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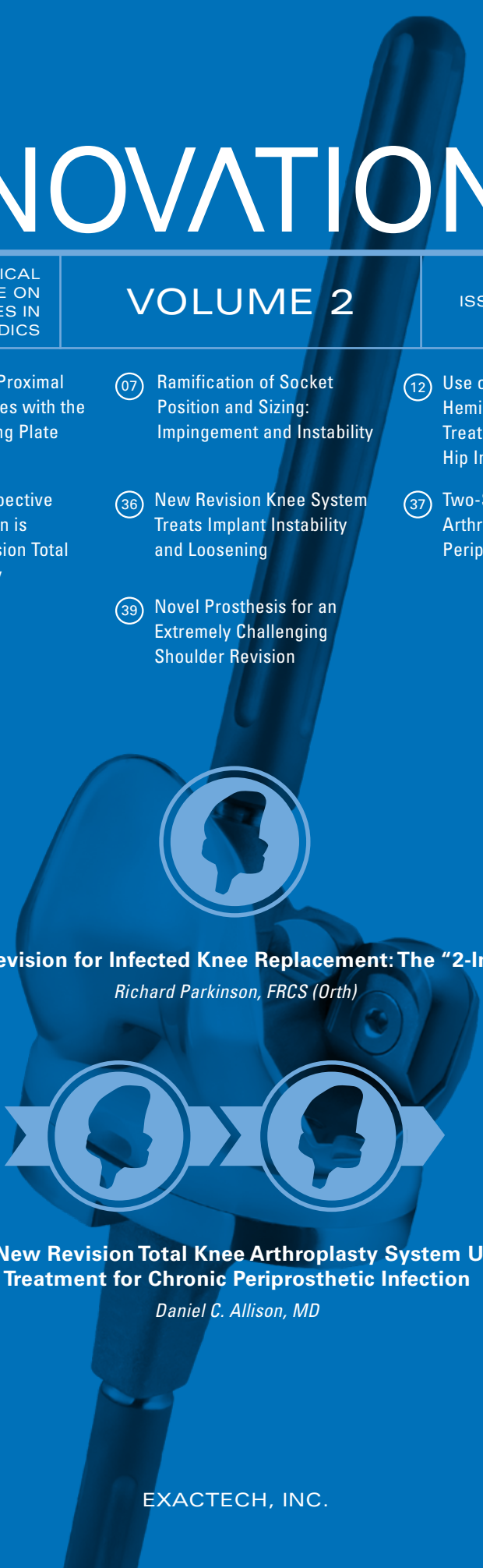
A CLINICAL EXCHANGE ON ADVANCES IN ORTHOPAEDICS

VOLUME 2

ISSUE 2



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PERSPECTIVES ON TREATING INFECTED TOTAL JOINT ARTHROPLASTY

Bill Petty, MD
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Gary Miller, PhD
Exactech Executive Vice President, Research and Development

Look for this symbol throughout this issue for educational opportunities to get hands-on experience with primary and revision prostheses.

Periprosthetic joint infection is one of the most serious complications we see in total joint replacement. Treating infected joints almost always requires surgical intervention and antibiotic therapy, which can be devastating for patients, challenging for surgeons and costly for hospitals.

At Exactech, we have always focused our vision on creating products and services to improve the quality of care provided to patients. When it comes to treating infected joints, we have an opportunity to make a substantial difference for patients and the surgeons who encounter this difficult condition.

Over the past year, we have introduced new revision products for hip, knee and shoulder arthroplasty, designed to deliver ease of use for surgeons and to improve patient outcomes. In this issue, we will share early clinical results from the three new systems: the Optetrak Logic® CC (p. 32), the Alteon® Monobloc Revision Stem with InterSpace® Tapered Wedge Spacer (p. 33) and the Equinoxe® Humeral Reconstruction Prosthesis (p. 35).

These outcomes are a direct result of the collaboration and input of the renowned design surgeons who give us input on product development and clinical challenges, like treating infected joints. We are pleased to have some of these thought leaders share their perspectives in this edition of *Innovations*.

Our featured articles represent two schools of thought on treating infected total knee arthroplasty (TKA). Mr. Richard Parkinson discusses surgical technique and clinical results from his single-stage approach, while Dr. Daniel Allison reviews seven periprosthetic infection cases using a two-stage surgical technique with the new Optetrak Logic® CC system.

Of course, infection isn't a challenge limited only to knees. Dr. Douglas D.R. Naudie discusses treating deep periprosthetic hip infection with a load-bearing hemi spacer and shares his clinical outcomes with InterSpace Hip (Spacer G) on page 12.

On page 30, Dr. James Huddleston shares his thoughts on developing a state-of-the-art system that uses computer-assisted surgery to achieve optimal outcomes in revision total knee arthroplasty (rTKA).

This edition also includes interesting perspectives on complicating factors of primary shoulder and hip arthroplasty. The number of proximal humerus fractures in the United States is rapidly increasing, and these injuries often come with high rates of complications. The importance of care for proximal humerus fractures and choosing a method of fixation when an operative treatment is selected is discussed on page 2.

Acetabular component position and size are important determinants of stability, wear and impingement after total hip arthroplasty (THA). On page 7, surgeons discuss ways to ensure reproducible and safe acetabular component sizing and positioning in direct anterior THA.

We're pleased that a professional communications association recognized *Innovations* with two Awards of Distinction this year, but what really matters is what you think. Please enjoy this edition and share your feedback with us at **www.exac.com/innovations**.•

MANAGEMENT OF PROXIMAL HUMERUS FRACTURES WITH THE EQUINOXE® LOCKING PLATE SYSTEM

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Fractures of the proximal humerus comprise approximately 5 percent of all fractures with between 300,000 to 700,000 reported cases per year.[1-3] These fractures occur commonly as a result of a low energy fall in patients with poor bone quality.[1] More than 70 percent of proximal humerus injuries occur in patients 60 years and older, overwhelmingly in women over men, with a 3-to-1 ratio predominance.[4]

With our population rapidly aging, orthopaedic surgeons in the United States should anticipate a three-fold increase in proximal humerus fractures within the next 30 years.[4,5] Already, the rate of proximal humerus fracture operative treatments increased by 25.6 percent from 1999 to 2005.[6,7] These facts underscore the importance of care of proximal humerus fractures as well as the method of fixation when an operative treatment is selected.

However, there is still no consensus in the literature concerning the optimal management of these injuries due to high rates of complications, such as osteonecrosis (ON) and screw penetration, and also due to the variety of implants and surgical techniques available that are utilized for fracture fixation.[7-10]

Options for treatment include percutaneous pinning, intramedullary nailing, locking plates, hemiarthroplasty, or reverse total shoulder arthroplasty, each offering advantages and disadvantages.[8,11] Locking plates have been a significant improvement in proximal humerus fracture fixation, as they potentially maintain anatomical alignment and stable fixation, especially in osteoporotic bone.[8] While one study has analyzed one company's proximal humerus locking plate, the Proximal Humerus Internal Locking System (PHILOS), there have not been detailed examinations of other implant types.[12]

In 2010, Exactech, Inc., (Gainesville, Fla.) released the Equinoxe® proximal humerus locking plate with several new improvements on existing locking plate designs. The purpose of this study is to present the patient outcomes and complication rates of 55 consecutive proximal humerus fractures treated with the Equinoxe proximal humerus locking plate.

Figure 1. The Equinoxe® fracture locking plate with (left) and without blade (right)

METHODS

This retrospective study was composed of patients who sustained proximal humerus fractures and were treated by fellowship-trained orthopaedic traumatologists at a single academic center between December 2010 and December 2014 using the Equinoxe proximal humerus locking plate. The institution's Institutional Review Board approved the study. All patients who underwent open reduction and internal fixation (ORIF) with the Equinoxe locking plate between December 2010 and December 2014 were identified.

Exclusion criteria included lack of complete functional data or follow-up of less than six months. Fractures were classified according to the Neer classification.[13] Surgical intervention was indicated for significantly displaced fractures and based on the number of anatomic parts. Surgeons experienced in the technique and the implant performed all the procedures. All surgeries were performed in the beach chair position. All patients were administered regional anesthesia, general anesthesia, or a combination of both. The surgeries were performed via a deltopectoral or superolateral approach.

The Equinoxe proximal humerus locking plate was developed to restore the anatomy of the native shoulder, incorporating contours that correspond to the lateral humerus to increase fit and stability.[14] The fracture plate system was introduced in the United States in 2010 and features a design that attempts to reduce humeral head collapse and improve outcomes for patients with suboptimal bone stock by maximizing contact area. Additional features include the ability to deploy bone filler after plate seating, multiple screw and blade configurations, and a design to allow suture placement after the plate is secured (Figure 1).

Patients undergoing treatment with the Equinoxe proximal humerus locking plate were followed at standard intervals using the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire to assess functional outcome and with physical examination and radiographic examination to determine clinical outcome or development of a complication at three, six and 12 months after surgery and as available beyond 12 months.[15] The DASH results in a score between 0 to 100, where 0 = no disability and 100 = extreme disability.[16]

Complications were also recorded, if present. Humeral head osteonecrosis (ON), surgical site infection, screw penetration, and heterotopic ossification limiting mobility were considered complications.

Descriptive statistics were utilized to identify mean DASH scores, complication rates, and most prevalent complications among the data set. Independent t-tests were utilized to determine if DASH scores were statistically significantly related to Neer classification or presence of complications.

RESULTS

A total of 55 consecutive patients underwent proximal humerus repair with the Equinoxe locking plate during the study period. Five patients were excluded from the study due to inadequate follow-up, and one patient was excluded due to concomitant fractures that affected extremity function. The remaining 49 patients with 50 fractures had a mean follow-up of 16.8 months (range: 6 to 44 months).

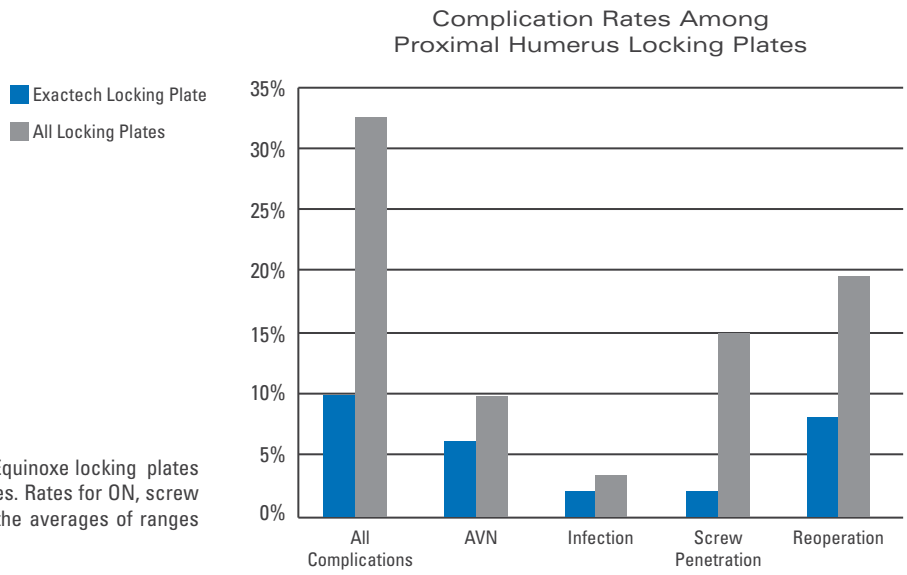

Figure 2. Complication rates for our cohort of Equinoxe locking plates versus literature-reported rates for all locking plates. Rates for ON, screw penetration, and reoperation were calculated as the averages of ranges put forth by multiple sources.[4,10]

Of the 49 patients, 31 (63 percent) were female and 18 (37 percent) were male, with a mean age of 60.7 ± 14.5 years (range: 25.9 to 87.7 years), with no statistically significant difference between mean ages of sexes. The mean age-adjusted Charlson Comorbidity Index (CCI) was 2.85 (range: 0 to 6).

The fracture classifications were: 19 (38 percent) two-part fractures, 18 (36 percent) three-part fractures, and 13 (26 percent) four-part fractures. The overall complication rate was 10 percent (N = 5). The most common complication was ON (N =3; 6.0 percent) followed by infection, heterotopic ossification, and screw penetration (N = 1; 2.0 percent each) (Figure 2).

Four patients required reoperation (8.0 percent). Two patients underwent removal of hardware with irrigation and debridement for infection; one patient underwent removal of hardware for ON and screw penetration; and one patient underwent arthroscopic release for adhesive capsulitis. All patients healed radiographically with the exception of one patient who had ON complications as a result of infection and subsequent removal of hardware.

At the latest follow-up, mean active forward flexion for the cohort was 140.8° ± 30.1°, mean passive forward flexion was 155.7° ± 25.2°, and mean active external rotation was 50.1° ± 17.9°. For patients with postoperative complications, mean active forward flexion was 106.0° ± 23.0°, mean passive forward flexion was 136.7° ± 23.1°, and mean active external rotation was 34.2° ± 24.4. Active forward flexion and external rotation were statistically significantly different in the presence of a complication ($p = 0.005$ and $p = 0.038$ respectively).

Mean DASH score for the cohort was 19.1 ± 20.9. Mean DASH score for patients who developed complications and/or underwent reoperations was 34.2 ± 24.3 (Figure 3).

DISCUSSION

We found favorable clinical and functional outcomes with use of the Equinoxe locking plate, with a safety profile comparable to any other plating system available on the market.[10,12] The implant allowed for reliable fracture healing, early range of shoulder motion, and a low complication rate. The mean DASH score reported in this series corresponds to a high level of functionality in patients treated in this series.

