INNOVATIONS

A CLINICAL EXCHANGE ON ADVANCES IN ORTHOPAEDICS

VOLUME 4

ISSUE 1

02 Positive Early Clinical Outcomes Indicate Good Initial Fixation of the Alteon® Tapered Wedge Stem Compared to Other Wedge Stem Designs

05 Assessing the Learning Curve of a Contemporary Total Knee System Using Advanced (CUSUM) Analysis

08 Learning of a CAOS Enhanced Mechanical Instrument System for Total Knee Arthroplasty: A CUSUM Analysis

11 InterSep® — The Latest Generation of Calcium Sulfate Bone Void Filler

16 Anterior Cruciate Ligament Reconstruction Using Platelet Rich Plasma and TenoMend™

20 State-of-the-Art in Reverse Shoulder Arthroplasty: A New Small Baseplate System Brings rTSA to a New Level

24 The Evolution of Innovation in Humeral Implant Options: Two Surgeons' Case Reviews

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VOLUME 4 | ISSUE 1

LETTER FROM THE EDITOR

01 | Sharing Outcomes and Insights | *Gary J. Miller, PhD*

SCIENTIFIC ARTICLES

02 | Positive Early Clinical Outcomes Indicate Good Initial Fixation of the Alteon® Tapered Wedge Stem Compared to Other Wedge Stem Designs | *Jeffery Pierson, MD, Hilary Spahr, Edmund Loftus, Gary J. Miller, PhD*

05 | Assessing the Learning Curve of a Contemporary Total Knee System Using Advanced (CUSUM) Analysis | *Yifei Dai, PhD, James B. Duke, MD, Mark W. Hollmann, MD, Phillip J. Lewandowski, MD, Laurent Angibaud, Dipl. Ing., Charlotte Bolch, Matthew J. Peterson, PhD, Jefferson Morrison, MD*

08 | Learning of a CAOS Enhanced Mechanical Instrument System for Total Knee Arthroplasty: A CUSUM Analysis | *Yifei Dai, PhD, James I. Huddleston III, MD, Matt Rueff, Laurent Angibaud, Dipl. Ing., Derek F. Amanatullah, MD*

11 | InterSep® — The Latest Generation of Calcium Sulfate Bone Void Filler | *Duran Yetkinler, MD, PhD*

FEATURED ARTICLES

16 | Anterior Cruciate Ligament Reconstruction Using Platelet Rich Plasma and TenoMend™ | *Paul R. Fleissner, Jr., MD*

20 | State-of-the-Art in Reverse Shoulder Arthroplasty: A New Small Baseplate System Brings rTSA to a New Level | *Rahul Deshmukh, MD*

CASE REPORTS

24 | The Evolution of Innovation in Humeral Implant Options: Two Surgeons' Case Reviews | *Stephanie Muh, MD, Rick Papandrea, MD*

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SHARING OUTCOMES AND INSIGHTS

Gary J. Miller, PhD
Exactech Executive Vice President, Research and Development

Meaningful improvements in patient care and outcomes are the reward for the introduction of innovative products and systems to the orthopaedic community. To assess their true impact on outcomes and "cost", it currently falls to medical professionals, clinical researchers and manufacturers to monitor their adoption to the industry. To do so requires significant commitment of all stakeholders to gathering both subjective and objective measures of the performance of these new technologies in the broadest sense.

In this issue of *Innovations*, we share early and midterm clinical results and case reports of several new product introductions. In addition, we take this opportunity to present examples of new methods for quantitatively assessing the "learning curve" for surgeons implementing new computer assisted orthopaedic surgical systems in their practice armamentarium. The latter is a key to fine-tuning the design of systems and the training of the early adopters of these important and potentially transformative techniques.

As these new and emerging products and technologies arise, it is important that dependable clinical studies are available to educate and inform surgeons who have the desire to improve patient care and outcomes. In the last couple of years, Exactech team members and dedicated surgeon partners worked together to gather and share the latest clinical data with their nearly 80 podium presentations, 40 journal publications and more than 130 abstracts and posters. From positive early clinical performances of a new tapered wedge femoral stem to the creation of a small reverse shoulder baseplate that assists in the treatment of smaller glenohumeral anatomies, Exactech continues to develop products to carry out its mission to help surgeons worldwide improve outcomes for their patients.

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POSITIVE EARLY CLINICAL OUTCOMES INDICATE GOOD INITIAL FIXATION OF THE ALTEON® TAPERED WEDGE STEM COMPARED TO OTHER WEDGE STEM DESIGNS

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Franciscan Physician Network

Hilary Spahr
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INTRODUCTION

The single-taper wedge stem design is derived from the cemented Mueller stem of the 1970s. Unlike fit-and-fill stems, which contact most of the metaphysis, tapered wedge femoral stems are designed to achieve proximal medial/lateral fixation. Wedge femoral stems used in total hip arthroplasty (THA) have evolved from first-generation implants such as the DePuy Synthes® TRI-LOCK®, Biomet® Taperloc®, Zimmer® ML Taper, and Stryker® Accolade (Figure 1). These stems typically featured longer geometries and more robust distal shape. Continuing with the evolution, stems became shorter in length, had reduced distal geometries, and sometimes incorporated modular necks.

These first-generation designs have shown great clinical success with some studies reporting over 98% survivorship at 10 years.[1,2,3] Despite this clinical success, a subset of the proximally-coated tapered wedge stems were failing to achieve stability and osteointegration. Cooper et al. retrospectively reviewed 320 tapered wedge femoral stems in non-cemented THA concluding that greater attention should be paid to femoral canals with a proximal-distal mismatch as well as stems that fill the canal in the mid- and distal-third of the stem.[4] In an effort to reduce the occurrence of distally potted tapered, proximally coated wedge stems, the Alteon® Tapered Wedge Stem evaluated in this study was designed with a further reduced distal geometry. This design change is intended to provide a wedge-fit within the metaphysis of the proximal femoral canal for all femur types (Dorr A, B, C). The objective of this study was to evaluate the early clinical outcomes of the Alteon Tapered Wedge Stem (Figure 2).

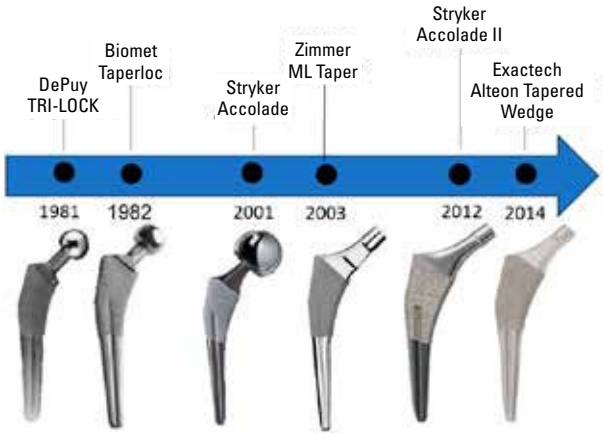

Figure 1. Timeline of the Tapered Wedge Stem Design

Figure 2. The Alteon Tapered Wedge Stem

METHODS

Three hundred and eighteen (318) subjects (163 males, 152 females and 3 not reported; mean age: 63.3±10.5 years; mean BMI: 28.1±6.0) underwent primary THA with a tapered wedge femoral stem. Subjects were enrolled in CR11-003 ("A post-Market Domestic (US) and International Data Collection to Assess Hip Replacement Systems Manufactured and/or Distributed by Exactech") or CR14-001 ("Exactech Alteon Tapered Wedge Femoral Stem Total Hip Arthroplasty"). IRB approval was received prior to conducting the studies and all participants signed the informed consent. Clinical data outcomes for these studies included the Harris Hip Score (HHS), the Oxford Hip Score (OHS) and revisions. Weight-bearing A/P radiographs were reviewed by an independent third party at all post-operative time points for the patients enrolled in CR14-001. During this review, subsidence was measured by an independent radiology core laboratory using femoral stem features to measure the distance to bone features. Subsidence was noted if the change in position was greater than 5mm. Student's t-tests were used to identify significant mean differences between genders ($p<0.05$).

RESULTS

The means and standard deviations for the HHS and OHS are shown (Figure 3). For patients returning for their 2-year post-operative visit (n=101), the HHS improved by 41.7 points to 90.7 from 49.0, and the OHS improved by 24.8 points to 43.0 from 18.2. There was no significant difference between genders with regard to age, BMI or pre-op HSS scores. However, the males had significantly higher pre-operative OHS scores, 3-month, 6-month and 1-year post-operative HHS and OHS scores and 2-year post-operative OHS scores. There was a total of eight (8) revisions. Three were revised due to infection and the others were for instability, fracture, acetabular loosening, pain and periprosthetic fracture. There were no observations of subsidence at 1 year (n=45) or 2 years (n=40).

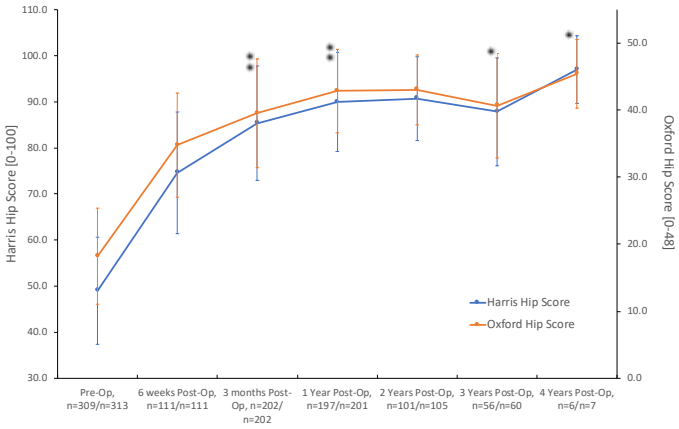

Figure 3. Clinical outcome scores. Data represent means +/- standard deviation. n= HSS count/OHS count. *Indicates significant difference from the previous time point (p,0.05).

DISCUSSION

This tapered wedge stem exhibited positive early clinical results as demonstrated by the significant improvement in functional outcome scores from the pre-operative visit to 2-years post-operative. These 2-year improvements are better than the moderate clinically important improvements reported in the literature (40.1 points for HHS).[5] Functional outcomes scores continued to improve at the 6-week, 3-month, 1-, 2- and 4-year post-operative visits.

There were no reports of subsidence at the 1- or 2-year post-operative time points for the radiographs examined by the third party. Jacobs and Christensen reported "significant progressive subsidence" between the 6-week and 1-year post-operative follow-ups of patients with the first generation cementless wedge stems. In their study, they reported that at 6 weeks 3 out of 130 hips showed signs of subsidence which then increased to 13 hips at the 1-year follow-up.[6]

Fifteen patients in the cohort that had their radiographs examined by the third party showed evidence of non-progressive radiolucent lines in the distal femoral component that were less than 2.2mm at 1 year. The low subsidence rates of the Alteon Tapered Wedge Stem indicate that the stem achieved good initial and short-term fixation, possibly due to the reduced distal geometry.

