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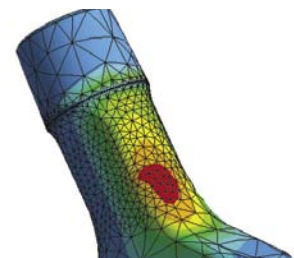
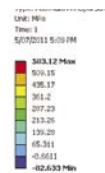


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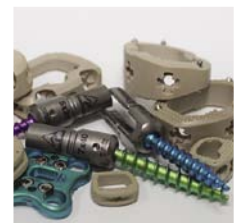
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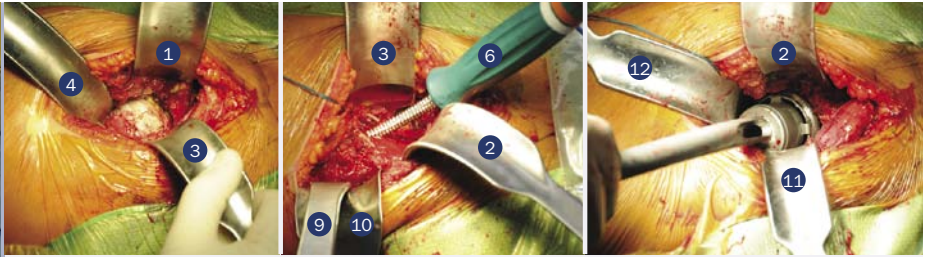
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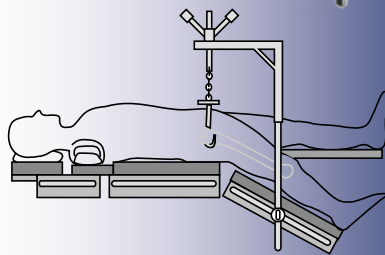
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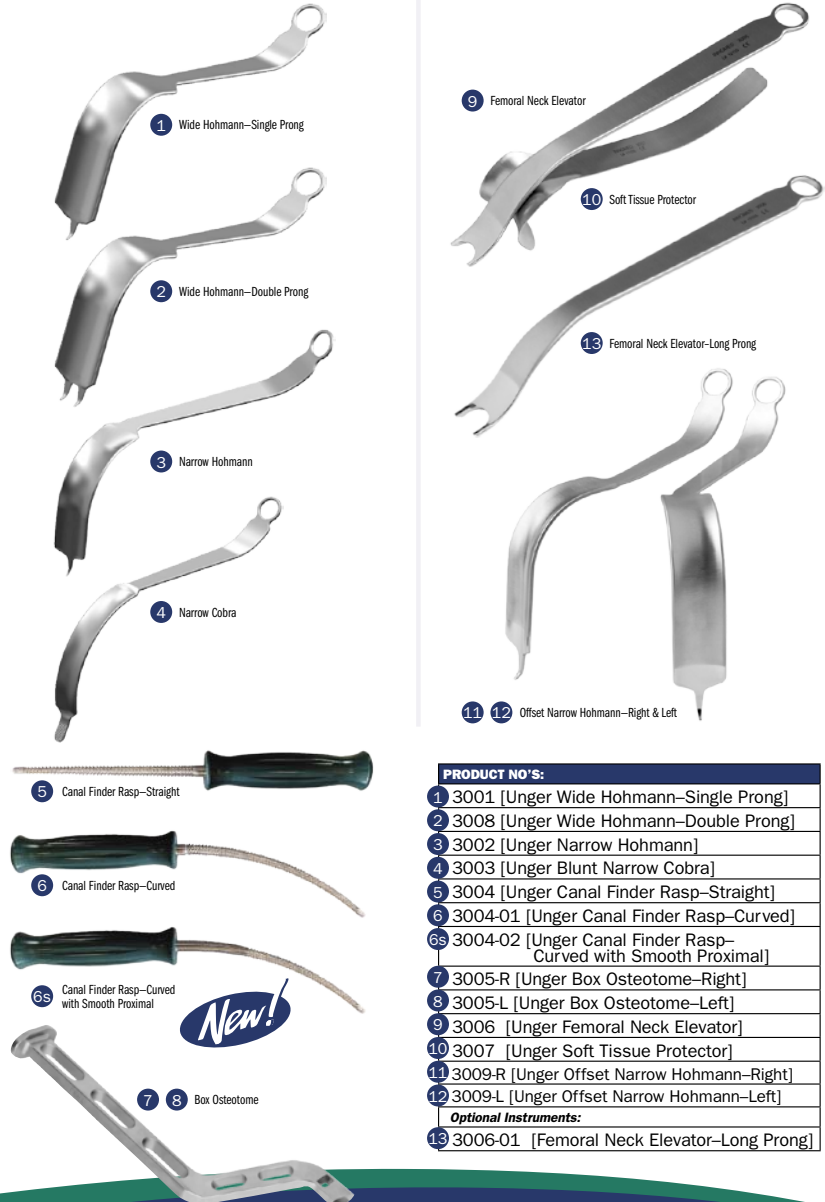


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CONTENTS

CASE REPORT

- 11 Popliteal Artery Complications of Total Knee Replacement – Our Experience In Large Volume Centre and Review of Literature
Nithin S, Reddy A, Muralidhar S
- 15 Conversion Knee Arthroplasty Using a Rotating Hinge as a Salvage Prosthesis Following Periprosthetic Joint Infection and Ligamentous Insufficiency: A Case Report
Minter J

ORIGINAL ARTICLE

- 21 Decreased Incidence of Periprosthetic Joint Infection in Total Hip Arthroplasty with Use of Topical Vancomycin
Crawford D, Berend K, Adams J, Lombardi A
- 27 Correction of Femoral Acetabular Impingement at the Time of Primary THA
McPherson E, Sherif S, Chowdhry M, Dipane M
- 37 Manipulation Rate Is Not Increased After Customized Total Knee Arthroplasty
Kay A, Kurtz W, Martin G, Huber B, Tait R, Clyburn T



Popliteal Artery Complications of Total Knee Replacement – Our Experience In Large Volume Centre and Review of Literature

Nithin S¹, Reddy A¹, Muralidhar S¹

Abstract

We present a case report and review of literature on injury to the popliteal vessel during total knee replacement. This is rare but would be limb-threatening with devastating consequences for the patient. Because of poor collateral circulation, severe ischemia may give rise to irreversible tissue damage necessitating amputation if not adequately recognized and treated. Incidence, prognosis, treatment, potential risk factors and measures to prevent injury are discussed here. Safe and careful surgical technique will be the most effective preventative measure.

Background

Total Knee replacement is one of the successful operations performed for arthritis of knee joint. Popliteal artery occlusion after total knee arthroplasty occurs at a very low incidence (0.03–0.17%) [1]. We here describe the incidence of popliteal artery complications in one of the large volume centre in Asia. Our case had complete occlusion of the popliteal artery at the 1st post-operative day. Our reported case of post-TKR popliteal artery thrombosis was without known risk factors. Reason for concern is because of poor collateral circulation, severe ischemia may give rise to irreversible tissue damage necessitating amputation if we do not recognize early and treat them. We reviewed cases from the literature in terms of incidence, prognosis,

treatment, potential risk factors and measures to prevent injury.

Case Report

A 67 year old gentleman presented to the orthopaedic out-patient department with bilateral grade -4 osteoarthritis. On examination the patient had restriction of movements, joint line tenderness present, crepitus, no flexion deformity and bilateral varus angulation of knee of 10 degree. The patient was counselled and operated for right TKR since right knee was more symptomatic. Genesis II Posterior Stabilized by Smith & Nephew Oxinium implant was used. Immediately in the post-operative period distal pulses were palpable. Patient was started on LMWH, but surprisingly in the post-operative day 1, ankle dorsiflexion and plantar flexion were absent. Toes were cooler and sensation was absent with the presence of femoral pulse and absence of dorsalis pedis and post-tibial pulse.

Vascular surgeon opinion was taken and a Doppler was done which showed acute arterial thrombosis in the distal 2/3 rd of the right popliteal artery with no phasic flow in the posterior and anterior tibial artery. CT angiogram

Keywords: total knee arthroplasty, popliteal artery thrombosis, angiography

Level of Evidence: AAOS Therapeutic Level IV

Educational Value & Significance: JISRF Level B

showed acute thrombosis and complete occlusion of the right popliteal artery. The patient was posted for percutaneous transluminal balloon angioplasty and thrombectomy was done. Check angiogram showed good distal flow.

Now the patient is at one month follow up with intact distal pulses. Knee range of movements showed 0-90 degree with no scar issues.

Discussion

Arterial vascular injury is a rare complication of total knee arthroplasty. Although this complication being rare, it deserves attention as consequences are devastating and involves amputation of the limb. Common causes being direct sharp trauma causing laceration and haemorrhage. Atherosclerotic occlusion and thrombosis may occur due to pre-existing atherosclerosis, joint manipulation or tourniquet causing intimal damage leading to atherosclerosis. Pre-operative risk factors include history of claudication pain, rest pain, absence of distal pulses, arterial ulcers, popliteal aneurysm, previous arterial reconstruction and calcification of arteries on plain radiographs.

In a review of 9022 Total Knee Arthroplasty (TKA) patients at the Mayo Clinic, only 3 were diagnosed postoperatively with arterial sequelae [1]. In another review of 4097 patients conducted at Pennsylvania Hospital, only 7 patients (0.17%) were found to suffer acute ischemia after the procedure [2]. Although infrequent, the arterial complications after TKA are heterogeneous; the most frequently reported are arterial thrombosis, arterial transection, arteriovenous fistula, and aneurysm formation [3]. Of these, popliteal artery thrombosis is the most frequent, accounting for 65.9% of all arterial problems [4]. In another study, 31 cases of acute popliteal artery occlusion after TKA, 11 cases (35.5%) reportedly required amputation [5].

Patients of acute limb occlusion with severe symptom such as sensory loss of more than toe, rest pain, and moderate motor deficit require emergent surgical revascularization [6]. Emergency thrombectomy would be the initial step, and if thrombus removal is not possible, surgical bypass will be the next choice. In our case, the patient presented foot coldness, decreased sensation, and paresthesias, so the thrombectomy with a Fogarty catheter for revascularization of acute arterial occlusion was immediately attempted.

In another study of 1182 patients who underwent TKA, 25% (6/24) of the patients with preexisting vascular disease suffered vascular injuries, whereas no patients without preexisting arterial disease had vascular injuries [7]. However, several patients without known risk factors have

developed arterial ischemic complications after TKA. The assumption that post-TKA arterial complications are, for the most part, limited to patients with a previous history of arterial disease [7] now appears incomplete.

Surgical procedure is of vital importance in preventing vascular injury. During TKA operation, insertion of the retractor into the posterolateral corner of the tibia should be avoided because it is the most vulnerable area of the popliteal artery [8,9]. The popliteal artery, vein, and posterior tibial nerve usually run through the posteromedial to the lateral corner of tibia, and more than one centimetre insertion of the retractor on this site poses a great risk of direct injury to the popliteal artery [10].

There are 4 moments of TKA surgical procedure during which vessels, especially popliteal artery can be damaged: 1) at the tibial cut, 2) at the posterior cut of the femoral condyles, 3) during the application of retractor for anterior dislocation of the tibia, and 4) during placement of the knee in hyperextension after the cuts and before the application of the hardware [8,11].

Revision surgery is associated with an approximately doubled risk of vascular injury, [12] which may reflect fixation of the artery closer to the knee joint in scar tissue [10] making it more susceptible to indirect and direct trauma. Presence of some of these risk factors may be an indication for pre-operative referral to vascular surgery with an appropriate threshold to avoid overwhelming vascular surgical services.

Conclusion

We want to conclude that from our cases, the need of pre-operative vascular Doppler in patients undergoing knee replacement arthroplasty. Prompt diagnosis depends on 2 things: clinical assessment of complications and careful Doppler assessment. Clinical assessment includes assessment for signs of vascular insufficiency such as pallor, poor capillary refill and disturbed neurological status. High index of suspicion in patients suffering from atherosclerotic conditions and co-morbid conditions. Complete assessment of risk factors for post operative arterial complication and if necessary pre-operative Doppler assessment to prevent this devastating complication.

