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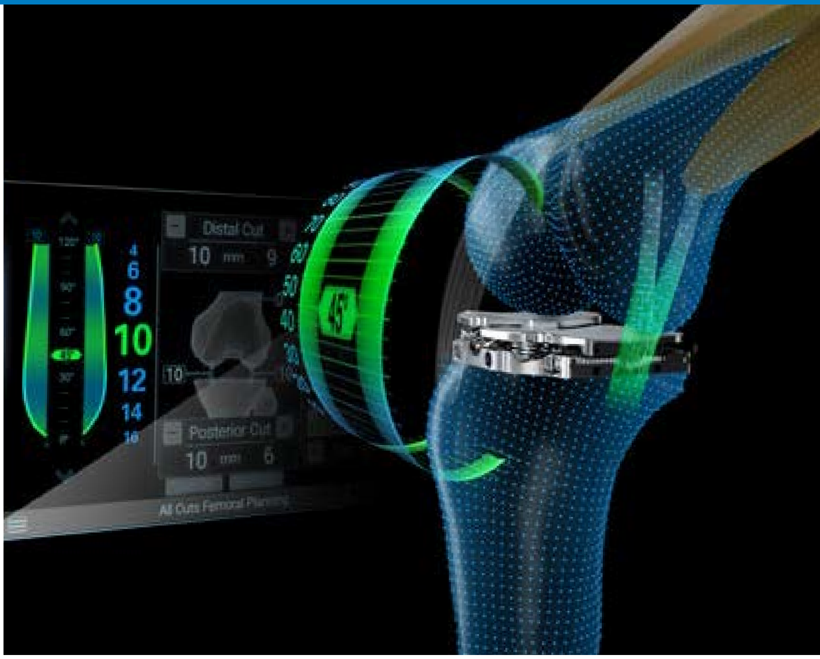


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# Intraarticular Quasi-Constant Force Tension in Total Knee Arthroplasty Regardless of Joint Gap and Knee Size


**Matt Rueff[1], Josh Glenboski[1], Roger Lacaille[1], Laurent Angibaud[1]**

[1]Exactech Inc, Gainesville, FL, USA
Presented at CAOS 2022 Annual Meeting.

## ABSTRACT

Balancing soft tissues in the knee with the patella in place and with regularly applied force helps surgeons make decisions for positioning knee components in a manner that is friendly to soft tissues. A novel intraarticular device has been developed for achieving a balanced knee joint over the range of motion of the knee without requiring manual adjustments during surgery. Quasi-Constant force output was generated by the device at usual joint gaps for the knee sizes encountered during total knee arthroplasty.

## INTRODUCTION

In total knee arthroplasty (TKA), instability and stiffness are key drivers of patient dissatisfaction and revision [1-3]. To improve patient outcomes, navigated ligament balancing techniques in TKA reference patient soft tissues and bony landmarks to position implants intended for preserving natural kinematics of the knee using stereotaxic instrumentation. To achieve this target, surgeons have used lamina spreaders, spoons or spacer blocks to apply tension between the tibia and the femur during the procedure to plan bone cuts. Other options for applying force between the femur and tibia include modifiable tensioners, but these devices require adjustment to accommodate a changing joint gap and require the adding of shims or the turning of a knob while requiring complex extraarticular apparatuses or eversion of the patella. An intraarticular device that can maintain a consistent joint tensioning force without eversion of the patella or any adjustment can reduce cognitive burden on the surgeon while continuing to reference the patient soft tissues for making clinical decisions. Within the proposed device, nearly constant force can be achieved by balancing two different internal mechanisms: a Hookian spring that increases force output as it is compressed and a non-Hookian spring mechanism that is defeated as it is compressed. The objective of this study was to report in-vitro verification testing of the novel device that generates nearly constant condylar forces independently on both medial and lateral compartments at typical tibiofemoral gap thicknesses encountered during TKA.

## METHODS

Using an Instron load frame and a 10kN calibrated load cell, a tibiofemoral gap was simulated by mounting size 0, size 3 and size 6 Exactech® femoral trials in extension with 30PCF bone foam at 9mm, 12mm, and 15mm distances from a flat stainless steel platen representing a tibial resection (Figure 1). The size 0 and size 6 femoral trials represent the minimum and maximum femoral sizes for the subject implant system while size 3 is the most used femoral size, and the 9mm, 12mm and 15mm gaps represent typical tibial insert implant thicknesses selected during a primary TKA. Five advanced ligament balancing intraarticular devices were placed within the gap to generate an in-vitro force. The force was recorded three times for each gap value and for each femur size for a total of 135 measurements. Finally, the force values were compared to the analytical solution that was used for device design.

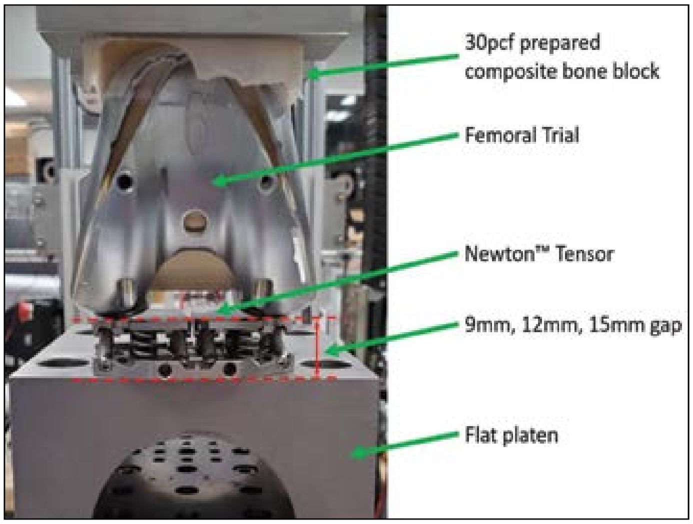


**Figure 1. Test Setup**

## RESULTS

Regardless of knee size and gap, the average force measurement combining both force plates for the Newton device across all measurements was 34.8lbf with a 1.64lbf standard deviation. At 9mm, 12mm and 15mm gaps, the average force values were 33.5lbf, 36.8lbf and 34.0lbf respectively with standard deviations of 0.57lbf, 0.87lbf, and 0.88lbf respectively. Deviation from the average force was 1-7% depending on the gap size and implant size. Though changes in force output were limited across all gap sizes and femoral implant sizes, the change in femoral implant size had a lower impact on force than change in gap size (Figure 2).

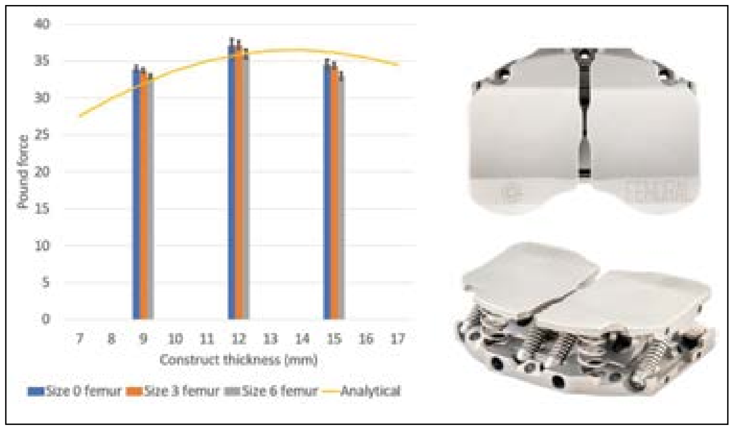


**Figure 2. Left: Test results. Right: Device Manifestation**

## DISCUSSION

Balancing the knee joint with a constant force on both medial and lateral compartments allows for obtaining patient specific information about the knee joint; which can be leveraged for setting up the femoral cut parameters. While conventional devices have allowed for obtaining the soft tissue information at specific flexion angles, this intraarticular spacer may facilitate the acquisition of patient data without everting the patella or adjustment while automatically applying a consistent force throughout an entire range of motion. This study is limited because the force data was acquired with rectangular gaps while the knee was only positioned in extension. Future work should be focused on acquiring force data at multiple flexion angles and across a gradient of variable gaps in cadaver medium. While the output was not perfectly constant across all knee sizes and gaps, the force magnitude was similar to the force output of currently marketed devices [4-7]. Use of a quasi-constant force tensor in surgery could allow for improvement of patient outcomes by providing real time patient data about the knee balance and kinematics during TKA.

