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A CLINICAL EXCHANGE ON ADVANCES IN ORTHOPAEDICS

VOLUME 3 ISSUE 1

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TRENDS IN THE ORTHOPAEDIC INDUSTRY

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

When we began Exactech in 1985, *Golden Girls* was the most popular TV show, Hall and Oates' *Out of Touch* was one of the year's best songs and dressing like a tennis player was the height of fashion. Although a lot has changed in the past 30 years—in popular culture and in orthopaedics—we've always held fast to our mission to create products and services that improve patient outcomes.

This edition of *Innovations* is devoted to some of the new techniques, technologies and efficiencies that are advancing the ever-evolving field of orthopaedics. Inside, you'll hear from surgeons and engineers who are looking beyond conventional wisdom and finding solutions to the remaining challenges facing our industry.

As more and more patients want a faster return to their homes and daily activities, the practice of outpatient joint replacement surgery has increased to accommodate these active lifestyles and demands. In our featured articles, two surgeons discuss their experience with outpatient procedures and developing successful outpatient programs (pages 15 and 23).

For an orthopaedic surgeon performing joint knee arthroplasty in today's environment, satisfactory component fit may have significant impact intraoperatively or postoperatively on patient outcomes, particularly in individuals with smaller anatomy. Scientific articles review clinical data related to component position and size of Exatech's new Truliant® Knee System, starting on page 2.

Additionally, Exactech is proud to introduce the latest advances in total ankle arthroplasty and computer assisted orthopaedic surgery. Hear from some of our surgeon designers and see early clinical outcomes, starting on page 32.

This edition also includes an interesting perspective on additive manufacturing technologies for orthopaedic implants (page 29). Although the first additive manufacturing (or 3D printing) technologies were developed in the 1980s, the field has grown exponentially in recent years and can provide many benefits to the orthopaedic industry in the future.

Trends come and go, but our focus on helping surgeons worldwide make patients more mobile remains steadfast. We hope you enjoy this issue of *Innovations*. Please be sure to share your feedback with us at **www.exac.com/innovations**. •

DISTAL FEMORAL MORPHOLOGY AND ITS CORRELATION WITH TWO CONTEMPORARY TKA DESIGNS

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INTRODUCTION

Morphological fit of the femoral component is important for the success of total knee arthroplasty (TKA)[1]. As mismatched femoral component size may affect proper flexion-extension gap balancing, patellofemoral kinematics, and tension in soft tissue. Furthermore, it has been shown that excessive femoral overhang (more than 3mm) may be related to postoperative knee pain[2], and this phenomenon is believed to be more prevalent in Asian knees compared to Caucasian knees. To avoid the negative impact from excessive overhang, it is important to understand ethnic differences in the distal femoral morphology, and its correlation with contemporary TKA designs. The purpose of this study was to evaluate distal femoral morphology in Asian and Caucasian knees and compare to two new TKA designs, Depuy Synthes Attune® and Exactech Truliant®.

MATERIALS AND METHODS

Digital femoral surface models of 50 Chinese (25M/25F) and 50 Caucasian (25M/25F) bones were used in this study. The anteroposterior (AP) dimension of the femur was measured from the anterior cortex to the tangent plane of both posterior condyles. A distal TKA resection was then performed virtually on each femur (3-matic Research, Materialise NV, Leuven, Belgium). The mediolateral dimension (ML) of the bones was measured at the anteroposterior mid-point of the distal resection. AP and ML dimensions, as well as the aspect ratio (ML/AP), were compared for the two ethnicities. The bone data was compared to two contemporary femoral implant designs with different sizing philosophies. Attune has multiple ML size offerings in the mid-size range. Truliant has a single ML offering across each AP size. Statistical significance was defined as $p<0.05$.

RESULTS

Significant differences found between ethnicities and genders are presented in Table 1. The majority of the differences were between male and female, but with less difference seen for ethnicity. Both the two contemporary designs assessed had component aspect ratios following the lower bound of the bone data across the sizes, therefore minimizing overhang (Figure 1). Truliant was shown to have aspect ratios slightly lower than Attune in small sizes, between the two sizing offerings of Attune in median sizes, and matching Attune in large sizes.

	Measurement*	P
ML (mm)		
Female	65.78 ± 3.11[a]	<0.01
Male	73.84 ± 3.57[b]	
AP (mm)		
Female	53.51 ± 3.44[a]	<0.01
Male	58.22 ± 3.27[b]	
Aspect Ratio (ML/AP)		
Female	1.23 ± 0.09[a]	0.02
Male	1.27 ± -0.07[b]	
ML (mm)		
Chinese Female	64.99 ± 2.51[a]	<0.01
Chinese Male	72.58 ± 3.69[b]	
Caucasian Female	66.57 ± 3.49[a]	
Caucasian Male	75.10 ± 3.01[b]	
AP (mm)		
Chinese Female	53.34 ± 3.98[a]	<0.01
Chinese Male	57.62 ± 3.47[b]	
Caucasian Female	53.69 ± 2.89[a]	
Caucasian Male	58.82 ± 3.00[b]	

*Different alphabetic letters represent significantly different groups.

Table 1. Significant differences found between genders and ethnicities.

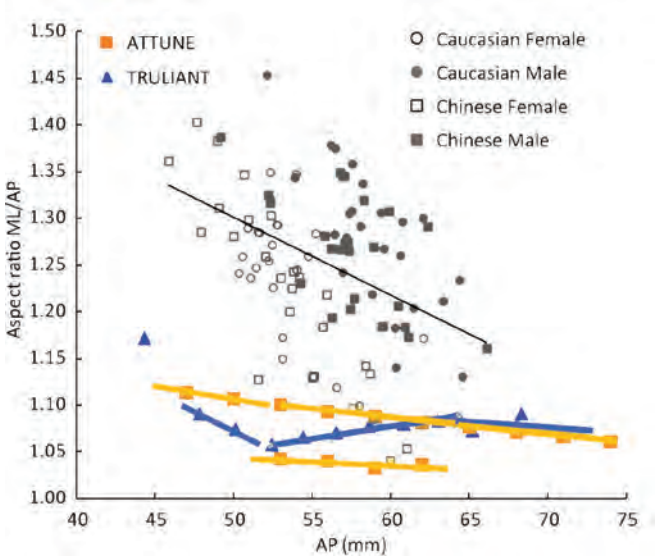

Figure 1. Aspect ratio of the bone data overlaid with the two contemporary femoral component designs.

DISCUSSION

The study compared femoral morphology between the Chinese knees and Caucasian knees, and demonstrated the majority of the differences exist between genders for these two ethnicities. The two newly released contemporary designs both have aspect ratios at the lower bound of the bone data, which may be translated to minimized component overhang in the dataset. Compared to Attune, Truliant varies the aspect ratio across the bone size range to match the morphology of the distal femoral resection.

SIGNIFICANCE

Virtual analysis of 100 femora demonstrated gender and ethnic differences in distal resection morphology between Caucasian and Chinese. Two newly released contemporary femoral component designs with different sizing philosophies (single and multiple ML offerings) both demonstrate minimization of component overhang. •

REFERENCES

1. **Bonnin MP, Schmidt A, Basiglini L, et al.** Mediolateral oversizing influences pain, function, and flexion after TKA. *Knee Surg Sports Traumatol Arthrosc.* 2013;21:2314–24.

2. **Mahoney OM, Kinsey T.** Overhang of the femoral component in total knee arthroplasty: risk factors and clinical consequences. *J Bone Joint Surg [Am].* 2010;92-A:1115–21.

TRULIANT® FEMORAL COMPONENT FIT IN MEDIUM TO SMALL SIZED KNEES

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INTRODUCTION

In the modern era of total knee arthroplasty (TKA), comprehensive consideration of an individual's bone and soft tissue characteristics has gained more focus. It is important to select a prosthesis that best fits the native morphology of the targeted patient population. Studies have shown that mediolateral (ML) oversizing of the components can compromise the clinical outcomes of the surgery, such as lower functional scores, less range of flexion, and may account for 27% of postoperative knee pain, possibly due to irritation of the soft-tissue around the knee.[1-3]

In the femur, the goal of minimizing component overhang can be complicated by other surgical considerations with unintended consequences. For example, ML overhang can be avoided by undersizing or using a narrower femoral component. In the undersizing circumstance, the undersized anteroposterior (AP) dimension of the component can increase flexion laxity or cause anterior notching. Although these situations may be resolved by additional femoral resections to prepare for the undersized femur, the resulting joint line will inevitably be elevated, which can negatively impact patellofemoral kinematics, increase the incidence of instability, or decrease knee flexion.[4-8] Studies have identified that an overhang of more than 3-4mm is clinically important. In a 2010 study, Mahoney et al. reported that more than 3mm of component overhang can increase the risk of clinically important knee pain by 90%.[2] A recent investigation by Chung et al. concluded that more than 4mm of overhang can significantly lower the maximum flexion angle postoperatively.[9]

Many studies have evaluated the ML morphological fit of modern femoral implants. Most analyses were focused on the component fit at limited locations, typically at the distal resection area.[2,9,10,11,12] However, complex variations in femoral morphology have been reported, which are not limited to the distal portion of the femur.[13]

The design and development of the Exactech's Truliant® Knee System employed a series of comprehensive morphological studies to minimize ML overhang of the femoral component. This present study computationally assessed the component of the Truliant femoral components superimposed on a dataset of medium to small knees.

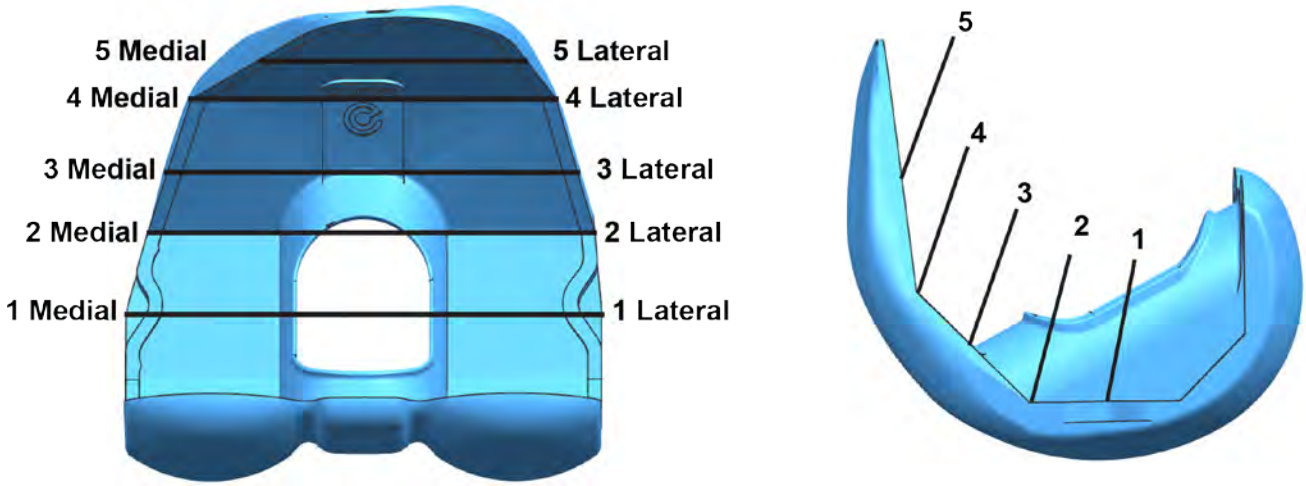

Figure 1. Representative views of the Truliant femoral component demonstrating the 10 anatomical locations for the measurement of component fit.

MATERIALS AND METHODS

Bone Data

Digital femoral surface models of 30 Chinese (11M/19F) and 24 Caucasian (5M/19F) knees were selected from a CT scan based virtual bone database. The selection included all the right femora in the database that had an AP dimension of no more than 57.9mm measured from the anterior cortex point to the tangent plane of both posterior condyles (corresponding to Truliant component sizes of 3 and under).

Component Sizing and Placement

Each femur was virtually resected in accordance with its proper component size following the Truliant anterior referencing surgical technique (Unigraphics NX, Siemens PLM Software, Plano, TX, USA). Virtual implantation of the femoral component was performed by a computational algorithm. The algorithm first lateralized the femoral component such that it aligned with the bony resection at the AP mid-point of the distal cut (Location 1, Figure 1). The fit of the femoral component was then measured at 10 anatomical locations on the distal, anterior chamfer, and anterior resection areas (Matlab, Mathworks Inc, Natick, MA, USA) (Figure 1). In some instances, if overhang of more than 3mm (clinically important overhang) was detected at any location, a secondary algorithm slightly adjusted the ML position of the component by allowing an ML translation in the opposite direction (no more than 3mm), optimizing the fit by minimizing both the number of locations and the severity of overhang.

Data Analysis

The subsequent ML fit of the component was assessed at the 10 anatomical locations. The incidence of the component extending beyond the resection bony profile were identified. The associated amount of mismatch between the component and bony resection was recorded. Clinically important overhang was defined when the component extended more than 3mm beyond the bony profile.

