Comparative Performance of Contemporary UHMWPE Total Knee Arthroplasty Bearings Under Aggressive Wear Testing

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Introduction

Early problems in total knee arthroplasty (TKA) attributed to wear have largely been solved with the introduction of highly crosslinked and antioxidant-containing UHMWPE bearings. Under normal expected in-vivo or simulated in-vitro conditions, it can be difficult to distinguish differences in performance of such materials. However, early clinical failures are still reported when contemporary sequentially irradiated and annealed TKA bearings are exposed to adverse conditions particularly when tibial inserts experience posterior edge-loading[1,2]. Posterior edge loading has been attributed to improper tensioning of the PCL in cruciate retaining (CR) TKA, and aggressive wear test methods have been investigated to simulate the reported clinical failure mode[3,4]. The aim of this study was to develop an aggressive wear test method that simulates the clinical failure mode observed with posterior edge loading of a CR tibial insert and to compare the performance of various contemporary bearing materials under these conditions. The bearing materials challenged in this study include conventional gamma-inert UHMWPE (CPE), sequentially irradiated and annealed UHMWPE (SXL), a 0.1wt% vitamin E gamma crosslinked to 100kGy (GVE), and a previously described compression molded UHMWPE/vitamin-E/di-cumyl peroxide blend followed by high-temperature melting in an inert gas oven (Activit-E™)[5,6].

Methods

CR tibial inserts were fabricated from CPE, SXL, GVE, and Activit-E materials. The CPE material consisted of compression molded GUR 1050 gamma sterilized under vacuum. The SXL samples were fabricated from compression molded GUR 1020 blocks that underwent three sequential gamma irradiation doses for a total dose of 100 kGy followed by annealing for 8 hours at 130°C after each gamma dose exposure. The GVE materials were fabricated from GUR 1020 resin blended with 0.1 wt% VE and gamma irradiated to 100kGy. SXL and GVE materials did not undergo subsequent sterilization as these materials are typically sterilized with ethylene oxide or gas plasma. The Activit-E samples consisted of a compression molded UHMWPE/vitamin-E/di-cumyl peroxide blend followed by high-temperature melting in an inert gas oven and then terminally sterilized via gamma under vacuum. Samples representing each material were tested under unaged conditions as well as after accelerated aging in a pressure vessel (5 atm of pure O2) and placed in a convection oven at 70°C for 28 days. Three specimens from each group were tested. The inserts were placed with an 11° posterior slope, which translated the femorotibial contact location approximately 11 mm posteriorly with respect to the tibial insert. A knee simulator ran the loading waveforms prescribed by ISO 14243-3:2014. The insert samples were evaluated for evidence of failure after 10k cycle increments until 50k cycles were completed. Testing continued another 50k cycles using a modified version of the ISO 14243-3:2014 waveforms which scaled the compressive load to 125%. After evaluation, the specimens were then subjected to another 50k cycles of the modified ISO 14243-3:2014 waveforms which scaled the compressive load to 150%.

Results

All four material groups in the unaged condition successfully completed 150k cycles (50k cycles at 100%, 125% and 150% force each) without evidence of cracking or delamination of the tibial insert. Aged specimens exhibited failure at timepoints described in Table 1. In the aged group, CPE samples exhibited subsurface cracking and fracture at the posterior condylar edge as early as 20k cycles. All specimen failures exhibited posterior fracture of the tibial insert in a manner consistent with clinical reports for this failure mode (Figure 1)[1-3].

Figure 1. SXL sample (left) and CPE sample (right) exhibiting fractures consistent with literature reports.

	Aged Sample Cycle Count						
Material	10k	20k	30k	40k	50k	50k @125%F	50k @150%F
CPE	No Failure	2 Samples Failed	Final Sample Failed				
SXL	No Failure	No Failure	No Failure	No Failure	No Failure	2 Samples Failed	Final Sample Survived
GVE	No Failure	No Failure	No Failure	No Failure	No Failure	No Failure	No Failure
Activit-E	No Failure	No Failure	No Failure	No Failure	No Failure	No Failure	No Failure

Table 1: Aged sample failure cycle counts. Specimens that did not contain antioxidants exhibited failures at the timepoints indicated. All antioxidant-containing samples completed testing with no failures.

Discussion & Conclusions

In this aggressive wear test, all unaged samples completed 150k cycles at three levels of loading schemes successfully without evidence of fracture or delamination. Samples that underwent accelerated aging and did not contain antioxidants experienced failures during testing. The aged SXL samples survived longer than the aged CPE samples but ultimately failed once exposed to the higher loading regime. All antioxidant containing samples completed testing with no evidence of fracture or delamination. This test successfully recreated posterior edge-loading failures described in literature and underscores the role antioxidants play in preserving mechanical properties of UHMWPE bearings when exposed to adverse conditions. The Activit-E UHMWPE samples performed equivalently to the traditional gamma crosslinked vitamin E specimens in this investigation.

Significance

Adverse articulating conditions leading to premature failure are not uncommon in TKA. This study compared relative performance of contemporary bearing materials subjected to posterior edge loading. Antioxidant samples exhibited superior toughness under adverse articulating conditions relative to other contemporary UHMWPE materials used in TKA bearings. This study highlighted the important role vitamin E plays in stabilizing UHMWPE material properties.

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Regional Differences in the Use of Mid-level Constraint Bearings in Total Knee Arthroplasty

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INTRODUCTION

In total knee arthroplasty (TKA), cruciate retaining (CR) and posterior stabilizing (PS) are two general types of bearings. Over the years, more variations of tibial bearings have been introduced to accommodate different surgical philosophies and specific patient needs, such as ultra-congruent (UC), medial pivot (MP), and mid-level constraint (MLC) designs [1]. The MLC bearing (a.k.a., PS Constraint) is a variant of the PS design, usually having a wider tibial insert spine which provides additional varus/valgus and axial rotation constraint (Figure. 1). While not as constrained as the constrained condylar (CC) bearings which are usually indicated for revision TKAs, the MLC design limits varus/valgus and axial rotation and is more often used in primary TKAs. In recent years, MLC bearings have gained increased interest and usage; however, there has been little published information on the trends in using this TKA bearing type. Joint registries do not isolate and stratify this particular bearing type, and hospital databases may be too narrow to represent broader practice. The goal of this study was to examine the prevalence of MLC bearing use on a broader scale, by leveraging a large commercial healthcare dataset and a major manufacturer's sales database. Trends and regional differences across hospitals were also assessed.

METHODS

First, a commercial healthcare database (ECRI, Plymouth Meeting, PA) was used. The ECRI database is one of US's largest GPO-agnostic datasets containing implant sales information across the nation. Several major manufacturers' TKA systems that offer an MLC bearing are reported in the ECRI database, including Zimmer Biomet Persona CPS, Vanguard PS Plus, Stryker Triathlon TS, Smith & Nephew Journey II BCS Constrained, and Genesis II PS Constrained. The sales data of these five implant systems from 2021 to 2023 and the prevalence of MLC bearings were examined. Secondly, the sales database of Exactech, one of the top-ten joint replacement implant manufacturers in the US, were analyzed for its MLC tibial insert (brand name "PSC") unit sales as a percentage of all PS primary implant sales. The nationwide usage was analyzed from 2012 (first year of Exactech's full launch of its PSC) to 2023. To assess regional/institutional variations in the use of PSC inserts, the top ten hospitals with the highest unit sales of PS and PSC inserts were calculated. High-volume hospitals were selected as they provide more stable data with less fluctuation. Additionally, to avoid scenarios where a single surgeon's practice dominated an institution's sales, those hospitals with one surgeon accounting for over 70% of that hospital's total sales were excluded.

Figure 1: A PS bearing (left) and an MLC bearing (right).

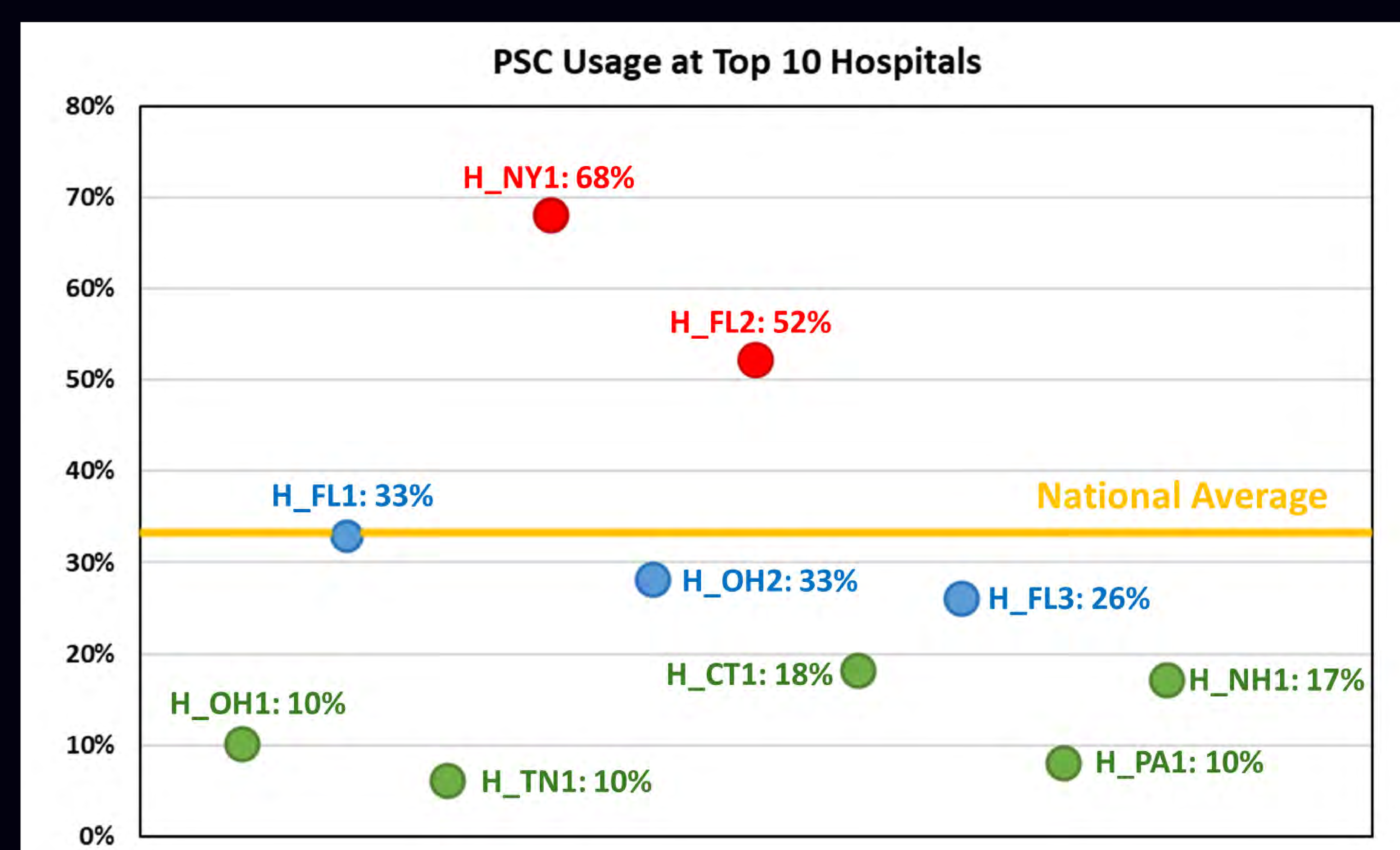

Figure 2: PSC bearing usage rates of ten highest volume hospitals from 2012 to 2023.

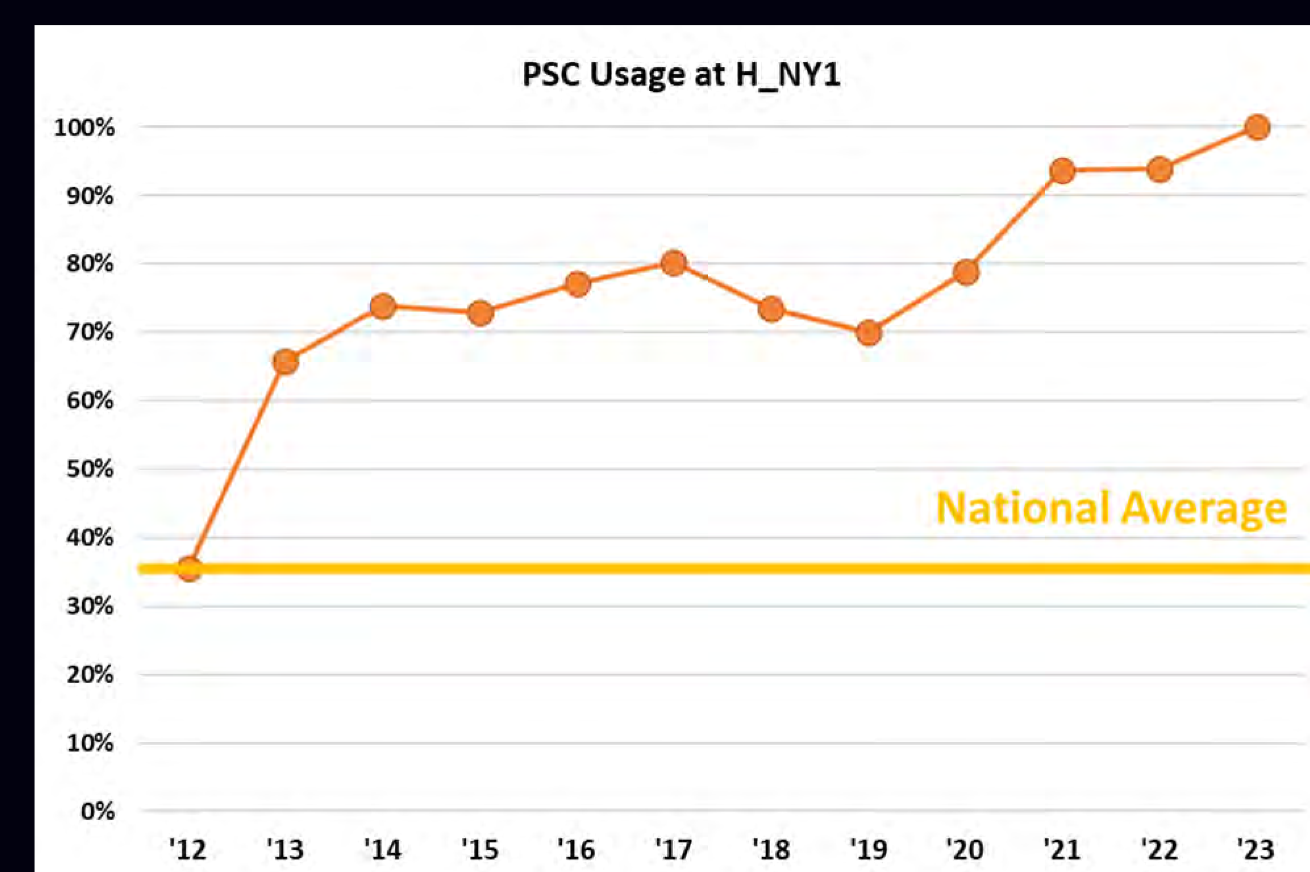

Figure 3: PSC bearing usage at hospital H_NY1.

RESULTS

The ECRI database recorded over 146,000 unit sales of PS and MLC inserts of the five aforementioned TKA systems in its US network hospitals from 2021 to 2023. The dataset showed that the MLC variant accounted for about 25% of all PS-style insert sales over the past three years, and the ratio has been on the rise (24%, 25% and 26% for 2021, 2022, and 2023, respectively). The Exactech database recorded over 70,000 unit sales of PS and PSC inserts from 2012 to 2023 in the US. Nationwide, the use of PSC accounted for about 33% of all PS-style primary inserts, with individual years' ratios ranging between 18% and 41%. Among the top ten hospitals, which spread across seven states, the average PSC usage was 34%, consistent with the national average. However, a wide regional and institutional difference was observed (Fig. 2). Two of the ten hospitals showed PSC usage higher than the national average, with the highest one (H_NY1) using PSC in 68% of all their primary TKAs from 2012 to 2023 and over 80% in recent few years (Fig. 3).

DISCUSSION & CONCLUSIONS

As a newer variant of PS bearing in TKA, the MLC has seen increased usage in recent years, with about 25% of PS TKAs using the MLC, based on a large healthcare database covering five major implant systems. The Exactech database showed a similar trend, with about 1/3 of its PS TKAs using the PSC variant, both nationally and in its top-volume hospitals. We observed a large difference in MLC usage across regions and hospitals, highlighting significant inconsistency in surgeons' philosophy and practice. A high-volume hospital (H_NY1) used PSC inserts at a significant higher rate (2x-3x times of the national average) for their primary TKAs. Interestingly, in the same hospital, non-Exactech users reported an MLC usage rate in line with the national average (24% to 32%) [2], indicating major practice inconsistencies intra-institutionally. MLC bearings were initially introduced for patients with slightly compromised collateral ligament who could benefit from the added constraint, but recent trend indicates that MLCs are used as a default PS bearing by some hospitals and surgeons. While MLCs offer several surgical conveniences (e.g., no need to stem the femoral and tibial components), the added constraint could transfer greater force to the bone/implant interface, increasing the risk of aseptic loosening. This biomechanical assumption has been supported by a 5-year clinical follow-up study reporting higher revision rates of MLC comparing to regular PS bearing [2]. While more studies are warranted to better understand the long-term risk/benefit profile of MLC devices, care should be taken when selecting patients and avoid over-use.

