



SCIENTIFIC & CLINICAL EVIDENCE

A collection of published data on the Truliant® Total Knee System

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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.

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Surgeon Experience in the Adoption of a CAOS Enhanced Total Knee Arthroplasty: A Global, Multi-Surgeon Evaluation

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INTRODUCTION

Limited studies have systematically assessed surgeons' experience while adopting a new surgical technology. While existing investigations often rely on surgical time and patient outcomes in the initial series as surrogate measurements, a focus on the operating room (OR) is also needed as it is a multifaceted environment that exposes surgeons to considerable stress-inducing conditions that may impact their performance¹. This situation is particularly magnified during the learning of a new technology.

Recently, a novel system has been introduced to enhance conventional mechanical instruments with computer assisted orthopaedic surgery (CAOS) without requiring significant instrument learning. This study aimed at measuring surgeons' OR experience under clinical setting during early adoption of the technology.

METHODS

The CAOS enhanced technology was introduced to 13 experienced conventional surgeons from 3 countries. None of the surgeons had used the technology previously. Each surgeon performed primary TKAs following their usual techniques except for the addition of CAOS guidance to the conventional instruments. After every case, each surgeon independently completed a survey on his/her experience in tibial and femoral



perpetration regarding: *Over all ease of use, Speed of Landmark Acquisition, Guided Resection Parameter Adjustment Range, Ease of Guided Resection Adjustments, Stability of Cutting Blocks, and Integration with Existing Surgical Process*. Each category was graded in 6 levels: "excellent"/"very good"/"good"/"neutral"/"poor"/"very poor".

RESULTS

A total of 66 TKA cases were performed by the 13 surgeons using CAOS enhanced conventional instrumentation. The number of cases performed by each surgeon ranged from 1 to 12. High levels of surgeons' rating were shown in the summary of grading results, with over 92% of the total case experiences being "good" or better in all categories for the bony preparations of both femur and tibia (Figure 1). More than 35% of the case experiences were reported as "excellent" in any given category. The top two surgeon experiences were "*Speed of Landmark Acquisition*" and "*Integration with Existing Surgical Process*" among all categories, with more than 50% of the case experiences as "excellent" (Figure 2), and over 95% with "good", "very good", or "excellent" (Figure 1).

DISCUSSION

The study demonstrated high levels of surgeons' experience during the introduction of CAOS guidance to the conventional instruments. The two top-rated categories reflected the advantages of the technology that minimizes the extension of surgical time introduced by landmark acquisition and avoids disruption of the existing surgical process.

When it comes to embracing a new surgical technology, it is unquestionably important to assess the objective measures of

the impact on operating room efficiency and patients' outcomes. However, the field of surgery has been slow to acknowledge the impact of surgeons' experiences on intraoperative stress, complexity, and physical demands on surgical performance¹, especially with the introduction of an advanced surgical technology specifically developed to address the learning hurdle. The studied technology demonstrated an easy to adopt solution for adding the proven benefit of CAOS to conventional surgeries without being a stress or demanding point for the surgeons.

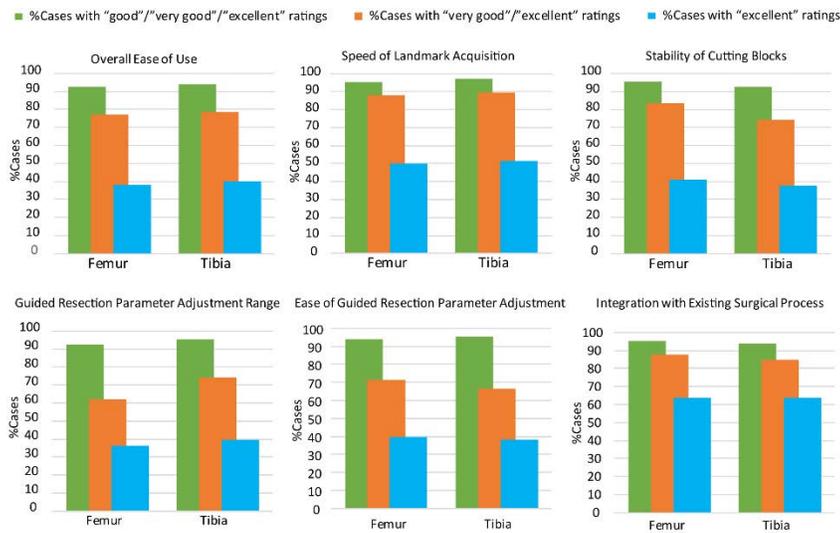


Figure 1. Percentage of cases in each experience category surveyed from the 13 surgeons.

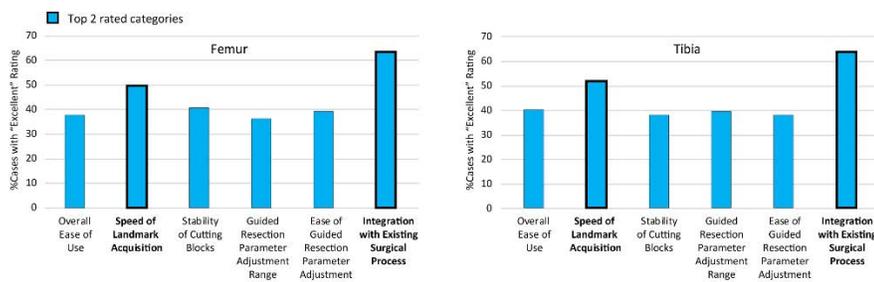


Figure 2. Comparison of "excellent" ratings in femoral and tibial categories, with the two highest rated categories highlighted.

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

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INTRODUCTION

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

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 (p_0), unacceptable failure rate (p_1), type I error rate (α), and type II error rate (β). From the parameters, two decision limits (h_0 and h_1) 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 CUSUM line crossing the lower decision limit (h_0), indicating completion of the learning period (met the acceptable failure rate). Conversely, the CUSUM line crossing upper decision limit (h_1) from below indicated the failure of the learning process (reaching an unacceptable failure rate).

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

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

CUSUM Variables	Description	Value	CUSUM Calculations	Formulae
p0	Acceptable failure rate	0.05	P	$\ln(p1/p0)$
p1	Unacceptable failure rate	0.30	Q	$\ln\{(1-p0)/(1-p1)\}$
α	Probability of type I error	0.05	s	$Q/(P + Q)$
β	Probability of type II error	0.20	a	$\ln[(1-β)/α]$
			b	$\ln[(1-α)/β]$
			h0	$-b/(P + Q)$
			h1	$a/(P + Q)$

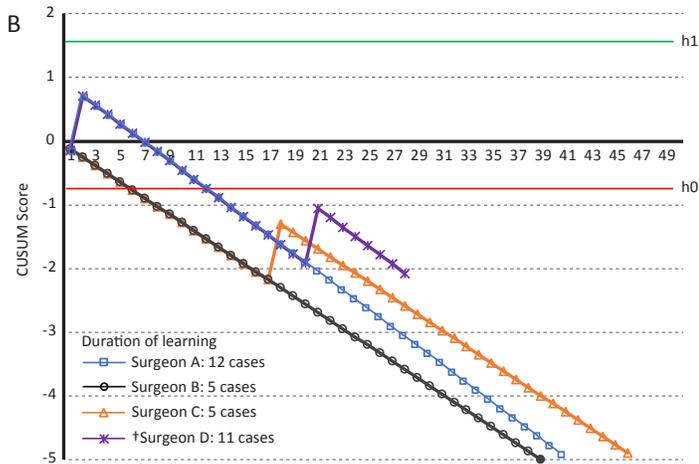


Figure 1. A) CUSUM parameters used for the analysis. B) CUSUM chart for the learning curves from individual surgeon, marked with his/her duration of learning (#cases).

*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.

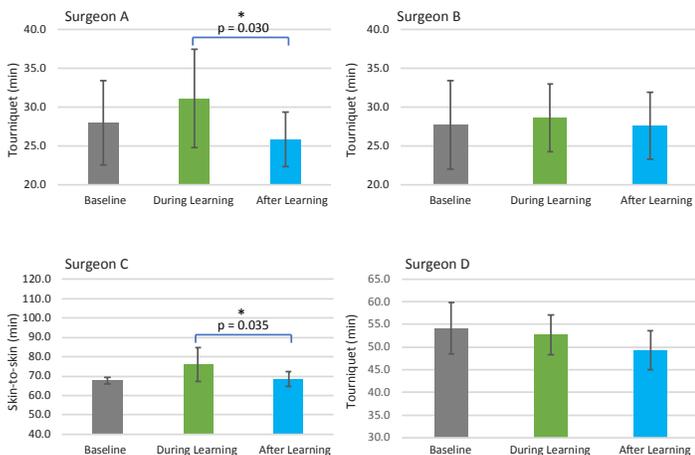


Figure 2. Comparison between baseline, during learning, and after learning in each of the four surgeons.

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.

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Design Modifications of Knee System Establish Early Learning Curve and Reduce Anterior Knee Pain: CUSUM Analysis

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INTRODUCTION

Assessing a learning curve acts as an appropriate way to compare a newly developed total knee replacement (TKA) system with the legacy knee system. Cumulate summation (CUSUM) was developed to monitor an individual's performance against a target success rate and determine if competency can be achieved. The purpose of this study was to i) use CUSUM to evaluate the learning curve of a new TKA system and ii) look at the impact of design modifications on anterior knee pain at a six-week follow-up period.

METHODS

A retrospective review was performed for a single, non-designer, orthopedic surgeon on his first 15 consecutive cases since the adoption of a new TKA system, as well as the last 30 cases using the legacy TKA system, performed before the adoption of the new TKA system (baseline). Tourniquet time, age, BMI, and gender were evaluated in each of the cohorts. CUSUM analysis was performed on the tourniquet time to identify the surgeon's learning period (number of cases) with the new instrumentation. The criteria, variables, and calculation formulae for CUSUM analysis were defined in Table 1. Tourniquet time in the baseline, during learning period, and after learning (cases #6-#15) were compared. We also performed comparison between the new and legacy TKA systems regarding anterior knee pain. Significance was defined as $p < 0.05$.

RESULTS

There were no significant demographic differences including BMI, age, and gender breakdown between the new TKA system and the legacy TKA system. CUSUM analysis showed learning of the new TKA system was achieved after the 5th case (Figure 1). No significant time increase was observed both during learning and after learning compared to the baseline (Figure 2). In addition, the standard deviation was reduced after the learning phase (cases#6-#15) compared to the current TKA system. Incorporating patellofemoral design improvements demonstrated a significant reduction in anterior knee pain with the new system compared to the legacy system (1.41 vs. 1.79, $p = 0.0045$).

DISCUSSION

Utilizing tourniquet time as a marker for operating room efficiency, an advanced learning curve analysis (CUSUM) demonstrated stabilization and proficiency after only 5 cases with the new TKA system compared to the legacy system. At six-week follow-up, the TKA cases performed using the new knee system exhibited the same level of outcomes as the clinically proven legacy system, with lower anterior knee pain. Compared to the legacy system, the new knee system offers an instrument system that employs multi-sensory feedback for a more intuitive surgical technique.

