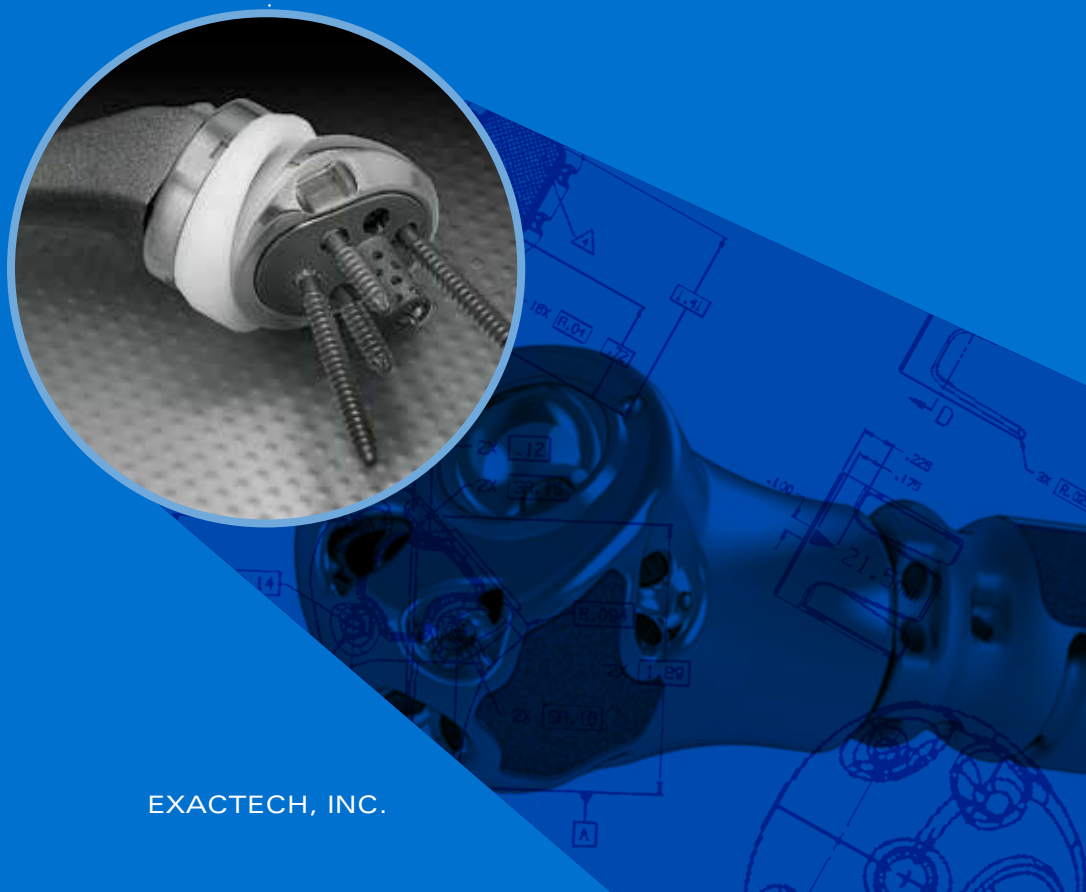
INNOVATIONS

A CLINICAL EXCHANGE ON ADVANCES IN ORTHOPAEDICS

ISSUE 1

PREMIERE ISSUE



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Fri., July 10	Chicago, IL	Gregory Gilot, MD; Moby Parsons, MD; Howard Routman, DO
Fri., Aug. 28	Kansas City, MO	Doug Lowery, MD; Kaveh Sajadi, MD
Fri., Sept. 25*	New York, NY	Pierre-Henri Flurin, MD; Robert Fullick, MD; Curtis Noel, MD; Ryan Simovitch, MD; Joseph Zuckerman, MD
Fri., Oct. 2	Asheville, NC	Lynn Crosby, MD; Kevin Farmer, MD; Richard Jones, MD
Fri., Oct. 16	Cincinnati, OH	Doug Lowery, MD; Stephen Maurer, MD; Kaveh Sajadi, MD
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As we continue to extend surgeon-focused, patient-driven service, we are excited to introduce "Innovations: A Clinical Exchange on Advances in Orthopaedics." With articles authored largely by your clinician peers, this publication is meant to aid you in your practice, focusing on clinical data, patient outcomes and efficiency.

This edition includes topics such as the argument for computer-assisted surgery (p. 2), the effect of computer-assisted surgery on operating time (p. 5), reflections on the past and future of shoulder arthroplasty (p. 8), patient outcomes from a neck-preserving approach to hip reconstruction (p. 12), scientific article reviews for proximal humerus fractures and peer-reviewed articles in brief for treating infected joints (p. 19).

We hope you enjoy Innovations and find its contents both useful and engaging. Feel free to share it with your colleagues, and we welcome your feedback to www.exac.com/innovations. Thank you for being an Exactech partner. We look forward to continuing this journey together toward improving patient care. •

WHY COMPUTER-ASSISTED SURGERY NOW?

Bernard Stulberg, MD
St. Vincent Charity
Medical Center

In an era where technological developments have led to greater and simplified communications, better products and generally lower overall costs in most activities we participate in, it remains puzzling that the use of technologically advanced tools to provide improved feedback to surgeons has not found widespread use. It is particularly puzzling that such has been the case in total knee arthroplasty (TKA) over the past decade, where the accumulated data supports substantially improved precision[1] in an operation where precision is critical to long-term success.

Computer-assisted orthopaedic surgery (CAOS) technologies for TKA were introduced in late 1999 and 2000, and the early devices used were slowly introduced into the marketplace in 2001 and 2002. I introduced CAOS for TKA in my practice in late 2003, and began using it routinely in 2004. Throughout that period of time there was continuous but cautious evolution of the software, and its adoption by the large proportion of TKA surgeons was minimal (<1%). Despite these evolutions,

My experience with 503 TKAs performed with CAOS techniques was a clinical failure rate of less than 2 percent, with one failure due to malalignment, two infections and one fracture above the implant unrelated to the CAOS procedure.

my own personal experience with 503 TKAs performed with CAOS techniques was a clinical failure rate of less than 2 percent, with one failure due to malalignment, two infections and one fracture above the implant unrelated to the CAOS procedure.

My experience was a small one among a broad population of interested investigators who have continued to demonstrate improved consistency of alignment for femoral and tibial components in all planes (90-95 percent consistency versus 70-75 percent with standard mechanical instrumentation). A meta-analysis by Hetaimish et al. revealed that patients undergoing navigated TKA demonstrated a significant improvement in prosthesis alignment.[2]

This demonstrated improvement in alignment has led many to infer a direct causation to a reduction in revision rates for patients who have undergone navigated TKA. This reduction in revision rates is highlighted by the 2014 Australian Registry data showing a 20 percent reduction in revisions at the nine-year follow-up for patients

less than 65 years of age when computer-assisted surgery was used.

These improved clinical outcomes, and reduction in revisions, have made a direct impact on patient outcomes following navigated TKA. A 2013 meta-analysis by Rebal et al. conducted literature searches for Level 1 randomized trials that compared TKA using imageless computer navigation to those performed with conventional instruments. The results of the meta-analysis concluded TKA using imageless computer navigation provided more accurate alignment and superior functional outcomes at short-term follow-up.[3]

More recently, there has been great interest in patient specific instrumentation (PSI), an approach that uses three-dimensional imaging modalities (i.e., CT or MRI) to reconstruct the geometry of the knee joint and allow an engineer to design pre-formed cutting blocks or pin blocks to properly position standard instrumentation. While popular because of their marketed ease of use, PSI technology has met with variable success due to the inconsistency of the results in the hands of experts[4], and its inability to be used in every case. It is interesting that CAOS has been used in some studies to confirm PSI's accuracy, and there are reported studies where its improvement compared to standard instrumentation was in the 85-90 percent range, where alignment with standard instrumentation was 70-75 percent.[4]

Computer-assisted TKA should be the initial approach for most surgeons, as this technology is the "gold-standard" of implant alignment and will be the foundation to document further improvements in precision of our procedures.

I believe that the time to become familiar with, and to routinely use, quantitative techniques to assist in implanting total knee prosthesis is NOW. Not only because the newer approaches to navigation allow us to position and evaluate kinematic performance of our implants intraoperatively, rapidly, and with no or little additional time[5], but also because they allow us to document what we have performed, and to help us form judgments about the performance of our operations to continually improve. In an era where we must demonstrate the VALUE of what we do, such an approach is critical. I would also suggest that computer-assisted

ExactechGPS® Guided Personalized Surgery

TKA should be the initial approach for most surgeons, as this technology is the "gold-standard" of implant alignment and will be the foundation to document further improvements in precision of our procedures.

I think that the ExactechGPS® system, in particular, has merged the computational improvements in the field with innovative instrumentation to enhance user friendliness of CAOS techniques through an approach that miniaturizes the equipment, improves clarity of understanding of baseline abnormalities through its morphing technology, allows customization of the software to fit each individual surgeon's approach, and helps decrease the cost of the intervention by improving the predictability of implant placement and balancing, to enhance the recovery process and overall outcome.