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Fatigue Performance of Acromion and Scapular Spine Fracture Plate System Under Cycled Bend Testing Using a Gap Model

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Introduction

Acromion and scapula spine fractures have an occurrence rate of 2-10% as a complication following reverse total shoulder arthroplasty (RTSA), with higher prevalence in the older female population, especially in the presence of osteoporosis. The cause of scapula fractures following RTSA remains unclear if not controversial. Current theories include increased deltoid tension due to increased mechanical advantage of a RTSA, screw stress risers resulting from baseplate implantation, acromial humeral impingement during abduction, and other implant and technique related factors. Furthermore, there is no consensus on the proper treatment for these RTSA related fractures. Non-operative treatment has been called into question because the underlying conditions which predisposed to fracture are not altered. Consequently, there is increase interest in spine and acromion fixation techniques. The goal of this study was to evaluate the fatigue performance of the Exactech Equinoxe Scapula Fracture Plate System by applying clinically relevant cyclic loads.

Results

Each of five specimens successfully completed. The required 35,280 cycles were completed for all 5 specimens without a single instance of plate fracture or fixation failure. Specifically, both the plate and hooks did not show evidence of fatigue cracks or fracture. Additionally, the screws did not disassociate from the plate during testing.

Methods

Five specimens were included in this study. Each scapula fracture plate was affixed to a machined scapula bone substitute using locking screws. The scapula bone substitute was machined to retain only the acromion section of the scapula, ensuring that all five screw holes on the lateral portion of the plate were inserted into the acromion block for the duration of the test (Figure 1).

Prior to construct assembly, an inelastic cord of aramid fiber was placed on the foam block such that it would be located between the hooks on the plate after assembly (Figure 2). A 4 mm gap model was created to mimic a Type IIa acromion fracture. This configuration was designed to simulate the force from the middle deltoid during abduction to challenge the ability of the hooks and locking screws to maintain fixation during testing. From a shoulder joint model, a vector was created from the deltoid insertion on the humerus to the origin of the middle intramuscular tendon. This trajectory is representative of the length and direction of the lateral deltoid muscle and was represented as a linear vector (Figure 3).

The upper 95th percentile of body weight listed for adult males in the CDC's Anthropometric Reference Data for Children and Adults was used as an estimate in this test.

A cycle count was derived from activity levels estimated for a healthy shoulder in conjunction with the prescribed post operative care regime and a factor of safety was applied.

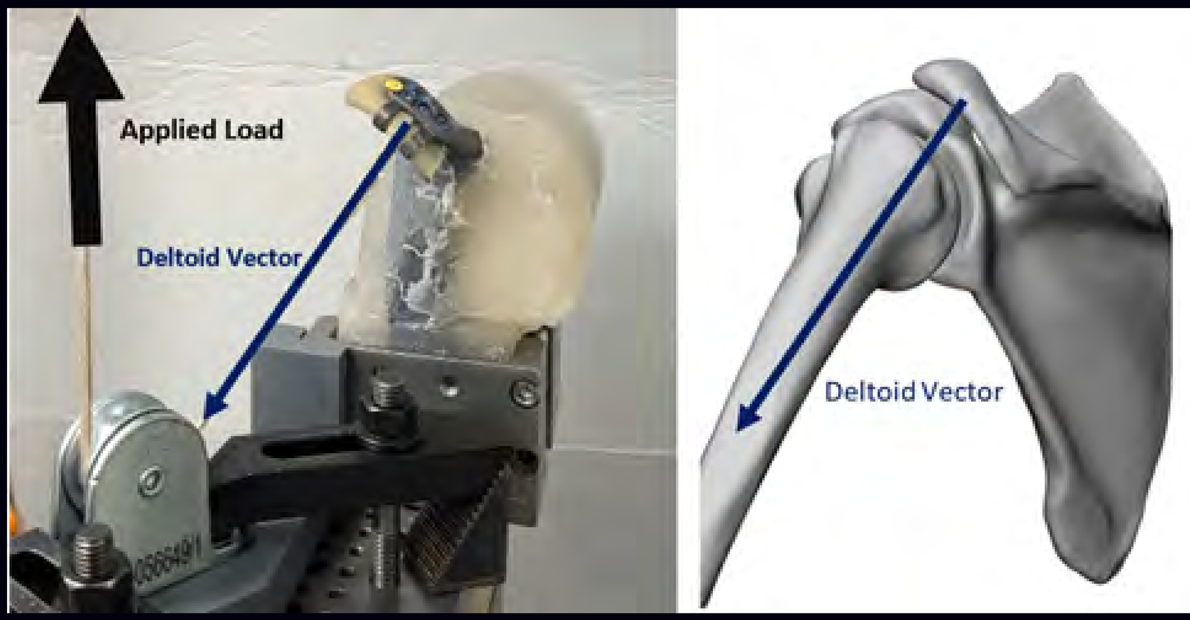

Figure 1. Photograph of test setup

Figure 2. Representative post-test photograph of test specimen

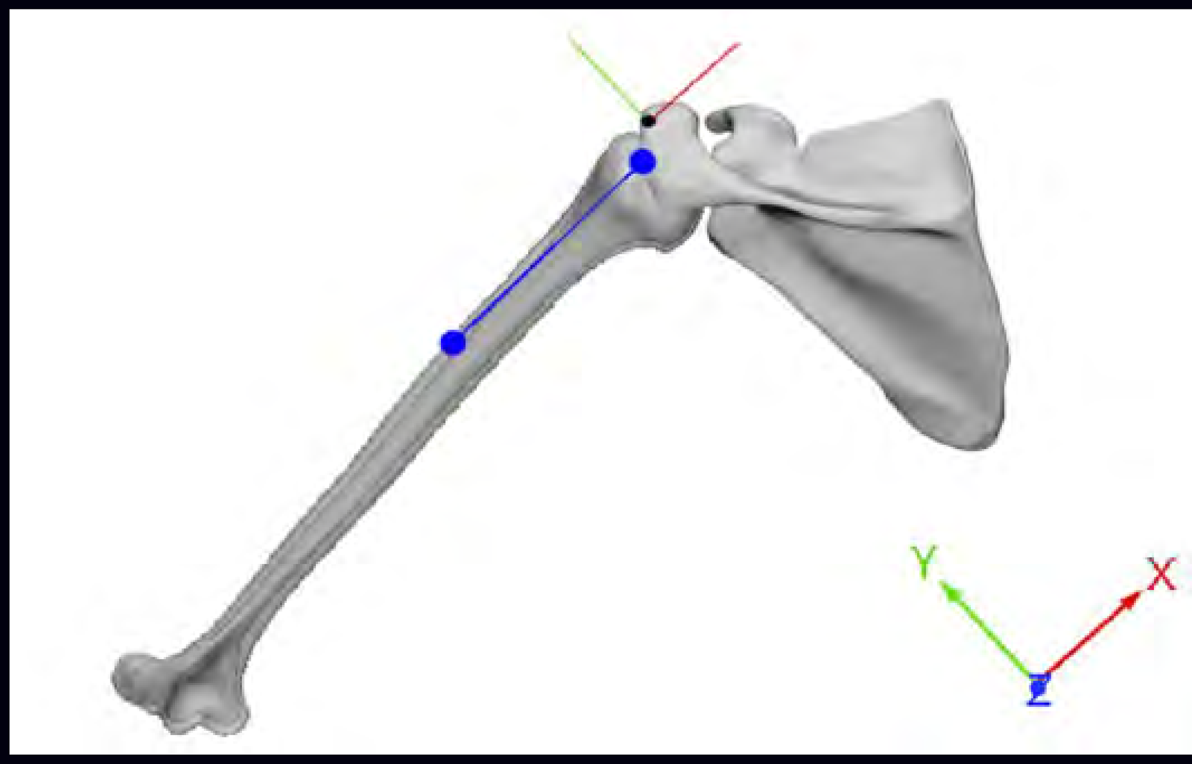

Figure 3. Linearized Deltoid Vector

Discussion & Conclusions

Our study focus was to simulate the correct physiological positioning of the scapula and load vector to accurately challenge the device, with loads and cycles that exceed the most likely clinical scenario. This experimental set up results in more meaningful data when compared to existing biomechanical literature for scapula fracture fixation devices that focuses on testing per a standard. It is notable that a gap model provides no intrinsic stability from a fracture reduction and may represent a worst-case scenario to study. This study provides mechanical performance data which can be utilized when considering operative fixation of scapula fractures following RTSA.

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Reduced Incidence Of Mid-Flexion Instability With Force-Controlled Gap-Balancing In Total Knee Arthroplasty

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Introduction

Instability is a common cause of early failure following total knee arthroplasty (TKA) and represents 11-26% of the revisions.[1-3] Among the different types of instability, mid-flexion instability (MFI) tends to be the most debated. MFI refers to the specific clinical situation where the knee is stable in full extension and at 90° of flexion, but unstable somewhere between these 2 points, generally between 30° and 60° of flexion. While the potential causes of MFI are numerous, one leading explanation relates to altered ligament tension during the range of motion. Toward this end, a recommendation is to routinely assess the varus-valgus stability in mid-flexion range during TKA. Most advanced enabling technologies for TKA allow the possibility of planning the bone cuts based on soft-tissue balance throughout the full arc of motion, which should mitigate the risk of MFI. The objective of this study was to evaluate the incidence of MFI during TKA enhanced with force-controlled gap-balancing by processing the appearance of the final joint laxity curves obtained under distraction during the trial reduction.

Methods

A retrospective review was performed on a proprietary cloud-based web database that archives technical logs of cases performed using an instrumented computer-assisted surgery system during tibia first TKA. A total of 2864 cases performed by 120 individual surgeons were considered without any exclusions. At the time of the trial reduction stage, the final joint laxities were acquired by placing an intra-articular force-controlled tensioner between the proximal tibial cut and the trial femoral component while manipulating the limb from extension to flexion. Each individual joint laxity curve was processed to detect the possibility of MFI. In the absence of a discrete definition of the MFI, for the purpose of this study, it was assumed that risk of MFI may occur if the maximal joint gap measured between 30° and 60° of flexion (mid-flexion range) was larger than the maximal gaps measured between 0° and 20° of flexion (extension range) and between 85° and 95° of flexion (flexion range) by more than 2mm. In addition, the individual joint laxity curves were combined to establish the mean and percentile gap values for both the medial and lateral compartments throughout the full arc of motion.

Results

The incidence of potential MFI was 1.05% (i.e., n=30 of 2864) and 1.12% (n=32 of 2864) for the medial compartment and lateral compartment, respectively. The incidence of potential MFI reported on both the medial and the lateral compartments for the same patient was 0.2 % (i.e., n=6 of 2864). Among the cases associated with potential MFI (i.e., n=56 of 2864), the mean MFI was 2.67mm (ranging from 2.03 to 5.03mm) and 2.77mm (ranging from 2.00 to 5.52mm) for the medial compartment and lateral compartment, respectively. The appearance of the mean laxity curves revealed that the gaps tend to be rectangular in extension with slight lateral opening in flexion. Flexion gap tends to be larger than the extension gap by ~1.5 mm (see Figure 1).

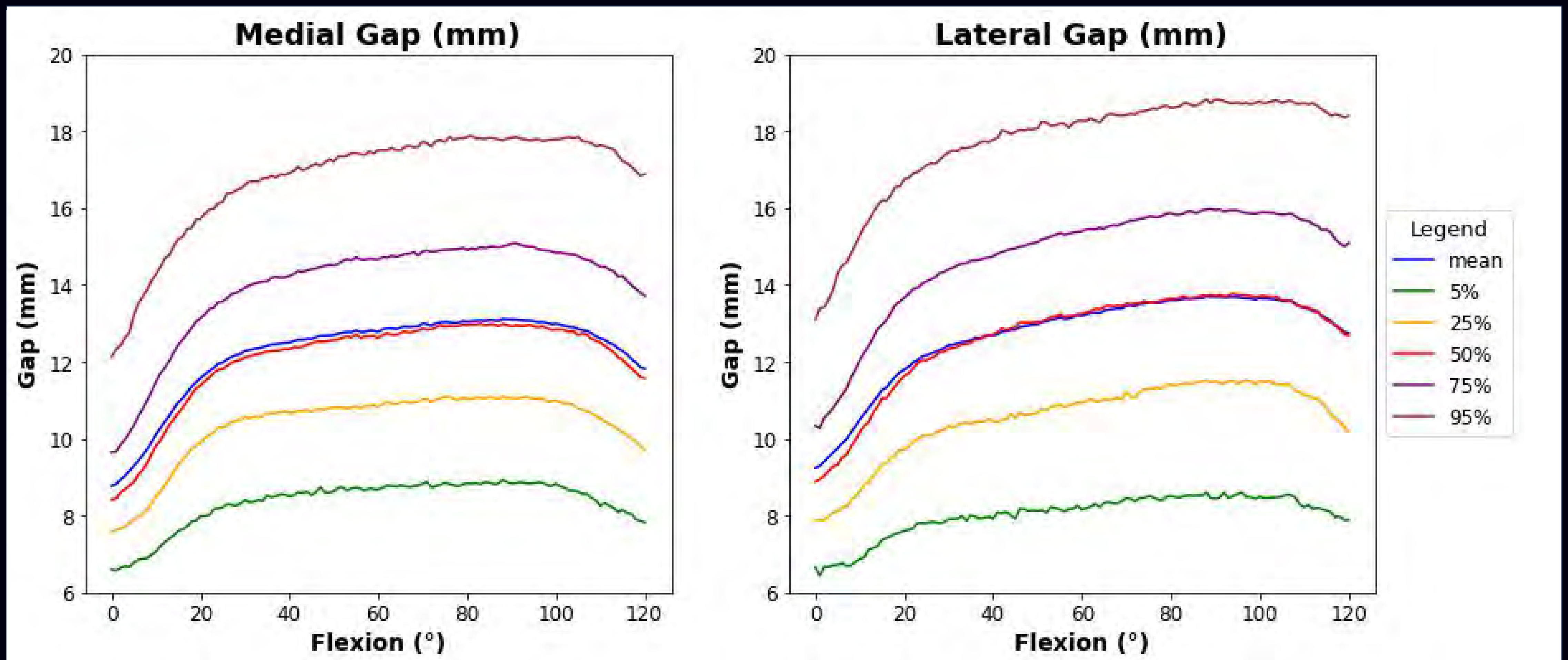

Figure 1: Mean and percentile of the medial and lateral gaps throughout the full arc of motion

Discussion & Conclusions

Despite the adoption of enabling technologies such as navigation or robotic assistance, MFI remains a challenge in TKA. A recent analysis of the American Joint Replacement Registry revealed that patients who had robotic-assisted TKA had higher odds of 2-year revision for instability than patients who had TKA with conventional mechanical instrumentation.[4] Therefore managing the soft-tissue balance could be a noticeable consideration when comparing different enabling technologies. Some technologies rely on manual assessment at discrete angles of flexion (e.g., extension and 90° only) at the beginning of the surgery, which tends to lack accuracy.[5] Other technologies allow for reliable acquisition of the laxities using force-controlled distractor throughout the entire range of motion for the set-up of the surgical plan. According to this study, despite the conservatism of the selected MFI threshold (i.e., 2mm of added laxity), such an approach translated into a reduced risk of MFI, which may explain the previously reported improved clinical outcomes using this platform[6].

This study demonstrated that the ability to manage the soft tissue envelope through reliable acquisition of the laxities throughout the full arc of motion has the potential to substantially reduce the risk of MFI.

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Impact Of The Individual Femoral Degree Of Freedom On The Restoration Of The Trochlea – A Sensitivity Analysis

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Introduction

Alignment philosophy in total knee arthroplasty (TKA) continues to be debated. A common ground about these different techniques relates to their focus on the femorotibial joint, at the potential detriment of the patellofemoral joint. The latest alignment techniques encompass the possibility of individually adjusting each of the six degrees of freedom (DOF) directly associated with the femorotibial joint. In this regard, this experimental study aimed to evaluate the individual impact of each femoral DOF on the position of the femoral component trochlea relative to the native trochlea.

Methods

Four TKAs were performed using an enabling technology on four cadaveric specimens. During the TKA procedure, the native femoral trochlea was identified by the senior surgeon and then mapped by probing the identified surface. Similarly, after TKA implantation, the femoral component was mapped by probing. Subsequently, the cloud of points of the native trochlea and the femoral component were exported to a computer-aided design software and mesh surfaces were generated. Transversal cross sections of interest were established to characterize the anteroposterior (AP) and mediolateral (ML) offsets between the native trochlea and the prosthetic trochlea. From its neutral position (i.e., implanted position), the femoral component was digitally translated/rotated along/around each DOF by 2mm/° increment. For each of the simulated position/orientation, the AP and ML offsets were measured (Figure 1) and the impact of each DOF on these offsets was evaluated by assessing the sensitivity factor (SF) defined as the magnitude (i.e., absolute value of the slope) of the linear regression between the increment value and its impact on the offsets.

Results

Regardless of the specimen, the DOF, and the offset, the R-squared values of each linear regression were consistently above 0.93, demonstrating the linear impact of each DOF on the offsets. As expected, both the AP and the ML translation DOFs had a direct impact on the AP offset and the ML offset, respectively, as demonstrated by an SF close or equal to 1. Both the flexion/extension and axial translation DOFs had a moderate impact on the AP offset, while the varus/valgus and axial rotation DOFs had minimal impact on the ML offset. The other SFs were negligible as being systematically below 0.1. The impact signature of each DOF was consistent (i.e., SD<0.11) among the four specimens (Figure 2).