SIGNIFICANCE

The tapered wedge stem evaluated in this study demonstrated positive early clinical performance with no reports of subsidence. This tapered wedge stem design is a promising alternative to conventional femoral stems. •

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ASSESSING THE LEARNING CURVE OF A CONTEMPORARY TOTAL KNEE SYSTEM USING ADVANCED (CUSUM) ANALYSIS

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INTRODUCTION

As hospitals are facing mounting financial pressures in the current economic environment, time spent in the operating room has been identified as one of the most costly areas of hospital operations. As such, introduction of a new total knee arthroplasty (TKA) system to clinical care should demonstrate a minimum learning effort requirement.

To date, limited studies have assessed the learning of new surgical technology or TKA systems. The methodology applied in existing studies usually compares surgical time between the cases performed during the "learning period" and those from the later cases, with an assumed duration (number of cases) of the learning period. In a study of computer assisted TKA, researchers have performed logarithmic regression on the initial case series to find the duration of the learning phase. However, as the surgical time data is often, by nature inconsistent, the regression result can be difficult to evaluate.

Cumulative sum control chart (CUSUM) has been widely applied in industry to assess the stabilization of a production process and has proven to be an objective and effective tool to evaluate a learning process. Although many successes have been achieved by this method in other medical fields, its usage for orthopaedic applications, notably TKA research, has been limited. The goal of this study was to leverage this advanced methodology and perform a CUSUM analysis to define the learning period of a newly released TKA system.

A

A case was considered	Criterion
Successful	Time < Surgeon's baseline average + 2 x Clinically acceptable std dev*
Failed	Time ≥ Surgeon's baseline average + 2 x Clinically acceptable std dev*

** The clinically acceptable std dev was defined as 5min for tourniquet time and 10min for skin-to-skin time. The definitions were stricter than the reported std dev from clincial studies on conventional TKA.*

CUSUM Variables	Description	Value
p0	Acceptable failure rate	0.05
p1	Unacceptable failure rate	0.30
α	Probability of type I error	0.05
β	Probability of type II error	0.20

CUSUM Calcuations	Formulae
P	ln(p1/p0)
Q	ln[(1-p0)/(1-p1)]
s	Q/(P + Q)
a	ln[(1-β)/α]
b	ln[(1-α)/β]
h0	-b/(P + Q)
h1	a/(P + Q)

B

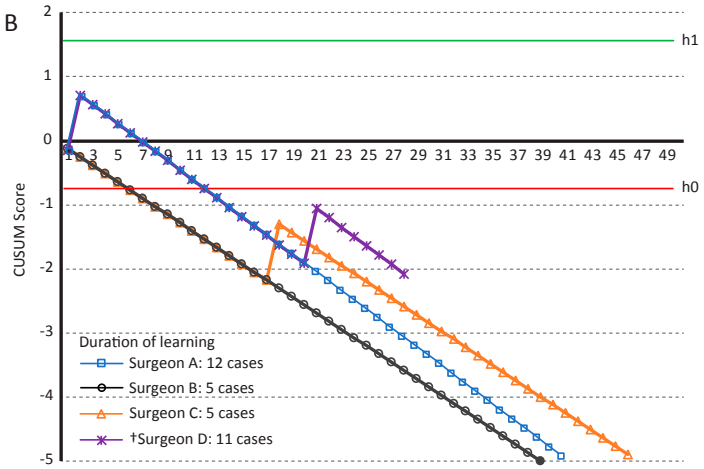

Figure 1. A) CUSUM parameters used for the analysis. B) CUSUM chart for the learning curves from individual surgeon, marked with his/her duration of learning (#cases).
†Surgeon D started to incorporate a new navigation technology from cases #29. Those cases were therefore excluded from the anlaysis. Cases #19-#28 were then used to calculate surgical time after learning instead of #41-#50.

MATERIALS AND METHODS

With institutional review board approval and waiver of informed consent, a retrospective review was performed on the surgical time from four orthopedic surgeons (A-D) on their first 50 consecutive cases since the adoption of a new TKA system, as well as their last 10 cases using their previously mastered TKA system performed before the adoption (baseline). For each surgeon, tourniquet time was used as the primary time measure; while if a surgeon did not routinely use tourniquet, the skin-to-skin time was reviewed instead. Since CUSUM assessed each individual surgeon's learning process independently, the time measure differences between surgeons did not affect the analysis of an individual's learning curve as a consistent time measure was used across all 50 cases and baseline for a given surgeon.

To perform the CUSUM analysis, four parameters must be defined (Figure 1A): acceptable failure rate (p0), unacceptable failure rate (p1), type I error rate (α), and type II error rate (β). From the parameters, two decision limits (h0 and h1) and the variable **s** are calculated. The first 50 cases from each surgeon are sorted chronologically. Each case was evaluated as to whether it "failed" or "succeeded" based on the surgical time criteria defined in Figure 1A. When a failure occurred, a "penalty value" 1-s was added to the CUSUM score; while when a success occurred, a "reward value" **s** was subtracted from the CUSUM score. A healthy learning process was marked as the CUSUM line crossing the lower decision limit (h0), indicating completion of the learning period (met the acceptable failure rate). Conversely, the CUSUM line crossing the upper decision limit (h1) from below indicated the failure of the learning process (reaching an unacceptable failure rate).

The duration of learning for each surgeon was identified by his/her own CUSUM chart as the number of the last case before crossing the lower decision limit (h0). Surgical time in the baseline, during the learning period and after learning (cases #41-#50) were compared. Significance was defined as $p<0.05$.

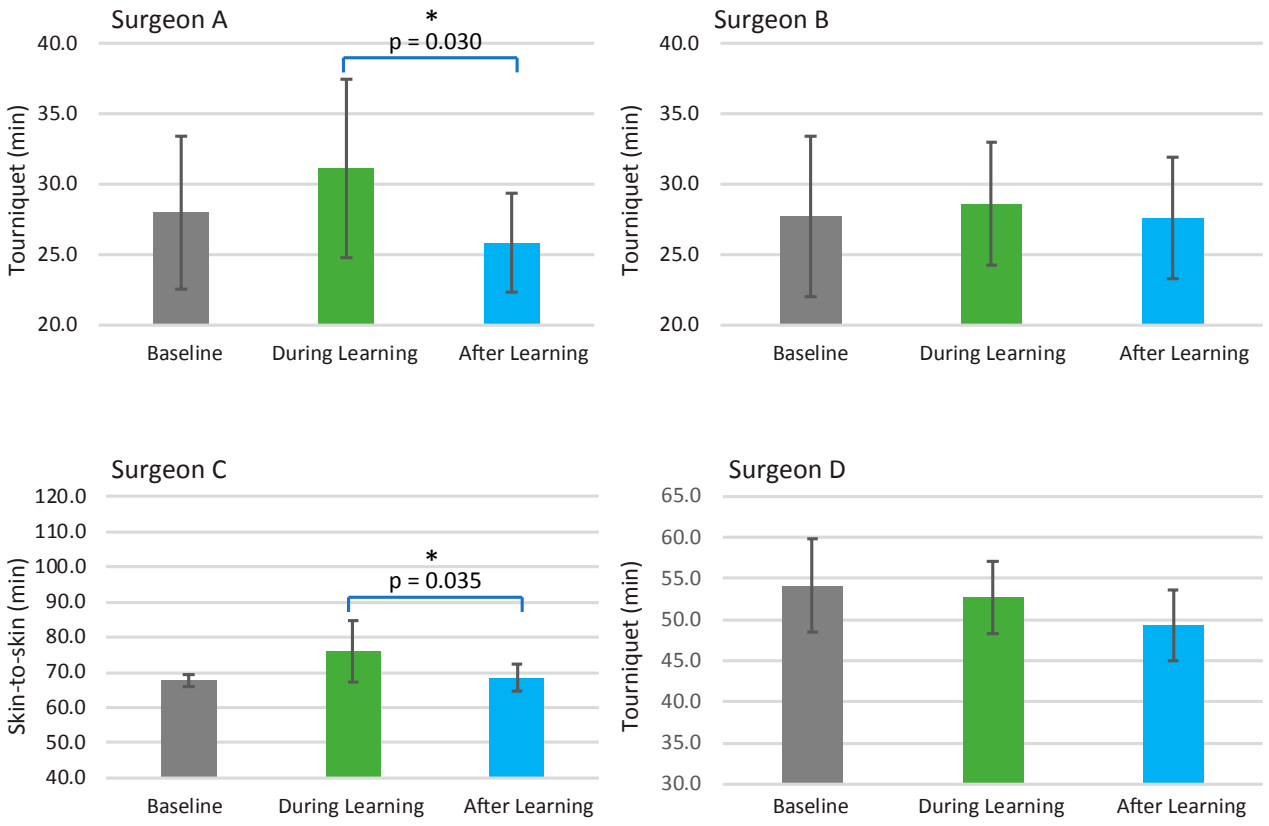

Figure 2. Comparion between baseline, during learning, and after learning in each of the four surgeons.

RESULTS

All CUSUM lines from the four surgeons crossed the lower decision limit, indicating their successful completion of learning (Figure1B). The duration of learning was on average 8.3 ± 3.8 cases with individual surgeons exhibiting unique learning characteristics, reflected by the shape of the CUSUM line. Surgeons A and C exhibited significant but moderate time decreases from the learning period to after learning (Figure 2). For all four surgeons, the learning period did not significantly increase their surgical time from the baseline, and the surgical time after learning showed a general trend of smaller standard deviations and shorter time compared to the baseline (Figure 2).

DISCUSSION

This study applied the CUSUM method to analyze the learning curve of a new TKA system based on surgical efficiency (time), relating the adoption of the surgery as a process that eventually stabilizes with mastery of the task. The data indicated that the learning of the new TKA system took approximately 8 cases. Cases performed, using the new TKA system remained time neutral with cases baseline both during and after the learning period. The data also demonstrated that learning the new TKA system did not result in a significant learning curve from the perspective of surgical efficiency.