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# Reliability of Laxity Acquisitions Under Controlled Load Environment During Navigated Total Knee Arthroplasty

**Laurent Angibaud[1], Florian Kerveillant[2] , Philippe Dubard[2], Marine Torrollion[2], Matt Rueff[1], Wen Fan[1], James Huddleston[3]**

[1]Exactech Inc, Gainesville, FL, USA, [2]Blue-Ortho, Meylan, FR,
[3]Stanford University Medical Center, Stanford, CA, USA
Presented at CAOS 2022 Annual Meeting.

## ABSTRACT

Proper soft tissue balancing during total knee arthroplasty (TKA) is critical to ensure successful clinical outcomes. As an attempt to offer an intra-operative characterization of the soft-tissue envelope, a novel method enables the possibility of acquiring the joint laxities under a quasi-constant distraction force throughout the entire range of motion. TKAs were performed using a computer-assisted orthopaedic surgery (CAOS) system on a fresh-frozen human cadaveric specimen. A total of 60 laxity acquisitions were performed by 5 surgeons using the CAOS system. There was an excellent interobserver reliability of the laxity acquisitions (ICC=0.913-0.992). Similarly, the intraobserver reliability was also excellent (ICC=0.846-0.984). These findings demonstrated that the acquisition of the knee joint laxities under the proposed controlled load environment is highly reliable.

## INTRODUCTION

Proper soft tissue balancing during total knee arthroplasty (TKA) is critical to ensure successful clinical outcomes.[1-4] However, most intra-operative techniques still rely on the subjective assessment of the joint balance and only encompass a few discrete angles of flexion (e.g., full extension and 90˚ of flexion). As an attempt to offer an intra-operative characterization of the soft-tissue envelope, a novel method enables the possibility of acquiring the joint laxities under a quasi-constant distraction force throughout the entire range of motion and then to leverage these acquisitions as inputs for the set-up of a patient-specific surgical plan. The aim of this study was to determine the inter- and intraobserver reliabilities of acquiring the knee joint laxities under controlled load environment during navigated TKA.

## METHODS

TKAs were performed using a computer-assisted orthopaedic surgery (CAOS) system on a fresh-frozen human cadaveric specimen (age 66 years, female). At the trial reduction stage, a trial femoral component was impacted onto the prepared distal femur and a novel intra-articular tibial distractor was introduced into the joint space. The distractor features 2 independent mechanically actuated compartments intended to apply (once released) a quasi-constant distraction force (nominally set-up at 20 lbs per compartment) regardless of the joint gap. Then, the limb was manually taken through a full arc of motion and the corresponding joint laxities were acquired by the CAOS system (see Figure 1). The manipulations were successively performed by a total of 5 surgeons (3 seniors and 2 juniors) on 3 occasions on 2 knees across both medial and lateral condyles. The inter- and intraobserver reliabilities were assessed using intraclass correlation coefficients (ICCs) and 95% confidence intervals (CIs).[5]

**Figure 1. Proposed method of acquisition of the laxity envelope under controlled load environment throughout the arc of motion**

| A | Knee | | Compartment | ICC | 95%CI |
|---|---|---|---|---|---|
| | #1 | | Medial<br>Lateral | 0.992<br>0.969 | 0.979-0.996<br>0.919-0.985 |
| | #2 | | Medial<br>Lateral | 0.966<br>0.913 | 0.886-0.985<br>0.801-0.954 |
| **B** | **Experience** | **User** | **Compartment** | **ICC** | **95%CI** |
| | Senior | #1 | Medial<br>Lateral | 0.984<br>0.926 | 0.964-0.991<br>0.858-0.958 |
| | | #2 | Medial<br>Lateral | 0.965<br>0.935 | 0.905-0.983<br>0.882-0.962 |
| | | #3 | Medial<br>Lateral | 0.943<br>0.846 | 0.847-0.973<br>0.614-0.926 |
| | Junior | #4 | Medial<br>Lateral | 0.976<br>0.956 | 0.953-0.986<br>0.939-0.969 |
| | | #5 | Medial<br>Lateral | 0.911<br>0.938 | 0.850-0.945<br>0.913-0.956 |

**Table 1: A) Details on interobserver reliability of the laxity acquisitions,**

**B) Details on intraobserver reliability of the laxity acquisitions**

## RESULTS

A total of 60 laxity acquisitions were performed using the proposed method. Regardless of the compartment (i.e., medial or lateral), there was an excellent interobserver reliability of the laxity acquisitions (ICC=0.913-0.992) (See Table 1A). Similarly, the intraobserver reliability was also excellent (ICC=0.846-0.984) (See Table 1B). It was observed that the reliability of the laxity acquisitions of the medial compartment was higher than the reliability of the laxity acquisitions of the lateral compartment but didn't reach statistical significance (p=0.385). Finally, the experience level of the observer had no impact on the reliability of the acquisitions (p=0.626).

## DISCUSSION

These findings demonstrated that the acquisition of the knee joint laxities under the proposed controlled load environment is highly reliable. This excellent reliability is assumed to be multi-factorial. First, the applied distraction force provides a stability of the joint during the acquisition due to consistent tension across the joint. Next, the intra-articular design of the distractor allows the possibility of maintaining the extensor mechanism in place, which also contributes to the stability of the joint. Finally, unlike other methods of laxity acquisition that sequentially apply stressed varus and valgus, the present method is intended to be performed under neutral manipulation, which greatly facilitates the acquisitions. In addition to its high reliability, this method distinguishes from other advanced methods[6-7] by offering a streamlined hardware with a fully intra-articular actuation mechanism.

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# Reliability of Laxity Acquisitions During Navigated Total Knee Arthroplasty – Comparison of Two Techniques

**Laurent Angibaud[1], Wen Fan[1], Philippe Dubard[2], Matt Rueff[1], Hernan A. Prieto[3], Hari Parvataneni[3]**

[1]Exactech, Gainesville, FL, USA, [2]Blue-Ortho, Meylan, FR, [3]University of Florida - Department of Orthopaedic Surgery, Gainesville, FL, USA

Presented at CAOS 2022 Annual Meeting.

## ABSTRACT

Recent developments have focused on the intra-operative management of soft-tissue balancing in total knee arthroplasty (TKA) using a computer-assisted orthopaedic surgery (CAOS) system. The aim of this study was to determine and compare the reliability of acquiring the knee joint laxities during navigated TKA with a conventional method versus a newly developed instrumented technique that uses an intra-articular quasi-constant force distractor integrated with a CAOS system. A total of 96 laxity acquisitions throughout the arc of motion were performed for the conventional and instrumented procedures. For the instrumented technique, the inter- and intraobserver reliabilities were significantly higher than the conventional manual varus/valgus stress test technique, regardless of surgeon variability and experience. Soft-tissue balance, while being a key determinant in improving outcomes in TKA, is difficult to objectively assess at the time of the surgery. This study established that the acquisition of the knee joint laxities using an instrumented technique was consistently associated with a significantly higher reliability than the conventional technique.

## INTRODUCTION

Total knee arthroplasty (TKA) continues to be one of the most successful surgical interventions in medicine. While patient-reported outcomes after TKA are shown to improve dramatically with respect to pain, function, and quality of life; there are still approximatively 20% of patients that report dissatisfaction.[1,2] Most contemporary developments have been based on bony references with the goal of restoring a neutral knee alignment.[3,4] As an attempt to improve the patient's satisfaction, more recent developments have focused on the intra-operative management of soft-tissue balancing surrounding the knee joint throughout the full arc of motion when using a computer-assisted orthopaedic surgery (CAOS) system. In order to acquire the laxities, conventional (unaided) technique relates to applying consecutive manual valgus and varus stress tests to the knee in extension and while flexing the limb to acquire the medial and the lateral laxities, respectively. An alternative is the placement of an intra-articular distractor intended to apply a quasi-constant stabilizing force to the knee joint during the manipulation of the limb in neutral alignment to simultaneously acquire both the medial and the lateral laxities. The aim of this study was to determine and compare the inter- and intraobserver reliabilities of acquiring the knee joint laxities during navigated TKA according to each technique.