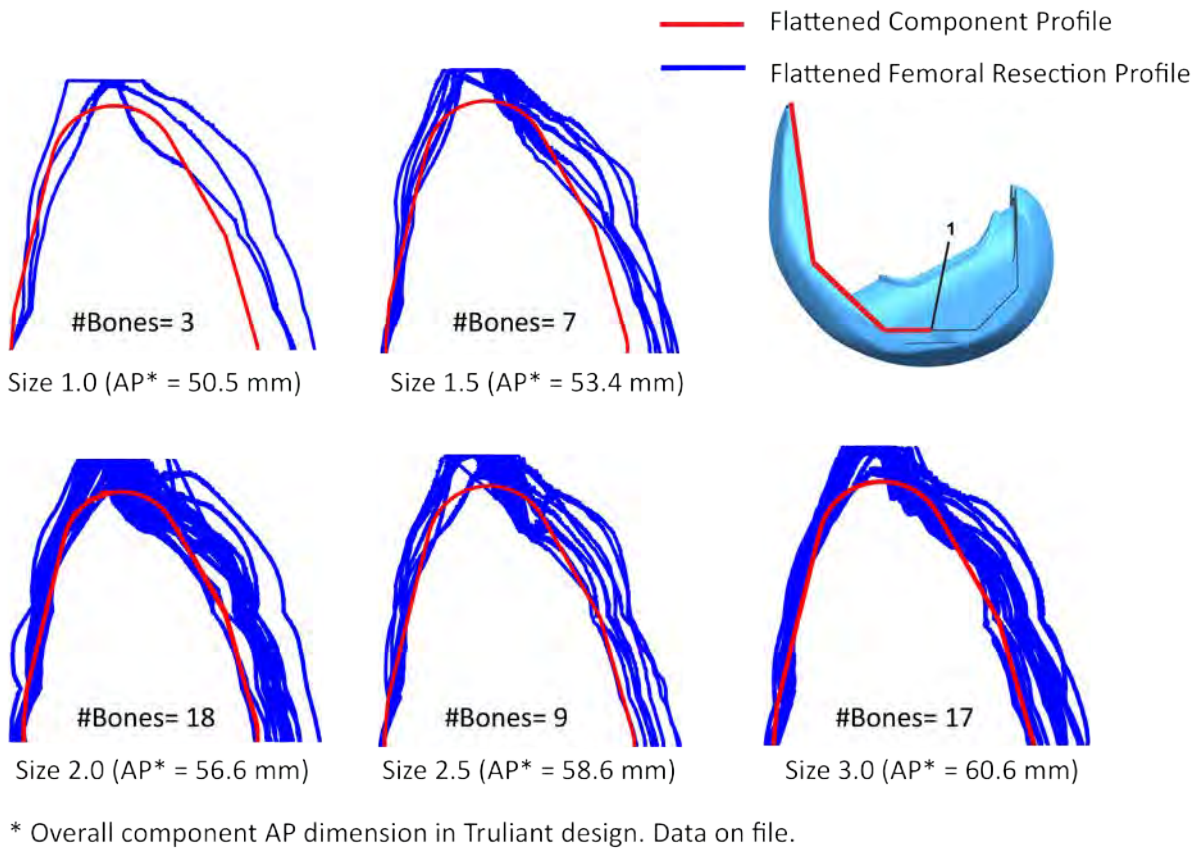

Figure 2. Illustration of "flattened" two dimensional Truliant femoral component profiles for each component size, overlaid with the associated resected femoral bone profiles in the dataset according to the component sizing and placement. The images were scaled to the same size, with the bone profiles truncated to only the region of interest.

RESULTS

Figure 2 illustrates the two dimensional unfolded or "flattened" profiles of the Truliant femoral component sizes used in this study (from location 1 to the proximal tip of the flange), overlaid with the associated flattened bony resection profiles according to the component placement. Across genders and ethnicities, the Truliant femoral component design consistently minimized clinically important overhang (Table 1, Figure 2, 3). Only one knee (Chinese, female) had a negligible additional amount (0.1mm) of overhang over 3mm at location 2 lateral.

DISCUSSION

Exactech's Truliant Knee System continues the successful evolution of the Optetrak Logic® Knee System, with renewed focus on the restoration of patient's natural anatomy in addition to the clinically proven, patented legacy design for articular and patellar performance.[14-16] The findings of this study showed excellent fit among medium to small sized knees studied in the dataset. Only one knee that had an overhang in excess of the clinically important threshold. Contrary to the common belief that the fit of western originated knee designs may be compromised in other populations, especially Asian patients,[9,10,17] the Truliant femoral design was shown to provide equally good fit for both ethnic groups studied. In addition, although it has been reported that component fit in female knees is inferior to that in male knees,[2,10] the Truliant femoral design did not demonstrate gender based differences in terms of clinically important overhang incidence.

Table 1. Incidence of clinically important overhang (> 3 mm) in the data set. Only one femur had clinically important overhang with an overhang amount of just 0.1 mm above the clinically important overhang threshold.

Incidence of Clinically Important Overhang

	Chinese	Caucasian	Female	Male	pooled
N	30	24	38	16	54
Number of bones with >3 mm overhang	1	0	1	0	1

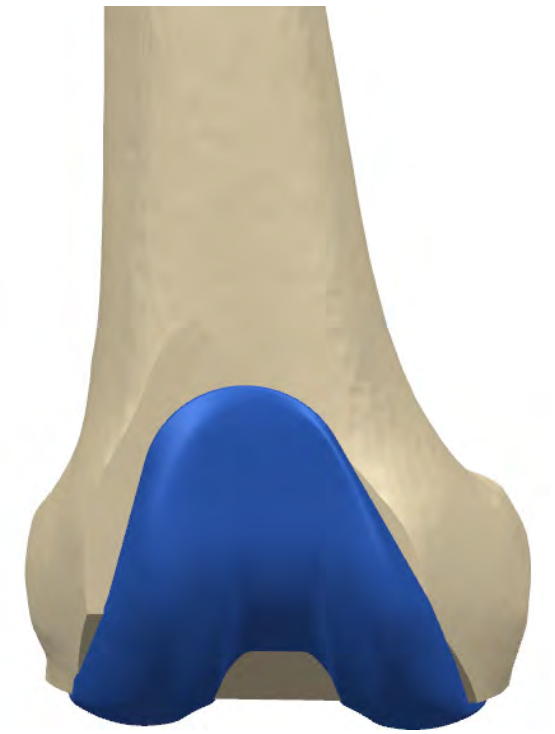

Figure 3. A representative femur (Chinese, female) with the placement of the Truliant femoral component. No clinically important overhang (> 3mm) was observed on this bone.

CONCLUSION

Computational assessment of the femoral fit of Exactech's Truliant femoral component design demonstrated minimal incidence of clinically important overhang in both genders and ethnic groups investigated. The data confirmed that the sizing of the Truliant femoral component respects the anatomy of the distal femur, potentially minimizing the risk of TKA complications related to femoral component overhang. •

REFERENCES

1. **Bonnin MP, Schmidt A, Basiglini L, et al.** Mediolateral oversizing influences pain, function, and flexion after TKA. *Knee Surg Sports Traumatol Arthrosc.* 2013;21:2314–24.

2. **Mahoney OM, Kinsey T.** Overhang of the femoral component in total knee arthroplasty: risk factors and clinical consequences. *J Bone Joint Surg [Am]* 2010;92-A:1115–21.

3. **Chau R, Gulati A, Pandit H, et al.** Tibial component overhang following unicompartmental knee replacement: does it matter? *Knee.* 2009;16:310–3.

4. **Bellemans J.** Restoring the joint line in revision TKA: does it matter? *Knee.* 2004;11:3–5.

5. **Yoshii I, Whiteside LA, White SE, et al.** Influence of prosthetic joint line position on knee kinematics and patellar position. *J Arthroplasty.* 1991;6:169–177.

6. **Figgie HE, Goldberg VM, Heiple KG, et al.** The influence of tibial-patellofemoral location on function of the knee in patients with the posterior stabilized condylar knee prosthesis. *J Bone Joint Surg [Am].* 1986;68:1035–40.

7. **Laskin RS.** Management of the patella during revision total knee replacement arthroplasty. *Orthop Clin North Am.* 1998;29:355–60.

8. **Singerman R, Davy DT, Goldberg VM.** Effects of patella alta and patella infera on patellofemoral contact forces. *J Biomech.* 1994;27:1059–65.

9. **Chung BJ, Kang JY, Kang YG, et al.** Clinical implications of femoral anthropometrical features for total knee arthroplasty in Koreans. *J Arthroplasty.* 2015;30(7):1220-7.

10. **Loures FB, de Araújo Góes RF, da Palma IM, et al.** Anthropometric study of the knee and its correlation with the size of three implants available for arthroplasty. *Revista Brasileira de Ortopedia.* 2016;51(3):282-9.

11. **Hitt K, Shurman JR II, Greene K, et al.** Anthropometric measurements of the human knee: correlation to the sizing of current knee arthroplasty systems. *J Bone Joint Surg [Am]* 2003;85-A(suppl 4):115–22.

12. **Dai Y, Scuderi GR, Penninger C, et al.** Increased shape and size offerings of femoral components improve fit during total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2014;22(12):2931-40.

13. **Mahfouz M, Abdel Fatah EE, Bowers LS, et al.** Three-dimensional morphology of the knee reveals ethnic differences. *Clin Orthop Relat Res.* 2012;470(1):172-85.

14. **Robinson RP, Green TM.** Eleven-year implant survival rates of the all-polyethylene and metal backed modular Optetrak posterior stabilized knee in bilateral simultaneous cases. *J Arthroplasty.* 2011;26(8):1165-9.

15. **Edwards J, Gradisar I Jr, Nadaud M, et al.** Eight and one-half year clinical experience with the Optetrak total knee prosthesis. Presented at the American Academy of Orthopedic Surgeons 2004.

16. **Ehrhardt J, Gadinsky N, Lyman S, et al.** Average 7-year survivorship and clinical results of a newer primary posterior stabilized total knee arthroplasty. *HSS J.* 2011;7(2):120-4.

17. **Yue B, Varadarajan KM, Ai S, et al.** Differences of knee anthropometry between Chinese and white men and women. *J Arthroplasty.* 2011;26(1):124-30.

FIT OF MODERN FEMORAL KNEE IMPLANT DESIGN TO NATIVE TROCHLEAR GROOVE

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INTRODUCTION

Total knee arthroplasty (TKA) is a mature surgical procedure for the treatment of endstage knee arthritis. Despite its overall high clinical success, many patients still report pain and discomfort after TKA, with approximately 20% of the patients not satisfied with the clinical outcomes.[1,2] Among the complications related to TKA, patellofemoral pain and instability have been found to be one of the most common reasons for revision.[1,3,4]

The causes of patellofemoral complications are multifactorial, including improper surgical technique (implant positioning and sizing, soft-tissue balancing, etc.) and limitations in implant design.[5-9] Numerous biomechanical studies suggest that even when the surgical technique is optimized, patellofemoral tracking is not always restored to physiological values due to the difference between the implant trochlea and the native trochlea.[5-8]

The ability of the implant to restore native trochlear groove morphology may be affected by the design philosophy. Currently, there are several designs in modern implant systems based on the orientation of the trochlear groove. One design philosophy (Philosophy I) employed by many device companies, is a trochlear compartment with a lateral groove orientation. With the rationale to capture perceived gender differences in Q-angle, a recent design refined this philosophy with "gender-specific" solutions. These solutions offer different amounts of lateral angulation in groove orientation based on the average Q-angle of male and female populations, respectively. Distinctly different, a second philosophy (Philosophy II) creates "forgiveness" for patella tracking by designing a neutral trochlear groove orientation with a widened proximal trochlear compartment on the femoral implant. The basis of this philosophy, encompassed by Exactech's Truliant® Knee System design, is to respect the natural variable motion path of the patella by allowing a moderate degree of proximal mediolateral (ML) freedom, which gradually changes to a constrained trochlea in high flexion (intercondylar region) (Figure 1).

To date, there is a paucity of data regarding direct comparison between the design philosophies in the context of restoring native trochlear groove orientation. This study computationally assessed the native trochlear groove orientation in a dataset of healthy femora and compared the results to current modern femoral implants representing the two design philosophies.

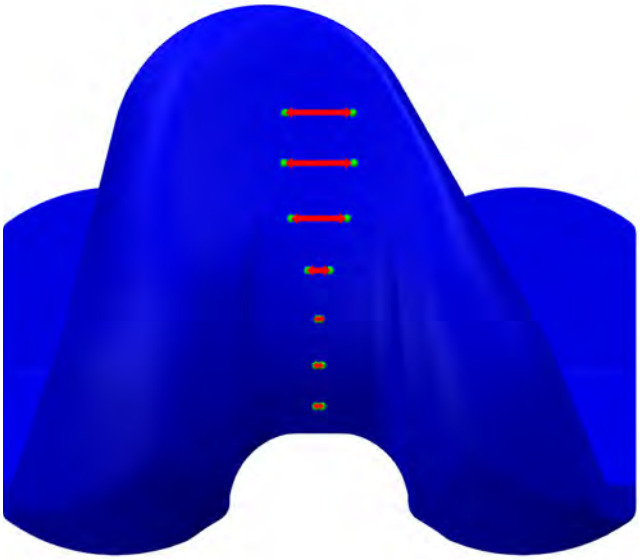


Figure 1. Illustration of allowed range of ML positions of the patella (patella center location) at different levels of the trochlear groove. The allowed ML ranges were highlighted in red.

MATERIALS AND METHODS

Bone Data

CT scan based virtual surface models of 94 healthy right femora were used in this study. The data set contained 49 Chinese (24M/25F) and 45 Caucasian (23M/22F) femora.

Measurement of Native Trochlear Groove Orientation

An automated virtual workflow was developed to extract the trochlear groove region from the femoral surface (3-matic research, Materialise NV, Leuven, Belgium). A virtual plane was constructed passing through the anatomical transepicondylar axis (TEA) and the apex of the intercondylar notch. The plane was rotated 130° proximally in 5° increments (Figure 2).[5] At each plane position, the intersecting curve between the plane and the femoral surface was generated and exported for further analysis.

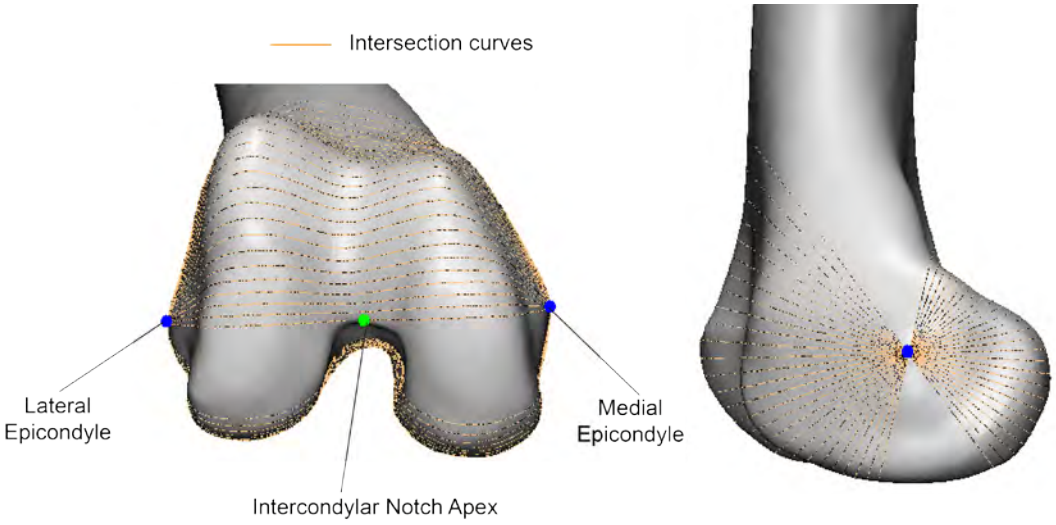


Figure 2. A representative femur illustrating intersecting curves created by rotating a plane around the transepicondylar axis.