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Conversion Knee Arthroplasty Using a Rotating Hinge as a Salvage Prosthesis Following Periprosthetic Joint Infection and Ligamentous Insufficiency: A Case Report

Minter J¹

Abstract

Background: In the event of a complex revision TKA in which there is extensor mechanism involvement and ligamentous instability or insufficiency, non-linked levels of constraint may not be adequate for achieving restoration of patient function. Total knee arthroplasty devices that incorporate a linked level of constraint are successful alternatives to unlinked devices (PS and PS-Constrained) in this clinical context.

Case Presentation: We present the case of a 62 year-old male patient that required a non-articulating knee fusion and multiple total knee arthroplasty revisions in conjunction with a ruptured and repaired extensor mechanism, ligamentous instability, bone loss and periprosthetic joint infection. (Revision knee prosthesis that includes an increasing degree of nodularity and physical constraint). The subsequent risk factors associated with the loss of bone and ligamentous insufficiency required performing conversion arthroplasty with a knee prosthesis that includes an increasing degree of modularity and physical constraint not commonly used in revision total knee arthroplasty.

Discussion: The authors report on a patient who underwent multiple operative procedures, we outline the step wise decision making progression that lead to the successful eradication of the PJI and reimplant device strategy based on the confounding factors presented. We assess the use of revision TKA systems that offer extreme degrees of

constraint which should be considered in complex revision knee revision procedures.

Background

The goals of primary total knee arthroplasty (TKA) include relief of pain, restoration of function and establishment of durable long term prosthesis to patient composite. Various factors that contribute to the long-term success of primary TKA include patient co-morbidities, patient compliance, surgical technique and arthroplasty implant design. [1-5] In the event of failure, it is important there is assessment and understanding of the factors resulting in the failure, these include patient co-morbidities, implant loosening, bone loss, knee ligament laxity and periprosthetic joint infection (PJI) [6-9]

For aseptic loose TKA requiring revision, without ligamentous involvement or significant bone loss, there are many non-linked device options. [10] In revision TKA in which there is ligamentous instability or insufficiency, loss of extensor mechanism or bone loss non-linked levels of

Keywords: Complex Revision TKA, Rotating Hinge TKA, Non-Articulating Fusion, Salvage TKA

Level of Evidence: AAOS Therapeutic Level IV

Educational Value & Significance: JISRF Level C

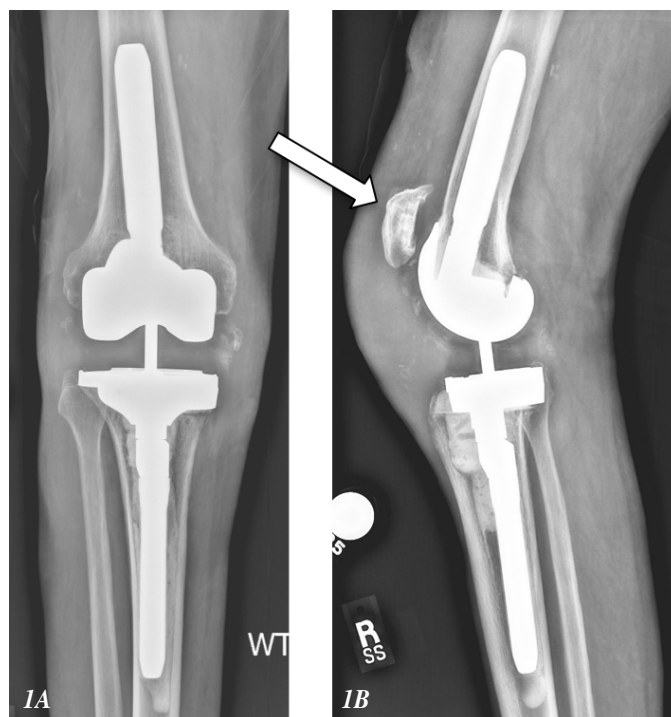
constraint may not be adequate for achieving restoration of function. [7,8] Total knee arthroplasty devices that incorporate a linked level of constraint are successful alternatives to unlinked devices (PS and PS-Constrained). [7,8] We describe a case in which a patient underwent revision reconstruction with a rotating hinged TKA system to manage ligamentous and extensor mechanism deficiency.

Case Presentation

Prior to this case presentation all patient information was de-identified or removed as per the Health Insurance Portability and Accountability Act (HIPAA, 1996) provisions for safeguarding medical information. In 2007, a 62 year-old male patient underwent a right posterior-stabilized (PS) primary TKA for the management of primary osteoarthritis. The patient reported pain relief and improved function for the first 8 post-operative years. In 2015, the patient reported increased pain and right knee instability during start-up, standing and walking without a history of specific injury. X-rays and bone scan revealed tibial component varus malalignment and radiolucency consistent with tibial component loosening. Physical exam revealed knee range of motion (ROM) was 5-120 degrees, there was significant AP laxity (drawer test) but the knee was stable under varus valgus stress. PJI was ruled out by laboratory investigations.

The patient underwent right knee revision TKA, 3 weeks post revision the knee “buckled” whilst the patient was transferring to bed and the patient suffered a fall. The patient experienced pain and loss of extension. X-rays revealed a “high-riding” patella (Figures 1A & 1B). An MRI was ordered but was inconclusive due to metal artifact. Ultrasound and MRI were inconclusive. Operative exploration revealed an extensor mechanism tear which was repaired and the patient was managed partial weight bearing in a locked knee brace in full extension for 4 weeks. Post operative radiographs revealed a well placed posterior stabilized (PS) revision right knee without evidence of patella alta.

Seven weeks post revision the patient was weaning out of the knee brace with 10-90 ROM. The patient presented to a local Emergency Room (ER) with severe back pain. The patient had a prior history of severe lumbar degenerative disc disease (DDD) with prior posterior instrumented interbody fusion that resulted in an early post spine surgery right foot-drop. Following the acute ER presentation the patient was commenced on steroids, muscle relaxing medication, NSAID and was referred to spinal physician. A subsequent MRI revealed evidence of lumbar osteomy-



Figures 1A & 1B. AP and Lateral radiographs following revision TKA and fall resulting in possible quadriceps rupture and subsequent radiographic evidence of patella alta (arrow).

elitis and discitis. The patient was hospitalised for treatment and during admission a diagnosis of septic arthritis of the right knee was confirmed after right knee aspiration grew staph-epidermidis. The patient was treated with a full course of vancomycin and rifampicin.

Two months post septic arthritis the patient presented to the lead author's office for a second opinion. Physical exam revealed active ROM 40-120 degrees, passive ROM 0-120 degrees. There was Grade II instability through ROM, and there was a palpable defect of the patella tendon. Laboratory results showed elevated CRP at 9.41 (0.5 high normal) and an ESR of 99 (20 high normal). Synovasure® (Zimmer Biomet, Warsaw, IN) testing of the knee aspiration was positive for infection with associated count of 5,391 total nucleated cells and 89.2 neutrophils with no bacterial growth noted at 7-days. Two stage revision surgery was scheduled with complete hardware removal and temporary placement of antibiotic impregnated spacer with planned temporary arthrodesis. The arthrodesis procedure was performed utilizing a double set-up technique and the patient exhibited pan-articular grade IV osteomyelitis of the knee. [11] The surgical procedure included a total synovectomy, radical resection of the distal femur and proximal tibia, and the patellar tendon was debrided back to a healthy tissue border. A LINK® Endo-Model® Knee Fusion Nail (Waldemar-LINK GmbH & Co. KG, Hamburg, Germany) was implanted with antibiotic impregnated ce-



Figures 2A & 2B. AP & Lateral radiographs following fusion utilizing the LINK Endo-Model® Knee Fusion Nail, implanted with antibiotic impregnated cement and antibiotic beads within the intramedullary canals.

ment and antibiotic beads within the intramedullary canals (Osteoblast™, Osteoremedies, Inc., Memphis, TN) (Figures 2A & 2B). Post-operative intravenous (IV) antibiotic which included Vancomycin and Rifampicin treatment that was co-ordinated with Infectious Disease Service.

Two months following the first stage operation the patient completed a full course of antibiotic therapy and two, staged aspirations of the knee were performed to rule out infection (1-month following completion of IV antibiotics, and prior to removal of the arthrodesis nail and revision TKA re-implantation). Both staged Synovasure® aspiration results were negative for infection and the patient was scheduled for revision/reimplantation surgery in November 2016.

At second stage a limb salvage procedure utilizing the LINK® Megasystem-C® rotating-hinge, segmental replacement knee system (Waldemar-LINK GmbH & Co. KG, Hamburg, Germany) was performed (Figures 3A & 3B). A Triathlon® TS Cone (Stryker, Kalamazoo, MI) was incorporated into the reconstruction due to significant tibial bone loss. Extensor mechanism repair utilized a Marlex® graft (C.R. Bard, Warwick, RI) (Brown-Hansen technique), with an associated medial gastrocnemius and split thickness skin graft flap closure as per the plastic surgery consult. Post-operatively, the patient was placed in



Figures 3A & 3B. Early post-operative AP and Lateral radiographs following conversion TKA from the antibiotic spacer to the LINK® Megasystem-C rotating-hinge, segmental replacement knee system. Images including the titanium tibial cone to correct for significant bone loss.

a long leg cast for 2 months and allowed only toe-touch weight-bearing. Three months post reimplantation (February 2017), long leg cast was removed, the patient reported minimal pain, physical exam showed no effusion and the patient was able to straight leg raise without extensor lag. A long leg hinged brace initially set at 0-10 degrees flexion was applied with instructions for the patient to remain in brace 24 hours a day and to increase flexion

by 10 degrees per week. This was performed with no formal physical therapy scheduled. Within six-weeks (March 2017), the patient returned to clinic with only occasional discomfort at the extremes of flexion, however the patient required narcotic pain relief for chronic lumbar pain. Physical exam revealed 0-75 ROM and the patient was advised to transfer to a shorter hinged knee brace upon returning to work. A home exercise program which included quadriceps strengthening and range of motion exercises was encouraged. At most recent follow up the patient's ROM was 0-100 degrees with ambulation up to one mile and stair climbing with alternating gait.

Discussion

Multiple factors contribute to the overall success or failure of primary and revision TKA. In revision TKA implant options include implant modularity and level of constraint which can assist in addressing various degrees of bone loss, ligamentous insufficiency or instability and extensor mechanism derangement. With the case the authors present revision was required for a combination of factors including component composite failure (aseptic loosening), patient compliance (fall and quadriceps rupture) and patient co-morbidities (infection and previous spine surgery).

This patient experienced knee "buckling" following revision surgery for aseptic loosening. The authors anticipate the patient suffered a patella tendon rupture due to the radiographic evidence of patella alta and PJI was confirmed using the Synovasure PJI test panel. Synovasure was developed to detect infection using local synovial fluid and includes a battery of tests including alpha defensin, CRP and hemoglobin in synovial fluid. [14,15] The current standard of care for deep infection is considered to be two-stage revision arthroplasty and the use of antibiotic-impregnated bone-cement spacers. [16,17] However, in this case the authors took the extra measure to assess on two occasions for any evidence of infection following discontinuation of the IV antibiotics, prior to conversion of the arthrodesis to TKA.

In periprosthetic joint infections with minimal bone loss or soft-tissue insufficiency the patients can be successfully treated utilizing static or mobile antibiotic impregnated spacers and a two-stage TKA re-implantation. [16,17] However, cases involving significant bone loss or soft-tissue insufficiency, an arthrodesis nail with antibiotic impregnated cement is preferred to allow the limb to be brought out to length to avoid soft-tissue contraction and for later placement of the limb salvage TKA system. [18-20] In the authors' case the finding of no serviceable ex-

tensor mechanism made the use of the fusion nail necessary. The argument for the use of a non-articulating spacer was discussed at the recent *International Consensus Conference on PJI* (2013), and it was agreed upon that only the technical feasibility of the procedure to be the contraindication for the selection of non-articulating versus articulating spacers. [21] Furthermore, it was the opinion of the consensus group that "patients with massive bone loss and/or lack of integrity of soft-tissues or ligamentous restraint, strong consideration should be given to the use of non-articulating spacers." [21]

In patients with ligamentous deficiency, combined with extensor mechanism disruption the pathology taxes the use of non-linked, lower constrained implants leading to overall knee instability and failure. [7,8,22] In the case the authors report there was significant ligament instability, extensor mechanism insufficiency, bone loss and PJI. The LINK Megasytem-C rotating hinge knee system offers a physically "linked" constraint which is appropriate to manage these deficiencies. Following revision TKA using the LINK Megasytem-C rotating hinge, the patient post-operatively presented with significant improvement in the reduction of pain and restoration of function. Sanguineti, et al reported 93.3% survival following complex primary and revision cases using the LINK Endo-Model rotating hinge in 45 patients at an average follow-up of 42.2 months. [22] Despite the high degree of constraint, the incidence of aseptic loosening is reported to be minimal, reflecting the manufacturer's claim of force dampening across the rotating hinge mechanism. [7,8,22,23]

In conclusion, in a complex knee arthroplasty revision scenario careful assessment of the reasons for the adverse outcome must be undertaken. Treatment of PJI prior to revision and confirmation of infection resolution are necessary to avoid further chronic sepsis. The use of revision TKA systems that offer high degrees of constraint should be considered to address issues of multiple ligament insufficiency, extensor mechanism disruption and bone loss.