Surgical fixation of proximal humerus fractures should offer the opportunity for anatomic restoration with the potential to meet the patient's expectations of functionality and postoperative shoulder movement. All internal fixation techniques have strengths and weaknesses. Percutaneous pinning and nailing provide a minimally-invasive surgical method but offer less stability than other constructs, leading to high nonunion and malunion rates.[17] While percutaneous pinning may be the least invasive method of operative fixation and therefore a theoretically lower chance of osteonecrosis, it carries potential complications of pin migration and osteomyelitis.[6,18] Intramedullary nailing may be useful in osteoporotic bone but has shown to have inferior stability compared to plating and is associated with rotator cuff dysfunction.[18] Maier and coworkers[6] demonstrated that nailing may be utilized

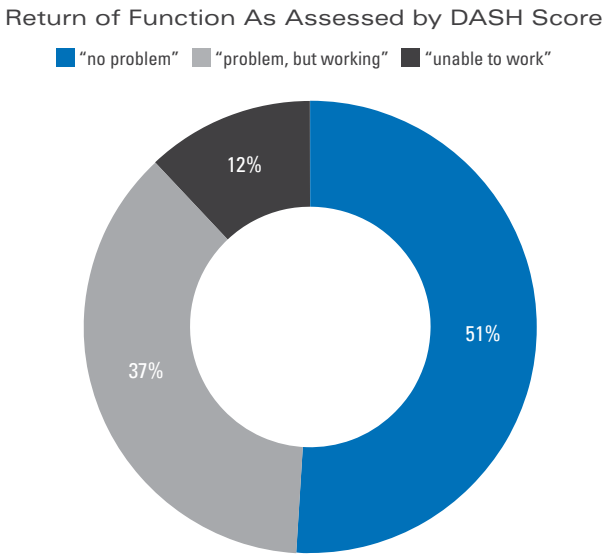

Figure 3. Functional healing as assessed by the DASH score for the patients in our cohort with complications. A DASH score of less than 15 corresponds to "no problem," a score between 15 to 60 tp "problem but working," and a score of more than 60 to "unable to work."[15]

for three-part and four-part fractures with either metaphyseal comminution or diaphyseal fracture with only minimal tuberosity displacement.

Non-locked plates for proximal humerus fractures have fallen out of favor, especially in poor bone due to screw pullout and implant failure.[5,8] Locking plates are considered the gold-standard implant for ORIF of the proximal humerus due to their strength and rotational stability.[2,19] One biomechanical study demonstrated that locking plates were less sensitive than other constructs to bone mineral density in the proximal humerus, making them a better choice for osteoporotic bone. The study also showed that, among intramedullary nail and plate constructs, locking plates offered the greatest stability under both bending and torsional loading.[20] This combination of strength and stability reduces the risk of failure that accompanies many other implants.[2,20]

The DASH score is considered a reliable and accurate method of ascertaining functionality and disability in the upper extremity.[16] A 2012 study of the PHILOS plate reported a mean DASH score of 36.12. In a review of all available proximal humerus locking plates currently in usage, Sproul and colleagues[10] identified an average DASH for patients of 26.6.

In comparison, the patients in the present study had a mean DASH score of 19.10, potentially achieving full functionality in many instances. According to de Kruijf and associates,[21] the highest functional outcome (DASH scores) for geriatric patients with proximal humerus fractures undergoing operative treatment, was achieved with the use of a locking plate, followed by intramedullary nail, and hemiarthroplasty.

Proximal humerus fracture ORIF is not without its share of complications. Osteonecrosis is most prevalent among Neer three-part and four-part fractures, with findings of 25 to 30 percent in percutaneous pinning and 3.1 to 16.4 percent prevalence in locking plate cohorts.[4,10] ON can develop long after initial trauma and surgery, in some cases after five years.[10] Correspondingly, results of ON, such as pain, joint arthritis, and decreased functionality, can take years to manifest. Although in such cases, ON is not an implant-related complication, but rather a result of the fracture itself.[10]

Because locking plates do not rely on frictional forces, less soft tissue stripping is required for plate placement. This may be the explanation for lower ON rates seen with locked plates compared to historical series.

Usually, intra-articular screw penetration occurs concomitantly with ON, as ON decreases bone quality and facilitates humeral head collapse leading to screw penetration.[5] The prevalence of intra-articular screw penetration ranges from 7.5 to 23 percent.[4,10] The complication rates with the Equinoxe® plates in our cohort are considerably lower than other locking plates series in the literature.[12] Our ON rate of 6 percent and screw pullout rate of 2.0 percent are markedly lower than rates for all locking plates and other methods of fracture repair.[4,10]

This study has some limitations. The cohort described in this study was operated on by fellowship-trained traumatologists who had extensive knowledge of the Equinoxe plate system and extensive operating experience. It was a retrospective study without a control group. Many cases of ON can occur

upwards of five years postoperatively. Since the implant has not been in clinical use for five years, we could see this reported rate increase with longer follow-up.

CONCLUSION

While locking plate fixation pitfalls are well documented, including high complication rates and loss of reduction, the Equinoxe proximal humerus locking plate, as reported in this study, provides excellent clinical results with a low complication rate. Proximal humerus fracture fixation is, and will continue to be, an important skill in any orthopaedic traumatologist's arsenal; additional and longer-term clinicalfollow-up is necessary to confirm these positive results. •

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RAMIFICATION OF SOCKET POSITION AND SIZING: IMPINGEMENT AND INSTABILITY

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INTRODUCTION

Acetabular component position and size are important determinants of stability, wear and impingement after total hip arthroplasty (THA). Previous authors have defined safe zones for cup positioning in posterior approach THA with the suggestion that dislocation rates are higher when the cup is placed outside of this zone.[1-3] In addition, acetabular component malposition has been associated with increased polyethylene wear and osteolysis.[4,5]

The "safe zone" for direct anterior THA is less clearly defined and may indeed be different from that of the posterior approach. The direct anterior approach (DAA) facilitates the use of intraoperative fluoroscopy, which some authors have suggested decreases variance with respect to cup positioning.[6] In our experience, we have found that variability in acetabular component anteversion was lower with a fluoroscopically assisted direct anterior approach as compared to a posterior approach, but a significant learning curve exists.[7]

To help mitigate the risks associated with component malposition, image-guided computer navigation and fluoroscopy have emerged as tools to aid in anatomic cup positioning. Most surgeons do not have access to computer navigation and use a freehand technique for choosing cup position, a technique shown to place the cup within Lewinnek's defined safe zone in a minority of cases.[8] Woolsen, et al. also demonstrated that lower volume community surgeons had more outliers in cup positioning, despite the aid of fluoroscopy.[9] This, again, suggests that there is a learning curve associated with fluoroscopic guidance, and that it is a tool rather than a silver bullet.

For this reason, we believe a comprehensive strategy is important for ensuring reproducible and safe acetabular component sizing and positioning. Here, we present our approach for achieving anatomic acetabular component positioning in direct anterior total hip arthroplasty. This strategy has evolved alongside our understanding of cup sizing and positioning and its ramifications on instability and impingement.

BACKGROUND

A retrospective analysis of primary anterior cementless THA was performed at a single institution done by a single surgeon (Jose A. Rodriguez, MD) between 2009 and 2011. Patients were divided into three consecutive groups based upon

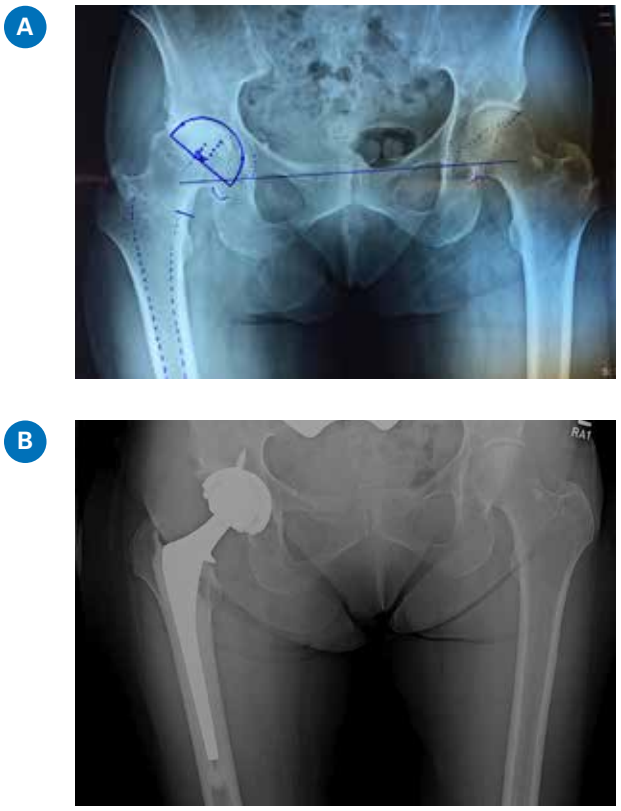


Figure 1. A) Pre-operative plan for right total hip arthroplasty. B) Standing AP showing final postoperative result.

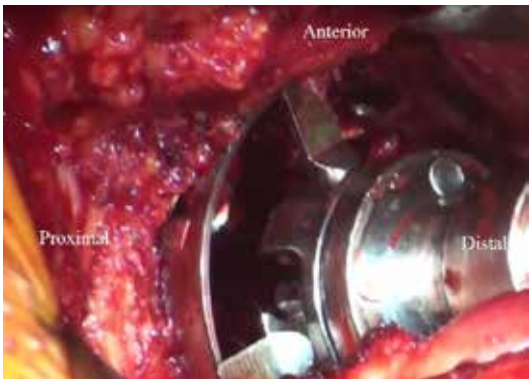


Figure 2. The final reamer is positioned flush with the anterior wall and protrudes 2-3mm posteriorly.

an evolving strategy of cup sizing and positioning. In group A, the first 100 DAA THAs performed by the senior surgeon, cup anteversion goals were similar to those for posterior approach THA, (avg. 24.3°) and no stability testing was performed intraoperatively. In group B, cup anteversion was modified based on intraoperative stability assessment and was significantly lower (avg. 12.5°). In group C, the same anteversion strategy was employed as in group B, however cup sizing was optimized to avoid anterior overhang. As such, the average cup size in group C was 4mm smaller than in groups A and B. In group A, there were two anterior dislocations. In group B, there were no dislocations but with the tradeoff of 12 patients developing groin pain due to psoas impingement. In group C, two patients developed groin pain, and there were no dislocations.

The results of this analysis have informed the strategy for cup positioning and sizing we use today. Its goal is to optimize cup position and reduce the likelihood of psoas impingement and instability.

PREOPERATIVE PLANNING

A standing AP of the pelvis, centered on the pubic symphysis, is obtained in every patient who will undergo surgery. Manual templating using acetate overlays is used for every patient at the institution (Figure 1). The teardrops and posterior cotyledons are marked, and a horizontal reference line is drawn between the bases of the teardrops. Next, the anterior and posterior walls of the acetabulum are identified and marked. Cup sizing is chosen to match the native acetabular size, which is initially set at 4mm larger than the native femoral head size as measured on a false profile X-ray of the pelvis. The cup position is templated so that the superior contact point coincides with the superolateral margin of acetabular subchondral bone, with the inferomedial corner of the cup at or just below the inter teardrop line. Medialization position is chosen, which will place the cup's face at or just inside the anterior wall. Each of these points is marked and the template is brought into contact with each of the three points as the final cup size and position are estimated.

ACETABULAR PREPARATION AND CUP POSITIONING

After acetabular exposure and labral resection, the contents of the cotyloid fossa are removed to clearly see the medial wall of the acetabulum. Reaming begins with a reamer 3mm smaller than the templated cup size, with the initial focus on medialization to within 1mm of the templated medial point.

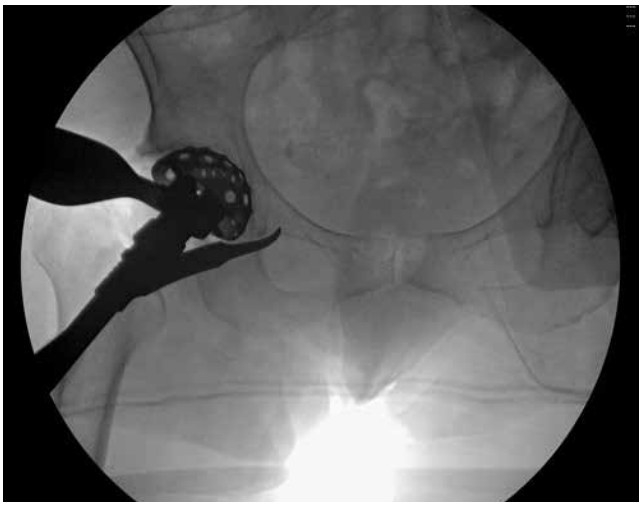


Figure 3. Once the final reamer's abduction, anteversion and position are optimized with respect to the anterior and posterior walls, a final shot is saved and used for comparison when implanting the cup.

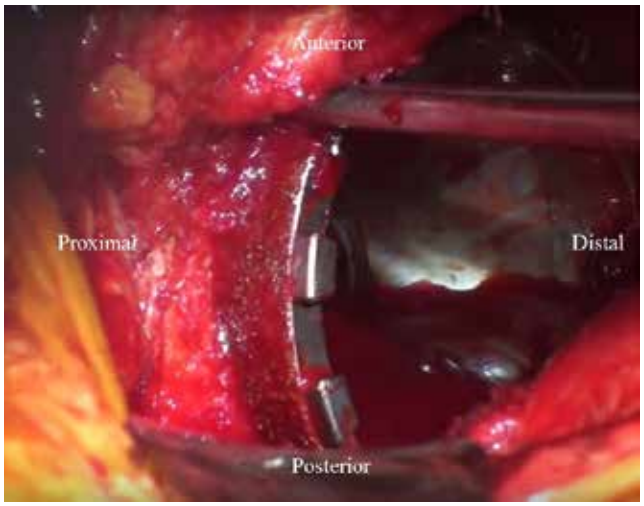


Figure 4. The implanted cup should extend approximately 1mm further posteriorly than the final reamer position but should remain at or just inside the anterior wall.

A fluoroscopic image is taken with the goal of reproducing the appearance of the patient's standing AP pelvis. Attention should be paid to neutralizing rotation of the pelvis in the axial plane so that the coccyx is midline. The patient's standing pelvic tilt should be reproduced as well, using the appearance of the obturator foramina as a guide. It should be noted that if a more lordotic pelvic position is produced in this fluoroscopic image, the cup will appear to be flatter and less anteverted. Conversely, if the obliquity of the X-ray beam creates a flat back appearance, the cup will appear more anteverted in the image. In either case, if the image reproduces the appearance of the standing pelvis, then it represents the actual position of the pelvis when standing and walking, and thus the position that should be used to perform provocative stability testing.

With the reamer in position, the medialization as well as superior and inferior points are evaluated and compared to the preoperative plan. Once these points are reached, attention is paid to optimizing cup abduction and anteversion. The final reamer is positioned so that the anterior edge of the reamer is at or just inside the anterior wall. Direct visualization as well as manual palpation is used to verify this position. If not excessively sized, the posterior edge of the reamer should extend no more than 2-3mm beyond the posterior wall. Inferiorly, the transacetabular ligament should be visible just at the inferior edge of the reamer (Figure 2).