Custom software was developed to locate the deepest point on the trochlear groove on each intersection curve (Matlab, Mathworks Inc, Natick, MA, USA) (Figure 3). ML discontinuity (> 3mm) in the deepest point across the entire curve set was detected, and the corresponding location was determined as the proximal boarder of the trochlear groove. For each femur, the set of deepest points within the trochlear groove region were projected onto the coronal plane. The best-fit line, representing the trochlear groove path, was calculated from the projected point set. The trochlear groove orientation was calculated as the angle between the trochlear groove path and the line perpendicular to transepicondylar axis (Figure 3). Ethnic and gender differences in the trochlear groove orientation were investigated. The groove orientation was correlated with bone size (AP). Statistical significance was defined as $p < 0.05$.

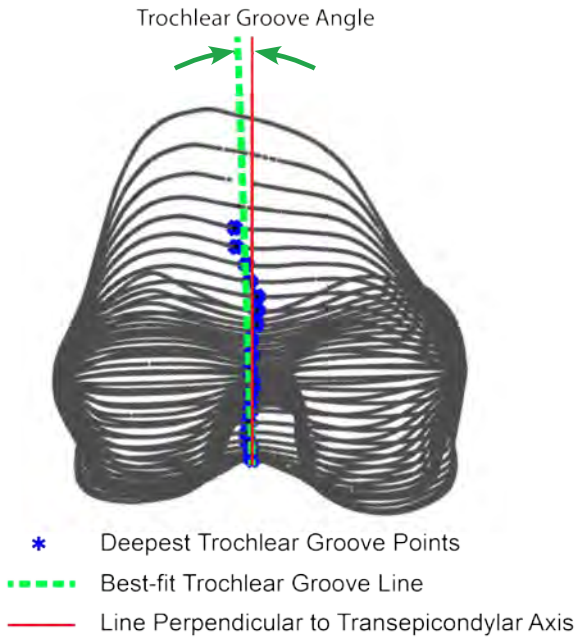


Figure 3. A representative femur demonstrating the calculation of the orientation of the trochlear groove. A negative trochlear groove angle indicates that the groove was oriented laterally from distal to proximal direction, as illustrated to the left.

EVALUATION OF MODERN FEMORAL DESIGNS

The trochlear groove orientation in five modern femoral designs was evaluated against the data on the native femur, including NexGen® Complete Knee Solution (Zimmer Biomet, Warsaw, IN, USA), Attune® Knee System (Depuy Synthes, Warsaw, IN, USA), GENESIS™ II Total Knee System (Smith and Nephew, Memphis, TN, USA), Triathlon® Knee System (Stryker, Kalamazoo, MI, USA), and Truliant® Knee System (Exactech, Gainesville, FL, USA). It is worth noting that the trochlear groove angle in the Attune Knee System proportionally changes based on component size (ranging from 10° to 14° lateral) under the design assumption that a patient's Q-angle and therefore their trochlear angle correlates with size. In contrast, the Truliant Knee System follows the philosophy of a fixed neutral groove orientation with a proximally widened trochlear compartment in order to provide more "forgiveness" to accommodate the naturally varying patella tracking (Figure 1), while the other four knee systems each present a fixed lateralized trochlear groove angle for patella tracking. The allowed range of trochlear groove orientation was measured on the Truliant femoral component based on tracking the center of the smallest sized patella component during simulated placement (Figure 4).

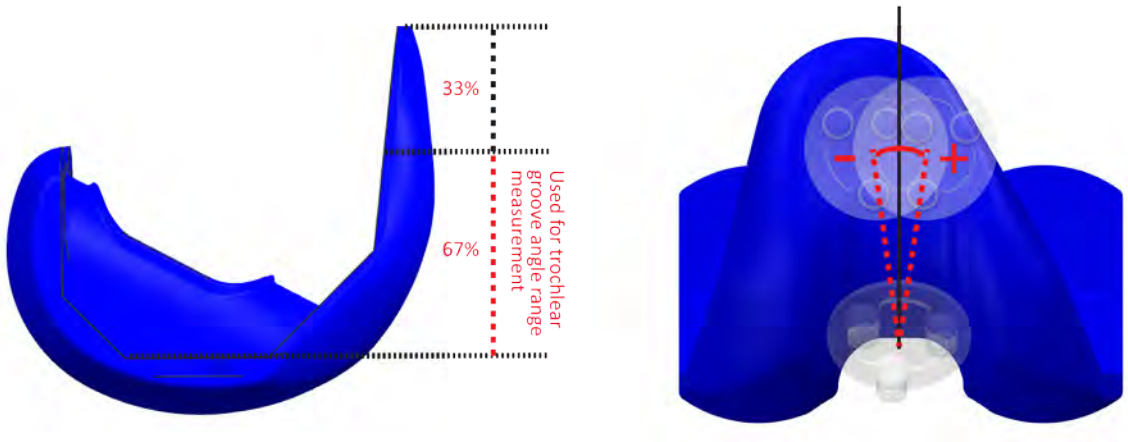


Figure 4. Measurement of the allowed range of trochlear groove orientation on the Truliant design.

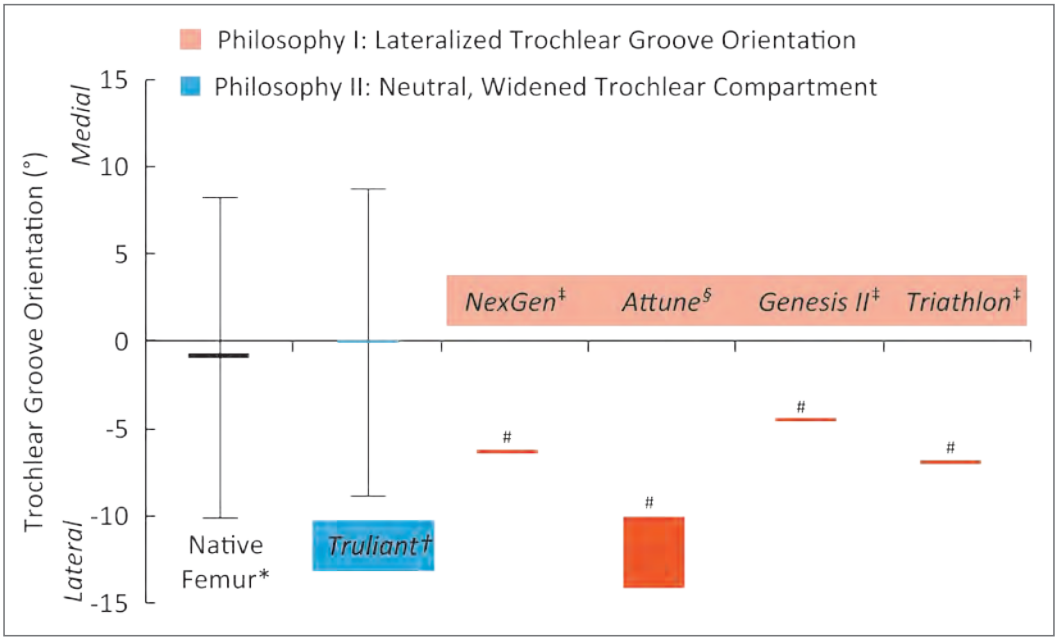
RESULTS

The pooled trochlear groove orientation in the native femur was near perpendicular to the transepicondylar line with only a slight tendency (~1°) of lateral orientation and quite variable from bone to bone (Table 1). Neither gender- nor ethnic- difference, nor correlation with AP dimension was found (N.S.). No significant difference was found between male and female femora (N.S.).

Among the five knee systems evaluated, only the Truliant Knee System closely matched the range of native groove orientation (Figure 5). In contrast, the other four knee systems each exhibited excessive lateralization of trochlear groove orientation, which was about 3°-13° more lateral compared to the native knee, depending on design and component size. The groove orientation was not found to be correlated with bone size (N.S.).

Trochlear Groove Orientation (°)* Mean ± Standard Deviation [95% range]		
Pooled	-1.4° ± 4.7° [-10.8°, 8.0°]	
Female	-1.0° ± 4.8° [-10.6°, 8.6°]	N.S.
Male	-1.8° ± 4.6° [-11.0°, 7.4°]	
Chinese	-2.1° ± 3.9° [-9.9°, 5.7°]	N.S.
Caucasian	-0.6° ± 5.3° [-11.2°, 10.0°]	

Table 1. A summary of native trochlear groove orientation. *Negative values indicate that the trochlear groove was tilted laterally in distal to proximal direction (illustrated in Figure 3).



* Data on native femur was illustrated with average and the 95% range.
‡Orientation angles referenced a published study [22].
§ Attune design has fixed trochlear groove angle proportionally changed by component size [Attune marketing brouchure]. The bar illustrated the range of the fixed angles.
† Truliant data was illustrated with the range of allowed groove orientation.
# Data on allowed range of trochlear groove angle not available.

Figure 5. Trochlear groove orientation in the native femur, compared to five modern femoral implant designs.

DISCUSSION

The design of the femoral component trochlear compartment is one of the critical factors that affects patellofemoral outcome after TKA.[10] This study demonstrated that the difference in TKA design philosophies may dramatically impact the restoration of native femoral trochlear groove orientation. Large variations in native trochlear groove angle orientation were found in this study, similar to data that has been reported by several morphological analyses (4°-6° in standard deviation).[11-14] Furthermore, a comparison of coronal alignment between the TEA and the line perpendicular to the femoral mechanical axis in the dataset demonstrated a very close match (deviation in alignment: 0.02° ± 0.04°). This confirmed that the results found in this study are relevant to the in-vivo placement of the femoral component referencing the mechanical axis. Studies in the literature revealed that the trochlear groove has varying orientation throughout the flexion range. Barink et al. reported that the trochlear groove is neutrally orientated in the intercondylar region, while it has a medial orientation in the proximal flange area.[15] This reported non-linearity in the groove orientation is accomodated by the Truliant design, which allows for moderate patella freedom in the ML direction in extension, accompanied by a gradually increasing ML constraint with more flexion.

The evaluation revealed that the four designs following the philosophy of a lateralized trochlear groove angle did not capture the average native groove orientation. This finding has been confirmed clinically by previous studies on several such femoral designs, which found that often times the normal patellar tracking was not restored.[7,8,16,17] This altered patellar tracking may pose an increased risk of patellofemoral complications postoperatively.[18-21] In addition, this data does not support the basis of designing a proportional trochlear groove angle with regard to femoral size as no significant correlation was found. On the contrary, in Truliant design, the femoral components' inclusion of a neutral orientation and widened proximal trochlear groove, allows the patella to track at an angle similar to the native knee and matches the morphological data examined in this study.

CONCLUSION

Compared to a lateralized trochlear groove angle, the design philosophy with a neutral groove orientation and widened proximal trochlear compartment may offer improved capability to restore the native trochlear groove orientation in TKA. •

REFERENCES

1. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. Adelaide: AOA 2013.

2. **Baker PN, van der Meulen JH, Lewsey J, et al.** The role of pain and function in determining patient satisfaction after total knee replacement: data from the National Joint Registry for England and Wales. *J Bone Joint Surg [Br]* 2007;89-B:893–900.

3. **Baldini A, Anderson JA, Cerulli-Mariani P, et al.** Patellofemoral evaluation after total knee arthroplasty: validation of a new weight-bearing axial radiographic view. *J Bone Joint Surg [Am]* 2007;89-A:1810–7.

4. **Stiehl JB, Komistek RD, Dennis DA, et al.** Kinematics of the patellofemoral joint in total knee arthroplasty. *J Arthroplasty* 2001;16:706–14.

5. **Varadarajan KM, Rubash HE, Li G.** Are current total knee arthroplasty implants designed to restore normal trochlear groove anatomy? *J Arthroplasty* 2011;26:274-81.

6. **Varadarajan KM, Freiberg AA, Gill TJ, et al.** Relationship between three-dimensional geometry of the trochlear groove and in vivo patellar tracking during weight-bearing knee flexion. *J Biomech Eng* 2010;132:061008.

7. **Anouchi YS, Whiteside LA, Kaiser AD, et al.** The effects of axial rotational alignment of the femoral component on knee stability and patellar tracking in total knee arthroplasty demonstrated on autopsy specimens. *Clin Orthop Relat Res.* 1993;170-7.

8. **Ostermeier S, Buhrmester O, Hurschler C, et al.** Dynamic in vitro measurement of patellar movement after total knee arthroplasty: an in vitro study. *BMC Musculoskelet Disord* 2005;6:30.

9. **Healy WL, Wasilewski SA, Takei R, et al.** Patellofemoral complications following total knee arthroplasty. Correlation with implant design and patient risk factors. *J Arthroplasty* 1995;10:197-201.

10. **Kulkarni SK, Freeman MA, Poal-Manresa JC, et al.** The patellofemoral joint in total knee arthroplasty: is the design of the trochlea the critical factor? *J Arthroplasty.* 2000;15:424–9.

11. **Eckhoff DG, Burke BJ, Dwyer TF, et al.** The Ranawat Award. Sulcus morphology of the distal femur. *Clin Orthop Relat Res.* 1996;(331):23-8.

12. **Iranpour F, Merican AM, Dandachli W, et al.** The geometry of the trochlear groove. *Clin Orthop Relat Res.* 2010;468(3):782-8.

13. **Feinstein WK, Noble PC, Kamaric E, et al.** Anatomic alignment of the patellar groove. *Clin Orthop Relat Res.* 1996;(331):64-73.

14. **Varadarajan KM, Gill TJ, Freiberg AA, et al.** Gender differences in trochlear groove orientation and rotational kinematics of human knees. *J Orthop Res.* 2009;27(7):871-8.

15. **Tanzer M, McLean CA, Laxer E, et al.** Effect of femoral component designs on the contact and tracking characteristics of the unresurfaced patella in total knee arthroplasty. *Can J Surg* 2001;44(2):127-33.

16. **Barink M, Meijerink H, Verdonschot N, et al.** Asymmetrical total knee arthroplasty does not improve patella tracking: a study without patella resurfacing. *Knee Surg Sports Traumatol Arthrosc* 2007;15(2):184-91.

17. **Parker D, Dunbar M, Rorabeck C.** Extensor mechanism failure associated with total knee arthroplasty: prevention and management. *J Am Acad Orthop Surg.* 2003;11(4):238-47.

18. **Leblanc J.** Patellar complications in total knee arthroplasty. A literature review. *Orthop Rev.* 1989;18(3):296-304.

19. **Brick G, Scott R.** The patellofemoral component of total knee arthroplasty. *Clin Orthop* 1988; (231): 163-78.

20. **Mont M, Yoon T, Krackow K, et al.** Eliminating patellofemoral complications in total knee arthroplasty: clinical and radiographic results of 121 consecutive cases using the Duracon system. *J Arthroplasty.* 1999;14(4):446-55.

21. **Sun HJ, Choi D, Lipman D, et al.** Comparison of trochlear grooves in contemporary total knee designs to native trochlear groove. Presented at International Society for Technology in Arthroplasty 2016 Congress.