The authors acknowledge the limitation of case reports of complex procedures which represent a small number of overall arthroplasty cases in the community. Our intent is to report on the sequential degradation on patient's knee that underwent multiple procedures and outline the step-wise progression of treatment that led to successful eradication of PJI and successful re-implantation of a highly constrained linked knee arthroplasty device appropriate for limb salvage procedures.

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AUTHOR DISCLOSURES

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

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6303-01	[Wide Lighted Retractor]
6304-01	[Narrow Lighted Retractor]
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Decreased Incidence of Periprosthetic Joint Infection in Total Hip Arthroplasty with Use of Topical Vancomycin

Crawford D¹, Berend K¹, Adams J³, Lombardi A²

Abstract

Background: Periprosthetic joint infections following total hip arthroplasty (THA) can cause significant patient morbidity and carry with them a substantial cost burden to the healthcare system. The purpose of this study was to assess whether the addition of topical vancomycin decreased the incidence of superficial and deep infections after primary total hip arthroplasty?

Methods: We performed a retrospective analysis of patients who underwent primary THA with (1070 hips) and without (815 hips) the use of topical vancomycin. Records were reviewed to determine incidence of PJI. Infections were categorized as deep or superficial. Medical comorbidity data was evaluated for known risk factors including diabetes, rheumatoid arthritis, and BMI. Records were further reviewed to determine surgical approach used and bacterial cause of PJI.

Results: The overall incidence of infection in the control group was 1.47% (12 hips) and significantly decreased to 0.47% (5 hips) with the addition of topical vancomycin ($p=0.022$). Deep infections also decreased from 0.86% (7 hips) in the control group to 0.09% (1 hip) in the vancomycin group ($p=0.011$). There was no difference in BMI or percent of patients with diabetes between groups. In all patients, regardless of vancomycin use, the incidence of infection in the direct lateral approach was higher (2.04%, 9 hips) than the anterior approach (0.055%, 8 hips) ($p=0.004$).

Conclusions: We found a lower incidence of periprosthetic joint infection after THA with the addition of topical vancomycin. We also found a decreased incidence of infection in patients who had surgery through an anterior approach compared with those who had a direct lateral approach.

Background

Periprosthetic joint infections (PJI) remain one of the most devastating complications following total hip arthroplasty. Prevention of deep infection is paramount for reducing patient morbidity and health care cost associated with management of PJI as multiple surgeries, hospitalizations and outpatient antibiotics are often required to eradicate a deep infection. It is estimated that the incidence of PJI will be 40,000 to 80,000 per year in the United States by 2030 and have a cost burden of \$2 to 4 billion annually [1]. Management of a single PJI costs on average \$50,000 and can increase up to \$100,000 in cases with resistant organisms [2,3].

Efforts to reduce infection begin preoperatively in optimizing patient factors. Obesity, malnutrition and poor dia-

Keywords: total hip, infection, vancomycin, antibiotic, arthroplasty

Level of Evidence: AAOS Therapeutic Level IV

Educational Value & Significance: JISRF Level A

betic control are all modifiable risk factors have all been shown to increase risk of infection [4-6]. Perioperative techniques to reduce risk of infection include proper surgical site prepping, perioperative antibiotics, use of laminar flow, decreasing surgical time and blood loss [5,7,8].

Local surgical site techniques to reduce risk of infection have also been employed. Some have advocated for copious irrigation with either antibiotic loaded solution or dilute betadine [9,10]. Topical antibiotics have been shown throughout the spine literature to significantly reduce surgical site infection [11-17]. Animal models have shown that the combination of local and systemic antibiotics significantly decrease the rate of wound infection compared to either modality alone [18].

Gram-positive bacteria are most commonly associated with PJI including staphylococcus aureus and staphylococcus epidermidis [19,20]. These bacteria adhere to implants and form a biofilm, which makes them difficult to treat [21]. Approximately 10% to 20% of infections are from gram-negative organisms and 20% of infections are polymicrobial [22,23].

The purpose of this study was to assess whether the addition of topical vancomycin decreased the incidence of superficial and deep infections after primary total hip arthroplasty. Secondly, we evaluated whether there was a difference in the incidence of infection between the direct lateral approach and the anterior supine intermuscular approach (ASI).

Methods

We performed a retrospective comparative cohort analysis of patients who underwent primary THA with and without the use of topical vancomycin. All patients signed a general research consent approved and monitored by our independent institutional review board (Western IRB; Puyallup, Washington) allowing retrospective research review. We separated patients by year in which they had surgery. In 2011, topical vancomycin was not used and this group served as the control. In 2015 all patients undergoing THA had 1g of sterile vancomycin hydrochloride sprinkled in the wound after component implantation and prior to closure. The 2011 control group consisted of 746 patients (815 hips) while the 2015 intervention group had 987 patients (1070 hips). All surgeries in both groups were performed by one of three fellowship trained adult reconstruction surgeons using cementless femoral and acetabular components with polyethylene liners. Both groups of patients cleaned their surgical site preoperatively with chlorhexidine antiseptic skin cleanser, and DuraPrep™ Surgical So-

lution (3M, St. Paul, Minnesota) was used intraoperatively for surgical preparation in both groups.

In 2011, patients had surgery performed at either an orthopaedic specialty hospital (639) or full service general hospital (176). In 2015, surgeries were performed at an orthopaedic specialty hospital (589), full service hospital (10) or outpatient surgery center (471).

Records were reviewed to determine incidence of PJI. Infections were categorized as deep or superficial based on a hip fluid cell count, culture and need for radical debridement. Medical comorbidity data was evaluated for known risk factors including diabetes, rheumatoid arthritis, and BMI. Records were further reviewed to determine surgical approach used and bacterial cause of PJI. Surgical approaches included a minimally invasive direct lateral approach and anterior supine intermuscular (ASI) or “anterior” approach.

Statistical Analysis

Chi-squared analysis was used to compare the incidence of infection with and without intrawound vancomycin as well as incidence of infection by approach. T-test was used to compare patients' height, weight and BMI between groups.

Results

Patient demographic information between the groups is listed on Table 1. Tables 2a and 2b show differences in demographics and surgical data between approaches and year groups. In combining demographics between groups, the mean BMI in patients who had a direct lateral was 33 kg/m² (range, 17.4 to 58.4), which was significantly higher than patients who had an ASI approach, BMI 30.46 (range, 12.2 to 62.02) $p < 0.001$. Operative time was significantly less in the 2015 vancomycin group both in patients who had an ASI approach ($p < 0.001$) and direct lateral approach ($p = 0.02$).

The overall incidence of infection in the control group was 1.47% (12 hips) and significantly decreased to 0.47% (5 hips) with the addition of topical vancomycin ($p = 0.022$). Deep infections also decreased from 0.86% (7 hips) in the control group to 0.09% (1 hip) in the vancomycin group ($p = 0.011$). Details of the infections that occurred are listed in Table 3a and 3b. The mean BMI of patients who developed an infection was 39.1 kg/m² (range, 26.6 to 58.2 kg/m²). Five patients (42%) in the control group who developed infections had diabetes mellitus, while three patients (60%) in the vancomycin group who developed infections had rheumatoid arthritis.

In comparing surgical approach, the 2011 control patients had their surgeries performed with a direct lateral in 314 hips (39%) and ASI approach in 501 hips (61%). There were 7 total infections (2.23%) in the direct lateral group compared to 5 total infections (1.0%) in the ASI group ($p=0.155$). There were 5 deep infections (1.59%) in the direct lateral group compared to 2 deep infections (0.4%) in the ASI group ($p=0.072$). Surgical approach in the 2015 vancomycin cohort was direct lateral in 126 hips (12%) and ASI in 944 hips (88%). There were 2 total infections (1.59%) in the direct lateral group compared to 3 total infections (0.32%) in the ASI group ($p=0.049$). There was 1 deep infection (0.79%) in the direct lateral group compared to 0 deep infections (0%) in the ASI group ($p=0.004$).

Comparing the 2011 to 2015 direct lateral patients, the overall infection rates decreased from 2.23% to 1.59% with the addition of vancomycin but this was not statistically significant ($p=0.667$). The deep infection rate also decreased from 1.59% in the control group to 0.79% in the vancomycin group but was not significant ($p=0.513$). Comparing the 2011 to 2015 ASI patients, the overall infection incidence decreased from 1% to 0.32% but was not significant ($p=0.097$). The deep infection rate decreased from 0.4% to 0% ($p=0.024$), which was significant.

In all patients, regardless of vancomycin use, the incidence of any infection in the direct lateral patients was 2.04% (9 hips) compared to 0.055% (8 hips) in the ASI approach ($p=0.004$). The incidence of deep infection in all direct lateral patients was 1.4% (6 hips) compared to 0.01% (1 hip) in the ASI approach ($p<0.001$).

In 2011, five infections occurred in patients who had surgery at the general hospital and seven infections occurred in patients who had surgery at the specialty hospital. In 2015, four of the infections occurred in patients who had surgery at the specialty hospital and one infection occurred in a patient who had surgery at the outpatient surgery center. Each of the three surgeons performed surgery on at least four of the patients who developed infections in both groups combined.

Discussion

With the addition of topical vancomycin powder, we observed a significant reduction in overall and deep infections with only one deep infection in 1070 hips for incidence of 0.09%. We further found that regardless of antibiotic use, the ASI surgical approach has a significantly lower frequency of any and deep infections than the direct lateral approach.

Table 1. Patient demographics compared between 2011 control group and 2015 vancomycin group

Characteristic	2011	2015	P Value
Gender (male:female)	48%:52%	49%:51%	0.621
Age (years)	63.3 (± 11.9)	64.8 (± 10.2)	0.004
Height (inches)	67.0 (± 4.3)	67.5 (± 4.3)	0.035
Weight (pounds)	199.8 (± 51.9)	201.6 (± 52.0)	0.472
BMI (kg/m ²)	31.1 (± 7.3)	31.0 (± 7.0)	0.828
Diabetes	15.9%	13.5%	0.15
Rheumatoid arthritis	2.6%	6.3%	<0.001

Table 2a. Patient demographics and operative differences compared between 2011 and 2015 THA performed with the anterior supine intermuscular (ASI) approach

Characteristic	2011 ASI	2015 ASI	P Value
Gender (male:female)	47%:53%	48%:52%	0.724
Age (years)	62.7 (± 11.9)	64.7 (± 10.2)	0.001
Height (inches)	67.1 (± 4.1)	67.5 (± 4.2)	0.115
Weight (pounds)	195.4 (± 50.3)	198.1 (± 48.9)	0.346
BMI (kg/m ²)	30.4 (± 6.9)	30.5 (± 6.6)	0.808
Operative time (minutes)	76.1 (± 37.7)	64.5 (± 23.3)	<0.001
Estimated blood loss (mL)	185.5 (± 171)	197.9 (± 116)	0.070

Table 2b. Patient demographics and operative differences compared between 2011 and 2015 THA performed via the direct lateral approach

Characteristic	2011 Lateral	2015 Lateral	P Value
Gender (males:female)	49%:51%	56%:44%	0.166
Age (years)	64.1 (± 11.9)	64.9 (± 10.8)	0.512
Height (inches)	67.0 (± 4.7)	67.7 (± 5.0)	0.163
Weight (pounds)	206.8 (± 53.9)	227.8 (± 65.7)	0.001
BMI (kg/m ²)	32.2 (± 7.9)	34.9 (± 9.1)	0.003
Operative time (minutes)	72 (± 29.4)	64.3 (± 23.3)	0.020
Estimated blood loss (mL)	182 (± 145)	158 (± 116)	0.200

Buchholz et al first described the use of local antibiotics in 1970 [24] and since then the local application of antibiotic has been investigated in orthopedics, cardiothoracic, vascular, and spine surgeries [25–28]. Topical vancomycin use in spine surgery has shown a greater than 50% decrease in surgical site infections in spine surgery [29]. Johnson et al studied the local and serum vancomycin concentration levels after topical administration of vancomycin [30]. They evaluated 34 patients in whom 1G of vanco-

Table 3a. Demographic and infection characteristics of 2011 control group patients who developed an infection.