Despite the CUSUM method being proposed in the 1970s for analyzing the learning curve for surgical procedures and since then being applied to various medical fields, the use of this method in TKA has been very limited. Utilization of this advanced method in studying the learning curve, not only can provide improved understanding of TKA learning in general, but also allows differences in learning between individual surgeons or surgeon characteristics to be explored. •

LEARNING OF A CAOS ENHANCED MECHANICAL INSTRUMENT SYSTEM FOR TOTAL KNEE ARTHROPLASTY: A CUSUM ANALYSIS

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INTRODUCTION

Computer-assisted orthopaedic surgery (CAOS) has been shown to offer improved accuracy to total knee arthroplasty (TKA) compared to conventional techniques.[1] Despite promising results, one of the drawbacks for surgeons to adopt CAOS technology may be the requirement of switching from conventional to CAOS-specific instruments. Recent advances in CAOS, introduced a system designed to enhance the existing conventional mechanical instruments, removing the need for significant instrument change. While TKAs performed by this system can benefit from the improved accuracy offered by CAOS technology, it is important to assess the learning of the system to evaluate the efficiency of its adoption. Cumulative sum control chart (CUSUM) has been applied to assess the stabilization of industrial production processes and proven to be an objective and effective tool to evaluate the learning process. This method is currently under-recognized in TKA research. The purpose of this study was to use CUSUM to assess the learning curve on the critical surgical steps using the new CAOS enhanced mechanical instrument system.

METHODS

Four surgeons (2 seniors, and 2 fellows with no prior CAOS experience) were included in this sawbone study. Each surgeon performed proximal tibial and distal femoral resections on 6 knee models using conventional instrumentation and six knee models with the same conventional instrument system enhanced by CAOS. All resections were created targeting neutral coronal alignment, 3° tibial slope, and 10mm resection depth. For each surgeon, the cumulative sum of deviations was calculated[2], specifically: the CUSUM score of the first case was the difference between the time of the first case and the mean surgical time. The CUSUM score of the second cases were the previous cases' CUSUM score, plus the difference between the surgical time of the second case and the mean surgical time. This recursive process continued until the last case, which was calculated as 0. CUSUM score was plotted in chronological order for each surgeon. A horizontal trend in the plot signified the process was operating with stability. The case number (cases to

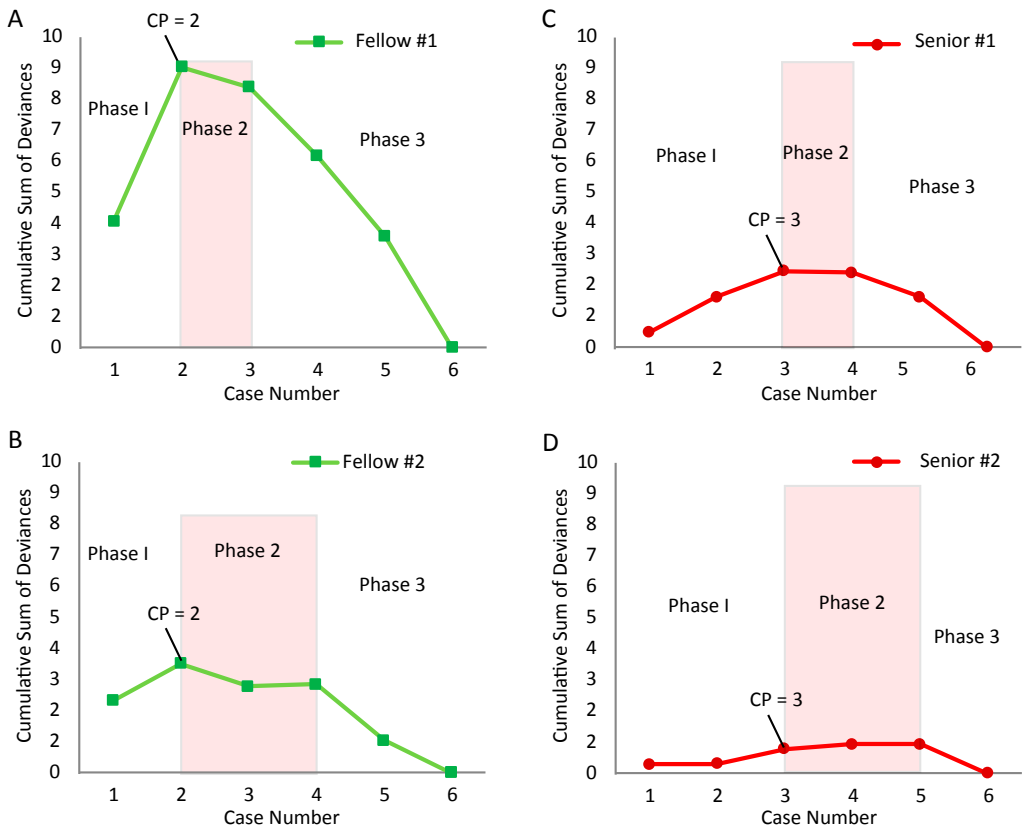

Figure 1. Graphs on the CUSUM deviance charts for A) senior surgeon #1, B) senior surgeon #2, C) fellow surgeon #1, and D) fellow surgeon #2. The fellow surgeons exhibited a steeper learning curve compared to the senior surgeons. The graph was plotted according to the chronological case numbers.

proficiency) by which the CUSUM plot entered the horizontal trend was identified as the end of learning for each surgeon. The cases to proficiency was compared between the senior and the fellow surgeons. The surgical time in CAOS-enhanced cases during and after learning was compared to the conventional cases within each surgeon. Due to limited case numbers per surgeon, statistical assessment of the differences was not performed. The increase in surgical time after learning the CAOS system was compared to conventional cases on the pooled data (significance defined as $p<0.05$).

Surgical Time (min)	Senior Surgeons	Fellow Surgeons	P
CAOS			
During Learning*	7.3 ± 0.6	11.9 ± 3.4	0.01
After Learning†	6.2 ± 0.6	7.2 ± 1.3	0.07
Mechanical Instrumentation	3.4 ± 0.8	5.4 ± 1.6	0.00
P (Mechanical Instrumentation vs After CAOS Learning)	0.00	0.01	

* Calculated as the average of all learning cases (combining *all surgeons' cases #1 - #CP).*
† Calculated as the average of all after-learning cases (combining all *surgeons' cases #CP+1 - #6).*

Table 1. Summary of learning characteristics in the senior surgeon and fellow surgeon groups.

RESULTS

The CUSUM plot exhibited three unique phases in the first six cases of each surgeon with Phase II demonstrating stabilization of the process (Figure1). No substantial difference between the senior and novice surgeon groups was found in the speed of learning (2-3 cases). However, compared to the senior surgeons, the fellow surgeons demonstrated slightly steeper learning curve by adding 3-4 minutes to their learning cases (Figures 1 and 2). Compared to the conventional TKA, adding CAOS enhancement slightly increased time by 4-6 minutes during learning, and the difference reduced to 2-3 minutes after learning. No significant difference in surgical time was found between senior and fellow surgeons after their learning (Figure 2B).

DISCUSSION

This study applied CUSUM method to analyze learning curve of a CAOS-enhanced mechanical instrument system for TKA. As the CAOS guidance is based on existing conventional mechanical instruments, the adoption of the technology exhibited minimum learning effort (2-3 cases to learn), independent of the surgeon's experience level.

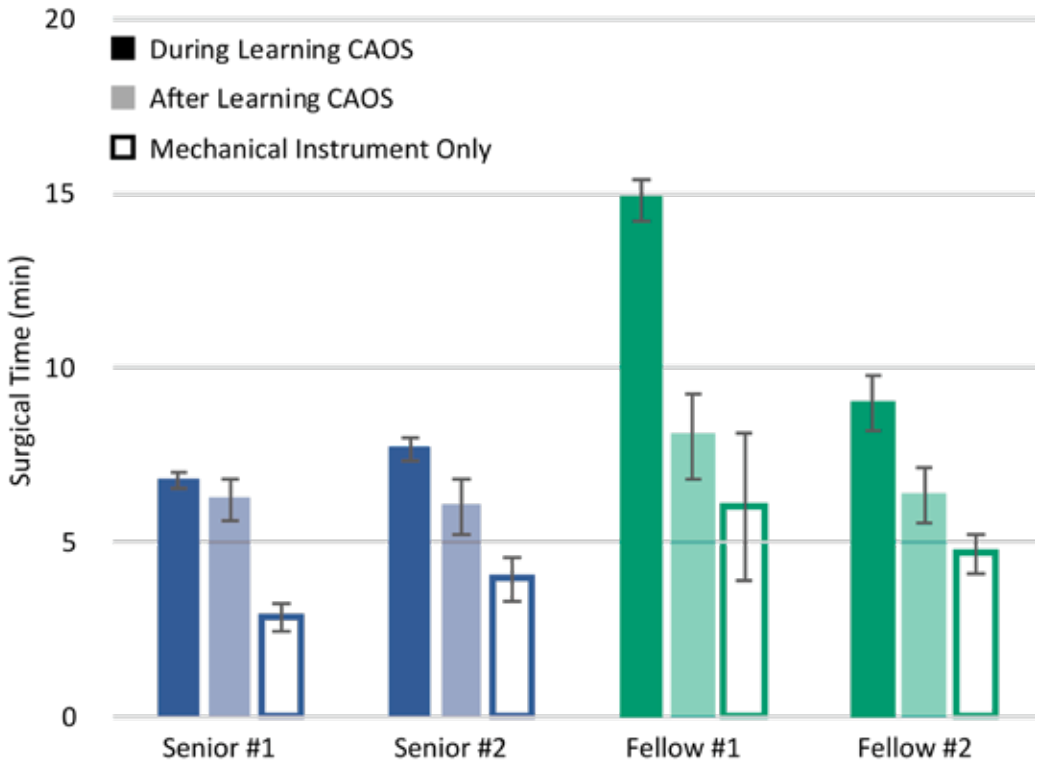

Figure 2. Comparison of surgical time between during learning CAOS enhancement, after learning CAOS enhancement, and mechanical instrumentation only case gruops in each individual surgeon. Due to limited cases number per surgeon, statistical assessment of the differences was not performed.

Compared to conventional cases performed using the same mechanical instrument system, using the CAOS-enhanced system moderately increased the surgical time in critical bony resection steps by 4-6 minutes during learning. After quick mastering of the technology, the surgical time was only slightly extended by 2-3 minutes compared to conventional cases. The results demonstrated minimum impact on surgical efficiency by introducing CAOS to the existing conventional mechanical instruments, offering the proven benefit of CAOS technology without major disruption in the surgical tools the surgeons are already familiar with. Utilization of advanced methods in studying learning curves can provide an improved understanding of CAOS learning in general, but also allows differences in learning between individual surgeons to be explored. Further investigation of this study may include expanding the CUSUM assessment to the entire TKA surgical duration with more surgeon groups with different characteristics.

