The Truliant® Total Knee System is a high performance, comprehensive platform that offers solutions to address clinical challenges in primary and revision total knee replacement. Leveraging Exactech's core principles, Truliant applies advanced design philosophies and surgical technologies to help you deliver reproducible clinical outcomes in a streamlined procedure.
INTRODUCTION

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

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

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

MATERIALS AND METHODS

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

To perform the CUSUM analysis, four parameters must be defined (Figure 1A): acceptable failure rate (p0), unacceptable failure rate (p1), type I error rate (α), and type II error rate (β). From the parameters, two decision limits (h0 and h1) and the variable s were calculated. The first 50 cases from each surgeon was sorted chronologically. Each case was evaluated as to whether it “failed” or “succeeded” based on the surgical time criteria defined in Figure 1A. When a failure occurred, a “penalty value” 1-s was added to the CUSUM score; while when a success occurred, a “reward value” s was subtracted from the CUSUM score. A healthy learning process was marked as the CUSUMline crossing the lower decision limit (h0), indicating completion of the learning period (met the acceptable failure rate). Conversely, the CUSUM line crossing upper decision limit (h1) from below indicated the failure of the learning process (reaching an unacceptable failure rate).
The duration of learning for each surgeon was identified by his/her own CUSUM chart as the number of the last case before crossing the lower decision limit (h0). Surgical time in the baseline, during learning period, and after learning (cases #41-#50) were compared. Significance was defined as p<0.05.

RESULTS

All CUSUM lines from the four surgeons crossed the lower decision limit, indicating their successful completion of learning (Figure 1B). The duration of learning was on average 8.3 ± 3.8 cases with individual surgeons exhibiting unique learning characteristics, reflected by the shape of the CUSUM line. Surgeons A and C exhibited significant but moderate time decreases from the learning period to after learning (Figure 2). For all four surgeons, the learning period did not significantly increase their surgical time from the baseline, and the surgical time after learning showed a general trend of smaller standard deviations and shorter time compared to the baseline (Figure 2).

DISCUSSION

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

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

Figure 1. A) CUSUM parameters used for the analysis. B) CUSUM chart for the learning curves from individual surgeon, marked with his/her duration of learning (#cases).

†Surgeon D started to incorporate a new navigation technology from cases #29. Those cases were therefore excluded from the analysis. Cases #19-#28 were then used to calculate surgical time after learning instead of #41-#50.

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

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

METHODS

Four surgeons (2 seniors, and 2 fellows with no prior CAOS experience) were included in this sawbone study. Each surgeon performed proximal tibial and distal femoral resections on 6 knee models using conventional instrumentation and six knee models with the same conventional instrument system enhanced by CAOS. All resections were created targeting neutral coronal alignment, 3° tibial slope, and 10mm resection depth. For each surgeon, the cumulative sum of deviances was calculated, specifically: The CUSUM score of the first case was the difference between the time of the first case and the mean surgical time. This recursive process continued until the last case, which was calculated as 0. CUSUM score was plotted in chronological order for each surgeon. A horizontal trend in the plot signified the plot indicated the process was operating with stability. The case number (cases to proficiency) by which the CUSUM plot entered the horizontal trend was identified as the end of learning for each surgeon. The cases to proficiency was compared between the senior and the fellow surgeons. The surgical time in CAOS enhanced cases during and after learning was compared to the conventional cases within each surgeon (due to limited cases number per surgeon, statistical assessment of the differences was not performed). The increase in surgical time after learning the CAOS system was compared to conventional cases on the pooled data (significance defined as \(p<0.05\)).

RESULTS

The CUSUM plot exhibited three unique phases in the first six cases of each surgeon, with Phase II demonstrating stabilization of the process (Figure1). No substantial difference between the senior and novice surgeon groups was found in the speed of learning (2-3 cases). However, compared to the senior surgeons, the fellow

<table>
<thead>
<tr>
<th>Surgical Time (min)</th>
<th>Senior Surgeons</th>
<th>Fellow Surgeons</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAOS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During Learning*</td>
<td>7.3 ± 0.6</td>
<td>11.9 ± 3.4</td>
<td>0.01</td>
</tr>
<tr>
<td>After Learning†</td>
<td>6.2 ± 0.6</td>
<td>7.2 ± 1.3</td>
<td>0.07</td>
</tr>
<tr>
<td>Mechanical Instrumentation</td>
<td>3.4 ± 0.8</td>
<td>5.4 ± 1.6</td>
<td>0.00</td>
</tr>
<tr>
<td>(P) (Mechanical Instrumentation vs After CAOS Learning)</td>
<td>0.00</td>
<td>0.01</td>
<td></td>
</tr>
</tbody>
</table>

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

Table 1. Summary of learning characteristics in the senior surgeon and fellow surgeon groups.
surgeons demonstrated slightly steeper learning curve by adding 3-4 minutes more to their learning cases (Figure 1,2). Compared to the conventional TKA, adding CAOS enhancement slightly increased time by 4-6 minutes during learning, and the difference reduced to 2-3 minutes after learning. No significant difference in surgical time was found between senior and fellow surgeons after their learning (Figure 2B).

DISCUSSION

This study applied CUSUM method to analyze learning curve of a CAOS enhanced mechanical instrument system for TKA. As the CAOS guidance is based on existing conventional mechanical instruments, the adoption of the technology exhibited minimum learning effort (2-3 case to learn), independent of the surgeon’s experience level. Compared to conventional cases performed using the same mechanical instrument system, using the CAOS enhanced system moderately increased the surgical time in critical bony resection steps by 4-6 minutes during learning. After quick mastering of the technology, the surgical time was only slightly extended by 2-3 minutes compared to conventional cases. The results demonstrated minimum impact on surgical efficiency by introducing CAOS to the existing conventional mechanical instruments, offering the proven benefit of CAOS technology without major disruption in the surgical tools the surgeons are already familiar with. Utilization of advanced method in studying learning curve can provide improved understanding of CAOS learning in general, but also in addition, allows differences in learning between individual surgeons to be explored. Further investigation of this study may include expanding the CUSUM assessment to the entire TKA surgical duration with more surgeon groups with different characteristics.

SIGNIFICANCE/CLINICAL RELEVANCE

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

REFERENCES

INTRODUCTION
Since the introduction of computer-assisted orthopaedic system (CAOS) to total knee arthroplasty (TKA), the perceived challenges in its adoption are increased costs and a significant learning curve. To date, limited studies have assessed the learning of new surgical technology in TKA. The methodology applied in existing studies usually compared surgical time between the cases performed during and after learning, with an assumed duration (number of cases) of the learning period [1]. Researchers have performed logarithmic regression on the initial CAOS case series to find the duration of the learning phase [2]. However, as the surgical time data often, by nature, noisy, the regression result can be difficult to evaluate. Cumulative sum control chart (CUSUM) has been widely applied in the industry to assess the stabilization of a production process and was proven to be an objective and effective tool to evaluate the learning process. Although many successes have been achieved by this method in other medical fields [3], its usage for orthopedic applications is limited. The goal of this study was to leverage this advanced methodology to define the learning period of a contemporary CAOS system.