Because alignment and stability data provide the baseline data upon which other 3-D technologies are based, (such as PSI technologies), these can easily be incorporated into the system. As such, PSI through this technique now allows the surgeon to provide the data, use the software to plan the size of component and position the components and position the pins for the cutting blocks — just as in PSI done remotely. But it also allows intraoperative adjustment by the surgeon, feedback that the resections are appropriate/accurate, and then kinematic feedback as to how these judgments have led to a properly balanced TKA — all in about the same time it takes to perform a primary TKA with mechanical instruments (+/- 5 minutes).[5] Clearly this is moving the technology in the right direction. Further approaches, such as to address the predictability of revision TKA with CAOS techniques, are not far away.

These newer approaches to TKA with CAOS, and ExactechGPS in particular, are continuing to evolve rapidly to make the instrumentation and software intuitive and desirable while avoiding the major inconveniences of the more traditional CAOS systems.

I encourage you to try them, commit a certain number of TKA surgeries to them, and then assess if you have found it useful. I think you will find, as I did, that it will help you become an even better TKA surgeon. •

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SCIENTIFIC ARTICLE

DOES COMPUTER-ASSISTED SURGERY INCREASE OPERATING TIME?

Pasquale Petrera, MD
Peninsula Orthopaedic Associates

James Petrera

INTRODUCTION

Success in total knee arthroplasty (TKA) depends on many factors. Although TKA is a very common procedure, approximately one in five primary TKA patients were not satisfied with the outcome following their surgery.[1] Traditional computer-assisted orthopaedic surgery (CAOS) has been shown to increase accuracy and improve clinical outcomes in TKA.[2] One of the main perceived drawbacks to traditional CAOS relates to an increased operating time when compared to a conventional TKA technique using standard mechanical instrumentation.

This study compared operating times, from incision to dressing, for TKA using conventional instruments to TKA associated with different levels of experience using a novel CAOS guidance system (ExactechGPS®, BlueOrtho, Grenoble, FR).

METHODS

This retrospective review compares operating times associated with three groups of 21 patients each. Conventional mechanical instrumentation was used for Group I (i.e., the control group). Group II represented early experiences using the CAOS guidance system (i.e., navigated cases #1 to 21) and Group III represented advanced experiences using the CAOS guidance system (i.e., navigated cases #75 to #96). All TKAs were performed by the senior author using spinal anesthesia with tourniquet.

No cases were excluded. All TKA procedures were performed using the same TKA system (Optetrak Logic® PS, Exactech, Inc., Gainesville, Fla.).

Compared to the conventional mechanical instrumentation, the differences in average operating times were an increase of seven minutes for the early CAOS guidance system experiences and a decrease of two minutes for the advanced CAOS guidance system experiences.

RESULTS

Compared to the conventional mechanical instrumentation, the differences in average operating times were an increase of seven minutes for the early CAOS guidance system experiences and a decrease of two minutes for the advanced CAOS guidance

system experiences (see Table I). Also, it was observed that the advanced CAOS guidance system experiences were associated with the lowest standard deviation among the three groups. None of these differences were significant.

Table I: Operating times among the three groups of patients

Group	I	II	III
Average operating time (minutes)	99	106	97
P-value (Compared to Group I)	N/A	0.201	0.690
Range (minutes)	79–134	71–144	79–131
Standard deviation (minutes)	15.2	17.7	13.9

DISCUSSION

It should be expected that introducing any new equipment or technology into the operating room may have an impact on the total operating time. This accounts for the learning curve of both the hospital staff becoming familiar with setting up and preparing instrumentation, as well as the learning curve the surgeon will experience initially while conducting the surgery. This being said, the results of this study demonstrated that once an initial learning curve is reached, usage of the ExactechGPS does not increase operative time compared to conventional mechanical instrumentation for TKA procedure; which departs from the conclusion of previously published literature.[3] It should be mentioned that even the first cases associated with the evaluated CAOS guidance system were associated with a small increase of the operating time, which is remarkable considering that the few initial cases were associated with training of the OR members.

Compared to other CAOS technologies, ExactechGPS' surgeon profiler allows surgeons to create a fully customizable workflows based on their preferences and patient indications. ExactechGPS' hardware technology is represented by a unique display unit featuring a touch screen and built-in proprietary optical camera. During surgery, the display unit is advantageously located on the contralateral side of the patient and draped inside the sterile field.

CONCLUSIONS

Following the initial learning curve, the average operating time for the TKA procedures performed using ExactechGPS proved to be equivalent to conventionally instrumented TKA procedures. ExactechGPS represents a unique package combining the accuracy of standard navigation systems[4] with personalization options in a user-friendly environment, helping achieve efficacy and efficiency in the intense environment of the operating room. •

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REFLECTIONS ON A 10-YEAR COLLABORATION

Joseph Zuckerman, MD
NYU Hospital for Joint Diseases

When I was approached by Exactech in 2003 to get involved in the development of the Equinoxe® shoulder arthroplasty system, little did I know that 10 years later I would be part of the fastest-growing system in the United States.

During my first 20 years in practice, I declined many opportunities to be involved in implant design. I didn't feel it was the right time in my career, and I was also concerned about avoiding conflicts of interest. When I was first approached by an Exactech representative, who I had known since I began practicing medicine in 1984, my decision to meet with Exactech was based on my long-standing relationship with him.

I knew of Exactech founders Bill Petty, MD and Gary Miller, PhD from their days at the University of Florida. It also was my interactions with Exactech product development experts that convinced me to move to the next stage of participating on the Equinoxe design team: meeting my potential collaborators Tom Wright, MD, and Pierre-Henri Flurin, MD.

Tom and Henri were fundamental to my participation on the Equinoxe design team. Tom is a skilled clinician and a very smart person, but most importantly he is a "regular guy," who is easy to work with, easy to talk to and easy to collaborate with. Henri is an outstanding shoulder arthroplasty surgeon and collaborator who brought tremendous knowledge and experience to the team. Everyone on our design team is comfortable with each other, we like one another and we look forward to our meetings.

Tom and Henri were fundamental to my participation on the Equinoxe design team.

With the close working relationship we developed, we built on Henri's replicator plate design to bring a complete shoulder arthroplasty system to market. It was—and still is—the only system that provides *in-situ* adjustment of retroversion, neck angle, medial and posterior offset of the humeral head.

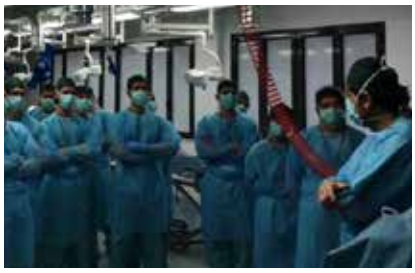
Over the years, we have worked together to create the first platform stem that allows surgeons to convert an aTSA to a rTSA without stem removal, and we developed a philosophy to conserve glenoid bone with augments and cage designs. Our goal was to minimize complications, such as scapular notching, that we had seen with other implant designs.

"The rest is history," as they say. Since 2003 we have added new members to our design team, our engineering team and our product development team. Strong collaboration is also an important part of our clinical evaluators program. The meetings we have with our clinical evaluators embody the basic approach we have followed since the beginning: we recognize the importance of relationships and we work hard to support them in any way we can.

To be successful in orthopaedics, of course we had to develop a superior and innovative product. But the single, most-important factor driving our success with the Equinoxe shoulder system is the relationships that developed from that first day more than 10 years ago. •

"In 2003, I was approached by Phil Matinale, who was working for Exactech. I had known Phil since I started in practice in 1984. Phil and I developed a very nice relationship that has continued through the years." **—Joseph Zuckerman, MD**

The Equinoxe core design team, collaborating since 2003.



From didactic lectures to cadaver courses to surgeon-to-surgeon training, the design surgeons' participation in medical education is critical to helping surgeons improve their outcomes.

Equinoxe technical exhibit at the European Society for Shoulder and Elbow Surgery SECEC Congress.

Advertising Equinoxe at The American Academy of Orthopaedic Surgeons AAOS Annual Meeting in San Diego.

Recent members of the Equinoxe team. "Without exception, each person we've added to the team has fit in very well and developed relationships that are productive, constructive and meaningful. This is nothing less than the foundational elements of the success of the Equinoxe."**—Joseph Zuckerman, MD**

Members of the Equinoxe team in 2003. "Although I wasn't quite convinced Darin Johnson [pictured fourth from the left] really played baseball at a Division I school (if you consider Ivy League baseball Division I), I liked what Darin had to say and what I learned about Exactech." **—Joseph Zuckerman, MD**

EQUINOXE®: CELEBRATING 10 YEARS OF CLINICAL USE

SHOULDER ARTHROPLASTY: THE NEXT 10 YEARS

Moby Parsons, MD
Seacoast Orthopaedics
and Sports Medicine

Arthroplasty remains an incredible intervention for patients with degenerative joint and tendon disease for which there is yet no biological solution. Although metal and plastic are foreign materials, our ability to engineer them in ways that recreates native anatomy and restores joint function is miraculous for those afflicted with pain and functional demise. Nevertheless, the durability of shoulder arthroplasty is limited both by the imminent wear of these materials as well as the forces that act upon them in relation to the underlying host bone and its pattern and degree of erosion. In the past decade, we have come to appreciate the difficulties in addressing posterior glenoid erosion; and recent advancements, like augmented glenoids, have improved our ability to address these defects while preserving host bone and joint biomechanics. The next decade will see evolutionary forward progress in materials science, prosthesis design, surgical planning and surgical techniques. These in turn will lead to revolutionary advancements that will relegate the current state of arthroplasty into historical perspective.