Gender	Age (years)	BMI (kg/m2)	Diagnosis, Risk Factors	Approach	Infection	Organism(s)
female	40	37.2	osteoarthritis, Larsen syndrome	anterior	deep	cultures negative
female	92	27.4	osteoarthritis	anterior	deep	enterobacter cloacae, staphylococcus epidermidis
female	60	34.8	osteoarthritis	anterior	superficial	staphylococcus coagulase negative, staphylococcus lugdenensis
female	80	36.1	osteoarthritis, diabetes mellitus	anterior	superficial	gram negative rods, enterobacter cloacae
female	73	31.4	osteoarthritis	anterior	superficial	staphylococcus epidermidis (resistant), propionibacterium acnes
male	57	45.4	osteoarthritis, diabetes mellitus	lateral	deep	klebsiella pneumoniae, enterobacter cloacae
female	60	58.2	osteoarthritis	lateral	deep	staphylococcus aureus (methicillin resistant), rare pseudomonas
female	66	46.2	osteoarthritis, diabetes mellitus	lateral	deep	staphylococcus epidermidis, escherichia coli, staphylococcus warneri, acinetobacter
female	59	26.6	developmental dysplasia	lateral	deep	group B beta streptococcus
female	71	42.6	osteoarthritis, history of infection	lateral	deep	proteus mirabilis, escherichia coli, pseudomonas
male	60	37.6	osteoarthritis, diabetes mellitus	lateral	superficial	staphylococcus aureus coagulase positive
female	42	56.6	osteoarthritis, diabetes mellitus	lateral	superficial	gram negative rods, escherichia coli

Table 3b. Demographic and infection characteristics of 2015 vancomycin group patients who developed an infection.

Gender	Age (years)	BMI (kg/m2)	Diagnosis, Risk Factors	Approach	Infection	Organism(s)
female	62	27.5	rheumatoid arthritis	anterior	superficial	staphylococcus aureus (methicillin resistant)
female	65	41.6	rheumatoid arthritis, history of infection	anterior	superficial	pseudomonas aeruginosa
female	68	36.1	osteoarthritis, coronary artery disease	anterior	superficial	pseudomonas aeruginosa
female	67	30.1	rheumatoid arthritis, coumadin therapy	lateral	deep	coagulase negative staphylococcus
female	69	48.5	osteoarthritis	lateral	superficial	escherichia coli, proteus mirabilis, peptostreptococcus anaerobius

mycin was mixed with 2G of tranexamic acid and injected into the drain tube after capsule closure. One gram of vancomycin was also sprinkled in the subcutaneous tissue. Intrawound and serum levels were measured at multiple time points up to 24 hours. They found the serum vancomycin levels remained on average below 5 $\mu\text{g/mL}$ which is well below the normal serum therapeutic level of 10 to 20 $\mu\text{g/mL}$. Meanwhile, the wound concentration of vancomycin peaked on average at 922 $\mu\text{g/mL}$. These findings support that topical vancomycin provides a highly therapeutic intrawound concentration, with low systemic absorption. Whiteside has described his technique of intra-operative irrigation of normal saline with vancomycin and polymyxin [17]. The wound is irrigated throughout the case with this solution as well as in the medullary canals prior to fi-

nal implantation. In his reported series of 2293 arthroplasties, there were no cases of primary infection. There was one case of a deep infection that was attributed to an unrecognized hematoma that became infected.

There has been some concern about the potential for third body wear with the application of topical vancomycin. Qadir et al. performed a wear simulation study with 6 articulation stations, 3 of which had topical vancomycin and 3 without [31]. After 10 million cycles they found no difference in wear mark length, width or gravimetric wear between groups.

The direct anterior approach for total hip arthroplasty has gained popularity over the past decade with purported benefits of the muscle sparing nature, faster early recovery and ability to use fluoroscopic assistance for component

placement and leg length assessment. While infection concern was not a driving factor behind our practice's transition to the anterior approach, we did find in this study a decreased incidence of overall and deep infections using the anterior approach compared to the direct lateral. In surgeons who perform both approaches, there may be some selection bias as the direct lateral (or alternate approach) may be chosen for patients who are more obese. This was shown in our current study in which the average BMI was significantly higher in patients who had their surgery done through a direct lateral approach. We also showed that as more THA were done through an anterior approach in 2015, the BMI of patients who had surgery via a direct lateral approach was significantly higher than patients in 2011 who had a direct lateral approach. Other studies have not shown a difference in risk of infection between anterior and other approaches. Ilchmann et al found no significant difference in the risk of infection in patients undergoing primary THA from either a direct anterior (2.3%) or lateral transgluteal approach (1.7%) [32]. Likewise, Malek et al did not find a significant difference in infection risk between the anterior or posterior approach [33]. With the differences in patient BMI between the two surgical approaches in our study, BMI itself may be more of a factor for risk of infection than the surgical approach.

This study has several limitations. The main limitation is the many variables that contribute to development of periprosthetic joint infections including medical comorbidities, obesity, nutritional status, surgical preparation, operative time, anemia, blood loss, and hospital arthroplasty volume [2,5]. We did find that the operative time was significantly less with either approach in the 2015 vancomycin group compared to the 2011 group. We did not however find a significant difference in blood loss between groups. We did not have data on preoperative hemoglobin/hematocrit or postoperative transfusion rates. Preoperative and intraoperative surgical preparation was the same in both groups and thus should not be a confounding factor. All 3 locations where the surgeries were performed in both groups were high volume facilities. The surgical location did change somewhat between groups with the addition of an ambulatory surgery center in the 2015 group. Only one patient who had surgery at the ambulatory surgery center developed a superficial infection and no patients developed a deep infection. There is likely some selection bias on surgical location as patients with significant medical comorbidities were likely taken to the hospital for surgery. We did not assess patient nutritional status, which has been shown as risk factor for infection and is a limitation in our findings [34]. The BMI between the groups was pretty well matched and not significantly dif-

ferent. Furthermore we did not find a difference in the incidence of diabetes between groups. The vancomycin group did have a significantly higher incidence of patients with rheumatoid arthritis and 60% of the patients who developed an infection in this group had rheumatoid arthritis. Even with the higher incidence of rheumatoid arthritis in the group, the incidence of overall and deep infections was lower. Other medical comorbidities, smoking status, and ASA class were not assessed, which limited our analysis of patient-related risk factors. Lastly was the limitation of the confounding finding of differences in the infection rates between the direct lateral approach and ASI approach as well as the increased usage of the ASI approach in the vancomycin group. We found significantly lower incidence of overall and deep infections in the ASI group regardless of vancomycin usage. The use of the ASI approach increased from 61% in 2011 to 88% in 2015. This increased use of the ASI approach which we found had a lower infection rate is likely contributing to our findings of lower incidence of infection with addition of vancomycin in this group. We did however find that with the addition of vancomycin there was a significant decrease in the incidence of infection in patients who had their hip replacement from the ASI approach, but we did not find a difference in the direct lateral approach.

While this study does have several limitations in controlling for confounding variables, we did find a lower incidence of periprosthetic joint infection after THA with the addition of topical vancomycin. We also found a decreased incidence of infection in patients who had surgery through an ASI approach compared with those who had a direct lateral approach.

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AUTHOR DISCLOSURES

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Correction of Femoral Acetabular Impingement at the Time of Primary THA

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Abstract

Background: Primary total hip arthroplasty (THA) is considered one of the most cost-effective and functionally beneficial procedures to treat end-stage coxarthrosis worldwide. However, there is a small percentage of patients who are plagued by residual anterior hip pain and limited hip flexion. One explanation for this problem is bone and soft tissue impingement in the anterior hip region. In the native hip, the problem is described as femoral acetabular impingement (FAI). FAI is a form of developmental dysplasia of the hip (DDH). Not infrequently, these dysplastic acetabula are also retroverted. In primary THA, a retroverted bony acetabulum adversely affects prosthetic hip function. Specifically, when the acetabular cup is inserted in an anteverted position and the native acetabulum is retroverted, the proximal femur will impinge upon the retroverted acetabular bone with flexion and internal rotation. This causes mechanical dysfunction, prosthetic subluxation, and pain. We aptly name this condition prosthetic femoral acetabular impingement (PFAI).

Methods: In this study we address PFAI with an anterior acetabular bone wall reduction (AABWR). In a consecutive series of 426 primary THA's, we prospectively removed all impinging anterior retroverted bone during the THA procedure. Specifically, after final socket preparation and insertion, an AABWR was performed when acetabular bone extended more than 5 mm beyond the prosthetic acetabular cup. All acetabular cups were placed between 25-35 degrees of anteversion. Retroverted acetabular bone extending beyond the acetabular cup was removed along with impinging capsular tissues. All femoral stems were

positioned between 15-20 degrees. We hypothesize that with an AABWR, groin pain and hip flexion will be commensurate with that of patients who did not require an AABWR (i.e., non-retroverted acetabulum).

Results: The study group consisted of 426 primary THA's. Three hundred patients (70%) had an AABWR and 126 patients did not require an AABWR. There were 140 females (47%) and 160 males (53%) in the AABWR group and 88 females (70%) and 38 males (30%) in the non-AABWR group. The average amount of bone resected in the AABWR group was 1.32 cm (0.3 cm to 3.4 cm). For females, the average bone resection measured 1.1 cm (0.3 to 2.0 cm). For males, the average bone resection measured 1.53 cm (0.3 cm to 3.4 cm). Harris Hip Scores (HHS) at minimum of 1 year follow-up (range 1 to 11.5 years) averaged 91 (64 to 100) for the entire study. In the AABWR group, HHS averaged 92 (71 to 100). Average hip flexion was 110 degrees (100 to 130 degrees). In the non-AABWR group, HHS averaged 87 (71 to 100). Average flexion was 109 degrees (88 to 125 degrees). In the AABWR group, 12 patients (4%) experienced groin pain symptoms. Ten of these patients rated his/her peak groin pain at a level of 1 (scale 0-4) and the remaining 2 patients rated his/her peak groin pain at a level of 2. As time progressed, 50% of these patients saw their groin pain resolve. In the non-AABWR

Keywords: THA, Total Hip Arthroplasty, FAI, Femoral Acetabular Impingement, PFAI, Prosthetic Femoral Acetabular Impingement, Hip Subluxation, Anterior Hip Decompression, AABWR, Anterior Acetabular Bone Wall Reduction, Groin Pain, Hip Flexion
Level of Evidence: AAOS Therapeutic Level III
Educational Value & Significance: JISRF Level A

group, 2 patients (1.6%) experienced groin pain and both patients rated his/her pain at a level of 1.

Discussion: Maximizing hip flexion and function for the active patient undergoing primary THA requires meticulous surgical technique. PFAI may be one reason for unexplained anterior hip pain in the highly active patient that demands higher hip flexion and rotation. Our experience shows that the anterior acetabular rim and part of the anterior column can be removed at the time of primary THA without compromising the THA procedure. The AABWR is now an integral part of our primary THA technique.

Background

Femoral Acetabular Impingement (FAI) causes hip pain when the native femoral neck contacts the acetabular rim in flexion. Impingement is most pronounced with flexion (above 80 degrees) and internal rotation. At the impingement point, soft tissues are damaged either by a pincer effect on the acetabular rim or via a cam effect upon the peripheral acetabular articular surface [1]. FAI more commonly occurs when the native acetabulum is retroverted (Figures 1a & 1b) [2,3]. This is a form of developmental dysplasia of the hip (DDH) that is underappreciated, as upon casual review radiographs of patients with retroversion dysplasia appear relatively normal. Retroversion dysplasia is a major cause of early degenerative arthritis in the middle-aged patient population and can lead to early Total Hip Arthroplasty (THA). Correction of acetabular retroversion with a periacetabular osteotomy in the pre-arthritic hip joint helps reduce pain and improve functional hip flexion [4-6].