METHODS
Surgical time (system usage time) from the early series of primary CAOSTKAs performed by 10 surgeons (7 seniors, 3 novice surgeons with no prior CAOS experience) were reviewed. For each surgeon, the cumulative sum of deviances was calculated as following [3]: The CUSUM score of the first case was the difference between the surgical of the first case and the average surgical time. This recursive process continued until case #50, which was calculated as 0. CUSUM scores was plotted in chronological order for each surgeon. A horizontal trend in the plot signified the deviances were equally balanced around 0, indicating the process was operating with stability. The case number (cases to proficiency, abbreviated as CP) by which the CUSUM value entered the horizontal trend was identified as the end of learning curve for each surgeon. The CP was compared between the senior and the novice surgeons. The difference in surgical time was compared between the cases during learning (cases #1 to #CP) and after learning (cases #41-50). Significance was defined as p<0.05.

RESULTS
Compared to the actual surgical time graph (Figure 1A,C), the CUSUM plot clearly exhibited three unique phases in the first 50 cases of each surgeon, with Phase II demonstrating stabilization of the process (Figure1B,D). The actual shape of the 3 phases differed between surgeons, reflecting each individual’s characteristics of learning. On average, it took 12-13 cases to complete the learning of the CAOS system, with no substantial difference between the senior and novice surgeons (Table 1). On average, both surgeon groups spent approximately 15min more during their learning period than their last 10 cases in the series (#41-50). The novice surgeons exhibited approximately 3min more time increase during their learning period compared to the senior surgeons. No significant difference was found between the senior and novice surgeons regarding CP and time increase.
DISCUSSION

This study applied the CUSUM method to analyze the learning curve of a CAOS system based on surgical efficiency (time), relating the adoption of the surgery as a process that eventually stabilizes with mastery of the task. The data suggested that the average learning of the system took 12-13 cases, regardless of the surgeon’s previous CAOS experience. Compared to the cases performed after learning, the learning period only moderately increased surgical time. For the novice surgeons, the increase of surgical time during learning, compared to their later cases, did not differ significantly from that of the senior surgeons (16min versus 13min). This indicated that having no CAOS experience did not result in substantially steeper learning curve.

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

SIGNIFICANCE/CLINICAL RELEVANCE

An advanced method (CUSUM) was employed to analyze learning of a CAOS TKA system in 10 surgeons from different experience levels. The data demonstrated a short and moderate learning period disregard of a surgeon’s experience level.

Table 1. Summary of learning characteristics in senior surgeon, novice surgeon, and pooled surgeon groups. No significant difference was found between senior and novice surgeons (N.S.) in CP and time increase.

<table>
<thead>
<tr>
<th></th>
<th>Senior Surgeon</th>
<th>Novice Surgeon</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>7</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>Cases to Proficiency (CP)</td>
<td>13.0 ± 7.1</td>
<td>12.0 ± 7.5</td>
<td>13.4 ± 7.4</td>
</tr>
<tr>
<td>Time Increase in Learning Curve (min)*</td>
<td>13.0 ± 8.6</td>
<td>16.2 ± 14.6</td>
<td>13.3 ± 10.7</td>
</tr>
</tbody>
</table>

* Calculated as Average(cases #1 - #CP) - Average(cases #41-50)
Total Knee Arthroplasty Using a Contemporary Computer-Assisted Surgical System: A Review of Resection Alignment on 8,000 Clinical Cases

Dai Y1, Bras G2, Hamad C2, Jung A2, Angibaud LD1

1Exactech Inc, Gainesville, FL, 32653, USA
2Blue-Ortho, Gieres, FR

INTRODUCTION

Computer-assisted orthopaedic surgery (CAOS) has been shown to offer increased accuracy and precision to the bony resections compared to the conventional techniques during total knee arthroplasty (TKA). Previous studies of CAOS surgeries were mostly focused on the alignment outcomes based on either limited number of patients, or meta-analyses reporting combined results from various CAOS systems, despite that system-dependency has been reported in alignment.1 In a previous study, we have benchmarked the ability of a specific CAOS system for its efficiency of achieving the intraoperatively defined surgical goals based a large number (4000+) of clinical cases.2 The purpose of this study was to provide the updated assessment of the accuracy and precision of achieving surgical goals with substantially expanded cohort of 8000+ cases.

METHODS

Alignment parameters were extracted from the technical logs of 8360 TKA surgeries performed between October 2012 and April 2017 using a contemporary CAOS system (ExactechGPS®, Blue-Ortho, Grenoble, FR). The following surgical parameters were investigated: 1) planned resection, resection parameters defined by the surgeon prior to the bone cuts. These parameters serve as inputs for the CAOS guidance; 2) Checked resection, digitization of the realized resection surfaces by manually pressing an instrumented checker onto the bony cuts. Due to that anterior, posterior and chamfer cuts of the femur were all corresponded to the distal resection, only the distal resection was evaluated for the femur. Deviations in the alignment between planned and checked resections were calculated in coronal and sagittal planes for both tibia and femur (planned vs checked). Acceptable resections were defined as resections with no more than 3° of resection deviations.

Figure 1. Deviations in tibial and femoral alignment parameters (planned vs. checked).

* Positive value in deviation indicates that compared to the planned resection, the checked resection was more valgus, and had less posterior slope (for tibia) or less flexion (for femur).
RESULTS
For the tibial resection, the deviations in coronal alignment (tibial varus/valgus angle) and sagittal alignment (posterior tibial slope) were 0.05 ± 0.89° and -0.11 ± 1.53°, respectively (Figure 1). For the femoral resection, the deviations in coronal alignment (femoral varus/valgus angle) and sagittal alignment (femoral flexion) were 0.00 ± 0.96° and -0.22 ± 1.39°, respectively. High percentages of the resections were found to be within the acceptable alignment range (>94%, Figure 2).

DISCUSSION
Studies have shown that malalignment can lead to various postoperative complications. However, only 70-80% of the TKA cases can achieve satisfactory alignment with conventional instruments. This study demonstrated that the use of the CAOS system investigated can provide an accurate and precise guidance to surgical resection with substantial reduction of unacceptable alignment. This study was based on big data analysis to summarize a large number of cases spanning the entire application history of a specific CAOS system, including both experienced users and new adopters. The data provided a complete clinical relevant evaluation demonstrating high accuracy and precision in resection alignment by using the CAOS system.

SIGNIFICANCE/CLINICAL RELEVANCE
This study reviewed a large number of cases spanning the application history of a specific CAOS system, providing a complete clinically relevant evaluation of its accuracy and precision in terms of bony resection alignment.