## METHODS

We performed bilateral TKAs using a CAOS system (ExactechGPS, Blue-Ortho, Meylan, FR) on a fresh-frozen human cadaveric specimen (age 79 years, female). After the incision and using a medial parapatellar arthrotomy, the anatomical landmarks of interest were acquired by inducing motion (hip center) and probing (other landmarks) to generate a patient-specific coordinate system for both the tibia and the femur. Because a posterior stabilized type of implant was selected, the lead surgeon resected both the anterior and the posterior cruciate ligaments as well as menisci and removed all osteophytes.

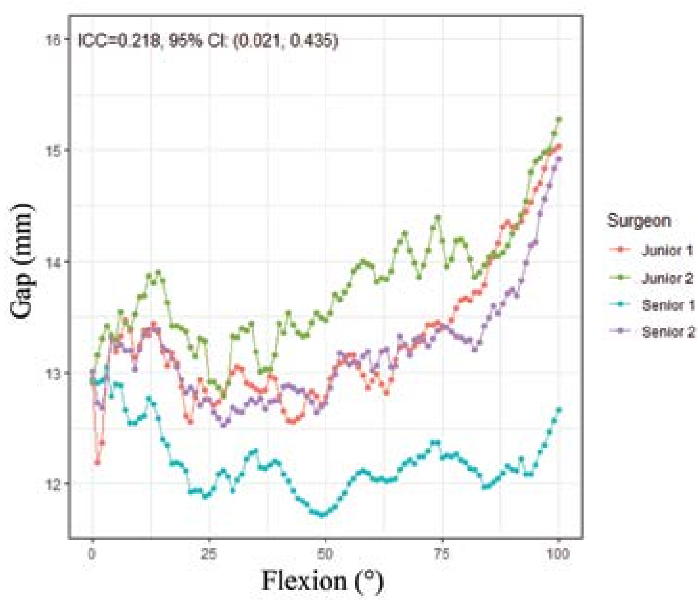
At this stage (i.e., prior to any bone cuts), the joint laxities were acquired by the CAOS system according to the conventional technique, by applying a varus stress test to the knee joint while flexing the limb to acquire the lateral laxities, and then, a valgus stress test to consecutively acquire the medial laxities.

Once completed, the proximal tibial cut was performed neutral to the mechanical axis and then an intra-articular tibial distractor (Newton, Exactech, Gainesville, FL, USA) was introduced into the joint space between the tibial resection and the native femur. The distractor features 2 independent mechanically actuated compartments intended to apply a quasi-constant distraction force (nominally set-up at 20 lbs per compartment) regardless of the joint gap. Then, the joint laxities were acquired by the CAOS system according to the proposed instrumented technique, by manually manipulating the limb through a full arc of motion with the knee joint being stabilized due to the distraction force of the intra-articular tibial distractor.

For each technique, the manipulations were successively performed by a total of 4 surgeons (2 senior and 2 junior surgeons) on 6 occasions on both knees across both medial and lateral compartments. The inter- and intraobserver reliabilities were assessed using intraclass correlation coefficients (ICCs) and 95% confidence intervals (CIs).[5]

## RESULTS

A total of 96 laxity acquisitions throughout the arc of motion were performed for each evaluated technique. Regardless of the considered compartment (i.e., medial or lateral), the instrumented technique was associated with a higher reliability than the conventional technique for the laxity acquisitions ($p=0.017$) (see Figure 1). For the instrumented technique, the interobserver reliability ranged from moderate to good (Mean ICC=0.72), while for the conventional technique, the interobserver reliability ranged from poor to moderate (Mean ICC=0.35) (see table 1). Similarly, the intraobserver reliability was consistently higher for the instrumented technique (Mean ICC=0.66) than the conventional technique (Mean ICC=0.41) (see table 1). Regardless of the considered technique, there was no significant difference in the reliability associated with the acquisition of the laxities between the medial compartment and the lateral compartment ($p=0.453$). Similarly, the experience level of the user had no statistically significant impact on the reliability of the acquisitions ($p>0.05$).



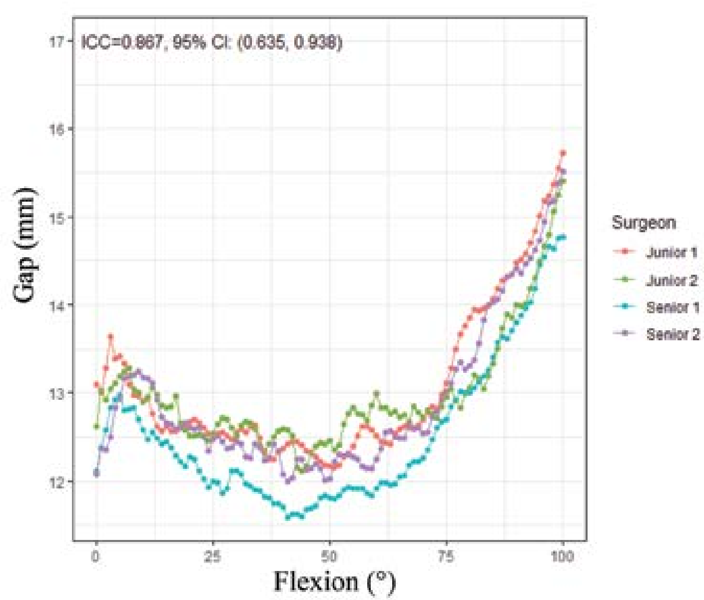




**Figure 1: Examples of laxity acquisitions throughout the arc of flexion for the conventional technique (Left) and the instrumented technique (Right)**

| | | Interobserver | Intraobserver | | | |
|---|---|---|---|---|---|---|
| | | | Junior #1 | Senior #2 | Senior #3 | Senior #4 |
| **Conventional Technique** | Mean ICC<br>95% CI | 0.35<br>(0.04, 0.67) | 0.59<br>(0.36, 0.82) | 0.34<br>(0, 0.77) | 0.31<br>(0, 0.68) | 0.39<br>(0, 0.84) |
| **Instrumented Technique** | Mean ICC<br>95% CI | 0.72<br>(0.43, 1) | 0.63<br>(0.2, 1) | 0.62<br>(0.37, 0.86) | 0.71<br>(0.26, 1) | 0.69<br>(0.46, 0.93) |

**Table 1 interobserver and intraobserver reliability for the conventional and instrumented techniques**

## DISCUSSION

It has been previously established that soft-tissue balance, while being a key determinant in improving outcomes in TKA, is difficult to objectively assess at the time of the surgery.[6,7] In this regard, the acquisition of the laxities using a CAOS system has the potential to provide valuable quantitative information to ultimately guide the definition of the femoral planning parameters in terms of size, alignment, as well as soft-tissue considerations. This being said, the reliability and predictability of the acquisition technique is key to provide proper input data.

This study established that the acquisition of the knee joint laxities using an instrumented technique was consistently associated with a significantly higher reliability than the conventional manual varus/valgus stress test technique. One aspect relates to the application of a distraction force to the knee joint, which tends to greatly stabilize the joint during the manipulation of the limb. Another consideration relates to the manipulation of the limb in neutral alignment for the instrumented technique, which is easier to consistently apply relative to manual application of valgus or varus stress.

Additionally, the instrumented technique yielded consistent reliability across all four surgeons regardless of experience level. Finally, while not relevant to the purpose of this study, the instrumented technique allows the acquisition of both the medial and lateral laxities during the same manipulation, a gain of time compared to the need for consecutive manipulation with the conventional varus and valgus stress technique.

This evaluation has a few limitations worth being mentioned. This study was performed on a single cadaveric specimen with a low body mass index (BMI) (i.e., 20kg/m2) compared to standard TKA patients (mean BMI of 31kg/m2).[8] Finally, there are still open discussions regarding the amount of distraction force to be applied to the knee joint during the acquisitions. In this regard, future developments include the possibility of fluctuating the input load according to patient-specific parameters.