THA in patients with uncorrected retroversion dysplasia is fraught with pitfalls. First, positioning of the acetabular cup in a manner that follows the native acetabular rim can result in clinical impingement [7]. Following the native acetabular rim is the most commonly accepted method of cup placement when there is normal acetabular anteversion and inclination [8]. However, if the surgeon does not appreciate that the native acetabular socket is retroverted, then placement of the prosthetic cup in this retroverted position will fail to solve the impingement problem that caused the original degenerative process. Additionally, excess femoral pelvic inclination resulting from lumbar hyperlordosis and/or spine fusion can cause the acetabular socket to be “functionally” retroverted [9]. Furthermore, if acetabular retroversion is recognized and the prosthetic acetabular cup is placed in the correct anteversion and inclination, clinical impingement can still occur if the retroverted bone is not removed. This is not an uncommon scenario

Figures 1a – 1b

Diagrams of anteroposterior view of the right hip demonstrating retroversion dysplasia.

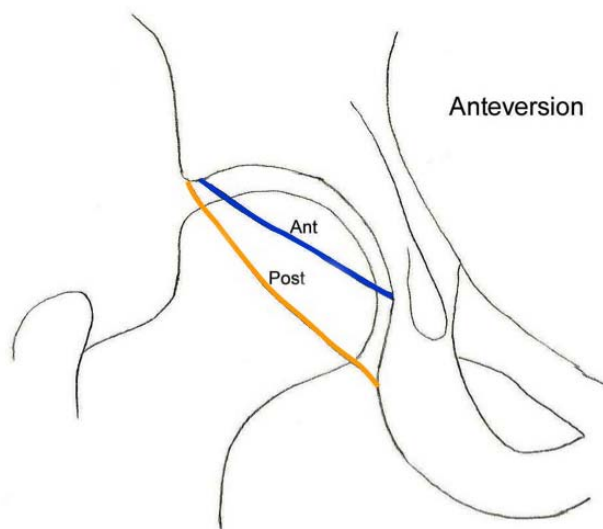


Figure 1a. Diagram of acetabulum on anteroposterior radiograph. In a normal acetabulum, the socket is anteverted. On the AP radiograph, the anterior rim is above the posterior rim. Three dimensionally, the acetabular socket is open and faces in an anterior direction.

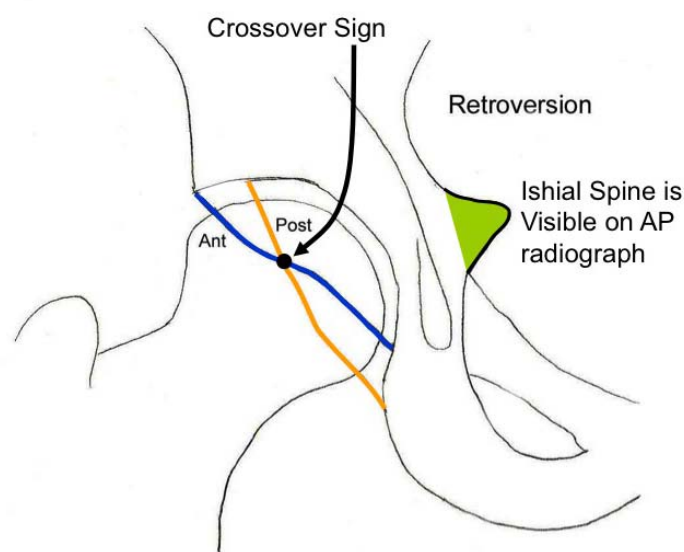


Figure 1b. Diagram of acetabular retroversion. On the AP radiograph, the anterior rim is in a lower position, whereas the posterior rim is higher. Radiographically, the two rim lines cross, creating the crossover sign. Frequently with acetabular retroversion, the ischial spine is prominently seen. Three dimensionally, the acetabular socket is closed and faces in a posterior direction. This configuration can also be seen with fixed flexed pelvic deformation, secondary to spine disease.

that we encounter clinically. The retroverted bone impinges upon the femur in hip flexion, causing pain and continued functional debility. We describe this latter scenario as Prosthetic Femoral Acetabular Impingement (PFAI). In the highly active young patient who demands a higher functional hip range, even mild relative retroversion of the acetabulum causes impingement in flexion and internal rotation. Repetitive PFAI can also adversely affect prosthetic bearing wear [5,10,11]. If significant PFAI occurs, repetitive subluxation movements of the total hip bearing can result in abnormal bearing wear patterns. With large diameter alternative bearings, such as ceramic-ceramic, metal-metal, or ceramic-metal, repetitive subluxation can cause stripe wear marks [12-15].

In primary THA, acetabular retroversion can be corrected by reaming the acetabulum to a hemisphere and inserting the prosthetic cup into the “normalized” anteverted position. However, if the retroverted bone still remains, this can cause impingement. In this study, we utilize the surgical technique of removing retroverted acetabular bone at the time of primary THA. We call this maneuver an “*Anterior Acetabular Bone Wall Reduction*” (AABWR). This study prospectively reviews the clinical results of 426 consecutive primary THA’s that utilized a large diameter monolithic acetabular cup. We review the incidence of AABWR and review the clinical results of patients that required this maneuver for correction of native acetabular retroversion. We hypothesize that with corrected acetabular cup placement and an aggressive AABWR, groin pain scores and overall Harris Hip function will be commensurate with that of patients not suffering from native acetabular retroversion.

Materials & Methods

Between August 2006 and June 2017, 455 primary THA procedures were performed at a single institution by the senior author (ejm). The study group included all patients who received a large diameter monolithic all-metal porous coated cementless acetabular cup. Patients who were excluded from the study group included those with traumatic or developmentally acquired acetabular deformities that needed an acetabular cage or a protrusio revision cup with augmentation and/or structural bone graft (29 patients). The study group thus included 426 consecutive primary THA’s utilizing a large diameter monolithic all-metal cup.

All THA’s utilized a standardized technique. A less invasive postero-lateral approach was used [16]. Patients were secured in the lateral decubitus position using the Hip Grip System (Sun Medical, Redding, CA). Positioning was

carefully performed by the operating surgeon (ejm). The anterior-inferior brace was positioned over the pubic symphysis and anterior superior iliac spine. The anterior-superior brace was centered over the xiphoid process. The posterior-inferior brace was centered over S1. The posterior-superior brace was positioned at the mid scapula level. The positioning technique allowed the posterior ilioischial line to be parallel to the length of the operative table. This line was used to help assist in cup positioning (Figure 2b).

With the less invasive postero-lateral approach, the superior one-half of the short external rotators were released from the upper posterior greater trochanter down to the base of the femoral neck. The hip capsule was preserved with transverse incisions made at the acetabular rim and the base of the femoral neck. A longitudinal incision was made along the femoral neck axis.

Acetabular cup preparation was performed with serial reaming in 2 mm increments, starting initially at 41 mm. The first ream was directed medially through the remaining cotyloid pads to the quadrilateral surface. Reaming was then performed in plane of 25-35 degrees of anteversion and a lateral opening of 40 degrees. Trialing was performed using a metallic hemisphere trial cup 1 mm larger than the last reamer. The trial cup was positioned at an anteversion angle of 25-35 degrees and a lateral opening of 40 degrees. The ilioischial line was used to assist as a reference (parallel to the long axis of the operative table). Any anterior acetabular bone that extended more than 5 mm beyond the acetabular cup was removed with osteotomes. This included the anterior rim, the anterior column, and the lateral portion of the superior ramus. Bone removal was performed as needed to assure flexion clearance up to 110-125 degrees, and to prevent impingement with the femur in flexion and internal rotation. The amount of bone removed (excluding osteophytes) was measured. If greater trochanteric impingement was evident with the combined flexion and internal rotation maneuver, then the anterior portion of the greater trochanter was trimmed with an osteotome to relieve this abutment. When necessary, as much as 20% of the greater trochanteric bone was removed. The acetabular cup utilized in the series was the Magnum™ Cup (Zimmer-Biomet, Warsaw, IN). The Magnum Cup is a monolithic cup with a metal internal bearing. The cup bearing was a Cobalt-Chromium (CoCr) alloy, treated with a hot isostatic pressure (HIP) technique that optimizes metal density. The carbide content was 2% by volume. The outer diameter was coated with a titanium plasma spray (applied as the cup was kept cool). The Magnum Cup also has four radial fins on its outer diameter. The cup was inserted with a flat face insertion device. Anteversion was selected between 25-35 degrees. The lateral opening was selected

Figures 2a – 2g

Case example of anterior acetabular bone wall reduction in a 69-year-old male (BMI 32) with end-stage arthritis of the left hip.



Figure 2a. Anteroposterior radiograph showing end-stage arthritis of the left hip. This patient also shows radiographic evidence of shallow socket dysplasia. Intra-operatively, after reaming the acetabulum to the native hip center, the acetabular socket was demonstrably retroverted.

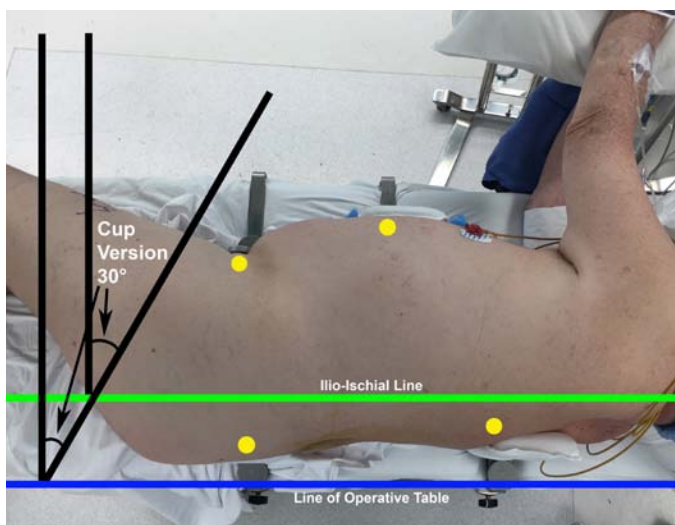


Figure 2b. Intra-operative positioning of patient for left THA in the lateral decubitus position. The yellow circles show fixation points of the Hip Grip devices. Anteriorly, the fixation points are the pubic symphysis and xiphoid process. Posteriorly, the fixation points are S1-S2 and the upper thoracic chest at T5-T6 region. The blue line depicts the edge of the OR table for reference. The patient is positioned such that the ilioischial line (green line) is parallel to the long axis of the OR table. Thus, when positioning the acetabular cup anteversion, the OR table can be used as a reference parameter to provide consistent cup version placement. In this case, cup version was selected at 30 degrees.

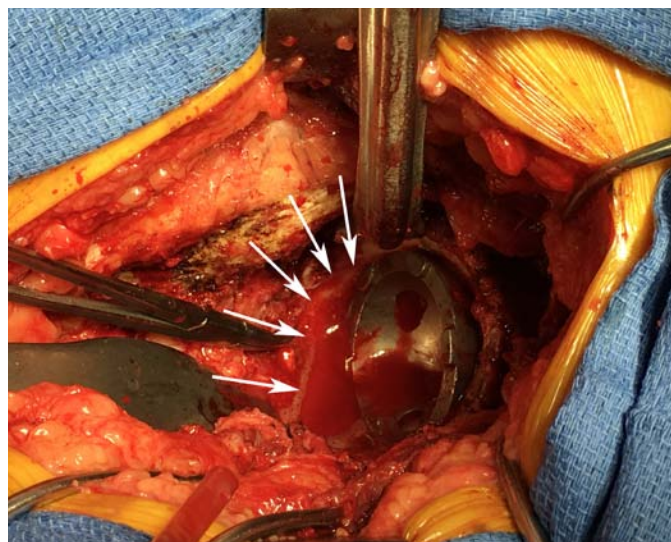


Figure 2c. Intra-operative picture of trial cup placement (viewed from the posterolateral approach). The cobra retractor (top of picture) is located at the 11 o'clock position of the left acetabulum. The retractor on the left side of the picture is placed just under the acetabular teardrop. The acetabular cup has been placed at 30° of anteversion, relative to the ilioischial line. This picture shows the retroverted acetabular bone anteriorly (arrows). All of this bone is removed with the “anterior hip decompression” maneuver. Inferiorly, the retroverted bone blends into the superior ramus and with the anterior bone wall reduction, some of the superior ramus is removed with the decompression maneuver.