SIGNIFICANCE/CLINICAL RELEVANCE

An advanced method (CUSUM) was applied to assess the learning curve of a CAOS-enhanced mechanical instrument system. The data demonstrated a short learning duration for both senior and fellow surgeons and a mild impact on surgical time during learning. •

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INTERSEP® — THE LATEST GENERATION OF CALCIUM SULFATE BONE VOID FILLER

Duran Yetkinler, MD, PhD
Pacific Bioceramics

INTRODUCTION

As long as there have been bone voids or defects, there has been a desire to fill them. The description of filling defects with various substances has been mentioned in ancient Hindu, Egyptian and Greek texts. One of the earliest well-documented examples of filling bone defects was by Dutch surgeon Jobi Meekren in 1682. Meekren implanted dog bone into the skull defect of a soldier. However, the church intervened in what they perceived as an unholy process and forced Meekren to remove the dog bone under threat of excommunication. Needless to say, there were no long-term outcomes to be reported to the literature.

Bone grafting was developed by many other European physicians such as Ollier, Duhamel and Syme, but the modern practice of bone grafting was invented by Scottish doctor Macewen in 1880. Fast forwarding to 1961, Peltier described his numerous experiments with using Calcium Sulfate Hemihydrate (CSH) to fill bone defects.

InterSep® Calcium Sulfate bone void filler consists of a latest generation, fully-synthetic CSH. CSH is also known as Plaster of Paris or in natural form – the mineral Bassanite. When CSH is mixed with the liquid solution included in the bone void filler kit, it reverts back to gypsum, which is also known as Calcium Sulfate Dihydrate (CSD).

Historically, gypsum deposits were found in the large hill of the Montmartre district of Paris. This is why CSH is called Plaster of Paris. Heating gypsum (CSD) releases water in the form of steam and results in CSH. The ancient Egyptians used Plaster of Paris to seal joints of the pyramids, as well as make casts of human figures. The Parisians used their plaster to plaster walls for fire resistance starting in the 18th century. The Dutch surgeon Mathysen popularized the use of Plaster of Paris as an orthopaedic dressing in the mid-19th century (1851 to be precise with a plaster bandage). In 1892, German physician Dreesmann documented healing of six of eight bone fractures with a mixture of phenoland Plaster of Paris, in what is possibly the first documentation of the use of a Calcium Sulfate bone void filler.

Since the use of Calcium Sulfate for medical purposes predated the existence of the Food and Drug Administration (FDA), Calcium Sulfate salts were classified as a Class II special controls device in 1998. These guidelines concern the purity and consistency of the material, as well as regulatory parameters required to bring new Calcium Sulfate-based products to market.

The summary below shows the biocompatibility, benchtop performance and animal testing carried out on InterSep® for the regulatory submission to the FDA. The product passed the acceptance criteria for the following required tests.

BIOCOMPATIBILITY TESTING

Cytotoxicity MEM Elution Test: The MEM Elution Test is designed to determine the cytotoxicity of extractable substances. An extract of InterSep was added to cell monolayers and incubated. The cell monolayers were examined and neither cell lysis nor any intracytoplasmic granules were found. ***The device is considered to be non-cytotoxic.***

Bacterial Mutagenicity Test - AMES Assay: The Salmonella Typhimurium Reverse Mutation (AMES) Test employs several stains of S. typhimurium, which requires the amino acid histidine for growth to detect point mutations. The InterSep extract tested against the five strains did not meet the criteria for a potential mutagen. ***The device is found to be non-mutagenic.***

ISO Maximization Test for Delayed Hypersensitivity: ISO 10993-10:2010 was used to determine if InterSep would cause delayed dermal contact sensitization in a guinea pig maximization test. The study results showed that InterSep extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. ***The device is considered to be non-sensitizing.***

ISO Acute Systemic Toxicity Test: The purpose of the study was to determine whether leachables extracted from InterSep would cause acute systemic toxicity following single-dose systemic injection into mice. The study result showed that there was no mortality or evidence of systemic toxicity form the extracts. Each test article extract met the test requirements. ***The device is considered to be nontoxic systemically.***

ISO Intracutaneous (Intradermal) Reactivity Test: The purpose of the study was to determine whether leachables extracted from InterSep would cause local dermal irritant effects following injection into rabbit skin. The study result showed that there was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. ***The device is not considered to be an irritant.***

Chromosome Aberration: This test determines if the device causes any structural chromosome aberrations in Chinese Hamster Ovary (CHO) cells. The test complies with OECD and ISO guidelines as an in vitro diagnostic for genotoxicity. ***Results indicate no aberration in chromosome structure following exposure to the device.***

ISO Materials Mediated Rabbit Pyrogen: This test determines whether a saline extract of the device causes a pyrogenic response (fever) in rabbits. This test is in compliance with ISO 10993-11. All extracts tested negative. ***The material is non-pyrogenic.***

ISO In Vivo Mouse Micronucleous Assay: This test determined if the device induces micronuclei formation in immature polychromatic erythrocytes present in the bone marrow of adult mice. The presence of polychromatic erythrocytes is an indication of a mutagenic substance leached from the device. The test complies with ISO 10993-3. ***All extracts tested negative indicating the device is non-mutagenic.***

InterSep bone graft material passed the requirements of all tests. ***It can be concluded that the product is biocompatible and non-toxic.***

BENCH TOP PERFORMANCE TESTING

The manufacturer completed performance tests that simulated the intended physiological environment as outlined in FDA's Class II Special Controls Guidance Document: *Resorbable Calcium Salt Bone Void Filler Devices* (2003). This section summarizes InterSep and the predicate devices' performance test results.

The critical specifications of InterSep were compared to the predicate device. These analyses consisted of:

- Chemistry
- Crystallinity
- Physical form
- Porosity
- Dissolution/solubility
- pH
- Working time
- Setting time
- Dimensional stability
- Setting reaction temperature

pH Testing: This test compared pH changes in surrounding simulated body fluids (Phosphate Buffered Saline (PBS)) of the predicate and subject test devices while the devices cured *in vitro* (Figure 1). The pH of the surrounding PBS for both devices were within the physiological pH of ~7.5.

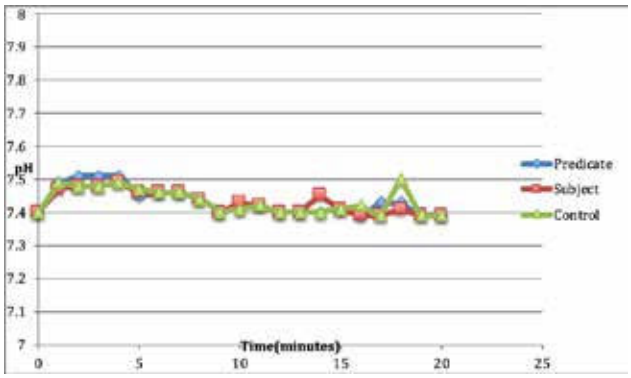

Figure 1: pH Change versus Time for PBS with DB CSD, Stimulan and Control (No Cement)

Dissolution/Solubility Testing – Solution Ionic Calcium Measurement by ICP-MS: Solubility of predicate and subject InterSep test devices were analyzed over 80 hours while immersed in Dulbecco's PBS and maintained at physiological conditions (pH=7.4, 37° C) (Figure 2). The test purpose was to evaluate the *in vitro* dissolution behavior of the InterSep device compared to the predicate device. The calcium ion concentration at 80 hours for the test device was 23.8 ppm, and at the same time point, the predicate device was 26 ppm. The tested devices' differences for the *in vitro* solubility test of the two minerals were negligible and were within experimental error (within 95% confidence interval). Over the course of the study, both products exhibited sparingly soluble calcium release.

The XRD results presented in Figure 2 displays the diffraction pattern for DB CSD.

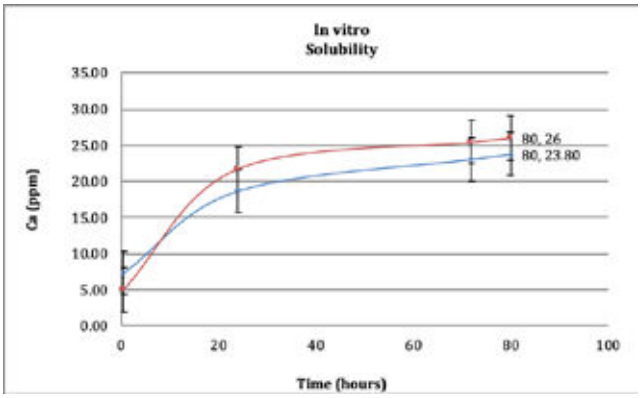

Figure 2. *In Vitro* Solubility Testing: DB-CSD (Blue) and Predicate (Red)

Working Time: The test purpose was to examine the interoperative handling properties of InterSep to ensure that the material has sufficient working time during surgical implantation in bone defects and/or voids (Figure 3).

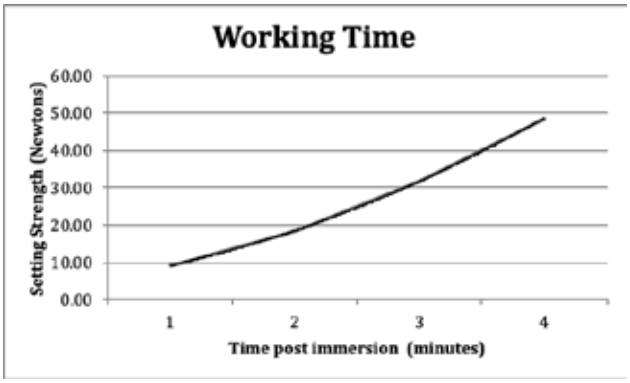

Figure 3. Working time of DB CSD after immersing in PBS solution at 32° C

The working time of InterSep at 32° C was determined per the modification of the setting test (ASTM C403/C403M-99). The data showed an initiation set times of 3 minutes to attain a recordable load greater than 25 Newton when the curing temperature was 32° C. This indicated the maximum working time allowed before the material begins to harden *in vivo* was 3 minutes post-implantation. This will provide an ample opportunity for surgical adjustment, if needed.

Setting Time: The test purpose was to examine the setting properties of InterSep to ensure the bone void filler would set sufficiently hard *in vitro* and within a clinically relevant time under physiologic pH and temperature conditions (Figure 4). This test was a modification of the standard setting test described in ASTM C403/C403M-99 in which the load required to drive needles at a prescribed distance into concrete or a similar setting material was measured.