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# Improved Mediolateral Gap Balance Achievement with Instrumented Navigated Total Knee Arthroplasty Compared to Conventional Instrumentation

**Laurent Angibaud[1], Wen Fan[1], Florian Kerveillant[2], Philippe Dubard[2], Marine Torrollion[2], Matt Rueff[1], Alex Sah[3], James Huddleston[4]**

[1]Exactech, Gainesville, FL, USA, [2]Blue-Ortho, Meylan, FR, [3]Washington Hospital, Fremont, CA, USA, [4]Stanford University Medical Center, Stanford, CA, USA
Presented at CAOS 2022 Annual Meeting.

## ABSTRACT

Total knee replacement (TKA) represents a well-established reconstructive procedure for end-stage knee joint disorders with the balancing of soft-tissue envelope throughout the full arc of motion as a newly emerging possibility. This cadaveric study evaluated the ability to achieve targeted mediolateral (ML) gap balance throughout the arc of motion using conventional mechanical instrumentation versus a computer-assisted orthopaedic surgery (CAOS) system featuring an intraarticular distractor while considering surgeon experience level. For the CAOS system, an intraarticular distractor applied a quasi-constant distraction force to the joint (instrumented) while the conventional system involved conventional spacers. Regardless of experience level, the instrumented TKAs were associated with a significantly lower ML gap differential than the conventional TKAs. In contrast, regardless of the type of instrumentation, there were no significant differences between the junior and senior surgeon mean gaps. Historically, soft tissue balancing during TKA has been reported as an art rather than a science. In this regard, the addition of dedicated technology to characterize the soft-tissue envelope during TKA has the potential to provide an augmented perspective to the surgeon and can be particularly beneficial for junior surgeons. The present study established that the usage of instrumented CAOS led to significantly lower ML gap differences than conventional instrumentation.

## INTRODUCTION

Total knee arthroplasty (TKA) represents a well-established reconstructive procedure for end-stage knee joint disorders. Soft-tissue balance is assumed to be a crucial determinant in achieving a successful outcome.[1,2] While soft-tissue balancing using conventional mechanical instrumentation was primarily based on subjective assessments at discrete static flexion angles, recent technological advancements encompass the possibility of characterizing the soft-tissue envelope throughout the full arc of motion. These technologies define and then execute personalized planning of the femoral cut parameters based on thorough soft-tissue information in addition of the usual size and alignment considerations.[3]

This cadaveric study evaluated the ability to achieve targeted mediolateral (ML) gap balance throughout the arc of motion using conventional mechanical instrumentation versus a computer-assisted orthopaedic surgery (CAOS) system featuring an intraarticular distractor according to two levels of user's experience.

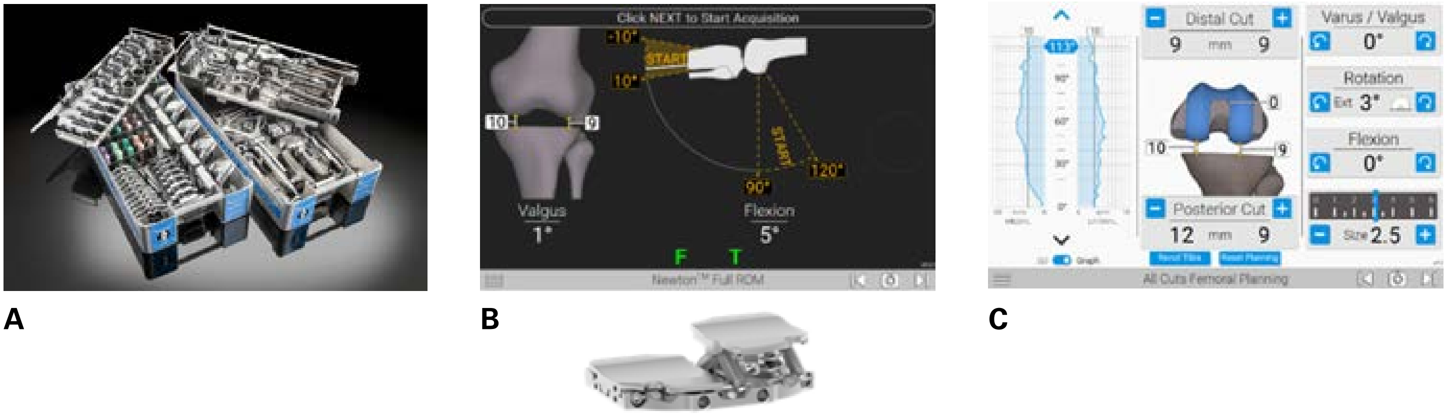


**Figure 1: Conventional mechanical instrumentation (A) and instrumented CAOS system (B)**

## METHODS

Four whole cadaveric specimens (pelvis to feet) were obtained from a tissue bank. Each cadaver provided two knees with no record of previous surgery or trauma with no evidence of deformity. Each cadaver was assigned to one of four surgeons (2 seniors and 2 juniors) with the declared goal of achieving rectangular gaps in both extension and flexion.

For each specimen, conventional mechanical instrumentation (Truliant, Exactech, Gainesville, FL) was used for the right side TKA (conventional TKA), while an instrumented CAOS system (Newton, Exactech, Gainesville, FL & ExactechGPS, Blue-Ortho, Meylan, FR) was leveraged for the left side TKA (instrumented TKA) (see Figure 1). The selection of the side order was randomized for each specimen.

The conventional TKAs were performed via the preferred technique of the user, while the instrumented TKAs were performed using a tibia first technique, where the intraarticular distractor intended to apply a quasi-constant distraction force was placed between the proximal tibial cut and the native femur while the knee was taken throughout the arc of motion and both the medial and lateral gaps were captured by the CAOS system. Then, the planning of the femoral cut parameters was fine-tuned by acting on the virtual position and orientation of the femoral component according to five axes.

At the end of each procedure, a laxity test was conducted to assess the ML gap balance by placing the intraarticular distractor between the proximal tibial cut and the trial femoral component previously impacted onto the prepared distal femur. Then, the limb was manipulated from extension to full flexion and the spatial positions of the simulated femoral component relative to the acquired proximal tibial cut were captured by the CAOS system, which led to the characterization of both the medial and lateral gaps, the varus-valgus, and the internal-external rotation as a function of the flexion angle.

For each degree of flexion from 5° to 90°, both the signed and the unsigned differences between the lateral and medial gaps were calculated and both the mean difference and the standard deviation through the range of motion were reported for each TKA among the four groups (i.e., 2 user experience levels and 2 types of instrumentation). A two-sample t-test was used to determine the statistical significance of mean gap difference between groups. Type II error was set to be 0.05. R-studio (version 3.6.1) was used for all statistical analysis.