A

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

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

B

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

C

CUSUM Calculations	Formulae
P	$\ln(p1/p0)$
Q	$\ln[(1-p0)/(1-p1)]$
s	$Q/(P + Q)$
a	$\ln[(1-\beta)/\alpha]$
b	$\ln[(1-\alpha)/\beta]$
h0	$-b/(P + Q)$
h1	$a/(P + Q)$

- s: Reward (subtract from CUSUM score) when a success happened
- 1-s: Penalty (add to CUSUM score) when a failure happened
- h0: Lower decision limit, crossing indicates the user had a successful learning experience
- h1: Upper decision limit, crossing indicates the user had a failed learning experience

Table 1. A) CUSUM criteria, B) variables defined for this study, and C) calculation formulae.

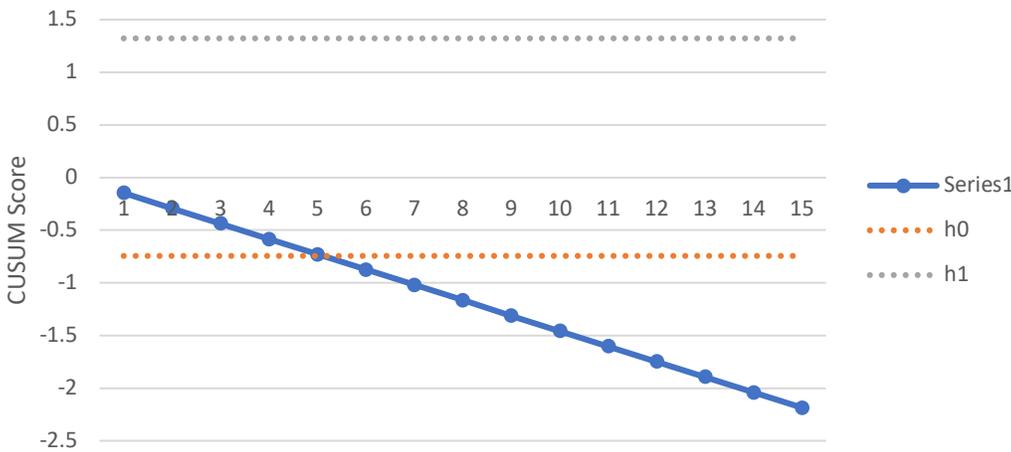


Figure 1. Learning curve plot.

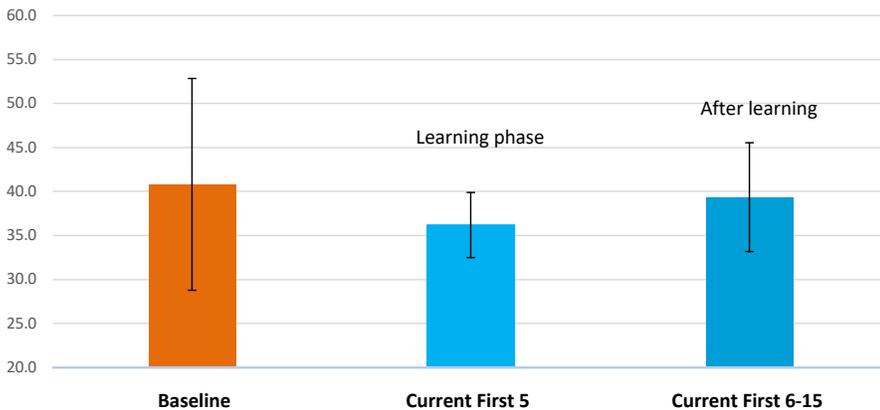


Figure 2. Tourniquet time comparison between New TKA system and Legacy TKA system.

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

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INTRODUCTION

Computer-assisted orthopaedic surgery (CAOS) has been shown to offer improved accuracy to total knee arthroplasty (TKA) compared to 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,² specifically: The CUSUM score of the first case was the difference between the time of the first case and the mean surgical time. The CUSUM score of



the second cases was the previous case's CUSUM score plus the difference between the surgical time of the second case and the mean surgical time. This recursive process continued until the last case, which was calculated as 0. CUSUM score was plotted in chronological order for each surgeon. A horizontal trend in the plot signified the 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 (Figure 1). 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

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

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

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

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

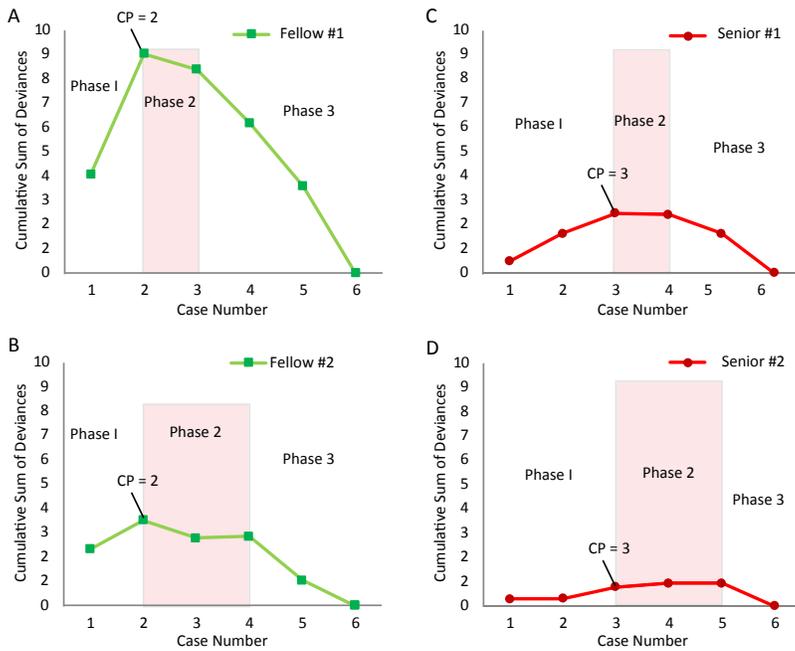


Figure 1. Graphs on the CUSUM deviance charts for A) senior surgeon #1, B) senior surgeon #2, C) fellow surgeon #1, and D) fellow surgeon #2. The fellow surgeons exhibited a steeper learning curve compared to the senior surgeons. The graph was plotted according to the chronological case numbers.

surgeons demonstrated slightly steeper learning curve by adding 3-4 minutes more to their learning cases (Figure1,2). 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 (Figure2B).

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.

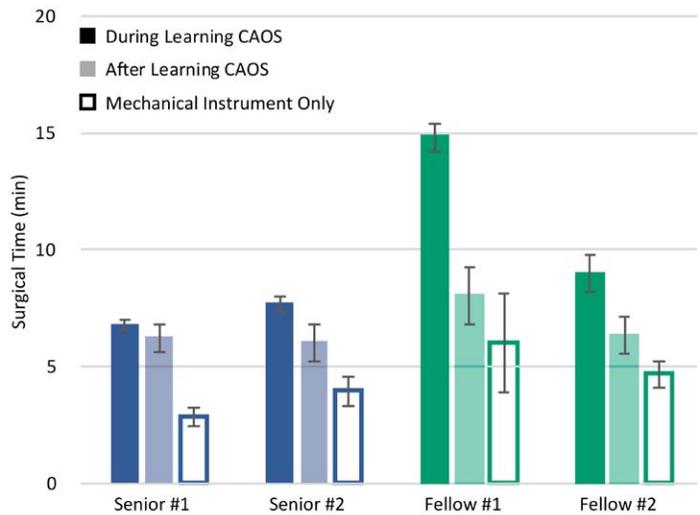


Figure 2. Comparison of surgical time between during learning CAOS enhancement, after learning CAOS enhancement, and mechanical instrumentation only case groups in each individual surgeon. Due to limited cases number per surgeon, statistical assessment of the differences was not performed.

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Advanced Analysis on Learning Curve of Computer-Assisted Total Knee Arthroplasty

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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 of all 50 cases. The CUSUM score of the second case was the previous case's CUSUM score plus the difference between the surgical



time of the second 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 (Figure 1B,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.

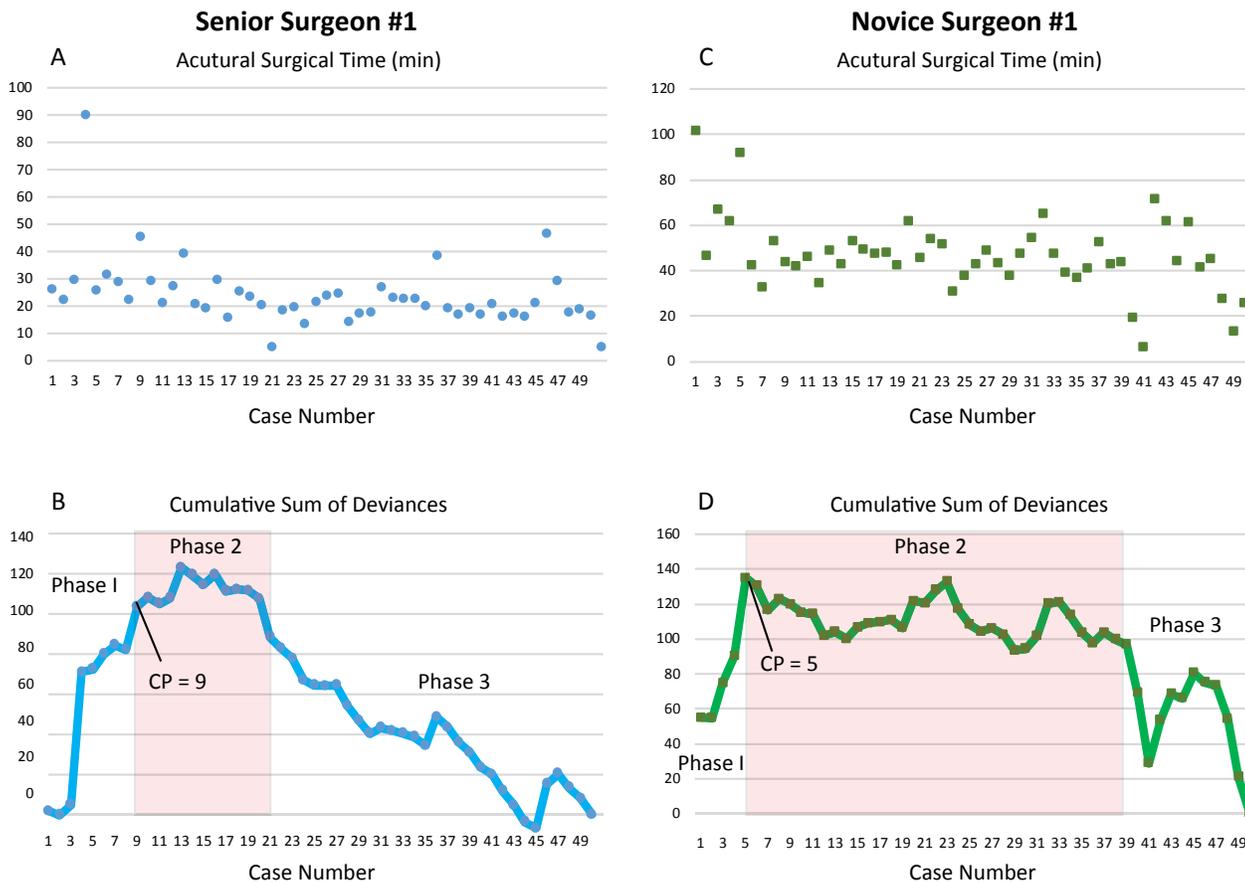


Figure 1. Graphs on the actual surgeon time and CUSUM deviance charts for A, B) a representative senior CAOS surgeon, and C, D) a representative novice surgeon. The graph was plotted according to the chronological case numbers.