Such forward progress will also confront the challenge that healthcare reform and value-based purchasing pose to scientific innovation, in that new technologies must improve value in cost-effective ways. This is particularly pertinent as the burden of arthritis at a public health level brings itself to bear on heath care delivery and health economics. A look at past use and forward projections shows the rate of shoulder replacement is doubling about every 10 years and is estimated to reach about 55,000-60,000 cases per year by 2025. The fastest increase is in reverse arthroplasty, which is steadily overtaking anatomical shoulder arthroplasty as its indications widen. In addition, more patients are presenting in their 40s and 50s with advanced arthritis or irreparable rotator cuff tears. These patients seek solutions that permit strenuous employment, high physical demand and sustained durability to mitigate the need for revision surgery. The synthesis of mechanical engineering and biomedical engineering will aim to confront these challenges and provide innovative, lasting solutions that translate directly into better long-term outcomes for patients, both individually and at a public health level. •

Recent advancements, like augmented glenoids, have improved our ability to address these defects while preserving host bone and joint biomechanics.

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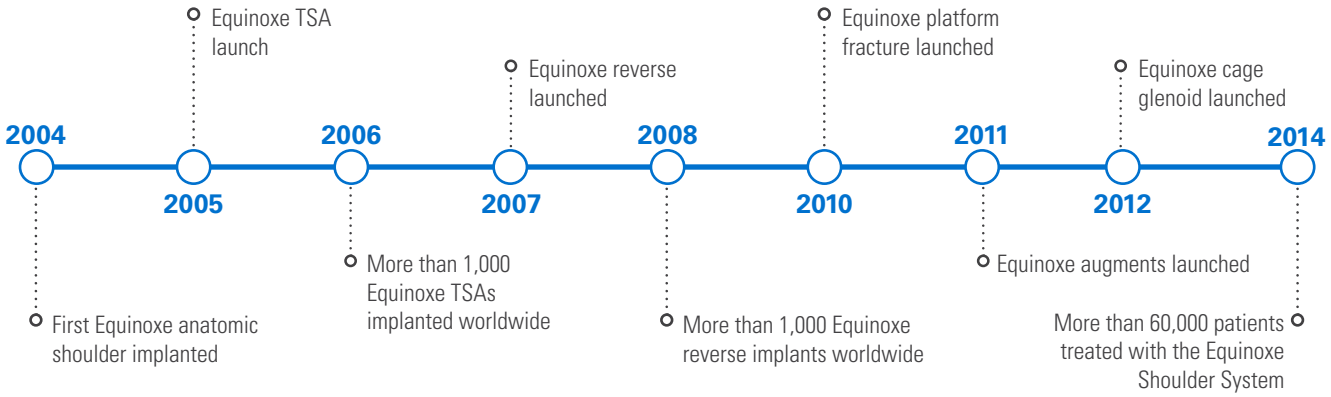
MILESTONES IN SHOULDER ARTHROPLASTY



As follows is a glimpse of where such innovation will lead shoulder arthroplasty both in terms of clinical care, clinical outcomes and biomedical engineering.

Evolutionary Changes

- Shorter humeral stems and an increasing use of resurfacing heads in both hemiarthroplasty and total shoulder arthroplasty will allow bone conservation on the humeral side.
- Tissue-sparing approaches, including preservation of the subscapularis insertion, will facilitate more rapid recovery and allow shoulder arthroplasty to increasingly be performed safely in an outpatient setting.
- Improvements in prosthesis design such as augmented glenoids will allow surgeons to better manage glenoid erosion and wear while preserving bone stock and proper rotator cuff tension.
- Joint registries and improved capture of retrieved failed glenoids will provide a more thorough understanding of modes of glenoid failure that will in turn lead to advancements in wear resistance, hybrid fixation and shape modification.
- Enhanced imaging and computer modeling and navigation will increasingly allow surgeons to virtually plan and perform the procedure preoperatively. These same technologies along with patient-specific instrumentation will allow improved placement of both anatomical and reverse prostheses that restore proper glenoid orientation, offset and bone fixation.
- Data analytics and the drive to improve patient value will innovate clinical care toward the goal of zero complications both medically and surgically.

Revolutionary Changes

- Materials innovation will allow for plastics that have more cartilage-like properties allowing deformation and compliance. Similarly, metals will continue to take on properties more like bone reducing problems like stress shielding and improving biological fixation on both sides of the joint.
- Progress in biomaterials will assist the incorporation of living tissue into mechanical scaffolds that will allow self-healing and remodeling of resurfaced joints.
- The increasing pervasion of 3-D printing in combination with imaging modalities will allow mass customization driving toward patient-specific implants designed to match native anatomy while addressing bone deficiency and wear.
- Finally, 3-D printing of biological tissues may advance to the point where foreign materials can be avoided altogether and joint replacement will be a purely biological procedure.

CASE REPORT

A NECK-PRESERVING APPROACH TO HIP RECON-STRUCTION

John Aldridge, MD
Hampton Roads
Orthopaedics and Sports
Medicine

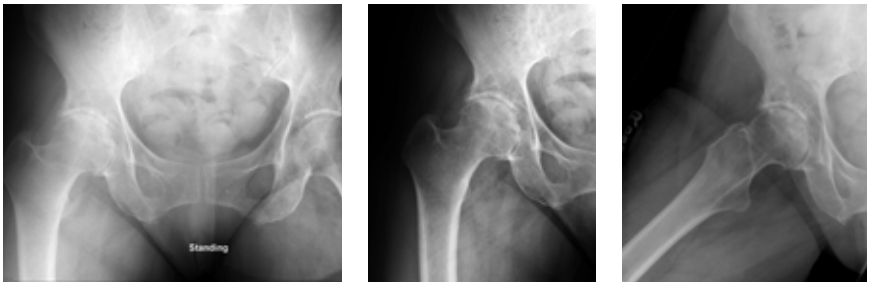
Radiographs are captured and evaluated by an independent reviewer.

CONCLUSION

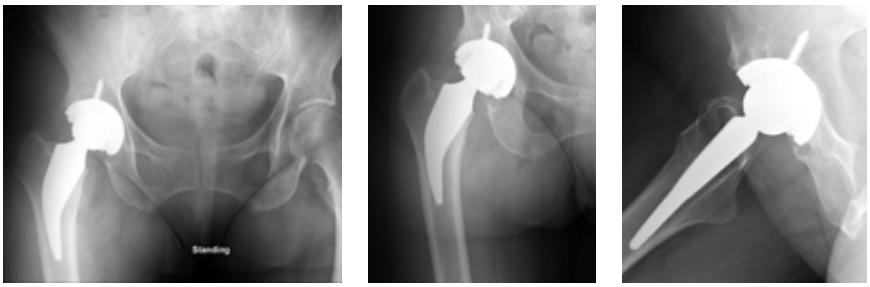
Before surgery, this patient presented low Harris Hip and Oxford Hip scores. Once she reached her one-year follow up, her scores increased by more than 63.0 percent on the Harris Hip and 60.4 percent on the Oxford Hip. The patient is satisfied with her total hip replacement with the direct anterior approach, which has been associated with faster functional recovery than the posterolateral approach. The outcomes of her surgery continue to be followed annually.

A 67-year-old Caucasian female weighing 190lbs diagnosed with osteo/degenerative arthritis received Exactech's Alteon® Neck Preserving Stem with a Biolox®-*delta* femoral head and Novation® Crown Cup acetabular shell. The patient went under general anesthesia using a direct anterior surgical approach with an incision size of 10cm. There was an estimated blood loss of 150cc and surgery duration was 41 minutes. The patient was discharged after one day postoperative with a walker to in-home care for rehabilitation. •

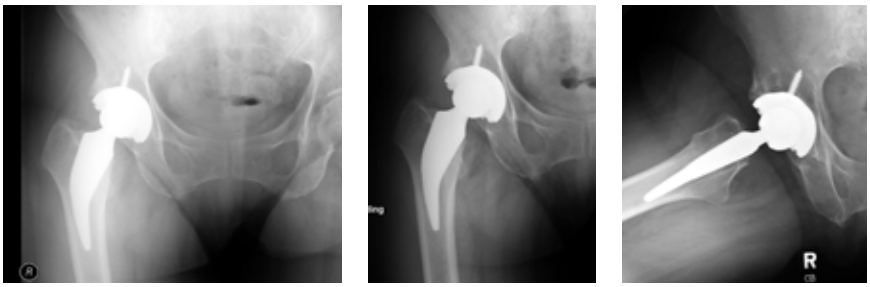
Pre-Op AP Pelvis | **Harris Hip Score 37 (max=100)**
Oxford Hip Score 19 (max=48)