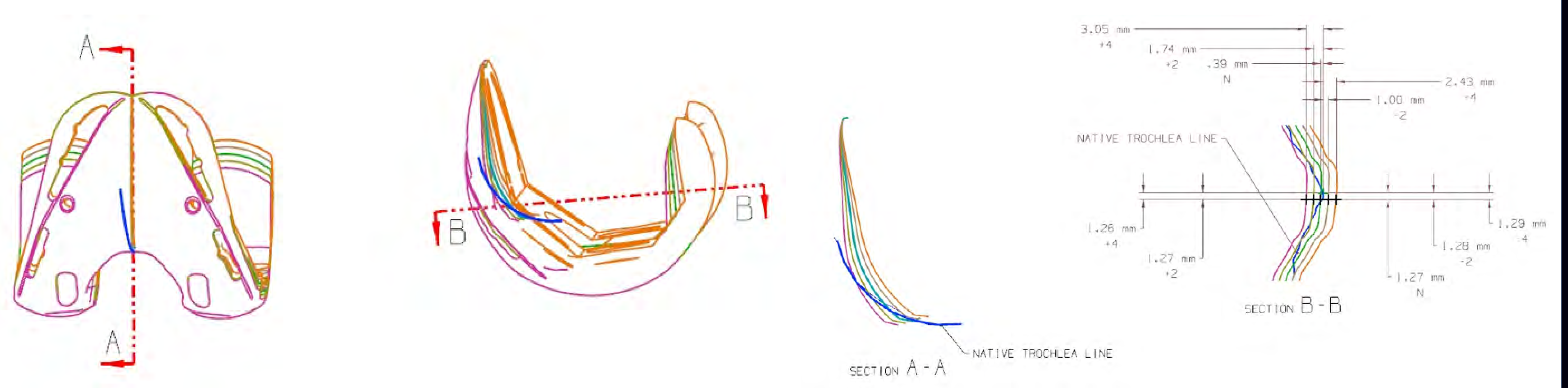

Figure 1: Impact of the flexion/extension DOF on the AP and ML offsets for TKA #1; where the femoral component was incrementally rotated by -4°, -2°, +2°, and +4° of flexion relative to the neutral position

DOF (Input)	SF for TKA#1		SF for TKA#2		SF for TKA#3		SF for TKA#4		Mean SF ±D	
	AP	ML	AP	ML	AP	ML	AP	ML	AP	ML
Flexion/extension	0.57	0	0.63	0.06	0.60	0.06	0.63	0.06	0.61 ±0.03	0.05 ±0.03
Varus/valgus	0.17	0.22	0.02	0.16	0.05	0.30	0.07	0.30	0.08 ±0.06	0.25 ±0.06
Axial rotation	0.01	0.05	0.03	0.12	0.05	0.22	0.07	0.33	0.04 ±0.02	0.18±0.11
AP translation	1	0.02	1	0.10	0.94	0.05	0.91	0.11	0.96 ±0.04	0.07 ±0.04
ML translation	0.03	1	0.05	1	0.11	0.99	0.13	0.99	0.08±0.04	1 ±0
Axial translation	0.53	0.02	0.44	0.04	0.49	0.03	0.55	0.16	0.50 ±0.04	0.06 ±0.06

Table 1: Definition of the SF for each specimen and each DOF

Discussion & Conclusions

During TKA implantation, the impact of each femoral DOF on the restoration of the trochlea is unique and surgeons should be aware of this finding. For example, while it can be recommended to flex the femoral component to close the flexion gap, such change impacts the AP position of the prosthetic trochlea. In addition to the offset, further studies should encompass the impact of the DOFs on the angular orientation of the trochlea. There exists an opportunity for enabling technology to feature insights regarding the management of the patellofemoral joint in addition to the femorotibial joint.
This study evaluated the role of each femoral degree of freedom on the restoration of the trochlea during total knee arthroplasty and demonstrated the wide variance between them in terms of impact.

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Evaluating Ligament Laxity Objectives Across Full Range Of Motion In Total Knee Arthroplasty: A Focus On Tibia First Technique

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Introduction

Alignment techniques in total knee arthroplasty (TKA) are constantly evolving, with modern approaches such as functional alignment[1] providing clear recommendations for bone cutting parameters. However, the definition of ligament laxities remains unclear. In tibia first technique, the acquired joint gaps between the proximal tibial cut and native femur used for femoral planning may vary depending on the tibial cut frontal orientation. This study evaluates the laxity signatures established by surgeons when defining femoral cut planning based on different tibial cut scenarios.

Methods

A retrospective review analyzed 1762 TKA cases performed by 20 surgeons, each with a minimum of 15 cases, using a computer-assisted surgery (CAS) system. The cases were stratified based on the bearing type into three classes: posterior-stabilized (PS) with 15 surgeons, cruciate-retaining constrained (CRC) with 6 surgeons, and cruciate-retaining (CR) with 3 surgeons. Additionally, some surgeons were considered as hybrid, utilizing more than one type of bearing and thus included in multiple classes. The surgical technique allowed planning femoral cuts in terms of alignment, size, and ligament balance. Planned laxities for each case were referenced to the planned medial laxity at 10° flexion under two tibial cut scenarios: the actual tibial cut during surgery (Group A) and a simulated cut perpendicular to the mechanical axis (Group B). While the simulated cut alters lateral gaps due to tibial cut angles, medial gaps remain consistent across both groups. Relative planned laxities were calculated for full flexion arc from 10° to 120° flexion. A two-way ANOVA compared surgeon effect on laxity definition. If significant, Tukey's multiple comparisons analyzed pairwise laxity differences between surgeons.

Results

ANOVA analysis indicated significant differences ($p < 0.05$) in relative laxities among the 20 surgeons in both groups, regardless of the bearing type class and compartment side. Box and whisker charts (Figures 1 and 2) illustrate the medial and lateral laxity curves for each surgeon in Group A and Group B across PS, CRC, and CR classes. The Tukey multiple comparison pairs results provided in Figure 3 revealed that the percentage of significant pairs in Group B lateral laxity across three bearing type classes (PS: 71.4%, CRC: 80%, CR: 66.7%) are nearly equal to or greater than those in group A lateral laxity (PS: 72.4%, CRC: 46.7%, CR: 66.7%). This suggests that the laxity definition during femoral planning depends on the surgeon, regardless of the tibial cut choice. Notably, 30% of the surgeons (6 out of 20) opted for tibial cut obliquity demonstrated a significant impact of the tibial cut on laxities.

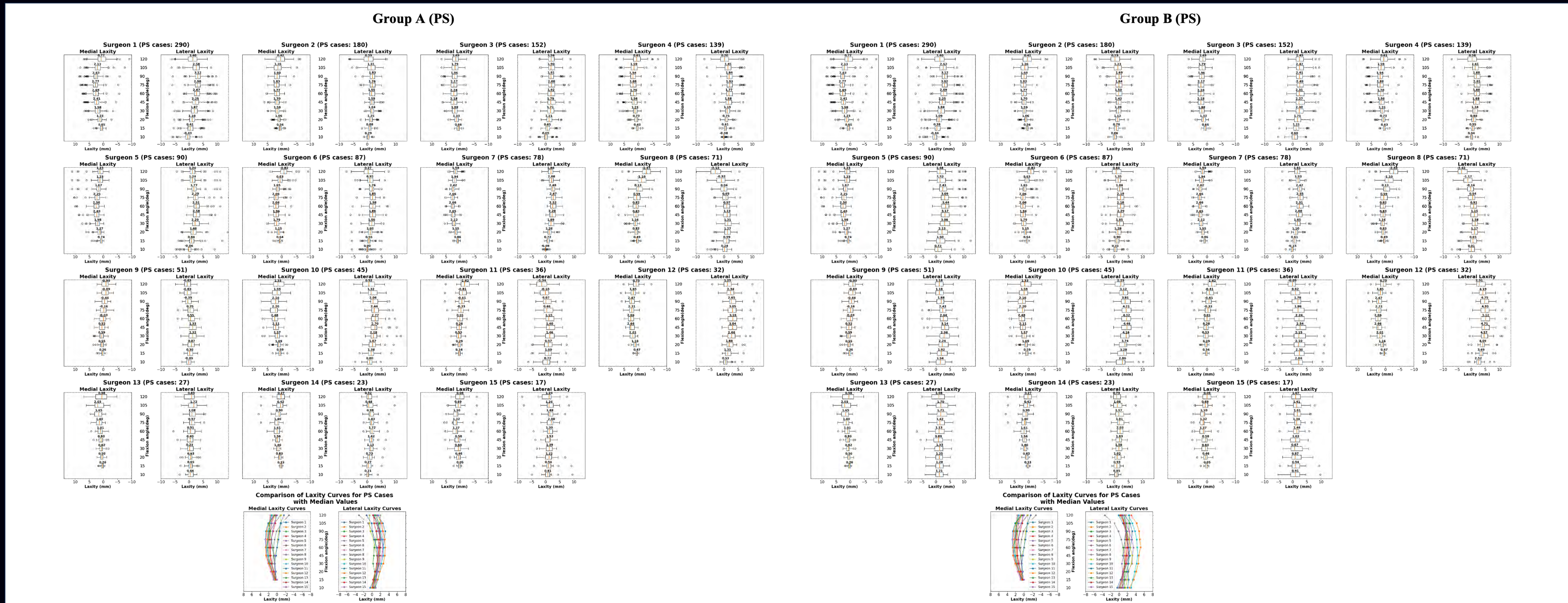

Figure 1: Box and whisker plots for 15 PS surgeons: Group A (left) and Group B (right)

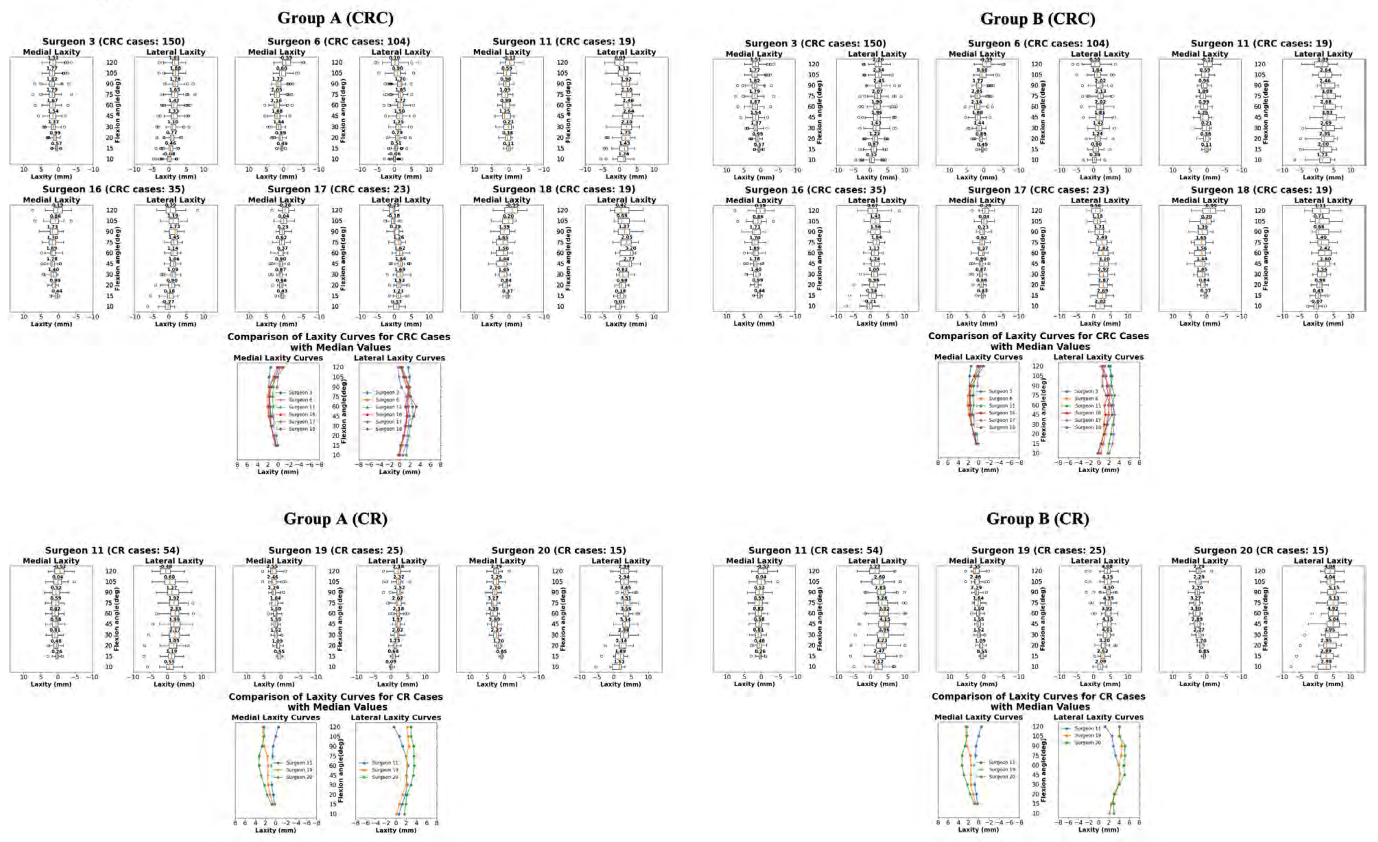

Figure 2: Box and whisker plots for 6 CRC surgeons and 3 CR surgeons: CRC Group A (top left), CRC Group B (top right), CR Group A (bottom left), and CR Grpup B (bottom right)

Laxity	Number of surgeons*	Type of bearing	Number of cases	Total number of comparisons	Number of comparisons (p<0.05)	% comparisons (p<0.05)
Medial laxity (Group A & B)	15	PS	1318	105	77	73.3%
Lateral laxity (Group A)	15	PS	1318	105	76	72.4%
Lateral laxity (Group B)	15	PS	1318	105	75	71.4%
Medial laxity (Group A & B)	6	CRC	350	15	10	66.7%
Lateral laxity (Group A)	6	CRC	350	15	7	46.7%
Lateral laxity (Group B)	6	CRC	350	15	12	80%
Medial laxity (Group A & B)	3	CR	94	3	3	100%
Lateral laxity (Group A)	3	CR	94	3	2	66.7%
Lateral laxity (Group B)	3	CR	94	3	2	66.7%

*: Some surgeons were considered hybrid (i.e., used more than 1 type of bearing), explaining the sum being more than 20

Table 1: Tukey multiple comparisons comparing pairwise laxity differences between 15 surgeons (PS), 6 surgeons (CR), and 3 surgeons (CR)

Discussion & Conclusions

There is wide variability among surgeons in defining laxities, with preferences ranging from rectangular gaps to trapezoidal gaps or greater flexion gaps than extension. Regardless of the tibial reference, laxity definition for femoral cutting planning tends to be surgeon specific. It is noteworthy that most of the surgeons in this study tend to prefer a tibial cut referenced to the mechanical axis or with limited obliquity, which reduces the difference between the two groups. The precise laxity required in TKA is yet to be determined[1]. Even though our study only considered cases using the same knee system and the same surgical technique, the laxity goals were found to be surgeon specific. As recent studies suggest that laxity as small as 2 mm may impact the outcomes[2-3], there exists an opportunity to develop solutions to further define the optimal laxity for a given patient. As knee arthroplasty customization progresses, there is an opportunity to define patient-specific laxities.

This study highlights the significant variability in ligament laxity definitions among surgeons during femoral planning in TKA, regardless of tibia cut choice and bearing type. It emphasizes the need for patient-specific laxity guidelines to enhance surgical outcomes.

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Evaluating Intraoperative Dynamic Hip-Knee-Ankle (dHKA) Angle Under Controlled Load During Navigated Total Knee Arthroplasty

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Introduction

Traditional knee alignment classification into neutral, varus, and valgus categories is often considered as overly simplistic and overlooking individual morphological differences. Growing interest in personalized alignment techniques, such as kinematic alignment (KA) and functional alignment (FA), has led to the development of more nuanced radiological classifications. However, these classifications[1,2], based on static, double-leg weight-bearing radiographs, do not account for dynamic changes in hip-knee-ankle (HKA) angle during the gait cycle. Preoperative technologies like motion capture systems and wearable sensors measure dynamic HKA (dHKA), but these measurements often differ from intraoperative readings obtained through computer-assisted orthopedic systems (CAOS) due to variations in technology and data acquisition. This discrepancy highlights the need for an intraoperative dynamic assessment system capable of monitoring knee alignment across the range of motion, enabling more precise, patient-specific surgical planning. Conventional intraoperative dHKA acquisition relies on manually manipulating the leg from extension to flexion in perceived neutral alignment. This study presents a novel dHKA acquisition method that uses an intra-articular tensioner to apply a quasi-constant distraction force through the knee's full range of motion, stabilizing the joint and therefore facilitating neutral alignment. The objective of this study is to compare conventional and proposed dHKA acquisition methods in tibia-first total knee arthroplasty (TKA) using CAOS.

Methods

This retrospective review utilized a proprietary cloud-based database that archives technical logs from an instrumented CAOS. A total of 1790 cases performed by 87 surgeons were included, with no exclusions. The tibia-first surgical workflow is outlined in Figure 1. After tracking arrays are attached to the femur and tibia, anatomical landmarks are acquired using imageless CAOS (Figure 1A). The knee is manipulated through its flexion arc (flexion 0° to flexion 120°), while CAOS captures dHKA to assess deformity and kinematics, including VV angles at distinct flexion angles (Figure 1B: pre-tibia cut kinematics). Proximal tibia resection is performed based on surgeon preferences for thickness, varus/valgus, and posterior slope (Figure 1C). The intra-articular device (Newton) is placed between the tibia cut and femur, applying a distraction force. This device maintains a consistent distraction force across compartments. The knee medial and lateral gaps, along with dHKA, are obtained (Figure 1D: pre-femoral cut Newton). These measurements guide femoral resection planning based on soft tissue balance, alignment, and sizing (Figure 1E). After femoral cuts, a trial component is placed (Figure 1F), and the intra-articular device is reinserted. The knee is flexed, and the trial component's position relative to the tibia cut is captured by CAOS to provide final gap measurements and dHKA (Figure 1G: post-femoral cut Newton). The second set of joint gaps (checked gaps) is compared with the planned gaps (Figure 1H). Finally, post-femoral cut kinematics and dHKA are captured (Figure 1I: post-femoral cut kinematics), and the selected implant parameters are displayed (Figure 1J). Differences in pre-cut dHKA between pre-tibia cut kinematics (conventional) and pre-femoral cut Newton (proposed) are calculated, as well as post-cut dHKA differences between conventional post-femoral cut kinematics and proposed post-femoral cut Newton measurements.