Figure 2d. Photograph of resected anterior acetabular bone. We resected the anterior acetabular rim and part of the anterior column. At the maximum retroverted position, 2.2cm of bone was removed. Technically, this bone was removed with 1.5cm straight and curved osteotomies.

at 40 degrees. The cup was mated with either a Magnum CoCr head (Zimmer-Biomet, Warsaw, IN) or a Dual Articulation (DA) bearing (Zimmer-Biomet, Warsaw, IN). The inner head of the DA bearing was always a 28mm Delta ceramic head (CeramTec, Plochingen, Germany) with a titanium sleeve inserted into the ceramic head for neck length adjustments. We used two femoral stem designs in this study. Both were titanium alloy stems with proximal

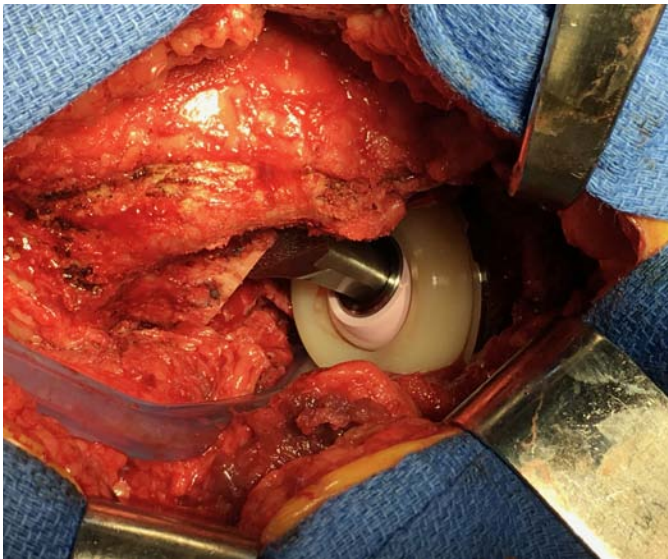


Figure 2e. Intra-operative photograph of the THA construct. In this case a Dual Articulation bearing was mated to the Magnum cup. The picture is taken with the hip in flexion of approximately 45 degrees and the femur internally rotated approximately 40 degrees.



Figure 2f. Intra-operative photograph showing hip stability after anterior hip decompression procedure. In this picture the patient's head is located to the right and the hip is flexed approximately 40 degrees. Notice that with 75 degrees of internal rotation, the hip still remains stable.

porous plasma spray coating. Depending on the bony architecture, we used either the Mallory-Head® stem (Zimmer-Biomet, Warsaw, IN) or the Taperloc® stem (Zimmer-Biomet, Warsaw, IN).

A careful, meticulous closure was performed. The hip capsule was closed as a separate layer. In all cases, the hip capsule was closed from the superior acetabulum down to the prosthetic femoral neck. The released proximal short external rotators were repaired to the posterior greater trochanter with sutures placed into the bone. All soft tissues



Figure 2g. Post-operative radiograph in recovery room. The pelvis is mildly externally rotated toward the left. The acetabular theta angle measures 32 degrees. Notice in the radiograph the retroversion of the native right hip in which the ischial spine is visible and there is a subtle crossover sign (black dot).

were anatomically closed as best as possible.

All surgeries were performed with body exhaust suits (Stryker Corporation, Kalamazoo, MI) in non-laminar flow rooms. Anesthesia consisted of a general anesthetic combined with epidural anesthesia with low dose intrathecal preservative free morphine sulfate (0.1 mg). Wound closure was performed without drains. Intravenous antibiotics were administered preoperatively and continued for 24 hours, adhering to SCIP guidelines [17].

Post-operatively, patients were kept to 50% weight bearing for six weeks then progressed to full weight bearing. Patients were examined at 6 weeks, 3 months, 1 year, and annually thereafter. Hip review assessment was recorded with Harris Hip Scoring. Radiographs were taken at 6 weeks, 1 year, and every year thereafter. All charts were reviewed for complications and implant failures. Complications were defined as requiring re-operations for any reason. Failures were defined as requiring implant removal for any reason or declaring the hip joint clinically infected based upon the International Consensus Meeting on Musculoskeletal Infection [18].

Statistical analysis was performed using IBM SPSS Statistics 25 software. Spearman correlation analysis was utilized to check the presence of statistical correlation between researched variables. In order to verify the statistical significance between the two independent groups, the Mann-Whitney U test was used. Chi-square testing made

it possible to compare if groups are equinumerous and if there is a significant relationship between nominal variables. For statistical significance a level of $p < 0.05$ was adopted.

Results

In this study group of 426 THA's, the average age was 64-years-old (21 to 93). There were 228 females and 198 males. Fifteen patients are now deceased. Of these 15 patients, there were no complications or reoperations. In the first 5.5 years of the study, we mated the Magnum cup with a Magnum CoCr head. Over these 5.5 years, 219 CoCr heads were used. After the Magnum head was discontinued in North America, we mated the Magnum cup with a DA bearing. Over the remaining 5.5 years of the study, we used 207 DA bearings. The study was comprised of two cohorts, one that underwent an anterior acetabular bone wall reduction (AABWR group) and one that did not (non-AABWR group). In the AABWR group, 267 of 300 femoral stems (89%) were of the lateral offset design (145 Mallory-Head and 122 Taperloc stems). In the non-AABWR group, 104 of 126 femoral stems (83%) were a lateral offset design (62 Mallory-Head and 42 Taperloc stems). The acetabular cup size ranged from 44 mm to 62 mm. The most common cup size utilized was 50 mm (93 cups).

Three hundred of the 426 patients (70%) had an AABWR. There were 140 females (47%) and 160 males (53%). The average age in the AABWR group was 62-years-old (21 to 88). The average amount of bone resected in the AABWR group was 1.32 cm (0.3 cm to 3.4 cm). In the non-AABWR group, there were 126 patients, of which 88 were females (70%) and 38 were males (30%). The average age in the non-AABWR group was 64-years-old (25 to 93).

In the entire study, 61% of females and 81% of males required an AABWR. For females, the average bone resection measured 1.1 cm (0.3 to 2.0 cm). For males, the average bone resection measured 1.5 cm (0.3 cm to 3.4 cm). Younger patients (< 55-years-old) required an AABWR 69% of the time (56 of 81 patients). Older patients (\geq 55-years-old) required an AABWR 71% of the time (244 of 345 patients). Statistical analysis revealed that males were more likely to require an AABWR than females ($p < 0.001$), while older patients are just as likely as younger patients to require an AABWR ($p = 0.778$).

In the AABWR group, Harris Hip Scores (HHS) averaged 92 (71 to 100). Average hip flexion was 110 degrees (100 to 130 degrees). In the non-AABWR group, HHS averaged 87 (71 to 100). Average flexion was 109 degrees (88

to 125 degrees). In the AABWR group, 12 patients (4%) experienced groin pain symptoms. On a scale from 0 to 4, the peak groin pain rating was 1 in 10 of the 12 patients and the remaining 2 patients rated his/her peak groin pain at a 2. As time progressed, 50% of these patients saw their groin pain resolve. In the non-AABWR group, 2 patients (1.6%) experienced groin pain and both patients rated his/her pain at a 1. Mann-Whitney U testing demonstrated that patients who had an AABWR showed a statistically higher HHS score ($U = 9344$, $p < 0.001$) and a statistically greater hip flexion range ($U = 16126.5$; $p < 0.05$) compared to the non-AABWR group. With Chi-square testing, the incidence of groin pain between the two groups was not statistically different ($\chi^2 (2) = 1.85$; $p > 0.05$).

In this series there have been 5 dislocations (1%). All dislocations occurred during the postoperative recovery period (i.e., within the first 6 weeks). Of these dislocations, 3 were posterior and 2 were anterior. All 3 posterior dislocations occurred in the non-AABWR group (2.4%), while both anterior dislocations occurred in the AABWR group (0.7%). One posterior dislocation in the non-AABWR group required a reoperation to change the modular head to a longer length. All other dislocations were treated with a closed reduction and Spica bracing for 6 weeks. In these 4 cases there were no further dislocations. Statistical analysis demonstrated that there was no significant correlation between the two groups in terms of dislocation rate ($p > 0.05$).

There were 13 failures (3%) in the study group. The reasons for failure are listed in Table 1. The most common reasons were for a periprosthetic femur fracture after a fall, and conversion to dual articulation from a metal-to-metal hip bearing due to metal-related synovitis. There were 4 femoral neck cracks noted during femoral stem insertion. None required cabling or stem exchange. Despite having used 219 metal-to-metal hip bearings, there have been only 4 reoperations (1.8%) for metal-related synovitis and pain. In these cases we did not see any large pseudotumors (defined as greater than 4 cm in diameter). Of the 13 failures, 9 occurred in the AABWR group and 4 in the non-AABWR group. Statistical analysis demonstrated that there was no significant correlation between the two groups in terms of failure rate ($p > 0.05$).

Discussion

In THA, positioning of the acetabular cup is technique-dependent. Many surgeons espouse placing the prosthetic cup in a manner that follows the native acetabular rim. Others suggest cup placement at a set angle (10 to 30 degrees

Table 1 – Failures

Reason for Failure	Number	AABWR/ Non-AABWR	Time from Index THA (months)
Periprosthetic Femur Fracture	4	3 / 1	1 – 14
Conversion to Dual Articulation from Metal-Metal THA due to Metal Synovitis	4	2 / 2	9 – 62
Periprosthetic Joint Infection	2	2 / 0	10 – 15
Recurrent Dislocation	1	0 / 1	1
Loose Acetabulum	1	1 / 0	5
Loose Femoral Stem	1	1 / 0	31

of anteversion) based upon approach and surgeon philosophy [7]. Acetabular cup positioning is more important in patients who require higher functional hip range and performance. If a patient requires high hip flexion, the placement of the acetabular cup in an orientation that follows the native acetabular rim can result in adverse consequences. Specifically, if the native hip is dysplastically retroverted, then the prosthetic cup will maintain this retroverted orientation [10]. With high hip flexion (beyond 90-95 degrees), impingement will occur, resulting in clinical anterior hip pain, repetitive subluxation, or possibly recurrent dislocation [19]. If a large diameter bearing (LDB) is placed, the risk of dislocation is reduced, but repetitive subluxation is still likely to occur [20,21]. This will also cause abnormal bearing wear. This is of special significance with an alternative bearing, such as metal-metal, ceramic-ceramic, or metal-ceramic, where repetitive subluxation creates a stripe wear phenomenon [12,14,15]. Furthermore, with an adverse wear scenario, the accelerated wear debris will result in adverse wear debris phenomenon including osteolysis, pseudotumor formation, bearing fracture, and/or implant loosening [7-9,19-24].

To optimize functional hip range and minimize repetitive subluxation, cup positioning should be centered within the patient's anticipated functional hip range. We have found that by placing the acetabular cup at a predetermined angle of 25 to 35 degrees of anteversion (relative to the ilioischial line) in every patient, we consistently center the acetabular cup to allow acceptably higher hip flexion, yet avoid hyperextension impingement with external rotation. This clinical study was conducted in an attempt to reduce the sequela of PFAI in primary THA. We chose to be ag-

gressive in removing impinging anterior acetabular bone in a manner that would provide salutary improvement in groin pain and improved hip flexion without incurring an increased complication rate. By performing an AABWR during primary THA, we have so far enjoyed a relatively satisfying course with this study. It is our observation that males are more likely to require an AABWR than females (p-value <0.001), while older patients (≥ 55) are just as likely as younger patients (<55) to need an AABWR (p-value = 0.778).

In this series, the incidence of unexplained groin and hip pain is low. We believe that by performing an AABWR, we restored functional hip flexion to a level that is commensurate with that of patients who do not have acetabular retroversion. Thus, both groups enjoy relative pain-free activities of daily living. Patients who have challenged their hips with increased functional activities have not experienced any adverse consequences at an average follow-up of 5.3 years. Flexion range was also a priority in this study, to allow for improved functional range for patients who demand a higher activity profile. Increased functional range was achieved by setting combined implant anteversion between 40 and 55 degrees. By additionally removing all anterior bone extending beyond the prosthetic acetabular socket, the hip can flex further. This is borne out with our hip range measurements. The AABWR group showed a statistically greater hip flexion range compared to those who did not require an AABWR. This observation was unexpected, as we had hypothesized flexion in the two groups would be commensurate, but nonetheless pleasing. In addition, by reducing the anterior impinging bone, overall HHS scores were distinctly better in the AABWR group. We attribute the improved scores mainly to overall improvement in pain reduction, as the HHS is highly weighted towards the patient pain score. By replacing the arthritic joint and removing anterior impinging bone, the pain score is optimized.