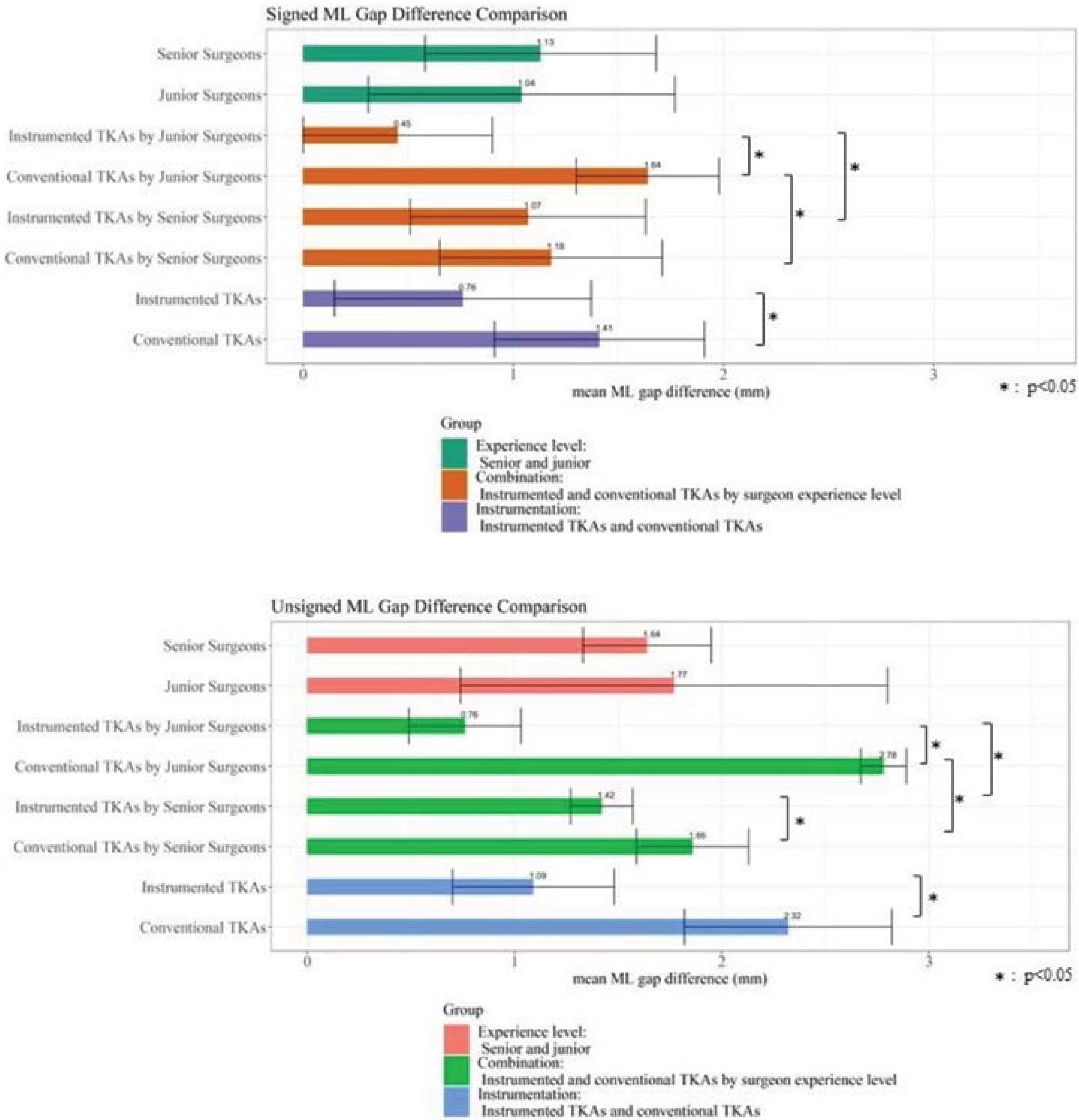


**Figure 2A: Mean and standard deviation of the signed and unsigned ML gap differential for the different considered groups**

## RESULTS

Regardless of the experience level, the instrumented TKAs were associated with a significantly lower ML gap differential than the conventional TKAs ($p<0.001$) (see Figure 2A). In contrast, regardless of the type of instrumentation, there were no significant differences between the junior and senior surgeon mean gaps (see Figure 2A). The lack of significance was due to the junior surgeon group that generated a higher ML gap differential relative to the expert surgeon for their conventional TKAs ($p<0.001$), but the junior surgeon group generated a lower ML gap differential for the instrumented TKAs ($p<0.001$). As a result, while the senior group achieved moderate gain regarding the ML gap differential between their conventional TKAs and their instrumented TKAs ($p<0.001$ for unsigned difference, $p=0.220$ for signed difference), the junior group achieved a significant reduction of the ML gap differential between their conventional TKAs and their instrumented TKAs ($p<0.001$ regardless of the signature) (see Figure 2B).

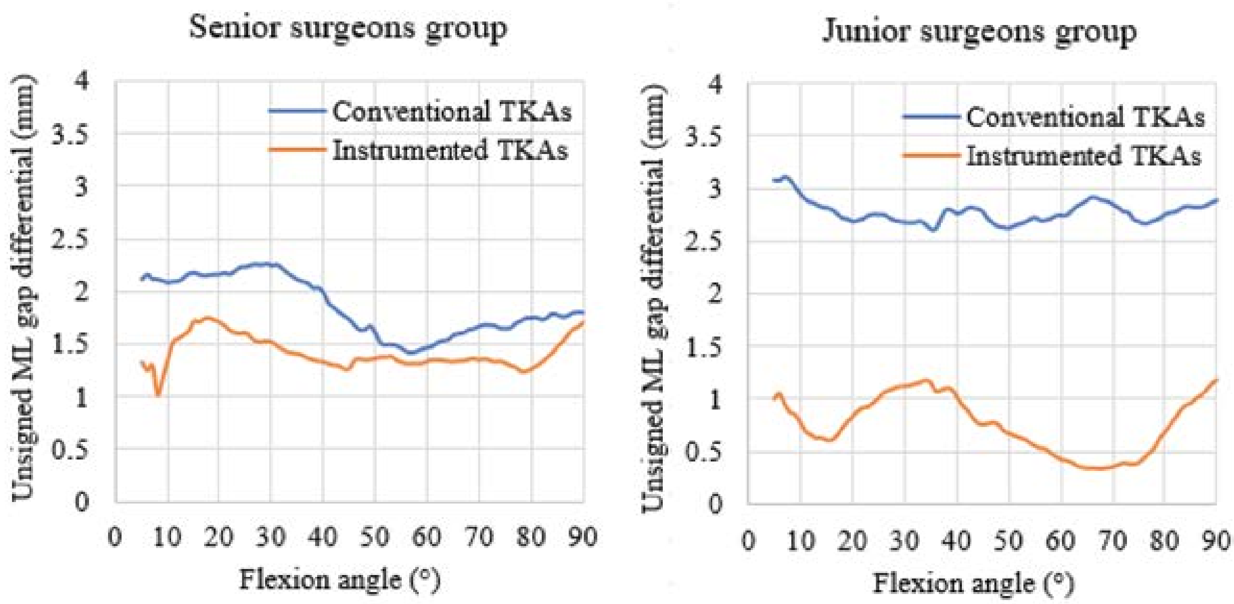


**Figure 2B: Impact of the instrumentation on the unsigned ML gap differential as a function of the flexion angle for the senior and the junior groups**

## DISCUSSION

Historically, soft tissue balancing during TKA has been reported as an art rather than a science.[4] This statement is mostly due to the difficulty to objectively assess the soft-tissue envelope leaving the surgeon with his/her subjective assessment. In this context, the surgeon's experience is deemed crucial.

In this regard, the addition of a dedicated technology to characterize the soft-tissue envelope during TKA has the potential to provide an augmented perspective to the surgeon.[4,5] As illustrated by the present study, this characterization may be particularly beneficial for junior surgeons.

As an attempt to evaluate the impact of the instrumentation and the user experience, it was asked that the surgeons aim for rectangular gaps in both extension and flexion. While this target is frequently considered the gold standard, several recent studies recommended adapting the balance to the conformity level of the considered implant and therefore contemplate a slightly asymmetric extension and flexion gaps with a tighter medial than lateral compartment.[6]

Another disputable topic relates to the permissible amount of ML gap differential distinguishing a balanced TKA from an unbalanced TKA. While some studies suggest that a differential as small as 1.5-2 mm may impact the outcomes[7,8], the perceived limit is assumed to be multi-factorial.

Finally, in contrast with a similar recent cadaveric study comparing robot assisted TKA and conventional TKA where there were no significant intergroup differences for laxity[9], the present study established that the usage of instrumented CAOS led to significantly lower ML gap differences than conventional instrumentation.

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# Ability to Achieve Mediolateral Gap Balance with Instrumented Navigated Total Knee Arthroplasty – A Review of the First 150 Cases

**Laurent Angibaud[1], Amaury Jung[2], Cyril Hamad[2], Wen Fan[1], Mark Davis[3], Brian Zirgibel[4], Jake Deister[5], James Huddleston[6]**

[1]Exactech, Gainesville, FL, USA, [2]Blue-Ortho, Meylan, FR, [3]Davis Orthopaedics, Prescott Valley, AZ, AZ, USA, [4]Tallahassee Orthopedic Clinic, Tallahassee, FL, USA, [5]Stormont Vail Health, Topeka, KS, USA, [6]Stanford University Medical Center, Stanford, CA, USA
Presented at CAOS 2022 Annual Meeting.