Results

The difference in dHKA for full flexion (from flexion 0° to 120°) between conventional and proposed methods was calculated for both the precut and postcut phases. The mean, 5th percentile, 25th percentile, 50th percentile, 75th percentile, and 95th percentile for dHKA differences across 1790 cases is presented in Figure 2. As shown in Figure 2A, the precut kinematics tend to apply a slight greater varus compared to the precut Newton method. In contrast, for postcut (Figure 2B), both methods show similar alignment in extension; however, postcut kinematics result in slightly more valgus compared to the postcut Newton method. Overall, the differential curves remain relatively flat, although there exists slight difference, which suggests that the overall signature between the two acquisitions is consistent.

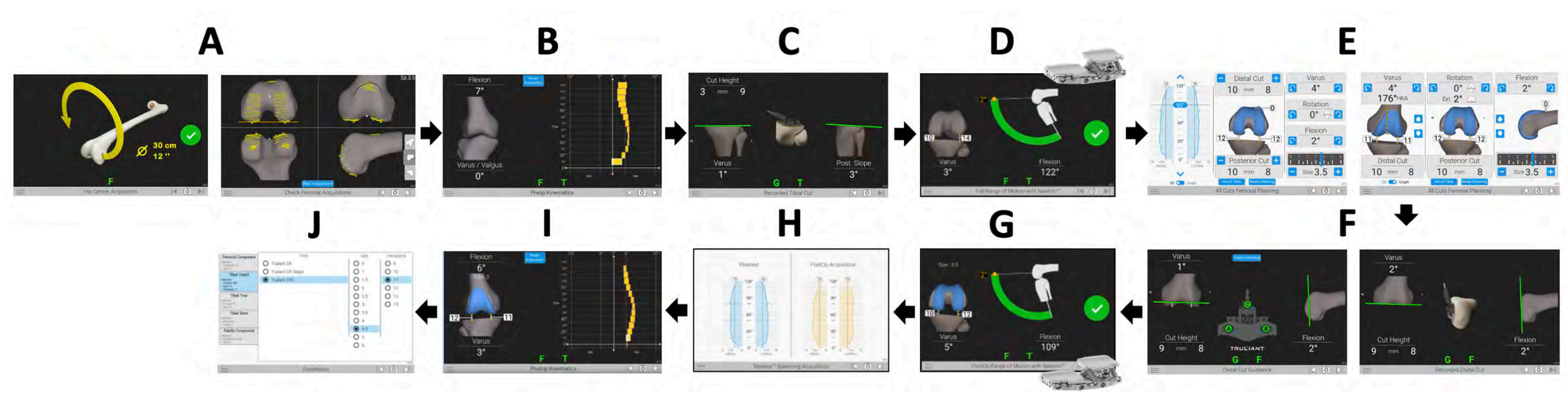

Figure 1: Tibia First Workflow with Newton and Exactech GPS (CAOS)

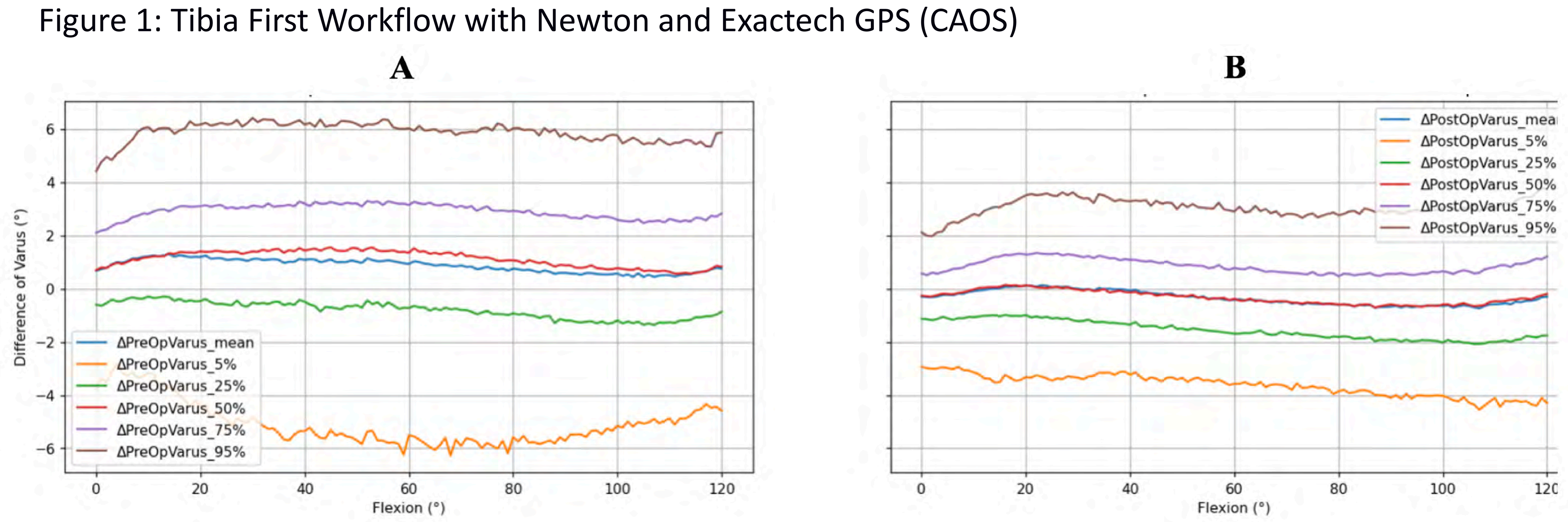

Figure 2: the mean and percentile differential curves for A) precut: pre-tibia cut kinematics dHKA and pre-femoral cut Newton dHKA and B) postcut: post-femoral cut kinematics and post-cut Newton acquisitions

Discussion & Conclusions

The flatter dHKA differential between kinematics and Newton acquisitions for full flexion arc suggest that Newton acquisitions could serve as reliable surrogates for conventional kinematics acquisitions methods. Moreover, the application of intra-articular distractor improves the stability for dynamic acquisition throughout the full flexion arc, enabling neutral manipulation. It is previously reported that Newton platform with CAOS reliably captures laxity acquisitions for TKA[3]. Acquiring both dHKA along with laxity data both precut and postcut, helps surgeons to better plan and execute bone cuts targeting personalized alignment techniques. The next step forward is to utilize the dHKA data from Newton acquisitions to develop models providing dynamic knee phenotypes. These phenotypes will enable a more comprehensive classification of alignment and dynamic movement behaviors, supporting personalized alignment strategies tailored to each patient's unique biomechanics.

The significance of this work lies in introducing an intraoperative method for assessing dynamic knee alignment using a novel distraction force technique, offering more precise alignment measurements during total knee arthroplasty.

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The Relationship Between Patient Demographics, Anatomic Humeral Measurements, and Placement of a Locking Plate that Achieves Recommended Screw Fixation in the Treatment of Proximal Humerus Fractures

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1. Exactech Inc., Gainesville, FL

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Introduction

- For displaced and complex proximal humerus fractures, open reduction internal fixation (ORIF) with plates is one of the pervading modalities of surgical treatments
- Studies have shown the pivotal role of the medial support with calcar screws in improving fixation
- The calcar screw, however, is commonly misplaced when using fixed angle plates

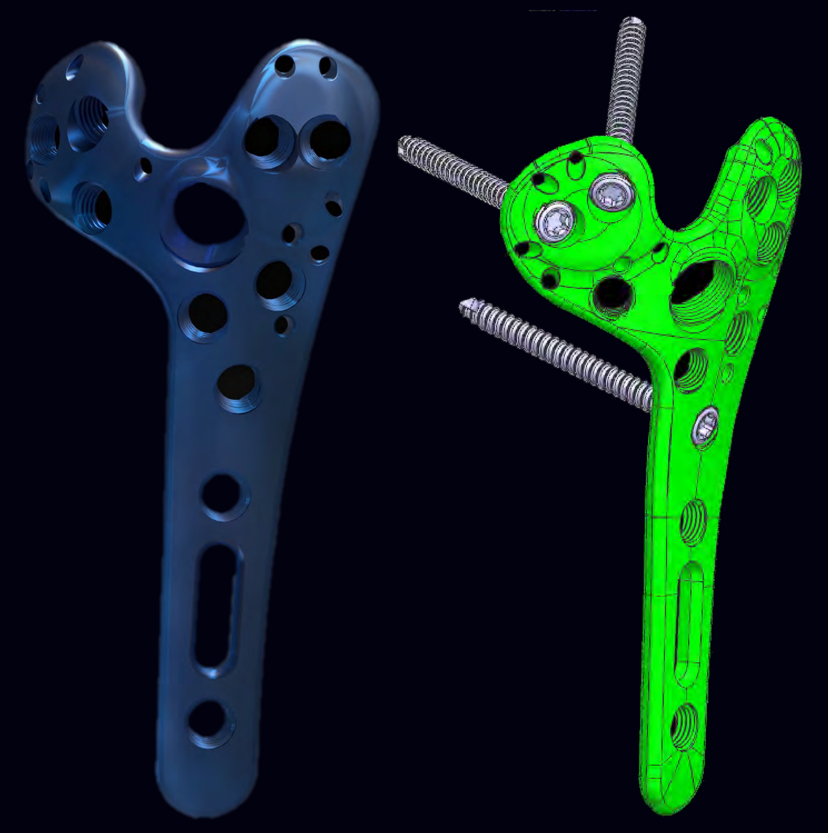


Figure 1. Proximal humerus fracture locking plate (Equinoxe PHx Victory Plate; Exactech Inc.) (left) and two screws on lesser tuberosity branch and calcar screw (right)

Objective

- Develop a reliable methodology for guiding plate placement that achieves satisfactory calcar (and central, if applicable) screw placement(s) across a wide range of humeral anatomies

Methods

- Thirty cadaveric humeri were virtually implanted with a proximal humerus fracture locking plate (Equinoxe PHx Victory Plate)
- Implantation constraints/assumptions driving final plate placement:
  1. Small plates for females and large plates for males
  2. Central screw passes through center of rotation
  3. Designated screw reaches calcar region
  4. Bicipital groove sits between two superior screws on lesser tuberosity branch of plate
- Post-implantation, distances between the top of the plate and landmarks of interest were measured in the AP view (see Figure 2 for definitions)
- Demographics were compared between the males and females using Welch's t-test, with significance set at $p < 0.05$
- Pearson correlations between demographics/anatomic variables and plate placement variables were calculated, with linear regressions for the strongest correlations (>0.8)

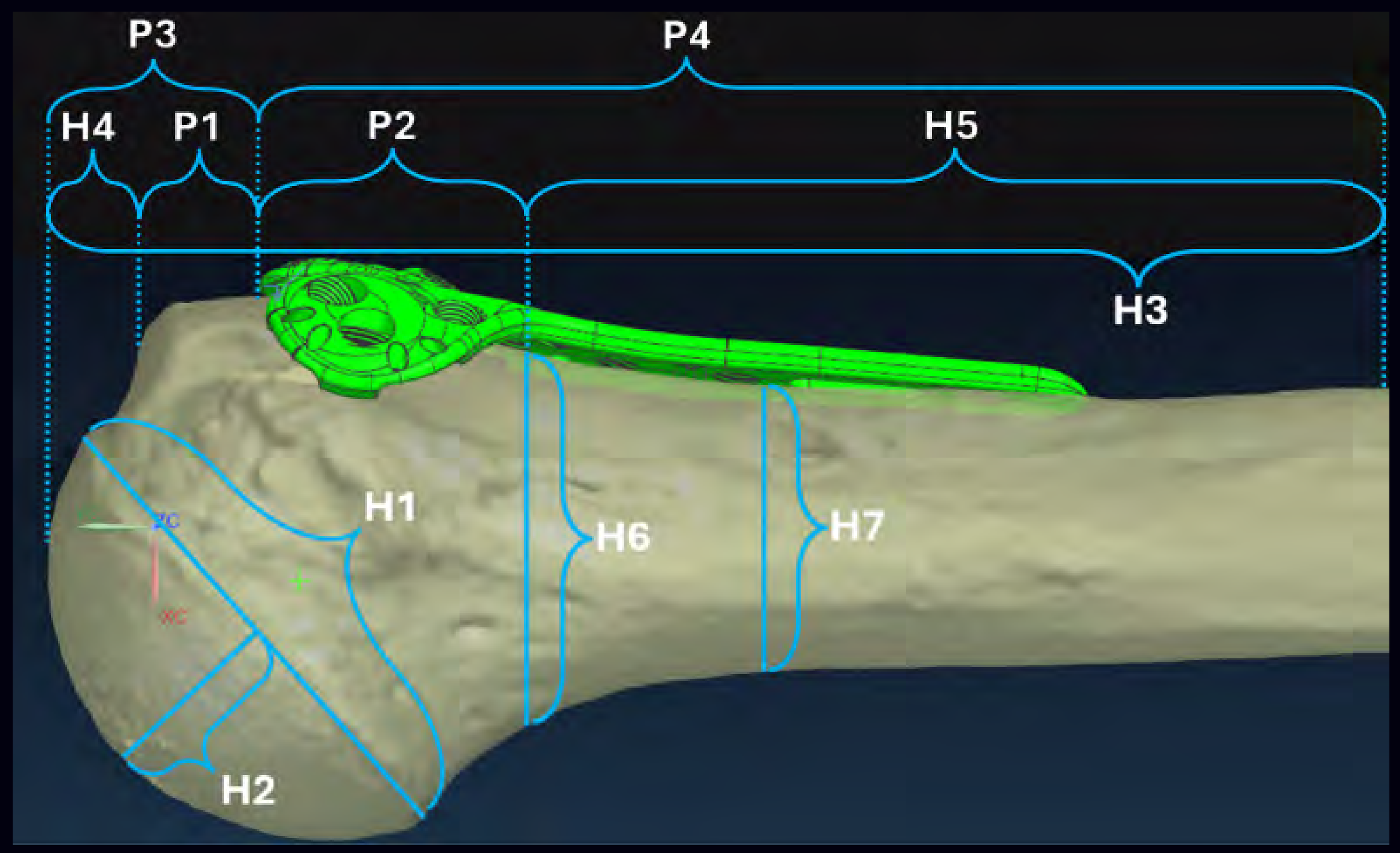
Results

- Thirty cadaveric specimens (15 males and 15 females), with an average age, height, weight, and BMI of 78 years, 169 cm, 64 kg, and 23, respectively, were included in this study
- No significant differences in demographics between males and females, except for height (176cm vs. 161cm, p=0.011)

Figure 2. Anatomic (H) and plate placement (P) variable definitions:

H1 –Humeral Head (HH) diameter
H2 – HH thickness
H3 – HH to Deltoid Tuberosity (DT)
H4 – HH to Greater Tuberosity (GT)
H5 – Surgical Neck (SN) to DT
H6 – SN diameter
H7 – Diaphyseal diameter at halfway point between HH and DT

P1 – GT to Plate
P2 – Plate to SN
P3 – HH to Plate
P4 – Plate to DT



- Strongest correlations between (Table 1 and Table 2):
  - P4 to H5 (R=0.98, p-value<0.001)
  - P4 to H3 (R=0.95, p-value<0.001)
  - P3 to H7 (R=0.91, p-value<0.001)
  - P3 to H1 (R=0.90, p-value<0.001)
- Other notable pairs (Table 1):
  - P3 to H2 (R=0.79, p-value<0.001)
  - P3 to sex (R=-0.78, p-value<0.001)
  - P3 to H6 (R=0.73, p-value<0.001)

Table 1. Pearson correlation coefficients between pairs of anatomic and plate placement variables

		Anatomic Variables											
		Sex	Age	Height	Weight	BMI	H1	H2	H3	H4	H5	H6	H7
Plate Placement Variables	P1	-0.71	-0.22	0.61	0.25	-0.25	0.72	0.61	0.42	-0.20	0.09	0.47	0.68
	P2	-0.31	0.16	0.08	-0.09	-0.08	0.42	0.40	-0.15	-0.20	-0.47	-0.30	0.11
	P3	-0.78	-0.38	0.52	0.53	0.03	***0.90***	0.79	0.63	0.49	0.27	0.73	***0.91***
	P4	-0.29	-0.25	0.30	0.53	0.14	0.28	0.31	***0.95***	0.26	***0.98***	0.60	0.32

Table 2. Linear regression model summaries for strongest pairs of anatomic and plate placement variables

Variables	Regression Equation	Standard Error	R-sq	p-value
P4 to H5	P4(mm) = 37.15 + 0.9041 H5(mm)	1.81703	96.09%	**<0.001**
P4 to H3	P4(mm) = 13.26 + 0.7821 H3(mm)	2.98927	89.43%	**<0.001**
P3 to H7	P3(mm) = - 6.890 + 0.9915 H7(mm)	1.63374	81.97%	**<0.001**
P3 to H1	P3(mm) = - 20.82 + 0.8089 H1(mm)	1.70248	80.42%	**<0.001**