REFERENCES
2. Dai Y, Bertrand F, Angibaud L, et al. Total knee arthroplasty using a contemporary computer-assisted surgical system: a review of surgical parameters on more than 4000 clinical cases. ISTA 2016 Congress

Figure 2. Distribution of the resection deviations in A) coronal alignment and B) sagittal alignment, marked with the percentage of acceptable resections.
INTRODUCTION

Total knee arthroplasty (TKA) improves the life of patients experiencing osteoarthritis of the knee joint. It has been shown that alignment of the knee implant is important to both short and long-term outcomes.\(^1,2\) An instrumentation system (ExactechGPS\(^\circledR\) TKA Plus, Exactech, Gainesville, FL) was developed that integrates principles of computer-assisted surgery (CAS) into a conventional mechanical instrumentation-based operative technique (Figure 1). The system does this by replacing conventional static distal femoral and proximal tibial cutting blocks with similar sized adjustable CAS-based cutting blocks. According to the presented technique, the surgeon gains knowledge of the resection parameters (before the actual cut) and therefore may elect to fine-tune them if deemed necessary. The objective of this study was to compare the difference between the orientation of the initial cutting block position (if used as a conventional mechanical instrument) and the adjusted cutting block position (based on guidance of the CAS system).

METHODS

From June 2017 through June 2018, a total of 49 cases were performed using the CAS-augmented instrumentation by four individual surgeons at four hospitals. During the surgery, the cutting blocks were pre-positioned using a conventional intramedullary and extramedullary guide on the femur and the tibia; respectively. A limited registration of the anatomical landmarks was performed. Then, a navigated guide was affixed to the cutting slot; which allowed the direct quantification of the resection parameters of the pre-positioned cutting block (Initial orientation) relative to the mechanical axis of the patient. Based on this information, the surgeon had the option to fine-tune the orientation of the cutting slot using the independent levers designed into the instrument to achieve preferred resection parameters (Adjusted orientation). Initial and adjusted orientation information in both the frontal and sagittal planes were compared (Adjustment amount) to evaluate the amplitude of changes performed by the surgeon based on the knowledge of the resection parameters.

RESULTS

Surgeons elected to adjust the initial orientation of the resection parameters in 82% and 71% of the procedures on the femur and tibia, respectively. The cutting blocks were adjusted an average of 1.3° for varus/valgus and 1.4° for slope when used on the tibia (Figure 2), and 1.7° for varus/valgus and 2.1° for flexion/extension when used on the femur (Figure 3). The varus/valgus parameter was adjusted by 3° or greater in 12% of cases for the tibia and in 14% for the femur. For the cases with varus/valgus adjustments of 3° or greater, the surgeons were able to correct the cutting parameters to within 2° of the mechanical axis in all but one case (98%).

DISCUSSION

The system allowed the surgeons to use conventional TKA alignment guides to position the adjustable cutting blocks, and if desired, to leverage CAS guidance to adjust the orientation and position of the cutting slot to achieve preferred resection parameters. This study is consistent with previous results showing conventional instrumentation systems reporting accuracy within \(\pm3°\) of varus/valgus relative to the mechanical axis in 70-80% of cases [3, 4]. Using the presented CAS-augmented cutting blocks, surgeons were able to achieve superior alignment in both the frontal and sagittal planes while maintaining a streamlined technique using conventional positioning guides.
SIGNIFICANCE/CLINICAL RELEVANCE

Surgeons using conventional instrumentation systems can use low profile adjustable cutting blocks instead of static cutting blocks to perform bone cuts perpendicular to the mechanical axes of the femur and the tibia.

REFERENCES

INTRODUCTION

Accurate positioning of the knee prosthesis is critical for the success of total knee arthroplasty (TKA). However, only 70-80% of the conventional TKA cases can achieve satisfactory lower limb alignment (within ±3° of varus/valgus relative to the mechanical axis).

Computer-assisted orthopaedic surgery (CAOS) offers increased accuracy and precision to the bony resections compared to the conventional techniques. Despite the benefits provided by CAOS, one of the drawbacks for its adoption may be the inconvenience of switching from conventional instruments to CAOS-specific instruments. A novel system has been introduced to enhance conventional mechanical instruments with CAOS technology. The purpose of this study was to investigate alignment accuracy achieved by surgeons with varying TKA experience levels using the CAOS enhanced mechanical instrument system.

METHODS

Two senior surgeons, two fellow surgeons, and four orthopedic residents participated in this sawbone study. First, each senior and fellow surgeon performed distal femoral and proximal tibial resections (6 knees) using conventional instrumentation. For the residents, each surgeon performed the same resections on 3 knees. The same resection activities were repeated on a matching set of knee sawbones with the addition of the CAOS enhancement. All resections targeted neutral coronal alignment relative to mechanical axis. The sawbones were scanned and digitized at the pre- and post- resections stages. Mechanical axes on the tibia and femur were annotated based on the intact bone surface. After registration of the pre- and post- resection surfaces, varus/valgus alignment (achieved alignment) was measured referencing the established mechanical axes.

Coronal alignment accuracy in each resection was defined as the signed and unsigned angular deviation between the alignment target (0° varus/valgus) and the achieved alignment. The unsigned differences represent the magnitude of resection errors. The signed differences however, identify any bias of the alignment error with a tendency towards more varus or valgus. Accuracy in varus/valgus alignment was compared between senior, fellow, and resident surgeons. The percentages of the cases with optimal resection (< 2° deviation) were compared between CAOS enhanced cases and conventionally instrumented cases, as well as between senior, fellow, and resident surgeons. Statistical significance was defined as p<0.05.

RESULTS

Compared to the cases performed with the conventional instrument system, those using the CAOS enhanced instrumentation exhibited improved varus/valgus alignment accuracy (Figure 1,2). Impact from a surgeon’s TKA experience was found in the conventionally instrumented tibial resections. Specifically, the fellow and the resident surgeons had higher alignment errors (both signed and unsigned) than those from the senior surgeons (p values ≤ 0.017), while no significant difference was found between surgeon experience levels in the femur (n.s.). In contrast, by adding CAOS enhancement, all surgeon groups achieved on average ≤ 1° accuracy (signed or unsigned) in both femur and tibial alignment. Significantly higher percentages of optimal alignment were found in the CAOS enhanced resections compared to the conventionally instrumented resections (Table 1). All cases performed with CAOS guidance achieved optimal alignment, except for tibial resections from the fellow surgeon group (92%).
DISCUSSION

This study showed significant improvement in coronal alignment accuracy when a conventional instrument system was enhanced with CAOS technology. Moreover, the result demonstrated that surgeons with varying experience level can all achieve equally high accuracy using the CAOS enhanced instrumentation. Substantial improvement (8%-59%) in optimal resection was observed in the CAOS enhanced resections, compared to the conventional cases. Though based on conventional mechanical instrument and being streamlined compared to its matching “full-size” CAOS solution, the system studied was demonstrated to offer comparable accuracy and the same robustness to surgeon’s TKA experience level. The system may provide an uncomplicated solution to add the benefit of CAOS to the conventional instrumentation without major disruption in the surgical tools and workflow.