## ABSTRACT

Appropriate management of the soft tissue envelope at the time of the surgery is critical to the long-term success of total knee arthroplasty (TKA). In this regard, this study evaluated the ability to achieve the targeted ML gap balance when using a computer-assisted orthopedic surgery (CAOS) system featuring a force-controlled intraarticular distractor. The first 150 cases performed by 16 surgeons were reported without any exclusions, and for each of these cases, the final mediolateral (ML) laxity was compared to the predicted ML laxity. The average signed ML laxity was well aligned with a neutral differential throughout the full arc of motion and ranged from -0.05mm at 35° of flexion to 0.37mm at 85° of flexion. The signed ML laxity curves tend to be surgeon-specific. The average unsigned ML laxity was linear throughout the full arc motion and ranged from 1.14mm at 85° of flexion to 1.27mm at 30° of flexion. Despite data from all the users (not only design surgeons) involved with this pilot release were considered and the learning curve cases were not excluded, it was observed a high ability to achieve the targeted ML laxity using the proposed method.

## INTRODUCTION

Appropriate management of the soft tissue envelope at the time of the surgery is critical to the long-term success of total knee arthroplasty (TKA) [1]. In this regard, recent computer-assisted orthopedic surgery (CAOS) systems encompass the possibility of characterizing the soft-tissue envelope throughout the full arc of motion so the planning for the bone cut parameters can be based on thorough soft-tissue information in addition to the usual size and alignment considerations [2]. Also, at the time of the trial reduction, these systems offer the possibility of performing a final check of the achieved ligament balance of the knee joint. However, only few studies have detailed the ability to achieve the targeted mediolateral (ML) gap balance [3].

The objective of this study was to assess this ability by comparing the final ML laxity measured during the trial reduction with the predicted ML laxity defined at the time of the femoral planning prior to any bone resections for the first 150 cases performed using an instrumented CAOS system.

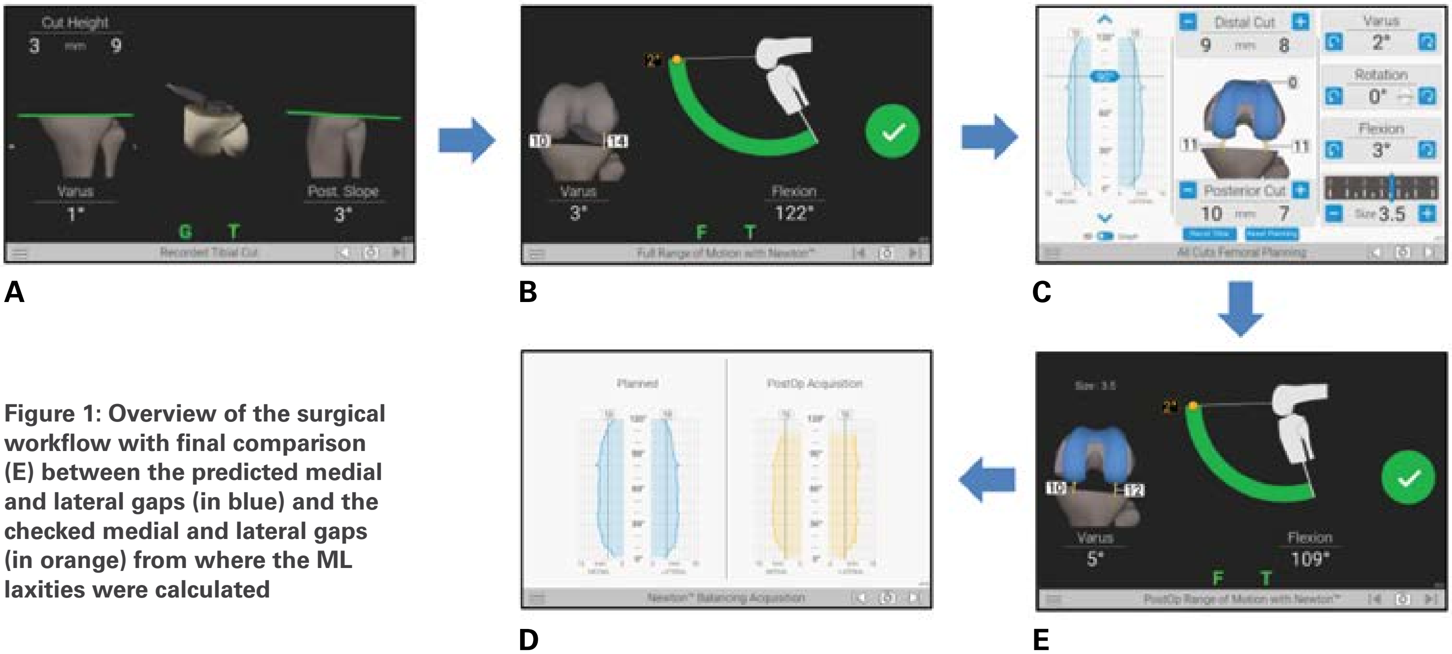


**Figure 1: Overview of the surgical workflow with final comparison (E) between the predicted medial and lateral gaps (in blue) and the checked medial and lateral gaps (in orange) from where the ML laxities were calculated**

## 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). The study cohort includes the first 150 cases associated with a tibia first technique performed by 16 different surgeons without any exclusions. All technical logs were stored as deidentified surgery reports that only contain technical information such as surgical time (defined as the intraoperative CAOS system usage duration), surgical workflow, surgical parameters, implant information, etc.

All the cases followed a similar surgical workflow; where after attachment of the active tracking arrays to the femur and the tibia, the anatomical landmarks were acquired by the imageless CAOS, and then the proximal tibia was resected according to the surgeon's preference (see Figure 1A). At this stage, an intraarticular distractor intended to apply a force-controlled distraction was placed between the proximal tibial cut and the native femur while the knee was taken throughout the arc of motion and both the medial and lateral gaps were captured by the CAOS system (see Figure 1B). Based on these inputs, the planning of the femoral cut parameters was set up and the first set of ML laxity (predicted ML laxity) was defined as the difference between the lateral gap and the medial gap considering both the virtual position/orientation of the planned femoral component and the previously characterized soft-tissue envelope (see Figure 1C).

After the completion of the femoral cuts according to the plan, a trial femoral component was impacted onto the prepared distal femur and the intraarticular tibial distractor was re-introduced into the joint space. Then, the limb was manipulated from extension to full flexion and the spatial positions of the femoral component relative to the acquired proximal tibial cut were captured by the CAOS system (see Figure 1D). From these acquisitions, the second set of ML laxity (checked ML laxity) was defined as the difference between the lateral gap and the medial gap calculated as the space between the most distal aspect of the femoral component and the proximal tibial cut (see Figure 1E).

Therefore, the ability to achieve the plan in terms of ML laxity was assessed by comparing the checked ML laxity and the planned ML laxity every 10° from 0° up to 120° as follows:

— Signed ML laxity = $\text{Checked}\,(Gap_{lateral} - Gap_{medial}) - \text{Planned}\,(Gap_{lateral} - Gap_{medial})$

— Unsigned ML laxity = $|\text{Checked}\,(Gap_{lateral} - Gap_{medial}) - \text{Planned}\,(Gap_{lateral} - Gap_{medial})$