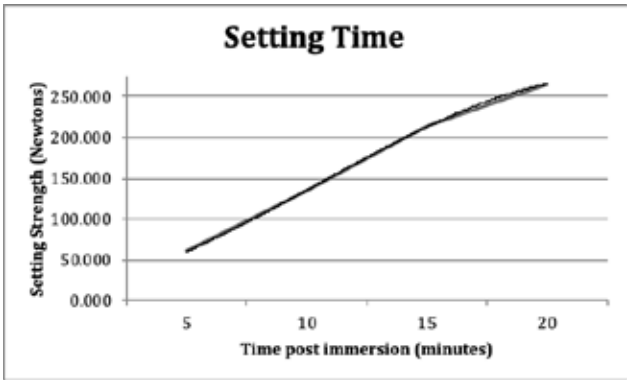

Figure 4. Setting time of DB CSD. Specimens immersed in 32° C PBS solution immediately after mixing.

After immersion of 10 minutes in physiological conditions of temperature and pH, InterSep reached adequate strength presented in Appendix J. Data analysis yielded a set time of ~10 minutes to reach a load greater than 135 Newtons (N).

Dimensional Stability: Dimensional stability testing measured the volume change following incubation and setting at physiologic pH and temperature. InterSep hardened at 30 minutes in a contained volume with no physical shape change at 24 hours. Therefore, no change in physical shape would be expected following implantation *in vivo*.

Setting Reaction Temperature: Some orthopaedic cement devices undergo an exothermic setting reaction that is of interest due to its biologic consequence. Both InterSep and the predicate devices had undergone hydration and setting via an *isothermic* reaction. The data indicated that the setting reactions of both tested devices did not significantly change the temperature of fluids within the setting material immediate vicinity (Figure 5). Temperature fluctuation was minimized and expected to ensure tissue compatibility. The results demonstrated that InterSep remained within the physiologic temperature range and is expected to have no adverse biologic consequence.

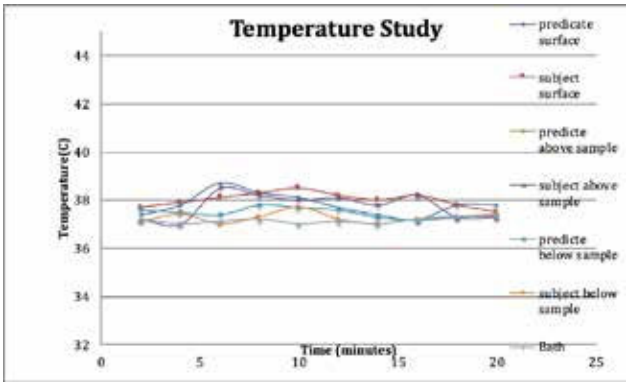

Figure 5. Setting reaction temperature change for (a) DB CSD and (b) Stimulan after immersion in PBS at 37° C

Chemical Analysis: Chemical and microstructural analysis per the FTIR, XRD, SEM and Porosimetry allowed a detailed composition and microstructure description of InterSep and predicate devices and to predict similarities in *in vivo* performance. All tests were performed on predicate and InterSep devices to establish substantial equivalence:

Properties Analyzed	Technique and Tool
Chemistry	Fourier Transform Infrared Spectroscopy (FTIR) and X-ray Diffraction (XRD)
Crystallinity	X-ray Diffraction (XRD)
Physical Form and Microstructure	Scanning Electron Microscopy (SEM)
Porosity	Mercury Intrusion Porosimetry

XRD and FTIR analyses confirmed that both predicate and subject devices were composed of CSD with no other phases detected (Figures 6 and 7, respectively). SEM and Porosimetry data indicated both tested devices resulted in the formation of intermingling, interlocking, nano-sized crystals of CSD after hydration and curing *in vitro*. Bulk density, pore diameter and total porous volume measured by mercury intrusion porosimetry showed that both subject and predicate devices were nano/micro porous materials with similar bulk densities.

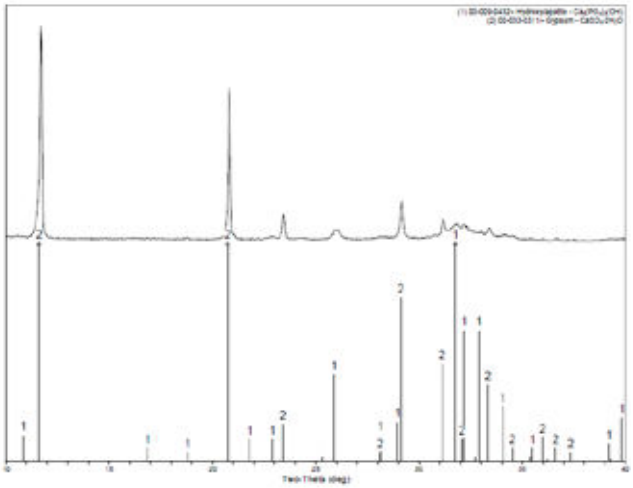

Figure 6. XRD pattern for final device: (DB CSD after curing and drying)

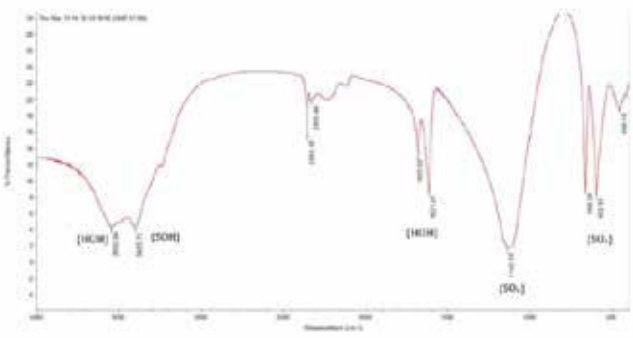

Figure 7. FTIR Patterns for DB CSD After Curing and Drying. The FTIR Pattern shows characteristic absorption bands for sulfate ion attributable to SO4 in CaSO4.2H2O.

Elemental Analysis: Heavy metal/trace elemental analysis was performed using inductively-coupled plasma mass spectroscopy (ICP-MS). ASTM standard F1185-03 (2009) suggests a limit for heavy metals/trace elements and is used as a reference. InterSep (DB CSD) contained substantially lower heavy metal/trace elements than limits described in the ASTM Standard with no heavy metal/trace elements present above 1 ppm (Table 1).

Element Other Metals	ASTM F1185-03	DB CSD
Pb- Lead	50	0.08
Hg-Mercury	5	ND*
As-Arsenic	3	ND
Cd-Cadmium	5	0.012

**ND –Not Detected*

Table 1. Heavy Metal/Trace Elements in DB CSD

ANIMAL TESTING

Ovine Cancellous Bone Defect

As described in the Class II Special Controls Guidance Document: *Resorbable Calcium Salt Bone Void Filler Device* (2003), Pacific Bioceramics, demonstrated that the subject device had the same critical specifications (i.e., chemistry, crystallinity, physical form, porosity, dissolution/solubility) and the same intended use as the predicate device.

A large animal critical-sized ovine defect model evaluated the biocompatibility, tissue reaction, implant resorption, bone formation and surgical handling properties of InterSep following implantation in the femoral and tibial metaphases. This ovine model compared the subject device (InterSep) with the predicate device (Stimulan®). Both devices are comprised of a calcium salt cementitious phase that is combined at time of use with an aqueous solution.

After implantation into sheep cancellous bone sites, histological data did not exhibit any adverse tissue response from either device. Both materials were biocompatible with normal bone remodeling that occurred around the periphery of the cylindrical implant area. There was no visible inflammatory reaction associated with the implanted devices, and no macrophages or giant cells were observed within the implant. Tissue fibrosis was not observed within the implanted regions. Histomorphometric analysis showed complete device resorption and similar bony ingrowth rates between subject and predicate devices over the implantation period of three months.

The InterSep device maintained the reported safety profile of the predicate device with no remarkable safety issues

DISCUSSION AND CONCLUSION

Calcium Sulfate bone void fillers come in many commercially available forms today such as putties, injectable pastes, beads and blocks. These products are biocompatible, which means they do not cause the body to react to it in an adverse manner. They are also resorbed by the body relatively quickly; therefore, these types of products cannot be used without some other form of mechanical fixation. The amount of time Calcium Sulfate bone void fillers resorb is typically a matter of the size of material, location and local physiological environment. In the 1960s, Peltier hypothesized that Calcium Sulfates did not promote bone healing; but once it had been resorbed, replacement with trabecular bone was observed.

The InterSep® Calcium Sulfate bone void filler kit is provided sterile for single patient use. The kit contains Calcium Sulfate powder and mixing solution in pre-measured quantities so when mixed together in a sterile mixing bowl, the resultant paste may be digitally packed into open bone void/gaps to set in situ. The mixture sets to form a solid calcium sulfate implantable medical device. InterSep is manufactured from medical grade CSD ($CaSO_4 2H_2O$) that resorbs and is replaced with bone during the healing process. The bone void filler material is biodegradable and biocompatible and may be used within an infected bone site.

InterSep Calcium Sulfate passed the acceptance criteria for the biocompatibility, bench-top performance, and animal testing required for the regulatory submission to the FDA. •

InterSep® is manufactured by Pacific Bioceramics and distributed by Exactech, Inc.

ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING PLATELET RICH PLASMA AND TENOMEND™

Paul R. Fleissner, Jr., MD
Crystal Clinic Orthopaedic Center

This article has been modified by the author for length to facilitate inclusion in Innovations. The original article," Outcomes of Anterior Cruciate Ligament Reconstruction Using Biologic Augmentation in Patients 21 Years of Age and Younger," is available at www.sciencedirect.com.

INTRODUCTION

Anterior cruciate ligament (ACL) injuries are commonly encountered in the practice of sports medicine with current literature estimating an incidence of 100,000 to 200,000 cases per year.[1,2] Among adolescent populations, these injuries are becoming more prevalent. Recent reports have suggested that the numbers are steadily growing, with an incidence of 0.1 to 2.4 patients per 100,000 annually.