SIGNIFICANCE/CLINICAL RELEVANCE:

Study of a CAOS enhanced mechanical instrument system showed that regardless of surgeon’s experience, CAOS enhancement improved TKA alignment and increased optimal resections compared to conventional instrumentation.

Table 1. Comparison of occurrence in optimal alignment between CAOS enhanced and mechanical instrument only resections.

<table>
<thead>
<tr>
<th>Optimal Resection (&lt;2° Deviation)</th>
<th>Senior</th>
<th>Fellow</th>
<th>Resident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tibia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical Instrument</td>
<td>92% (11/12)</td>
<td>33% (4/12)</td>
<td>50% (6/12)</td>
</tr>
<tr>
<td>CAOS Enhanced</td>
<td>100% (12/12)</td>
<td>92% (11/12)</td>
<td>100% (12/12)</td>
</tr>
<tr>
<td>P</td>
<td>1.000</td>
<td>0.009</td>
<td>0.014</td>
</tr>
<tr>
<td>Femur</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical Instrument</td>
<td>42% (5/12)</td>
<td>67% (8/12)</td>
<td>58% (7/12)</td>
</tr>
<tr>
<td>CAOS Enhanced</td>
<td>100% (12/12)</td>
<td>100% (12/12)</td>
<td>100% (12/12)</td>
</tr>
<tr>
<td>P</td>
<td>0.005</td>
<td>0.093</td>
<td>0.037</td>
</tr>
</tbody>
</table>

REFERENCES

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) is 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, especially the most recently released 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\(^\circledR\) and Exactech Truliant\(^\circledR\).

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 point 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 between the two ethnicities. The bone data was then 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 were presented in Table 1. The majority of the differences were between male and female, but not so much 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, in between the two sizing offerings of Attune in median sizes, and matching Attune in large sizes.

<table>
<thead>
<tr>
<th>Measurement*</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>ML (mm)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>65.78 ± 3.11*</td>
</tr>
<tr>
<td>Male</td>
<td>73.84 ± 3.57*</td>
</tr>
<tr>
<td>AP (mm)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>53.51 ± 3.44*</td>
</tr>
<tr>
<td>Male</td>
<td>58.22 ± 3.27*</td>
</tr>
<tr>
<td>Aspect Ratio (ML/AP)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.23 ± 0.09*</td>
</tr>
<tr>
<td>Male</td>
<td>1.27 ± -0.07b</td>
</tr>
<tr>
<td>ML (mm)</td>
<td></td>
</tr>
<tr>
<td>Chinese Female</td>
<td>64.99 ± 2.51*</td>
</tr>
<tr>
<td>Chinese Male</td>
<td>72.58 ± 3.69*</td>
</tr>
<tr>
<td>Caucasian Female</td>
<td>66.57 ± 3.49*</td>
</tr>
<tr>
<td>Caucasian Male</td>
<td>75.10 ± 3.01b</td>
</tr>
<tr>
<td>AP (mm)</td>
<td></td>
</tr>
<tr>
<td>Chinese Female</td>
<td>53.34 ± 3.98*</td>
</tr>
<tr>
<td>Chinese Male</td>
<td>57.62 ± 3.47b</td>
</tr>
<tr>
<td>Caucasian Female</td>
<td>53.69 ± 2.89*</td>
</tr>
<tr>
<td>Caucasian Male</td>
<td>58.82 ± 3.00b</td>
</tr>
</tbody>
</table>

*Different alphabetic letters represent significantly different groups.

Table 1. Significant differences found between genders and ethnicities.
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


INTRODUCTION

In the modern era of total knee arthroplasty (TKA), the surgery has become more focused on comprehensive consideration of an individual’s bone and soft tissue characteristics. 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 3-4 mm is clinically important. In a 2010 study, Mahoney et al. reported that more than 3 mm 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 4 mm 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

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 57.9 mm 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 to 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 3 mm (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 3 mm), 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 incidences of the component extending externally beyond the resection bony profile were identified. The associated amount of mismatch between the component and bony resection was recorded. Clinically important overhang was determined if the component extended more than 3 mm beyond the bony profile.
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 (0.1 mm) of overhang over 3 mm at location 2 lateral.

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

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.

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.

<table>
<thead>
<tr>
<th>Incidence of Clinically Important Overhang</th>
<th>Chinese</th>
<th>Caucasian</th>
<th>Female</th>
<th>Male</th>
<th>pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>30</td>
<td>24</td>
<td>38</td>
<td>16</td>
<td>54</td>
</tr>
<tr>
<td>Number of bones with &gt;3 mm overhang</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

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.

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. The findings of this study showed excellent fit among medium to small sized knees studied in the dataset. Only one knee 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, 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, the Truliant femoral design did not demonstrate gender based differences in terms of clinically important overhang incidence.
CONCLUSION

In conclusion, computational assessment on 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


INTRODUCTION

Total knee arthroplasty (TKA) is a mature surgical procedure for the treatment of end stage 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. Among the complications related to TKA, patellofemoral pain and instability have been found to be one of the most common reasons for revision.

The causes of patellofemoral complications are multifactorial, including improper surgical technique (implant positioning and sizing, soft-tissue balancing, etc.) and limitations in implant design. 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.

The ability of the implant to restore native trochlear groove morphology may be determined by the design philosophy. Currently, there are several design philosophies in modern implant systems regarding the orientation of the trochlear groove. One design philosophy (Philosophy I) is employed by many device companies, in which they design 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).
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 (> 3 mm) in the deepest point across the entire curve set was detected, and the corresponding location was determined as the proximal border 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 then 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.

**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 height. 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 designed 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).
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). No gender- or ethnic-difference, or 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.).

DISCUSSION

The design of the femoral component trochlear compartment is one of the critical factors that affects patellofemoral outcome after TKA. 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

![Figure 4. Measurement of the allowed range of trochlear groove orientation on the Truliant design.](image)

![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).](table)

<table>
<thead>
<tr>
<th>Trochlear Groove Orientation (°)*</th>
<th>Mean ± Standard Deviation [95% range]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pooled</td>
<td>-1.4° ± 4.7° [-10.8°, 8.0°]</td>
</tr>
<tr>
<td>Female</td>
<td>-1.0° ± 4.8° [-10.6°, 8.6°]</td>
</tr>
<tr>
<td>Male</td>
<td>-1.8° ± 4.6° [-11.0°, 7.4°]</td>
</tr>
<tr>
<td>Chinese</td>
<td>-2.1° ± 3.9° [-9.9°, 5.7°]</td>
</tr>
<tr>
<td>Caucasian</td>
<td>-0.6° ± 5.3° [-11.2°, 10.0°]</td>
</tr>
</tbody>
</table>

![Figure 5. Trochlear groove orientation in the native femur, compared to five modern femoral implant designs.](image)

* Data on native femur was illustrated with average and the 55% range.
‡ Orientation angles referenced a published study [22].
§ Attune design has fixed trochlear groove angle proportionally changed by component size [Attune marketing brochure]. The bar illustrated the range of the fixed angles.
† Logic data was illustrated with the range of allowed groove orientation.
‡ Data on allowed range of trochlear groove angle not available.
that the trochlear groove is neutrally orientated in the intercondylar region, while it has a medial orientation in the proximal flange area. This reported non-linearity in the groove orientation is accommodated 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. This altered patellar tracking may pose an increased risk of patellofemoral complications postoperatively.