AN OUTPATIENT APPROACH AND PROTOCOL FOR TOTAL HIP ARTHROPLASTY

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INTRODUCTION

Total hip arthroplasty (THA) has been a successful, increasing practice for caring for hip arthritis in the aging and active population. The advent of new techniques and efficiency has advanced the practice to one of the more reproducible and beneficial operations orthopaedic surgeons perform. Because of the increasing age of the American population, the need and number of hip replacements performed is expected to increase over the coming decades.[1] With that in mind, surgeons have been advancing the practice of joint replacement in both the knee and the hip to accommodate the active lifestyles and demands of patients.[2,3] More and more patients desire to be home in a timely manner and get back to work and daily activities as soon as they can tolerate. Several studies have shown the benefits and successful outcomes of an outpatient approach to joint replacement surgery.[3-5]

This article presents one surgeon's experience with transitioning to outpatient total hip arthroplasty and the development of a successful outpatient program. Over the past two and a half years, the technique has evolved and patients were followed to determine whether this idea was plausible. The thought being that patients who are healthy enough and motivated to go home after surgery might recover just as well as those who had traditionally stayed in a hospital for two—sometimes three—days. Our practice has instituted an outpatient hip replacement model that has been used successfully in both the hospital and ambulatory surgery center settings.

This article presents one surgeon's experience with transitioning to outpatient total hip arthroplasty and the development of a successful outpatient program.

METHODS

Preoperative Evaluation

The discussion of any surgery can be an anxious and stressful time for patients. Setting the patient up for success starts with the in-office discussions. Oftentimes conversations are directed at finding and understanding their goals and expectations. Just like all procedures, we discuss the surgery in detail, including the risks and benefits. However, patients are often surprised to hear that they might be able to go home the same day as their surgery. As the reader knows, patients come with preconceived notions from the experiences of friends and family members, so hearing for the first time that outpatient surgery is an option can help alleviate some anxieties regarding surgery.

We have come to understand that the pre-operative discussions help set the patient up for the best possible outcomes. When a patient feels educated, they also feel empowered, and we spend a good amount of time discussing the advantages and disadvantages of a hospital stay versus going home. The discussion often focuses on comfort and control. Obviously, surgery can be a stressful experience, and the comforts of home can allow them to rest and recover in a more hospitable environment. Between the call lights, beeping IV equipment, other patients' needs on the floor, nurses doing assessments at all hours of the night and unknown surroundings, it can be difficult for patients to even find an uninterrupted night of rest. Being able to have the comforts of home, literally, at their fingertips often dilutes some of the anxieties patients feel when discussing surgery. The ability to sleep in their own bed, use their own restroom facilities and sit in their favorite recliner eases the tension when surgery is in the future.

In addition to the discussion, we stratify patients whom we consider to be good candidates for outpatient surgery in partnership with our primary care and anesthesia providers. All patients are assessed pre-operatively by both services for proper clearances, lab studies and further work-up if needed. Patients with co-morbidities, which might lead to untoward events, are not considered for an outpatient procedure. ASA scores of three or greater are automatically marked as overnight stays. Patients with diabetic control issues are likewise deemed to be better hospital admits. Regarding diabetics, we typically will not schedule

any elective total hip unless hgbA1c levels are seven or less. Morbidly obese (i.e., BMI greater than 40) patients are set up with a dietician and bariatric surgery consult prior to surgery scheduling and return every three months prior to surgery while we follow trends in their weight loss. Patients who show consistent weight loss and are moving toward their goal weight with BMI less than 40 are considered for surgery. We have a strict cutoff for BMI less than 40 at the surgery center for all cases. Patients with prior complications of surgery or anesthesia are not scheduled as outpatient cases.

After stratifying patients for hospital versus surgical center-based surgery, we then have patients attend a pre-operative class designed for total joints. It is run by the hospital and includes topics to expect before, during and after surgery. It includes discussions on what to expect the day of surgery, anesthesia approach, ambulation protocols, wound care discussion, home care, pain control, follow up expectations and therapy protocols. The class was designed by our combined years of practice experience and common core practices, with input from pre-anesthesia nurses, physical therapy, social cares advisors and nursing staff. In addition to the pre-operative testing and the anesthesia evaluation, this class serves to answer basic questions patients have regarding issues they may experience at home. For instance, placement of rugs at home, the use of crutches or walker at home, or bath mats in the shower, to name a few, are discussed. Again, our approach is to educate the patient as much as possible before the surgery, so they know what to expect when the time comes for recovery. This limits anxious phone calls to the office, decreases unexpected case cancellations and empowers the patient to feel confident when preparing for their surgical experience.

Day of Surgery Pre-op

As with most surgeons, the legwork before surgery depends on a dedicated team of medical assistants, schedulers and nursing staff committed to providing the best experience for the patient as possible. By the time the day of surgery comes, patients have been properly evaluated and educated on expectations, have had their questions answered and are confident when they arrive.

Most patients receive the same anesthesia care for our total hip replacements. What started in 2014 as spinals for all patients has evolved to the use of epidurals with catheters. Our facility happens to be the largest infant delivery center in the state, and thus, the anesthesia providers are quite proficient at both spinals and epidurals. After careful consideration, and discussion, we have chosen the epidural route for a couple of reasons. First, the ability to perform in the pre-operative area allows the flow of surgery to proceed more smoothly throughout the day. With two surgical suites available, this process allows the anesthesia team to remain ahead of the day's schedule and requires less room coordination. Second, the ability to re-dose an epidural has several advantages. With a spinal, cases need to be more strictly coordinated to be performed within the two-hour surgical window. Also, in the event of uncontrolled post-operative pain, a re-dosing of the epidural in the post-anesthesia unit is possible. As with both spinal and epidural anesthesia, the potential for urinary retention is possible, and we have instituted the use of 0.4 mg of Flomax (tamsulosin hydrochloride) one week prior to surgery for patients 50 years of age and older. In addition, our anesthesia team uses a multimodal approach for pain control the day of surgery, which includes 200 mg of Celebrex, 300 mg of Gabapentin, and 400 mg of IV Acetaminophen.

Intra-Operative

All cases are performed with the same team involving the room nurse, surgical scrub tech and a first assist. At the hospital, we use two rooms with two teams, while at the surgery center we have one room for these procedures. All cases are performed using the Hana® table, and we utilize the modified Smith-Peterson approach described by Matta et al.[6] The preferred instrumentation is the Novation® Crown Cup and the Alteon® Tapered Wedge Stem. In addition, we use an intra-operative fluoroscope to assist with abduction angle, medial placement and ante-version of the cup, as well as determining proper leg length and abductor offset with overlaying radiographs while in the surgical suite. The patient is transferred to post-anesthesia recovery with a cooling device placed over the dressing intended to be started in recovery and without any use of abduction pillows or bracing.

Goals to be accomplished before discharge are: ambulating greater than 75 feet, ability to perform and climb stairs (we have a stair model in recovery) and ability to void urine before discharge.

Post-Anesthesia Recovery and Transition to Home

Once in the recovery unit, the patient is almost immediately encouraged to sit up in bed. The nursing staff first will determine the patient's level of pain and begin oral pain medications as soon as they are consciously aware to drink and eat. They will begin to allow the patient to begin the process of eating more solid foods and sitting at the side of the bed. In addition, the Physical Therapy team is notified of the patient's arrival, and our goal is to have them ambulating within one hour of transfer to post-anesthesia care. We encourage the use of crutches after surgery for ambulation. In coordination and discussions with our physical therapy providers, it was decided that we use crutches instead of a walker, when feasible, reducing the awkwardness and difficulty of managing a walker in the home and transportation. However, patients are assessed for coordination and comfort of both devices before discharge. Goals to be accomplished before discharge are: ambulating greater than 75 feet, ability to climb stairs (we have a stair model in recovery) and ability to void urine before discharge. The team is instructed that the accomplishment of these goals is paramount to their discharge, and in some cases a second round of therapy before discharge is undertaken.

As discussed, the pre-operative assessment and plan upon discharge has been discussed with the patient prior to arriving at the hospital. Our office's pre-operative nurse and social services team have coordinated an in-home nurse to meet them at the house on the day of discharge. This allows the patient to have access to coordinated care, and addresses any questions should the need arise on the day of surgery. Oftentimes, this visit serves to answer any lingering questions after surgery as well as asses the home for any possible transfer or ambulatory issues (such as chairs and rugs) which might prove challenging for their recovery. In addition, we utilize in-home physical therapy on post-operative day one. Our goal is to have the patient transitioned to an outpatient therapy center as soon as they feel comfortable to be out of the house more consistently.

Post-Operative Follow-up

All patients are followed up in our office four weeks after surgery for wound check and radiographs. Most questions of pain and renewal of medications are handled by our office nurse. Patients are anti-coagulated with 325mg of enteric-coated Aspirin twice daily for 21 days. Those patients with prior history of chemotherapy, DVTs, PEs, etc. are usually prescribed 2.5mg of Eliquis twice daily. This is all pre-determined by our office and their primary care providers, and usually the therapy is concluded before the first office visit. As discussed, the use of crutches versus a walker is made prior to discharge, and many patients have transitioned to a cane or no assistive device by the time of follow-up. Patients with wound care concerns are brought into the office sooner, and coordinated with our office nurse handling those calls. Patients will then follow-up at the three-month interval for radiographs and activity assessment. If recovery has proceeded smoothly, they are then seen again at their one-year appointment.

RESULTS

We only considered and defined outpatient surgery as those patients discharged the same day as surgery. While developing this protocol, we started to follow our average length of stay in the hospital. Prior to developing our outpatient program, in 2014 our average length of stay in the hospital was 2.3 days. We performed one outpatient total hip in that year. In 2015 we performed a total of 147 primary total hip replacements. Of those, 27 (or 18%) were performed on an outpatient, same day as surgery, discharge basis. In addition, in the first full year of actively scheduling outpatient hip replacements, our average length of stay in the hospital dropped to 1.7 days. In 2016 we performed 167 primary total hip replacements. Of those, 56 (or 34%) were performed on an outpatient basis. In 2016 our average length of stay for those admitted dropped again to 1.3 days. The length of stay data was only recovered for total hips that were admitted. In 2015 we had no re-admissions from our outpatient population. In 2016 we had one re-admission for urinary retention issues while at home.

DISCUSSION

The transition to performing outpatient total hip replacements is an evolving process. My senior partner performed the first total knee and total hip in our state back in the 1970s. After spending time with Maurice Edmond Mueller in Bern, Switzerland, he returned and began performing the procedure in our local hospitals. At the time, patients would stay admitted to the surgical floor for 5-7 days, followed by an extended stay in the therapy unit. Oftentimes patients were not allowed to ambulate fully weight bearing for the first 1-2 weeks, and abduction braces were occasionally utilized, for fear of dislocation. We have come a long way since the 1970s.

Prior to developing our outpatient program, our average length of stay in the hospital was 2.3 days. In 2015 the first full year of actively scheduling outpatient hip replacements, our average length of stay dropped to 1.7 days.

In 2014 we performed the first outpatient total hip at one of our facilities. By chance, the patient had a prior total hip replacement on the opposite side, was healthy and very active. He requested and inquired if it was possible we might let him go home after the procedure. After his first procedure, he was walking the hallways that night on the hospital floor, independently climbing stairs and went home the next morning. He relayed that he could not sleep well in the hospital and that he did not like being around patients that might be sick. That got us thinking, and after careful consideration and evaluation by both his primary care providers and the anesthesia team, we scheduled our first total hip as an outpatient procedure. That experience led us to begin developing a pathway of protocols for developing an outpatient experience for total hip replacements.

As a fellow in Nashville, it was not rare to have patients discharged on post-op day one. However, they weren't listed, nor expected, to be discharged unless they had met certain discharge criteria. While developing this protocol, we started to follow our average length of stay in the hospital. Prior to developing our outpatient program, our average length of stay in the hospital was 2.3 days. In 2015 the first full year of actively scheduling outpatient hip replacements, our average length of stay dropped to 1.7 days. The following year in 2016, our average length of stay dropped again to 1.3 days. That data was for all total hips, which were full admits to the hospital. We found that in conjunction with the development of outpatient total joint program, our scheduled overnight admissions stayed for shorter periods. In addition, the number of outpatient procedures went up. We believe that as expectations went up for those expected to go home on the same day, so too did the expectations rise for those being admitted to the hospital.

We have recognized that most of the success of this program starts in the office. When patient's expectations are met with their surgeon's expectations, the results changed and improved regarding admissions. If a patient is expected to get up and ambulate on the same day as surgery, most of the time they will accomplish that goal. One of the keys to that success is reiterating your desires and goals for patients with the nursing staff and physical therapy

teams. We meet regularly (once a month) to review protocols, discuss challenges, make changes when necessary, and adjust plans if patterns that do not work are identified. In addition, in the age of rising medical care costs, increased patient insurance premiums and demand, the discharge of patients in a timely manner will help decrease the overall burden on the system.

The author believes that outpatient total hip replacements have a place in the realm of total joint arthroplasty. The development of that process takes time and effort to coordinate and execute. Our next step will be to include VAS as well as Harris Hip scores, and specifically stratifying those patients who have experienced both an inpatient and outpatient surgery. We also would like to assess the cost savings to the system and compare inpatient and outpatient costs, as has been done in other studies.[7] With time, outpatient total joint replacements may become the norm. After all, it was not too long ago when patients were admitted for months on end. •

REFERENCES

1. **Kurtz S, Ong K, Lau E, Mowat F, Halpern M.** Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J Bone and Joint Surgery*. 2007; 89:780-785.

2. **Berger RA, Sanders S, Gerlinger T, Della Valle C, Jacobs JJ, Rosenberg AG.** Outpatient total knee arthroplasty with a minimally invasive technique. *J Arthroplasty.* 2005;20(Suppl 3):33–38.

3. **Berger RA, Sanders SA, Thill ES, Sporer SM, Della Valle C.** Newer anesthesia and rehabilitation protocols enable outpatient hip replacement in selected patients. *Clin Orthop Relat Res*. 2009;467:1424–1430.

4. **Dorr LD, Thomas DJ, Zhu J, Dastane M, Chao L, Long WT.** Outpatient total hip arthroplasty. *J Arthroplasty.* 2010;25:501–506.

5. **Goyal N, Chen AF, Padgett SE, Tan TL, Kheir MM, Hopper Jr RH, Hamilton WG, Hozack WJ.** A multicenter, randomized study of outpatient versus inpatient total hip arthroplasty. *Clin Orthop Relat Res.* 2017; 475: 364-372.