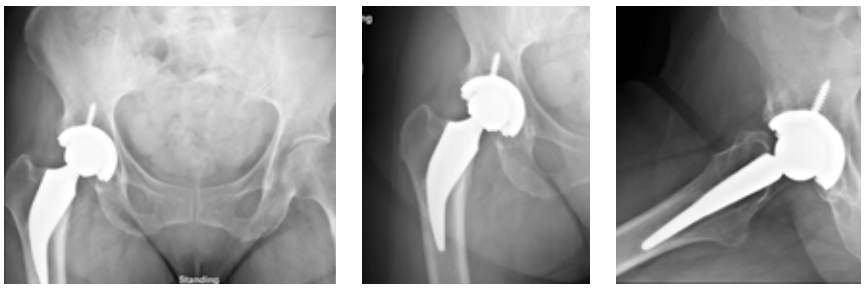
6-Week Post-Op | **Harris Hip Score 98 (max=100)**
Oxford Hip Score N/A



3-Month Post-Op | **Harris Hip Score 94 (max=100)**
Oxford Hip Score 43 (max=48)



1-Year Post-Op | **Harris Hip Score 100 (max=100)**
Oxford Hip Score 48 (max=48)

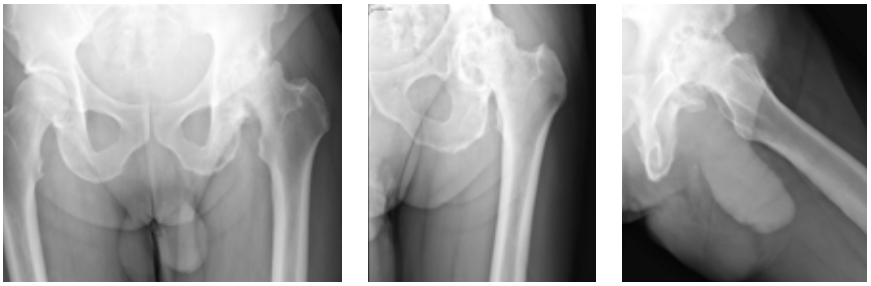


A 62-year-old African American male weighing 185lbs diagnosed with osteo/degenerative arthritis received Exactech's Alteon Neck Preserving stem with a Biolox®*delta* femoral head and InteGrip® acetabular shell. The patient underwent general anesthesia using a direct anterior surgical approach with an incision size of 9cm. There was an estimated blood loss of 200cc and surgery duration was 30 minutes. The patient was discharged the same day as the operation with a walker to in home care for rehabilitation. •

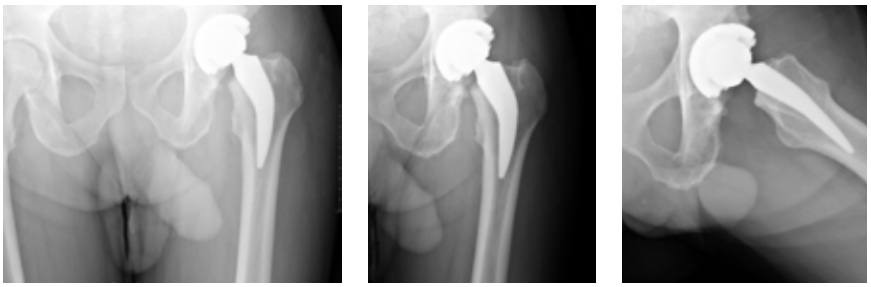
CONCLUSION

This patient presented with low Harris Hip and Oxford Hip scores before his total hip replacement. The direct anterior approach, which was used in this surgery, has been associated with faster functional recovery than the posterolateral approach. One year after surgery, his Harris Hip score increased by more than 50.0 percent, and his Oxford Hip score increased by more than 58.7 percent. The outcomes of his surgery continue to be followed each year, and the patient is satisfied with his total hip replacement.

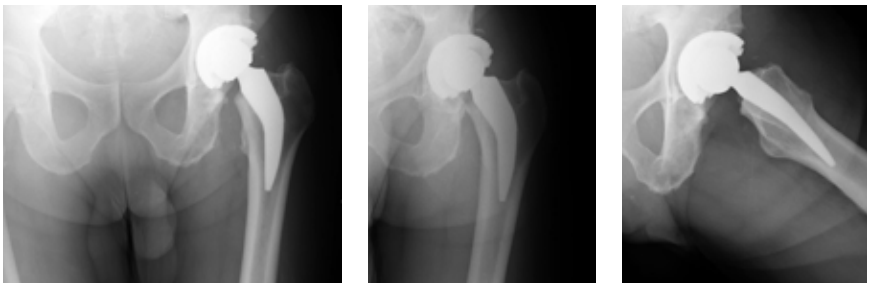
Pre-Op AP Pelvis | **Harris Hip Score 48 (max=100)**
Oxford Hip Score 19 (max=48)



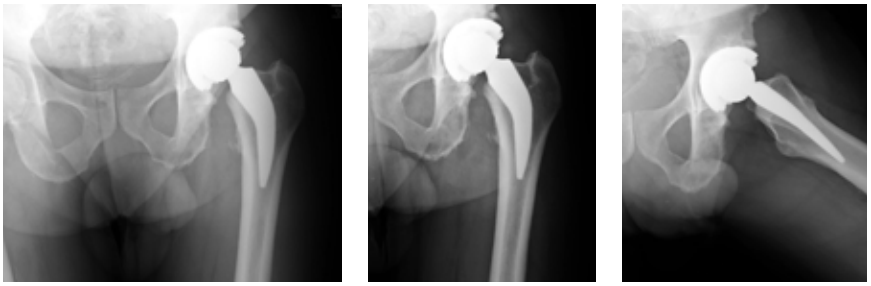
6-Week Post-Op | **Harris Hip Score 96 (max=100)**
Oxford Hip Score 38 (max=48)



3-Month Post-Op | **Harris Hip Score 89 (max=100)**
Oxford Hip Score 44 (max=48)



1-Year Post-Op | **Harris Hip Score 96 (max=100)**
Oxford Hip Score 46 (max=48)



CASE REPORT

A NECK-PRESERVING APPROACH TO HIP RECON-STRUCTION

Scott Dunitz, MD
Tulsa Bone and
Joint Associates

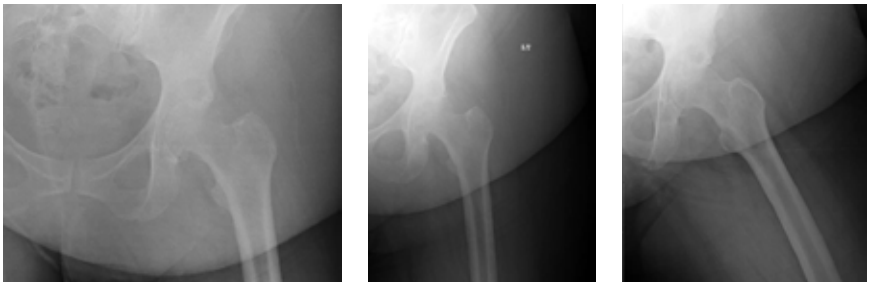
Radiographs are captured and evaluated by an independent reviewer.

CONCLUSION

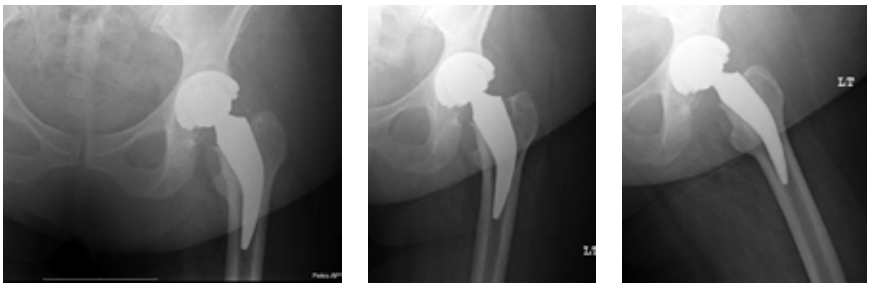
Pre-op, this patient presented with low Harris Hip and Oxford Hip scores. The direct anterior approach used in her surgery has been associated with faster functional recover than the posterolateral approach, and one year post-op, her scores increased by more than 69.0 percent on the Harris Hip and 80.4 percent on the Oxford Hip. The patient is satisfied with her total hip replacement, and her surgical outcomes continue to be followed on an annual basis.