In this review, we would be remiss in not discussing our favorable findings regarding the large diameter Magnum cup. Our aseptic loosening rate was low (<1%). The number of revisions due to reactive metal wear was also low (1.8%). We attribute our favorable results to three main factors: 1) implant mating, 2) implant design, and 3) implant biomaterial. Repetitive subclinical subluxation (as opposed to dislocation) is a problem with LDB cups that are not well-mated [24]. With the less invasive posterolateral approach, we chose a "combined" hip version of 40 to 55 degrees [8]. On the acetabular side, our cups were placed with an anteversion of 25 to 35 degrees with a theta angle no greater than 40 degrees. Femoral anteversion was chosen to be between 15 and 20 degrees. This combined

anteversion allows for functional hip flexion while minimizing head subluxation and cup edge scratching, which can lead to excess metal wear. The Magnum cup is a pure 180-degree hemisphere with insertion tabs on the extra-articular surface of the cup. This minimizes any bearing overload points. Additionally, the Magnum cup has 4 anti-rotation fins that help with initial stability. Finally, the CoCr alloy used for the bearing was treated with a hot isostatic pressure (HIP) technique that optimizes metal density, guarding against excess metal wear. This assumes first that the bearing couple is well-mated.

Although the Magnum cup continues to be sold, the large diameter metal head was discontinued in 2011. Since that time, we continue to use the Magnum cup as our first line choice in all primary THA's. We now utilize the dual articulation bearing, which thus far, at short- to intermediate-term follow-up (6 years), provides similar functional efficiency for our THA patients.

There are limitations to this study. First, the study was not randomized. A more definitive study would have exclusively identified patients with acetabular retroversion and randomized this group into two cohorts, those receiving an AABWR and those not. This study design was considered, but upon initial interrogation of study enrollees, we encountered a near unanimous opposition to this methodology. Secondly, this study used a large diameter cup and head construct. We believe this may have artificially reduced our complication rate. Had we utilized a traditional 32 or 36 mm head with a high molecular weight polyethylene socket, we may have incurred a higher dislocation rate. Thus, our AABWR maneuver cannot be extrapolated to provide similar efficacy with 32 or 36 mm head constructs. We recommend a similar study should be conducted in patients with 32 and/or 36 mm heads.

In essence, we performed an aggressive periacetabular "decompression" with removal of all bone extending beyond the prosthetic acetabular cup and with the removal of hypertrophic capsular tissue. We believe this maneuver complements the pain reducing effect of the THA procedure by decreasing the chance of mechanical impingement that can be a significant pain generator. This was borne out in our low groin pain scores. We further submit that had we not performed this maneuver, the hip flexion range in the AABWR group would have been significantly lower. Patients who suffer from stiff hips are limited not only by the arthritic process, but also by retroverted anterior acetabular bone that mechanically blocks flexion. We did worry that an over-aggressive anterior bone resection could weaken the pelvic ring, resulting in fracture or long-term pain, but the groin pain scores seen in the AABWR group improved over time as bone remodeling progressed. Additionally, we

did not have any clinical cases of pelvic ring fractures. We believe the AABWR maneuver to be a safe and effective technique.

If a LDB THA is chosen for hip reconstruction, we advocate careful cup and stem positioning. The combined anteversion of 40 to 55 degrees chosen in this series appears to be acceptable for high flexion and combined hyperextension-extension-external rotation range. Based on our experience, we believe the removal of all retroverted acetabular bone extending more than 5 mm beyond the prosthetic acetabular cup is a critical step when using this bearing construct. The combination of careful cup/stem positioning along with an AABWR will minimize lever impingement. Our intermediate-term results in this study are encouraging. We hope that in the long-term this will have the salutary effect of minimizing abnormal bearing wear patterns. This series requires long-term follow-up to validate this claim. In this series we are also monitoring serum cobalt and chromium ion levels in our metal-metal bearing patients. Lastly, we advise against any cup additions (e.g., elevated posterior hoods) that would reduce implant range of motion. Hip stability should be obtained with careful selection of implant positioning, stem offset, and intraoperative trialing using a hemisphere cup without additions. Our experience shows that the anterior acetabular rim and part of the anterior column can be removed at the time of primary THA without compromising the THA procedure. The AABWR is now an integral part of our primary THA technique.

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AUTHOR DISCLOSURES

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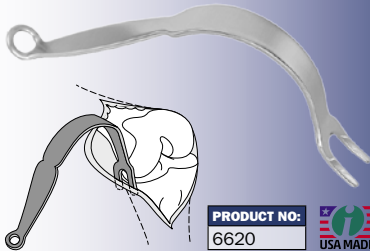


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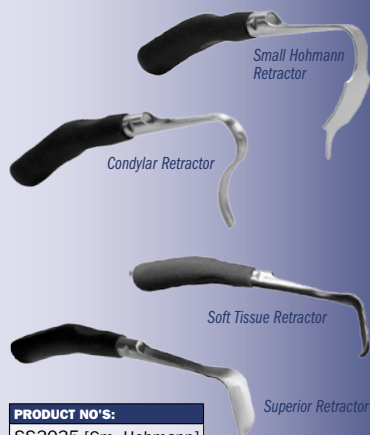


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Pistol Grip handle lessens hand fatigue and slippage, and allows for better visualization



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Manipulation Rate Is Not Increased After Customized Total Knee Arthroplasty

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ABSTRACT

Background: Manipulation under anesthesia (MUA) is a standard treatment for arthrofibrosis after total knee arthroplasty (TKA), with reported rates of 1.5-6%. Customized TKA may have better outcomes by matching individual patient anatomy. However, a previous study reported an unacceptably high rate of MUA for customized TKAs. This study reports the incidence of MUA in a large cohort of second generation customized TKAs.

Methods: Data was collected prospectively on 360 2nd generation ConforMIS iTotal cruciate retaining TKAs. MUA was performed for clinically significant arthrofibrosis. Range of motion (ROM) and New Knee Society Scores (KSS) were evaluated at regular intervals for two years.

Results: 11/360 (3.05%) knees underwent MUA. ROM overall improved from 115° to 125°, and from 112° to 122° in patients undergoing MUA. KSS objective and functional scores in MUA patients increased from 57 to 98 and 41 to 90, respectively, and in the entire cohort increased from 65 to 96 and 45 to 86 at 2 years ($p < 0.05$). No MUA patients underwent revision surgery.

Discussion and Conclusion: Customized TKA with second generation ConforMIS iTotal implants results in a MUA rate consistent with the literature for all designs. Additionally, patients exhibit significant increases in ROM and Knee Society Scores.

BACKGROUND

Arthrofibrosis can occur after total knee arthroplasty (TKA), with an incidence reported of 1-13%. [1] Manipulation under anesthesia (MUA) is a common first-line treatment for stiffness after TKA. The incidence of patients undergoing MUA after a TKA has been reported between 1.5-6%. [2-7] It is often recommended that MUA be done within 6-12 weeks of surgery if possible in order to achieve optimal gains in range of motion. [1,2,4,5,8-10] MUA has been shown to be effective at increasing range of motion, with gains of 33° persisting at long-term follow-up. [11] These gains have been shown to be similar to open or arthroscopic release. However, patients who undergo MUA have a significantly higher rate of eventual revision surgery, with an odds ratio of 2.43 in a review of a large national database. [3] MUA is generally considered safe, although low rates of fracture, wound dehiscence, patellar tendon avulsions, quadriceps strain or rupture, hemarthrosis, heterotopic ossification, and pulmonary embolism have been reported. [12,13]

Risk factors for arthrofibrosis include decreased preoperative range of motion, higher complexity of surgery (history of trauma, length of surgery), and history of prior surgery. [6,14-16] Additionally, after surgery, poor patient

Keywords: total knee arthroplasty, manipulation under anesthesia, customized total knee arthroplasty, Arthrofibrosis, outcomes, complications

Level of Evidence: AAOS Therapeutic Level IV

Educational Value & Significance: JISRF Level B

motivation, immobility, delay in starting rehabilitation, poor pain tolerance, and infection can contribute to development of arthrofibrosis. [10,17,18]

Prosthesis design has been implicated as a possible contributor to arthrofibrosis, although overall results are mixed. Several studies have compared cruciate-retaining (CR) versus posterior stabilized (PS) prostheses, with some finding decreased range of motion with CR designs, but others showing no significant difference. [4,19–21] Ultracongruent TKA's have also been shown to have similar rates of MUA as compared to conventional designs. [22]

A recent prospective evaluation has also reported that patients undergoing CR TKA with a patient-specific design have a significantly higher rate of postoperative stiffness and need for manipulation versus matched controls [23]. In the patient-specific design group, the mean range of motion from flexion to extension was 3-98° postoperatively, versus 2-111° in the posterior stabilized controls, and 2-117° in the cruciate-retaining controls. Of patients receiving the patient-specific implant, 6/21 underwent MUA, versus 0/53 in the control group. [23] Given these results, the present study seeks to investigate the incidence of MUA in a large cohort of knees implanted with a newer generation of the patient-specific CR design.

METHODS

The study protocol was reviewed and approved by the institutional review board. Data was collected prospectively at 9 institutions on 360 cemented, total knee arthroplasties performed using the cruciate-retaining iTotal implant (ConforMIS, Billerica, Massachusetts). The ConforMIS iTotal CR has evolved since its genesis through several design changes, the Generation 1 (G-1), to the current design, the Generation 2. All arthroplasties in the present study were performed with the second generation device. All TKAs were performed via the medial parapatellar approach. Manipulation under anesthesia was performed for clinically significant arthrofibrosis and reduced range of motion as judged by individual surgeons.

Inclusion criteria were clinically significant osteoarthritis of the knee requiring a total knee replacement in patients over 18 years of age. Exclusion criteria were simultaneous bilateral procedures, BMI > 40, fixed varus or valgus deformity >15°, rheumatoid or other inflammatory arthritis, history of prior implant surgery on the treated knee, compromised posterior cruciate ligament (PCL) or collateral ligament, and osteoporosis.

Range of motion (ROM) and 2011 New Knee Society Scores (KSS) were evaluated preoperatively, and postoperatively at 6 weeks, 6 months, and annually thereafter. A paired t-test was used to compare pre-and postoperative results.

RESULTS

A total of 393 patients were offered participation in the study. 33 patients were excluded. (Table 1). 360 patients met eligibility criteria and agreed to participate, 154 male and 196 female. The mean patient age was 65.7 (range 40-96). Mean BMI was 30.1 (range 18.5-42). The mean patient age and BMI for patients undergoing MUA was 61.7 and 28.5, respectively. Mean preoperative range of motion was 115° (range 80-142°). A total of 298 patients had completed follow-up and outcome scores at one year, and 202 patients at 2 years.

Table 1: Excluded patients

Reason	n
BMI > 40	2
Active Malignancy	5
Simultaneous Bilateral TKA	1
Osteoporosis	3
Other physical disability of hip, spine, or contralateral knee	1
Fixed coronal deformity > 15°	1
Fixed flexion deformity > 15°	2
Unwilling or unable to comply with study requirements	14
Rheumatoid or other inflammatory arthropathy	4
Total	33

Preoperatively, ROM was 115° (2° extension to 117° flexion), and improved to 123° (0° extension to 123° flexion) in the entire cohort ($p < 0.001$). Prior to surgery, 43 patients demonstrated a flexion contracture, of these 29 were 1-5°, 12 were 6-10°, and 2 11-15°. 57 patients had an extensor lag prior to surgery, 50 were 0-10°, and 7 were 10-15°. At one year, 11 patients had a flexion contracture, 10 were 1-5° and 1 11-15°. 6 patients had an extensor lag at one year, all were under 10°. All but two patients achieved ROM > 90° by one year, but both had ROM > 100° at their 6 month visits.