Discussion & Significance

- Surgeons typically aim to position the plate relative to the top of the humeral head (P3) or greater tuberosity (P1), and although this study did find strong correlations between those plate placement variables and anatomic measurements, there were stronger correlations between other pairs
- There exists a tradeoff between model accuracy and practicality of anatomic landmarks involved
- Highest correlations occurred when using the DT as a reference landmark (i.e., P4 to H5; P4 to H3), but that landmark may not be as accessible as other, more proximal landmarks
- On the other hand, using the top of the HH as a reference landmark also resulted in high correlations (i.e., P3 to H7; P3 to H1), but the complexity of fracture and quality of provisional reduction could impact final plate placement
- Considering the surgical workflow, there were other correlations that, albeit weaker, may still be relevant (i.e., P3 to sex; P3 to H6)
  - Using patient sex or SN diameter to determine plate placement as a function of the distance between the plate and the top of the HH may help streamline the surgical workflow, as they are known, can be measured on pre- or intra-operative imaging, or can be translated to physical intra-operative measurements
- Limitations of this study include:
  - Relatively small sample size
  - Lack of consideration for other rationales on implantation methods that prioritize different constraints (e.g., best fit for tuberosities, avoid impingement with acromion during elevation, etc.)
  - Usage of intact humeri, as opposed to fractured humeri (fracture complexity/ provisional reduction could impact the distance measurements)

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Comparing Utilization and Clinical Outcomes for a Reverse Total Shoulder Arthroplasty System with Different Baseplate Designs

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Introduction

- **Reverse total shoulder arthroplasty (rTSA) is increasingly selected as the treatment of choice for end-stage degenerative shoulder conditions**
- **Numerous designs offered to accommodate varying anatomy, morphology, and wear/ deformity patterns**
- **Lack of research on how one design is selected over another**

Objective

- **Compare demographics, clinical/radiographic outcomes, and complication/revision rates of patients with small-size versus standard-size rTSA baseplate**

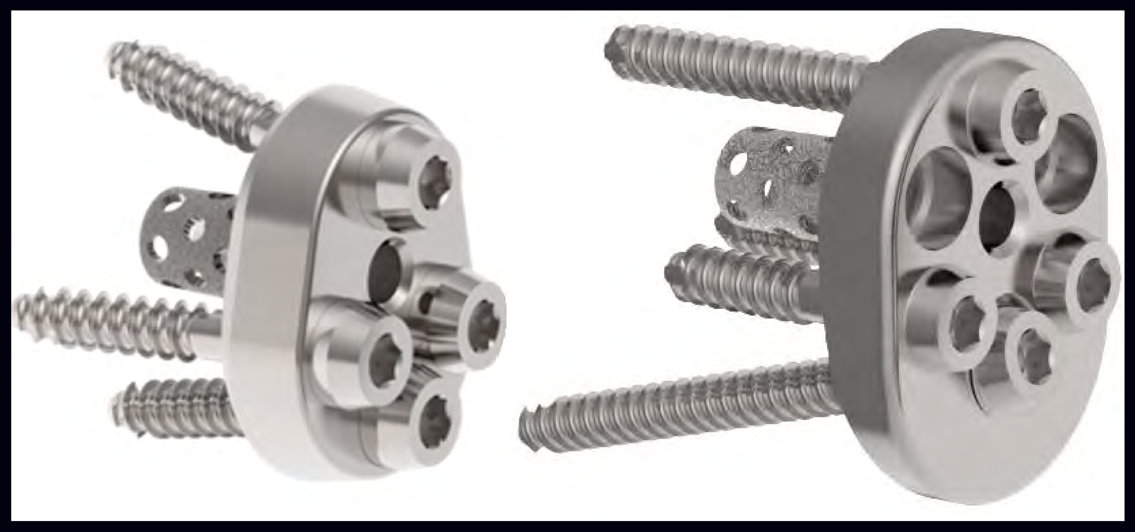

Figure 1. Small- (left) and standard- (right) size baseplates (Equinoxe; Exactech, Inc.)

Methods

- **Retrospectively reviewed prospectively collected patient data in IRB-approved, international, multicenter database for a single platform shoulder system (Equinoxe; Exactech, Inc.)**
- **Inclusion:**
  - **Primary rTSA with either small- or standard-size baseplate**
  - **Surgery after December of 2018 (both products available)**
  - **2-year minimum follow-up**
- **Exclusion:**
  - **Revision, fracture, and infection indications**
- **Compared rTSA baseplate utilization and clinical/radiographic outcomes of standard-size and small-size baseplate cohorts:**
  - **Demographics**
  - **Range of motion (ROM): abduction, forward elevation, internal rotation (IR) score, and external rotation**
  - **Patient reported outcome measures (PROMs): Constant-Murley, ASES, and Shoulder Arthroplasty Smart (SAS)**
  - **Complication/revision rates, scapular notching rates**
- **Statistical analyses: Welch's t-test or Fisher's exact test**

Results

- **1,670 rTSA patients included in analysis: 568 in Small rTSA group / 1,102 in Standard rTSA group**

<u>Demographics:</u> Small rTSA group had more females (91.0% vs. 37.8%, p<0.0001); no differences in average age or BMI

<u>Clinical Outcomes for Overall (Table 1):</u>

- **Average follow-up of 32.4 ± 8.9 months and 35.0 ± 11.0 months for Small and Standard rTSA groups, respectively**
- **Pre-operative: Small rTSA group had lower IR and universally lower PROMs**
- **Post-operative (2 yr min): Small rTSA group had lower ASES**
- **Improvement: Small rTSA group had greater improvements in IR and Constant, likely as a result of pre-operative differences**

<u>Radiographic Outcomes and Complication/Revision Rates for Overall:</u>

- **Small rTSA group had higher scapular notching rate (13.0% vs. 6.2%, p<0.0001); no differences in complication/revision rates (1.9% / 0.9% for Small rTSA vs. 2.5% / 1.5% for Standard rTSA)**

<u>Clinical Outcomes for Females (Table 2):</u>

- **Average follow-up of 32.4 ± 8.9 months and 35.3 ± 11.5 months for Small and Standard rTSA groups, respectively**
- **Pre-operative: Small rTSA group had greater abduction and forward elevation**
- **Post-operative (2 yr min): Small rTSA group had lower IR**
- **Improvement: No differences**

<u>Radiographic Outcomes and Complication/Revision Rates for Females:</u>

- **Small rTSA group had higher scapular notching rate (13.7% vs. 5.0%, p<0.0001); no differences in complication/ revision rates (1.9% / 1.0% for small rTSA vs. 1.9% / 1.0% for Standard rTSA)**

<u>Clinical Outcomes for Males (Table 3):</u>

- **Average follow-up of 33.1 ± 9.0 months and 34.9 ± 10.7 months for Small and Standard rTSA groups, respectively**
- **No differences in any ROM or PROMs for all timepoints**

<u>Radiographic Outcomes and Complication/Revision Rates for Males:</u>

- **No differences in scapular notching rates (5.9% for Small rTSA vs. 6.9% for Standard rTSA); no differences in complication/ revision rates (2.0% / 0.0% for Small rTSA vs. 2.9% / 1.9% for Standard rTSA)**

Table 1. Comparison of rTSA Clinical Outcomes for All Patients with Small-Size and Standard-Size rTSA Glenoid Designs

Timepoint	rTSA Design Cohort	Abduction	Forward Elevation	IR Score	Ext. Rotation	Constant	ASES	SAS
Pre-op	Small	90.6±43.8	100.5±43.7	2.9±1.9	26.8±21.4	35.0±15.1	37.3±16.6	47.8±13.9
	Standard	89.8±40.9	98.8±40.6	3.2±1.8	25.7±20.7	39.8±15.2	39.9±16.0	49.3±12.4
	P Value	0.7191	0.4533	**0.006**	0.3308	**<0.0001**	**0.0037**	**0.045**
Post-op (2 yr min)	Small	133.8±33.7	145.5±28.6	3.8±1.6	41.0±16.8	64.9±15.2	82.5±18.1	74.0±12.0
	Standard	136.5±30.6	145.3±26.6	3.8±1.7	41.5±17.4	67.1±14.4	84.6±17.7	74.9±11.8
	P Value	0.1354	0.8814	0.4043	0.5878	0.0502	**0.0251**	0.2195
Improve	Small	46.0±43.9	46.3±41.6	0.9±2.2	14.4±22.6	30.6±18.0	44.9±22.0	26.1±16.4
	Standard	47.9±43.3	46.1±41.2	0.6±2.0	15.7±21.2	26.5±18.2	44.6±21.8	25.3±15.0
	P Value	0.4512	0.9445	**0.0085**	0.3156	**0.0126**	0.8155	0.4623

Table 2. Comparison of rTSA Clinical Outcomes for Female Patients with Small-Size and Standard-Size rTSA Glenoid Designs

Timepoint	rTSA Design Cohort	Abduction	Forward Elevation	IR Score	Ext. Rotation	Constant	ASES	SAS
Pre-op	Small	89.6±43.4	99.3±43.4	2.9±1.9	26.2±21.2	34.8±15.0	36.7±16.6	47.3±13.9
	Standard	83.5±37.3	92.1±36.1	3.0±1.9	25.6±18.9	35.4±13.7	35.2±14.8	46.4±11.6
	P Value	**0.0256**	**0.0067**	0.2039	0.6686	0.6323	0.1472	0.3240
Post-op (2 yr min)	Small	133.8±33.7	145.5±28.7	3.8±1.6	41.2±16.8	64.6±15.2	82.6±18.1	74.2±12.2
	Standard	131.7±32.6	141.5±29.1	4.2±1.8	43.6±18.4	63.4±14.7	83.0±18.2	74.6±13.3
	P Value	0.3839	0.0581	**0.0013**	0.0686	0.4158	0.7393	0.6565
Improve	Small	46.7±44.1	47.0±41.8	1.0±2.2	15.1±22.0	30.4±18.0	45.5±22.1	26.5±16.4
	Standard	49.5±41.0	48.8±38.8	1.0±2.1	17.4±22.0	26.6±19.0	47.3±22.0	27.4±15.4
	P Value	0.3808	0.5297	0.8528	0.1593	0.0621	0.2325	0.4727

Table 3. Comparison of rTSA Clinical Outcomes for Male Patients with Small-Size and Standard-Size rTSA Glenoid Designs

Timepoint	rTSA Design Cohort	Abduction	Forward Elevation	IR Score	Ext. Rotation	Constant	ASES	SAS
Pre-op	Small	101.8±46.9	113.7±45.8	3.5±1.9	32.7±23.0	38.0±16.0	42.9±15.8	53.2±13.1
	Standard	93.6±42.4	102.9±42.6	3.3±1.8	25.7±21.8	43.2±15.5	42.8±16.0	51.1±12.5
	P Value	0.2508	0.1252	0.4633	0.0501	0.2224	0.9462	0.2989
Post-op (2 yr min)	Small	133.3±34.1	146.0±27.7	3.5±1.4	37.9±16.0	69.2±15.3	81.2±17.7	72.5±9.4
	Standard	139.3±29.0	147.4±24.9	3.6±1.6	40.3±16.7	69.0±13.8	85.5±17.4	75.1±10.9
	P Value	0.2987	0.7585	0.5596	0.3825	0.9614	0.0996	0.1315
Improve	Small	37.1±41.6	37.6±38.6	0.1±2.1	5.9±28.5	32.3±18.2	38.6±19.7	20.3±14.7
	Standard	47.0±44.6	44.6±42.5	0.4±1.9	14.7±20.7	26.4±17.6	42.9±21.5	24.1±14.7
	P Value	0.1892	0.3179	0.5088	0.0845	0.2971	0.1758	0.1892

Discussion & Significance

- **This large-scale clinical outcome study of 1,670 rTSA patients demonstrated that both Small and Standard rTSA glenoid designs achieved positive outcomes and low revision rates at a 2-year minimum follow-up**
- **Post-op, the only outcome measures that differed were ASES in overall and IR in females, but the differences were small (lower than associated MCID)**
- **Limitations:**
  - **Retrospective database analysis of patients from multiple clinical sites introduces variability in technique and implant selection**
  - **2-year minimum clinical results were analyzed, where longer term follow-up is necessary to determine if results are maintained**

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Sensitivity Analysis Quantifying the Impact of Processing Parameters on Radiomic Feature Extraction Across Different CT Image Acquisition Parameters

[1]Rajabzadeh-Orgaz H, [1]Elwell J, [1]Kumar V , [1]Roche C

1. Exactech, Inc.

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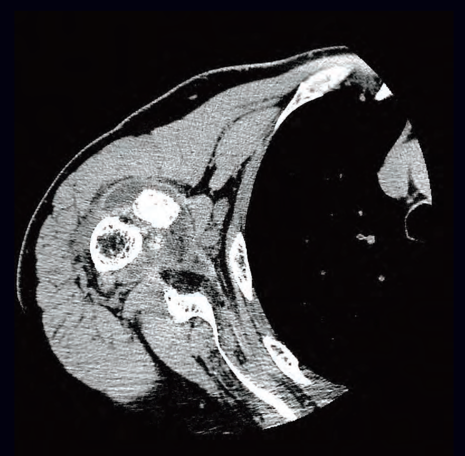
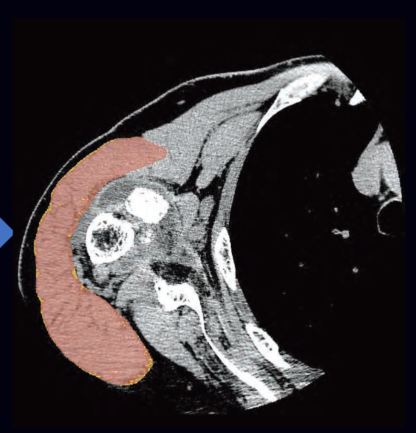
Introduction



CT Scan

AI



3D Segmentation

RADIOMICS

SHAPE
ex: sphericity, flatness, volume

FIRST-ORDER
intensity-based
ex: mean HU, max HU, min HU

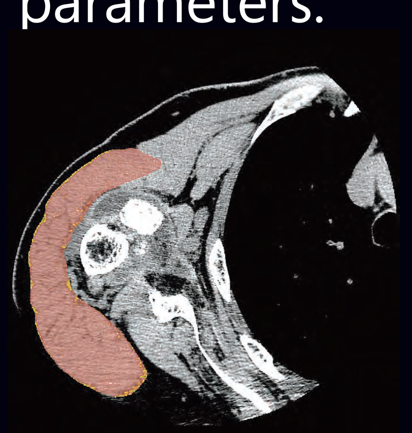
SECOND-ORDER
texture-based
ex: gray uniformity, entropy

Quantification

Radiomics transforms image data into numerical representations that can characterize a patient's 3D anatomy. However, these measurements are impacted by image acquisition & processing parameters.

Methods

This study analyzes pre-operative images of deltoid muscle in shoulder joint CT scans to identify radiomic features that are stable, robust, and non-redundant across a range of image acquisition/processing parameters.



3D Segmentation

PRE-PROCESSING

Normalization
Resampling
Discretization
Correlation

Analysis

RADIOMICS

SHAPE
ex: sphericity, flatness, volume

FIRST-ORDER
intensity-based
ex: mean HU, max HU, min HU

SECOND-ORDER
texture-based
ex: gray uniformity, entropy

Robust/Non-redundant Quantification

1000 pre-operative CT images of the shoulder from a multicenter database (Exactech, Inc; Gainesville, FL). All CT images were acquired using same imaging protocol with slice itchiness of 0.3 – 1.25 mm.

Top 6 CT image kernels: 40% Bone, 25% FC30, 19% Boneplus, 6% Standard, 5% I31s,3, and 5% B60s.

Normalization adjusts image gray-level intensity values.

Resampling adjusts image resolution to a standard voxel size.

Discretization converts continuous range of intensity values into fixed bins.

Correlation identifies set of redundant radiomic measurements.

PyRadiomics (v3.0.01) was used to extract standard radiomic features.

107 distinct radiomic features were identified **14** SHAPE features, **18** FIRST-ORDER features, and **75** SECOND-ORDER features.

Test of robustness and correlation was conducted using Intra-class correlation (ICC) and pearson's correlation respectively.

Results

	Standard	Robust (ICC<0.9)	Non-redundant (R>0.9) - %reduced
SHAPE (ex: sphericity, flatness, volume)	14	14	10 (71.4%)
FIRST-ORDER intensity-based (ex: mean HU, max HU, min HU)	18	16	8 (44.%)
SECOND-ORDER texture-based (ex: gray uniformity, entropy)	75	57	19 (25.3%)
TOTAL:	107	87	37

The table (on the right) shows the 37 of 107 standard radiomic features that were identified to be robust, stable, and unique & non-redundant across various image acquisition/processing parameters.

Discussion & Conclusions

The results of this sensitivity analysis demonstrate that our ML framework and image processing techniques can successfully segment and analyze standard of care pre-operative CT images, acquired using multiple scanners/imaging protocols, to generate robust, stable, and unique radiomic features of the deltoid muscle.

SHAPE features were least impacted by image processing parameters; whereas, SECOND-ORDER texture features were most impacted by variations in image processing. Future work is required to identify features that are clinically relevant and useful for predicting clinical outcomes after shoulder surgery.