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

INTRODUCTION

Proper fit of the knee implant with the native morphology of the patients is critical to the success of total knee arthroplasty (TKA). In the femur, achieving this goal requires consideration of minimizing mediolateral (ML) overhang of the femoral implant as well as accurate alignment between the trochlear and the patella for proper patellofemoral kinematics. Both considerations can be influenced by the design of the femoral component. This study accessed the femoral component of a newly released knee design for ML fit and restoration of native trochlear groove at high flexion.

MATERIALS AND METHODS

CT based surface models of 48 Chinese (24M/24F) and 43 Caucasian (22M/21F) right femora was virtually resected according to its proper component size following anterior referencing surgical technique for Truliant® Knee System (Exactech Inc, Gainesville, FL, USA). A computer algorithm first placed and lateralized the femoral component such that it aligned with the bony resection at the anteroposterior (AP) mid-point of the distal cut. The ML fit of the component was then measured at the AP mid-point of the distal resection. The placement was further optimized by slightly adjusting the component ML to reduce the incidence of clinically important overhang (>3mm)

2,3 Significant difference was defined as p<0.05.

Figure 1. A representative femur demonstrating the measurement of mediolateral deviation between the component intercondylar notch and the corresponding deepest point on the native trochlear groove.

and minimized the ML deviation between the center of the component intercondylar notch and the deepest point on native trochlear groove at the same proximal-distal level as the component notch (Figure 1). The fit of the component was assessed by the incidence and severity of clinically important overhang based on the optimized placement, as well as the ML deviation between component and native intercondylar notch locations. A <5mm deviation was considered proper restoration of the notch by the femoral component.
**RESULTS**

Only one out of the 91 bones had component overhang of more than 3mm (Chinese, female), with the amount of overhang exceeding the clinically important threshold being clinically negligible (0.8mm) (Table 1A). The notch of the placed femoral component closely restored the native location, which was on average ~1mm medial to that of the femur across all ethnic and gender groups (Table 1B). 95% of the bones had the femoral component notch placed within 5mm ML of the native femoral intercondylar notch. No ethnic or gender difference was found in the deviation of notch location.

**DISCUSSION**

The findings demonstrated excellent femoral fit by the newly released Truliant® Knee System, which not only minimize the component overhang, but also restore the ML position of the native intercondylar notch in the femur. Without offering narrow components, this knee design was shown to provide equally good fit among both ethnic groups studied and both genders. Compared to the reported data on several femoral designs, the intercondylar notch in this design may offer less patella displacement at high flexion, potentially facilitating normal patella tracking.

**REFERENCES**


---

**Table 1. A) Incidence of >3mm overhang in the data set. B) Mediolateral deviation in the location of intercondylar notch between the placed femoral component and the native bone.**

<table>
<thead>
<tr>
<th></th>
<th>Chinese</th>
<th>Caucasian</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>48</td>
<td>43</td>
<td>45</td>
<td>46</td>
</tr>
<tr>
<td>Number of bones with &gt;3mm Overhang</td>
<td>1 (3.8mm)</td>
<td>0</td>
<td>1 (3.8mm)</td>
<td>0</td>
</tr>
</tbody>
</table>

*B* Negative values indicate that intercondylar notch in the femoral component is medial to the native notch.

**B**

<table>
<thead>
<tr>
<th></th>
<th>Deviation (mm)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pooled</td>
<td>-1.0 ± 1.6</td>
<td>—</td>
</tr>
<tr>
<td>Chinese</td>
<td>-1.3 ± 1.9</td>
<td>0.10</td>
</tr>
<tr>
<td>Caucasian</td>
<td>-0.7 ± 1.3</td>
<td>0.13</td>
</tr>
<tr>
<td>Female</td>
<td>-1.3 ± 1.9</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>-0.8 ± 1.3</td>
<td></td>
</tr>
</tbody>
</table>
Compromise in Patellar Component Placement: a Comparison Between Symmetric and Anatomic Patellar Designs

INTRODUCTION

Patellofemoral complications are among the most common causes of complaints and revisions following total knee arthroplasty (TKA). There are several critical considerations during patellar resurfacing, including patellofemoral tracking, thickness of the implanted patellar composite, component coverage of the bony resection and overhang of the component. The patella composite should have the thickness equivalent to that of the native bone to avoid disruption of the extensor mechanism, and good coverage of the resection surface is required for better load transfer in the patellar bone to reduce the incidence of fracture, soft tissue impingement and lateral facet syndrome. However, with symmetric round patellar design, a surgeon sometimes finds him/herself compromising composite thickness and bony coverage in order to avoid component overhang. Asymmetric patellar components offered by modern knee systems may offer improved component fit with less compromises. This study compared the incidence and severity of compromises between a symmetric round patellar design and a newly released anatomic patellar design in a multi-ethnic group of 100 subjects.

METHODS

After obtaining institutional review board approval and informed consent, CT based models of 50 Asian (25M/25F) and 50 Caucasian (25M/25F) right patellae were generated to evaluate the fit of a symmetric patellar design (Standard Patella components, Exactech Inc, Gainesville, FL, USA) and an anatomic patellar design with asymmetric facets (Advanced Patella components, Exactech Inc, Gainesville, FL, USA) (Figure1). A clinician validated computational algorithm was developed to resurface the patellae. First, a series of design-specific resections were created on the patella by removing the exact thickness corresponding to each component size (3-matic research, Materialise NV, Leuven, Belgium). In the cases that the remaining bone thickness was less than 12mm, the resection was made to maintain the 12mm bone stock. The proper resection level and its corresponding “ideal” component size was then determined on each patella for each design. During component placement, the “ideal” sized component was placed on the patellar resection. If more than 1mm overhang was observed, the next smaller component size will be trialed for the placement. The incidence and severity of downsizing, as well as compromise in bony coverage and thickness due to downsizing were compared between the two designs. Significance was defined as p<0.05.

RESULTS

Compared to the symmetric patellar design, the anatomic patellar design exhibited better component fit bone (Table 1) with lower incidence and severity of downsizing (Table 2 and Figure1). No gender- or ethnic- difference was found in the fit of both designs. Ideal sizes of the anatomic patellar component were implanted in 84% of the bones, avoiding the compromises in coverage and thickness. In contrast, only 37% of the bones

Table 1. Bony coverage and difference in patellar thickness between the native and implanted patella, presented in A) pooled and B) gender- and ethnic- specific values.