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.

	Senior Surgeon	Novice Surgeon	Pooled
N	7	3	10
Cases to Proficiency (CP)	13.0 ± 7.1	12.0 ± 7.5	13.4 ± 7.4
Time Increase in Learning Curve (min)*	13.0 ± 8.6	16.2 ± 14.6	13.3 ± 10.7

* Calculated as $Average(cases \#1 - \#CP) - Average(cases \#41-50)$

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.

SIGNIFICANCE/CLINICAL RELEVANCE

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

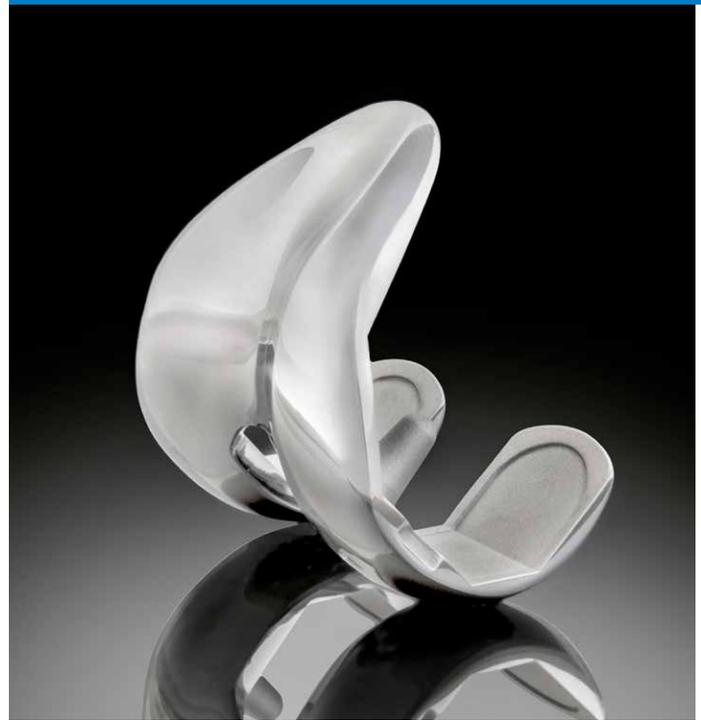
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Clinical Outcomes and Patient Satisfaction of a New Total Knee Design: A Follow-Up of the Early Series

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INTRODUCTION

Total knee arthroplasty (TKA) is a widely accepted, clinically proven treatment for advanced knee arthritis. With device manufacturers continuously re-designing and developing new implants to advance the procedure, a new TKA design should demonstrate improvement in patient outcomes. The purpose of this study is to compare the early clinical results of a newly designed TKA system to a predicate design with a successful clinical history by the same manufacture.

METHODS

Following IRB approval and patient's consent, two consecutive series of primary cruciate-retaining TKA were performed by the senior surgeon. The first series, the predicate control cohort, included TKA implanted with the standard predicate knee design from Dec 2011 to Jun 2017 and had a minimum of 2-year follow-up. The second series included all cases implanted with the new design from Jun 2017 to Mar 2018, and all these cases had a minimum 1-year follow-up. The latest available follow-up data from the new design cohort was used for analysis. Similar follow-up visit timepoints were extracted from the predicate cohort.

Comparisons were performed between the two implant designs for patient demographics, preoperative baseline, and postoperative outcomes. The specific clinical instruments assessed were range of motion (ROM), Knee Society Score (KSS: knee, function, and pain), Hospital for Special Surgery Knee Score (HSS), Oxford Knee Score (OKS), and patient satisfaction VAS (1-10 scale). Statistical significance was defined as $p < 0.05$.

RESULTS

138 and 207 patients received the new TKA design and the predicate design, respectively. 110 patients with the new design and 148 with the predicate design were available for data analysis. Subjects in the new design group were significantly younger, had a greater male/female ratio, and higher BMI (Table 1). However, no significant differences were found between the two groups in preoperative baseline measures. Postoperatively, subjects in the new design group demonstrated significantly higher KSS Knee and HSS scores, and greater ROM compared to the predicate design (Table 2). Both designs achieved significant improvement from their preoperative baseline status and high satisfaction rates (Table 3). At the latest follow-up, 5 patients (2 infection, 1 pain, 2 instability, 1 patellar subluxation) in the predicate group and 2 subjects (1 stiffness, 1 infection) in the new design group were revised.

DISCUSSION

The study demonstrated high satisfaction rates and improved early clinical results for the new knee design by revealing several significant differences between the new and predicate TKA implant designs, including ROM, KSS Knee and HSS scores and patient satisfaction.

Compared to the predicate system, the new TKA design provides improved clinical outcomes in the short term. With these promising initial clinical data, longer term follow-up with multiple surgeons will determine if these results continue to improve over time.

Analyzed Cohort	Predicate	New	P
Age (yr)	66.2 ± 9.6	61.9 ± 9.4	0.003
BMI	33.7 ± 7.5	36.2 ± 8.4	0.041
N Male/Female	42/106	29/36	0.027

Table 1. Patient demographics of the study cohort.

	Predicate	New	P
KSS Knee	84.9 ± 20.8	90.0 ± 1.1	0.021
KSS Function	72.4 ± 23.1	75.9 ± 25.0	0.338
KSS Pain	42.1 ± 10.7	41.6 ± 12.2	0.776
HSS	80.0 ± 19.5	85.1 ± 10.8	0.016
OKS	39.5 ± 7.9	40.1 ± 8.6	0.632
ROM	113.7 ± 13.2	117.8 ± 12.6	0.033
Satisfaction VAS	9.1 ± 1.6	9.2 ± 1.3	0.632

Table 2. Comparison between the new and predicate knee designs in postoperative outcomes.

Design	Preop	Postop
Predicate		
KSS Knee	53.7 ± 12.5	84.9 ± 20.8
KSS Function	45.5 ± 16.6	72.4 ± 23.1
KSS Pain	12.4 ± 9.7	42.1 ± 10.7
HSS	53.9 ± 11.4	80.0 ± 19.5
OKS	16.9 ± 8.9	39.5 ± 7.9
ROM	103.8 ± 19.9	113.7 ± 13.2
New		
KSS Knee	53.5 ± 12.4	90.0 ± 11.1
KSS Function	47.2 ± 23.4	75.9 ± 25.0
KSS Pain	10.7 ± 10.2	41.6 ± 12.2
HSS	54.4 ± 13.9	85.1 ± 10.8
OKS	17.8 ± 8.7	40.1 ± 8.6
ROM	109.1 ± 18.3	117.8 ± 12.6

Table 3. Summary of the preoperative baseline and postoperative outcomes in the predicate and new design cohorts. Significant improvements were achieved in all clinical measurements (p values < 0.01).

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Do Men and Women Benefit Equally From Total Knee Arthroplasty?

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INTRODUCTION

Gender differences in morphology related to total knee arthroplasty (TKA) have been well demonstrated. Studies have recognized that women tend to have a smaller, narrower mediolateral width with any given anteroposterior dimension, and a greater Q-angle than men.^{1,2} Implants have been designed to accommodate these differences, such as offering multiple aspect ratios (i.e. "standard" and "narrow") and trochlear groove angles in the femoral component. In contrast, some implant systems offer a single femoral aspect ratio varied by implant size and a neutral groove orientation with a widened proximal trochlear compartment. The mono-aspect ratio design has been shown in previous computational studies to provide equivalently good fit between genders. The purpose of this study was to determine if the mono-aspect ratio femoral design affects the short term clinical outcomes differently between males and females.

METHODS

Following IRB approval and patient's consent, a consecutive series of primary TKAs performed by three board-certified orthopaedic surgeons between September 2010 and June 2017 were studied prospectively. All cases were implanted using a knee system with mono-aspect ratio and widened neutral trochlear groove in the femoral implant design. Cases with at least 12-month follow-up were included with the latest available follow-up data used for analysis. Comparisons were performed between genders for range of motion (ROM), Knee Society Score (KSS: knee, function, and pain), Oxford Knee Score (OKS), and patient satisfaction VAS. Statistical significance was defined as $p < 0.05$.



RESULTS

458 TKA were available for analysis, including 245 female knees (196 patients) and 174 male knees (129 patients) (Table 1A). Patients from both genders were similar in age, with female patients having a slightly higher BMI (by 1.6) than the male patients. Female patients exhibited lower preoperative baseline KSS Function, OKS, and ROM (Table 1B). Mean follow-up was 3 years for all patients. Both genders achieved significant postoperative improvements in KSS and OKS, as well as ROM (Table 2). No significance was found between the two genders regarding postoperative improvement (Table 3). Both genders achieved satisfaction scores greater than 9 (out of 10), with 9.1 and 9.2 for female and male knees, respectively. Four female knees and seven male knees underwent revision surgery, due to infection.

DISCUSSION

This study demonstrated that a TKA system with mono-aspect ratio femoral design and widened neutral femoral groove provides equal benefits in male and female knees. The results exhibited significant postoperative improvement in KSS, OKS and ROM in both genders, with no significant differences between the two groups. Although gender-specific designs may improve the overall implant fit, no clinical advantage was found in this study or in previously published studies.³⁻⁴ The need for gender-specific implants does not appear to be necessarily for patients of either gender to benefit from TKA.

A

	Female (N)	Male (N)
Enrolled	269	189
Deceased	2	0
Lost to Followup	9	5
Revised	4	7
Withdrawn	9	3
12-month+ Follow-up	245	174
Analyzed	245	174

B

Analyzed Cohort	Female	Male	P
Age (yr)	63.1 ± 8.7	63.1 ± 8.2	0.95
BMI	35.2 ± 7.2	33.6 ± 6.2	0.02
Follow-Up Period (yr)	3.1 ± 1.8	3.1 ± 1.8	0.96

Table 1. A) Detailed breakdown, and B) patient demographics of the study cohort.

	Preop	Postop
Female		
KSS Knee	46.0 ± 11.9	91.0 ± 11.2
KSS Function	45.7 ± 13.7	78.8 ± 20.0
KSS Pain	6.2 ± 9.0	43.8 ± 11.2
OKS	15.3 ± 5.7	42.2 ± 6.9
ROM	107.0 ± 13.5	118.1 ± 11.9
Male		
KSS Knee	47.0 ± 12.9	91.9 ± 12.2
KSS Function	51.3 ± 9.3	87.1 ± 17.6
KSS Pain	6.8 ± 9.7	45.3 ± 9.8
OKS	17.5 ± 5.6	43.2 ± 7.0
ROM	110.5 ± 15.9	121.4 ± 8.5

Table 2. Summary of the preoperative baseline and postoperative outcomes in female and male cohorts. Significant improvements were achieved in all clinical scores (p values < 0.01).