6. **Matta JM, Shahrdar C, Ferguson T.** Single-incision Anterior Approach for Total Hip Arthroplasty on an Orthopaedic Table. *Clin Orthop Relat Res.* 2005; 441: 115-124.

7. **Bertin, Kim C MD.** Minimally Invasive Outpatient Total Hip Arthroplasty: A Financial Analysis. *Clin Orthop Relat Res.* 2005; 435: 154-163.

PERFORMING TOTAL SHOULDER ARTHROPLASTY IN AN OUTPATIENT SETTING

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Although considered cutting edge only a few years ago, outpatient total shoulder arthroplasty (TSA) has now become routine at some facilities. What follows are some current thoughts, as well as recent past experiences of the author performing total shoulder arthroplasty in an outpatient setting.

In this article, outpatient total shoulder arthroplasty will include both same day discharges, and 23 hour, overnight stays. Total shoulder arthroplasty, whether an anatomic, or reversed implant, is deemed an inpatient procedure by Medicare. Therefore, total shoulder arthroplasty cannot be done at an outpatient facility for a Medicare patient. This review will not consider any specifics of the Medicare population for that reason.

Over the past four years, this author's ambulatory surgery center has performed 369 total shoulder arthroplasties. One hundred seventy nine were anatomic devices, 190 were reversed devices.

Before embarking on outpatient total shoulder arthroplasty, both the surgeon and facility must consider the necessary components required for both a safe and successful program.

Surgeons who desire to utilize such a program should first have the skill set to reliably and efficiently perform total shoulder arthroplasty. There needs to be confidence in not only completion of the procedure, but the awareness necessary to predict in whom the procedure can most efficiently and effectively be carried out. Surgeons who routinely require prolonged operative times, especially for glenoid exposure might want to consider honing their skills set prior to performing outpatient arthroplasty. Likewise, the surgeon must be cognizant of the challenging factors that make certain patients more appropriate in a hospital setting. Severe bone loss, significant stiffness, and obesity are all reasons to give pause when considering patient selection. The surgeon must be completely aware of, and confident in the capabilities of the specific arthroplasty system chosen.

Over the past four years, this author's ambulatory surgery center has performed 369 total shoulder arthroplasties. One hundred seventy nine were anatomic devices, 190 were reversed devices.

I have found the Exactech Equinoxe® system ideal for outpatient arthroplasty due to the extreme flexibility it provides. When utilizing the anatomic system, a backup with the reverse system will allow treatment of unexpected severe rotator cuff pathology, or glenoid deficiency and deformity. Augmented glenoid components, both reverse and anatomic, have essentially eliminated the need for bone graft. This not only saves time in the operating room, it limits the additional equipment and support needs of the facility.

When planning and implementing a shoulder arthroplasty service at an outpatient facility the support staff, the surgeon, and the implant representative need to be aware of, and in sync with the ancillary equipment needs. There needs to be clear understanding of any potential need, such as alternative retractors, cerclage fixation for iatrogenic fractures, polymethylmethacrylate and associated delivery systems for unexpected fixation needs.

Although it may not be the first thought or consideration, insurance reimbursement must be understood prior to initiation of a program for outpatient shoulder arthroplasty. Many, if not most commercial contracts will include arthroplasty, consisting of CPT codes 23472, 23473, and 23474. The contracted reimbursement may or may not be sufficient to cover the overhead of the procedures. In our experience, some contracts needed to be revisited, with special carve out for these codes, prior to initiating the outpatient arthroplasty program. Having an accurate knowledge of local reimbursement rates at the hospital, by specific payors, allows for efficient and effective negotiation of outpatient reimbursement rates. Prior to initiating discussions with payors, it is helpful to obtain EOBs, or explanation of benefits forms, from patients who have undergone total shoulder arthroplasty at an inpatient facility locally. Collecting as many of these as possible will allow the surgeon and outpatient facility to formulate a competitive negotiation plan.

During the same time that the surgeon and facility are considering their ability to carry out outpatient shoulder arthroplasty, and make it financially viable, they need to be considering their physical needs.

The physical needs of the facility extend beyond the operating room. Of course, the procedure must be able to be safely, efficiently, and effectively performed in the operating room. Considerations beyond the operating room include the potential need for additional imaging, the potential for physical therapy, food service needs and recovery needs.

We have found that image fluoroscopy is sufficient for imaging in the operating room, and that it is only needed if there is concern for fracture during the case. In review of my inpatient procedures, I found that postoperative xrays, obtained in the recovery room, did not change the postoperative course of the patient. I have not been obtaining postoperative images routinely in the outpatient setting, although if one desired to do so, current mini c-arms are sufficient.

Having physical therapy see the patient prior to discharge is something that can be considered, if the facility has therapy on site, or therapy is going to visit the patient. There could be some advantages to this, especially if there is a desire to capture the patient for outpatient therapy at a specific facility postoperatively.

We have found that it is quite effective to have the patient watch a pre-recorded video of exercises prior to discharge, they can review at home prior to their first follow up as well. This home-based program has been well received, is convenient, and at times patients differ on going to formal therapy. Recent studies have shown equivalence in home therapy or formal therapy after shoulder arthroplasty.[5]

Planning should include consideration for the length of recovery period for a patient to be considered outpatient, Medicare rules dictate that an outpatient must be discharged 23 hours or less after they were admitted. Admission is the time of check into the facility, not the time of discharge from PACU. While these rules are Medicare based, it is our experience that commercial providers follow them.

One possible initial plan for outpatient total shoulder arthroplasty is to discharge all patients home on the same day. This obviates the need for any overnight facilities, limits food service needs, and—if the patients are recovered the same as non-arthroplasty outpatients—additional staffing needs are mitigated. This can be accomplished in a few patients, without regional anesthetic, but for the great majority most likely would require regional anesthesia. Single shot scalene blocks have the issue of wearing off in less than one day. This may cause difficulty with the patient being discharged with no pain, and then struggling with pain control at home, often in the evening hours. Patient satisfaction may suffer, there may be increased opportunities for admission or emergency department visits. Indwelling scalene catheter will eliminate this problem, but opens the possibility of other problems such as injury to the anesthetic limb, noncompliance due to lack of pain, and the potential for anesthetic complications from the block. While complications from regional anesthetic are rare, local anesthetic nerve toxicity is dose and time dependent.[1,3,6,7]

We decided to initiate our program with a 23 hour, overnight stay. This requires the facility to have overnight capacity which is not only structural, but staff based. Staffing needs may be accommodated with local staffing agencies, or providing bonuses to pre-existing staff. The evening staff must start when the routine shift is done. We have found having a single nurse with ancillary help is effective for one to two patients. If we have three to four patients we have additional staff. The ancillary help with typical utilize is an EMT. We have maintained 2:1 or 1:1 staff to patient ratio overnight. This is obviously much higher than done in the hospital setting. This provides not only safety, but high satisfaction.

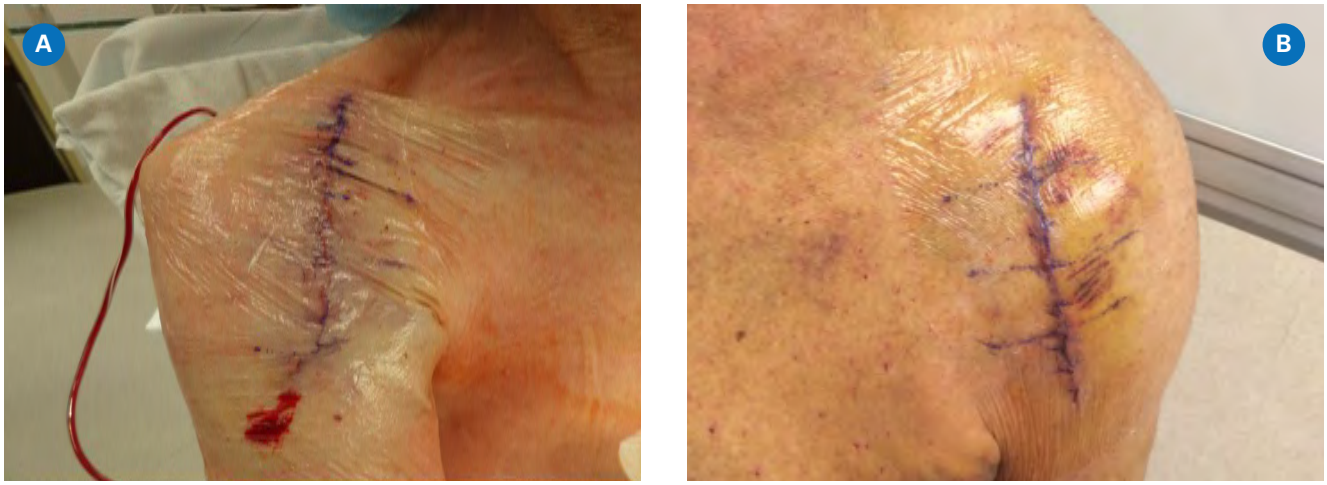

Figure 1. Routine postoperative dressing utilized by the author for all total shoulders. 1a: Immediate appearance in the operating room. Note the blanching due to epinephrine in the local anesthetic injected at the start of the case. This case had enough oozing that a single drain was placed exiting posterior, through the deltoid, with a separate Tegaderm. 1b: This is a typical appearance of a postoperative Tegaderm at the time of removal, two weeks from surgery.

We decided to initiate our program with a 23 hour, overnight stay. This requires the facility to have overnight capacity which is not only structural, but staff based.

Most outpatient facility centers will not have on-site food services for full meal preparation. We have found that a stocked pantry is well received by patients, when combined with local food delivery from multiple restaurants.

Our shoulder arthroplasty program has given us the opportunity to contemplate much of what we do for all our shoulder arthroplasty patients. Improvements made prior to the onset of outpatient shoulder arthroplasty made it possible to consider sending patients home the day after a shoulder replacement. Additional improvements have made the process even more reliable and effective. Continued improvements have benefited both inpatient and outpatient shoulder arthroplasty, in both Medicare and commercial payor populations.

All shoulder arthroplasty patients now receive multimodal pain management. Pre-operative treatment with transexamic acid (TXA), gabapentin and MS Contin, combined with intraoperative Tylenol and Toradol gives excellent pain control, even without a block. Use of a scalene block, with or without an indwelling catheter, has been left to the discretion of the surgeon and patient. I choose to limit the use of blocks, as I find they are typically not necessary for an effective recovery and will not allow for nerve exam postoperatively. Additionally, they will often limit active use for commencement of exercises. If there are plans to stay overnight regardless, I also feel that the block will not give as much time for the patient, with the guidance of nursing, to accommodate the postoperative pain that does occur. I do also have concerns that the block that has just worn off may delay discharge within the necessary 23 hour window.

My protocol for mitigating infection risks include some maneuvers that have ancillary benefits helpful for same or next day discharge. My post-operative bandage has evolved and is now quite aligned with outpatient shoulder arthroplasty.

Patients are instructed to prescribe with Hibiclens the night before and day of surgery. Additionally, I have recently added a daily prep with benzoyl peroxide for three days to decrease skin colonization with *Propracnesionibacterium acnes*. At surgery, skin preparation starts with an alcohol wash, followed by Chloraprep. Ioban is used to cover and seal the entire shoulder. The incision is injected with 1% lidocaine with epinephrine, not only for some analgesia, but also for hemostasis. One gram of Kefzol is dissolved in the local, to help sterilze the intradermal layer.[2,4] This, combined with the TXA makes for minimal blood loss and typically no need for a drain. The skin is closed with a

The growing experience of outpatient shoulder arthroplasty has confirmed that it is safe and effective.

subcuticular closure with Monocryl, and sealed with Dermabond. Tegaderm is applied directly over the incision. This has multiple benefits. The incision can be monitored. The Tegaderm is left in place for two weeks, and has an excellent seal due to the skin prep and lack of bleeding. Typically, the Tegaderm does not come off until it is removed at the first visit at 14 to 15 days. It is waterproof and patients can shower and even swim. This has high acceptance from the patients. They are pleased there is no need for a bandage. The appearance makes for a less "severe" appearing wound, which I believe adds confidence to the patient leaving a facility less than 23 hours after a shoulder replacement.

The growing experience of outpatient shoulder arthroplasty has confirmed that it is safe and effective. Value in healthcare has been defined as outcomes over cost. There is no doubt that outpatient shoulder arthroplasty has, and will continue to provide value to our patients. •

REFERENCES

1. **Hogan, Q. H.** Pathophysiology of peripheral nerve injury during regional anesthesia. *Reg Anesth Pain Med* 33:435-441. 2008.

2. **Lee, M. J., P. S. Pottinger, S. Butler-Wu, R. E. Bumgarner, S. M. Russ, and F. A. Matsen, 3rd.** Propionibacterium persists in the skin despite standard surgical preparation. *The Journal of bone and joint surgery* 96:1447-1450. 2014.

3. **Lenters, T. R., J. Davies, and F. A. Matsen, 3rd.** The types and severity of complications associated with interscalene brachial plexus block anesthesia: local and national evidence. *J Shoulder Elbow Surg* 16:379-387. 2007.

4. **Matsen, F. A., 3rd, S. Butler-Wu, B. C. Carofino, J. L. Jette, A. Bertelsen, and R. Bumgarner.** Origin of propionibacterium in surgical wounds and evidence-based approach for culturing propionibacterium from surgical sites. *The Journal of bone and joint surgery* 95:e1811-1817. 2013.

5. **Mulieri, P. J., J. O. Holcomb, P. Dunning, M. Pliner, R. K. Bogle, D. Pupello, and M. A. Frankle.** Is a formal physical therapy program necessary after total shoulder arthroplasty for osteoarthritis? *J Shoulder Elbow Surg* 19:570-579. 2010.

6. **Verlinde, M., M. W. Hollmann, M. F. Stevens, H. Hermanns, R. Werdehausen, and P. Lirk.** Local Anesthetic-Induced Neurotoxicity. *Int J Mol Sci* 17:339. 2016.

7. **Werdehausen, R., S. Fazeli, S. Braun, H. Hermanns, F. Essmann, M. W. Hollmann, I. Bauer, and M. F. Stevens.** Apoptosis induction by different local anaesthetics in a neuroblastoma cell line. *Br J Anaesth* 103:711-718. 2009.