A 63-year-old Caucasian female weighing 244lbs diagnosed with osteo/degenerative arthritis received Exactech's Alteon Neck Preserving stem with a Biolox®*delta* femoral head and InteGrip® acetabular shell. The patient went under spinal anesthesia using a direct anterior surgical approach with an incision size of 9cm. There was an estimated blood loss of 200cc and surgery duration was 80 minutes. The patient was discharged after one day postoperative with a walker to in home care for rehabilitation. •

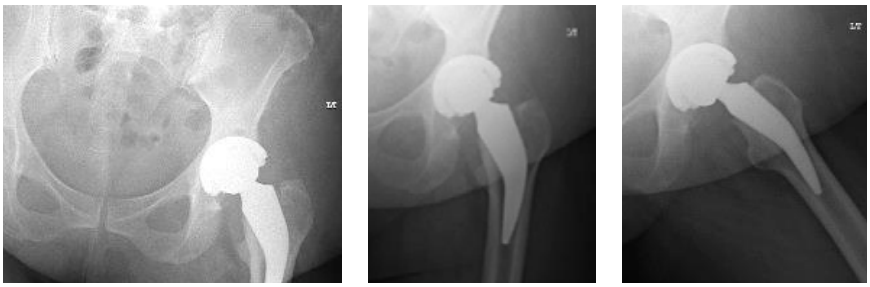
Pre-Op AP Pelvis | **Harris Hip Score 31 (max=100)**
Oxford Hip Score 9 (max=48)



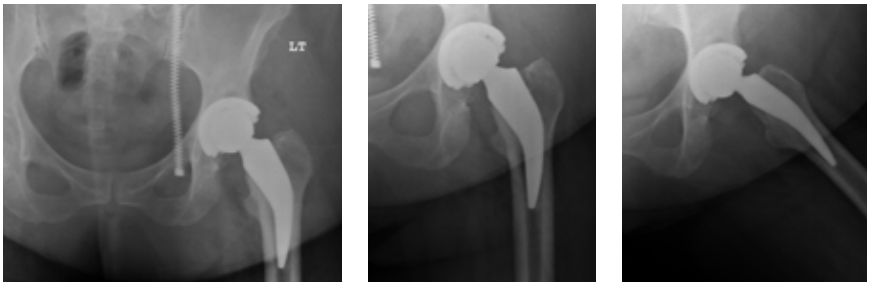
6-Week Post-Op | **Harris Hip Score 68 (max=100)**
Oxford Hip Score 38 (max=48)



3-Month Post-Op | **Harris Hip Score 84 (max=100)**
Oxford Hip Score 37 (max=48)



1-Year Post-Op | **Harris Hip Score 100 (max=100)**
Oxford Hip Score 46 (max=48)

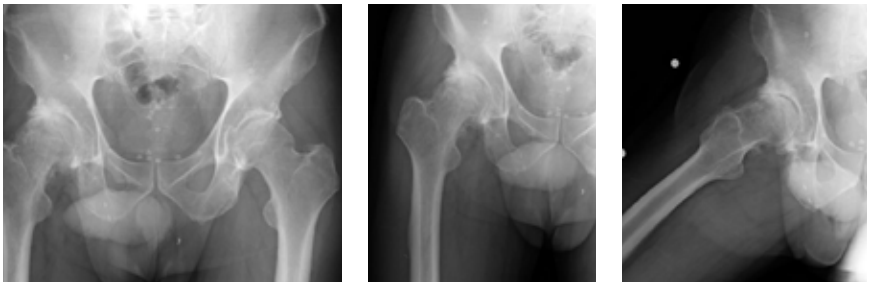


A 59-year-old Caucasian male weighing 192lbs diagnosed with osteo/degenerative arthritis received Exactech's Alteon Neck Preserving stem with a Biolox®delta femoral head and InteGrip® acetabular shell. The patient went under spinal anesthesia using a direct anterior surgical approach with an incision size of 9cm. There was an estimated blood loss of 200cc and surgery duration was 63 minutes. The patient was discharged after one day postoperative with a walker to in home care for rehabilitation. •

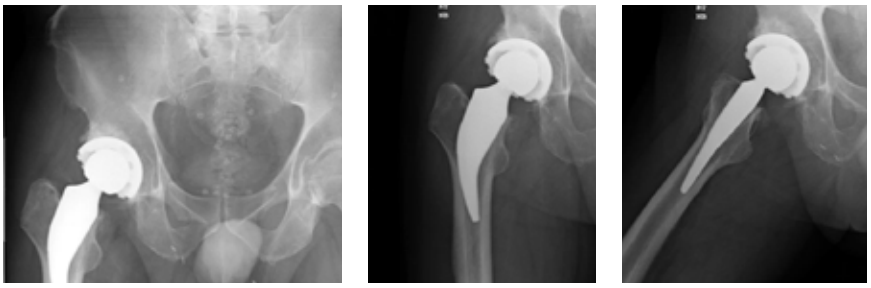
CONCLUSION

Previous to his total hip replacement, this patient presented with low Harris Hip and Oxford Hip scores. The outcomes of this case continue to be followed annually, and this patient is satisfied with his hip replacement. One year after his surgery, his scores increased by more than 38.1 percent on the Harris Hip and 43.2 percent on the Oxford Hip. The direct anterior approach used in this surgery has been associated with faster functional recover than the posterolateral approach.

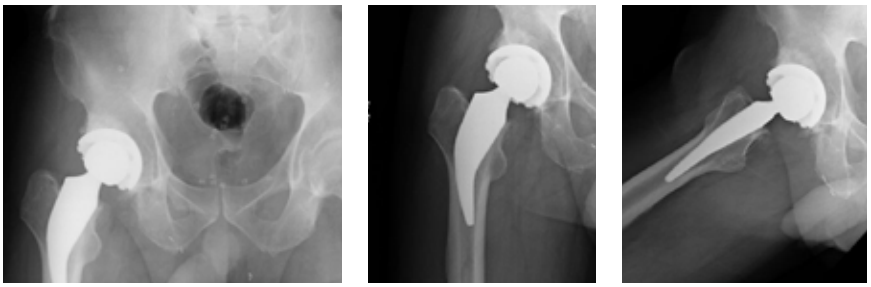
Pre-Op AP Pelvis | **Harris Hip Score 60 (max=100)**
Oxford Hip Score 25 (max=48)



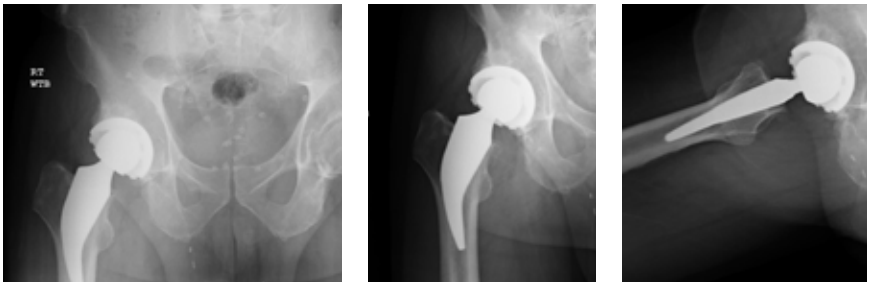
6-Week Post-Op | **Harris Hip Score 96 (max=100)**
Oxford Hip Score 42 (max=48)



3-Month Post-Op | **Harris Hip Score 96 (max=100)**
Oxford Hip Score 37 (max=48)



1-Year Post-Op | **Harris Hip Score 97 (max=100)**
Oxford Hip Score 44 (max=48)



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OBSERVATIONS ON PROXIMAL HUMERUS FRACTURES

LOCKING PLATE FIXATION OF FRACTURES OF THE PROXIMAL HUMERUS: ANALYSIS OF COMPLICATIONS, REVISION STRATEGIES AND OUTCOMES

Jost, B, Spross C, Grehn H, Gerber C. *J Shoulder Elbow Surgery* (2013) 22, 542-549 | Level of Evidence: Level IV, Case Series

TO REVIEW IS TO OPINE

It appears that the large majority of patients who present with complications following locking screw ORIF are those with a high likelihood of vascular disruption of the humeral head (four-part fractures, short metaphyseal segment) at the time of injury. While the risks of avascular necrosis, varus collapse with secondary screw cut out are relatively high, under the age of 60 years in patients with adequate bone stock a joint preserving procedure should be attempted. Failure of locking screw ORIF can be recognized as early as nine months and the secondary treatment entertained.

Gregory Gilot, MD
Cleveland Clinic Florida

SUMMARY

The purpose of the study was to report the complications, their treatment and outcome of 121 patients referred after primary locking plate ORIF for proximal humerus fractures. The authors recognized the increasing numbers of complications following such surgeries being referred to the tertiary referral center. Among the known complications of AVN, varus collapse and screw cutout being reported, the previously unknown complication of iatrogenic glenoid destruction due to perforated head screws was reported.

MATERIALS AND METHODS

One hundred twenty one patients with complications were collected. Sixty-seven patients were women and 54 were men. The mean age at initial injury was 59 years. All 121 patients were treated with the PHILOS plate (Synthes, Paoli, PA, USA). Of the 114 classified fractures, 17 were 2-part, 37 3-part, and 60 4-part. All patients presented with restricted function and pain and were seen after a mean of 15 months after index ORIF.

RESULTS

A mean of three complications occurred per patient.

Complication	Number of patients (%)
Malreduction	67 (55%)
Primary screw cutout	14 (12%)
Malunion	76 (63%)
Nonunion	16 (13%)
AVN	82 (68%)
Infection	5 (4%)
Secondary screw cutout	69 (57%)
Glenoid destruction	40 (33%)

TREATMENT AND OUTCOMES

One hundred seven (88 percent) patients underwent revision surgery. A mean of 1.5 surgeries were performed per shoulder. Partial and total hardware removals were the most common revision operations in this study. Overall, over 50 percent of patients finally needed secondary arthroplasty.