A fluoroscopic image with the final reamer in the optimized position is taken (Figure 3). This allows a final verification of anteversion and abduction. The ellipse created by the open reamer face is evaluated and compared to the position of the anterior and posterior walls on the preoperative plan.

The cup is implanted in the same version and abduction as the final reamer. Fluoroscopy as well as direct visualization and manual palpation of the anterior edge of the cup are used to verify anatomic cup positioning at or just inside the anterior wall. Posteriorly, the cup will protrude 1mm beyond the final reamer position, depending on the reaming strategy employed (Figure 4). Nonetheless, the cup should not protrude more than 2-3mm from the posterior wall, to minimize the potential for posterior impingement and anterior luxation (Figure 5).

On rare occasions where avoidance of anterior overhang dictates an excessively anteverted cup, stability testing may determine that an elevated liner be chosen with the elevation centered anterosuperiorly.

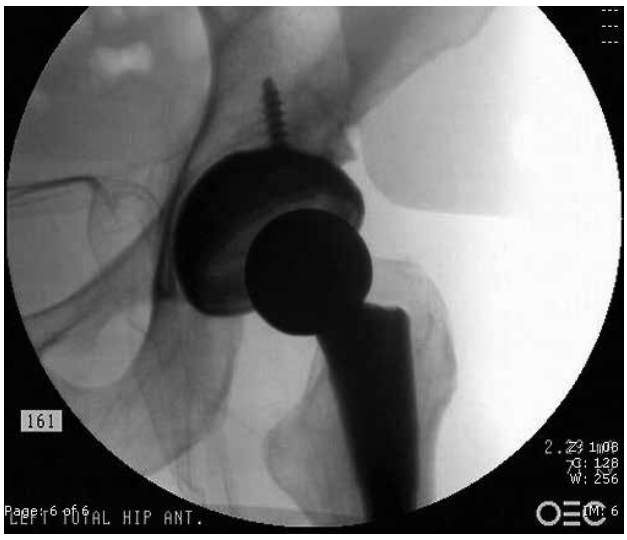


Figure 5. Intra-operative dynamic fluoro exam in a patient with excessive posterior cup overhang and anterior subluxation with provocative external rotation testing.

STABILITY EVALUATION

DAA was performed on a standard operating table with both legs prepped into the surgical field. This allows for direct limb length evaluation and more readily facilitates stability testing. After trial reduction, provocative external rotation is performed with the leg in neutral and again at 30º of extension. The options that will affect stability include increasing the leg length, elevated liner use or socket repositioning. On rare occasions, if stability cannot be achieved without excessive limb lengthening, an elevated liner is used or the cup is repositioned with less anteversion.

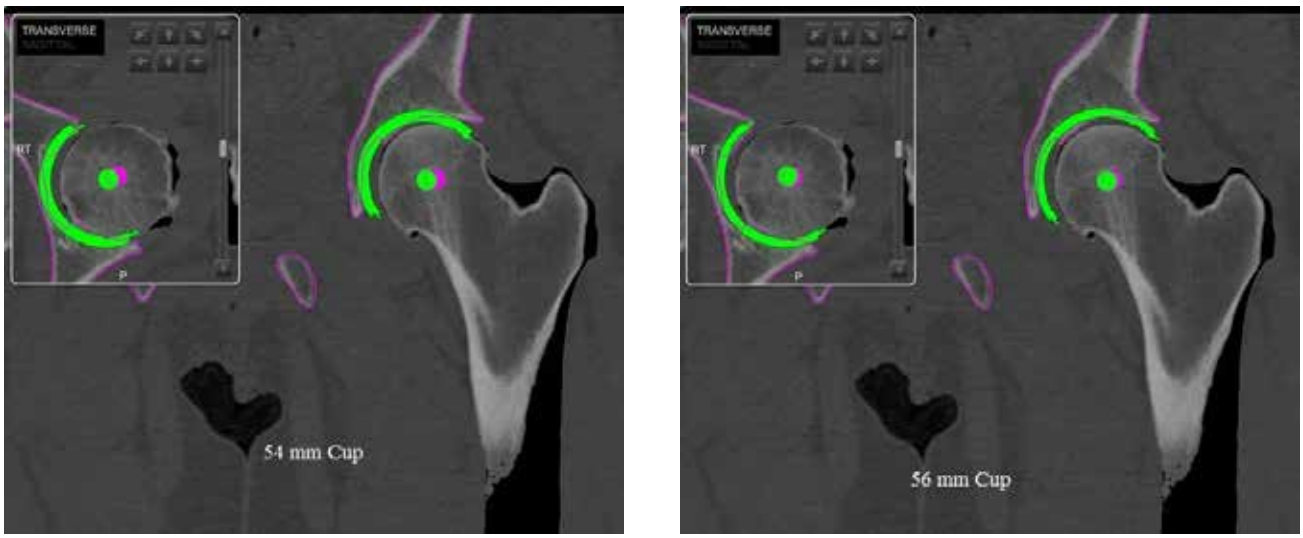
DISCUSSION

Acetabular component positioning is a critical element in achieving a stable, durable THA. Guidelines for cup positioning have been described in the literature, however the reliability of the safe zone has been recently called into question.[10] An analogous safe zone for the anterior approach has not yet been described, though it has been suggested that optimal anteversion may be less than that of the posterior approach.

In our experience, cups positioned via anterior approach but using anatomic guidelines borrowed from the posterior approach were more anteverted and more likely to dislocate anteriorly (group A). Conversely, when cup position was optimized based upon intraoperative stability (group B), anteversion was notably less; however, a significant proportion of patients developed psoas impingement. Iliopsoas impingement after THA is an uncommonly described finding with most of the cases in the literature involving a posterior approach. In the second 100 direct anterior THAs, nearly 14 percent of patients developed groin pain. This high rate of a relatively uncommon complication was attributed to anterior overhang of the prosthesis. In the third group, (group C) anteversion was unchanged compared to group B; however, a more anatomic cup sizing strategy was utilized. This resulted in a drastic decrease in the incidence of groin pain (2.1 vs 13.6 percent).

At the crux of our cup positioning and sizing strategy is an understanding of the anatomic constraints of the native acetabulum. The anterior wall provides a natural barrier between the iliopsoas tendon and the prosthesis. Positioning the anterior edge of the cup at or behind the anterior wall will reduce the likelihood of psoas irritation. This will effectively set the cup anteversion equal to the patient's native acetabular version but does not, in itself, guarantee stability. One must also be mindful of the degree of posterior cup overhang, which may result in impingement and subluxation or frank dislocation of the hip anteriorly. If the anterior point remains fixed, increasing cup size will result in greater posterior overhang (Figure 6). For this reason, we advocate choosing a cup size within 1mm of the patient's native cup size. We have found that the use of such a strategy results in posterior overhang of less than 2-3mm and reduces the likelihood of posterior impingement in a majority of cases.

There are some limitations of the cup sizing and positioning strategy. It is not an infallible approach guaranteed to eliminate instability and psoas irritation. It does not factor in patient-specific considerations such as capsular laxity, excessive acetabular anteversion, or generalized ligamentous laxity, which may predispose the patient to instability. But, following a sound, anatomically-based cup sizing and positioning strategy, augmented by the patient's specific considerations, and assessed with provocative testing, will reduce the likelihood of the problems associated with a malpositioned acetabular component. •



A B

Figure 6. A) CT based model showing a size 54mm cup tucked into both anterior and posterior walls. B) A 56mm cup positioned at the same point anteriorly protrudes posteriorly to a greater degree.

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USE OF A LOAD-BEARING HEMI-SPACER IN THE TREATMENT OF PERIPROSTHETIC HIP INFECTION

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INTRODUCTION

Deep periprosthetic infection following total hip arthroplasty (THA) is a rare but devastating problem. For chronic, delayed infections, most surgeons would recommend a one- or two-stage revision, or resection arthroplasty, depending on the chronicity of the infection, and the organism involved.[1-3] Proponents of single-stage revision contend that the quality of the initial debridement is the most important factor in resolving the infection. So long as strict protocols are followed, some authors report low reinfection rates with single-stage revision.[4,5] With direct one-stage implant exchange arthroplasty, however, comes some uncertainty regarding complete eradication of infection at the time of implant removal.

Two-stage revision, through the use of antibiotic-impregnated polymethylmethacrylate (PMMA) spacers with concurrent parenteral antibiotic therapy, is a frequently used technique with reported high success rates.[6-8] While many studies report good infection control with a two-stage procedure, they provide no clear attribution to the need or effect of the various spacers used in these studies. In fact, there is a general lack of consensus on the type of spacer that should be implanted, as well as the antibiotic and its concentration that should be incorporated into these spacers.[9-10]

Different types of spacers have been described in the literature.[6-10] In general, interpositional hip spacers used in two-exchange arthroplasty can be divided into static or dynamic spacers that may or may not allow load bearing. Dynamic partial load-bearing spacers, so called hemi-spacers, offer high local delivery of antibiotics with the conferred benefits of ease of use and availability, improved joint function, and facilitation of second-stage reimplantation through maintenance of leg length and tissue planes. These spacers encourage early patient mobilization, and may help reduce the average hospital stay. These spacers may also reduce the risk of dislocation and fracture compared to dynamic articulated spacers, which include

Figure 1. The InterSpace Hip, or Spacer G, is a pre-fabricated, stainless steel reinforced load-bearing spacer coated with antibiotic cement and is available as a flat stem variation (image on the left) to facilitate insertion in thinner metaphyseal femoral canals. The InterSpace Hip, or Spacer G, illustrated in a short and a long stem design, is available with three different diameter femoral heads (46, 54, and 60mm).

both acetabular and femoral components, because of the large unipolar-type head.[11-20]

The InterSpace® Hip (Exactech, Gainesville, Florida, USA) or Spacer G (Tecres SpA Sommacampagne, Verona, Italy) is a prefabricated gentamicin impregnated bone-cement spacer with a stainless steel reinforcing core. It is rigid due to the stainless-steel endoskeleton, making it easy to trial and implant, and reliable in terms of construct strength and antibiotic concentration. The potential for diaphyseal-metaphyseal mismatch exists with these spacers, but newer flat stem variations have improved the ability to use these implants in most femoral morphologies (Figure 1A). These spacers are also available in short and long lengths, but are restricted to three sizes on the acetabulum (Figure 1B).

We have previously reported our experience with the prefabricated gentamicin impregnated Spacer G[10]. In that study, we reported our ability to control infection after a single two-stage procedure in 28 of 33 (85 percent) patients. The purpose of the current study is to update our experience with this hemi-spacer, particularly with regard to our use of the flat stem variation.

PATIENTS AND METHODS

This study involved a retrospective review of all Spacer G hemi-spacers (Tecres SpA Sommacampagna, Verona, Italy, distributed by Exactech, Gainesville, Florida, USA) identified from our institutional arthroplasty database. Patients were eligible if they had their index first-stage revision surgery (i.e., Spacer G insertion) and active follow-up at our center. Patients were excluded if they had their index first-stage revision surgery performed at another center, but were then subsequently referred for follow-up at our institution. In general, Spacer G interpositional hemi-spacers were employed in all first-stage hip revision procedures by four of the seven joint reconstructive surgeons at our center. These spacers were not employed when there was major acetabular insufficiency, pelvic discontinuity, or when a second-stage reimplantation was not planned. Patient demographic data, laboratory values, infecting organism, size of spacer, antibiotic selection, complications, and infection control rates were collected.

SURGICAL TECHNIQUE

Either a posterolateral or direct lateral surgical approach was employed for the first-stage revision hip surgery. Both acetabular and femoral implants were removed ensuring minimal iatrogenic bone loss. Joint fluid cultures and tissue membrane samples were sent for microbiology. An aggressive debridement of the joint and soft tissues was performed. Implantation of the Spacer G hemi-spacer was performed with a thin layer of proximal cement to accommodate for any relative metaphyseal-diaphyseal mismatches and to provide additional rotational stability. In this extra bag of tobramycin-impregnated cement, we typically added

2.4 grams of tobramycin and 3 grams of vancomycin. In our center, this extra cement was also dyed with methylene blue for easier identification and removal at time of the patient's second-stage reimplantation. When an extended trochanteric osteotomy was required, two to three low-profile Luque wires were generally employed to secure the osteotomy. Moreover, when an extended trochanteric osteotomy was required, a long Spacer G hemi-spacer was used to bypass the distal level of the extended trochanteric osteotomy by at least two cortical diameters to avoid the risk of femoral fracture. Closure was performed in standard manner.

Postoperatively, physiotherapists worked with patients to assist with mobilization. Patients were permitted to bear half of their weight (50 percent weight-bearing) on their hemi-spacer to facilitate discharge home. Cultures were followed to identify the infecting pathogen and direct antibiotic treatment. Antibiotics were initiated and delivered parenterally for a minimum of six weeks via a peripherally inserted central catheter. After completion of this period, ESR and CRP levels were drawn to establish a baseline, and then followed through until time of second-stage reimplantation. Patients were always given an "antibiotic holiday" and normalization or trend toward normalization of ESR and CRP levels was required prior to reimplantation. Hip joint aspirates were not routinely performed in patients prior to reimplantation, unless there was a concern about residual elevation of their ESR and CRP levels. In cases where ESR and CRP levels failed to normalize, patients were recommended to undergo a repeat first-stage procedure using the same technique described above.

RESULTS

We identified 70 eligible patients who underwent first stage revision with the Spacer G hemi-spacers at our institution. Two patients died in the early post-operative period from complications unrelated to the insertion of their hemi-spacer. Of the 68 remaining patients, 35 were treated with the conventional hemi-spacer implant and 33 received the flat stem variation.