Improvement	Female	Male	P
KSS Knee	45.9 ± 17.9	45.6 ± 18.5	0.87
KSS Function	33.2 ± 22.0	35.8 ± 17.6	0.18
KSS Pain	37.9 ± 15.9	38.4 ± 14.5	0.71
OKS	27.2 ± 8.9	25.9 ± 9.1	0.15
ROM	11.0 ± 15.6	10.6 ± 16.0	0.77

Table 3. Postoperative improvement from preoperative baseline.

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Logic PS Knee System Mid-term Clinical Results

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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.^{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
- Have 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.

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.

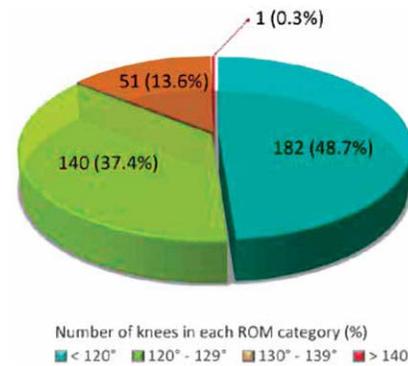


Figure 1. Distribution of ROM outcome at average 5-year follow-up.

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)³ 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°).

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).

Patients	
Number of operated knees	467
Lost to follow-up	70
Deceased	23
Knees available for analysis	374
Male/Female	135/239
Age (years), Mean (\pm SD)	67.0 (\pm 9.0)
BMI, Mean (\pm SD)	31.0 (\pm 9.9)

Table 1. Summary of patients.

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.

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

†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

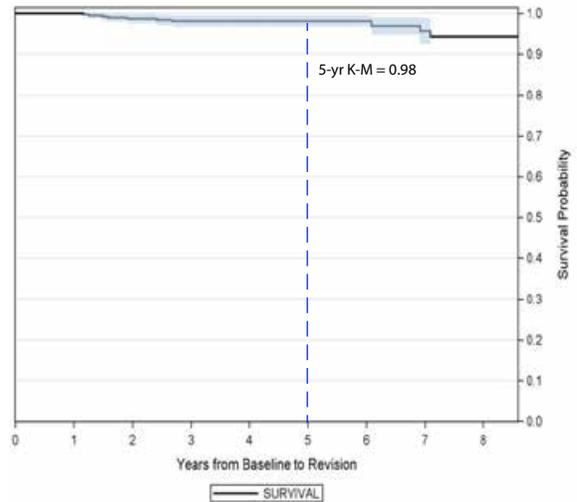
Table 2. Summary of clinical data measured preoperatively and average 5-year follow-up.

Revisions	% follow-up group (N)
All causes	2.9% (11)
Infection	1.1% (4)
Aseptic loosening*	0.8% (3)
Instability	0.5% (1)
Osteolysis	0.3% (1)
Periprosthetic fracture	0.3% (1)
Causes excluding infection and periprosthetic fracture	1.6% (6)

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

Table 3. Summary of revision cases and causes.

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.

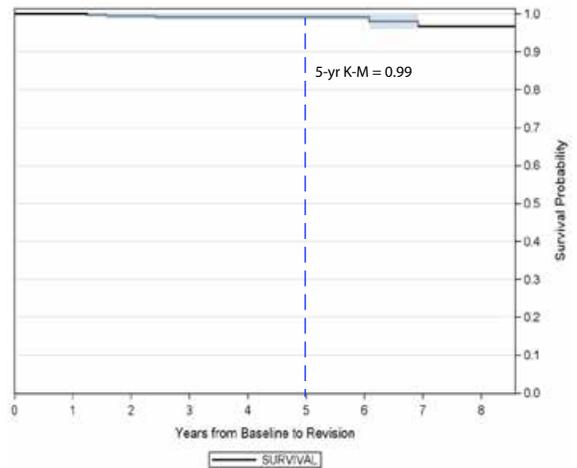


Figure 2. Survivorship analysis marked with 95% Confidence Interval for A) all causes of revision and B) causes excluded infection and periprosthetic fracture.

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Design modifications of Posterior Stabilized Knee System May Reduce Anterior Knee Pain and Reduce Complications following Total Knee Replacement at Minimum 2 Years Follow-Up

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INTRODUCTION

To extend the lineage of a predicate posterior stabilized (PS) knee system, a newer knee system was developed for improved femoral rollback, greater femoral dislocation resistance, minimized wear and extended longevity. In this study, the authors sought to confirm the effect of the design modifications by comparing the clinical results of the current knee system to the predicate knee system, specifically in patient reported outcomes, revision rate, and manipulation rate.

METHODS

Prospective clinical data was collected on PSTKAs performed between January 2000 and January 2018 by one senior surgeon using the predicate knee system and the updated current knee system. Outcomes were compared between the two knee systems at the latest follow-up time for range of motion (ROM), University of California Los Angeles Activity Scale (UCLA), Visual Analogue Pain Scales (Pain VAS), Veterans Rand 12 Item Health Survey (VR-12), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). In addition, we assessed revision rate, and manipulation rate, between the two knee systems. Statistical significance was defined as $p < 0.05$.

RESULTS

There were 1,482 knees in the current knee cohort and 445 knees in the predicate knee cohort. There were no significant demographic differences between groups in regards to BMI, age, gender, and follow-up. Pain VAS was significantly less in the current knee group compared to predicate group (1.72 vs. 2.75, $p < 0.001$). There was also a significant reduction in anterior knee pain favoring the current knee cohort (5.6%) vs. the predicate knee cohort (11.8%) ($p < 0.001$). In addition, manipulation rate showed differences between the current and predicate knee groups, 3.2% vs. 11.9%, respectively ($p < 0.001$) (Table 1). The reason for revision showed aseptic loosening to be highest in both cases, favoring the current knee system (.9% vs. 1.3%, Table 2).

DISCUSSION

Compared to the predicate knee system, the current knee system showed favorable clinical outcomes, revision rates, and manipulation rates, with a significant reduction in anterior knee pain. The design improvements in the current PS knee system appear to demonstrate a marked improvement from the predicate knee system.

	Current Knee System	Predicate Knee System	
	Post-op, Mean	Post-op, Mean	P-value
ROM	112.62	107.03	.11
UCLA	4.80	4.85	.78
WOMAC	74.02	75.74	.36
Pain VAS	1.72	2.75	<.001
VR-12	40.35	38.74	.10
Anterior Knee pain	5.6%	11.8%	<.001
Revision rate	1.5%	2.2%	.27
Manipulation rate	3.2%	11.9%	<.001

Table 1. Patient Reported Outcome Measurements (PROMs).

	Current Knee System	Predicate Knee System
Total revisions (%)	22 (1.5%)	10 (2.2%)
Aseptic loosening	13 (.9%)	6 (1.3%)
Instability	5 (.3%)	1 (.2%)
Infection	2 (.1%)	1 (.2%)
Osteolysis	1 (.07%)	0 (0%)
Soft tissue procedure	0 (0%)	1 (.2%)
Periprosthetic fracture	1 (.07%)	0 (0%)
Stiffness	0 (0%)	1 (.2%)

Table 2. Reason for Revision.

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“Standard” Versus “Challenging” Patients – Perioperative Outcomes Using Computer-Assisted Total Knee Arthroplasty

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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.⁶⁻⁹ 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 CAOSTKA. 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.

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

	Challenging Patients	Standard Patients	P
N	26	46	-
Age (years, mean, range)	63.9 ± 10.1, 41-82	67.5 ± 8.5, 51-80	0.174
Female (%)	62	41	0.000
BMI (mean, range)	35.7 ± 6.2, 26.2-47.0	29.8 ± 2.7, 23.5-34.9	0.005
Count of Comorbidities (mean, range)*	1.7 ± 1.0, 0.0-4.0	1.1 ± 1.0, 0.0-3.0	0.021

*The total number of comorbidities per patient.

Challenging Patients	N†
Age > 80 yr	3
BMI > 35	17
Coronal Deformity > 15°	1
ROM < 90°	10

† Each difficult case had one or more listed conditions.

Table 1. A) Patient conditions. B) Distribution of conditions in the challenging TKA group.

standard group. A summary of perioperative outcomes in the standard and challenging 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.

	Challenging Patients	Standard Patients	P
Intraop Blood Loss (ml)	154 ± 162	130 ± 139	0.529
Haemoglobin Loss (g/dL)	2.1 ± 2.9	2.3 ± 1.8	0.700
First Ambulation (day)	0.4 ± 0.5	0.4 ± 0.5	0.914
Length of Stay (day)	3.3 ± 1.5	3.2 ± 1.7	0.915
Discharge to Home (%)	69	78	0.149

Table 2. Summary of perioperative outcomes for the challenging and standard TKA groups.

DISCUSSION

With a previous study proving consistent accuracy using CAOS in TKA performed by surgeons of varying experience levels¹⁰, this investigation sought to investigate the sensitivity of the perioperative outcomes of CAOSTKA 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 results⁶⁻⁹, 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 deformity³⁻⁵, this study highlights the advantages CAOSTKA may offer in demanding cases where patient or joint factors increase the surgical challenges.

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What to Expect in Short-term Outcomes of “Challenging” Patients With Computer-Assisted Total Knee Arthroplasty?

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ABSTRACT

This study investigated if CAOSTKA cases in higher risk patients would impact the outcomes of surgery. An average of 14-month postoperative outcomes on 58 TKAs from a prospective multicenter study were analyzed. The patients were grouped into challenging and standard case groups according to the criteria of age, BMI, comorbidities, and alignment deformity. Both groups demonstrated significant postoperative improvement in all outcome measures. Compared to the standard patients, the challenging patients achieved significantly higher improvement after TKA in KSS Knee score, while demonstrating the same level of improvements in all other outcome measures. Similarly, the two groups generally exhibit equivalent postoperative outcomes. The data demonstrated consistent postoperative results by CAOSTKA irrespective of patient conditions.

INTRODUCTION

Since its introduction to total knee arthroplasty (TKA), computer-assisted orthopedic system (CAOS) has been proven to significantly improve implant alignment in the knee consistency compared to conventional instrumentation.^{1,2} Numerous studies on the CAOSTKA have been published focusing on postoperative implant alignment, intraoperative parameters, and postoperative outcomes and survivorship.^{3,4} Additionally, the benefits of CAOS TKA in the patients with increased risks has been published. However, most of these studies are case reports and single arm series focusing exclusively on extra-articular alignment deformity.⁵⁻⁷



Studies on conventional instrumented TKA concluded patient factors such as advanced age, obesity, multiple comorbidities, and severe alignment deformity may increase the risk of worse postoperative outcomes and early failure.⁸⁻¹¹ To date, it remains unclear how the outcomes CAOSTKAs are impacted by the “challenging” cases, as compared to the “standard” CAOSTKAs. This study analyzed a case series to investigate if there is a difference between challenging and standard cases in terms of the clinical short-term outcomes.