Treatment		Secondary Arthroplasty
Re-osteosynthesis	8	3
Arthroscopy	10	3
Partial hardware removal	16	7
Total hardware removal	41	17
Secondary arthroplasty	61	

CONCLUSIONS

In this collective of patients with complications following locking screw ORIF, 50 percent had four-part fractures, 20 percent were head splitting or fracture-dislocations, and 80 percent had no metaphyseal segment attached to the head. These factors are known to be associated with poorer outcomes underscoring that the primary surgery should be definitive if possible. Lastly, neither secondary hemiarthroplasty, total shoulder arthroplasty or reverse total shoulder arthroplasty yielded results comparable to primary arthroplasty. •

REVERSE SHOULDER ARTHROPLASTY VERSUS HEMIARTHROPLASTY FOR ACUTE PROXIMAL HUMERUS FRACTURES. A BLINDED, RANDOMIZED, CONTROLLED, PROSPECTIVE STUDY

Sebastia-Forcada, E, Cebrian-Gomez R, Lizaur-Utrilla, A, Gil-Guillen, V. *J Shoulder Elbow Surgery* (2104) 23, 1419-1426 | Level of Evidence: Level I, Randomized Controlled Trial, Treatment Study

TO REVIEW IS TO OPINE

While the radiographic outcomes in terms of tuberosity healing appear comparable, it is the differences in clinical outcomes, forward flexion and revision rate that would lead the reader to believe that rTSA is superior to HA for the treatment of proximal humeral fractures in the elderly. Forward flexion results appear to be independent of tuberosity healing with a predictable low number of patients who do not achieve a minimum of 90 degrees forward flexion following a rTSA. Implant survival is superior for rTSA when compared to HA.

Gregory Gilot, MD
Cleveland Clinic Florida

SUMMARY

The surgical treatment of complex proximal humerus fractures in the elderly with poor quality bone remains controversial. These factors negatively impact the results of internal fixation and hemiarthroplasty (HA) has been considered a good surgical option in these patients. Reverse shoulder arthroplasty (rTSA) has the theoretical advantage of independence of tuberosity healing and rotator cuff integrity. Useful clinical conclusions and clear guidelines for treatment currently do not exist. The aim of this study was to compare the outcomes of rTSA and HA for acute proximal humerus fractures in elderly patients.

MATERIALS AND METHODS

This blinded, randomized, controlled prospective study included patients 70 years or older whose complex fractures were not amenable to reconstruction. To avoid selection bias patients found to have irreparable cuff tears were not excluded. Sixty-two patients were randomized to rTSA (31) and HA (31). The mean follow-up was 28.5 months. The modular shoulder replacement system (SMR; Lima, Udine, Italy) was used in both groups. Surgery was performed similarly in both groups. Tuberosities were handled identically. Postoperative regimens were similar in both groups. In the HA group, a rotator cuff tear was found in 11 cases; in three cases the tear was irreparable. In the rTSA group, a rotator cuff tear was found in 14 cases; in five cases the tear was irreparable.

Clinical evaluation included the Constant-Murley score, the UCLA score, the DASH score, range of motion and strength. Radiographic evaluation included the status and position of the tuberosities, implant loosening, proximal migration in the HA group and inferior scapular notching in the rTSA group.

RESULTS

There were no statistically preoperative differences between the groups.

Outcome	rTSA Group	HA Group
Constant score (p=0.001)	56.1	40.0
UCLA score (p=0.001)	29.1	21.1
DASH score (p=0.001)	17.5	24.4
Forward flexion (p=0.001)	120.3	79.8
Forward flexion <90 degrees	1 (3.2%)	10 (33.3%)
External rotation (p=0.023)	4.7	3.3
Internal rotation (p=0.914)	2.7	2.6
Tuberosity healing	20 (64.5%)	17 (56.7%)
Tuberosity resorption	5 (16.2%)	9 (30.0%)
Revisions	1	6
40-month implant survival	96.8%	80.0%

CONCLUSIONS

In this study, rTSA was superior to HA with respect to pain, functional outcome, and revision rate. While forward flexion and abduction were significantly better in the rTSA group there was no significant difference in internal rotation. There was one (3.2 percent) case of scapular notching observed. The six revisions within the HA group were due to proximal migration resulting in severe pain and limited function. There was one deep wound infection within the rTSA group requiring a two-stage revision. All revised patients suffered poor Constant scores and unsuccessful functional outcomes. Revision from HA to rTSA did not appear to improve outcomes. •

REVERSE SHOULDER ARTHROPLASTY FOR THE TREATMENT OF THREE- AND FOUR-PART FRACTURES OF THE PROXIMAL HUMERUS IN THE ELDERLY. A PROSPECTIVE REVIEW OF 43 CASES WITH SHORT-TERM FOLLOW UP

Bufquin, T, Hersan, A, Humert, L, Massin, P. *J Bone Joint Surg (US)* [Br] (2007) 89-B:516-20

TO REVIEW IS TO OPINE

The management of complex proximal humeral fractures in the elderly continues to be a difficult problem to solve with a predictable solution. This study is one of the first to report short term results. What is well demonstrated is the need for reliable tuberosity reconstruction to optimize outcomes. These conclusions argue strongly for disease specific implants that allow for anatomical tuberosity.

Gregory Gilot, MD
Cleveland Clinic Florida

SUMMARY

The use of reverse shoulder arthroplasty in complex proximal humerus fractures cannot be routinely recommended due to the paucity of clinical studies. While mid-term results appear to be encouraging, to date its use in trauma has been described in only small series. The aim of this study was to describe the author's experience with this technique in the short term in elderly patients.

MATERIALS AND METHODS

Forty-three patients with a mean age of 78 years with an acute proximal humerus fracture were treated with a Delta reversed shoulder prosthesis (Depuy, Saint Priest, France). Operative treatment and post-operative care were similar for all patients. While the tuberosities were repaired, the supraspinatus, when present, was divided and removed. Mean follow-up was 22 months. Clinical outcomes included Constant and Murley score, the ASES score, the DASH score, and mobility. Radiographic evaluation included recording inferior scapular notching, assessing the position of the centre of the shoulder, the glenoid inclination angle, heterotopic ossification and healing of the tuberosities.

RESULTS

Complications occurred in 12 patients. While greater tuberosity healing did improve external rotation this was not significant. The shoulder centre medialization had a mean of 21mm and a mean of 9mm below the centre of rotation of the contralateral side. Patients with a lower center had better results but this difference was not significant. Of the scapular notching that was observed, only one was Sirveaux grade 3.

Clinical & Radiographic Outcomes	rTSA Group
Constant score	44
ASES score	9
DASH score	44
Anterior elevation	97
External rotation	8
Tuberosity displacement	19 (53%)
Tuberosity malunion	5 (13.8%)
Tuberosity nonunion	14 (3.8%)
Scapular notching	10 (25%)
Glenoid component inclination	15 degrees
Shoulder center medialization	21mm
Heterotopic ossification	36 (90%)

CONCLUSIONS

In this study, satisfactory mobility was obtained with the use of a reversed shoulder arthroplasty in complex proximal humerus fractures despite a 53 percent rate off displacement of the tuberosities. When anatomical reconstruction of the tuberosities was achieved (41.5 percent) the effect on the Constant score appeared to be moderate. •

TREATING INFECTED JOINTS

LOW-DOSE GENTAMICIN-LOADED SPACERS ARE EFFECTIVE FOR TWO-STAGE REVISION

Romano CL, Drago L, Logoluso N. Musculoskeletal Infection Society (MSIS). 2013 July 30.

SUMMARY

Peri-prosthetic infection is among the most common reason for revision in the United States and in Europe. Two-stage revision with antibiotic-loaded spacers is the gold standard with an eradication rate greater than 90 percent. High antibiotic concentration (greater than 2 percent) and the association of more than one antibiotic in the spacer are proposed by different authors in a limited series of patients.

MATERIALS AND METHODS

A systematic review of published papers on two-stage revisions of infected total hip and knee arthroplasties treated with the routine use of an industrial low-dose (1.9 percent) gentamicin-loaded, preformed spacer has been performed. This systematic review evaluated the hypothesis: are high antibiotic concentrations and antibiotic associations necessary for interim spacers in routine two-stage revision surgery? Papers that were included were published in peer-reviewed journals from the years 1995 to 2013 and reported an infection eradication rate of two-stage hip or knee joint prosthesis with the use of an industrial, preformed low-dose gentamicin spacer (Spacer G or Spacer K, Tecres SpA, Italy. InterSpace® Hip or InterSpace Knee, Exactech, Inc. USA). The systematic review excluded case reports, clinical series with less than 10 patients, duplicate studies and mean follow-up less than 24 months.

RESULTS

Twenty-four papers were retrieved, 10 of which met the inclusion criteria, yielding a total of 491 spacers implanted in 10 centers (seven in Europe, two in North America and one in Oceania). Nineteen patients (3.9 percent) had an infection recurrence/persistence that required a spacer exchange or a resection arthroplasty. Twenty-five of the 480 patients (5.2 percent) that underwent the second stage procedure had an infection recurrence/persistence at an average follow-up of 46 months.