ADDITIVE MANUFACTURING TECHNOLOGY FOR ORTHOPAEDIC IMPLANTS

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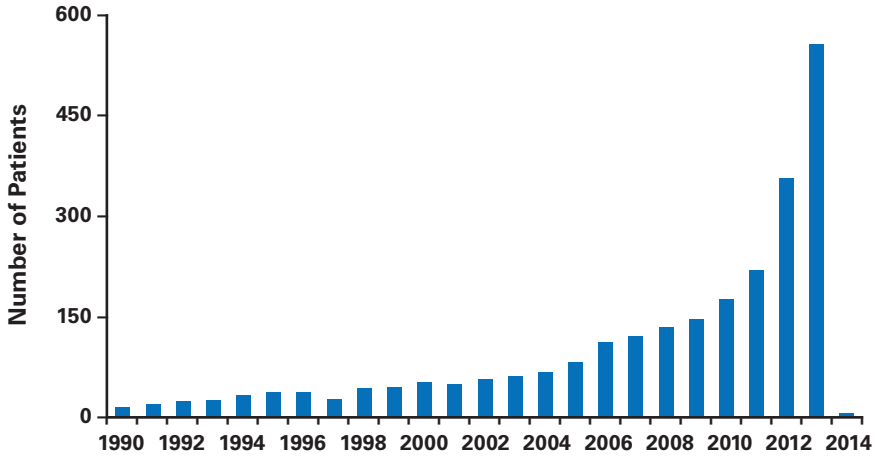
Additive manufacturing, also known as 3D printing, is a process that creates a three-dimensional object by building successive layers of raw material, such as metal, plastic, tissue scaffolds, concrete and even food. Each new layer is attached to the previous one until the object is complete, as opposed to subtractive manufacturing methodologies, such as traditional machining. Objects are produced from a digital 3D file, such as a computer-aided design (CAD) drawing or an MRI image.

IS ADDITIVE MANUFACTURING A "NEW" TECHNOLOGY?

The first 3D printing processes were developed in the 1980s, patents were developed in the 1990s and with the first metal 3D technologies were introduced in the early 2000s. Low-cost 3D printing companies started to emerge in 2005, and the technology has grown exponentially since. In 2005, additive manufacturing was a $750 million market; today it has grown to more than $5 billion.[1] The number of 3D technology manufacturers has grown from 14 in January 2012 to 431 as of September 2016.[1]



The application of 3D printing for orthopedic implants can provide many benefits, including: the customization and personalization of implants, cost effectiveness, increased productivity as well as the democratization of design and manufacturing.

IS ADDITIVE MANUFACTURING FOR PROTOTYPES ONLY?

This technology has moved well beyond prototyping, rapid tooling and toys. Additive manufacturing is creating durable and safe products for sale to real customers in moderate to large quantities. For example, one out of every 30 hip surgeries involves components that come from an Arcam Electron Beam Melting (EBM) system.[2] Patient specific cutting blocks or pin guides are manufactured at a quantity of almost 100,000 per year.[3,4] More than 10,000,000 hearing aid components have been manufactured by additive manufacturing.[5]

WHAT ARE THE ADVANTAGES OF ADDITIVE MANUFACTURING?

The flexibility of 3D printing allows designers to make changes easily without the need to set up additional equipment or tools. It also enables manufacturers to create devices matched to a patient's anatomy (patient-specific devices) or devices with very complex internal structures (e.g., porous structure). An engineer can design the surgeon's part as he or she envisions it without manufacturing constraints. This "manufacturing on demand" process streamlines the supply chain and can save hospitals on the cost of inventory.

Additive manufacturing is a green technology. Because only the material that is needed is used, there is very little (if any) material wasted. These capabilities have sparked huge interest in 3D printing of medical devices.

EXACTECH EXPERIENCE WITH ADDITIVE MANUFACTURING

In 2016, Exactech confirmed the purchase of two Arcam Q10plus machines to expand its in-house manufacturing capabilities. This investment will advance Exactech's long-term commitment to additive manufacturing technology.

"Integrating the Arcam Q10plus technology into our operations will bring numerous benefits to our already robust manufacturing systems," said Raymond Cloutier, Exactech vice president of engineering & development for spine. "In 2010, Exactech became the first company to receive FDA clearance for a 3-D printed orthopaedic implant and has since received multiple additional clearances for other implants. We will now be able to leverage this knowledge and experience to enhance the design of our hip, knee, extremities and spine implants, reduce product development lead times and further supplement supply."

The Arcam Q10plus is Arcam's latest Electron Beam Melting (EBM) machine that has been designed specifically for cost-efficient production of orthopaedic implants. Studies have shown that build times can be reduced up to 25 percent with improved surface finishes, compared to previous generations of EBM systems.[6]

"Exactech was the first company in the U.S. to mass-produce medical implants using additive manufacturing. We are happy to see their confidence in our EBM technology and in the Arcam Q10plus as a volume production system for the medical device industry. We truly look forward to partnering with Exactech to grow production of their joint restoration products," said Arcam Chief Executive Officer Magnus René.

WHAT ARE THE LIMITATIONS?

The application of 3D printing for orthopedic implants can provide many benefits, including: the customization and personalization of implants, cost effectiveness, increased productivity as well as the democratization of design and manufacturing.

However, it should be cautioned that despite recent significant and exciting medical advances involving 3D printing, notable scientific and regulatory challenges remain and the most transformative applications for this technology will need time to evolve. Design complexity makes post process inspection and qualification challenging. The FDA has cleared more than 85 3D printed medical devices, but from a Regulatory perspective, it is difficult to keep up with the pace of this fast-moving technology.

The additive manufacturing process occurs "layer by layer"; which introduces anisotropy in mechanical properties resulting in high strength in the transverse plane, but lower strength along the vertical axis. This aspect is mainly a concern for small implant under substantial loading.

An engineer can design the surgeon's part as he or she envisions it without manufacturing constraints.

CONCLUSION

Additive manufacturing is both the present and the future. It is likely to have an enormous impact on all our lives, but that doesn't mean it is going to be good for every business. As the technology continues to evolve, the orthopaedic industry will be paying attention to its benefits as well as its limitations. •

REFERENCES

1. **Espen Sivertsen.** A Brief History of Additive Manufacturing. www.typeamachines.com
2. **Michael Petch.** 3D Printing Metal Interview with Arcam CEO Magnus René. www.3dprintingindustry.com
3. **Thienpoint E et al.** Patient-specific instruments: industry's innovation with a surgeon's interest. Knee Surg Sports Traumatol Arthrosc. 2013 Oct;21(10):2227-33
4. **Gabelli & Company, Inc.** Inside 3D printing conference and industry review. www.gabelli.com
5. **Rakesh Sharma.** The 3D Printing Revolution You Have Not Heard About. www.forbes.com
6. Data on file at Arcam

A NEW PERSPECTIVE IN TOTAL ANKLE ARTHROPLASTY

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Duke Health

www.exac.com/courses

May 18 | Vantage Total Ankle Cadaveric Surgical Skills Lab **| Chicago, Ill.**

I have had the distinct privilege serving on the Exactech total ankle design team with three other surgeons, my Duke University partners Jim DeOrio, MD and Jim Nunley, MD and our Swiss colleague, Victor Valderrabano, MD. Over the past 25 years we have had extensive experience with most every major total ankle system, including fixed- and mobile-bearing designs. Jim, Jim and Victor are unequivocally international thought leaders in total ankle arthroplasty (TAA). As a group, arguably we have unparalleled clinical and research experience with TAA.[1-5] Each of us has formulated potential improvements to the existing body of knowledge of TAA and has had some hand in the improvement of existing total ankle systems or development of potential new systems. Roughly five years ago, we realized that our collective efforts would be far more effective.

Exactech offered the perfect opportunity for the four of us to optimize our contributions to optimal treatment of patients with endstage ankle arthritis. The Exactech team of Matt Hamilton, PhD (Manager of Lower Extremity Engineering), Steve Norton (Product Development Engineer), Medhut Alnadi (Product Design Engineer), Phong Diep (Sr. Designer), Emery Patton (Director of Marketing), and Rick Andrews (Sr. Product Manager), with its experience in Exactech's other joint arthroplasty systems, provided us with the engineering and implant development expertise needed to convert our visions into a superior and practical total ankle implant. The combination of our surgical experience and the Exactech's team's talent for implant development proved to be ideal.

The Vantage® Total Ankle System incorporates numerous features favored in currently used total ankle designs while introducing several new ones. What especially stands out for the Vantage is that rather than use imaging or cadaver specimens of physiologic normal ankles, 73 CT scans of arthritic ankles served as the template to optimize the tibial and talar implant backside designs.[6] The Vantage is available in both fixed- and mobile-bearing designs. The fixed-bearing implant is cleared for sale in the United States, and the mobile-bearing implant is cleared for sale in Europe, as of this writing.

Figure 1. The Vantage tibial component features a recessed area to accommodate the fibula while maximizing tibial component cortical support.

The Vantage tibial component maximizes the contact area on the prepared tibial plafond surface, featuring a recessed area to accommodate the fibula while maximizing tibial component cortical support. (Figure 1) To diminish joint fluid gaining access to the tibial component's backside and creating component loosening, recent trends in TAA technique favor not violating the anterior tibial cortex. (Figure 2) The Vantage's technique confers the advantage of vertically oriented tibial component fixation in contrast to most other modern systems that utilize obliquely orientated tibial pegs to avoid violating the anterior tibial cortex or traditional horizontally oriented tibial fixation that require anterior tibial cortex penetration. (Figure 3) Finite element modeling suggests that vertically oriented pegs provide ideal loading characteristics on the tibial bone-implant interface, thereby diminishing the risk of eccentric stresses, stress shielding and the chance of tibial component loosening. (Figure 4) Moreover, the Vantage tibial component's central cage, similar to the cage featured on the Exactech reverse total shoulder system, affords not only reliable press-fit fixation but adds the potential for bone ingrowth and superior long-term fixation. (Figure 5) The instrumentation to prepare the tibia for vertical peg and cage orientation is unique and simple to use (Figure 6); the Exactech engineering team was brilliant in creating this impaction system disproving many doubters, including myself, that such an impactor could be safely introduced despite the ankle joint's relatively limited access.

The Vantage talar component's backside has a uniform curve that optimizes compressive forces on the prepared dome-shaped talus throughout the ankle's full range of motion. In contrast, nearly all competitors' talar components provide

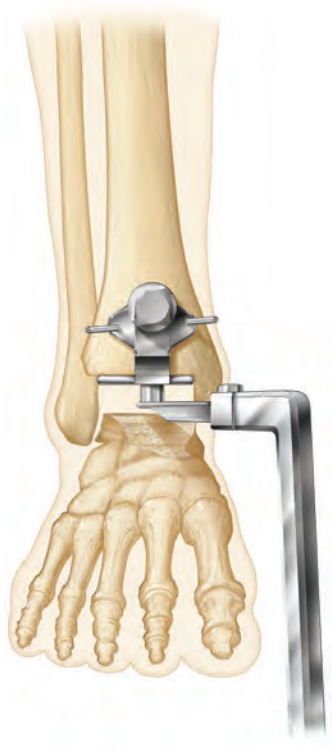

Figure 2. Recent trends in TAA technique favor not violating the anterior tibial cortex.

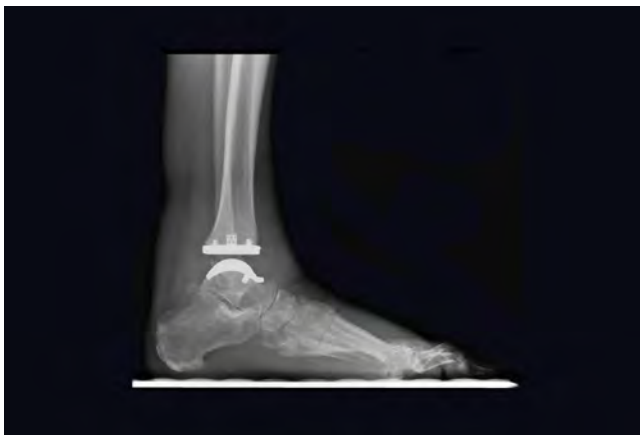

Figure 3. The Vantage's technique confers the advantage of vertically oriented tibial component fixation.

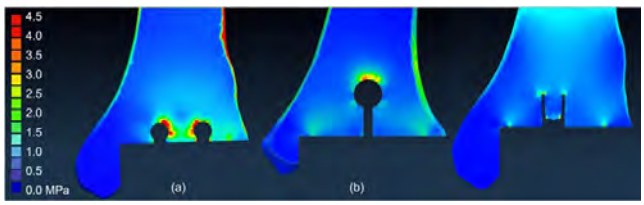

Figure 4. Finite element modeling suggests that vertically oriented pegs provide ideal loading characteristics on the tibial bone-implant interface.

Figure 5. The Vantage tibial component's central cage affords not only reliable press-fit fixation but adds the potential for bone ingrowth and superior long-term fixation.

talar component stability via chamfer cuts that tend to create the potential for shear stresses. (Figure 5) One recently released total ankle system, features a uniform dome-shaped talar preparation like that of the Vantage but requires a lateral approach and fibular osteotomy for component implantation. The Vantage' talar component confers the same talar component advantages via the far more commonly used anterior approach and does not require a fibular osteotomy. Unique to the Vantage total ankle system, a simple manual rasp is used to complete the uniform talar dome preparation. (Figure 7) Two anterior pegs designed to provide initial component stability do not detract from the uniformly compressive forces throughout the range of motion. The central talar component sulcus on the components articulating surface maintains the Vantage's coronal plane stability for the polyethylene and ankle.

Based on the successful Exactech total knee polyethylene implant, the Vantage's polyethylene component, affords high fracture toughness and low wear rates. The polyethylene, with its congruent articulation on the talar component, affords satisfactory coronal plane ankle stability without creating undue constraint. (Figure 2) Unique to the Vantage fixed-bearing total ankle system is the locking clip technology that secures the polyethylene to the tibial tray. (Figure 8) Through exhaustive stress and cyclic load testing, the Vantage team of engineers confirmed that the locking clip maintains satisfactory polyethylene fixation to the tibial tray; yet, extraction is easy should the polyethylene need to be exchanged.

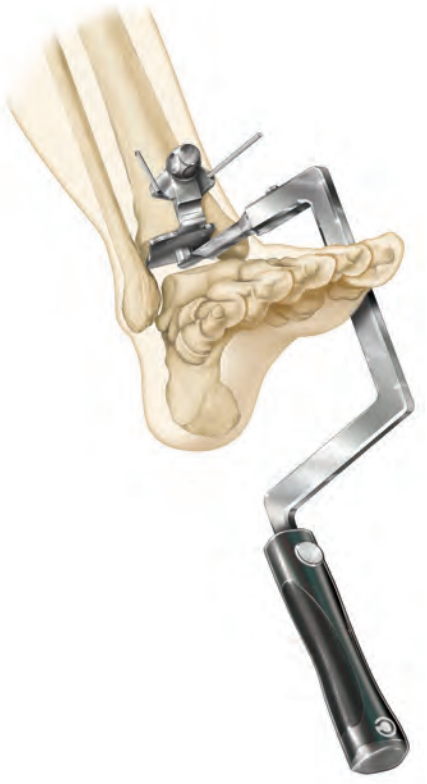

Figure 6. The instrumentation to prepare the tibia for vertical peg and cage orientation is unique and simple to use.