METHODS

With institutional review board-approval and patient’s signed informed consent, a prospective multicenter, consecutive TKA case series was conducted by 5 surgeons in a total of 70 patients (72 knees). All cases were primary TKA with the assistance of a contemporary CAOS system. 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) 3 or more comorbidities, 4) coronal deformity greater than 15°, and 5) preoperative range of flexion (ROM) less than 90°. The latest available postoperative visit that was categorized as 1 year and beyond (starting from 9-month postoperatively) were reviewed and compared between the standard and challenging case groups. Specific outcomes assessed were: Range of Motion (ROM), Knee Society Score (KSS, knee and function), Hospital for Special Surgery Knee Score (HSS), Oxford Knee Score (OKS), Knee Injury and Osteoarthritis Outcome Score (KOOS: Symptom, Pain, ADL, QOL), and patient satisfaction Visual Analog Scale (VAS 1-10, with 10 indicating the highest satisfaction). Statistical significance was defined as $p < 0.05$.

A	Challenging Patients	Standard Patients	P
N	28	30	-
Age (years, mean, range)	67.0 ± 10.5, 41-82	66.0 ± 8.2, 51-78	0.687
Female (%)	57	43	0.066
BMI (mean, range)	34.2 ± 6.4, 23.5-47.0	29.9 ± 2.5, 25.0-34.9	0.001
Follow-up period (months)	14.5 ± 5.2, 9-24	14.3 ± 4.4, 9-23	-

B	Challenging Patients	N†
Age > 80 yr		4
BMI > 35		22
Coronal Deformity > 15°		1
ROM < 90°		10
Num Comorbidities > 2		10

† Each difficult case had one or more listed conditions.

Table 1. A) Patient conditions. B) Distribution of conditions in the challenging TKA group.

RESULTS

Fifty-eight knees were available for the analysis with an average follow-up period of 14 month. A detailed breakdown of challenging (N=28) and standard (N=30) cases is presented in Table 1. A summary of postoperative outcomes in the standard and challenging groups is presented in Table 2. Preoperatively compared to standard patient, the challenging patients had significantly worse scores in KSS Knee and HSS, and near significant worse score in KSS Function. Both groups demonstrated generally equivalent outcomes postoperatively and achieved significant postoperative improvement in all outcome measures compared to the preoperative baseline (p values < 0.001). The challenging patients improved even more in KSS Knee score compared to the standard patients (p=0.02, Table 2). Although standard patients had a higher KSS function score compared to that of the challenging patients (p=0.009), the challenging patients exhibited equivalent postoperative KOOS ADL (p=0.948) and generally higher satisfaction (VAS: 9.1 ± 1.4) compared to the standard patients (VAS: 8.8 ± 2.2) (N.S.). No device-related outstanding adverse events or revision was found in both groups at the time of analysis.

Improvement from Baseline	Challenging Patients	Standard Patients	P
HSS	25.0 ± 16.6	26.6 ± 25.3	0.783
OKS	17.9 ± 10.3	16.0 ± 10.2	0.493
KSS			
Function	23.2 ± 21.4	28.3 ± 22.1	0.375
Knee	33.7 ± 19.2	20.2 ± 20.7	0.020
KOOS			
Pain	40.0 ± 24.6	39.3 ± 23.3	0.988
Symptoms	34.8 ± 22.8	25.6 ± 23.4	0.855
ADL	38.9 ± 23.4	32.7 ± 22.0	0.313
QOL	46.7 ± 23.6	44.0 ± 27.9	0.699

Table 2. Summary of postoperative improvements for the challenging and standard TKA groups.

DISCUSSION

With a previous study proving consistent accuracy using CAOS in TKA performed by surgeons of varying experience levels,¹² this investigation sought to assess the sensitivity of the short-term postoperative outcomes of CAOS TKA to patient conditions. Although the conditions used to determine challenging cases in this study (age, BMI, number of comorbidity, degree of alignment deformity) have been shown by previous clinical investigations to negatively impact conventional TKA results,^{6,9} the present data did not suggest inferior postoperative outcomes should be in general expected in the challenging 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,⁵⁻⁷ this study highlights the advantages CAOS TKA may offer in demanding cases where patient or joint factors increase the surgical challenges.

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Multilevel Modeling of Resection Accuracy: Insights From 10,144 Clinical Cases Using a Contemporary Computer-Assisted Total Knee Arthroplasty System

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ABSTRACT

This study applied an advanced statistical tool (multilevel modeling) to assess the accuracy of bony resection during total knee arthroplasty on 10144 cases performed using a modern CAOS system. An extensive list of factors was included for the modeling, including geographic region, inter-surgeon difference, surgeon's adoption of the technology (learning or proficient phases), and historical progression of the CAOS application (software versions). The comprehensive analysis demonstrated that the CAOS system is an accurate and precise solution to assist the surgeons to achieve his/her surgical resection goals.

INTRODUCTION

Accurate positioning of the implants is critical for the success of total knee arthroplasty (TKA).¹⁻⁴ Numerous studies have confirmed the benefit of computer assisted orthopedic surgery (CAOS) in improving the accuracy of bony resection and limb alignment.^{5,6} However, there are some common limitations shared across the existing studies that often fall into the following categories: 1) the studies were not powered enough to investigate geographic and inter-surgeon variance; 2) longitudinal performance of a specific CAOS system was overlooked, despite improvements and updates in the software applications are the standard practice in marketed systems.



It is unquestionably difficult to initiate clinical studies that encompass the clinical cases performed by a specific CAOS system with sufficient sample size for stratifying geographic regions, variation of usage between individual surgeons, and software updates over the system's application history. Nowadays, modern cloud-based data infrastructure allows archiving of technical data without the need to assess patient information, providing possibilities to comprehensively assess the accuracy of a CAOS system across its users, geographic regions, and history of its application. This study aimed to apply an advanced statistical analysis (multilevel modeling) to assess resection accuracy across the entire TKA application history of a modern CAOS system. Specifically, the authors sought to determine the impact on accuracy from 1) geographic region; 2) inter-surgeon difference; 3) surgeon's adoption of the technology (learning curve); and 4) historical progression of the CAOS application (software versions).

METHODS

A retrospective review and analysis of a proprietary cloud-based web that archives all TKAs performed using a modern CAOS system from its first application to the time of this study. All logs contained technical information recorded on the surgical cases. The database did not include patient information of any sort. Similarly, all surgeons were de-identified with only their geographic information available.

Resection errors (accuracy) in the proximal tibia and distal femur were evaluated in this study. Multilevel modeling was used to understand whether and where the variability is located in the resection errors in both tibia and femur. The errors were from two sources: 1) a level-1 variability that reflects resection errors across surgeries; and 2) a level-2 variability that describes the attribution of resection errors across a grouping variable, including geographic region, inter-surgeon differences across established surgeons, adoption phases (learning/proficient), and version of the CAOS software application (Table 1).

A total of 24 unconditional multilevel models were run to determine whether there were differences within each of the 4 level-2 grouping variables across six accuracy measurements (tibia: varus/valgus alignment, posterior slope, resection depth; and femur: varus/valgus alignment, flexion/extension, and resection depth). The model was formulated as following:

$$(1) \text{ Accuracy measurement}_{ijk} = \gamma_{00k} + U_{0jk} + \varepsilon_{ijk}$$

Where γ_{00k} = the grand mean of the resection error, U_{0jk} = random residual for level II variance, ε_{ijk} = random residual for level I variance, $U_{0j} \sim N(0, \sigma^2_{\mu\sigma})$, $\varepsilon_{ij} \sim N(0, \sigma^2_{\varepsilon})$, and i = individual cases, j = level-2 variable (ID of grouping categories), k = accuracy measurement for tibia (1) or femur (2). For each model, level-1 and level-2 variance estimates were used to compute an intraclass correlation (ICC). The ICC quantifies the proportion of variance at level-2 ranging between 0 (no variance) and 1 (100% of the variance). All models estimated used maximum likelihood estimation methods and were performed in SAS 9.3 (SAS Institute, Cary, NC, USA).

RESULTS

A total of 10,144 CAOS TKA cases from December 2010 to August 2018 were reviewed. For the tibial resection, the deviations in coronal alignment (tibial varus/valgus angle) and sagittal alignment (posterior tibial slope) were $0.06 \pm 0.94^\circ$ and $-0.09 \pm 1.73^\circ$, respectively. For the femoral resection, the deviations in coronal alignment (femoral varus/valgus angle) and sagittal alignment (femoral flexion) were $0.00 \pm 0.97^\circ$ and $-0.17 \pm 1.44^\circ$, respectively.

ICC values are summarized in Table 2. Variation in geographic region, CAOS software application versions, and adoption phases (learning/proficient) all exhibited to account for negligible amounts of total variability in tibial and femoral resection errors (< 0.02). Notably, inter-surgeon differences accounted for between 0.0223 and 0.2444 of the total variability in tibia and femur resection errors, which was within the commonly acceptable natural variations in observational studies.⁷ A further investigation of the inter-surgeon differences revealed that for the tibia, 100%, 97.6%, and 95.2% of the surgeons had less than $2^\circ/\text{mm}$ standard deviations in the resection errors of varus/valgus alignment, posterior slope, and resection depth, respectively. Similarly for the femur, the percentages were 100%, 97.6%, and 97.6% for varus/valgus alignment, flexion/extension, and resection depth, respectively.

DISCUSSION

Malpositioning of the implants negatively impacts the outcomes of TKA.¹⁴ The study demonstrated high accuracy in bony resections by using the CAOS system. Furthermore, the resection accuracy was not sensitive to geographic region, CAOS software application version, or learning period. Although some variations were shown in established surgeons, the ICC values reported were within the established definition of commonly accepted variabilities from observational studies (ICC between 0.15 and 0.25.⁷ As such, no meaningful variability was observed from this study with regard to established surgeons.

To date, this is the first big data analysis applying advanced statistical modeling to assess the accuracy of a CAOS system across all its application history, extensively considering factors that may influence the bony resections. All, not just selective, surgeons, geographic regions, software versions, and phases of adoption were assessed, making this analysis an objective and comprehensive review of the accuracy performance of the system.

It has been questioned by many investigators that the accuracy in the alignment measured based on standard long-leg standing load-bearing radiograph may be compromised by the quality of the image, inter- and intra- observer variability, and can be sensitive to the position of the limb or direction of the beam that lead to an oblique (not strict anteroposterior) view. The intraoperative resection alignment check by directly pressing the instrumented checker on the bony resection surface provided a robust and consistent measurement of the bony resection alignment directly against the intraoperatively established alignment reference system.

Grouping Variables	Definition of Categories	Number of Categories
Geographic Regions	APAC: Japan, Australia, Korea, Singapore, India EU: France, Switzerland, United Kingdom, Italy, Spain USA	3
Individual Established Surgeons	A data subset containing surgeons with $\geq 50^*$ cases experience with the CAOS system. Each individual surgeon was treated as one category.	41
Adoption Phases	Learning: combined cases #1-15 from all established surgeons Proficient: combined cases #36-50 from all established surgeons	2
Software Application	Software versions	6

* The selection of ≥ 50 cases to define established surgeons was based on consideration of maintaining sufficient sample size per category.

Table 1. Grouping variables for the assessment of level-2 variability.