KEY QUOTE

"This systematic review provides evidence in favor of the routine use of an industrially, preformed spacer loaded with a standardized, relatively low concentration of gentamicin, [and] that in different centers, showed an average infection eradication rate of 96.1 percent at spacer removal and 94.8 percent at the latest follow-up after reimplantation. The systematic review does not support the hypothesis that the antibiotic associations or antibiotic concentrations higher than 1.9 percent are routinely needed for spacers used in two-stage revision surgery." •

MEASUREMENTS OF *IN-VIVO* INTRA-ARTICULAR GENTAMICIN LEVELS FROM ANTIBIOTIC-LOADED ARTICULATING SPACERS IN REVISION TOTAL KNEE REPLACEMENT

Mutimer J, Gillespie G, Lovering AM, Porteous AJ. *Knee*. 2009 Jan;16(1):39-41. doi: 10.1016/j.knee.2008.07.009. Epub 2008 Sep 10.

SUMMARY

Previous *in-vitro* studies have found high levels of antibiotic release in the days immediately following implantation of antibiotic-loaded, articulating spacers. However, there is relatively little data describing the elution profile beyond this immediate period. This study was designed to measure if gentamicin levels continue to be clinically therapeutic after an extended period following *in-vivo* implantation.

MATERIALS AND METHODS

Twelve patients received a gentamicin-loaded, articulating spacer between a first- and second-stage revision total knee arthroplasty. At the second stage procedure, synovial fluid and blood samples were collected and assayed for the presence of gentamicin. The second-stage revision occurred at a median of 99 days following the spacer insertion.

RESULTS

The median intra-articular gentamicin levels were 0.46 mg/L (0.24 to 2.36 mg/L), which would be considered therapeutic. There were no cases of re-infection.

CONCLUSIONS

In this study, preformed articulating spacers containing gentamicin provided therapeutic concentrations in the synovial fluid surrounding the joint throughout the period of implantation. This data confirms the observations from *in-vitro* studies where a prolonged elution profile was observed for such spacers (Spacer K, Tecres SpA, Italy. InterSpace Knee, Exactech, Inc. USA).

KEY QUOTE

"It is therefore interesting to see potentially therapeutic levels of gentamicin at an average of 99 days post insertion of the spacer suggesting that good antibiotic levels are maintained around the spacer for most of the time it is in position."

TREATMENT OF THE GLENOHUMERAL SEPSIS WITH A COMMERCIALLY-PRODUCED, ANTIBIOTIC-IMPREGNATED CEMENT SPACER

Coffey MJ, Ely EE, Crosby LA. *J Shoulder Elbow Surg.* 2010 Sep;19(6):868-73. doi: 10.1016/j.jse.2010.01.012. Epub 2010 Apr 14.

SUMMARY

This study evaluated treating an infected shoulder arthroplasty and primary shoulder sepsis using a commercially-produced, antibiotic-impregnated cement spacer.

MATERIALS AND METHODS

Sixteen shoulders in 15 patients with infected arthroplasty or osteomyelitis of the proximal humerus were treated with irrigation and debridement; hardware removal, humeral head resection, or both; and placement of an interval articulating hemiarthroplasty with a commercially-made, gentamicin-impregnated cement spacer (InterSpace Shoulder, Exactech, Inc. USA).

RESULTS

The mean follow-up was 20.5 months after spacer placement. At the time of debridement, 12 shoulders had positive cultures; the most common organisms were methicillin-resistant Staphylococcus aureus (n = 3) and S. epidermidis (n = 3). Twelve patients underwent revisions while four refused revisions and have retained antibiotic spacers. There was no recurrence of infection.

CONCLUSIONS

Treatment of glenohumeral sepsis with a commercially-produced, antibiotic-impregnated cement spacer appears to be an effective treatment modality, and serum interleukin-6 levels appear to be useful in the evaluation of shoulder infection.

KEY QUOTE

"The incidence of reinfection in our series of 16 infected shoulders was zero, whereas the incidence in other series of infected shoulders treated with staged revision arthroplasty with an antibiotic spacer ranges from 0 to 40 percent. In addition to absence of reinfection, patients in our series demonstrated clinical improvements with regards to visual analog pain scale, range of motion, and other subjective and objective shoulder evaluation scores." •

PREFORMED ARTICULATING KNEE SPACERS IN TWO-STAGE TOTAL KNEE ARTHROPLASTY: MINIMUM TWO YEAR FOLLOW-UP

Wan Z, Karim A, Momaya A, Incavo SJ, Mathis KB.
J Arthroplasty. 2012 Sep;27(8):1469-73. doi: 10.1016/j.arth.2012.01.027. Epub 2012 Mar 14.

SUMMARY

Two-stage revision arthroplasty using articulating spacers for the treatment of infected total knee arthroplasty (TKA) is a successful management technique. Our purpose was to report our results using preformed, commercially-available articulating spacers made of gentamicin-impregnated cement (Spacer K, Tecres S.p.A. Italy. InterSpace Knee, Exactech, Inc. USA).

MATERIALS AND METHODS

Thirty-three patients with an infected primary or revision TKAs were treated with these spacers using a two-stage revision technique. In most cases, the spacers were modified intraoperatively by adding a stem of reinforced antibiotic-impregnated acrylic cement.

RESULTS

Successful eradication was achieved in 30 of 33 cases at a minimum two-year follow-up interval. Two patients required a second spacer before a successful TKA revision. No spacer fractures or dislocations occurred in this series. No adverse soft tissue effects were noted from the use of this type of articulating spacer.

KEY QUOTE

"Our lower eradication rate (91 percent) compares favorably with other reports even with the inclusion of more complex cases involving multiple previous surgeries, resulting in longer times of active infection as well as compromised bone and soft tissue." •

DOES A PREFABRICATED, GENTAMICIN-IMPREGNATED, LOAD BEARING SPACER CONTROL PERIPROSTHETIC HIP INFECTION?

Degen RM, Davey JR, Davey JR, Howard JL, McCalden RW, Naudie DD. *Clin Orthop Relat Res.* 2012 Oct;470(10):2724-9. doi: 10.1007/s11999-012-2350-3.

SUMMARY

Treating deep infection following THA has been a challenge. While the standard treatment has remained a two-stage revision, spacer designs, incorporated antibiotics and concentrations have varied. Since control of infection may relate to the choice and concentration of antibiotics, it is important to report rates of control from various spacers. This study determined the rate of infection control and complications associated with a prefabricated, load bearing, gentamicin-impregnated hip spacer (Spacer G, Tecres S.p.A. Italy. InterSpace Hip, Exactech, Inc. USA) in treating periprosthetic hip infections.

MATERIALS AND METHODS

Thirty-three patients with periprosthetic THA infections were retrospectively reviewed and treated with a prefabricated, partial load bearing, gentamicin-impregnated hemiarthroplasty spacer. Thirty of the 33 patients underwent second-stage reimplantation after a mean of 15 weeks. Patient demographic data; laboratory values; infecting organism; size of spacer; antibiotic selection; complications; and infection control rates from two academic centers were collected. Recurrent infection at last follow-up was determined by the presence of physical symptoms or signs or elevated serologic tests. The minimum follow-up was 24 months (mean- 43 months; range- 24–70 months).

RESULTS

Twenty-eight of the 30 patients who underwent reimplantation remained infection free at last follow-up. One patient became reinfected with a different organism secondary to wound problems. Another became reinfected with the same organism, but was restaged with the prefabricated spacer used in this study, reimplanted, and subsequently remained free of infection. Two of the 33 patients had persistently elevated inflammatory markers at the completion of the first stage and were restaged with this spacer. Both underwent reimplantation and remained free of infection at latest follow-up. One of the 33 patients was satisfied and ambulatory with their spacer. There were no major complications.

CONCLUSIONS

Overall, the data supports the use of a partial load bearing, gentamicin-impregnated hemiarthroplasty spacer in treating deep periprosthetic THA infections.