Regardless of graft and technique, reports have shown an increased risk of graft failure in the younger population compared with the adult population. Graft failure after successful anterior cruciate ligament reconstruction (ACLR) in patients 21 years of age or younger is as high as 25% or more in some studies.[1,3] The use of biologic agents, such as platelet-derived growth factors, remains an area of interest as surgeons explore new means to improve healing. In cases of ACLR, this adjunct is thought to enhance the overall integrity of the reconstructed ligament.[4]

Although a certain amount of fibrin clot forms in vivo after post-surgical trauma, concentrating specific growth factors that are found within a clot, (e.g., PRP), may have unrealized potential. Plasmin, which is also found with increased intra-articular concentrations after athletic or post-surgical trauma, has been shown to degrade fibrin and may prevent effective delivery of beneficial growth factors.[5] With this in mind, collagen scaffolds represent an intriguing adjunct, as soluble collagen can slow plasmin-mediated degradation of fibrin.[6]

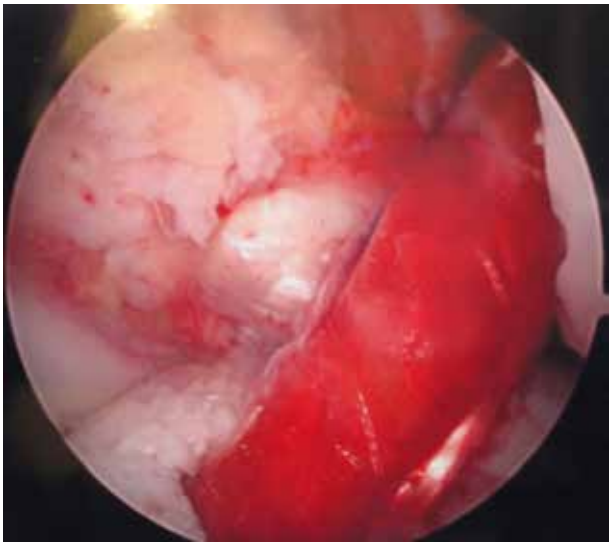

Figure 1. Intraoperative arthroscopic photograph of a left knee from a standard anterolateral viewing portal demonstrating final anterior cruciate ligament graft placement. An overlying porous collagen carrier has been sutured to circumferentially cover the hamstring autograft, and platelet rich plasma has been injected into the graft.

METHODS

Institutional review board approval was obtained. Patients 21-years of age or younger who underwent ACLR utilizing autologous hamstrings and biologic augmentation (PRP and porous bovine collagen membrane, TenoMend™, Collagen Matrix, Ramsey, NJ), with a minimum of two years follow-up were enrolled. All patients completed physical therapy and answered outcome questionnaires, including IKDC, Lysholm, Tegner and SANE. They also answered questions concerning whether they had sustained an ipsilateral or contralateral ACL injury since their initial ACLR, positive family history for ACL injury, return to the same sport after ACLR that they had played previously and subsequent surgery on the reconstructed knee since the ACLR (Figure 1).

Patients were rehabilitated using the protocol developed by the MOON study group. Patients were required to complete all 5 phases of the protocol and pass functional testing prior to returning to sports. Serial Lachman testing was performed postoperatively and at final follow-up. Patients were tested at final follow-up for pivot shift phenomenon and by KT-1000 arthrometer.

RESULTS

Initially, there were 194 patients eligible for this study; 143 patients involving 151 knees met the inclusion criteria and completed follow up questionnaires. The mean patient age was 16 years, range 8 to 21 years. The average time to complete physical therapy was 22 weeks, range 12 to 41 weeks. After completion of physical therapy, 132 patients (92%) returned to their preinjury level of activity. The average total follow-up duration was 52 months, range 25 to 94 months. Seven cases (5%) of ipsilateral ACL injury occurred that required revision surgery, with an average time to injury of 17 months. There were 23 contralateral ACL injuries (15%) at an average time of 28 months from the initial surgery.

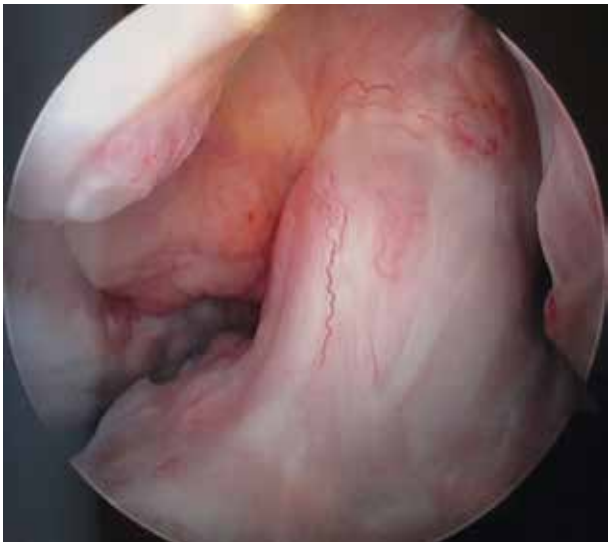

Figure 2. The same patient as in Fig 1, 7 months after the initial procedure. Patient was reevaluated with diagnostic and operative arthroscopy after sustaining a new injury while playing basketball. The reconstructed ACL has fully incorporated, with demonstrated ligamentization and neovascularization, again visualized from a standard anterolateral viewing portal.

Mean IKDC and Lysholm scores were 91 and 91, with a range of 55 to 100 and 57 to 100, respectively. Tegner scoring was the same both preoperatively and postoperatively in 138 of 151 knees; 11 scores were lower postoperatively than preoperatively, whereas 4 scores were higher postoperatively. The mean Tegner score preoperatively was 9, range 5 to 10, whereas the mean Tegner postoperative score was 9, range 4 to 10. The average SANE score was 94, range 60 to 100.

DISCUSSION

Graft failure after successful ACLR in adolescent populations is reported to be as high as at least 25% or more. PRP has received much attention recently in sports medicine surgery, as it contains many growth factors that may enhance graft maturation and bony ingrowth.[7,8] This has prompted others to explore its capabilities with regard to improving both the duration and quality of the healing process.[1,2,4,7-14] In this study, it was hypothesized that by using a collagen carrier (TenoMend), the clot of growth factors that formed after PRP injection would remain in place to maintain an optimal biologic environment during ACL graft incorporation. In this study, the graft failure rate was 5%. The major difference between this study and the studies in the literature with the much higher failure rate is the use of PRP and TenoMend (Figure 2).

Of 143 patients in this review, 132 (92%) returned to competitive sports at the same level of competition as before their injury. The patients in this study were able to return to competition at an average of 22 weeks after surgery, with minimal incidence of graft failure.

CONCLUSIONS

This study using biologic augmentation (PRP with porous bovine collagen membrane, TenoMend), with hamstring autograft in ACL reconstruction in patients 21-years of age or younger shows a decreased rate of second ACL injury, specifically regarding ACL revision surgery. The patients in this study also show a higher return to preinjury level of competition at a faster rate than other studies have shown.

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STATE-OF-THE-ART IN REVERSE SHOULDER ARTHROPLASTY: A NEW SMALL BASEPLATE SYSTEM BRINGS rTSA TO A NEW LEVEL

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Southeast Orthopedic Specialists

Shoulder arthroplasty is currently the most effective means of treating end-stage glenohumeral osteoarthritis in modern medicine. While over the past decades innovation has created substantial improvements in primary shoulder arthroplasty (rTSA) , it was not until the advent of reverse shoulder arthroplasty that a substantial expansion of the overall indications and applications for shoulder arthroplasty could actually occur. Present day, rTSA has eclipsed primary shoulder arthroplasty as the most commonly performed shoulder arthroplasty procedure worldwide, as the indications have rapidly expanded from treating rotator cuff tear arthropathy to proximal humerus fracture, and irreparable rotator cuff tears to primary osteoarthritis. Despite this rapid growth in indications, innovation in rTSA design has lagged behind—until now.

Exactech's Equinoxe® Platform Shoulder System has been a market leader in helping surgeons treat patients with an increasing variety of clinical scenarios. By providing a robust number of options in terms of angled augments, as well as variability in offset and lateralization, the Equinoxe System provides a platform arthroplasty solution for surgeons. Until now, a critical limitation of the Equinoxe Reverse System had been the size of the baseplate. Originally based upon dimensions of the larger stature individuals seen in the western world, the standard Equinoxe baseplate has distinct limitations when used for smaller stature patients commonly encountered in Asian populations. With the creation of the Small Reverse Shoulder, rTSA with the Equinoxe System can now be accurately and effectively performed in virtually all anatomy types.

Small-stature and associated small glenoid morphologies have long proven challenging for surgeons interested in performing primary and especially rTSAs. This challenging clinical scenario is a common occurrence in the U.S. rTSA markets but even more critical in the Asian markets. This discrepancy is even more apparent given the difference in clinical presentation of shoulder pathology in Asian populations. The incidence of primary osteoarthritis in Asian populations is exceedingly low. Rather, the most common indication for shoulder arthroplasty in Asian markets is for treatment of rotator cuff tear arthropathy. Indeed, rTSA represents 80% of the shoulder arthroplasty market in Asia.[1] Furthermore, this market is growing rapidly with an expected 41% growth rate in China and over 300% growth rate in Korea in the next five years.[1,2]

With the standard baseplate, fully half of the world's population has been excluded from the benefits of the Exactech Equinoxe Reverse System. In computer modeling studies of 100 small-stature glenoids, detailed analysis of height, width and vault depth were performed. Results demonstrated substantial size differences compared to the Western population, especially significant in females. With an average glenoid height and width of 33 x 24 mm respectively and a vault depth of less than 15 mm, small-stature females start off with smaller dimensions than the actual standard Equinoxe baseplate.[3] With onset of arthritis, erosions and bone loss, the size discrepancy becomes even more pronounced. Indeed, one study examining accuracy of baseplate implantation in Asian glenoids demonstrated that implantation with a standard baseplate had a 33% perforation rate of the bone cage. Of the remaining cases in which the cage remained in the vault, 25% were in suboptimal positioning. Just slightly over 40% were able to be correctly placed.[1]

The Small Reverse Shoulder has multiple features which may provide for enhanced glenoid fixation.

The new Small Reverse Shoulder and enhanced reverse shoulder system comprise a major evolutionary step for the Exactech Equinoxe platform stem. Using data from the proprietary CT analysis discussed previously, the Equinoxe Small Reverse Shoulder achieves a width dimension similar to competitors on the market yet has expansion capabilities (through augments, glenosphere options and humeral liners) to handle a variety of clinical scenarios in both small and large stature patients. Furthermore, by incorporating key design features of the standard Equinoxe Shoulder System, the team was able to provide the same robust characteristics that have led to over a decade of clinical success. Among these critical elements include enhancements intended to reduce scapular notching, improve glenoid fixation and provide a seamlessly integrated design within the Equinoxe System.

The Equinoxe Reverse Shoulder has been shown to dramatically reduce scapular notching by seven-fold;[4,5] the Small Reverse Shoulder design was based on the clinically proven Equinoxe design. The baseplate is anatomically shaped with dimensions of 29.5mm x 23.9mm and is 24.4% smaller than the current Equinoxe baseplate.[6] This combination, along with built-in baseplate offset, enables a shift in glenosphere position in an effort to avoid scapular notching while maintaining precise glenoid placement. Furthermore, the elongated glenosphere articular surface and new chamfered sides were designed to facilitate easier insertion, improve inferior offset and increase range of motion. The matching humeral implant retains the same 145-degree neck angle, which enables lateralization of the humerus without lateralizing the center of rotation.