ICC Accuracy Measurement	Grouping Variables			
	Geographic Regions	Individual Established Surgeons	Adoption Phases	Software Versions
Tibial Resection Errors				
Var/Val Alignment	0.0000	0.0736	0.0000	0.0038
Posterior Slope	0.0037	0.1909	0.0000	0.0093
Resection Depth	0.0014	0.2444	0.0000	0.0073
Femoral Resection Errors				
Var/Val Alignment	0.0016	0.0223	0.0001	0.0003
Flexion/Extension	0.0069	0.1024	0.0197	0.0075
Resection Depth	0.0005	0.0707	0.0046	0.0019

Table 2. ICC values for level-2 variables from multilevel models.

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Intraoperative Refinement of Cut Orientation in Total Knee Arthroplasty

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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® 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 $\pm 3^\circ$ 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.



Figure 1. Left – Photograph of the adjustable instrumentation in surgery; Right – Photograph of the navigated guide.

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.

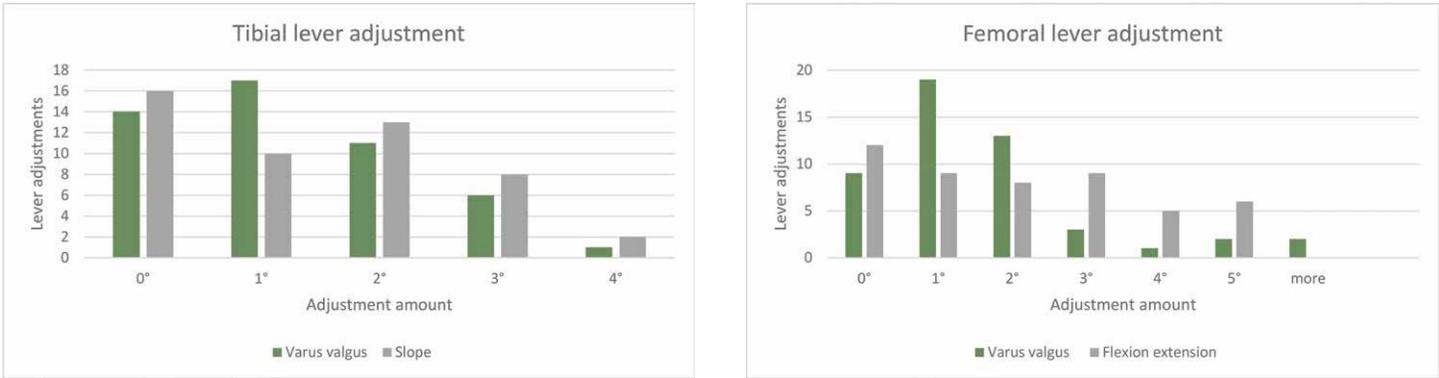


Figure 2. Left – Tibial Adjustment; Right – Femoral Adjustment.

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Accuracy of a CAOS Enhanced Mechanical Instrument System For Total Knee Arthroplasty

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INTRODUCTION

Accurate positioning of the knee prosthesis is critical for the success of total knee arthroplasty (TKA).¹ However, only 70-80% of the conventional TKA cases can achieve satisfactory lower limb alignment (within $\pm 3^\circ$ of varus/valgus relative to the mechanical axis).^{2,3} Computer-assisted orthopaedic surgery (CAOS) offers increased accuracy and precision to the bony resections compared to the conventional techniques.⁴ 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 ($< 2^\circ$ 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 $\leq 1^\circ$ 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%).

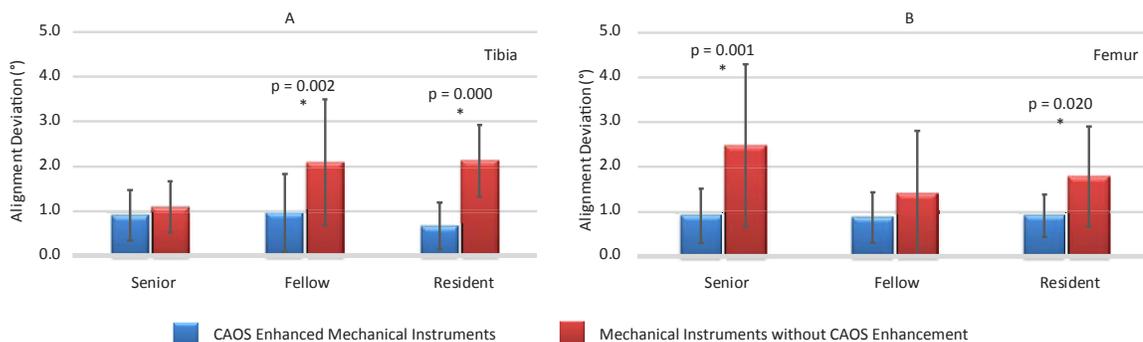


Figure 1. Unsigned alignment deviation in A) tibia and B) femur. Significances found between CAOS enhanced and mechanical instrument only resections were marked with p values.

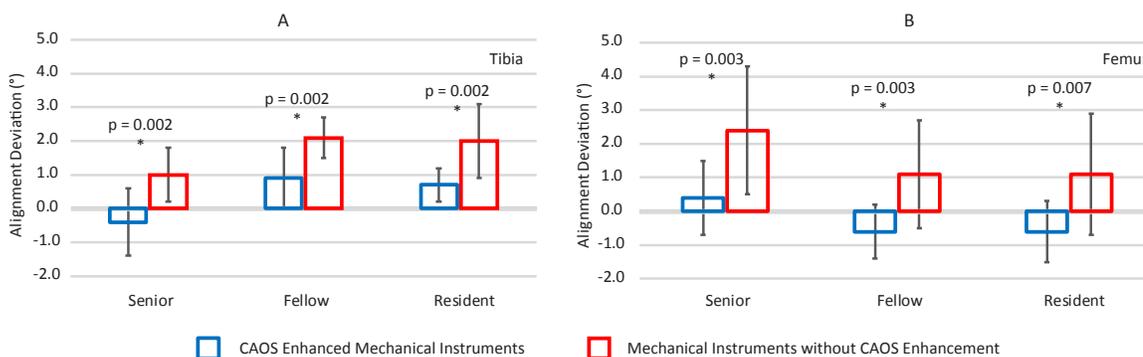


Figure 2. Signed alignment deviation in A) tibia and B) femur. Significances found between CAOS enhanced and mechanical instrument only resections were marked with p values.

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 accuracy⁶ and the same robustness to surgeon’s TKA experience level⁷. 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.

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

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

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Intraoperative Assessment of a Modern Total Knee Arthroplasty Femoral Design

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INTRODUCTION

Selecting a prosthesis that best fits the native morphology of the targeted population during total knee arthroplasty (TKA) is important for the success of the surgery and longevity of the implants. Studies have shown that mediolateral (ML) component overhang of more than 3-4mm negatively impacted the clinical outcomes, possibly due to irritation of the soft-tissue around the knee.^{1,2} While some designs offer multiple aspect ratio (standard and narrow femoral components) to mitigate the risk of component overhang, a contemporary knee system took a different approach by varying a mono aspect ratio across its femoral component sizes and an anterior flange shape designed to accommodate native femoral morphology. This study assessed the fit of this contemporary design intraoperatively during TKA surgeries.

METHODS

After obtaining institutional review board approval and informed consent, a prospective study was conducted by two surgeons at two separate clinical sites. During the TKA surgeries, the surgeon used the AP sizer to measure the ideal component size based on the anteroposterior (AP) dimension of the distal femur. The final implanted femoral size was recorded, and a special designed depth gauge was used to measure the fit of the trial placement at 12 locations on the periphery of the femur, defined based on the distal, anterior chamfer, and anterior resections (Figure 1). The incidence of downsizing from the ideal size and implant over-/under- hang at each measurement location from the trial placement were assessed. Clinically important overhang and associated overhang location was identified if the component overhang extended beyond 3mm.^{1,2}



RESULTS

Fifty-six knees were enrolled and measured in this study (34F/22M, age 72.2 ± 7.2 yr, BMI 28.8 ± 6.3). Two knees downsized from the ideal size by a half size (3.6%), due to considerations other than overhang exceeding 3mm with the use of the ideal sizes. None of the knees had clinically significant implant overhang and zero overhang was reported in 10 out of the 12 tested location. More than 96% of the knees fit within 2mm of overhang at the 2 remaining tested locations, Lateral Locations 3 and 6 (Figure 2). All incidences of overhang by any amount was observed in 5.4% of the knees (3 out of 56).

DISCUSSION

The findings demonstrated excellent fit under the clinical cases with the use of a modern femoral implant design with mono aspect ratio offerings. Under the ideal femoral component size selected based on the AP dimension, 100% of the knees studied provided proper morphological fit without clinically significant implant overhang in any of the 12 tested locations around the periphery of the distal femoral resection. Even for the two cases that the surgeon downsized the femoral component by half size, the use of the original ideal size would not cause clinically significant overhang as the dimensional difference between the two sizes was less than 3mm. Contrary to the common belief that a standard and narrow femoral aspect ratio options are required to properly fit the resection morphology^{3,4}, the femoral design studied,

without offering narrow components, demonstrated similar total incidence of overhang of any amount within the reported clinical and computational results from multi-aspect ratio designs (5.0%-7.5%).^{6,7} The results aligned with previous reports that multiple aspect ratio femoral designs may not fit better than mono aspect ratio femoral designs.⁷⁻¹⁰

SIGNIFICANCE/CLINICAL RELEVANCE

Intraoperative assessment of femoral component fit of a modern knee system revealed that mono aspect ratio femoral design can provide good implant fit without clinically significant overhang.

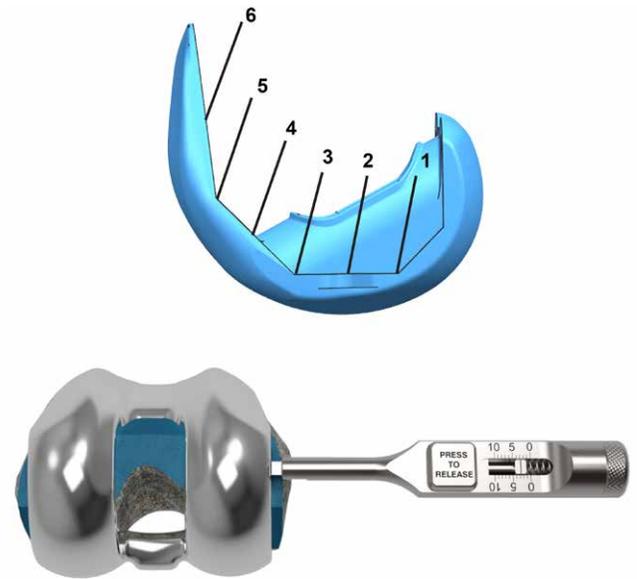
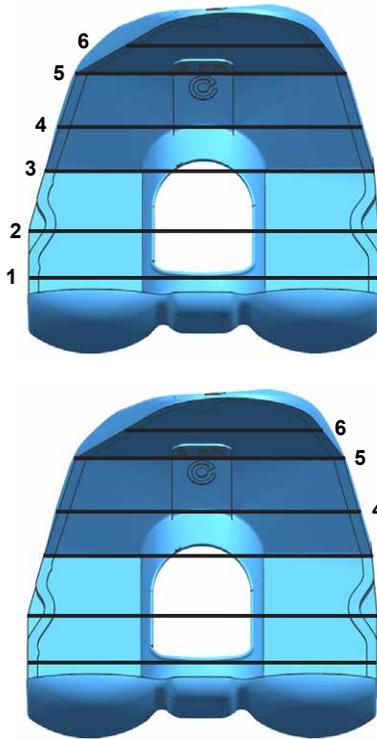


Figure 1. Illustration of the 12 locations (6 medial and 6 laterals) measured for the implant fit by the special gauge.