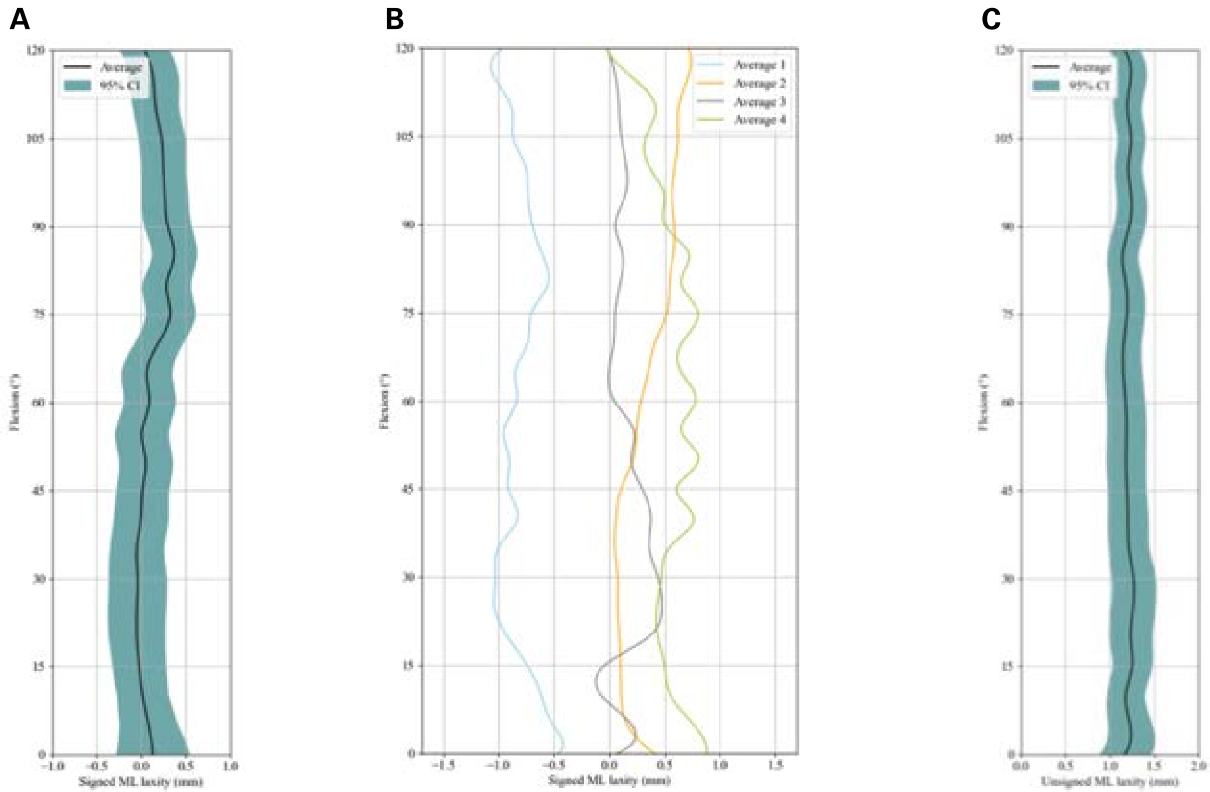


**Figure 2: Signed ML laxity (A), examples of signed ML laxity for individual surgeons 1-4 (B), and unsigned ML laxity (C).**

The ML laxity for the individual surgeons with more than 10 cases were reviewed as an attempt to identify individual trend(s).

The overall difference of either signed or unsigned ML laxities acquired at 15°, 45°, 75°, and 105° was tested by ANOVA test. To examine heterogeneity of distributions of signed ML laxity on a surgeon basis, a pairwise two-sided Kolmogorov-Smirnov test was performed. The significance level was set to be 0.05. R-studio (version 3.6.1) was used for all statistical analyses.

## RESULTS

The average signed ML laxity was well aligned with a neutral differential throughout the full arc of motion, with a local minimum of -0.05mm at 35° of flexion and a local maximum of 0.37mm at 85° of flexion. In terms of the general trend, the portion from 60° to 120° of flexion was exclusively positive meaning that the ML laxity between the lateral compartment and the medial compartment was higher during the trial reduction compared to the plan, however there was no statistical difference between the signed ML laxities acquired at 15°, 45°, 75°, and 105° ($p=0.41$) (see Figure 2A).

When considering the signed ML laxity for the 4 individual surgeons associated with more than 10 cases, it was observed that the signature of the ML laxity tends to be surgeon specific. Except for the comparison between surgeon 2 and surgeon 3, all other combinations have a significantly different distribution of the ML laxity ($p<0.05$) (see Figure 2B).

The average unsigned ML laxity ranged from a minimum of 1.14mm obtained at 85° of flexion to a maximum of 1.27mm at 30° of flexion (see Figure 2C). Like the signed ML laxity, there was no statistical difference among the signed ML laxity acquired at 15°, 45°, 75°, and 105° ($p=0.94$) (see Figure 2C).

## DISCUSSION

This study investigated the ability to achieve ML gap balance during tibia first TKA using a force-controlled intraarticular distractor integrated with a CAOS system to optimize the soft-tissue balance. The proposed technique achieved final ML laxity that was similar to the planned ML laxity throughout the full arc of motion, which demonstrated its ability to successfully execute the expected plan. Such ability is aligned with the outcomes from a previous study using a robotic tensioning device integrated with a CAOS system [3], however in the present study, data from all the users (not only the design surgeons) involved with this pilot release were considered and the learning curve cases were not excluded.

The slight differences between the final and the planned ML laxity are assumed to be multifactorial. First, for some of these cases, posterior condylar osteophytes were not fully removed at the time of the initial acquisition of the ML laxity, which would impact the gap balancing plan [4]. In addition, slight discrepancies of the actual femoral cuts compared to the plan are expected, which would impact the joint balance too. In this regard, it should be mentioned that the CAOS system has a claimed accuracy of ±1mm and ±1° [5] and the physical execution of the cuts may slightly deviate from the plan (within 1 mm).

No instructions were given regarding the set-up of the plan in terms of ML laxity and were at the surgeon's discretion. While some aim for a rectangular gap, others elected to add a lateral laxity of 1-2 mm. This personalization may explain the observed tendency for the ML laxity curved to be surgeon-specific.

Further evaluation will encompass the impact of the femoral plan on the ML laxity as well as the evolution of gap thicknesses along with the case.

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# CAOS TKA Provides Improved Functional Outcomes Compared to Conventional TKA

**Wen Fan[1], Yifei Dai[1], Gérard Giordano[2*]**

1* Exactech Inc, Gainesville, FL 32653, USA
2 Hôpital Joseph Ducuing, Toulouse, FR
Presented at CAOS 2022 Annual Meeting.

## ABSTRACT

This study examined the advantages of CAOS TKA in short-term functional outcomes compared to conventional instrumented TKA. Data were collected from a prospective, multi-center study where 334 were treated with CAOS TKA, and 461 were treated with conventional TKA. Postoperatively at 2-3 year, the CAOS cases had significantly better range of motion (ROM), KSS function, and sub-component measures of KSS function than the conventional cases. Further analysis revealed that geographic region was associated with ROM but had no significant impact on KSS function. CAOS TKA was associated with higher postoperative KSS function and its sub-component measures. The short-term results reported support the use of CAOS technology with the goals of better function.

## INTRODUCTION

Computer-assisted orthopedic surgery (CAOS) has been shown to offer clear advantage regarding surgical accuracy in total knee arthroplasty (TKA), with a body of research studies demonstrating significant reduction of alignment outliers compared to conventional TKA [1-2]. However, conflicted data exists in the literature for a consensus regarding the advantage of CAOS technology in clinical outcomes or satisfaction rates for the patient. While some studies have shown superior functional outcomes in CAOS TKA compared to its conventional counterparts[3], others reported no difference between CAOS and conventional cases.[4] More studies are needed to further contribute knowledge and evidences to this topic. The objective of this study was to compare short-term clinical outcomes between TKA cases performed using a contemporary CAOS system and cases with conventional instrumentation.

## MATERIALS AND METHODS

With institutional review board-approval and patient's signed informed consent, a prospective, multicenter, consecutive TKA case series was collected by 3 surgeons from 3 different clinical sites [2 US sites, 1 EU site] using the same implant system. Seven hundred and ninety-five patients were enrolled with surgery date between November 2009 and September 2018, including 334 CAOS TKA cases and 461 conventional TKA cases. Each surgeon performed both CAOS and conventional surgeries. Patient demographics, baseline clinical measurements, and the latest minimum 1yr follow-up visit were reviewed and compared between the CAOS TKA group and the conventional TKA group. The clinical measurements investigated were Range of Motion (ROM), Knee Society Score (KSS: knee, function, pain, and each sub-component measure), and patient satisfaction Visual Analog Scale (VAS 1-10, with 10 indicating the highest satisfaction). All data analyses were performed using custom scripts in R 3.6.1 (RStudio, Inc., Boston, MA, USA). Two-sample t-test was used for continuous outcomes, and chi-squared test was used for binary outcomes. To further assess the detected postoperative significance, a multivariate regression analysis was performed to assess the impact of region (EU vs US) and treatment type (CAOS vs conventional). Statistical significance was defined as $p \leq 0.05$.