<table>
<thead>
<tr>
<th></th>
<th>Bony Coverage (%)</th>
<th>Thickness Difference (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong> Pooled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symmetric Design</td>
<td>80.5 ± 5.6</td>
<td>1.4 ± 1.2</td>
</tr>
<tr>
<td>Anatomic Design</td>
<td>84.1 ± 6.2</td>
<td>0.6 ± 1.2</td>
</tr>
<tr>
<td>P</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symmetric Design</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>80.7 ± 6.0</td>
<td>1.5 ± 1.2</td>
</tr>
<tr>
<td>Male</td>
<td>80.3 ± 5.2</td>
<td>1.3 ± 1.2</td>
</tr>
<tr>
<td>P</td>
<td>0.771</td>
<td>0.468</td>
</tr>
<tr>
<td>Asian</td>
<td>81.3 ± 6.3</td>
<td>1.6 ± 1.2</td>
</tr>
<tr>
<td>Caucasian</td>
<td>79.7 ± 4.8</td>
<td>1.3 ± 1.2</td>
</tr>
<tr>
<td>P</td>
<td>0.171</td>
<td>0.280</td>
</tr>
<tr>
<td>Anatomic Design</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>85.5 ± 5.3</td>
<td>0.8 ± 1.3</td>
</tr>
<tr>
<td>Male</td>
<td>83.0 ± 6.0</td>
<td>0.5 ± 1.0</td>
</tr>
<tr>
<td>P</td>
<td>0.053</td>
<td>0.232</td>
</tr>
<tr>
<td>Asian</td>
<td>84.5 ± 6.3</td>
<td>0.9 ± 1.3</td>
</tr>
<tr>
<td>Caucasian</td>
<td>83.8 ± 6.1</td>
<td>0.3 ± 0.9</td>
</tr>
<tr>
<td>P</td>
<td>0.542</td>
<td>0.010</td>
</tr>
</tbody>
</table>

*Positive value indicates that the native patella is thicker than the implanted patella.
were implanted with the ideal sizes for the symmetric design. The majority of the downsizing cases in the anatomic design (12/16) required components just one size smaller than the ideal size, while for the symmetric patellar implantations, a fair amount of cases required two sizes (23/63) or even three sizes (3/63) smaller. In the downsized cases, downsizing caused thinning of the patellar composite from native thickness by 2.1±0.9 mm and 2.4±0.9 mm for symmetric and anatomic designs, respectively. Even with downsizing, the coverage in the downsized anatomic design group (83.1±4.6%) was significantly higher compared to the symmetric design group (Table 2).

DISCUSSION

Avoiding over- or under-stuffing the patellofemoral joint is important in order to control the incidence of peripatellar crepitation, maintain the efficiency of the quadriceps tendon, and reduce the risk of patellar fracture. Furthermore, uncovered bony resection surface as a result of placing an undersized component increases the risk of soft tissue impingement and lateral facet syndrome. All these considerations stress the importance of patellar design for a proper component fit. The results from this study demonstrated that the anatomic design can offer significantly improved bony coverage compared to the symmetric round design, while providing a closer restoration of the native patellar thickness. Compared to the symmetric patellar design, the anatomic design significantly lowered the incidence and severity of compromising composite thickness and bone coverage due to downsizing the component during patellar implantation. Even in the downsized group, the coverage of the anatomic design was higher than the symmetric design. In conclusion, the anatomic patellar design greatly improved the component fit than the traditional symmetric design.

**Table 2. Summary of % case downsized, coverage and thickness difference in the symmetric and anatomic designs.**

<table>
<thead>
<tr>
<th>Downscaled Group</th>
<th>% Cases Downsized</th>
<th>Bony Coverage (%)</th>
<th>Thickness Difference (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symmetric Design</td>
<td>63%</td>
<td>80.0 ± 5.7</td>
<td>2.1 ± 0.9</td>
</tr>
<tr>
<td>Anatomic Design</td>
<td>16%</td>
<td>83.1 ± 4.6</td>
<td>2.4 ± 1.0</td>
</tr>
<tr>
<td><strong>P</strong></td>
<td>0.0000</td>
<td>0.048</td>
<td>0.238</td>
</tr>
</tbody>
</table>

*Positive value indicates that the native patella is thicker than the implanted patella.

**REFERENCES**


Logic PS Knee System
Mid-term Clinical Results

Westrich G, Muskat A
Hospital for Special Surgery/Cornell University Medical Center, New York City

INTRODUCTION
Total Knee Arthroplasty (TKA), is recognized as a proven and effective treatment option to relieve pain and restore joint function in arthritic knees. Exactech introduced the Optetrak Logic® PS Knee System in 2009 as an evolution to the Optetrak PS knee launched in 1994. Optetrak demonstrates excellent 94 to 98% 10-year survivorship and is implanted in patients around the world.\textsuperscript{1,2} The Optetrak Logic retained many of the features from the Optetrak PS knee with a few modifications to improve function and reduce additional bone loss for the patient.

The Optetrak Logic PS Knee System was designed to:
• Improve femoral rollback from 120° to 145°
• Improve femoral dislocation resistance
• Preserve 30% more natural bone during notch resection
  Optimized 0.96 congruency designed to reduce contact stresses, minimize wear and improve longevity of the device
• Proportional tibial trays to help reduce tibial bone loss

The Optetrak Logic knee system has been widely accepted in the medical community and continues the Optetrak legacy to positively impact patient pain relief, functional restoration, satisfaction, and quality of life.

This report summarizes the mid-term (average 5 year) outcomes of the Logic PS primary knee system from a single-center clinical study.

PATIENTS AND METHODS
From 2009 to 2011, 467 Logic PS TKAs were performed by the surgeon author (Table 1). At the time of this analysis, 23 patients are deceased and 70 patients were lost to follow up, which resulted in 374 knees available for reporting an average of 5-year outcomes (average 61 months; range 12-100 months).

Clinical data were collected prospectively following Institutional Review Board (IRB) approval. The outcome instruments collected included range of motion (ROM), the Knee Society Clinical Rating Scale (KSCRS), the University of California Los Angeles Activity Scale (UCLA), Pain Visual Analogue Scale (VAS), and the Veterans Rand 12 Item Health Survey (VR-12) for self-reported global health. Incidence of revision was identified and analyzed for the reason for revision. Survivorship analysis was performed.

<table>
<thead>
<tr>
<th>Patients</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of operated knees</td>
<td>467</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>70</td>
</tr>
<tr>
<td>Deceased</td>
<td>23</td>
</tr>
<tr>
<td>Knees available for analysis</td>
<td>374</td>
</tr>
<tr>
<td>Male/Female</td>
<td>135/239</td>
</tr>
<tr>
<td>Age (years), Mean (±SD)</td>
<td>67.0 (±9.0)</td>
</tr>
<tr>
<td>BMI, Mean (±SD)</td>
<td>31.0 (±9.9)</td>
</tr>
</tbody>
</table>
CLINICAL RESULTS

Summaries of ROM, KSCRS, UCLA, and VR-12 are provided in Table 2. An analysis was performed to cross-walk UCLA to the Lower Extremity Activity Scale (LEAS) which was adopted more recently and replaced the UCLA activity score in our institutional registry. Significant improvements in all clinical results were found postoperatively compared to the preoperative baseline (p values ≤ 0.001).