KEY QUOTE

"In the end, infection control was ultimately achieved in 32 of 33 (97 percent) patients." •

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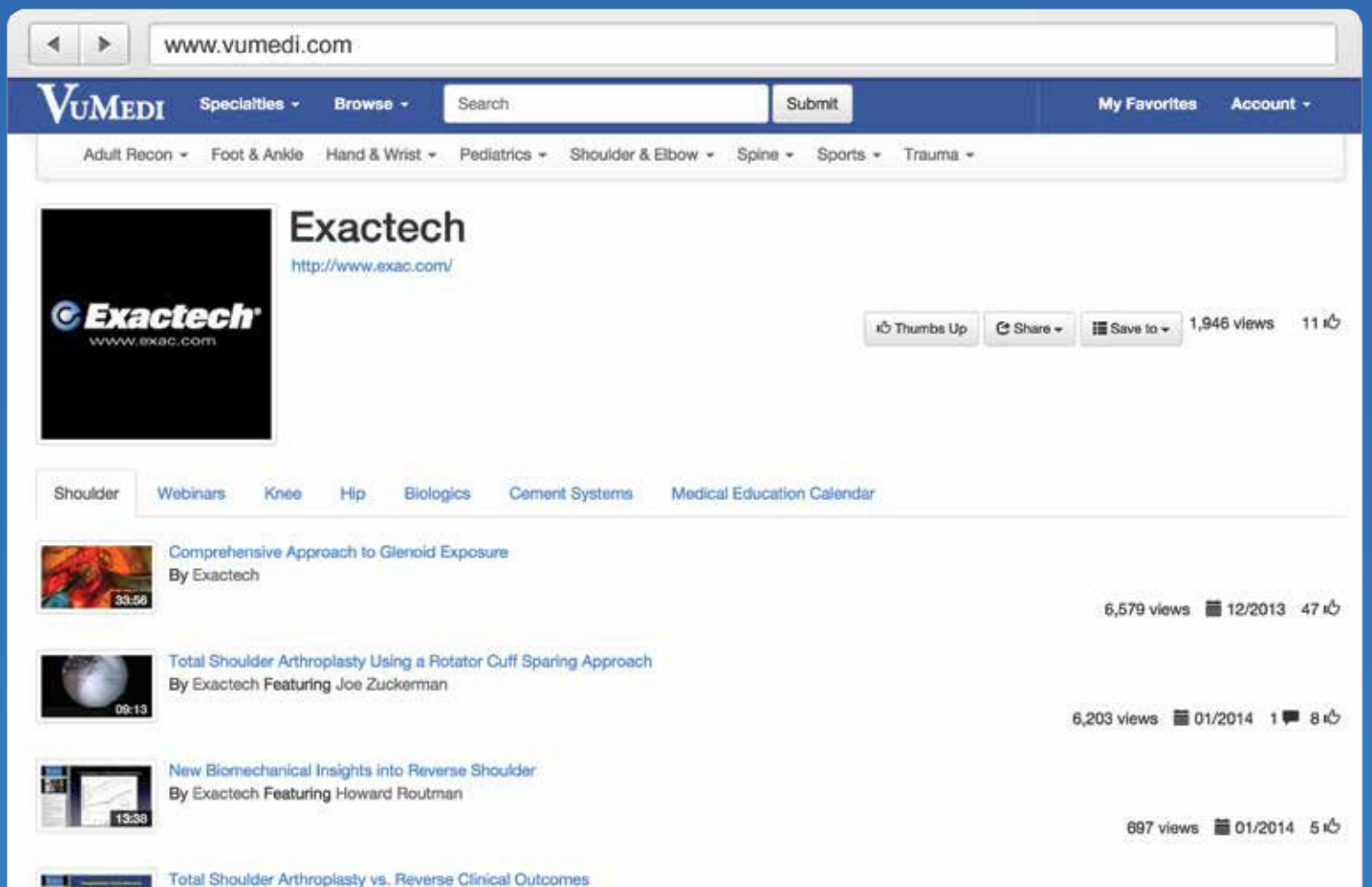

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Reduces the cost significantly, and helps reduce surgical time as blades don't need to be changed interoperatively. Can typically be used for several procedures, then can be returned for a nominal replacement charge.

Optional Large Delrin Heads (39-60mm)*

Designed to provide tight, secure surface contact when removing larger size acetabular cups, and can also be used if the cup liner of a standard size cup is worn and must be removed. Available in diameters from 39 to 60mm in 1mm increments.

*US Patent #7,998,146 B2

Widest available range of blade and head sizes

Blades from 42 to 80mm in 2mm increments, and heads from 22 to 60mm.

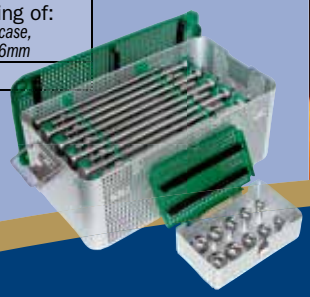
Optional Wrench Drive Handles

Works like a socket wrench, allowing improved torque without changing positions.

Fully Customizable Sets

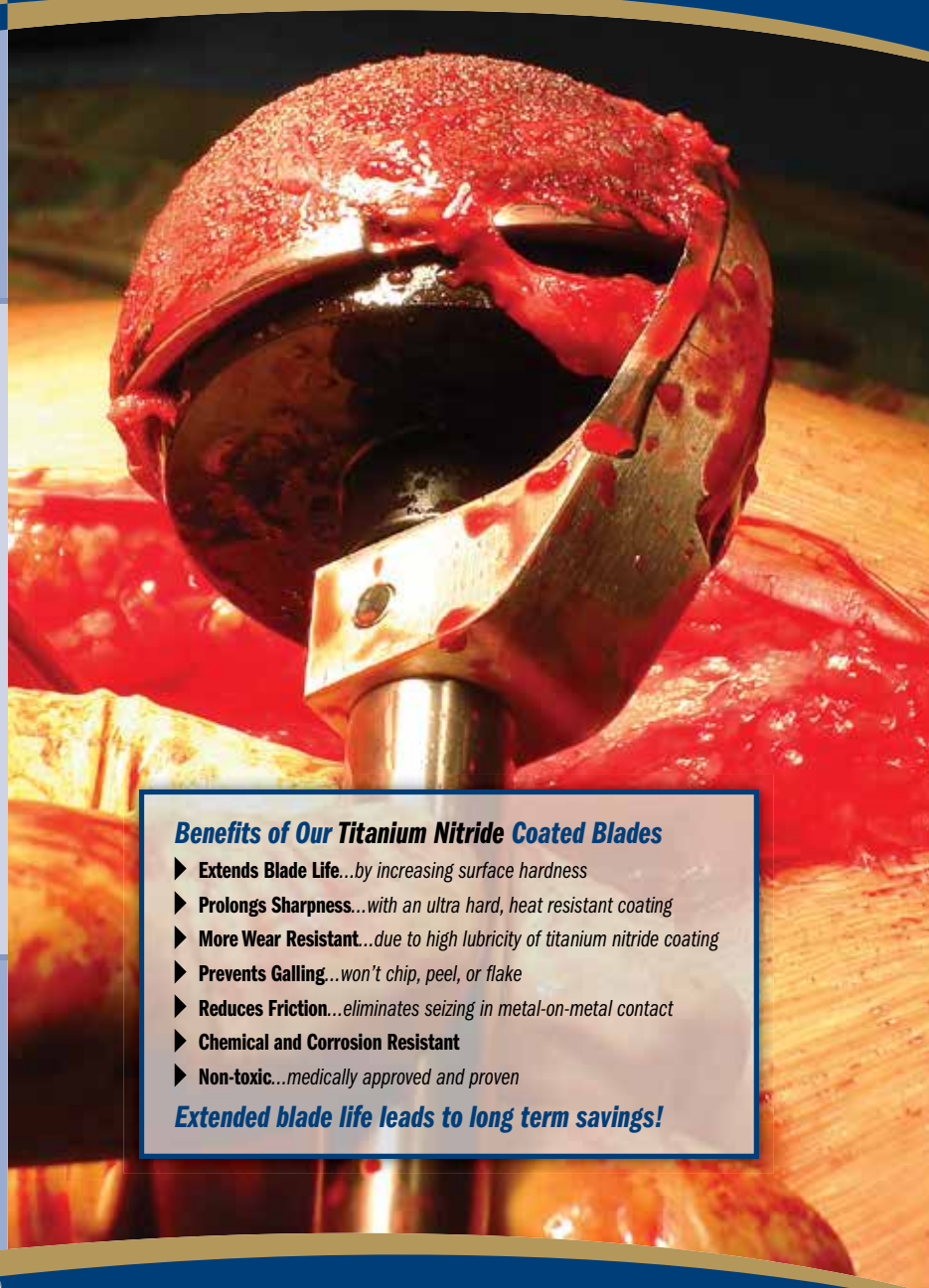
Rent or purchase – configure with as few or as many options required.

PRODUCT NO:
5200-00 [Complete Set] *20 Starter, 20 Finish, 3 each of 5 Head Sizes, and 5 cases*
Smaller Sets Also Available, consisting of: *5 Starter and 5 Finish Instruments (5 sizes) with case, and 2 each of 5 head sizes with case – 22mm–36mm*
Components also sold individually



PROUDLY MADE IN THE USA

System Designed by James Kudrna, MD and Stephen Incavo, MD
Wrench Drive Handle Designed by Guido Grappiolo, MD
Delrin Heads Designed by Adolph Lombardi, MD



Benefits of Our Titanium Nitride Coated Blades

- **Extends Blade Life**...*by increasing surface hardness*
- **Prolongs Sharpness**...*with an ultra hard, heat resistant coating*
- **More Wear Resistant**...*due to high lubricity of titanium nitride coating*
- **Prevents Galling**...*won't chip, peel, or flake*
- **Reduces Friction**...*eliminates seizing in metal-on-metal contact*
- **Chemical and Corrosion Resistant**
- **Non-toxic**...*medically approved and proven*

Extended blade life leads to long term savings!

ISO 9001:2008 • ISO 13485:2003

SYSTEM RENTAL AVAILABLE

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