Of these 68 patients, 36 (19 conventional and 17 flat) went on to uneventful two-stage revision without need for further surgery or evidence of reinfection at last follow-up. Five patients (four conventional and one flat) required an irrigation and debridement for a wound problem in the early post-operative period following their second-stage reimplantation, but remain free of infection at latest follow-up. Fourteen patients (seven conventional and seven flat) required a repeat first-stage procedure (or repeated first-stage procedures) with the Spacer G implant in order to control the infection. Twelve of these patients went to successful second stage reimplantation without evidence of reinfection at latest follow-up; one conventional spacer went on to second-stage reimplantation but got re-infected (and is classified as a failure of this technique) and one flat spacer was left *in situ*. Of the 68 patients, eight Spacer G implants (two conventional and six flat) have been left *in situ* without complications or need for further surgery. Five (three conventional and two flat) of the 68 patients underwent second-stage revision, but got re-infected with the same or an alternate organism. These five patients underwent repeat staged revision procedures and remain on suppressive antibiotic therapy. We have classified these five patients as having failed eradication of their infection with this technique. In all, although 14 patients required repeat staging, 62 of the 68 patients (91 percent) were considered to have successfully eradicated their infection using this technique at latest follow-up.

DISCUSSION

In our previous report with this prefabricated gentamicin impregnated hemispacer, we were able to control infection after a two-stage procedure in 28 of 33 patients (85 percent).[10] Of the five failures in that report, two patients had persistently elevated inflammatory markers after the first stage, and subsequently underwent repeat staging with repeat debridement and spacer exchange at the date of their intended second stage. Both had interim control of their infections and went on to reimplantation at an average of 19 weeks. Both of these patients had an infection with methicillin-resistant *Staphylococcus Aureus* (MRSA). Subsequent reimplantation controlled the primary infection. Two additional patients had re-infection after undergoing reimplantation at their second-stage procedure: one became infected with the same bacteria that caused their initial infection, while the other became infected with a different bacterium. Both of these patients underwent a repeat two-stage revision with another Spacer G hemi-spacer implant. At latest follow-up, both had control of their infections. The fifth patient elected to forego reimplantation. This patient had numerous medical comorbidities, was deemed high-risk for further operations, and had a functional, painless limb, and thus elected to retain their hemi-spacer as a prosthesis. Although two patients in that study required repeat staging, 31 of 33 patients

(94 percent) did not require further surgery and were free of infection at latest follow-up. There were no major spacer-related complications in that series. In the current series, although fourteen patients required repeat staging, 62 of the 68 patients (91 percent) did not require further surgery and were considered free of infection using this technique at latest follow-up. Similarly, there were no major spacer-related complications in this series. Taken together, this rate of infection control is comparable to ranges reported in the literature from 83 to 95 percent. [1-3, 6-20]

In one of the few long-term follow-up studies, Sanchez-Sotelo et al. performed a retrospective review of 169 patients undergoing two-stage revision THA for infection. They reported a success rate of 88 percent in preventing re-infection at 10-year follow-up.[1] The majority of their patients underwent resection arthroplasty during the first stage and did not receive a spacer for the duration between the first and second stages. Toulsen et al. reported on the outcomes for infected periprosthetic THA undergoing two-stage revisions with antibiotic-impregnated articulating spacers. They followed 84 patients for an average of three years and reported a 95 percent success rate.[2] Wentworth et al. investigated the success rate of infection control with a dynamic articulating spacer. They followed 116 patients after two-stage revision utilizing the Prostalac® spacer (Depuy, Warsaw, IN, USA). This spacer is constructed intra-operatively using a cobalt-chrome core with a mold that allows for the addition of antibiotic-laden PMMA to the femoral stem. This stem was then coupled with a 32mm modular cobalt-chrome head that articulated with an acetabular component that was a polyethylene snap-fit liner. Their success rate was 83 percent.[18] Finally, Biring et al followed 103 patients who had a Prostalac spacer inserted as part of a two-stage treatment regimen for infection. These authors report eradication in 89 percent of cases with a mean follow-up of 12 years.[6]

Several studies have reviewed the outcomes of the Spacer G implant. In a similar study to ours, Pignatti et al. followed 41 patients undergoing two-stage revisions for infected THA. Thirty-six of those patients underwent revision with the Spacer G. Although nine patients required repeat staging, at the completion of their study, they reported a control rate of 100 percent.[14] More recently, Neumann et al reported on the use of a preformed cemented Spacer G in 44 patients with late hip arthroplasty infections. Component reimplantation was performed after a mean spacer period of 15 weeks (range, 12-26 weeks). They reported only one infection after reimplantation after a mean follow-up of 67 months. Interestingly, they reported a 14 percent complication rate, including spacer dislocation and perispacer fractures. After subsequent treatment, all of the cases went on to successful reimplantation.[7] Similar results were reported by D'Angelo et al, who reported only one recurrence of infection in 28 hips treated with the Spacer G at a mean follow-up of 53 months.[15]

Some authors have suggested that use of load-bearing hemi-spacers, such as Spacer G, may result in additional bone erosion in the acetabulum complicating subsequent acetabular reimplantation. A recent study by Garcia-Oltra et al analyzed the radiological changes in the acetabulum after using a Spacer G for the treatment of a chronic hip infection.[21] The authors found that patients with a Spacer G for less than one year did not develop acetabular erosions. During reimplantation, most patients received primary cups. Three patients did require acetabular rings and jumbo cups were necessary in four patients. In these four patients, however, the defects were already present at the moment of the acetabular cup resection during the first-stage and it was not possible to attribute these defects to the Spacer G implant.

CONCLUSION

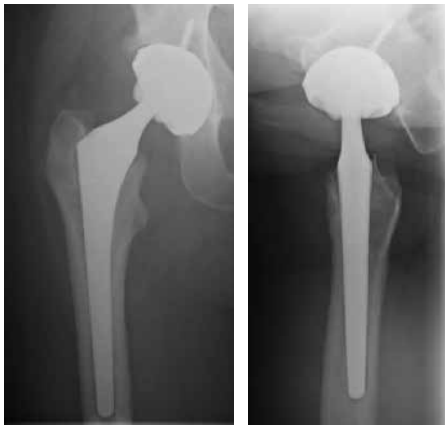
The contemporary literature favors two-stage re-implantation arthroplasty over other methods for the control of deep periprosthetic infection following total hip arthroplasty. Coupled with a thorough soft-tissue debridement and an extended course of parenteral antibiotics, our experience and data support the use of a load bearing hemi-spacer for treating chronic deep periprosthetic hip infections. We have reported infection control rates similar to that of other studies in the literature and a low complication rate associated with the use of the Spacer G hemi-spacer. Two recent studies further report comparable rates of infection eradication in the treatment of periprosthetic hip joint infections with surgeon-made or prefabricated antibiotic-loaded spacer implants.[22-23] The high proportion of patients requiring re-staging with this technique (and reported in the literature) reinforces how difficult it can be to manage the infected total hip arthroplasty. Additional studies investigating the use of a hemi-spacer in treating antibiotic resistant bacteria are required to better delineate timelines for two-stage procedures using interpositional spacers.

CASE REPORT

A 54 year old male presented with a right primary ceramic-on-ceramic total hip arthroplasty performed for avascular necrosis at another institution. This gentleman had a remarkable past medical history of hepatitis C, Crohns disease, and a 70 pack per year smoking history. He began to develop fevers, chills, and night sweats approximately two years after his index procedure. He complained of right groin and thigh pain, and required a cane to assist with mobilization. Oral antibiotics were initiated for three weeks prior to referral to our institution. On clinical examination, he walked with an antalgic gait. The distal aspect of his surgical incision was erythematous and swollen. His hip was irritable with active and passive flexion and internal rotation. Serologic investigations revealed an elevated ESR and CRP of 74mm/h and 77.5mg/L respectively. Fluoroscopic-guided aspiration of the involved hip did not grow any organisms (likely because he had been started on oral antibiotic therapy prior to referral). Pre-operative radiographs suggested septic loosening of the femoral component (Figure 2A).

This patient underwent a first-stage revision with a long flat Spacer G hemi-spacer (Figure 2B). Three grams of vancomycin and 2.4 grams of additional tobramycin were added to tobramycin-laden cement and used to coat the proximal aspect of the hemi-spacer. Intra-operative soft tissue cultures grew methicillin-sensitive staphylococcus Aureus. He received organism-specific parenteral antibiotics for 6-weeks, followed by a six week "antibiotic holiday". Serologic inflammatory markers normalized and he underwent the second-stage of his revision procedure (Figure 2C). He has been free of infection for six years. •

See additional case reports with InterSpace Hip Spacers on page 37.



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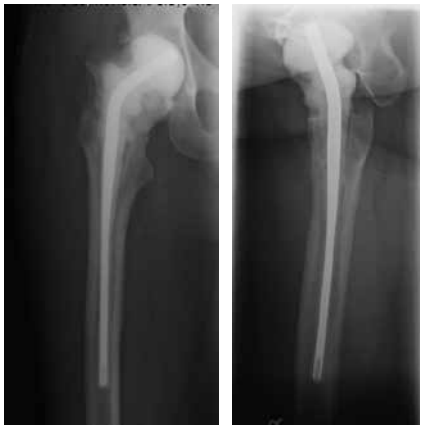

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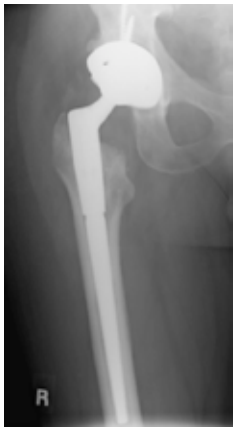

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Figure 2. Anteroposterior and lateral radiographs of a 54 year-old man who developed a periprosthetic infection two years after right total hip arthroplasty performed at another institution. The femoral component was loose (as evidenced by the circumferential radiolucency around the stem) allowing for extraction without the need for an extended trochanteric osteotomy.

This patient underwent a first-stage revision with a long flat Spacer G hemi-spacer. Three grams of vancomycin and 2.4 grams of additional tobramycin were added to tobramycin-laden cement and used to coat the proximal aspect of the hemi-spacer. Intra-operative soft tissue cultures grew methicillin-sensitive *staphylococcus Aureus*. He received organism-specific parenteral antibiotics for six weeks, followed by a six week "antibiotic holiday".

Serologic inflammatory markers normalized and he underwent the second stage of his revision procedure. He has been free of infection for six years.

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SINGLE STAGE REVISION FOR INFECTED KNEE REPLACEMENT: THE "2 IN 1" TECHNIQUE

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INTRODUCTION

In the last issue of *Innovations*, Daniel C. Allison MD, MBA, FACS, eruditely described the rationale and technique for performing a two-stage revision for an infected knee arthroplasty, and in this edition, Dr. Allison presents some of his patient outcomes with two-stage procedures. We all know that deep infection after a knee replacement is a disaster for the patient, a heart sink for the surgeon and a costly financial burden for the healthcare provider.

There is no doubt that the traditional and time-honored way of dealing with established infection in a prosthetic joint is the two-stage revision technique, with the first stage to explant to the infected prosthesis, debride and irrigate the joint, insert some form of spacer and administer appropriate antibiotics. The second stage, performed after an interval of several weeks, is to reimplant a revision prosthesis. Most series report an 80-90 percent "success rate" using this regime, and there is no doubt that it is still regarded as the gold standard.

Over the years, there have been very few reports of the single-stage technique[1,2], but two papers, one by Freeman, et al.[3] and one by Beuchal, et al.[4] reported a success rate of 85 percent—exactly the same as for the two-stage technique. So, why has there not been a more positive uptake by the profession? There is no doubt that the period of time between the first and second stage is a difficult time for the patient. They often struggle to mobilize, the knee often gets stiff, a prolonged hospital stay is not uncommon, repeat blood tests are needed, and there is an uncertain waiting time until it is deemed safe to proceed with the second stage. In addition, surgical access at the second stage may require a tibial tubercle osteotomy or a patella turndown.

In 2005, after attending a conference at which Fred Beuchal, MD presented his single-stage results, I decided to put theory into practice. At the British Association for Surgery of the Knee (BASK) Spring Meeting in Telford, U.K. in 2015, results and surgical technique from a single surgeon (Richard Parkinson, FRCS [Orth]) at

Over the years, there have been very few reports of the single-stage technique[1,2], but two papers, one by Freeman, et al.[3] and one by Beuchal, et al.[4] reported a success rate of 85 percent—exactly the same as for the two-stage technique. So, why has there not been a more positive uptake by the profession?

a single institution were reported for this "2 in 1" single-statge revision. Between 2005 and 2014, the 24 patients with infected knee replacements whose average age was 72 were treated. The time from index surgery to revision ranged from five months to 10 years. Seven patients had discharging sinus (Figure 1).

SURGICAL TECHNIQUE

The key to successful treatment is to identify the infecting organism(s). Over the years, the yield from a simple knee aspiration has been very disappointing despite the lab performing extended cultures. I have seen knees that are obviously infected, but extended culture has failed to grow any bacteria. Likewise, when a knee that does not appear infected, but has been aspirated for the sake of thoroughness, grows a bug, it may just be a contaminant. In other words, needle aspiration of a potentially infected joint yields false positives and false negatives. To overcome this problem, my current practice is to arthroscope the knee. This provides the opportunity not only of sampling fluid but also of the "sludge" that is often present in the infected knee. Synovial biopsies are also taken from the joint so that a minimum of six samples are sent to the lab. This technique has yielded an organism in 23 of the 24 cases studied (Table 1).[5]

Table 1. Organisms Isolated (Pre-Op)

The following organisms were isolated:	
Coagulase negative staphylococcus	9
Staphylococcus aureus	8
Mixed growth	3
Staphylococcus Lugenensis	1
Escherichia Coli	1
Enterococcus faecalis	1
No growth	1

Figure 1. Active discharging sinus, which was found in seven patients in this study and healed quickly in all cases.

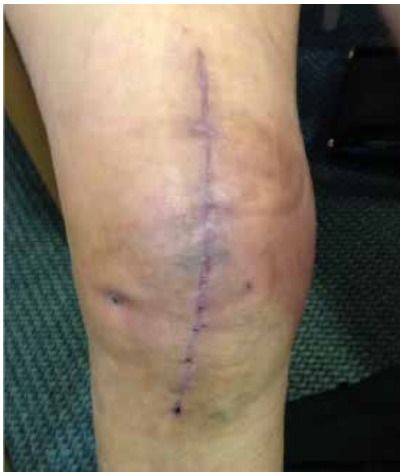

Figure 2. Patient follow-up, six weeks post-op

All antibiotics are discontinued at least two weeks before the knee arthroscopy to give the patient an "antibiotic holiday." When the organism has been identified by culture and sensitivity, a date is fixed for the single-stage revision (usually three or four weeks after the knee arthroscopy). While the patient is under general anaesthesia, the first stage is performed with a tourniquet. The infected prosthesis is explanted, and a thorough debridement and irrigation with 9 liters of normal saline is performed. Multiple cultures are sent to the lab for microbiology analysis, and appropriate antibiotics are given intravenously by the anaesthetist. The wound is loosely closed with a few interrupted sutures to give the knee some shape, a firm double wool and crepe bandage applied and the tourniquet deflated.