- High ROM was reported in the follow-up data (on average 121°, with more than 50% of the patients achieving greater than 120° and 14% beyond 130°.

Table 2. Summary of clinical data measured preoperatively and average 5-year follow-up.

<table>
<thead>
<tr>
<th></th>
<th>Pre-op Mean (± SD)</th>
<th>Post-op Mean (± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROM (°)</td>
<td>114 (±13)</td>
<td>121 (±9)</td>
</tr>
<tr>
<td>KSCRS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Function</td>
<td>42.7 (±23.8)</td>
<td>70.5 (±29.9)</td>
</tr>
<tr>
<td>Knee</td>
<td>42.7 (±6.9)</td>
<td>89.0 (±14.4)</td>
</tr>
<tr>
<td>Total</td>
<td>85.3 (±32.1)</td>
<td>160.3 (±39.5)</td>
</tr>
<tr>
<td>UCLA</td>
<td>4.8 (±2.2)</td>
<td>5.5 (±3.2)</td>
</tr>
<tr>
<td>LEAS†</td>
<td>9.0</td>
<td>10.5</td>
</tr>
<tr>
<td>Pain VAS</td>
<td>7.2 (±2.1)</td>
<td>2.6 (±1.3)</td>
</tr>
<tr>
<td>VR-12</td>
<td>31.5 (±8.4)</td>
<td>42.6 (±10.3)</td>
</tr>
</tbody>
</table>

†Average values are presented as the LEAS scores were based on the cross-walk from the average UCLA scores.

Abbreviations for instruments:
- KSCRS - Knee Society Clinical Rating System
- UCLA - University of California, Los Angeles Activity Scale
- LEAS - Lower Extremity Activity Scale
- Pain VAS - Pain Visual Analogue Scales
- VR-12 - Veterans Rand 12 Item Health Survey
CONCLUSION

This mid-term (5-year average follow-up) study reported excellent results for the Optetrak Logic PS Knee System.

- Good clinical outcomes with significant improvement in pain and function
- Excellent ROM, with more than half of the patients attaining over 120°
- Superior results in survivorship (99% excluding revision for infection and periprosthetic fracture)

The Optetrak Logic PS Knee System clearly maintains the proven results with the Optetrak system, with minor design changes to further improve patient and surgeon satisfaction.

### Table 2. Summary of clinical data measured preoperatively and average 5-year follow-up.

<table>
<thead>
<tr>
<th>Pre-op</th>
<th>Post-op</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROM (°)</td>
<td>114 (±13)</td>
</tr>
<tr>
<td>KSCRS Function</td>
<td>42.7 (±23.8)</td>
</tr>
<tr>
<td>KSCRS Knee</td>
<td>42.7 (±6.9)</td>
</tr>
<tr>
<td>KSCRS Total</td>
<td>85.3 (±32.1)</td>
</tr>
<tr>
<td>UCLA</td>
<td>4.8 (±2.2)</td>
</tr>
<tr>
<td>LEAS†</td>
<td>9.0</td>
</tr>
<tr>
<td>Pain VAS</td>
<td>7.2 (±2.1)</td>
</tr>
<tr>
<td>VR-12</td>
<td>31.5 (±8.4)</td>
</tr>
</tbody>
</table>

†Average values are presented as the LEAS scores were based on the cross-walk from the average UCLA scores.

**Abbreviations for instruments:**
- KSCRS - Knee Society Clinical Rating System
- UCLA - University of California, Los Angeles Activity Scale
- LEAS - Lower Extremity Activity Scale
- Pain VAS - Pain Visual Analogue Scales
- VR-12 - Veterans Rand 12 Item Health Survey

### SURVIVORSHIP

At an average 5-year follow up, 11 knees were revised for an overall revision rate of 2.9%, including three aseptic loosening cases associated with obesity (one patient was overweight and two patients were morbidly obese). The specific causes of the revisions were summarized in Table 3.

Kaplan-Meier analysis indicated an overall survivorship of 98% when accounting for all causes of revision at 5 years (Figure 2A). Excluding revision caused by infection or periprosthetic fracture that are unrelated to the implant, a survivorship of 99% was reported at 5 years (Figure 2B).

### Table 3. Summary of revision cases and causes.

<table>
<thead>
<tr>
<th>Revisions</th>
<th>% follow-up group (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All causes</td>
<td>2.9% (11)</td>
</tr>
<tr>
<td>Infection</td>
<td>1.1% (4)</td>
</tr>
<tr>
<td>Aseptic loosening*</td>
<td>0.9% (3)</td>
</tr>
<tr>
<td>Instability</td>
<td>0.5% (1)</td>
</tr>
<tr>
<td>Osteolysis</td>
<td>0.3% (1)</td>
</tr>
<tr>
<td>Periprosthetic fracture</td>
<td>0.3% (1)</td>
</tr>
<tr>
<td>Causes excluding infection and periprosthetic fracture</td>
<td>1.6% (6)</td>
</tr>
</tbody>
</table>

*All 3 patients were overweight and 2 suffered from morbid obesity.

**Figure 2. Survivorship analysis marked with 95% Confidence Interval.**

A. Kaplan-Meier curve showing implant survivor after TKA for all causes of revision

B. Kaplan-Meier curve showing implant survivor after TKA excluding infection and periprosthetic fracture.
CONCLUSION

This mid-term (5-year average follow-up) study reported excellent results for the Optetrak Logic PS Knee System.

- Good clinical outcomes with significant improvement in pain and function
- Excellent ROM, with more than half of the patients attaining over 120°
- Superior results in survivorship (99% excluding revision for infection and periprosthetic fracture)

The Optetrak Logic PS Knee System clearly maintains the proven results with the Optetrak system, with minor design changes to further improve patient and surgeon satisfaction.

REFERENCES


Dai Y1, Cui Q1, Bolognesi MP2, Wellman SS3, Seyler T3, Najmabadi Y1, Bolch C1, Liu D4

1 Exactech Inc., Gainesville, FL, 32653, USA
2 University of Virginia School of Medicine, Charlottesville, VA, USA
3 Duke Orthopaedics, Durham, NC, USA
4 The Gold Coast Centre for Bone and Joint Surgery, Queensland, Tugun, AU

ABSTRACT

This study investigated if CAOS TKA cases in higher risk patients would impact the perioperative outcomes of surgery. Intraoperative and recovery/discharge data on 70 patients (72 knees) from a multicenter, consecutive series were analyzed. The patients were grouped into challenging and standard case groups according to the criteria of age, BMI, and degree of deformity. Despite a general trend observed between the challenging and standard cases, the two groups did not exhibit significant differences in terms of surgical time, blood loss, recovery and time to discharge. The data demonstrated consistent perioperative results by CAOS TKA irrespective of patient conditions.