Robust Deltoid Radiomic Feature	Radiomic Feature Type	ICC
Elongation	Shape	1.0
Flatness	Shape	1.0
Least Axis Length	Shape	1.0
Major Axis Length	Shape	1.0
Max 2D Diameter, Column	Shape	1.0
Max 2D Diameter, Row	Shape	1.0
Max 2D Diameter, Slice	Shape	1.0
Mesh Volume	Shape	1.0
Sphericity	Shape	1.0
Surface to Volume Ratio	Shape	1.0
10th Percentile	First-Order	1.0
Entropy	First-Order	0.99
Interquartile Range	First-Order	1.0
Kurtosis	First-Order	0.98
Maximum	First-Order	1.0
Mean	First-Order	1.0
Minimum	First-Order	0.99
Skewness	First-Order	0.99
glcm Autocorrelation	Second-Order	0.92
glcm Cluster Tendency	Second-Order	0.92
glcm Contrast	Second-Order	0.91
glcm Correlation	Second-Order	0.99
glcm Id	Second-Order	0.99
glcm Joint Energy	Second-Order	0.96
glcm MCC	Second-Order	0.98
glcm Sum Entropy	Second-Order	0.99
gldm Dependence Entropy	Second-Order	0.99
gldm Large Dependence High Gray Level Emphasis	Second-Order	0.97
gldm Large Dependence Low Gray Level Emphasis	Second-Order	0.93
gldm Low Gray Level Emphasis	Second-Order	0.96
gldm Small Dependence Low Gray Level Emphasis	Second-Order	0.95
glrlm Run Entropy	Second-Order	0.97
glszm Gray Level NonUniformity Normalized	Second-Order	0.97
glszm Gray Level Variance	Second-Order	0.95
glszm Size Zone NonUniformity Normalized	Second-Order	0.94
ngtdm Coarseness	Second-Order	0.91
ngtdm Strength	Second-Order	0.92

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Navigated Instrumentation Improves Reproducibility Of Laxity Acquisition During A Total Knee Arthroplasty

Laurent Angibaud[1], François Boux de Casson[2], Florian Kerveillant[2], Leonard Duporte[3], Gerard Giordano[4], Louis Dagneaux[3]
[1]Exactech, Gainesville, FL, USA, [2]Blue-Ortho, Meylan, FR, [3]Montpellier University Hospital, Montpellier, FR,
[4]Joseph Ducuing Hospital, Toulouse, FR

2025 ORTHOPAEDIC RESEARCH SOCIETY

Introduction

In total knee arthroplasty (TKA), laxity assessment is crucial for joint balance and bone cut planning, but its reproducibility and reliability may vary with the acquisition method and operator experience. This experimental study compares laxity measurements reproducibility between two acquisition methods.

Methods

Five operators (3 senior and 2 junior surgeons) measured laxity during navigated TKA with a poster stabilized prosthesis. This study included 8 knees (4 cadaveric specimens). Each operator assessed knee joint laxity through the full flexion arc, first manually manipulating the limb in varus and valgus, then using an instrumented method with a distractor inserted between the tibial cut and the native femur, repeating the process six times per knee. Reproducibility of measurements was evaluated via inter-operator and intra-operator intra-class correlation coefficients (ICC), varying with method and operator experience.

Results

The four female specimens, aged 79 to 96 (mean 90±7.9), comprised two with valgus, one with varus, and one neutral. A total of 960 gap acquisitions were recorded with the CAOS system to evaluate both techniques across the motion arc. The instrumented method had a significantly greater inter-operator ICC than the manual method for the lateral laxity (0.92 versus 0.25; p<0.0001) [Fig 1] and the medial laxity (0.87 versus 0.60; p=0.02) [Table 1]. For the manual method, the lateral laxity acquired under varus stress was less reproducible than the medial laxity acquired under valgus stress (0.25 versus 0.60; p=0.01), while the instrumented method showed no difference (0.92 versus 0.87; p=0.8) between the two compartments. For both manual and with the distractor, the seniors had better inter-operator ICCs than the juniors, although this was not significant (manually 0.55 versus 0.39; p=0.1, with the distractor 0.92 versus 0.90, p=0.3). The intra-operator ICC was significantly higher with the instrumented method than with the manual method for laxity assessment in all tests (0.78 versus 0.51; p<0.0001) and for the lateral compartment (0.84 versus 0.40; p<0.0001), but not for the medial compartment (0.71 versus 0.63; p=0.07).

Discussion & Conclusions

The instrumented method, with an intra-articular distractor, improved knee laxity acquisition reproducibility, minimizing the impact of experience and acquisition challenges inherent in maintaining varus force during flexion compared to the manual method. The controlled force application by the distractor, along with its ease of use in the neutral position, could contribute to gap acquisition reproducibility. Using a distraction device with navigation enhanced knee laxity measurement reproducibility compared to manual varus/valgus acquisitions.

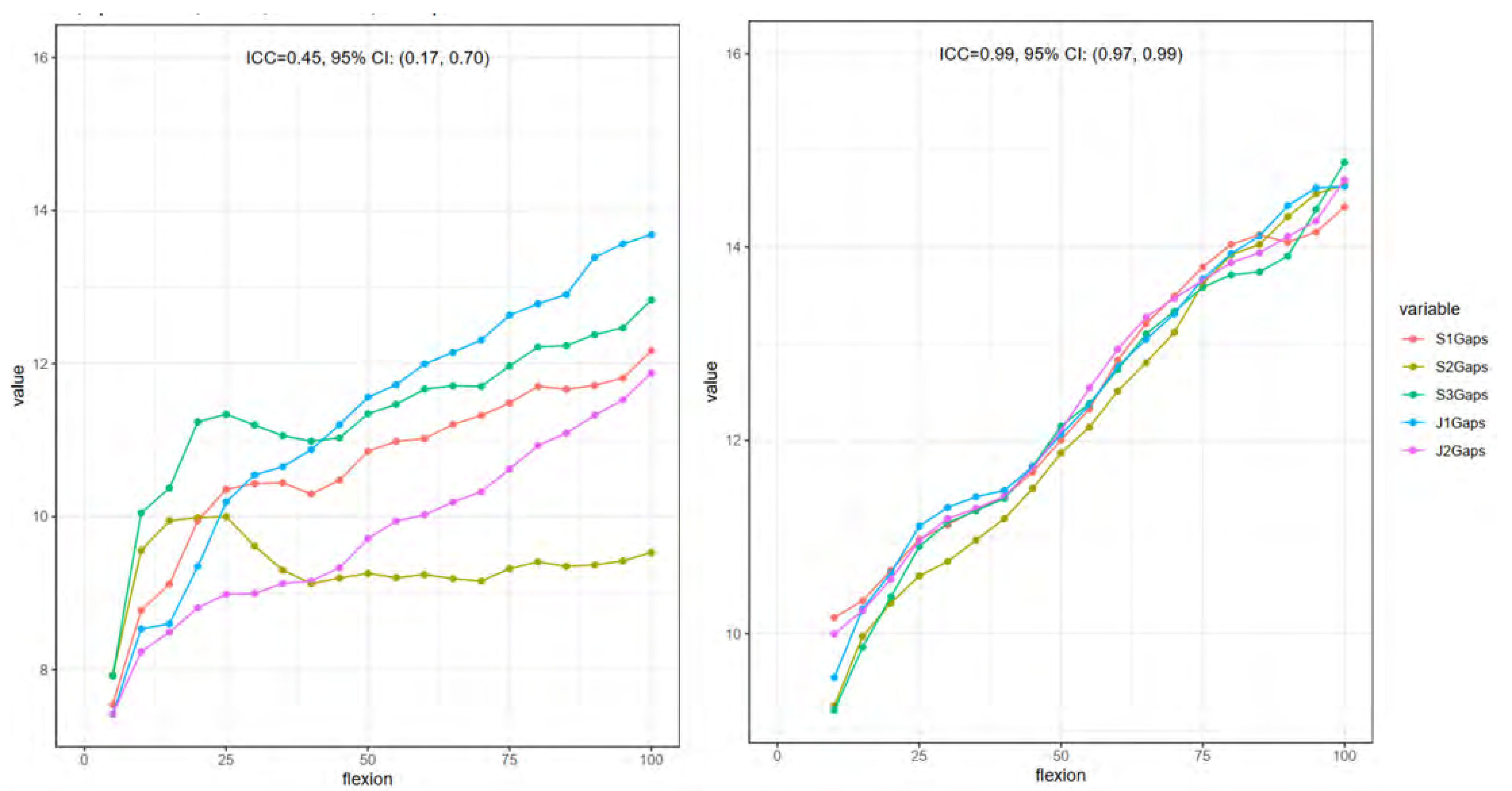

Figure 1: Lateral compartment gaps measured by the manual method (left) and the instrumented method for specimen #4, left knee.

	Conventional Technique	Instrumented Technique	
	mean ICC (95% CI)		1-sided t-test
	Inter-operator		
All tests	0.43 (0.23, 0.60)	0.90 (0.76, 0.96)	**p<.0001**
Varus tests (lat. gaps)	0.25 (0.09, 0.43)	0.92 (0.81, 0.97)	**p<.0001**
Valgus tests (med. gaps)	0.60 (0.37, 0.76)	0.87 (0.71, 0.95)	**p=.002**
	Intra-operator		
All tests	0.51 (0.33, 0.70)	0.78 (0.64, 0.88)	**p<.0001**
Varus tests (lat. gaps)	0.40 (0.22, 0.60)	0.84 (0.71, 0.92)	**p<.0001**
Valgus tests (med. gaps)	0.63 (0.44, 0.80)	0.71 (0.57, 0.84)	p=.07

Table 1: Inter-operator and intra-operator intraclass correlation coefficient (ICC) for each technique of laxity acquisition for all tests, varus tests, and valgus tests.

DYNAMIC KNEE DEFORMITY CLASSIFICATION: UNSUPERVISED MACHINE LEARNING CLUSTERING OF TKA CASES WITH A COMPUTER ASSISTED SURGERY SYSTEM

Prudhvi Chinimilli[1], Laurent Angibaud[1], Amaury Jung[2], Francois Boux de Casson[2], James Huddleston[3]

[1]Exactech, Gainesville, FL, USA, [2]Blue-Ortho, Meylan, FR, [3]Stanford Medicine, Stanford, CA, USA

I (and/or my co-authors) have something to disclose.

All relevant financial relationships have been mitigated.

Disclosure information is available via:

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Background

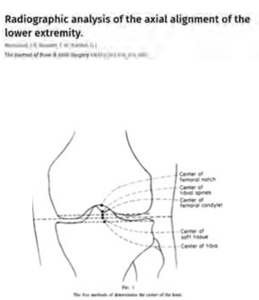
- TKA has been considered a safe and effective treatment for end-stage knee arthritis[1]. However, up to 20% of patients remain dissatisfied with their outcomes[2]
- High percentage of dissatisfied patients may be explained by systematic alignment technique (e.g., neutral mechanical alignment) for each TKA patient:
  - ➢ One size fits all technique
  - ➢ Too simplified approach
  - ➢ Doesn't sufficiently consider anatomical variabilities
- At the same time, optimal personalized alignment for each TKA patient is unknown[3]

1. Cram P et al. 2012. Total knee arthroplasty volume, utilization, and outcomes among Medicare beneficiaries, 1991–2010. *JAMA* 308:1227-1236.
2. DeFrance et al. 2023. Are 20% of Patients Actually Dissatisfied Following Total Knee Arthroplasty? A Systematic Review of the Literature. *The Journal of Arthroplasty* 38:594-599.
3. Hirschmann MT et al. 2019. Functional knee phenotypes: a novel classification for phenotyping the coronal lower limb alignment based on the native alignment in young non-osteoarthritic patients. *Knee Surgery, Sports Traumatology Arthroscopy* 27:1394-1402.

Alignment Classification

1980s | 1990s | 2000s | 2010s | 2020s

1987



1997

2018

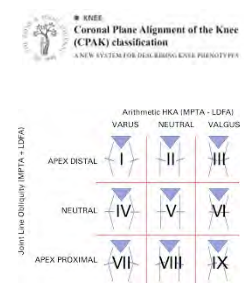
Lin's study[1]

2019

Functional knee phenotype[2]

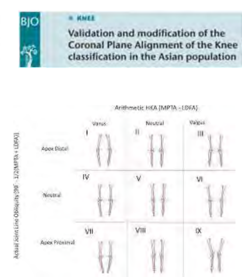
2021

CPAK[3]



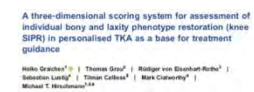
2022

Modified CPAK[4]



2025

3D scoring[5]

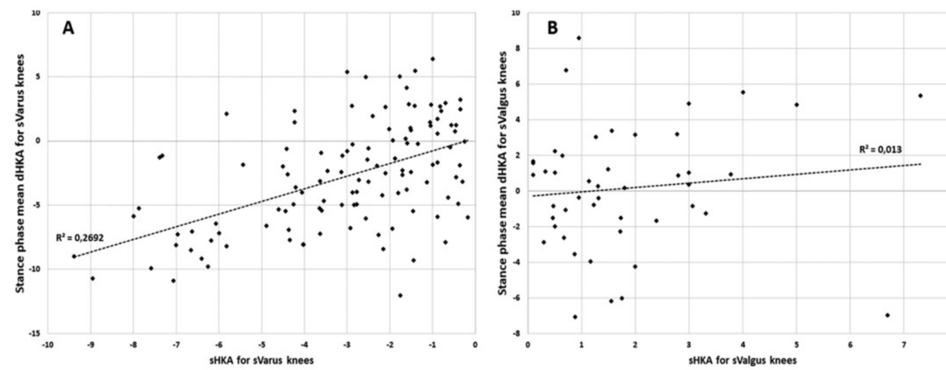


1. Lin YH et al. 2018. Mismatch between femur and tibia coronal alignment in the knee joint: classification of five lower limb types according to femoral and tibial mechanical alignment. *BMC Musculoskeletal Disorders* 19: 1-9
2. Hirschmann MT et al. 2019. Functional knee phenotypes: a novel classification for phenotyping the coronal lower limb alignment based on the native alignment in young non-osteoarthritic patients. *KSSTA* 27:1394-1402
3. MacDessi SJ et al. 2021. Coronal plane alignment of the knee (CPAK) classification: a new system for describing knee phenotypes. *The bone & joint journal* 103: 329-337
4. HSU CE et al. 2022. Validation and modification of the coronal alignment of the knee classification in the Asian population. *Bone & Joint Open* 3:211-217
5. Graichen H et al. A three-dimensional scoring system for assessment of individual bony and laxity phenotype restoration (knee SIPR) in personalized TKA as a base for treatment guidance. *KSSTA*. Published online February 10, 2025

Alignment Classification

- These recent classifications have gained adoption with the the targets of personalized surgical techniques (e.g., KA, rKA, FA) to match the patient's constitutional alignment[1]

- However, these classifications still represent a simplification by only considering the standing coronal alignment (i.e., static HKA)[2]

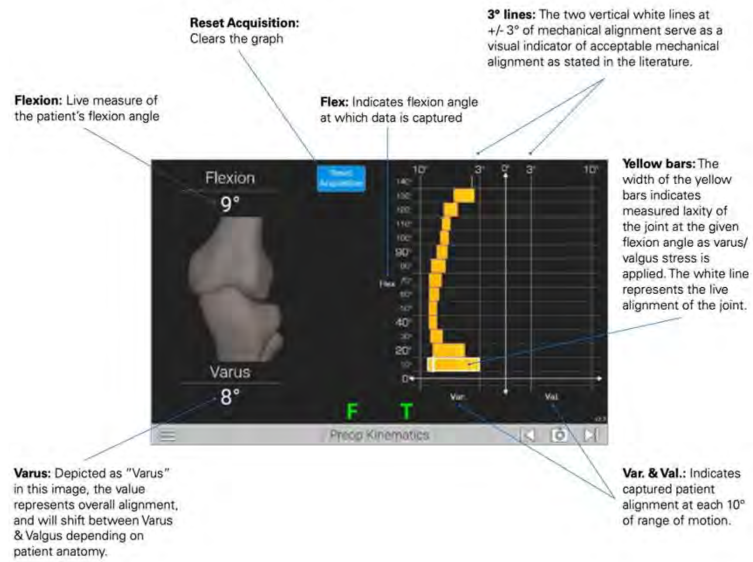


➢ **Improved approach would consider the alignment throughout the entire arc of flexion (i.e., dynamic HKA)**

1. Indelli PF. 2024. The epidemic of alignment classifications in total knee arthroplasty forgives the kinematic of the human knee. *Journal of Experimental Orthopaedics* 11: e70052.
2. Clément J et al. 2019. Hip-knee-ankle (HKA) angle modification during gait in healthy subjects. *Gait & Posture* 72: 62–68.

