



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

Laurent Angibaud¹, Amaury Jung², Cyril Hamad², Wen Fan¹, Mark Davis³, Brian Zirgibel⁴, Jake Deister⁵, James Huddleston⁶

¹Exactech, Gainesville, FL, USA, ²Blue-Ortho, Meylan, FR, ³Davis Orthopaedics, Prescott Valley, AZ, AZ, USA, ⁴Tallahassee Orthopedic Clinic, Tallahassee, FL, USA, ⁵Stormont Vail Health, Topeka, KS, USA, ⁶Stanford University Medical Center, Stanford, CA, USA

Laurent.angibaud@exac.com

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.

1 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) (Gustke, et al., 2014). 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 (Shalhoub, et al., 2018). 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 (Shalhoub, et al., 2019).

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.

2 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).

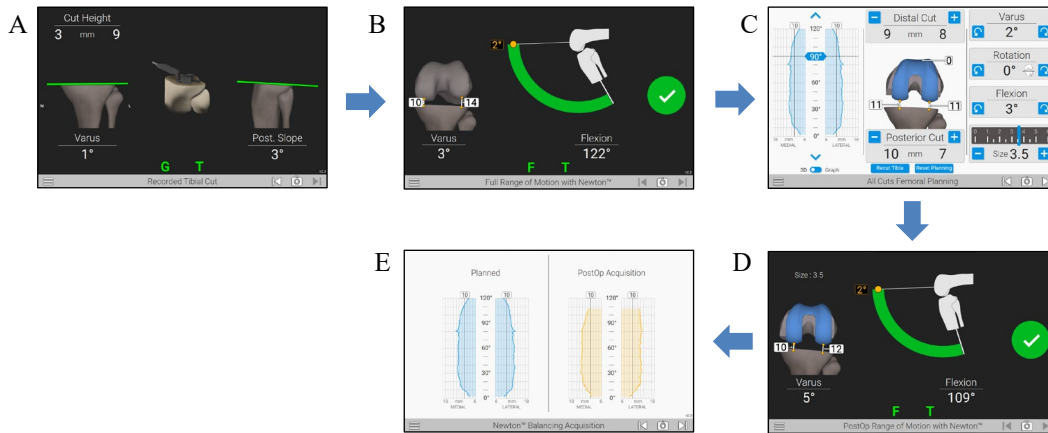


Figure 1: Overview of the surgical workflow with final comparison (E) between the predicted medial and lateral gaps (in blue) and the checked medial and lateral gaps (in orange) from where the ML laxities were calculated

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 = Checked (Gap_{lateral}-Gap_{medial}) – Planned (Gap_{lateral}-Gap_{medial})
- Unsigned ML laxity = |Checked (Gap_{lateral}-Gap_{medial}) – Planned (Gap_{lateral}-Gap_{medial})|

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.

3 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).

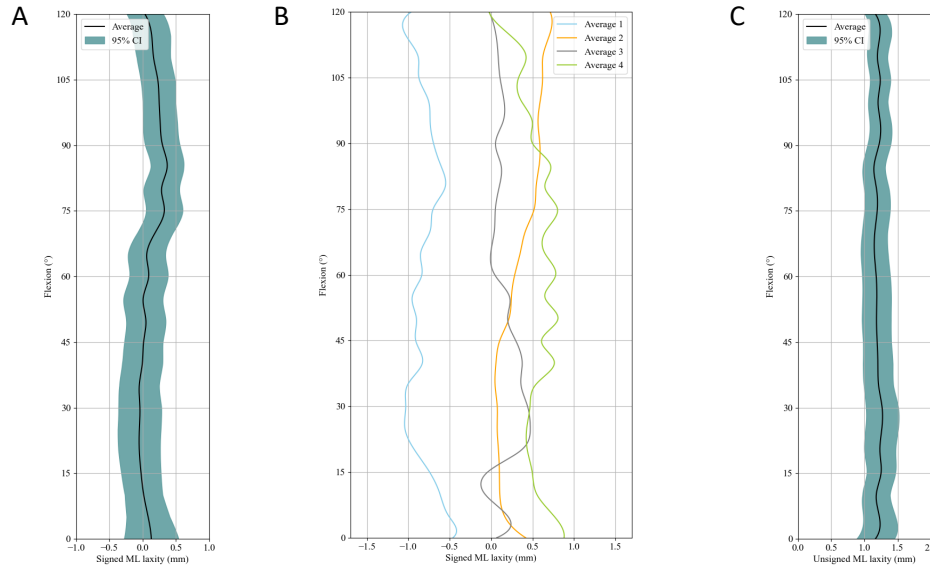


Figure 2: Signed ML laxity (A), examples of signed ML laxity for individual surgeons 1-4 (B), and unsigned ML laxity (C).

4 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 (Sriphirom, et al., 2018). 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 ± 1 mm and $\pm 1^\circ$ (Angibaud, et al., 2015) 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.

References

- Angibaud, L. et al., 2015. Evaluation of the Accuracy and Precision of a Next Generation Computer-Assisted Surgical System. *Clinics in orthopedic surgery*, 7(2), pp. 225-233.
- Gustke, K. A. et al., 2014. Increased satisfaction after total knee replacement using sensor-guided technology. *The bone & joint journal*, Volume 10, pp. 1333-1338.
- Shalhoub, S. et al., 2019. Imageless, robotic-assisted total knee arthroplasty combined with a robotic tensioning system can help predict and achieve accurate postoperative ligament balance. *Arthroplasty Today*, 5(3), pp. 334-340.
- Shalhoub, S. et al., 2018. Laxity Profiles in the Native and Replaced Knee-Application to Robotic-Assisted Gap-Balancing Total Knee Arthroplasty. *The Journal of arthroplasty*, 33(9), pp. 3043-3048.
- Sriphirom, P., Siramanakul, C., Chanopas, B. & Boonruksa, S., 2018. Effects of posterior condylar osteophytes on gap balancing in computer-assisted total knee arthroplasty with posterior cruciate ligament sacrifice. *European journal of orthopaedic surgery & traumatology : orthopedie traumatologie*, 28(4), pp. 677-681.