INTRODUCTION

Total knee arthroplasty (TKA) performed with computer-assisted orthopedic system (CAOS) has been proven to significantly improve implant alignment consistency compared to conventional instrumentation.1,2 Additionally, the benefits of CAOS TKA in the patients with extra-articular deformity has been published. However, most of these studies are case reports and single arm series focusing on alignment and short-term outcomes.3-5 Results of conventional instrumented TKA concluded factors such as advanced age, obesity, and coronal deformity increased the risk of longer surgical times and length of stay, poor function and early failure.6,7 These findings indicated that patient type or local condition of the knee may sometimes require special perioperative attention, which makes a challenging patient. To date, it remains unclear how perioperative outcomes are impacted by the challenging cases, as compared to the “standard” cases for CAOS TKA. This study analyzed a case series to investigate if there is a difference between challenging and standard cases in terms of perioperative outcomes, specifically in surgical time, blood loss, hospital recovery and discharge.

MATERIALS AND METHODS

With institutional review board-approval and patient’s signed informed consent, a multicentre, consecutive case series study was conducted by 5 surgeons in a total of 70 patients (72 knees). All cases were primary TKA using the Optetrak Logic Knee System (Exactech Inc, Gainesville, FL, USA) with the assistance of a contemporary CAOS system (ExactechGPS, Blue-Ortho, Gieres, FR). The two bilateral patients in this series had their knees operated separately with at least 90 days apart.

“Challenging” cases were defined from the series as having one or more of the following conditions: 1) age greater than 80 years, 2) BMI greater than 35, 3) coronal deformity greater than 15°, and 4) range of flexion (ROM) less than 90°. Perioperative outcomes were compared between the standard and challenging case groups. Specific outcomes assessed were: surgical time, intraoperative blood loss, haemoglobin change (preoperative – postoperative), days to initial ambulation, hospital length of stay, and discharge destination. Statistical significance was defined as p < 0.05.

RESULTS

Twenty-six knees were identified as challenging cases, whereas the remaining forty-six were grouped as standard cases (Table 1). The challenging case group consisted of more female patients, had a higher BMI, and more comorbidities compared to the standard group. A summary of perioperative outcomes in the standard and challenging case groups is presented in Table 2. The challenging cases tended to have more intraoperative blood loss (by 24 ml) and a lower discharge to home rate (by 9%) than the standard cases. Compared to the standard cases, a higher
variability (standard deviation) was associated with the challenging cases in both intraoperative blood loss and haemoglobin change. The challenging cases tended to require a slightly longer surgical time (by 7 min) than the standard cases. Despite the general trends found between challenging and standard cases, none of the differences were statistically significant. No blood transfusion or implant related early complications were reported in either group by the time of discharge.

**DISCUSSION**

With a previous study proving consistent accuracy using CAOS in TKA performed by surgeons of varying experience levels\(^9\), this investigation sought to investigate the sensitivity of the perioperative outcomes of CAOS TKA to patient conditions. Although the conditions used to determine challenging cases in this study (age, BMI, deformity) have been shown by previous clinical investigations to impact conventional TKA results\(^6-9\), the present data did not suggest inferior perioperative outcomes in the challenging cases compared to the standard cases using CAOS. This may be due to the benefits of CAOS facilitating intraoperative surgical guidance to help the surgeon mitigate surgical challenges and uncertainties while operating on the challenging patients, as well as avoiding intramedullary instrumentation. Like previous case studies and clinical series that have proposed the benefits of CAOS in TKA cases with severe coronal deformity\(^3-5\), this study highlights the advantages CAOS TKA may offer in demanding cases where patient or joint factors increase the surgical challenges.

**REFERENCES**


ABSTRACT
This study investigated if CAOS TKA cases complicated by challenging patient conditions would negatively impact the perioperative outcomes of surgery. Early outcome data on 51 TKA’s from a multicenter, consecutive series were analyzed. The patients were separated into challenging and standard case groups according to the criteria of age, BMI, and severity of deformity. The two groups did not exhibit significant differences in any of the early outcomes. Our study demonstrates consistent early results using CAOS TKA irrespective of patient conditions.

INTRODUCTION
Total knee arthroplasty (TKA) is a largely successful surgical treatment for end-stage osteoarthritis. However, it has been shown that some challenging conditions, such as advanced age, obesity, and severe deformity or stiffness can increase surgical time and length of stay, as well as the risk of inferior function and early failure for conventional TKA.1-4 These findings indicate that the type of patient or local condition of the knee may sometimes challenge the results of the surgery.

Computer-assisted orthopedic system (CAOS) TKA has been introduced as an advanced surgical tool intended to provide intraoperative guidance that may mitigate the impact of these challenges, potentially making the surgery particularly beneficial for the “challenging” case. Multiple studies on CAOS TKA concluded that it offers significant advantages in both intraoperative outcomes and implant alignment.5-7 However, limited data is available assessing the outcomes of challenging patient conditions as compared to “standard” TKA cases. Current available reports on challenging CAOS TKA outcomes have mainly focused on the impact of coronal extra-articular deformity.8-10

The goal of this study was to investigate if CAOS TKA also exhibits differences between challenging and standard cases in terms of the early outcomes, similar to those observed with conventional TKA.

MATERIALS AND METHODS
With institutional review board-approval and patient’s signed informed consent, a multicentre, consecutive case series study was conducted by 5 surgeons in a total of 51 patients (51 knees). All cases were primary TKA using the Optetrak Logic® Knee System (Exactech Inc, Gainesville, FL, USA) with the assistance of a contemporary CAOS system (ExactechGPS®, Blue-Ortho, Gieres, FR).

“Challenging” cases were identified from the series with one or more of the following conditions: 1) age greater than 80 years, 2) BMI greater than 35, 3) coronal deformity greater than 15°, and 4) range of flexion (ROM) less than 90°. The remaining cases were grouped as “standard” cases. Early outcomes from the 6-month postoperative visit were compared between the standard and challenging case groups. Patients were assessed for: Range of Motion (ROM), the Hospital for Special Surgery Knee Score (HSS), the 2011 Knee Society Score (KSS), and the Knee Injury and Osteoarthritis Outcome Score (KOOS). In addition, patient satisfaction in Visual Analog Scale (VAS, 1 to 10 with 10 indicates highest satisfaction) at 6-month postoperatively and implant related complications were reviewed. Statistical significance was defined as p < 0.05.

RESULTS
Nineteen patients were identified as challenging cases, whereas the remaining thirty-two patients were grouped as standard cases (Table 1). A summary of 6-month outcomes in the standard and challenging groups is presented in Table 2. The challenging patients were found to have approximately 9° less flexion compared to the standard patients. A general trend was observed that the challenging cases tended to gain more improvement in outcome scores (Table 2), though the differences in improvement were statistically insignificant between the two groups. All the gains in clinical scores in both groups were well above the Minimal Clinically Important Difference (MCID), suggesting significant improvement in the condition of these patients in both groups after TKA. Similarly, no statistical difference was found in the 6-month outcome scores and patient satisfaction VAS between the groups. No implant related early complications were reported in this series.
REFERENCES