The Small Reverse Shoulder has multiple features which may provide for enhanced glenoid fixation. The implant features the same curved backside as the standard baseplate, designed to minimize bone removal and convert shear forces into stabilizing compressive forces. By maintaining the same central cage diameter but shortening it (13.1mm vs 16.6mm) and shifting it to a slightly more central position, the small reverse baseplate provides initial fixation strength while limiting vault penetration or malposition in smaller glenoid anatomy.[6,7] The same variable angle compression screws with locking caps enhance the initial fixation and compression, while unique to the Equinoxe Reverse Shoulder; the central cage with addition of bone graft inserted inside helps to promote bone through-growth and long-term biologic fixation.[8] As a result of the smaller size and anatomic shape, the smaller baseplate design allows for greater percent surface area of contact with eroded glenoids such as those with a biconcave pattern. Finally, for more complex glenoid morphology, the baseplate will soon be offered in a superior (10 degrees), posterior (8 degrees) and superior/posterior configuration.

The Small Reverse Shoulder is designed to seamlessly integrate with the entire Equinoxe System. The current 36mm and 40mm glenospheres are available with 0mm and 2.5mm liners and lock into the existing humeral tray system providing full compatibility with the Equinoxe Platform stems. Lateralized versions of both 36 and 40mm glenospheres will be released in 2019 allowing for even greater flexibility with soft tissue balancing, anatomic tensioning of the remaining rotator cuff and improved deltoid wrap. With a wide range of augmented glenoid baseplates available to address various types of glenoid wear, the small reverse baseplate was designed to allow for revision flexibility even in the most limited of bone stock.

The Small Reverse Shoulder system is a game-changing innovation for the Equinoxe Shoulder System. The Equinoxe Reverse Shoulder has long been a leader in reducing scapular notching, providing enhanced glenoid fixation and providing a seamlessly integrated design.[9,10] With the addition of the Small Reverse Shoulder, Exactech now sets the industry standard for providing this robust array of features in treating both small and large glenoid morphology. Indeed, with the new Exactech Small Reverse Shoulder, surgeons worldwide will be able to address a wider range of clinical shoulder problems than ever before making sure to have a great day in the O.R.

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THE EVOLUTION OF INNOVATION IN HUMERAL IMPLANT OPTIONS: TWO SURGEONS' CASE REVIEWS

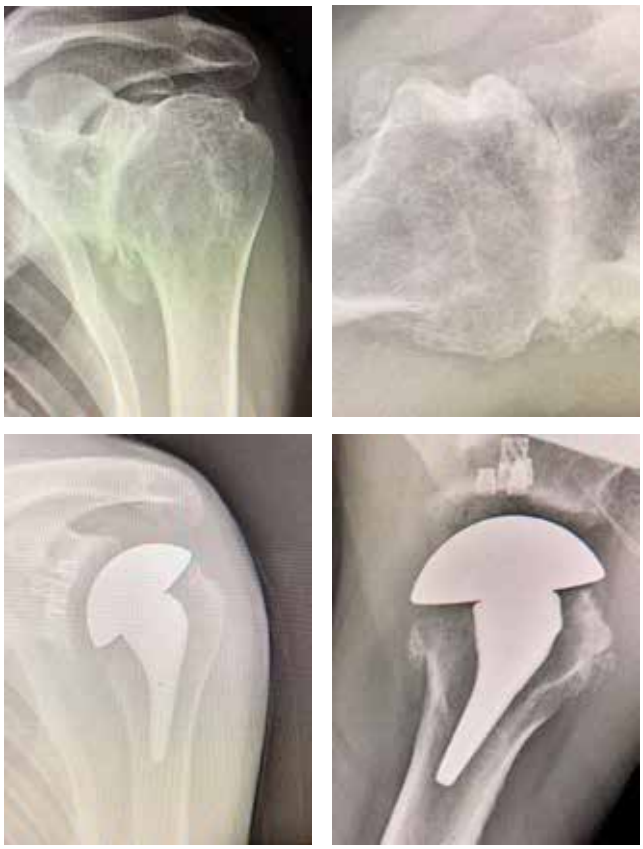
Throughout the field of orthopaedics, there is a trend moving toward preserving as much of the patient's natural anatomy as possible. Likewise, having access to a wide range of bone conserving implants affords the surgeon the opportunity to treat each patient with respect to anatomical preservation.

In shoulder arthroplasty, understanding the benefits of innovative, canal-sparing humeral implant options brings new considerations in treatment including patient demographic, surgical time and returning patients to post-operative lifestyle in concert with their expectations. Incorporating innovative implants that surgeons believe will improve patient outcomes requires thoughtful consideration and a respect for the required learning curve.

Rick Papandrea, MD, and Stephanie Muh, MD, two fellowship-trained surgeons, share their newly-acquired knowledge—choosing bone-conserving, canal-sparing humeral implants. In the following case reports, they juxtapose patient selection with surgical experiences and outcomes.

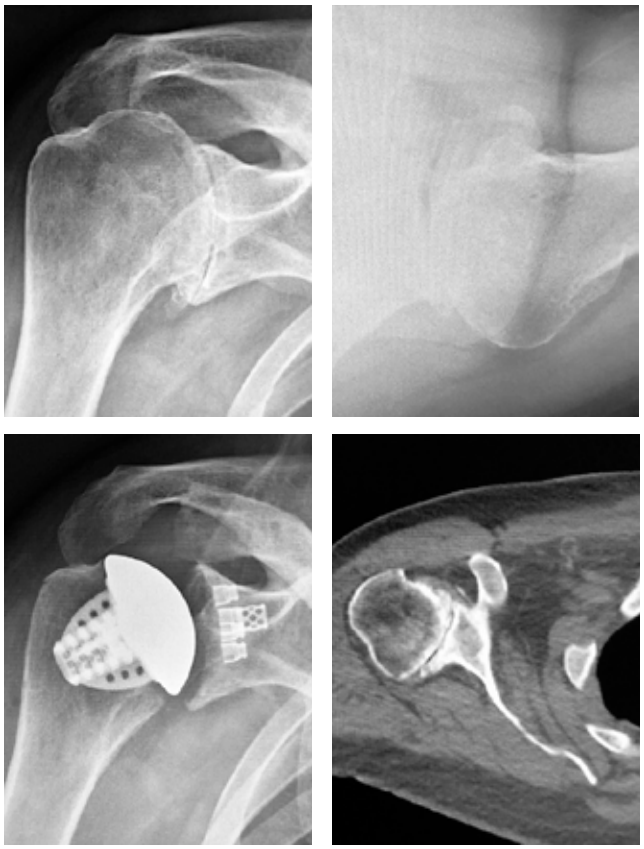
Rick Papandrea, MD
Orthopaedic Associates of Wisconsin

"With the advent of shorter stems, I have come to analyze my longer-term follow-up with more scrutiny, and thusly now select shorter stems more frequently, bone quality permitting, due to concerns of proximal stress shielding of the tuberosities. Though I am not sure what length of the shorter style stem is the best choice, I believe the stemless [implants] will be incorporated far more frequently whenever the bone is good enough. I have been able to continue to use an LTO (lesser tuberosity osteotomy) on these cases. Lately, I have only used the standard length stem with significant osteopenia proximally."



Patient 1: *Primary anatomic total shoulder arthroplasty using Equinoxe Preserve short stem and caged glenoid.*

- Active male in his 60s, retired reporter with surprisingly good preop motion
- This patient is a good candidate for either a stemless anatomic or a short stem anatomic
- Six (6) weeks postop his external rotation (ER) has returned to preop baseline of 45 degrees and his forward flexion (FF) has improved from 90 to 145 degrees.



Patient 2: *Primary anatomic total shoulder arthroplasty using a stemless implant.*

- Active male in his 60s, retired radiologist
- Typical pain and significant range of motion limitations

Patient 3: *Revision of a failed anatomic total shoulder with loose humeral stem to reverse total shoulder arthroplasty*

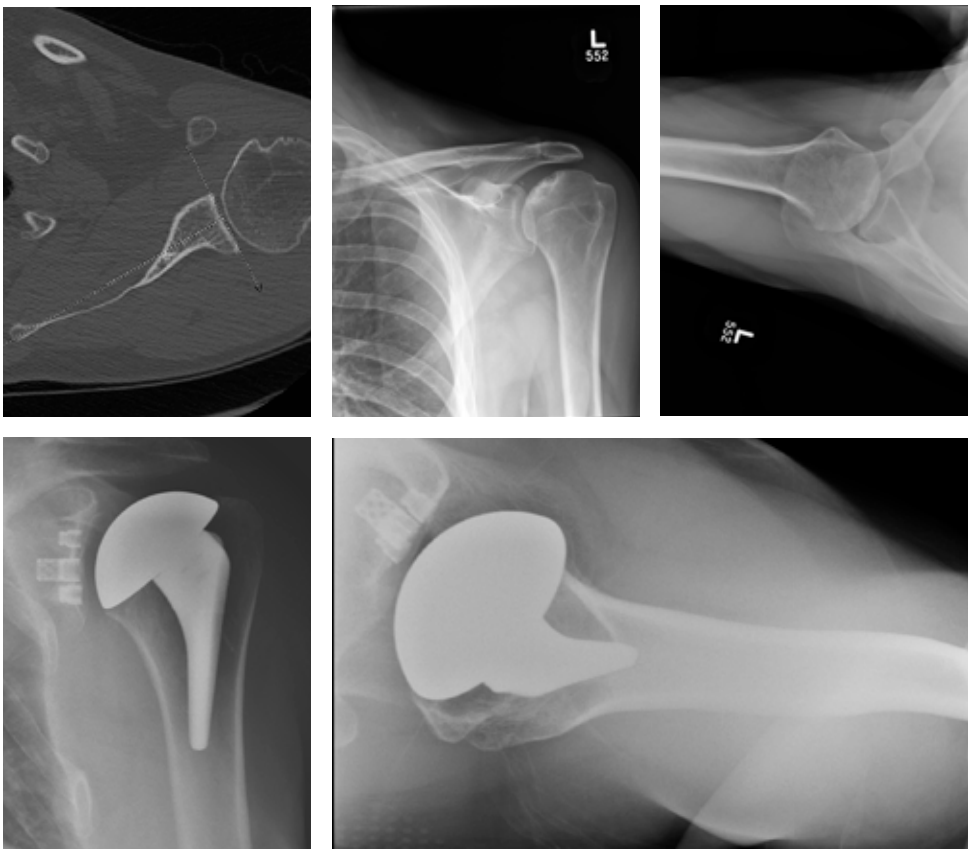
- The humeral stem was loose, so it was replaced with the short stem for the aggressive proximal geometry, which fit nicely and improved the proximal press-fit
- Revised an anatomic to a reverse, replacing stem from another company
- Significant glenoid wear led to augmented baseplate choice – superior posterior augment

