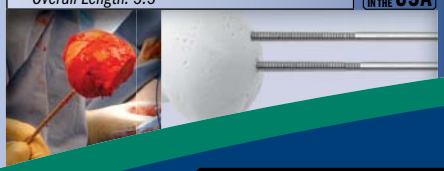
Two Pin Extractor

Helps to control rotation when removing a recected femoral head

Can be used with two femoral head removal pins to help remove a femoral head in total hip or hip fracture surgery. The side by side pins help to control rotation, giving the surgeon better control of the resected head.

PRODUCT NO:
3032 [For pins up to 3/8" (4.8mm)] *Overall Length: 5.5"*

PROUDLY MADE IN THE USA

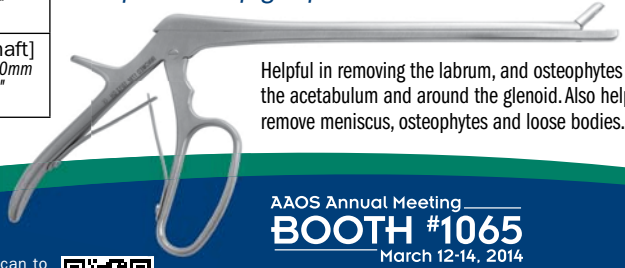


PRODUCT NO'S:
1798 [Standard] *Jaw Size: 6mm x 10mm* *Overall Length: 10"* *Shaft Length: 7"*
1799 [Long Shaft] *Jaw Size: 6mm x 10mm* *Overall Length: 12"* *Shaft Length: 9"*

Shark Tooth Grasper

Designed by Luis Ulloa

Sharp teeth help grasp onto tissue and bone



Helpful in removing the labrum, and osteophytes around the acetabulum and around the glenoid. Also helps to remove meniscus, osteophytes and loose bodies.

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