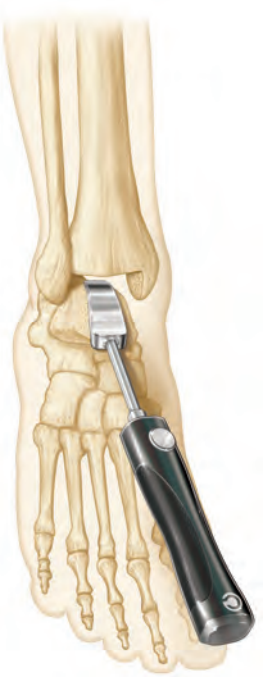

Figure 7. A simple manual rasp is used to complete the uniform talar dome preparation.

Figure 8. Unique to the Vantage fixed-bearing total ankle system is the locking clip technology that secures the polyethylene to the tibial tray.

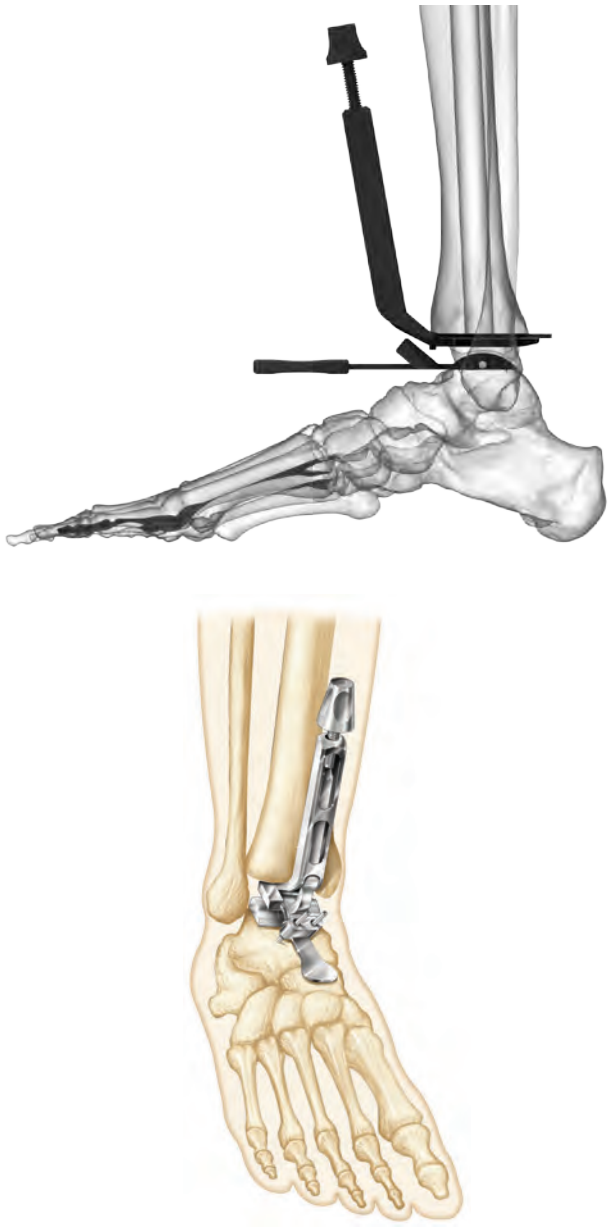

Figure 9. Talar preparation is uncomplicated, with reproducible positioning of the talar component in both the coronal and sagittal planes.

Our ankle design team spent the better part of four years devising and perfecting the Vantage surgical technique. Our initial thoughts favored sophistication and complexity to confer advantages over the competitors' ankles. However, complexity and its accompanying frustrations soon gave way to simplicity. The current surgical technique and instrumentation is remarkably straightforward. I recently taught a Vantage cadaver lab to a group of residents; none of the residents had prior experience performing a total ankle replacement. I can confidently state that the residents' implanted Vantage ankles were on par with the first Vantage cadaveric ankle implantations of nearly every experienced foot and ankle surgeon at our training labs. The external tibial alignment guide is reliable in properly orienting the tibial cut, and punching the relief areas for the tibial component pegs and cage is easily learned. Talar preparation is uncomplicated, with reproducible positioning of the talar component in both the coronal and sagittal planes (Figure 9); creating the uniform talar dome arc is facilitated by the user-friendly manual rasp.

September 30, 2017 was the one-year anniversary of the first Vantage total ankle implantation, a fixed-bearing ankle that Dr. Nunley and I performed at Duke University Medical Center. Since then my Duke colleagues and I have performed more than 100 Vantage total ankles, have trained numerous foot and ankle specialists throughout the United States and have seen the first wave of successful Vantage implantations by a talented group of surgeons that now favor the Vantage for treating endstage ankle arthritis. Dr. Valderrabano will soon begin implanting the mobile-bearing Vantage in Switzerland and train many European foot and ankle specialists.

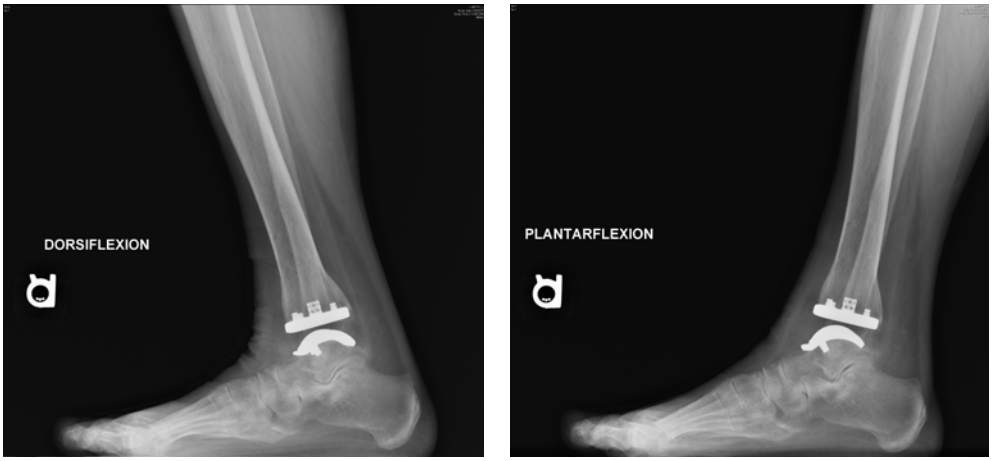

Figure 10. To date, our observations reflect high patient satisfaction, low complication rates and a trend toward favorable range of motion.

Follow-up is too short at this point to report outcomes for the Vantage. However, my colleagues and I have been collecting data on every Vantage that we implant, including validated patient-reported outcomes, accepted objective outcomes measures and standardized radiographic evaluations. (Fig 10 A and B) To date, our observations reflect high patient satisfaction, low complication rates and a trend toward favorable range of motion confirmed with objective postoperative radiographic dorsiflexion and plantarflexion measurements. While my colleagues and I initially limited the Vantage to endstage ankle arthritis with minimal deformity, more recently we expanded indications to include varus and valgus ankle arthritis. At early follow-up our results are equally favorable for endstage ankle arthritis with and without deformity.

The future of the Vantage is, in my mind, rather bright. Within the next six months the Exactech team of engineers anticipates completion of a dome-replacing "flat top" talus that will allow surgeons to safely perform TAA for ankle arthritis associated with talar dome cysts, focal AVN, and extensive talar dome wear.* The dome-replacing talar component will also be used in revision TAA.* We have also begun designing an augmented tibial component for ankle arthritis associated with a deficient distal tibia or for revision surgery. Although some competitors have similar augmented or revision components, they lack the advantages of the Vantage total ankle design. Computer assisted orthopaedic surgery and patient-specific options for the Vantage are planned. Drs. DeOrio, Nunley, Valderrabano and I look forward to the continued success working with Exactech's ankle design team. •

REFERENCES

1. **Stewart MG, Green CL, Adams SB Jr, DeOrio JK, Easley ME, Nunley JA.** Midterm Results of the Salto Talaris Total Ankle Arthroplasty. *Foot Ankle Int.* 2017 Jul 1:1071100717719756. doi: 10.1177/1071100717719756. [Epub ahead of print]

2. **Adams SB Jr, Demetracopoulos CA, Queen RM, Easley ME, DeOrio JK, Nunley JA.** Early to mid-term results of fixed-bearing total ankle arthroplasty with a modular intramedullary tibial component. *J Bone Joint Surg Am.* 2014 Dec 3;96(23):1983-9. doi: 10.2106/JBJS.M.01386.

3. **Queen RM, Sparling TL, Butler RJ, Adams SB Jr, DeOrio JK, Easley ME, Nunley JA.** Patient-Reported Outcomes, Function, and Gait Mechanics After Fixed and Mobile-Bearing Total Ankle Replacement. *J Bone Joint Surg Am.* 2014 Jun 18;96(12):987-993.

4. **Nunley JA, Caputo AM, Easley ME, Cook C.** Intermediate to long-term outcomes of the STAR Total Ankle Replacement: the patient perspective. *J Bone Joint Surg Am.* 2012 Jan 4;94(1):43-8. doi: 10.2106/JBJS.J.01613.

5. **Brunner S, Barg A, Knupp M, Zwicky L, Kapron AL, Valderrabano V, Hintermann B.** The Scandinavian total ankle replacement: long-term, eleven to fifteen-year, survivorship analysis of the prosthesis in seventy-two consecutive patients. *J Bone Joint Surg Am.* 2013 Apr 17;95(8):711-8. doi: 10.2106/JBJS.K.01580.

6. **Wiewiorski M, Hoechel S, Anderson AE, Nowakowski AM, DeOrio JK, Easley ME, Nunley JA, Valderrabano V, Barg A.** Computed Tomographic Evaluation of Joint Geometry in Patients With End-Stage Ankle Osteoarthritis. *Foot Ankle Int.* 2016 Jun;37(6):644-51. doi: 10.1177/1071100716629777. Epub 2016 Feb 3.

*Pending FDA clearance.

IF COMPUTER-ASSISTED SURGERY IS MORE ACCURATE, WHY ISN'T IT MORE PREVALENT?

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There are two things that all total knee surgeons can agree on when it comes to imageless computer navigation: It is more accurate than mechanical instrumentation in obtaining coronal alignment of the limb, and it is painful to adopt into one's practice. Countless studies looking at different computer assisted orthopaedic surgery (CAOS) systems have shown improvement in alignment, but full adoption of this technology into surgeon's operating rooms is uncommon.[1] Most of us can easily list the reasons we tried and ultimately gave up on navigation. The cameras take up too much space. The lines of sight to the arrays are hard to keep open with assistants in the sterile field. The work flows are set and not customizable. The interface is outside of the sterile field so the surgeon has to rely on a company representative or nurse to "run" the system. The arrays require extra pins, sometimes outside of the incision. The reflective spheres quit working when they get blood on them or someone gets in between the array and the camera. Registration takes too long. The cutting blocks and instruments are specific to navigation, so if the case starts to go off the rails, converting back to conventional instruments is difficult and time consuming.

We should not, however, ignore the first point. CAOS is more accurate. The question, of course, is does this matter? There is plenty of evidence in the literature that alignment improves longevity.[2-4] There is even good registry data that navigated total knees have a lower revision rate in one of the more high-risk demographics.[5] There is even some literature to suggest that functional outcomes are better in navigated total knees.[6]

If we believe that navigation is more accurate, and that accuracy improves longevity and functional outcomes, what will it take to get us to fully adopt navigation into our operating rooms? Assume cost is not the roadblock. The system would have to be smaller and be fully incorporated into the surgical field. The software interface would have to be intuitive, run by the surgeon in the sterile field and customizable in real time. The arrays would have to be placed inside the incision, unaffected by blood and fluid and minimally affected by line of sight issues.

The ExactechGPS® computer assisted surgery system does all of this, and its accuracy has been validated in thousands of cases. I personally have used this system on and off for five years. Its accuracy allows me to do away with the intra-operative x-ray I typically take of my tibia cut. This saves me time, but the registration and "fiddle factor" still adds nine minutes on average to my navigated tourniquet times. While I am very accustomed to the extra pins needed to fix the arrays to the femur and tibia as well as the navigation specific adjustable cutting blocks, I remember that the learning curve was frustrating. So, when Exactech asked me to work with its team to come up with an easier way to navigate that incorporates the power of CAOS into the simplicity of mechanical instruments without extra pins I was intrigued and agreed to participate.

The initial offering from this work group is ExactechGPS TKA Plus. TKA Plus uses familiar Truliant® mechanical instruments to guide TKA Plus specific cutting guides into an initial position for cutting the distal femur and proximal tibia. The cutting blocks, once fixed to the bone, then become foundations for the arrays that allow bone registration and cut guidance.

For the distal femoral cut, an intramedullary guide is still utilized. While this eliminates one of the purported advantages of navigation, it is familiar and will place the block within the range of adjustment to allow for a perfectly planned resection. Intramedullary distal femoral cuts fall outside an acceptable varus/valgus angle up to fourteen percent of the time.[7,8] The ability to adjust the cut to the desired valgus angle, flexion, and resection depth will improve alignment. The block offers plus/minus four degrees of varus/valgus adjustment, plus/minus four degrees of flexion/extension, and plus four/minus two millimeters of resection. Registration is six quick points. Only the distal medial and lateral femur require painting, so registration takes about one minute.

> What I have found is that I'm not that accurate with mechanical instruments. Probably none of us are.

The tibial side uses the familiar extramedullary guide. Once pinned to the bone, it takes six quick points to register without any painting. Registration is fast! The intended cut is then verified and adjustments can be made on the block before resection. Much like the femoral block adjustment is plus four/minus four degrees of varus/varus, plus four/minus four degrees of tibial slope, and minus two/plus four millimeters of resection depth.

Lab testing has shown that when the blocks are pinned with the appropriate technique (threaded headed pins) for stable, secure fixation that angular play of the block with attempted movement is only 0.2 degrees. So the trackers are stable. In surgery, I have found the system to be very intuitive. Registration and block adjustment only adds three to five minutes compared to my mechanical instruments if I don't need to recut. Recuts do not happen when I use the TKA Plus navigation so I may save time over many cases.