This provides the opportunity for the surgeon and theater team to have a 15-minute break during which time all the instruments are removed, the theater is cleaned and a new sterile set of instruments is brought in. The tourniquet is reinflated, the bandage removed, and the knee reprepped and redraped. The loose sutures are removed, and the surgical field represents itself to the surgeon. The bone surfaces are prepared with the revision instruments, augments added where required and the knee rebalanced with appropriate soft tissue releases. The housing of the femoral and tibial components is cemented with preloaded gentamicin-containing cement, often with the addition of extra antibiotic powder, depending on the organism. The most common antibiotic we add is 2G of vancomycin powder to an 80G mix of polymethylmethacrylate.

After closure of the wound, a firm wool and crepe bandage is applied, and the patient is rehabilitated in the same way as a primary knee. The only difference is that antibiotics are prescribed for a total of six weeks by the advice of a

microbiologist. Usually intravenous antibiotics are given for the first seven days, and after discharge from hospital, antibiotics are given for another five weeks.

The whole procedure usually takes me four hours — two hours for the first stage and two hours for the second stage. The procedure fits in well to a morning's operating list.

The patient is then followed up in outpatients with regular checks of FBC, ESR and CRP (Figure 2). Radiographs are taken at immediate post-op, at four months and at 12 months.

All 24 patients have a minimum of 12 months follow-up. Only one patient had a further revision. This patient had continuing unexplained pain despite having no evidence of ongoing infection. She had normal inflammatory markers, a normal X-ray and a negative aspiration. She went to another surgeon who further revised the knee with a two-stage procedure. All cultures were negative for infection, and she continues to complain of unexplained pain and dissatisfaction.

All 24 patients were therefore, cured of infection. The seven patients with active discharging sinuses all healed quickly, and indeed this sub group appeared to do particularly well. All patients demonstrated a return to normal of inflammatory markers (ESR and CRP). The CRP fell more quickly than the ESR. Twenty three out of 24 had excellent pain relief, and all had a good range of movement (Average 100°). We had no stiff knees, and none of the cases required either a tibial tubercle osteotomy or a patella turndown.

All patients had a pre-op and post-op WOMAC and SF12 score (Figure 3). On WOMAC, we demonstrated a statistically significant improvement in the three domains of pain, stiffness and function ($P<0.05$). On SF12 testing, however, we did not demonstrate an improvement in either the physical or mental health scores.

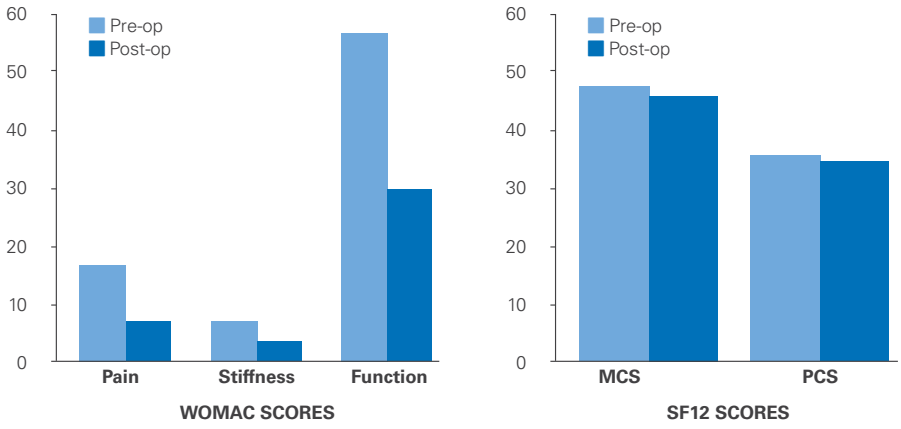

Figure 3. On WOMAC, pain, stiffness and function were improved. However, on SF12 testing, physical and mental health scores were not improved.

Over the last few years, there has been a resurgence of interest in the single-stage revision technique in Europe.

LIMITATIONS OF THE STUDY

With only 24 cases, this study represents a relatively small series. Nevertheless, I have been carrying the procedure now for more than 10 years, and the surgical technique has been adjusted and refined over time. All these cases were first-time revisions, and there were no multiply revised knees in the series. It may, therefore, be argued reasonably that these were "easy cases," but revision knees are rarely straightforward in the true sense of the word. None of these cases had a combined plastic surgical procedure, such as a gastrocnemius flap. This was mainly for logistical reasons, but if it were routine for a plastic surgeon and orthopaedic surgeon to be working in the same hospital, then there is no reason why this technique should not work. That is an area for future study. During this study period, I did perform some traditional two-stage procedures for what I judged to be "difficult cases," so I may be justifiably accused of cherry picking.

Also, there were no cases of particularly virulent organisms such as MRSA, VRE or CPE.

DISCUSSION

Over the last few years there has been a resurgence of interest in the single-stage revision technique in Europe. Some specialized units have been performing it out, although there is still a paucity of supporting peer-reviewed literature.

The importance of the very short break between the first stage and second stage is unknown. The rationale for the break is that instead of waiting at least six weeks between stages, we only wait 15 minutes. It seems to make sense, but I know of other surgeons who roll the single-stage revision into a continuum. I believe the break does no harm, and putting bacteriology issues to one side, it also does allow for a pause for thought and the opportunity to plan the second stage, knowing exactly where the bone loss is and the state of the ligaments and soft tissues.

Further support for a single-stage technique comes from literature reporting the results of two-stage revisions. Rather than inserting a cement spacer (static or articulating), some surgeons use a basic cemented total condylar primary

knee prosthesis to act as a temporary articulating spacer with a view to removing it at the second stage before implanting a definitive revision prosthesis. Some of these patients have been so satisfied with their "temporary spacer" that they have refused to undergo second stage surgery and have done well, living for years with an implant that was only intended to be implanted for a few weeks. Therefore, why not take the next logical step and consider implanting a stemmed revision construct, and thereby save the patient from an unnecessary second operation?

There is no doubt that the most difficult step for me in the early days was to leave my comfort zone of performing a traditional, two-stage revision technique and tell my first few patients that I was going to use a new and rarely-reported surgical strategy. However, a single-stage revision has several considerable potential advantages. For the patient, it means only one major procedure rather than two. The overall length of hospital stay is considerably reduced, and there are enormous cost savings for the health care provider.

The problem of stiffness appears to be avoided, which is an issue that bedevils the two-stage technique from time to time. The technique can definitely be used when there is osteolysis. Patients with a discharging sinus can likewise be treated, and it is my personal observation that this group appears to do particularly well.

In summary, the results of "2 in 1" single stage revision appear at least as good as two-stage revision, and there are many advantages for the patient, the surgeon, the hospital and the funder of the treatment. •

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EARLY RESULTS OF A NEW REVISION TOTAL KNEE ARTHROPLASTY SYSTEM USED IN THE STAGED TREATMENT FOR CHRONIC PERIPROSTHETIC INFECTION

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Cedars-Sinai Medical Center

INTRODUCTION

Periprosthetic infection is a devastating complication that complicates approximately 1 percent of primary total knee arthroplasties (TKA).[1] In chronic cases, the condition often requires implant removal with subsequent delayed reimplantation, to offer the best chance at remission of infection.[2] Extensive bone loss often occurs in these settings, as a consequence of the infection itself, the removal of implants, the initial debridement, from erosions caused by an unstable cement spacer, or combinations thereof. In addition to bone deficiencies, soft tissue compromise and loss also frequents these conditions, for similar reasons. To minimize and address the bone and soft tissue deficits at the time of reimplantation in these challenging cases, a robust, versatile, and complete instrument and implant system remains an essential part of the revision knee surgeon's arsenal.

We report the early results of a small case series of a new condylar constrained revision total knee replacement system (Optetrak Logic® CC, Exactech, Inc. [Gainesville, FL) used in the staged treatment of chronic periprosthetic infection. The system contains advances on both the instrument and implant sides, which may be beneficial in these difficult cases.

MATERIALS AND METHODS

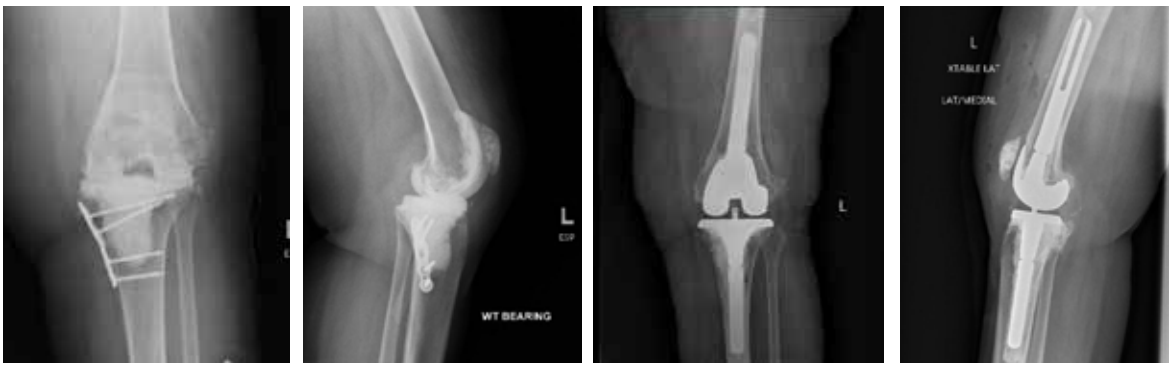
The first seven periprosthetic infection cases using the new Optetrak Logic CC system performed by a single surgeon (Daniel C. Allison, MD) were restrospectively reviewed. All cases involved the treatment of chronic periprosthetic infection, as diagnosed by MSIS criteria.[3] All cases were initially treated with implant removal, debridement, and articulating antibiotic cement spacer placement. In one case, the patient was referred with a previous antibiotic spacer placed by another surgeon, with persistent periprosthetic infection and severe instability (Case 2). In another case, the antibiotic cement spacer was placed three years previously at an

outside hospital (Case 4). In the remainder of cases, the initial implant removal and antibiotic spacer placement was performed by the final treating surgeon (Daniel C. Allison, MD). The decision to proceed with total knee arthroplasty reimplantation was based on clinical examination, serum ESR / CRP values, joint aspiration cell count, intraoperative gross examination, and intraoperative frozen section sampling. In all cases, low dose antibiotic (1gm vancomycin, 1.2 gm tobramycin per 40 gm PMMA) cement was used during reimplantation. Early clinical and radiographic results were collected, and mean follow up was 14 weeks from reimplantation (range 4-17 weeks). There were no unplanned readmissions or surgeries within 30 days, and all cases sustained remission of infection during the follow up period.

CASE REPORTS

CASE 1

A 57 year-old African American female with persistent right total knee arthroplasty fibrosis, treated with previous open lysis of adhesions and tibial insert exchange at an outside hospital, presented with persistent pain and severe stiffness. Intraoperative frozen section revealed >10 WBC per high power field (HPF) in > 5 HPFs. At the time of implant removal, no specialized extraction instrumentation was used, and iatrogenic, complete, displaced fracture of the posteromedial tibial plateau occurred. The condition was immediately treated with titanium plate fixation, followed by articulating antibiotic spacer placement, and the patient's weight bearing was limited (Figure 1A, 1B). The fracture healed, remission of infection was achieved, and the patient underwent reimplantation with the Optetrak Logic CC revision system (Figure 1C, 1D). At 27 weeks follow up, she remains free of infection, is ambulating without assistive devices, and knee motion ranges from 15° to 100° (a 65° improvement in arc of motion compared to preoperatively).



A B C D

Figure 1.

CASE 2

An 81 year-old morbidly obese Caucasian female with multiple medical problems was referred by a colleague for persistent methicillin sensitive *S. Aureus* right knee periprosthetic infection, along with severe instability and extensor mechanism dysfunction, status post previous implant removal and articulating antibiotic spacer placement (Figure 2A, 2B). The patient was taken to surgery for repeat debridement, antibiotic spacer exchange, and extensor mechanism reconstruction (Figure 2C, 2D). After a postoperative course of IV antibiotics, remission of infection was confirmed, and she underwent reimplantation, using extensive augmentation on the tibial and femoral sides (Figure 2E, 2F). Her severe instability was managed with soft tissue balancing and use of the condylar constrained design. At 24 weeks follow up, she has no pain or instability, with 0 – 100° of knee flexion / extension, actively and passively.

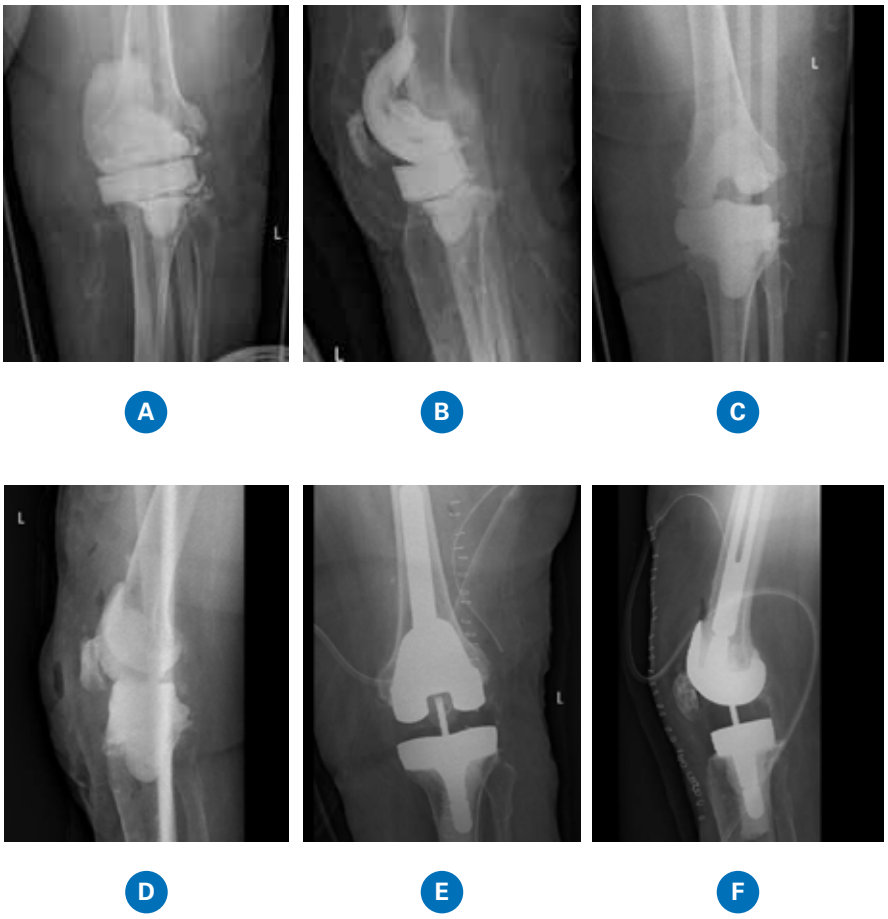


Figure 2.