Objectives

- Develop an unsupervised machine learning model to classify dynamic knee deformity and alignment trained using full arc-of-motion coronal kinematics data captured intraoperatively by a computer assisted orthopaedic surgery (CAOS) system
    - ➢ **Unsupervised learning**: identifies patterns in unlabeled datasets
    - ➢ **Full arc of motion data:** categorizes dynamic deformity based on varus and valgus (VV) angles from 0° to 120° flexion
    - ➢ **Consistency:** same intraoperative technology (CAOS) is used for both the acquisition of kinematics data, the planning of the bone cuts, and then the execution of the planning

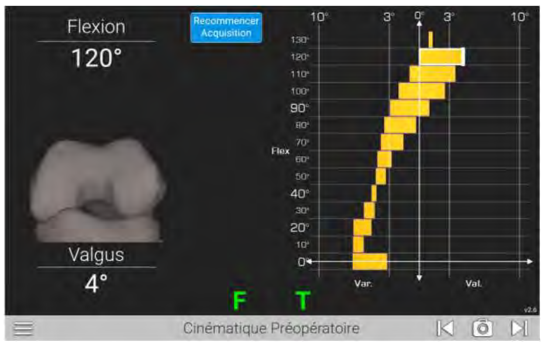


Methods | Dataset

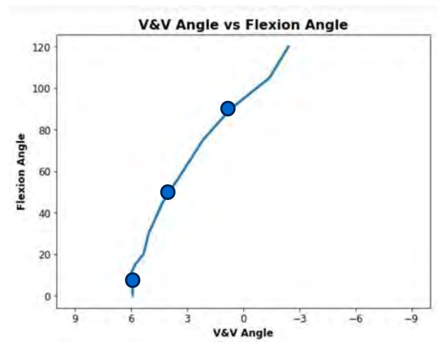
- A retrospective review was performed on a proprietary cloud-based web database that archives the technical logs of the cases performed using an instrumented CAOS system (Newton, Exactech, Gainesville, FL & ExactechGPS, Blue-Ortho, Meylan, FR)
- A total of 1336 TKAs performed by 11 individual surgeons, with at least 20 cases each, were considered without any exclusions
- All cases followed a tibia first workflow using the instrumented CAOS system

Anatomical landmarks acquisition → Kinematics acquisition → Tibia resection → Gaps acquisition → Femoral planning and resection

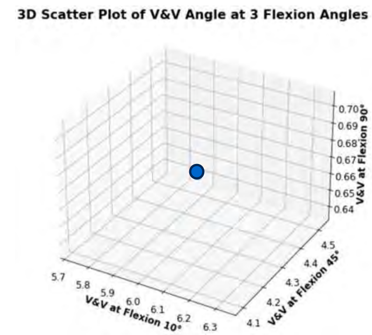
Methods | Classification Process (1/2)



Step 1



Step 2



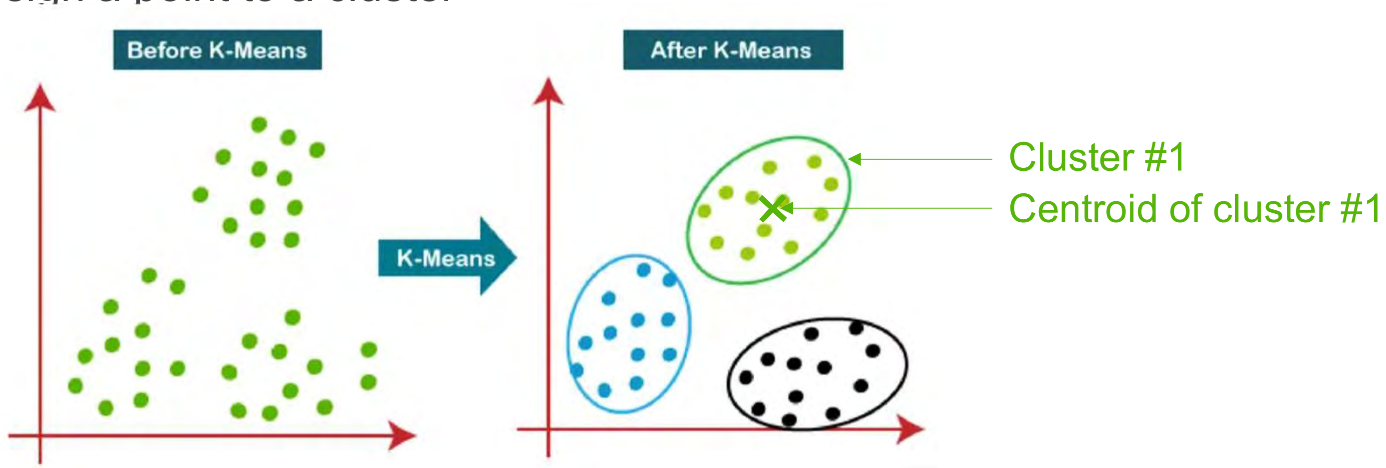
Step 1. From the kinematic acquisition throughout the full arc, extract 2D trajectory represented by the mean varus-valgus (VV) angles at N distinct flexion angles

Step 2. Transform 2D trajectory into a N-dimensional feature space

- **VV angles are available at 12 distinct flexion angles (0°, 5°, 10°, 15°, 20°, 30°, 45°, 60°, 75°, 90°, 105°, 120°), each case 2D trajectory will be transformed into 12-dimensional space for training**

Methods | Classification Process (2/2)

- K-Means clustering[1] is an unsupervised learning algorithm, which groups dataset into different clusters
- The goal is to group similar data points together and discover underlying patterns or structures
- K-Means is a centroid-based algorithm or a distance-based algorithm, where we calculate the distance to assign a point to a cluster



1. Jin X, Han J. 2011. K-Means Clustering. Encyclopedia of Machine Learning :563–564.

Methods | Training

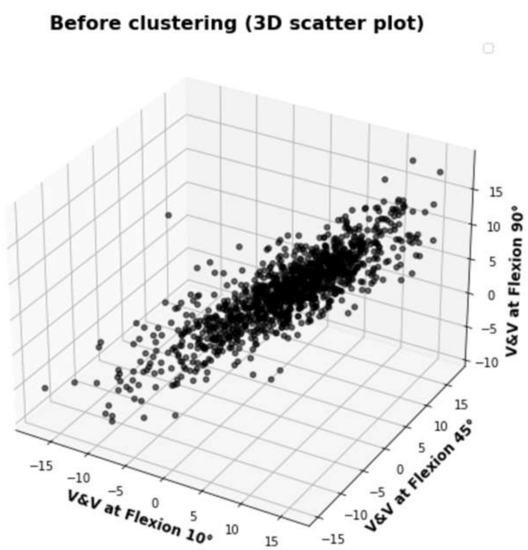
- The cases were categorized into flexion-contracture (FC: 115 cases) and non-flexion contracture (NFC: 1221 cases)
- The Elbow technique[1] with within Cluster Sum of Squares (WCSS) was used to determine optimal clusters size
- Clustering metrics: Davies-Bouldin (DB) index[1], Calinski-Harabaz (CH) index[1], Silhouette score[1] were analyzed to determine optimal combination (clusters and features)

Attributes	Description
Training size [num cases, num features)	NFC: [1221, 12], FC: [115,12]
Number of clusters search space	K = [3,10]
Number of features search space	I = [3,12]

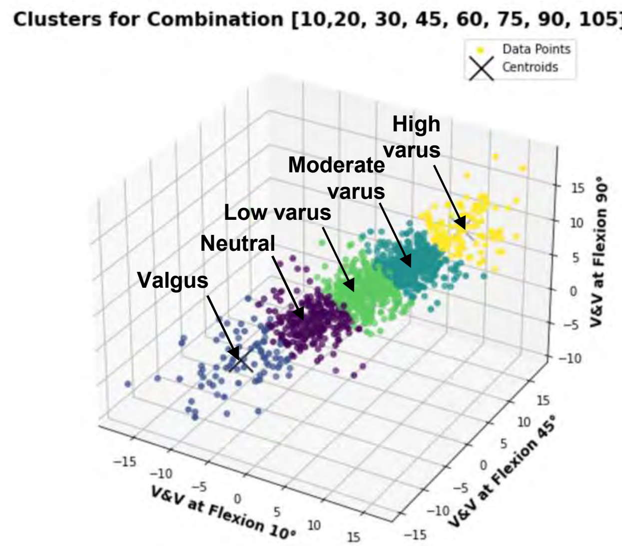
Groups	Optimal combination
NFC	K =5, VV at flexion angles (10°, 20°, 30°, 45°, 60°, 75°, 90°, 105°)
FC	K =5, VV at flexion angles (15°, 20°, 30°, 45°, 60°, 75°, 90°, 105°)

1. Jin X, Han J. 2011. K-Means Clustering. Encyclopedia of Machine Learning :563–564.

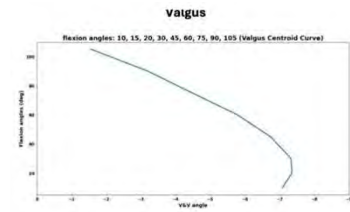
Results | Clustering

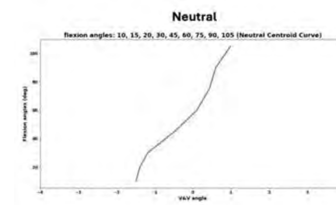


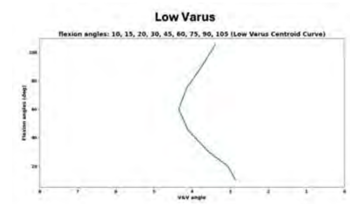
K-Means fitting

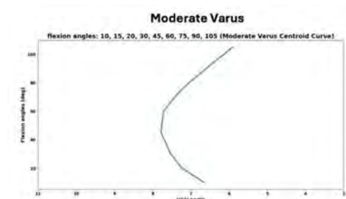


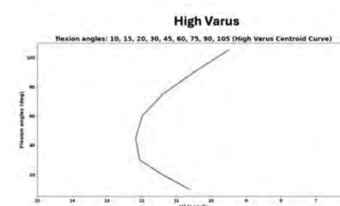
5 Centroids 2D Trajectories





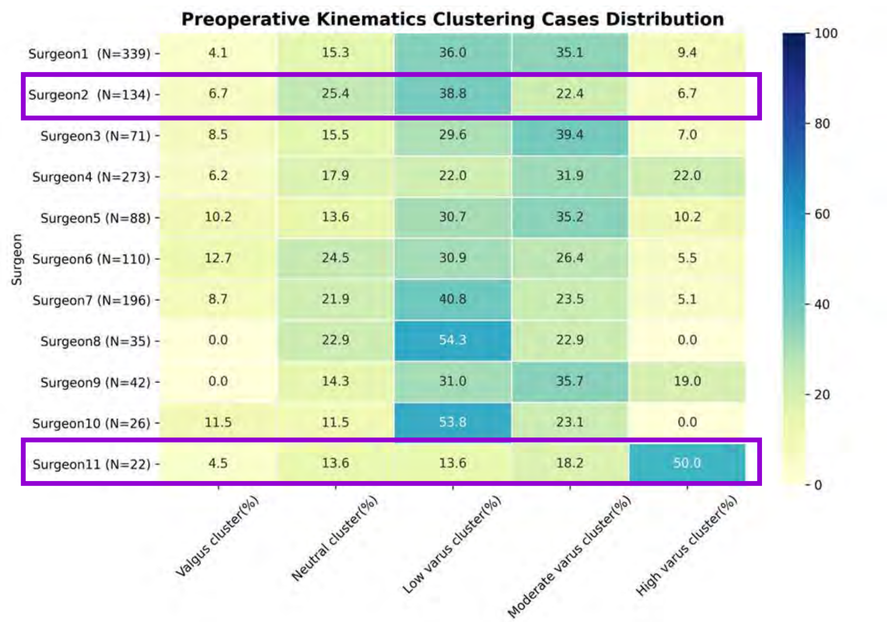






Results | Case Distribution

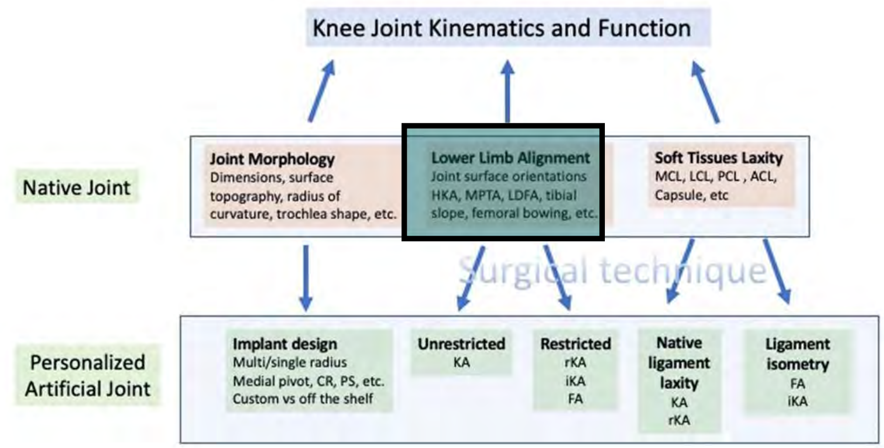
Cases distribution (%) **Total cases: 1336**	Valgus N = 90 (6.7%)	Neutral N = 248 (18.6%)	Low varus N= 445 (33.3%)	Moderate varus N= 403 (30.2%)	High varus N= 150 (11.2%)



Heatmap displaying cases distribution of 11 surgeons and 5 clusters. Surgeons (1,2,4,5,7,8,10) from US, surgeons (3,6,9) from Europe, and Surgeon 11 from Japan

Discussion

- Application of clustering methods to categorize dynamic patient deformity using kinematics data for full flexion arc
- This study results demonstrated that 5 clusters and 8-dimensional VV-flexion feature space sufficiently categorizes dynamic deformity
- This model will help surgeons to better understand knee deformities across full flexion arc, rather than relying on single static measurement (e.g., extension or 90° flexion)



1. Vendittoli PA et al. 2023. Why personalized surgery is the future of hip and knee arthroplasty: a statement from the Personalized Arthroplasty Society. *EOR* 8:874-882.

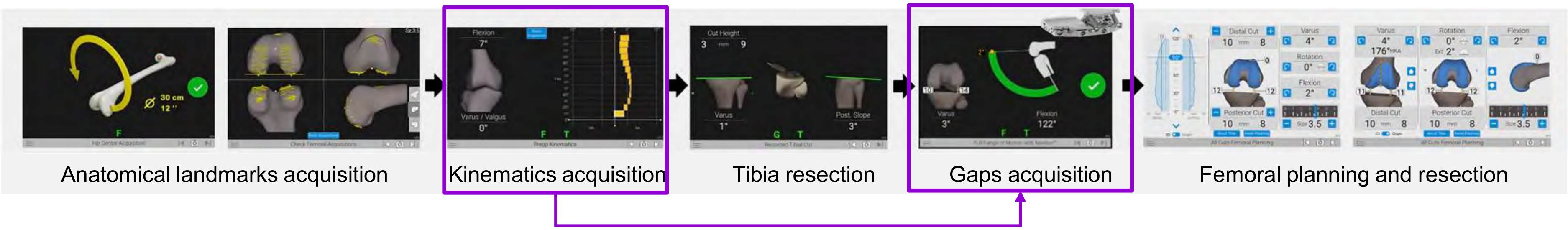
Limitations

- Dynamic alignment classification results were not compared to CPAK[1] and functional knee phenotypes[2]
- Surgeons may tend to apply a VV stress to the limb while acquiring full flexion arc kinematics instead of performing neutral manipulation
- Limited surgeon cohort; no information on patient demographics and post-operative clinical outcomes

1. MacDessi SJ et al. 2021. Coronal plane alignment of the knee (CPAK) classification: a new system for describing knee phenotypes. *The bone & joint journal* 103: 329-337.
2. Hirschmann MT et al. 2019. Functional knee phenotypes: a novel classification for phenotyping the coronal lower limb alignment based on the native alignment in young non-osteoarthritic patients. *KSSTA* 27:1394-1402.

Conclusion & Future Work

- Newton acquisition stage provides more stable and reliable data than pre-cut kinematics stage in terms of neutral manipulation without VV stress[1,2]



- Clustering models will be explored on Newton acquisitions datasets

➢ **Vision: Develop an intraoperative, robust automated clinical support decision tool (CDST) for dynamic knee deformity/alignment classification to aid personalized surgical techniques**

1. Boux de Casson et al. 2025. Navigated instrumentation and ligament tensioning device enhances initial gap acquisition during TKA procedure: A cadaveric study. *JEO* 12: e70107
2. Chinimilli P et al. 2025. Evaluating Intraoperative Dynamic Hip-Knee-Ankle (dHKA) Angle Under Controlled Load During Navigated Total Knee Arthroplasty. *ORS*


THANK YOU
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DEFINITION OF THE LAXITY GOALS DURING TOTAL KNEE ARTHROPLASTY TENDS TO BE SURGEON SPECIFIC

Laurent Angibaud[1], Prudhvi Chinimilli[1], Francois Boux de Casson[2], Amaury Jung[2], James Huddleston[3]

[1]Exactech, Gainesville, FL, USA, [2]Blue-Ortho, Meylan, FR, [3]Stanford Medicine, Stanford, CA, USA

I (and/or my co-authors) have something to disclose.

All relevant financial relationships have been mitigated.