A total of 11/360 patients (3.05%) underwent MUA at an average of postoperative day 97 (Range 34-364). Of these patients, 8 were available for follow-up at one year, and 4 at two years. In patients who underwent MUA, ROM

improved minimally at one year from the index procedure from 116° (1° extension to 116° flexion) to 117° (-1° extension to 116° flexion) ($p=0.78$). ROM averaged 86.3° (65-107) for these patients immediately prior to undergoing MUA, and improved to 117.1° at the next scheduled visit.

Patients who underwent MUA, as well as patients in the entire cohort exhibited statistically significant ($p<0.05$) increases in KSS objective, functional, and satisfaction scores. (Tables 2 and 3) Expectation scores showed a slight decrease, but remained above the threshold for “met expectations.” The MUA rate for centers with >40 patients enrolled was 2.4%, whereas the MUA rate for centers with <25 patients enrolled was 6.0%. No MUA was performed at 3/9 centers (including 1 center that enrolled 29 patients). At 1 year, all but 2 (99.2%) patients achieved functional range of motion (>90°).

Six patients have been revised at an average of 62 weeks. Four were polyethylene exchange for diagnoses of complex regional pain syndrome (CRPS), ligamentous laxity, infection, or scar tissue removal. None of these patients had previously undergone MUA, and all had range of motion of 105° or greater at 6 months after the index procedure. Additionally, one revision was performed for a peri-prosthetic fracture, and another for metal hypersensitivity. Thus, there are three patients who have been converted to a different prosthesis in this study. Based on the last follow-up of all patients, the revision rate was 1.7% (6/360, including polyethylene exchanges) and survivorship was 99.2% at an average follow-up of 1.9 years.

Table 2: New Knee Society Scores for the entire cohort at 1 yr follow up (n=278)

	Pre-op	6-Week	6-Month	1-Year	p (Preop vs 1 yr)
Objective (0-100)	65	85	92	94	<0.001
Satisfaction (0-40)	14	25	31	34	<0.001
Expectations (0-15)	14	9	10	10	<0.001
Functional (0-100)	45	56	78	83	<0.001
Pain (0-100)	45	62	81	86	<0.001
Symptoms (0-100)	47	59	76	81	<0.001
ADL (0-100)	50	69	85	88	<0.001
Recreation (0-100)	19	36	59	69	<0.001
QOL (0-100)	18	45	65	72	<0.001
ROM	115	109	120	123	<0.001

DISCUSSION

The rationale for creating a patient-specific TKA is to improve clinical outcomes and patient satisfaction. [24] Described benefits over an “off the shelf” implant include lower incidence of blood transfusions and adverse events, improved tibial plateau coverage, and more normal femoral rollback. [25–27] However, a prior study on the first generation (G1) iTotal implant demonstrated a 28.6% rate of MUA. [23]

The present study demonstrates a MUA rate of 3.05% for the cruciate-retaining, second generation (G2) ConforMIS iTotal implant, which is similar to rates reported throughout the literature, irrespective of implant design. [2–7] Additionally, patients overall achieved functional range of motion (>90°) at 1 year, including patients who underwent MUA. Although White et al. reported a markedly higher rate of MUA with a patient-specific design, the current findings are similar to data presented by Kurtz et al demonstrating a 3.8% incidence of MUA at 90 days with the ConforMIS G1 implant. [28] The difference in MUA rate in the present study compared to the White et al paper may be the result of design changes, or potentially due to the comparisons of one surgeon versus nine surgeons in nine centers.

The rate of MUA varied across institutions from 0-9%, with 3/9 centers reporting no manipulations. Centers with <25 patients enrolled reported a higher average manipulation rate (6.0%), versus those with >40 patients (2.4%)

Table 3: New Knee Society Scores for patients undergoing MUA at 1 yr follow up (n=8)

	Pre-op	6-Week	6-Month	1-Year	p (Preop vs 1 yr)
Objective (0-100)	57	75	83	92	0.021
Satisfaction (0-40)	9	20	24	29	0.007
Expectations (0-15)	14	7	9	10	0.051
Functional (0-100)	41	46	72	74	0.015
Pain (0-100)	38	53	74	76	0.010
Symptoms (0-100)	43	46	63	70	0.028
ADL (0-100)	45	61	80	81	0.009
Recreation (0-100)	11	25	54	64	0.001
QOL (0-100)	14	30	53	55	0.007
ROM	112	84	113	117	0.780

This may indicate that factors associated with higher MUA rates may include surgeon volume and experience with the patient-specific implant. However, a recent registry analysis of 59,696 TKAs found no association with volume and MUA. [29]

In addition to a lower manipulation rate, the present study also demonstrated good patient-reported outcomes. Across the entire cohort, patients reported statistically significant improvements in all KSS outcome measures with the exception of the expectation score. Pre-operatively, patients reported high expectations (expectation score of 14/15) for the surgical procedure. At the 6 week postoperative visit patient expectations had dropped, but on average patients reported the surgery to have met expectations (9/15, with 9 being the threshold for “met expectations”). By the 6 month visit, patient expectations had improved from the 6 week time point, with patients on average reporting the procedure to have marginally exceeded expectations (10/15). Throughout the current literature, patients often report unmet expectations after total knee arthroplasty, possibly due to excessive optimism about results. [30–32] A prior study using the 2011 KSS to evaluate TKA outcomes found that although patient satisfaction and all other scores improved after surgery, the expectation score decreased slightly, leading researchers to postulate that patients may be satisfied after TKA in different ways than expected. [33] Additionally, it is possible that patients receiving a patient specific design may have higher expectations for their outcomes as opposed to those who receive a conventional implant. An earlier study showed a high dissatisfaction rate (11.1%) with the earlier, G1 version of the iTotal implant. [23] However, the present study found that only 6/298 (2.0%) of patients reported being “dissatisfied” or “very dissatisfied” with their results at 1 year (KSS satisfaction score <10), with an average KSS satisfaction score of 34 in the entire study. This compares favorably with the existing literature, which reports overall patient satisfaction rates of 81–89%, as well as KSS satisfaction scores of 23–38 for primary TKA. [33,34,43–52,35–42] Revision surgery was rare, with only 1.7% (6/360) patients requiring revision surgery within 2 years. Three of these patients continue to have the device, yielding an implant survivorship of 99.2%.

Limitations to this study include a lack of standardized indications for undergoing MUA and incomplete follow up (298 of 360 patients at 1 years, including 8 of 11 patients who underwent MUA). However, patients who did not complete 1 year follow up did not report problems that would be indications for MUA at the 6 week or 6 month visit. Thus, it is unlikely that additional patients in the study will require MUA in the future. Strengths of

the study include the size of the cohort (360 patients). Additionally, all patients in the study were prospectively recruited at 9 centers, thus providing a more robust estimate of expected MUA rates after surgery with the second generation iTotal CR device as compared to single center experiences.

In conclusion, the present study demonstrates an acceptable rate of MUA in a large cohort of patients who underwent TKA with the ConforMIS G2 iTotal CR patient-specific TKA. Additionally, patient reported outcomes demonstrated significant improvements in pain, function, and satisfaction. Further follow-up continues at all sites. Data from longer term follow-up on the entire cohort as well as the patients that experienced MUAs in this study population will provide a deeper understanding of overall survival, patient outcomes and long term effects of MUA on patients receiving this device.

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AUTHOR DISCLOSURES

Andrew Kay declares that there are no disclosures regarding the publication of this paper. All other authors declare either their family, institutions they are associated with, or themselves have received benefits or funds either directly or indirectly regarding this article.

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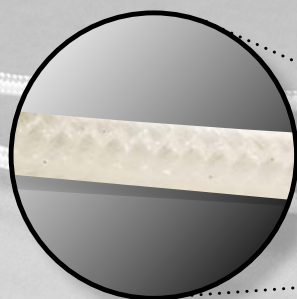
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Levels of Evidence

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

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	<ul style="list-style-type: none"> • High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review² of Level I RCTs (and study results were homogenous³) 	<ul style="list-style-type: none"> • High quality prospective study⁴ (all patients were enrolled at the same point in their disease with $\geq 80\%$ follow-up of enrolled patients) • Systematic review² of Level I studies 	<ul style="list-style-type: none"> • Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review² of Level I studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review² of Level I studies
Level II	<ul style="list-style-type: none"> • Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) • Prospective⁴ comparative study⁵ • Systematic review² of Level II studies or Level I studies with inconsistent results 	<ul style="list-style-type: none"> • Retrospective⁶ study • Untreated controls from an RCT • Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) • Systematic review² of Level II studies 	<ul style="list-style-type: none"> • Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) • Systematic review² of Level II studies 	<ul style="list-style-type: none"> • Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review² of Level II studies
Level III	<ul style="list-style-type: none"> • Case control study⁷ • Retrospective⁶ comparative study⁵ • Systematic review² of Level III studies 	<ul style="list-style-type: none"> • Case control study⁷ 	<ul style="list-style-type: none"> • Study of non-consecutive patients; without consistently applied reference “gold” standard • Systematic review² of Level III studies 	<ul style="list-style-type: none"> • Analyses based on limited alternatives and costs; and poor estimates • Systematic review² of Level III studies
Level IV	Case Series ⁸	Case series	<ul style="list-style-type: none"> • Case-control study • Poor reference standard 	<ul style="list-style-type: none"> • Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

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

Educational Value & Significance

JISRF has established a guideline as to the level of Educational Value & Significance. This will now become part of the Peer Review process with the following rating system:

JISRF Levels of Educational Value & Significance

A = Novel and extremely significant for all.

B = Novel and significant for many.

C = Novel and interesting for limited readership.

D = Novel and mild interest to readership.

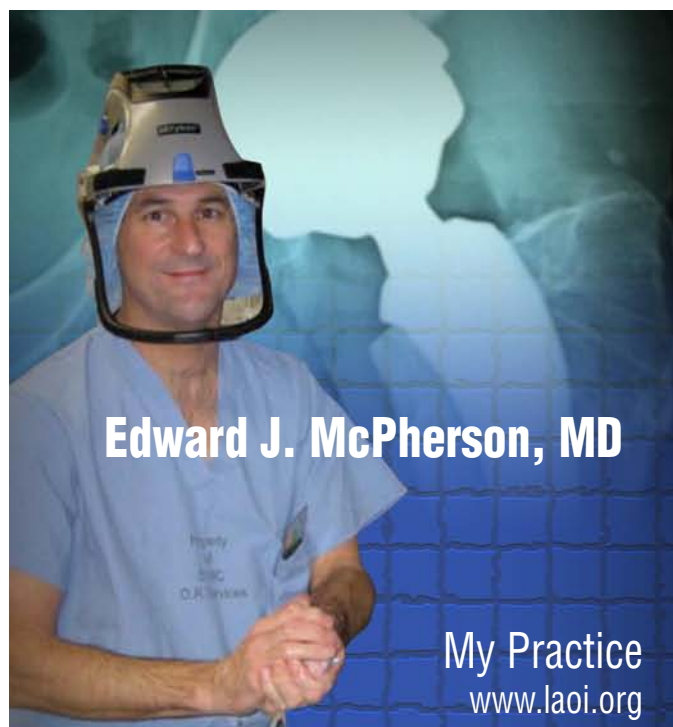
JISRF Founder



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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As an Orthopaedic surgeon in Los Angeles, CA, I'm grateful to practice medicine in an area with exceptional healthcare. My choice is to practice at St. Vincent Medical Center. My research is in collaboration with JISRF, Founded here in L.A. in 1971 by Prof. Charles O. Bechtol, MD.

JISRF Mission Statement



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

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Future Site Selected For This Cutting-Edge Medical Initiative



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

This phase will include an expansion of our world renowned executive health and wellness practice, The Greenbrier Clinic, which will be bolstered by a world-class sports medicine program, including an orthopedic surgery center and athletic performance/rehabilitation facility, all led by the Founder of the American Sports Medicine Institute, Dr. Jim Andrews and Chair of Cleveland Clinic Innovations, Thomas Graham. Rounding out the Institute's services will be a first-



in-class plastic and cosmetic surgery and Lifestyle Enhancement Academy, helping people look and feel their best. Physicians, universities, research foundations, medical journals and other healthcare industry leaders, all of whom are on the cutting edge of medical technology, research and care, have committed to join the project and establish an international research and education destination or "think tank" to stimulate research, drive innovation, force change and redefine how the world approaches health, wellness and longevity.

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

For more information, please contact:

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