CASE 3

A 52 year-old male presented one-year status post left total knee arthroplasty with persistent left knee pain, drainage, and inability to bear weight (Figure 3A, 3B). The diagnosis of chronic periprosthetic infection was confirmed, and the patient was taken to surgery. Removal of femoral and tibial components was facilitated with a specialized Exactech extraction device (Figure 3C, 3D), and an articulating antibiotic spacer was placed. Intra-operative cultures grew *Enterococcus sp*. After six weeks of IV antibiotic therapy, remission of infection was achieved, and the patient was taken for uneventful reimplantation (Figure 3E, 3F). A posterior stabilized constrained (PSC) insert was used, given the patient's competent collateral ligaments. At 13 weeks follow up, the patient is well healed, free of infection, ambulates without assistive devices, with range of motion from 0 – 110°.

Figure 3.

CASE 4

This patient is a 57 year-old male with a history of incomplete spinal cord injury resulting in partial hemiparesis of his right lower extremity. The patient underwent prior total knee arthoplasty, which became infected, and was treated with implant removal and articulating antibiotic cement spacer placement at an outside hospital three years prior to consultation. He presented to our clinic for reimplantation, complaining of knee instability and pain (Figure 4A, 4B). Infection workup was negative, and the patient was taken for complex reimplantation, with a kinematic rotating hinged knee prosthesis as a back up implant option, given the extensive bone and soft tissue loss in the setting of weakened dynamic stabilizers. Intra-operatively, accommodation of bone defects, as well as achievement of balance and stability, was accomplished with the Optetrak Logic CC system (Figure 4C, 4D), and hinged knee replacement was not necessary. At 12 weeks follow up, the patient is well healed, ambulatory with no pain, with range of motion from 0 – 100°, actively and passively.

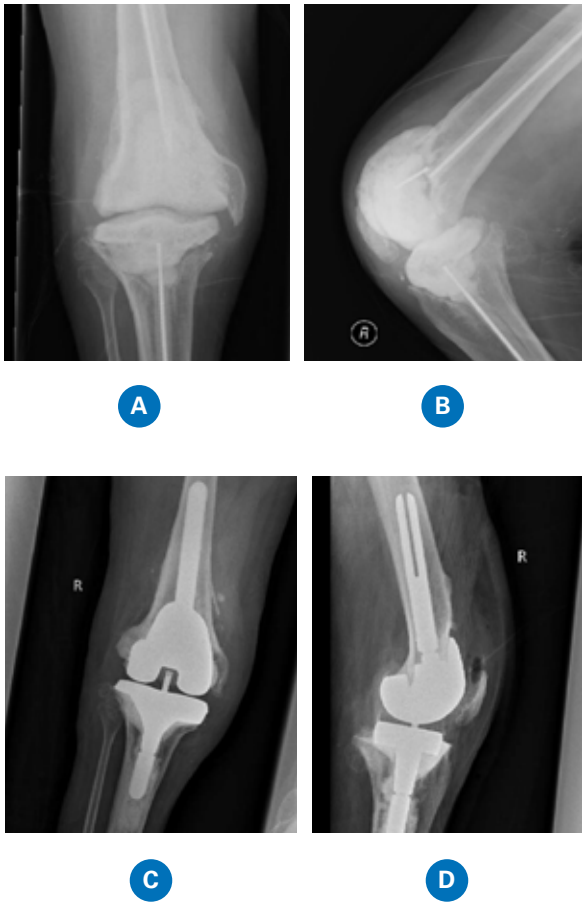


Figure 4.

CASE 5

A 73 year-old male S/P total knee arthroplasty presented with persistent pain, swelling, and drainage (Figures 5A, 5B). Evaluation revealed methicillin resistant *S. Aureus* infection, and the patient was taken to surgery. His implants were very well fixed, and safe removal was facilitated with the Exactech AcuDriver® pneumatic device to disrupt the cement-bone interface, followed by the Exactech extraction instrumentation for removal (Figures 5C, 5D). The implants were removed with relative ease and minimal bone loss (Figures 5E, 5F). After remission of infection was confirmed, the patient underwent reimplantation (Figures 5G, 5H). A PSC insert was used, since the patient's collateral ligaments afforded natural articular stability. At nine weeks follow up, he is well healed, with no evidence of infection, and a 0 -100° arc of motion.

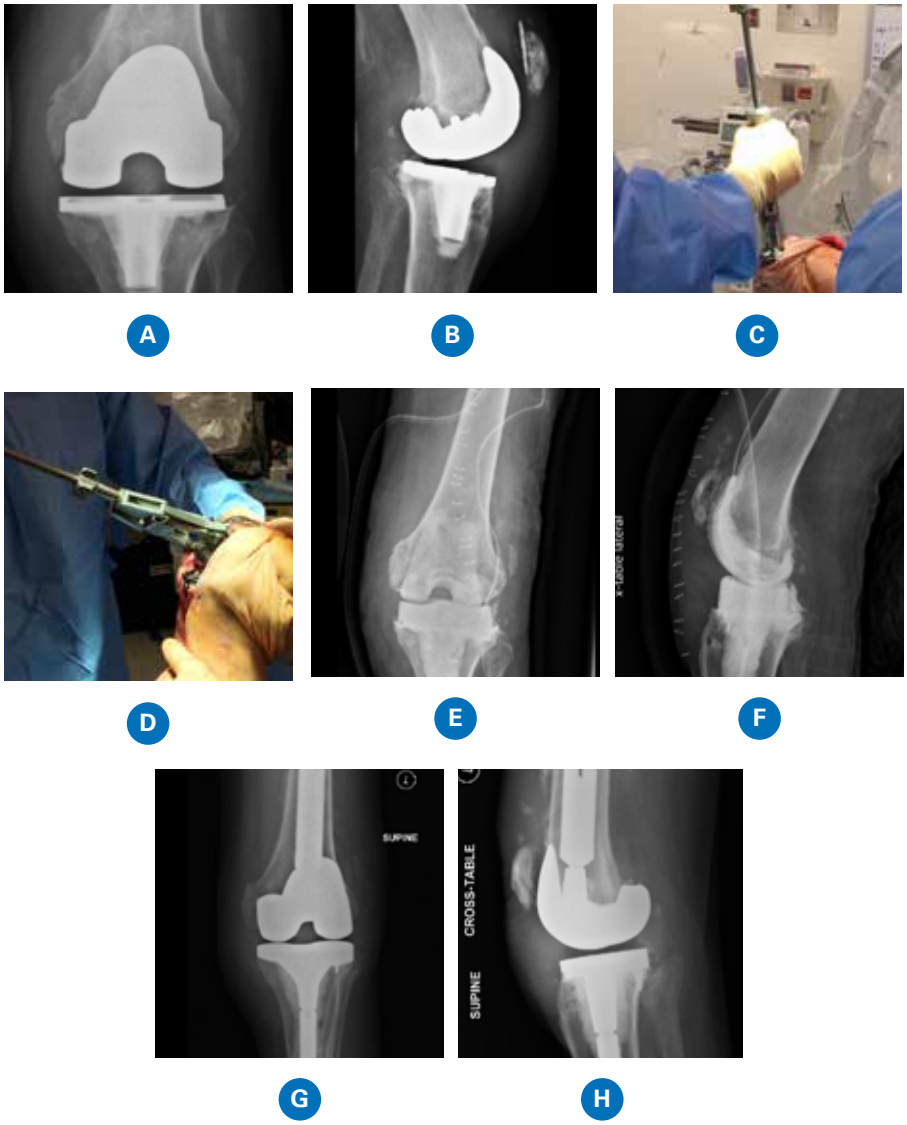


Figure 5.

CASE 6

A 71 year-old female presented to our service status post implant removal and antibiotic spacer placement with gastrocnemius rotational flap coverage at an outside hospital, with loss of patellar tendon at time of initial debridement, as well as failure of her original flap (Figures 6A, 6B). We took the patient for repeat debridement with articulating antibiotic spacer exchange with reconstruction of the patellar tendon with allogenic collagen matrix, followed by free latissimus dorsi flap coverage by the plastic surgery service (Figure 6C). After her IV antibiotic course, remission of infection was achieved, and the patient was taken back to surgery for reimplantation. Intraoperative examination revealed that her extensor mechanism remained intact (Figures 6D, 6E). At six weeks follow up, she is well healed with no evidence of infection, with an intact extensor mechanism, and ambulating with a front wheeled walker.

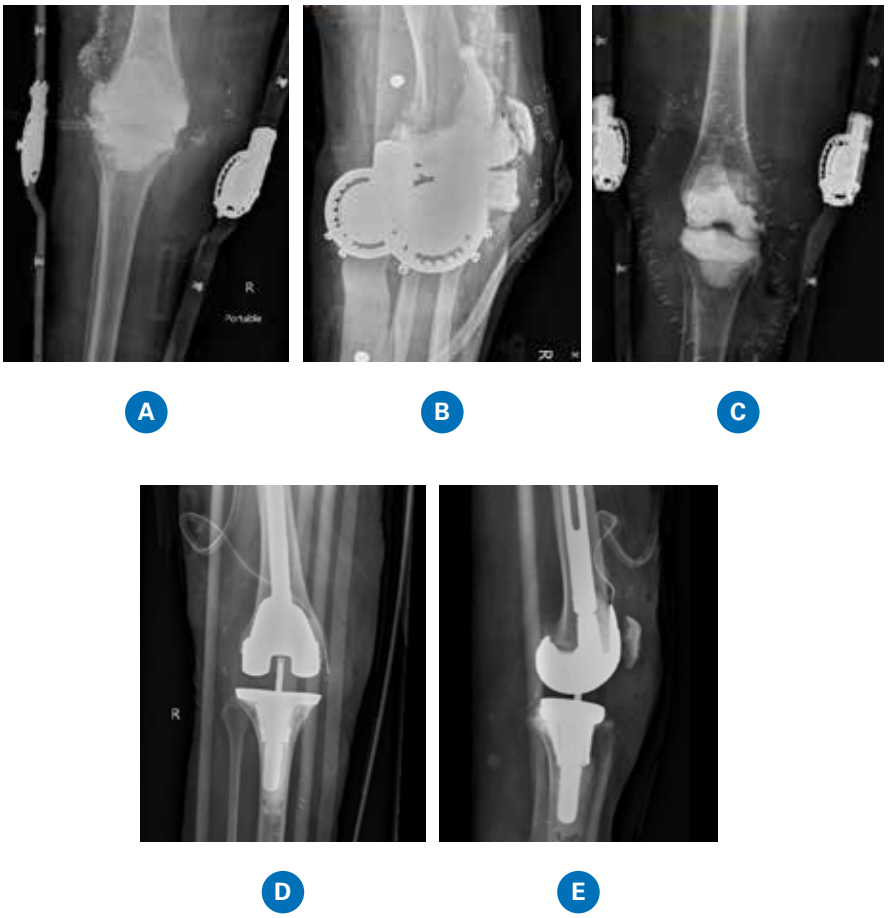
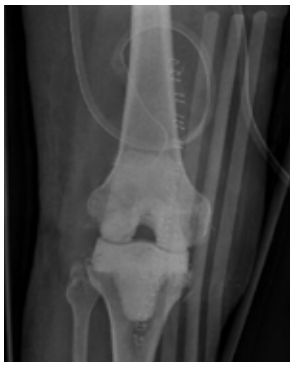


Figure 6.

CASE 7

An 80 year-old male on chronic high dose anticoagulation therapy presented with chronic periprosthetic infection, secondary to *Morganella morganii*. The patient was treated with implant removal and antibiotic spacer placement (Figure 7A, 7B) followed by staged reimplantation (Figures 7C, 7D). At the time of reimplantation, gastrocnemius rotational flap coverage was performed by the orthopedic service, in order to augment attenuated anteromedial soft tissues. At four weeks follow up, the patient is well healed, with no evidence of infection, and ambulatory with a front wheeled walker.



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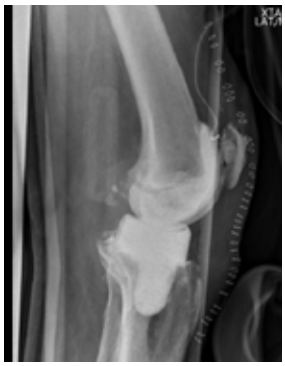

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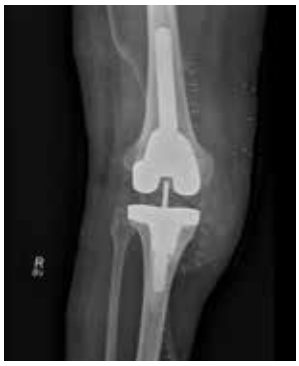

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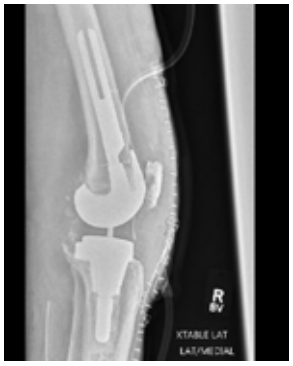

D

DISCUSSION

The treatment of chronic periprosthetic infection of the knee can be challenging, especially with regard to the extensive bone loss and soft tissue compromise that occurs in these cases. Having the optimal equipment with regard to implant removal (especially with well fixed implants in the setting of weakened bone), bone preparation (in the setting of loss of landmarks and weakened fixation platform), articular constraint, fixation dependability, and bone defect management is essential. The new Exactech Optetrak Logic CC system may offer benefits in this regard when compared to older implant systems.