Disclosure information is available via:

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or the
AAOS Orthopaedic Disclosure Program: www.aaos.org/disclosure

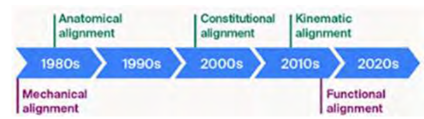
Background

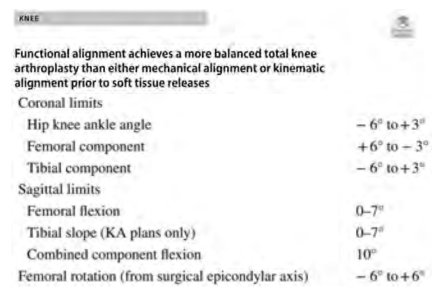
- Proper soft tissue balancing during total knee arthroplasty (TKA) is critical to ensure successful clinical outcomes[1]
- Knee balancing is often presented as an art and is largely dependent on the surgeon’s subjective “feel”[2]
- Traditional soft-tissue balance techniques tend to only encompass a few discrete and static angles of flexion[3-4]

1. Gustke et al. A new method for defining balance: promising short-term clinical outcomes of sensor-guided TKA. *J Arthroplasty*. 2014 May;29(5):955-60
2. Nielsen ES, Hsu A, Patil S, Colwell CW Jr, D'Lima DD. Second-Generation Electronic Ligament Balancing for TKA: A Cadaver Study. *J Arthroplasty*. 2018: 33(7)-2293-2300
3. Daines et al. Gap balancing vs. measured resection technique in total knee arthroplasty. *Clin Orthop Surg*. 2014 Mar;6(1):1-8
4. Jhurani et al. Do spacer blocks accurately estimate deformity correction and gap balance in TKA? A prospective study with computer navigation. *Knee*. 2020 Jan;27(1):214-220

Background

- Alignment techniques in TKA continue to evolve from 2D to 3D as technologies of implantation progress
- Possibility of reliably characterizing the soft-tissue envelope throughout the arc of motion[1] enables the development of alignment techniques based on sizing, alignment, and soft-tissue considerations
- While these techniques offer guidelines for the bone cut parameters in terms of alignment, the definition of the ligament laxity target is still unclear[2]




KNEE

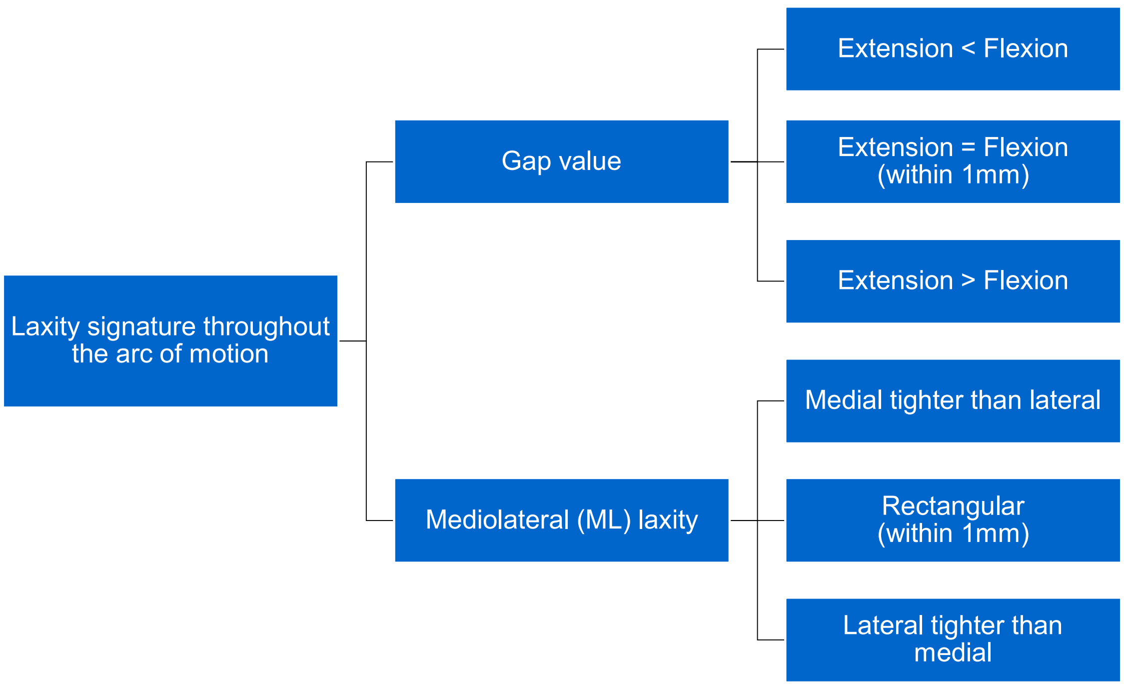
Functional alignment achieves a more balanced total knee arthroplasty than either mechanical alignment or kinematic alignment prior to soft tissue releases

Coronal limits	
Hip knee ankle angle	− 6° to + 3°
Femoral component	+ 6° to − 3°
Tibial component	− 6° to + 3°
Sagittal limits	
Femoral flexion	0–7°
Tibial slope (KA plans only)	0–7°
Combined component flexion	10°
Femoral rotation (from surgical epicondylar axis)	− 6° to + 6°

1. Angibaud et al. Reliability of Laxity Acquisitions During Navigated Total Knee Arthroplasty – Comparison of Two Techniques. *EPiC Series in Health Sciences*. 2022 (5);1-4
2. Clark et al. Functional alignment achieves a more balanced TKA than either mechanical or kinematic alignment prior to soft tissue releases. *KSSTA* 2023 Apr;31(4):1420-1426

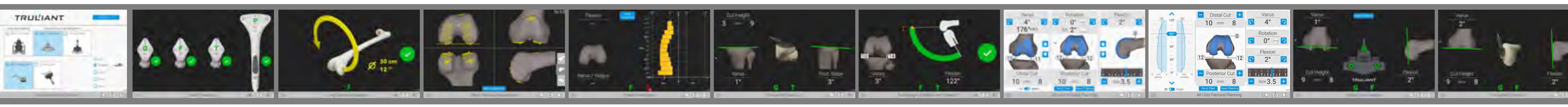
Objectives

- Evaluate the laxity signatures set-up by surgeons at the time of the planning of the femoral cut parameters during TKA with a tibia first surgical workflow

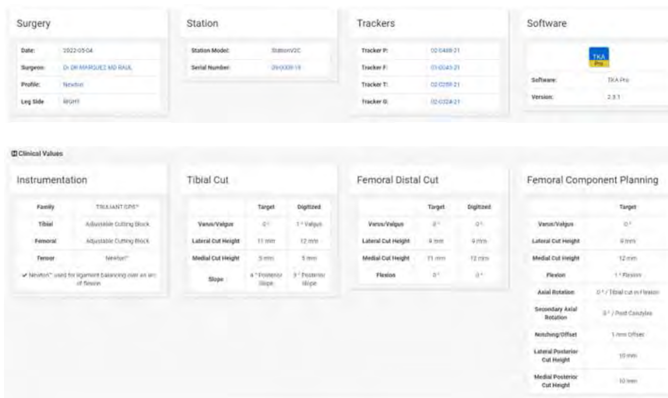


Methods

- A retrospective review was performed on a proprietary cloud-based web database that archives the technical logs of the cases performed using an instrumented CAOS system (Newton, Exactech, Gainesville, FL & ExactechGPS, Blue-Ortho, Meylan, FR)

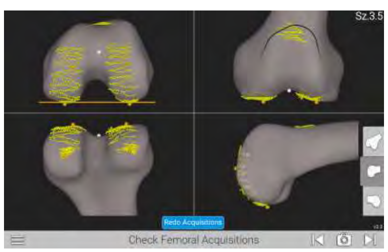


- All technical logs were stored as deidentified surgery reports that only contain technical information such as surgical time, workflow, cut parameters, implant information…



Methods

- A total of 1762 TKAs performed by 20 individual surgeons, with at least 15 cases each, were considered without any exclusions
- Based on the potential impact of the status of the posterior cruciate ligament, cases were separated between the different bearing options (i.e., PS, CRC, CR)
- All cases followed a tibia first workflow using the instrumented CAOS system:



Acquisition anatomical landmarks

Proximal tibial cut under CAOS guidance

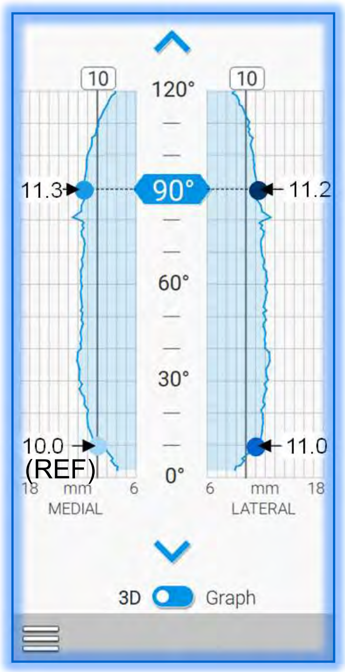
Acquisition of the medial & lateral gaps throughout the arc of motion under quasi-constant distraction force

Planning of the femoral cut parameters

Methods

- For each case, the planned laxities throughout the arc of motion were referenced relative to the planned medial gap at 10° of flexion

  - ➢ For example, at 10° and 90°:

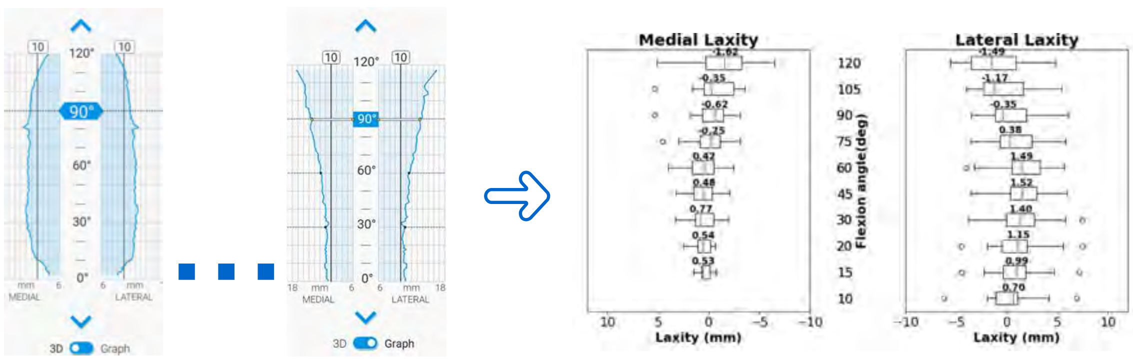


	Absolute gaps (mm)	Relative gaps* (mm)
Medial at 10°	10.0	0 (Reference)
Lateral at 10°	11.0	+1.0 (=11.0-10.0)
Medial at 90°	11.3	+1.3 (=11.3-10.0)
Lateral at 90°	11.2	+1.2 (=11.2-10.0)

*: Positive: looser than reference; negative: tighter than reference

Methods

- For each surgeon, calculate relative planned laxities for both medial and lateral compartments from 10° to 120° of flexion, at every 15° increment



- Two Way ANOVA was used to compare the surgeon effect on the laxity definition. If the effect was significant, Tukey multiple comparisons of means were used to compare pair-wise laxity difference between surgeons

Results

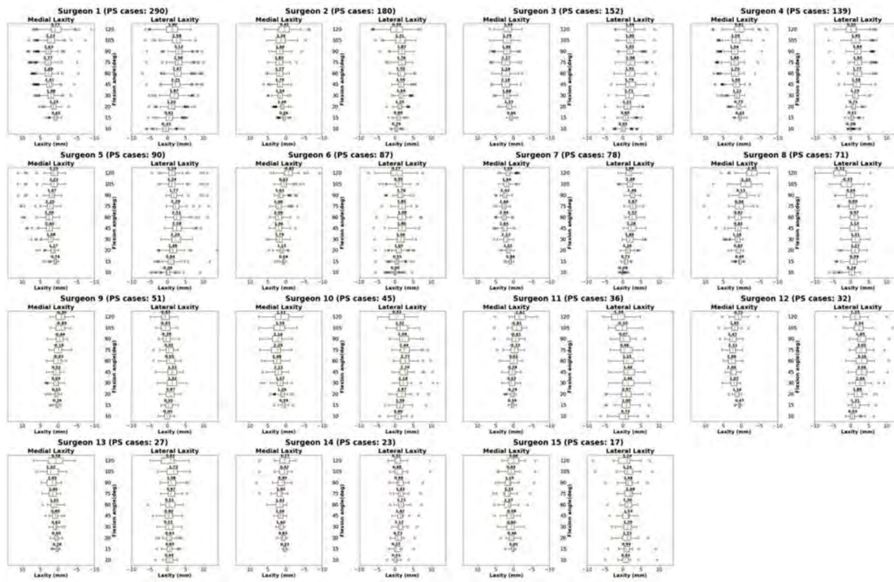
- Regardless of the bearing type and the compartment side, the relative laxities were significantly different between the 20 surgeons ($p<0.05$)
- Tukey multiple comparisons of means:

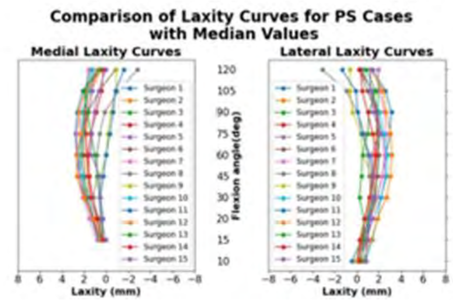
Type of bearing	# of surgeons*	# of cases	# of total comparisons	Medial laxity ($p<0.05$)		Lateral laxity ($p<0.05$)	
				#	%	#	%
PS	15	1318	105	77	73.3	76	72.4
CRC	6	350	15	10	66.7	7	46.7
CR	3	94	3	3	100	2	66.7

*: Some surgeons were considered hybrid (i.e., used more than 1 type of bearing), explaining the sum being more than 20

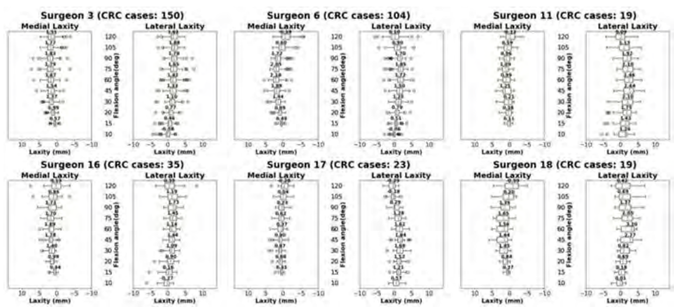
71% of the pair-wise laxity comparison between surgeons were significant

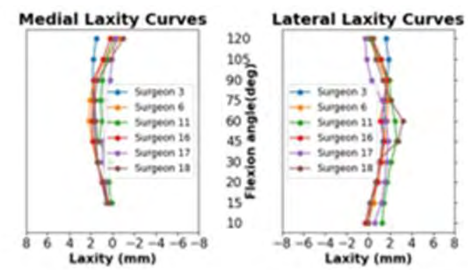
PS TKA
15 surgeons
1318 cases



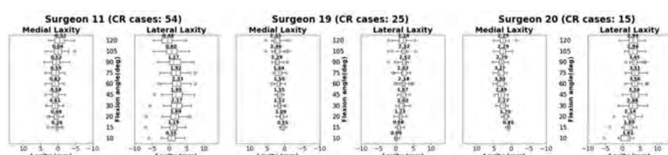


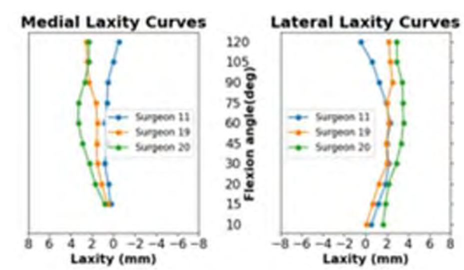
CRC TKA
6 surgeons
350 cases





CR TKA
3 surgeons
94cases



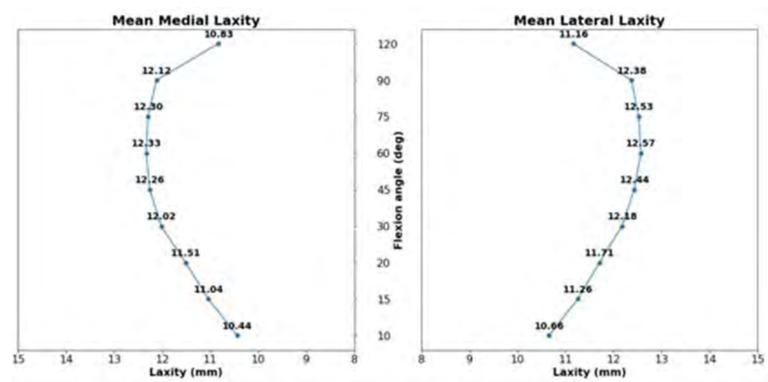


Discussion

- Even though our study only considered cases using the same knee system, the same calibrated force-controlled distractor device, and the same surgical workflow, the laxity goals were found to be surgeon specific

- While patient specific laxity in TKA is yet to be determined, mean laxity signature tends to follow general recommendations for functional alignment[1]
  - ➢ Rectangular gap with slight lateral opening in flexion
  - ➢ Flexion gap tends to be larger than extension gap by ~1.5mm

Mean laxity curves (All cases combined)



1. Shatrov et al. Functional Alignment Philosophy in Total Knee Arthroplasty - Rationale and technique for the varus morphotype using a CT based robotic platform and individualized planning. SICOT J. 2022;8:11

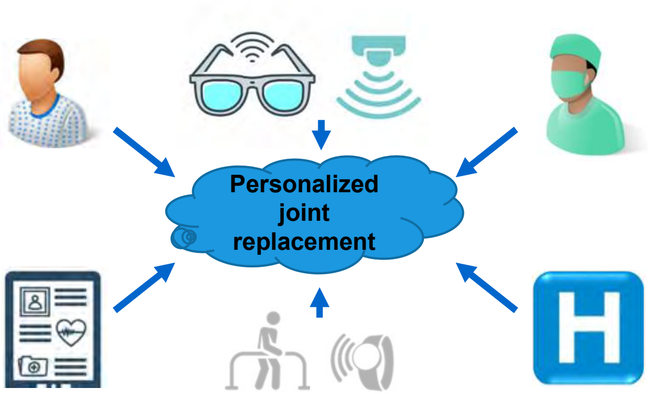
Limitations

- No information regarding the alignment technique (notably in terms of the obliquity of the proximal tibial cut)
- No information regarding the demographic information of the patients
- No post-market clinical follow-up / post-operative information

No ability to provide guidance in terms of laxity target at this early stage

Conclusion

- This study demonstrated that the definition of the targeted joint laxities during TKA tends to be influenced by the surgeon.
- Future developments may enable diagnostic capabilities to tailor the laxity targets based on patient's inputs further enabling personalized joint replacement based on:
  - ➢ Surgeon (e.g., training, preference)
  - ➢ Patient (e.g., activity, goals, phenotypes)
  - ➢ Pre-operative data (e.g., deformity)
  - ➢ Intraoperative data (e.g., ligament laxities)
  - ➢ Hospital (e.g., inpatient, outpatient)
  - ➢ Rehabilitation (e.g., home, rehab center)




THANK YOU
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