What I have found is that I'm not that accurate with mechanical instruments. Probably none of us are. In a sawbones study at Stanford in which 36 tibia and 36 distal femoral cuts were made by surgeons with varying levels of training, all cuts required at least one of the three adjustments to get to the intended cut angles and depths. Many times all three parameters were adjusted. I have found a similar trend. Prior to using navigation, I x-rayed all of my tibia cuts to ensure a 90 degree cut the mechanical axis. Twenty three percent of the time I was more than two degrees off and had to recut the tibia. In my TKA Plus cases I have had to adjust at least one parameter two thirds of the time! On the femoral side I have always taken it for granted that my cut was accurate. I was wrong. Studies show that an improperly placed starting point, a femur with medial to lateral bow, or a patulous intramedullary canal can all lead our cuts to be outside of an acceptable range.[7,8] In my TKA Plus cases I have adjusted one of the three parameters twenty five percent of the time!

We all agree that CAOS makes us better. After using TKA Plus, I know it is making me better without disrupting my normal workflow. It adds very little additional time, and if it prevents recuts, will probably save time in the long run. ExactechGPS navigation already gets past many of the hurdles to the adoption of CAOS. Its accuracy has been validated. TKA Plus takes the next step toward mainstream use of navigation by incorporating it into our standard mechanical instrumentation. Future plans with TKA Plus may incorporate sizing and femoral rotation. •

REFERENCES

1. **Hetaimish BM et al.** Meta-analysis of navigation versus conventional total knee arthroplasty. *Journal of Arthroplasty,* 2012 Jun;27(6):1177-82.

2. **Jeffery RS et al.** Coronal alignment after total knee replacement. *Journal of Bone and Joint Surgery Br,* 1991 Sep;73(5):709-14.

3. **Berend ME et al.** Tibial component failure mechanisms in total knee arthroplasty. *Clinical Orthopaedics and Related Research,* 2004 Nov;(428):26-34.

4. **Collier MB et al.** Factors associated with the loss of thickness of polyethylene tibial bearings after knee arthroplasty. *Journal of Bone and Joint Surgery Am,* 2007 Jun;89(6):1306-14.

5. Australian Orthopedic Association, National Joint Replacement Registry, Annual Report 2013 – Hip and Knee Arthroplasty.

6. **Rebal BA et al.** Imageless computer navigation in total knee arthroplasty provides superior short term functional outcomes: a meta-analysis. *Journal of Arthroplasty,* 2014 May;29(5):938-44.

7. **Cates HE et al.** Intramedullary versus extramedullary femoral alignment systems in total knee arthroplasty. *Clinical Orthopaedics and Related Research,* 1993 Jan;(286):32-9.

8. Teter KE et al. The efficacy of intramedullary femoral alignment in total knee replacement. Clinical Orthopaedics and Related Research, 1995 Dec;(321):117-21.

INSIGHTS IN COMPUTER-ASSISTED SURGERY FOR TSA

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Total shoulder arthroplasty (TSA) can be challenging surgery, due to exposure difficulties and limited access to portions of the anatomy. In the past, working your way through a steep learning curve was the only option to achieve success in some of the most difficult shoulder arthroplasty cases. The inability to expose certain portions of the scapula make it nearly impossible using conventional methods to precisely determine version (Friedman's axis) and inclination of the glenoid intraoperatively, not to mention accurately correct it.

Unfortunately, accurate reproduction of these anatomical parameters are the key ingredients to successful shoulder arthroplasty outcomes. We know that anatomic TSA outcomes are correlated with the quality of reproduction of the patient's anatomy. During reverse shoulder arthroplasty, position and orientation of the implants can play a role in range of motion, stability, and scapular notching.

Tools that help us with reproduction of the anatomy are ever improving. Today, as shoulder surgeons, we are armed with modern implants allowing modularity to assist reconstruction. Also, the recent popularization of augmented implants further improves our ability to improve glenoid deformity. However, recognition of the deformity and exactly how to correct it using an augment remain some the greatest difficulties in shoulder surgery.

Fortunately, new technology is available to give us modern solutions to these problems. These include sophisticated preoperative planning software, patient specific instrumentation (PSI), and Computer Assisted Orthopaedic Surgery (CAOS). Preoperative planning allows us to identify deformities, virtually plan reconstruction, and accurately place implants. This alone has been shown to improve the accuracy of implant placement. However, the ability to take that information to the operating room provides the most optimal situation. PSI does this to a limited degree by assisting placement of a K-wire into the glenoid vault. This allows the surgeon to ream in a predetermined version and inclination. Information on reaming depth or screw placement is not possible. Furthermore, if the K-wire becomes loose or displaced the accuracy is lost.

CAOS is well proven in the knee and has shown great promise in the shoulder. Advantages of CAOS in the shoulder include: having complete control of version and inclination with adjustability intra-op, feedback on reaming depth, navigation of screw placement in RTSA, potential navigation of implant placement, and no dependance on K-wires. Also, future applications are possible for the humeral side.

I began using ExactechGPS® computer assisted surgery for total knee arthroplasty (TKA) approximately two years ago. This has really streamlined my approach to knees and improved my consistency with balancing the knee and subsequently outcomes. It was, therefore, a natural progression to the ExactechGPS Total Shoulder Application. To date, I have performed approximately 35 shoulder cases with ExactechGPS and have learned some things along the way.

First, the registration of points on the glenoid requires a little extra exposure around the coracoid and time to strip off remaining cartilage on the glenoid. However, after a few cases, this only adds around five minutes including attaching the tracker. Speaking of the tracker; early in the development process, there was concern about the stability of the coracoid tracker. I'm happy to say that there has been only one case in which the tracker came loose requiring me to abandon the navigation. One interesting observation I have found since starting navigation has been that my use of augmented implants has increased. Of my initial cases to date, there have only been four non-augmented glenoids placed. This stresses the point that we may not always be as accurate as we think in recognizing deformity and performing reconstructions of the glenoid in the absence of navigation (or at least I wasn't).

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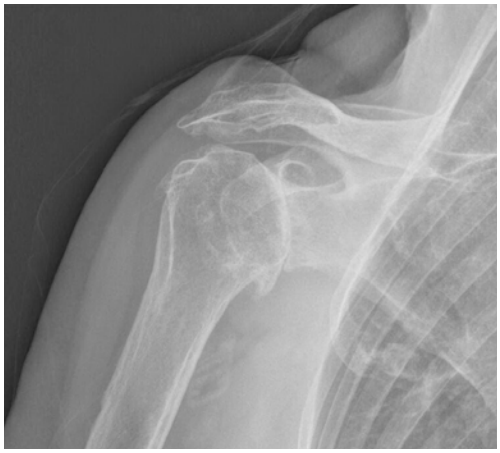
Aside from improvement in recognizing and correcting deformity, the ExactechGPS Shoulder Application has also made the process of placing augmented implants easier and more efficient. No longer do I need to worry about placing a K-wire down what I think is the center of the vault, use a bulky guide and a second K-wire to ream over for a set amount of version, or try to determine how much I'm correcting with eccentric reaming. Now I just navigate my central starting point and ream based on my preoperative plan.

On the folllowing pages, I demonstrate two cases where CAOS helped me identify deformity and perform an accurate reconstruction on the glenoid side during RTSA.

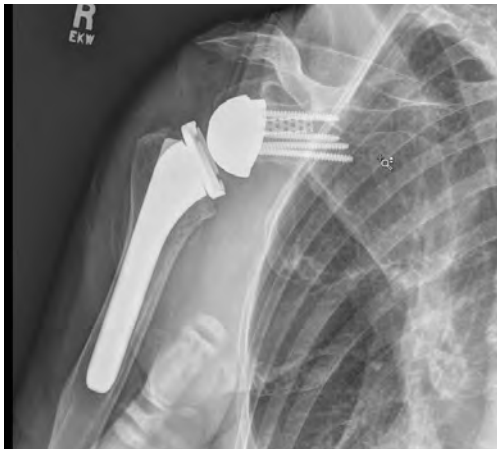
CASE 1

This is a 74-year-old male with history of prior failed cuff repair now with rotator cuff tear arthropathy. There is significant posterior wear of 18 degrees combined with 10 degrees of superior inclination. This is a common wear pattern in rotator cuff tear arrthropathy. By planning the posterior superior augment preoperatively I was able to move the center starting point slightly posterior and place it in 6 degrees of retroversion, allowing the cage to stay within the vault and ream almost no bone. The 10 degree superior portion of the augment fit almost perfectly. Without the preoperative planning and the GPS navigation it would have been easy to ream away significant bone anteriorly to attempt a correction of the version. There also would have been no way to determine how much retroversion I was leaving the implant in order to ream minimally.

Pre-Op



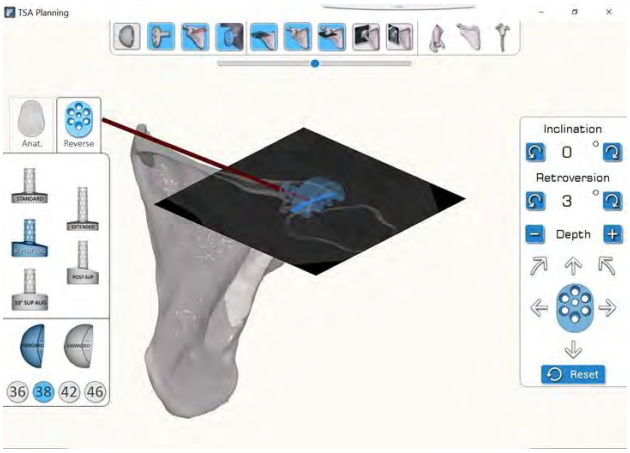
Post-Op



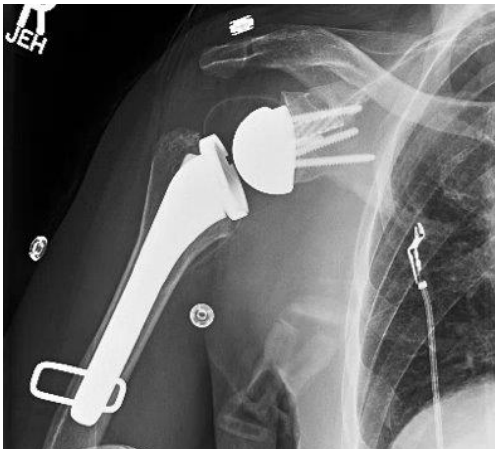
CASE 2

This is a similar case of posterior superior wear, but with a slightly smaller vault. There is 15 to 20 degrees of retroversion and 10 degrees of superior inclination. It should be noted that there is a posterior osteophyte that I didn't want to use as support for the implant. As in the previous case, the goal is to place the implant while removing as little bone as possible and maintaining as much of the cage as possible in the vault. To avoid reaming the subchondral bone, the posterior superior augment baseplate was used. I undercorrected the version to 8 degrees and moved the center point slightly anterior to avoid the posterior osteophyte. This left the slightly longer cage of the posterior/superior augment barely penetrating the anterior cortex which is of little to no consequence. As in case 1, in the absence of preoperative planning and GPS, finding a proper starting point on the glenoid face to place the implant in the appropriate amount of acceptable retroversion, avoiding the posterior osteophyte, and reaming minimal to no subchondral bone would be extremely difficult. •

Pre-Op



Post-Op



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The Industrial Designers Society of America (IDSA) honored the Truliant® Knee System's surgical instrumentation with a Bronze Award in its 2017 International Design Excellence Awards.

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6130-L [Standard]
Overall Length: 12"
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Blade Width: 33mm

6135-L [Deep]
Overall Length: 14.5"
Handle Length: 7"
Blade Width: 33mm

Lighted Cobra Retractors

PRODUCT NO:

6210-02L
Overall Length: 12.5"
Blade and Tip Length: 3"
Blade Width: 15mm

Lighted Single Prong Double Bent Hohmann Acetabular Retractor – Long

PRODUCT NO:

6255-L
Overall Length: 12"
Handle Length: 8"
Blade Width: 32mm

Lighted Inferior Acetabular Retractor

Jana Sheilded Lighted Cobra Retractor

Designed by Ajoy K. Jana, MD

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

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

New!

PRODUCT NO:

6119-L
Overall Length: 14.2"
Blade at Widest: 33 mm

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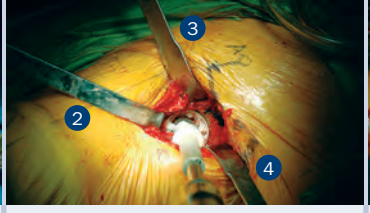
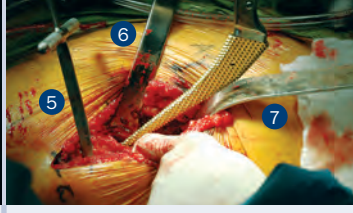
Exposure of the hip joint & removal of the femoral head



Acetabular exposure, reaming and cup insertion



Femoral broaching and stem insertion

Das/Seng Anterior Total Hip Instruments

Designed by Amal Das, MD and Brian Seng, DO

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

1 *Posterior Femoral Neck Retractor*

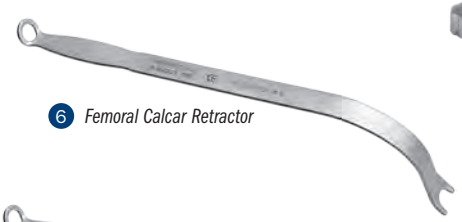
2 *Anterior Femoral Neck Retractor*

3 *Anterior Acetabular Retractor*

4 *Posterior Acetabular Retractor*

5 *Elevator Hook*

Table Assembly 8



6 *Femoral Calcar Retractor*

7 *Greater Trochanter Retractor*

PRODUCT NO'S:

1 6221 [#1 - Posterior Femoral Neck Retractor]
Blade Width: 25mm
Blade Depth: 3"
Overall Length: 14"

2 6222 [#2 - Anterior Femoral Neck Retractor]
Blade Width: 31.5mm, 10mm @ Tip
Blade Depth: 4.5"
Overall Length: 15"

3 6223 [#3 - Anterior Acetabular Retractor]
Blade Width: 25mm
Blade Depth: 2.25"
Overall Length: 13.25"

4 6224 [#4 - Posterior Acetabular Retractor]
Blade Width: 25mm
Blade Depth: 2.75"
Overall Length: 14"

5 6226-RH [#5A - Round Elevator Hook]
Blade Width: 10mm
Blade Depth from T-Handle: 5.75"
Overall Length: 9.25"

6 6227 [#6 - Femoral Calcar Retractor]
Blade Width: 25mm
Blade Depth: 3.625"
Overall Length: 14"

7 6225 [#7 - Greater Trochanter Retractor]
Blade Width: 25mm
Blade Depth: 2.5"
Overall Length: 14.25"

8 6226-TA [#8 - Table Assembly]
This product number includes one 6226-RH Elevator Hook
Folds to approx: 21" x 5" x 5"

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