Medial Locations	1	2	3	4	5	6
Average fit (mm, "-" indicates overhang)	5.1 ± 2.6	5.1 ± 2.5	3.4 ± 2.2	3.9 ± 2.4	3.0 ± 1.8	3.8 ± 2.4
% Knees with overhang of any amount	0.0	0.0	1.8	3.6	1.8	0.0
% Knees with overhang > 1mm	0.0	0.0	1.8	1.8	1.8	0.0
% Knees with overhang > 2mm	0.0	0.0	0.0	0.0	0.0	0.0
% Knees with overhang > 3mm (clinically important)	0.0	0.0	0.0	0.0	0.0	0.0

Lateral Locations	1	2	3	4	5	6
Average fit (mm, "-" indicates overhang)	1.8 ± 1.2	2.0 ± 1.1	0.8 ± 1.1	1.8 ± 1.6	2.6 ± 1.7	3.6 ± 2.0
% Knees with overhang of any amount	0.0	3.6	5.4	3.6	5.4	5.4
% Knees with overhang > 1mm	0.0	3.6	3.6	3.6	3.6	3.6
% Knees with overhang > 2mm	0.0	0.0	1.8	0.0	0.0	1.8
% Knees with overhang > 3mm (clinically important)	0.0	0.0	0.0	0.0	0.0	0.0

Figure 2. Summary of implant fit for each tested location. All the overhang incidents were observed in 3 knees.

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Clinical Assessment of Patellar Fit Between Symmetric and Anatomic Designs

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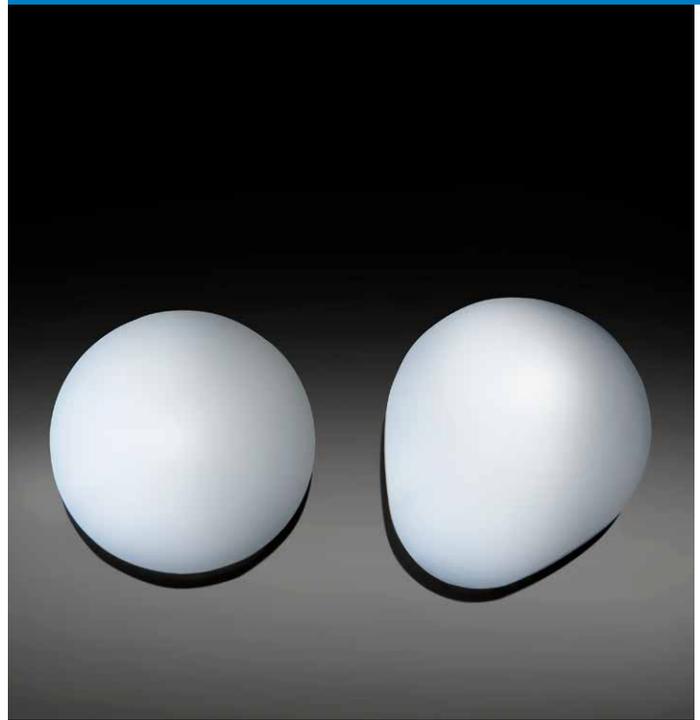
Disclosures: Yifei Dai, Andrew Jensen, and Pierre Angibaud (3A-Exactech), H Morton Bertram III (5-Exactech Inc), Mark Hollmann (3B,5-Exactech Inc, 5-J&J)

INTRODUCTION

Patellofemoral complications are among the most common causes of complaints and revisions following total knee arthroplasty (TKA).¹⁻³ There are several critical considerations during patellar resurfacing, including thickness of the implanted patellar composite, component coverage of the bony resection, and overhang of the component. The patella composite should restore native bone thickness to avoid disrupting the extensor mechanism. Good coverage of this resection surface is required for better load transfer in the patella bone, minimizing the risk of fracture, soft tissue impingement, and lateral facet syndrome. However, with symmetric round patellar design, a surgeon sometimes finds him/herself compromising bony coverage in order to avoid component overhang. Anatomic patellar components may offer improved component fit with less compromises. This study assessed the component fit between a symmetric round patellar design and an anatomic patellar design during TKA surgeries.

METHODS

After obtaining institutional review board approval and informed consent, a prospective clinical study was conducted with two orthopedic surgeons. The surgeons measured the pre- and post-resection thickness of the patella and photographed the patellar resection surface with a calibration marker on the side (29mm diameter round patellar template). The bony resection surface was then templated and photographed with a symmetric round patellar design and an anatomic patellar design, respectively (Figure 1A). Postoperative image analysis was performed with custom script (Matlab, Mathworks, Natick, MA, USA) to recreate the patellar component placement by registering the bony profile



of the patellar resection with the profiles of the templated patellar component placements. Bony coverage was calculated as the percentage covered area on the resection surface by the template placement for each design (Figure 1B). Bony coverage, as well as the change from native patellar thickness to the templated patellar composite thickness was compared between the two designs. Significance was defined as $p < 0.05$.

RESULTS

Forty knees were enrolled in this study (24F/16M, age 71.3 ± 7.9 yr, BMI 29.2 ± 6.6). Compared to the symmetric round design, the anatomical design exhibited a significantly less postoperative change of the patellar thickness (Figure 1A). The anatomic design had a closer restoration of the native thickness than the symmetric design in 38 out of the 40 knees. Significant higher percentage of cases were restored within 2mm of the native patellar thickness (170% more than that of the symmetric design, $p < 0.001$). With ten knees excluded from the image analysis due to poor quality of the photographs, image analysis on bony coverage was performed on thirty knees (18f/12m). Compared to the symmetric patellar design, the anatomic patellar design exhibited significant higher component coverage (Figure 2B).

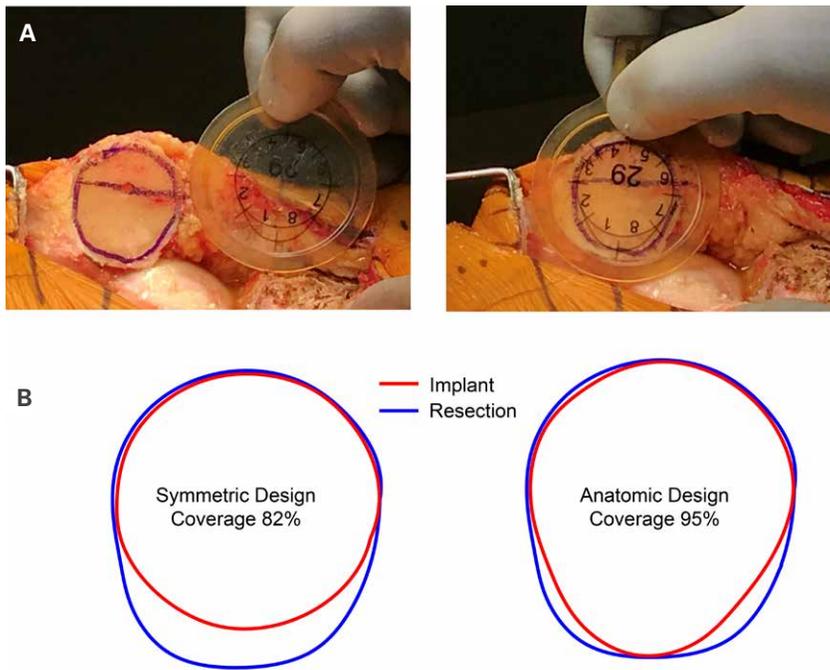


Figure 1. A) Intraoperative templating of the patellar designs. B) Illustration of coverage analysis from intraoperative templating images on a representative knee.

DISCUSSION

Compared to the symmetric patellar design, the anatomic design significantly improved the restoration of the native patellar thickness and bony coverage. The difference found demonstrated the anatomical design can provide reduction of the incidence and severity of compromising composite thickness and bone coverage due to downsizing the component during patellar implantation. This study may be limited to the small cohort and variability introduced from image registration and analysis. However, the data exhibited similar results compared to the computational study of the same designs under consistent algorithm and based on a large CT scan-based dataset.⁴ The clinical results provided from this study further confirmed the advantage of the anatomical patellar design over the symmetric round patellar design.

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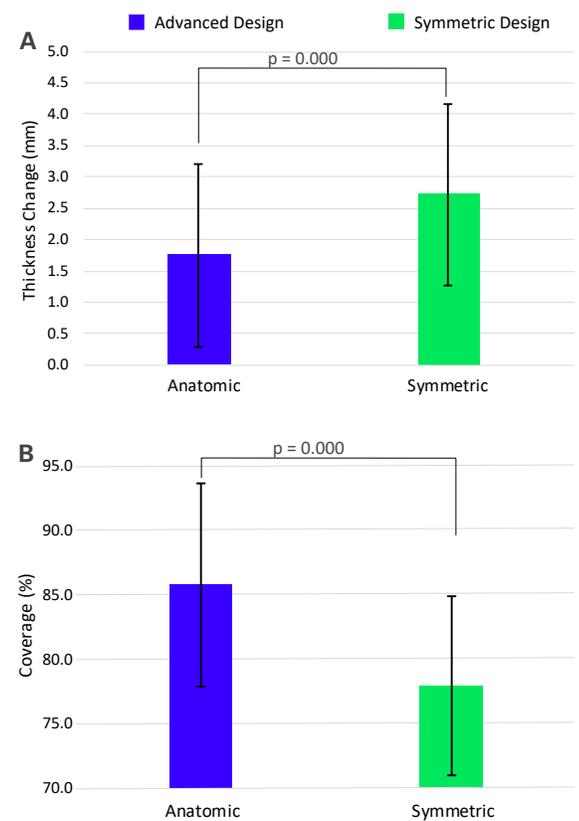


Figure 2. A) Change of patellar thickness. B) Coverage for the anatomic and symmetric designs.

SIGNIFICANCE/CLINICAL RELEVANCE

Intraoperative patellar templating demonstrated that an anatomic patellar design significantly reduced the compromises in composite thickness and improved bony coverage compared to a symmetric round design.

TRULIANT®

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) is related to postoperative knee pain², 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® and Exactech Truliant®.

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 $p < 0.05$.

	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.

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.