Stephanie Muh, MD
Henry Ford Hospital West
Bloomfield

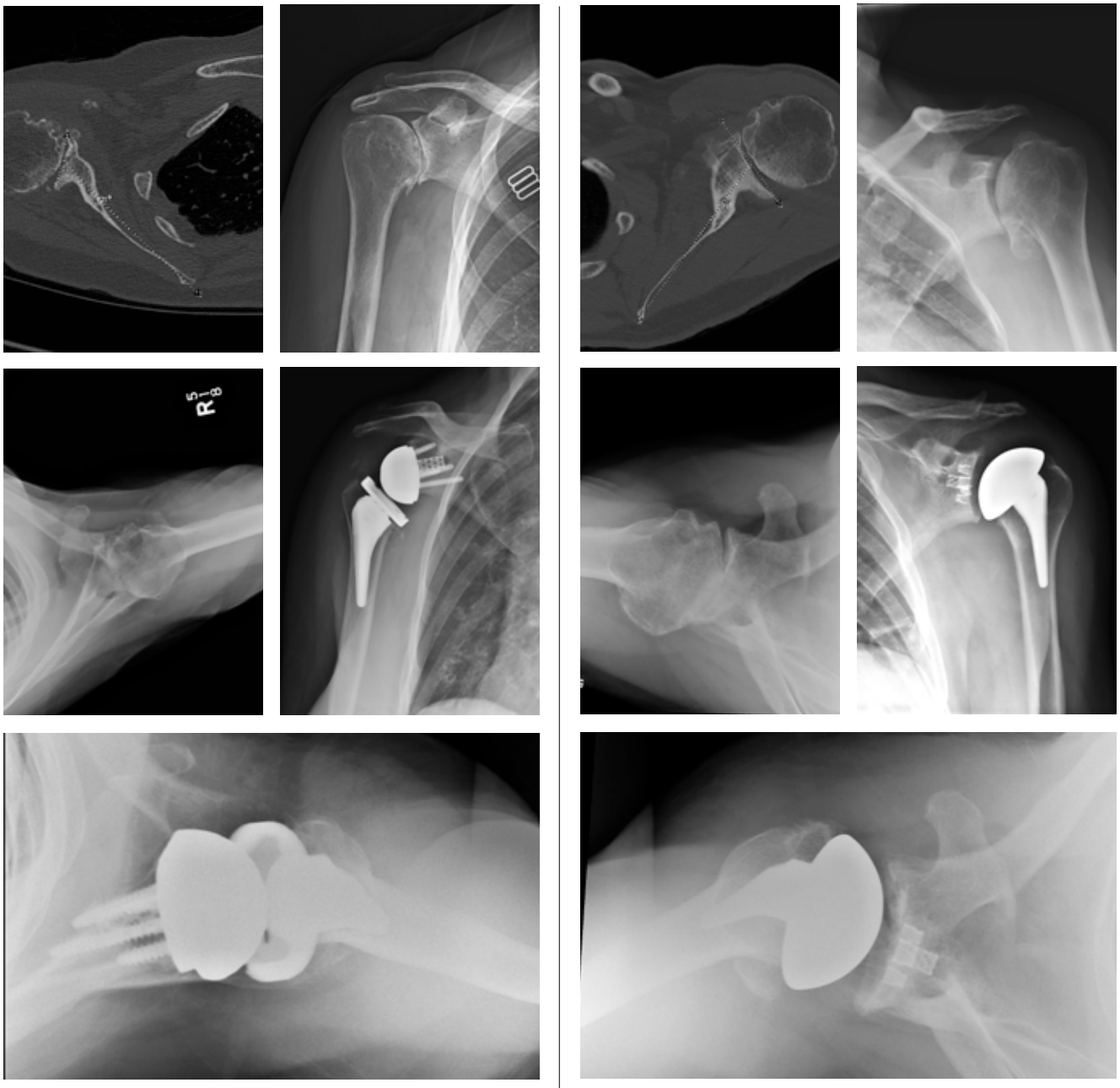
"I try to use the Equinoxe® Preserve short stem as my primary stem of choice. The only time I will use the standard length stem is if the patient has poor osteoporotic bone during surgery. Generally, I will start with a Preserve preparation, and if I have to broach to a size 8 or larger, I am considering a transition to the primary length stem for better fixation.

Moving from standard to short stem is surgeon-friendly, avoids reaming the canal and is a simple technique. As a surgeon, you have to be cautious and pay close attention to the broach technique so that the stem does not go into varus or valgus.

The short stem has become my primary stem of choice. It is a platform stem allowing for future revisions from TSA to rTSA, avoids reaming the canal, which I believe increases postoperative pain in patients. The short stem allows for more bone preservation for revisions. In my practice, I have also noted there appears to be less proximal osteolysis/resorption as compared to competitor implants. I will also use the stemless implant for very young patients who I am concerned will require multiple revisions in the future."



Patient 1: *59-year-old male with avascular necrosis of the humeral head. Left primary anatomic total shoulder arthroplasty using Equinoxe Preserve short stem and cage glenoid.*



Patient 3: *74-year-old female with cuff tear arthropathy. Right primary reverse shoulder arthroplasty with augmented baseplate to treat glenoid wear.*

Patient 4: *63-year old male with osteoarthritis. Left primary anatomic total shoulder arthroplasty using Equinoxe Preserve short stem with 8-degree cage glenoid.*

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Designed by Michael P. O'Reilly, MD

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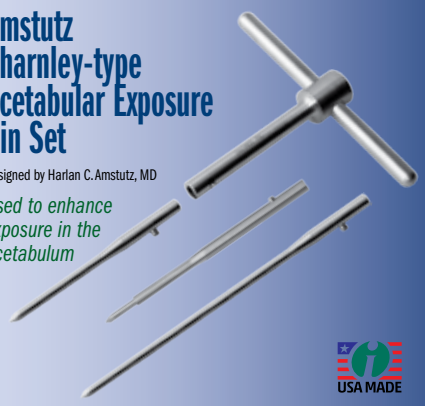
Amstutz Charnley-type Acetabular Exposure Pin Set

Designed by Harlan C. Amstutz, MD

Used to enhance exposure in the acetabulum



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1200-0A [Set: Ins/Ext & Two Pins w/Stop]
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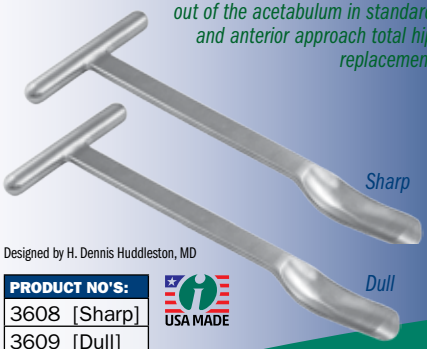

Designed by H. Dennis Huddleston, MD

PRODUCT NO'S:
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3609 [Dull]

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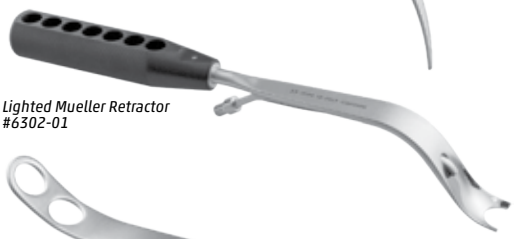
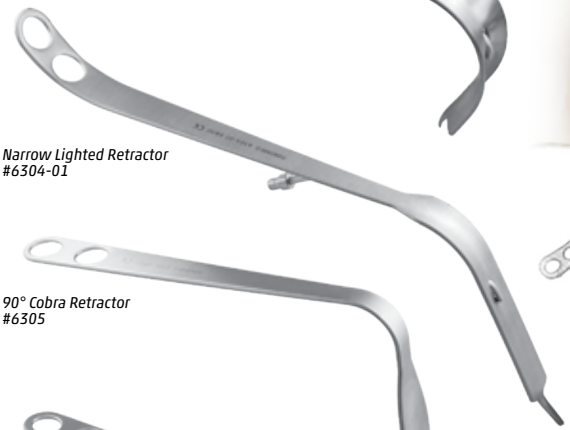
1. *Awl – Left #6301-L*
2. *Awl – Right #6301-R*

3. *Lighted Mueller Retractor #6302-01*



4. *Wide Lighted Retractor #6303-01*



5. *Narrow Lighted Retractor #6304-01*

6. *90° Cobra Retractor #6305*

7. *Straight Hohmann Retractor #6306*

8. *Deep Hohmann Retractor #6307*

9. *Femoral Starter Drill #6308*

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2 6301-R [Awl – Right]
3 6302-01 [Lighted Mueller Retractor]
4 6303-01 [Wide Lighted Retractor]
5 6304-01 [Narrow Lighted Retractor]
6 6305 [90° Cobra Retractor]
7 6306 [Straight Hohmann Retractor]
8 6307 [Deep Hohmann Retractor]
9 6308 [Femoral Starter Drill]

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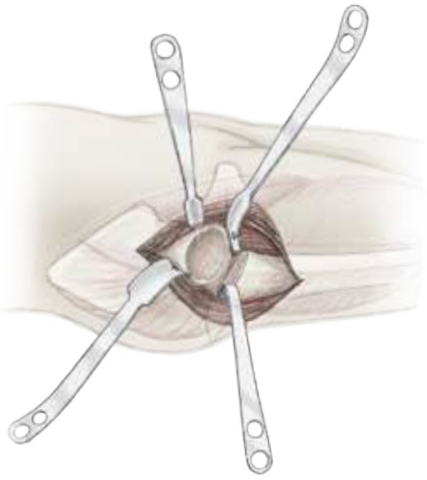

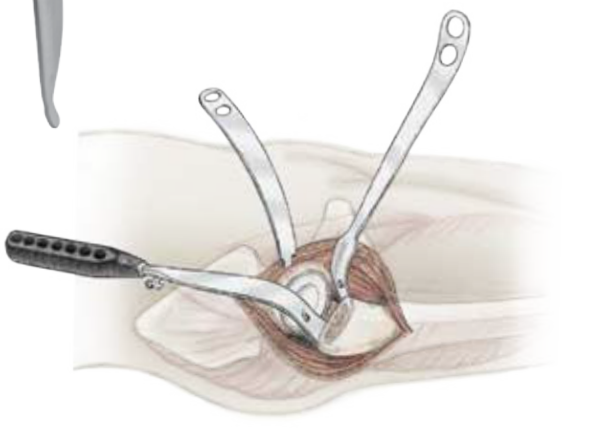

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