## RESULTS

At the time of study, 215 CAOS and 350 conventional patients were available for analysis of patient reported outcomes, with mean postoperative follow-up periods of approximately 2-3 year (Table 1A). Patients from CAOS group were older and had higher BMI than those from conventional group (p values $< 0.01$, Table 1A). Preoperatively in the baseline measures, although CAOS patients had higher KSS function score than patients in conventional group, no significant difference was found in each sub-component measure under KSS function ("Walking", "Stairs", and "Walking Aid") (Fig 1). No other differences existed between the two groups regarding patient characteristics and preoperative baseline.

Postoperatively, significant higher ROM was achieved in the CAOS group compared to the conventional group ($p < 0.01$, Table 1B). In addition, higher KSS function score were found in CAOS compared to conventional group ($p < 0.01$, Table 1B). The differences were further expressed in the sub-component measures. Compared to the conventional patients, CAOS patients scored significantly better in all sub-component measures (p values $\leq 0.05$, Fig 2). No difference was found in KSS knee, and KSS pain scores. Alth ough EU patients was found associated with higher postoperative ROM, geographic region was not significantly correlated with KSS function and its sub-component measures. In contrast, CAOS

A

| | CAOS | Conventional | P |
|---|---|---|---|
| N | | | |
| Enrolled | 334 | 461 | - |
| 1yr+ Follow-up Available | 215 | 350 | - |
| Mean Follow-up Period (months) | 20.7 | 38.1 | - |
| Age (year) | 67.5 ± 9.2 | 63.9 ± 9.5 | < 0.01 |
| BMI (year) | 30.7 ± 7.1 | 32.1 ± 6.4 | < 0.01 |
| Male (%) | 37.7% | 44.2% | 0.09 |
| Primary OA (%) | 89.2% | 85.8% | 0.22 |

B

| | CAOS | Conventional | P |
|---|---|---|---|
| Preop | | | |
| ROM | 111.2 ± 15.8 | 113.5 ± 13.2 | 0.07 |
| KSS Function | 49.2 ± 20.4 | 45.4 ± 19.3 | 0.02 |
| KSS Knee | 44.9 ± 16.7 | 45.2 ± 16.3 | 0.70 |
| KSS Pain | 8.9 ± 11.9 | 7.5 ±10.2 | 0.11 |
| Postop | | | |
| ROM | 121.7 ± 12.3 | 117.5 ± 12.2 | < 0.01 |
| KSS Function | 78.3 ± 20.5 | 71.8 ± 23.3 | < 0.01 |
| KSS Knee | 80.5 ± 20.1 | 79.8 ± 21.3 | 0.63 |
| KSS Pain | 40.4 ± 13.2 | 42.1 ± 12.6 | 0.12 |

**Table 1. A) Details on demographics and characteristics of the study cohort. B) Summary of pre- and post- operative outcomes.**

surgery was significantly associated with better KSS function and its sub-component measures ("Walking" and "Stairs") compared to conventional surgery (p values < 0.04). Both groups achieved a mean satisfaction rate of 9 (N.S.). Fourteen conventional cases were revised due to pain (5), loosening (3), infection (2), instability (1), and patellofemoral complications (3). Four knees in the CAOS group were revised due to infection (4).

## DISCUSSION

This study demonstrated significantly better short-term functional outcome for the patients received CAOS TKA compared to those received conventional TKA. Aligned with the reports from previous studies[3,5], the findings from this study added to the existing evidences on the benefits of CAOS regarding achieving improved clinical outcomes compared to conventional TKA. Additionally, compared to conventional TKA, the CAOS group demonstrated excellent short-term survivorship with zero case of early failure due to causes linked to postoperative mal-alignment.

This study may be limited by only presenting short-term outcomes, mid- to long- term performance of the CAOS TKA in the studied cohort remains to be shown. The short-term results reported by this study support the use of CAOS technology with the goals of better function and greater range of motion. Future steps of the study include longer follow-up periods and further recruitment of global study sites for a more robust patient cohort.

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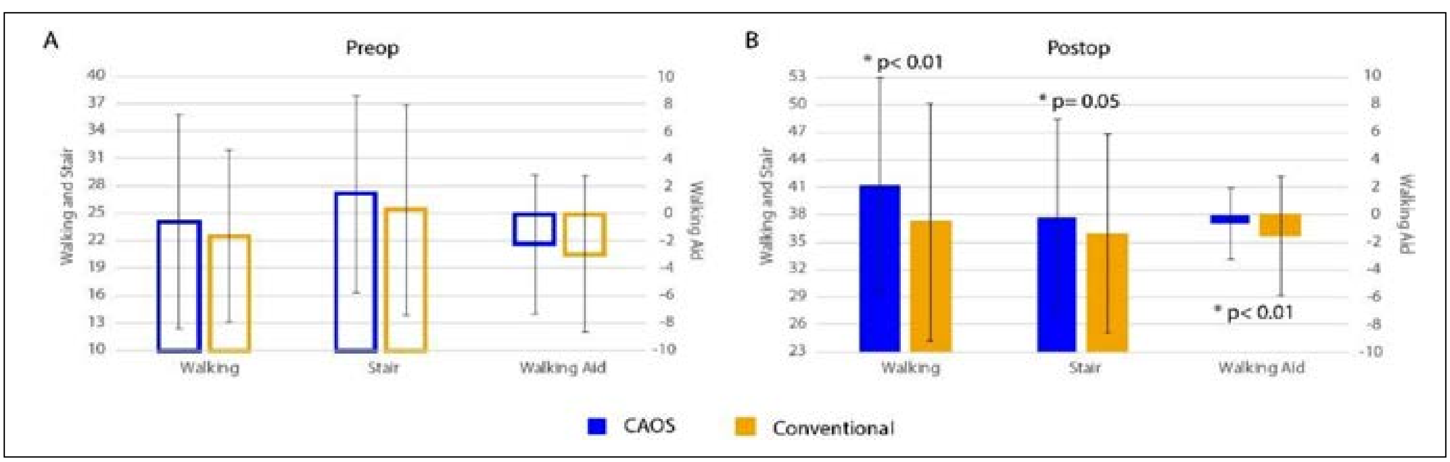


**Table 2. Comparisons between CAOS and conventional TKA groups regarding sub-component measures under A) preop and B) postop KSS function. Preoperatively, all sub-component measures were statistically equivalent between CAOS and conventional groups. In contract, all sub-component measures demonstrated better outcome in the CAOS group compared to the conventional group. Charts on KSS knee was not shown due to no difference was found in the postoperative comparisons.**

GPS | KNEE

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

**Dai Y[1], Bolch C[1]*, Jung A[2], Hamad C[2]**

[1]Exactech Inc, Gainesville, FL, 32653, USA
[2]Blue Ortho, Gieres FR
Presented at CAOS 2022 Annual Meeting.


TKA Pro

## 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) Accuracy measurement*$_{ijk} = \gamma_{00k} + U_{0jk} + \varepsilon_{ijk}$

*Where* $\gamma_{00k}$ *= the grand mean of the resection error,* $U_{0jk}$ *= random residual for level II variance,* $\varepsilon_{ijk}$ *= random residual for level I variance,* $U_{0j} \sim N(0, \sigma^2_{\mu o})$, $\varepsilon_{ij} \sim N(0, \sigma^2_{\varepsilon})$, *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 ± 0.94° and -0.09 ± 1.73°, respectively. For the femoral resection, the deviations in coronal alignment (femoral varus/valgus angle) and sagittal alignment (femoral flexion) were 0.00 ± 0.97° and -0.17 ± 1.44°, 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°/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.[1-4] 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<br>EU: France, Switzerland, United Kingdom, Italy, Spain<br>USA | 3 |
| Individual Established Surgeons | A data subset containing surgeons with ≥ 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<br>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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12-0002835 Rev. A 0922