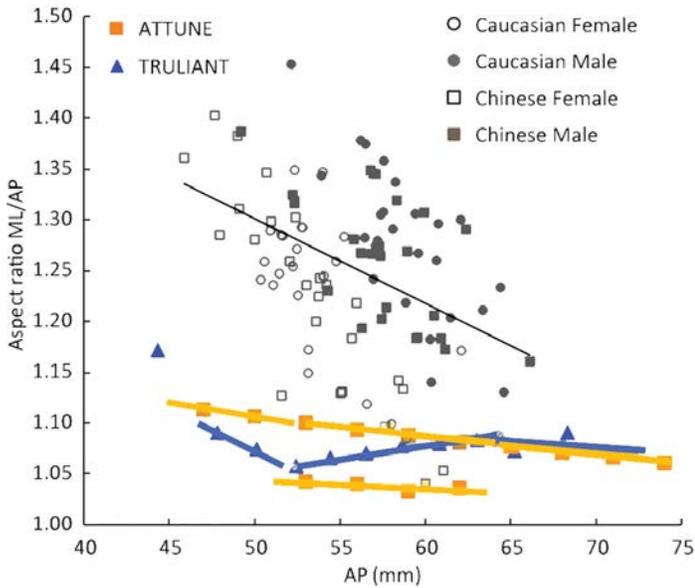


Figure 1. Aspect ratio of the bone data overlaid with the two contemporary femoral component designs.

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.

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TRULIANT®

Fit of Modern Femoral Implant Design on Native Trochlear Groove

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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.^{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 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) (Figure 1).

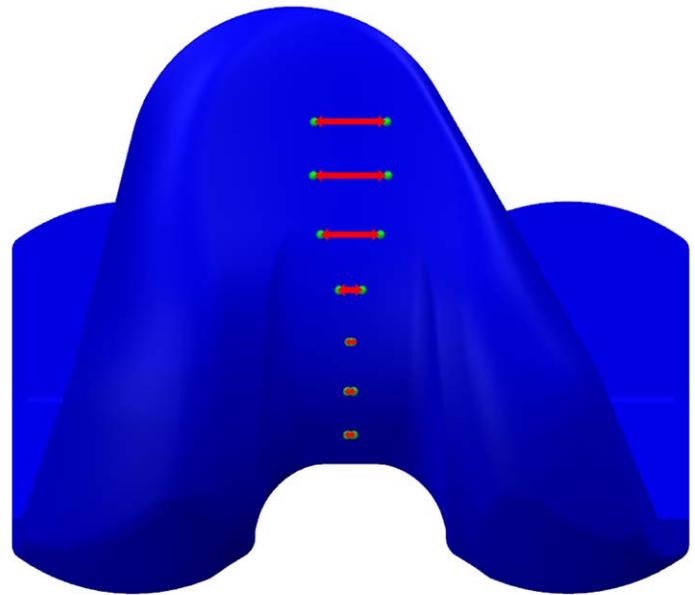


Figure 1. Illustration of allowed range of ML positions of the patella (patella center location, based on the smallest compatible patella size) at different levels of the trochlear groove. The allowed ML ranges were highlighted in red.

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

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.

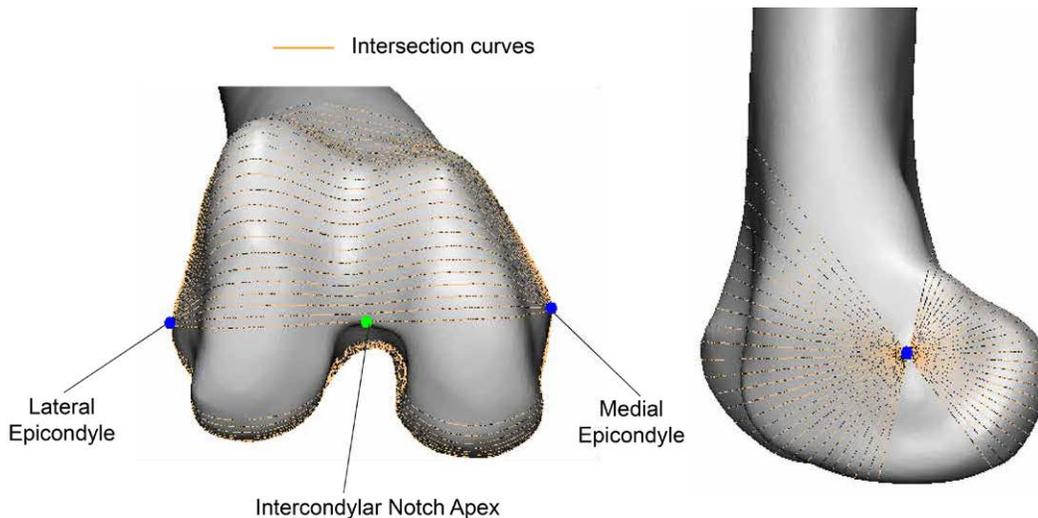
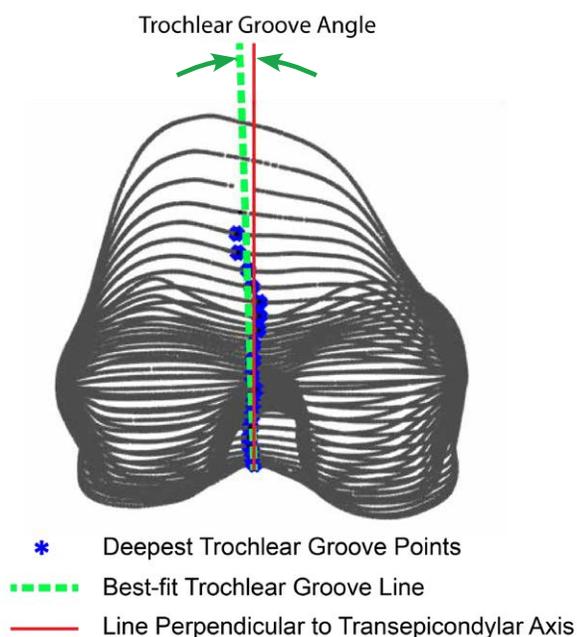


Figure 2. A representative femur illustrating intersecting curves created by rotating a plane around the transepicondylar axis.

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 (> 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).

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.

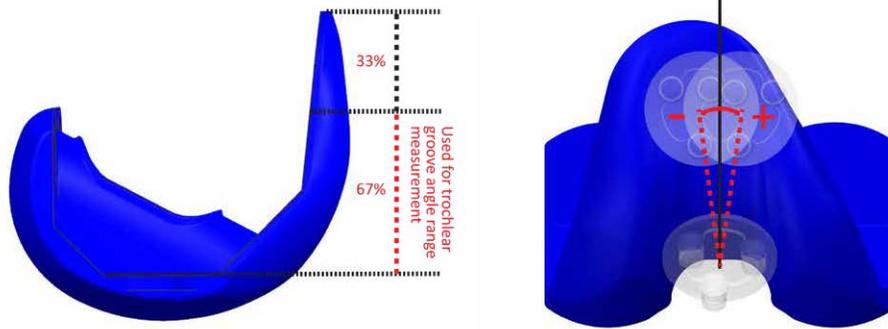


Figure 4. Measurement of the allowed range of trochlear groove orientation on the Truliant design.

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). 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.).

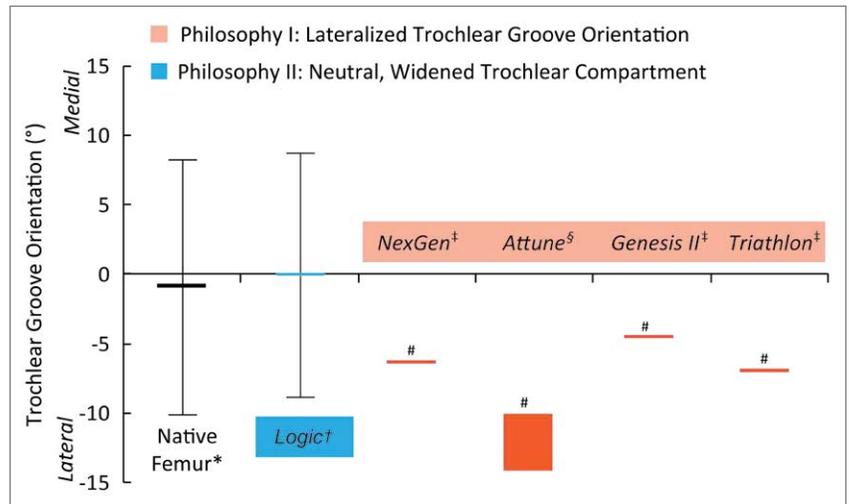
Among the five knee systems evaluated, only the Truliant Knee System closely matched the range of native groove orientation (Figure 5). In contrast, the other four knee systems each exhibited excessive lateralization of trochlear groove orientation, which was about 3°-13° more lateral compared to the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

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

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



* 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 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.

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

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 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.^{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.

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TRULIANT®

Femoral Mediolateral and Sulcus Fit of a New Knee System

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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.

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 (>3mm¹)

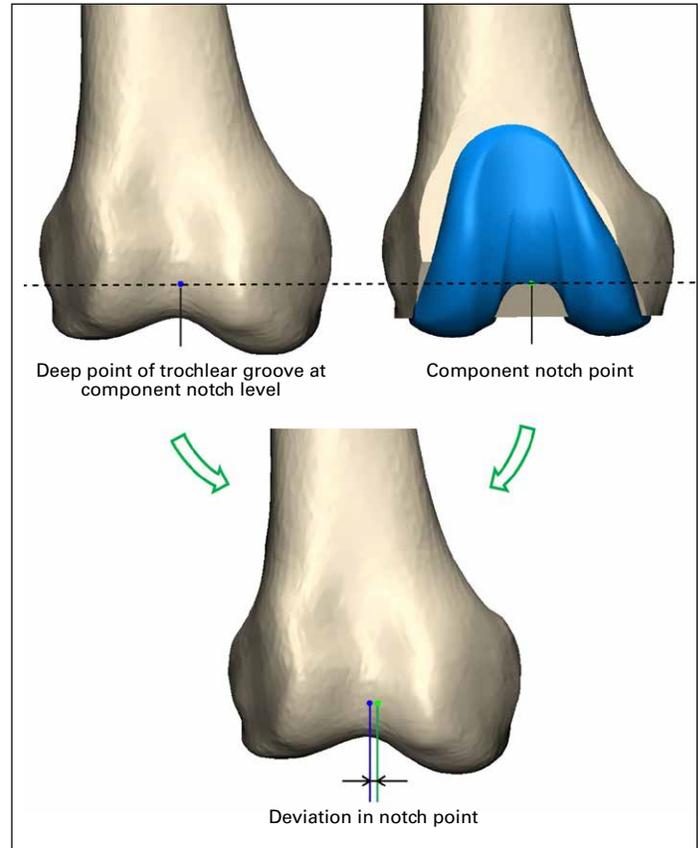


Figure 1. A representative femur demonstrating the measurement of mediolateral deviation between the component intercondylar notch and the corresponding deepest point on the native trochlear groove.

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.^{2,3} Significant difference was defined as $p < 0.05$.

A	Incidence of Clinically Important Overhang			
	Chinese	Caucasian	Female	Male
N	48	43	45	46
Number of bones with >3mm Overhang	1 (3.8mm)	0	1 (3.8mm)	0

B	Deviation (mm)	p
Pooled	-1.0 ± 1.6	—
Chinese	-1.3 ± 1.9	0.10
Caucasian	-0.7 ± 1.3	
Female	-1.3 ± 1.9	0.13
Male	-0.8 ± 1.3	

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.

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

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,^{3,4} the intercondylar notch in this design may offer less patella displacement at high flexion, potentially facilitating normal patella tracking.

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