With regard to extraction, Case 1 was used with no specialized extraction devices, and in the hands of the author, medial tibial condylar fracture occurred. Though this healed with plate fixation, the fracture could have caused a more complicated treatment course. In the subsequent cases, a specialized pneumatic cement–implant disruption system (AcuDriver) and extraction device (Exactech extractor) were used, which allow for safe disruption of the bone implant interface, facilitated by the application of axial forces to remove the implant, instead of compressive, bending, or torsional forces, which may predispose bone loss or fracture upon extraction. Since this extraction instrumentation has been used, and implant removal has been achieved with relative ease, with very minimal bone loss and no further bone compromise, in all cases.

With regard to bone preparation, the intramedullary and extramedullary fixation options for cutting guides on both the femoral and tibial sides, provide the significant stability necessary to achieve accurate bone cuts. The low profile and anatomic nature of the cutting blocks and associated instrumentation allow their placement to be facilitated with minimal additional soft tissue dissection. These factors prove very important in the setting of periprosthetic infection management, where bone integrity is often compromised, and preservation of the soft tissue envelope is essential.

With regard to fixation stability and management of bone loss, implant options are essential in achieving a durable long term construct. For example, in Case 7, to achieve optimal femoral stability from both the stem and the distal femoral interface, the 4 mm stem offset function was used, allowing for optimal stem fixation, while conforming well to the patient's natural distal femoral geometry, which proved to be altered from previous surgery (Figures 7C, 7D). Tibial cones prove to be important adjuvants to make up for the central tibial defects that inevitably occur in revision surgery, allowing for the achievement of stability, even with the use of shorter stems (Figures, 6D, 6E, 7C, 7D). Extensive distal femoral augmentation options allow for management of concomitant distal femoral and posterior femoral bone loss, achieving secure geometric stability, even in severe cases (Figures 2E, 2F, 4C, 4D).

With regard to managing constraint, the standard condylar constrained (CC) allows for articular stability to +/- 1.5° of varus/ valgus constraint, and +/- 2° of rotational constraint, as is standard with most revision knee systems, and is very appropriate in the setting of collateral ligament incompetence. A differentiating feature of the Optetrak Logic CC system is the ability to use a PSC tibial insert, which provides +/- 3° of varus/ valgus and +/- 4° of rotational constraint. The system even allows for use of the standard posterior stabilized insert, which provides the least amount of constraint possible in the revision setting. A convenient intra-operative insert trialing system allows for easy determination if the less constrained options are appropriate. In Case 3 and Case 5, because of excellent soft tissue stability and competent collateral ligaments, the less constrained (PSC) insert was chosen. This option to reduce constraint in the event of collateral ligament competence could be very important with regard to optimizing implant longevity, and decreasing unnecessary stresses on the bone – implant interface.[4]

CONCLUSION

The challenges associated with treatment of chronic periprosthetic infection with regard to bone loss and soft tissue compromise offer an ideal model to test the performance and ability of a revision total knee replacement system, which can then be readily applied to less complicated cases. From the extraction instrumentation, to the bone preparation instrumentation, to augmentation and fixation options, to varying levels of constraint, the new Optetrak Logic CC system maintains the ideal of simplicity and ease of use, while still providing extensive features and options that allow for the management of virtually any revision knee arthroplasty scenario. •

See additional case reports with Optetrak Logic CC on page 36.

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A SURGEON'S PERSPECTIVE ON WHY NAVIGATION IS IMPORTANT IN REVISION TOTAL KNEE ARTHROPLASTY

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Stanford University Medical Center

Navigation, or computer-assisted surgery, has been around for many years. Many of us have had experience with at least one of the major systems on the market. Most recently, I have been using ExactechGPS® for my primary TKA procedures. Personally, I have had great success with the system and believe that my patients have benefited accordingly. So when Exactech asked me to be a part of the team to design their new revision knee system, Optetrak Logic® CC, and they informed me that it included an opportunity to develop the first-of-its-kind application to use the ExactechGPS system for revision procedures (rTKA), I was intrigued and ultimately decided to accept the opportunity.

In my career as an orthopedic surgeon, I have performed 750 revision TKAs using most of the major revision knee systems on the market. The majority of these systems had room for improvement. I knew there was an opportunity to create a state-of-the-art system that uses computer-assisted surgery to achieve optimal outcomes in the revision setting. Before I began to think through inputs on how the revision platform for ExactechGPS could be beneficial to surgeons and patients, I knew that it would be helpful to review data on how computer-assisted surgery is being used in the primary knee setting.

During this journey, I realized that most orthopedic surgeons use computer-assisted surgery to achieve better alignment, to be faster in the O.R., to have an overall reduction in instrumentation, to avoid violating the IM canal and be able to access pre and post-op kinematics. For the most part, the majority of these are achieved through the use of computer-assisted surgery in TKA. In fact, one of the most compelling pieces of literature I discovered came out of the 2013 Australian Orthopaedic Association National Joint Replacement Registry. These data showed that when using navigation, there was a 20 percent reduction in the revision burden in patients 65 years of age and younger.[1] Additionally, the research highlighted that in cases where aseptic rTKA was necessary, the primary cause was mechanical loosening of the prosthetic joint (American Joint Replacement Registry & California Joint Replacement Registry 2014).[2] Another study "The Epidemiology of Revision Total Knee Arthroplasty in the United States" found that out of 60,355 knees, 16 percent failed due to mechanical loosening.[3] Adding to the issue of loosening, Sharkey et al. determined that 55.6 percent of revisions were performed less than two years

after the initial operation.[4] These data led me to believe there is a clinical need for computer-assisted surgery in the revision setting. What remains to be seen is if the use of navigation will consistently yield better patient-reported outcomes in the revision setting. Our hypothesis is that we will see improvements in rTKA, based on the success of navigation in the primary setting.

With the conclusion that computer-assisted surgery for rTKA was something we wanted to continue developing, we discussed features and benefits required to: 1) assist with adoption of the technology and 2) to offer an improvement in how revision procedures are performed. We decided to focus on three key goals: 1) increasing the number of orthopedic surgeons performing rTKA procedures, 2) making rTKA procedures easier and more reproducible, and 3) collecting data to see if the use of navigation in the revision setting will yield clinical benefits. Because the number of revision knees in the United States is expected to increase, it was important to the team that the ExactechGPS revision application make it easier for surgeons to perform rTKA procedures without years of revision experience. This goal has been achieved by developing a system that conducts acquisitions from the previously implanted primary knee components, which allows us as surgeons to easily document why it was sub-optimal. A key feature of the revision application is the ability for the surgeon to align with either the mechanical or anatomical axis to produce the desired alignment. Overall, I believe the ExactechGPS revision platform should make revisions easier and more efficient with improved functional outcomes. •

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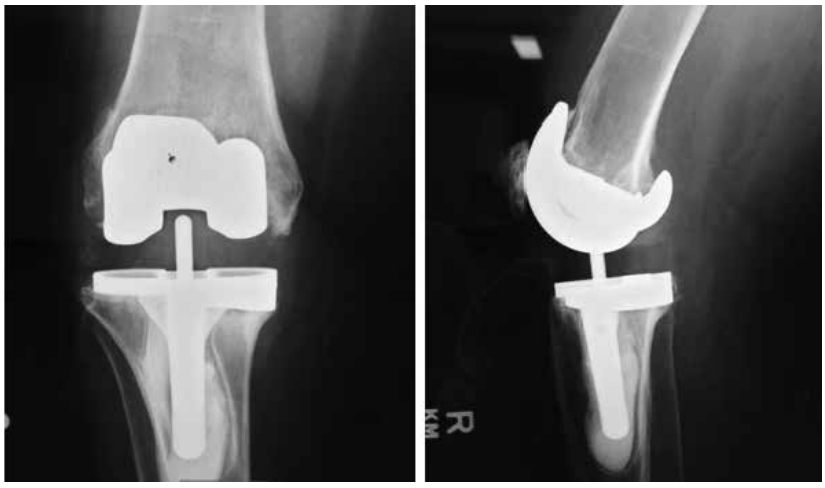
NEW REVISION KNEE SYSTEM TREATS IMPLANT INSTABILITY AND LOOSENING

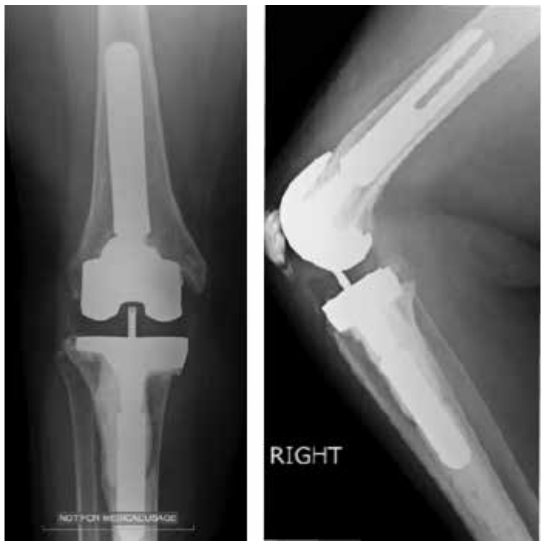
Bernard Stulberg, MD
St Vincent Charity Hospital

A 60 year old female with instability and loosening received the first Optetrak Logic® CC revision knee implant. In this case, a size 2 Optetrak Logic femur with femoral augments and a 22x120mm stem extension, a size 2F/2T Optetrak Logic FIT tibial tray with tibial augments and an 18x80mm stem extension, and a 17mm CC poly were implanted. At her six-month follow-up appointment, she was very happy with the stability of her knee. •

Pre-Op



Six Months Post-Op

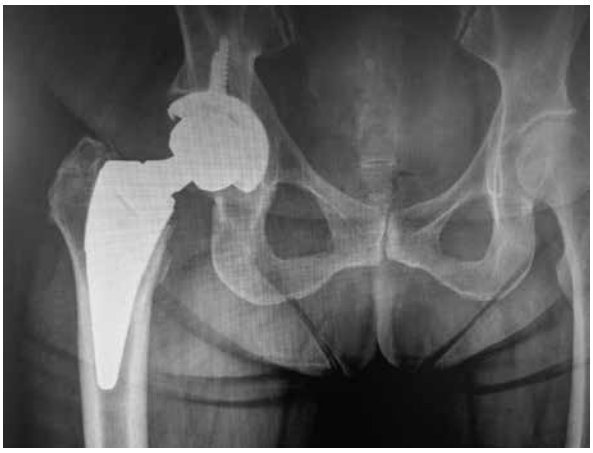


TWO-STAGE REVISION HIP ARTHROPLASTY FOR DEEP PERIPROSTHETIC INFECTION

Timothy J. van de Leur, MD
Fort Wayne Orthopedics

A 68 year old female presented with a deep periprosthetic total hip infection. The infecting organism was MRSA, identified by a serologic test during an irrigation and debridement with retention of the prosthesis while completing a bearing exchange. This treatment failed, which subsequently required a two-stage hip revision arthroplasty. Utilizing the Vancouver Protocol of treating periprosthetic joint infection (3.6 tobramicin and 1.0 vancomicin) the patient underwent irrigation and debridement initially with a hemiarthroplasty cement spacer as detailed below in stage one of a two-stage revision.

Pre-Op

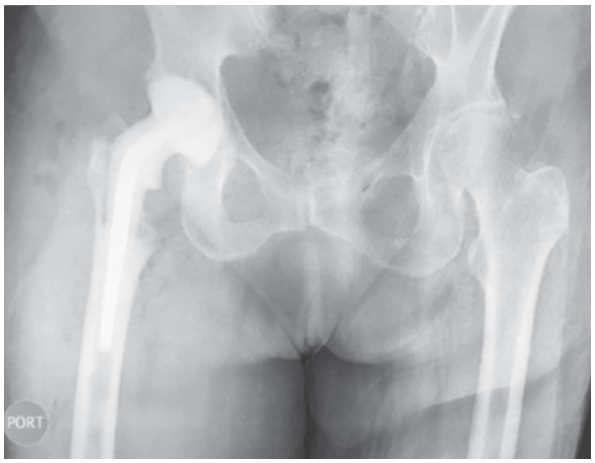


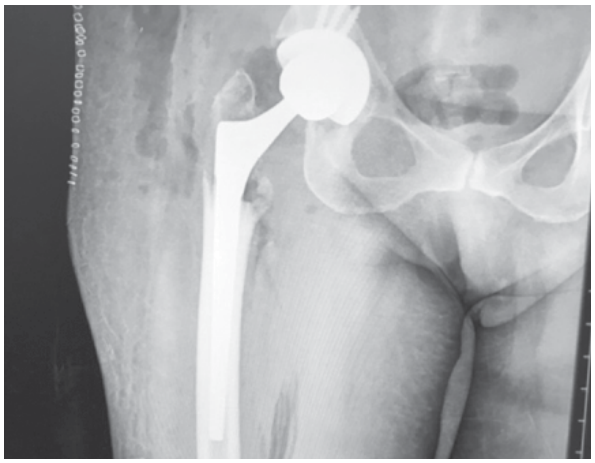
The Exactech InterSpace® Tapered Wedge Stem, a preformed, load-bearing PMMA hip spacer impregnated with gentamicin, was used for six weeks until the infection was eradicated. This particular cement spacer is designed to preserve bone stock due to the geometry of the cross section proximally, allows the patient to ambulate as tolerated (typically 50 percent), and it has a consistent, high-release antibiotic formulation for elution of the antibiotics throughout the time it's implanted. In addition to the gentamicin elution, a combination of further antibiotics was mixed into the bone cement that was used around the most proximal portion of the cement spacer for initial fixation.

Once the patient was documented to be infection free with an ESR/CRP and a hip aspiration, the Exactech Alteon® Monoblock Revision Stem was implanted to complete the two-stage revision. This press-fit, distally fixed, one-piece tapered, splined stem is ideal for reimplantation post InterSpace Tapered Wedge in Paprosky classifications I-IIIb of Femoral Bone Loss. The implant has anti-rotational splines that provide short- and long-term axial and rotational stability in diaphyseal fixation. The instrumentation and trialing system provides a very predictable relationship with the final implant.

The patient is now seven months post-op. She has no signs of radiographic changes to implant positioning and remains infection-free as of last follow up. •

Post-Op



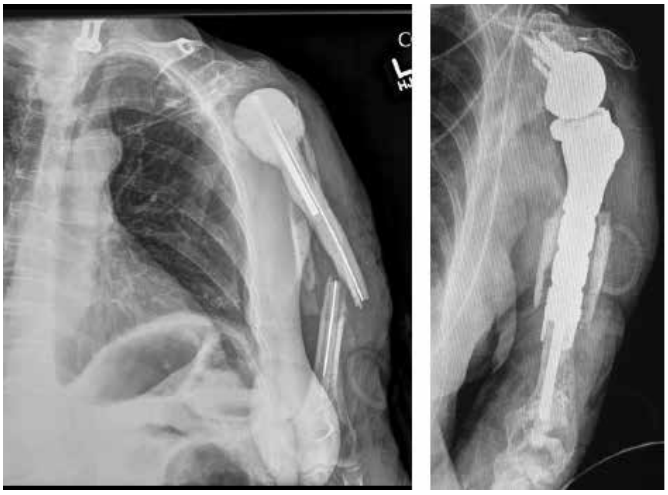


NOVEL PROSTHESIS FOR AN EXTREMELY CHALLENGING SHOULDER REVISION

Thomas Wright, MD
University of Florida

A 74 year old female presented with a comminuted spiral humeral fracture. Her glenoid was severely eroded with irreparable rotator cuff tear, and she had five previous surgeries on the arm. She received an InterSpace® preformed shoulder spacer for a recent infection that was eradicated prior to the revision surgery.

Pre-Op

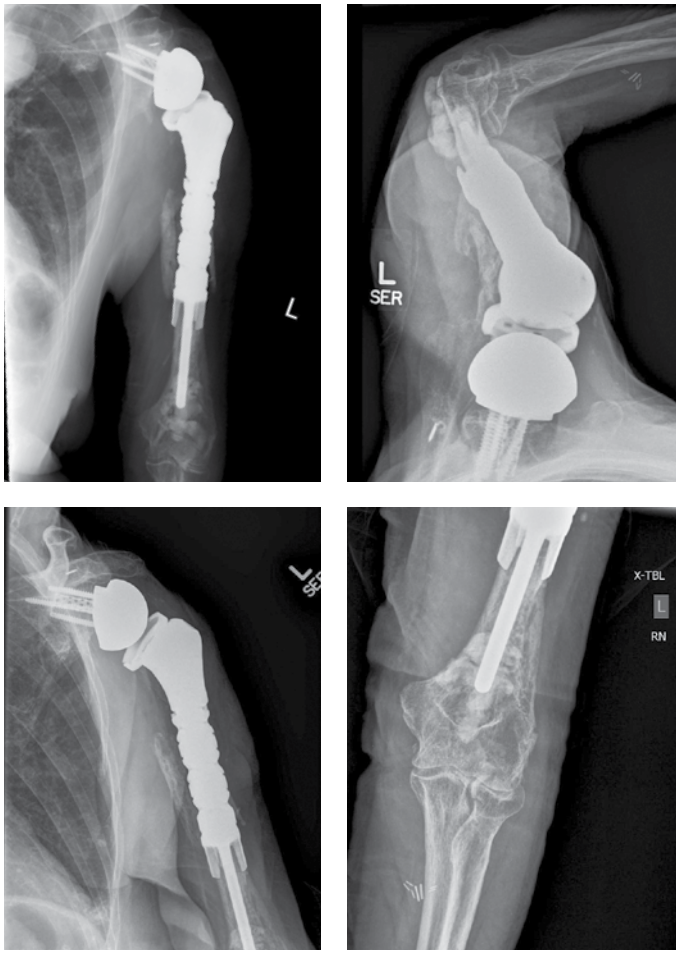


The Equinoxe® Humeral Reconstruction Prosthesis was implanted and secured with a 19mm collar around the humeral diaphysis. A 7x80mm humeral stem was used to obtain distal fixation and bone fragments with the deltoid tuberosity were secured around a 75mm middle segment to achieve soft tissue stability. The modular proximal body was attached to build the prosthesis to help restore the patient's original humeral length. To replace the patient's bone, 147.5mm of build-up was used.

The Equinoxe Humeral Reconstruction Prosthesis is the only device available in the United States with an FDA labeled indication for reverse shoulder arthroplasty with proximal bone loss. This reverse was completed using an Equinoxe expanded glenosphere with an augmented baseplate to obtain glenoid fixation while lateralizing the joint line to achieving sufficient deltoid wrapping and joint stability. An Equinoxe posterior superior augment, 42mm lateralized glenosphere, with a constrained liner also was used.

Prior to the patient's six month post-op follow up, she sustained a fall directly on the prosthesis, and the implant survived. She now has 30 to 130° elbow motion. •

Six Months Post-Op



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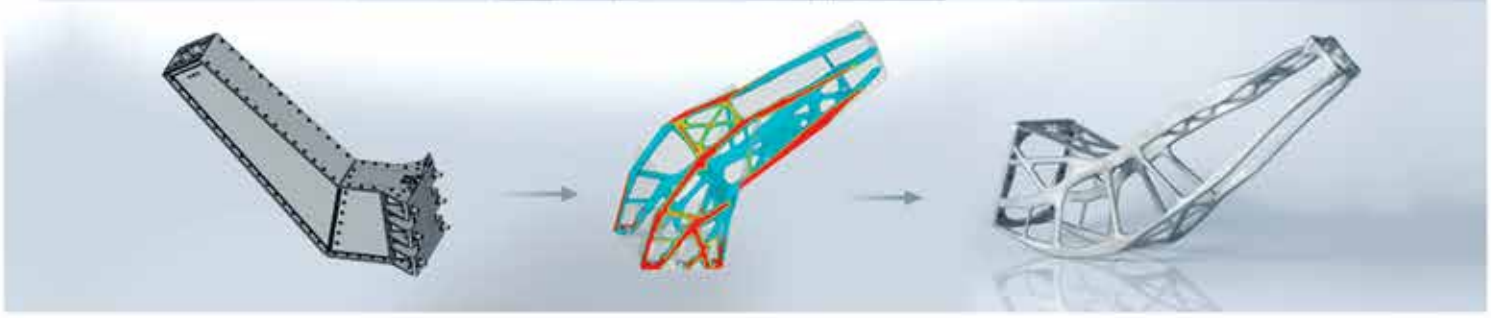

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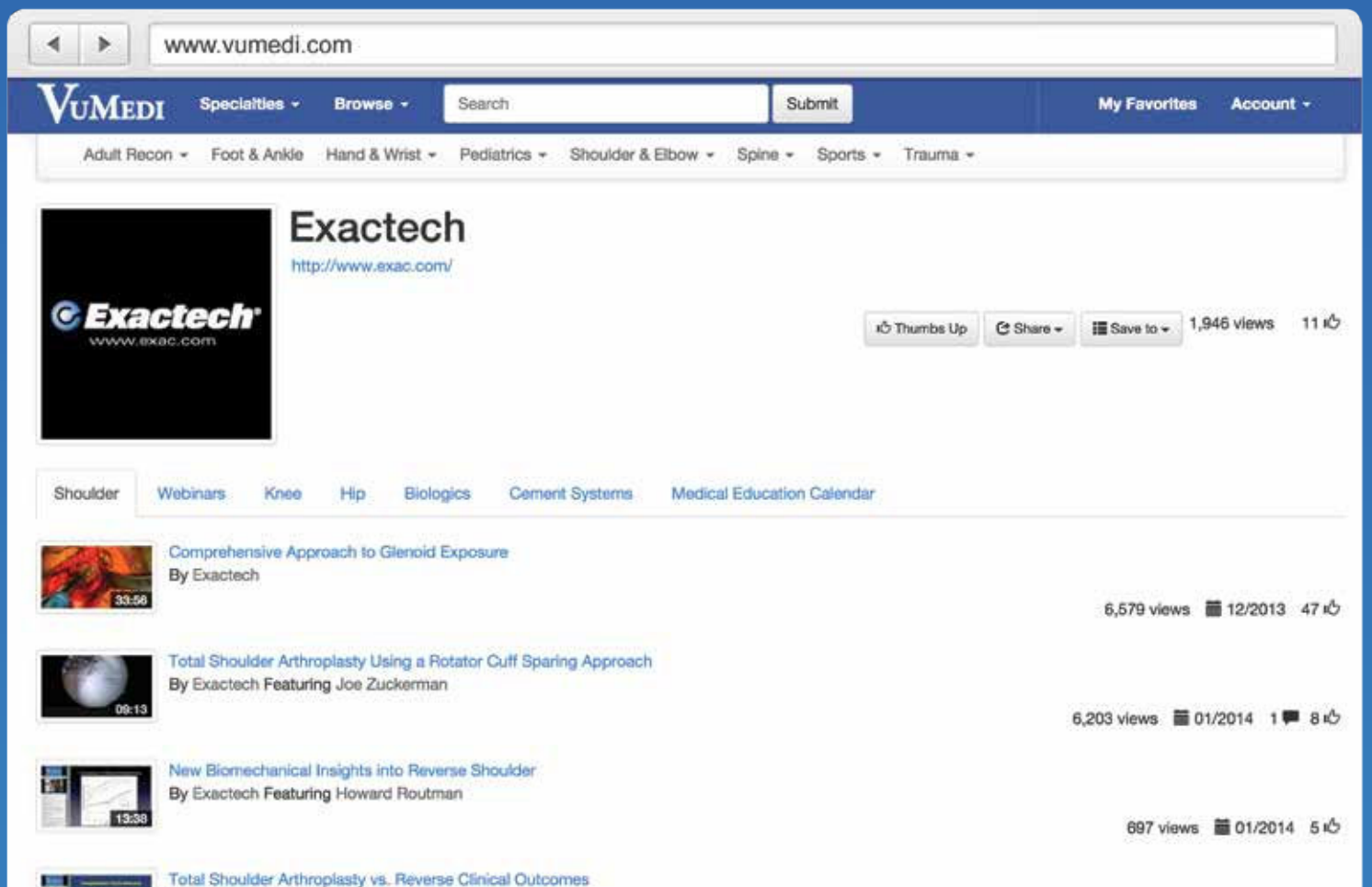

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Lighted Cobra Retractors

PRODUCT NO:	
6210-02L	*Overall Length: 12.5" Blade and Tip Length: 3" Blade Width: 15mm*

Lighted Single Prong Double Bent Hohmann Acetabular Retractor – Long

PRODUCT NO:	
6255-L	*Overall Length: 12" Handle Length: 8" Blade Width: 32mm*

Lighted Inferior Acetabular Retractor

Jana Sheilded Lighted Cobra Retractor

Designed by Ajoy K. Jana, MD

Designed to enhance exposure, visualization and protect the removable light source

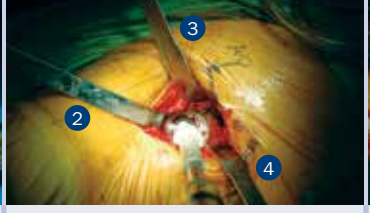
Excellent for use in acetabular exposure and total hip replacements. Especially useful for anterior approach.

New!

PRODUCT NO:	
6119-L	*Overall Length: 14.2" Blade at Widest: 33 mm*

USA MADE

Exposure of the hip joint & removal of the femoral head



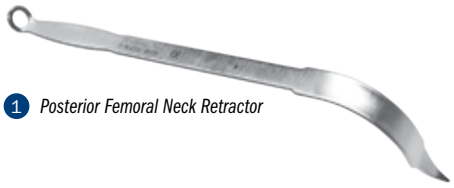
Acetabular exposure, reaming and cup insertion

Femoral broaching and stem insertion

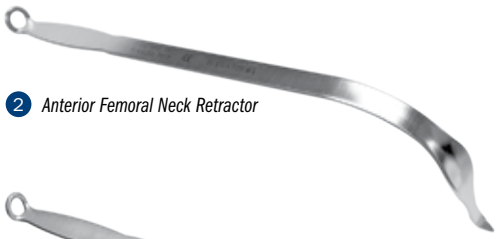
Das/Seng Anterior Total Hip Instruments

Designed by Amal Das, MD and Brian Seng, DO

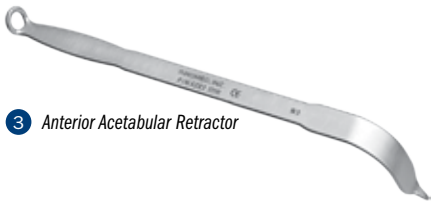
Retractor set with included table-mounted controlled-release ratcheting elevator hook, specifically designed to help simplify anterior approach total hip arthroplasty



1 *Posterior Femoral Neck Retractor*



2 *Anterior Femoral Neck Retractor*

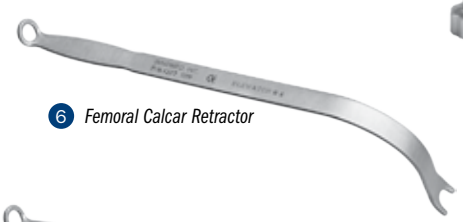


3 *Anterior Acetabular Retractor*

4 *Posterior Acetabular Retractor*

5 *Elevator Hook*

Table Assembly 8



6 *Femoral Calcar Retractor*

7 *Greater Trochanter Retractor*

PRODUCT NO'S:	
1 6221 [#1 - Posterior Femoral Neck Retractor]	*Blade Width: 25mm Blade Depth: 3" Overall Length: 14"*
2 6222 [#2 - Anterior Femoral Neck Retractor]	*Blade Width: 31.5mm, 10mm @ Tip Blade Depth: 4.5" Overall Length: 15"*
3 6223 [#3 - Anterior Acetabular Retractor]	*Blade Width: 25mm Blade Depth: 2.25" Overall Length: 13.25"*
4 6224 [#4 - Posterior Acetabular Retractor]	*Blade Width: 25mm Blade Depth: 2.75" Overall Length: 14"*

5 6226-RH [#5A - Round Elevator Hook]	*Blade Width: 10mm Blade Depth from T-Handle: 5.75" Overall Length: 9.25"*
6 6227 [#6 - Femoral Calcar Retractor]	*Blade Width: 25mm Blade Depth: 3.625" Overall Length: 14"*
7 6225 [#7 - Greater Trochanter Retractor]	*Blade Width: 25mm Blade Depth: 2.5" Overall Length: 14.25"*
8 6226-TA [#8 - Table Assembly]	*This product number includes one 6226-RH Elevator Hook Folds to approx: 21" x 5" x 5"*

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