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

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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.

1 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

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outcome (Gustke, et al., 2014) (Golladay, et al., 2019). 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 (Shalhoub, et al., 2018).

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.

2 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.

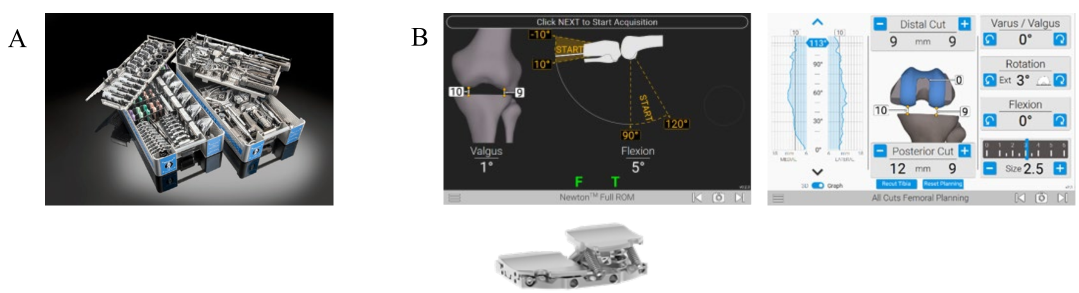


Figure 1:Conventional mechanical instrumentation (A) and instrumented CAOS system (B)

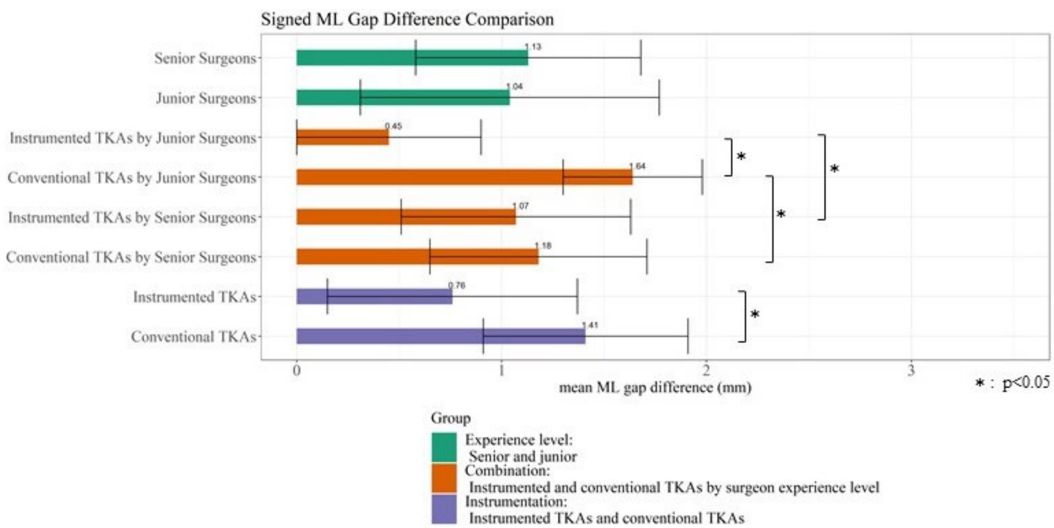
The conventional TKAs were performed via the preferred technique of the user, while the instrumented TKAs were performed using a tibia first technique, where the intraarticular distractor intended to apply a quasi-constant distraction force was placed between the proximal tibial cut and the native femur 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.

3 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).



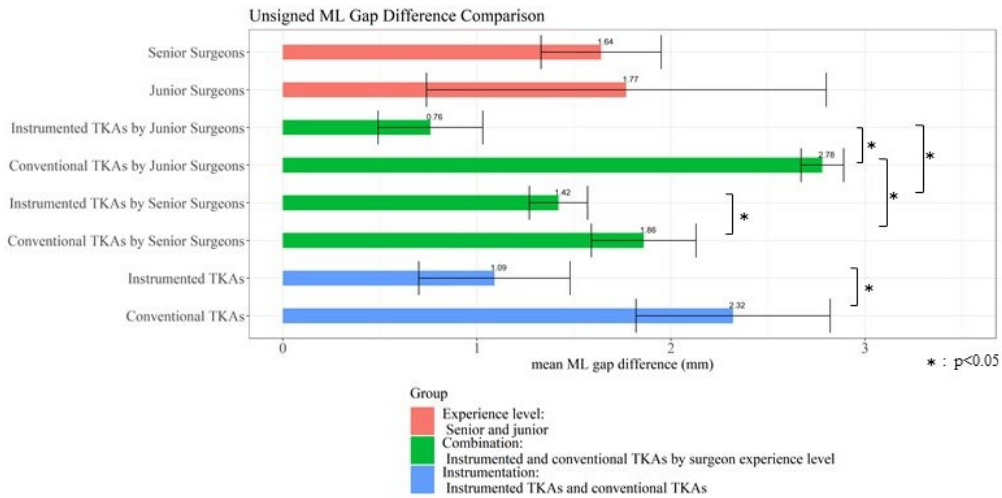


Figure 2A: Mean and standard deviation of the signed and unsigned ML gap differential for the different considered groups

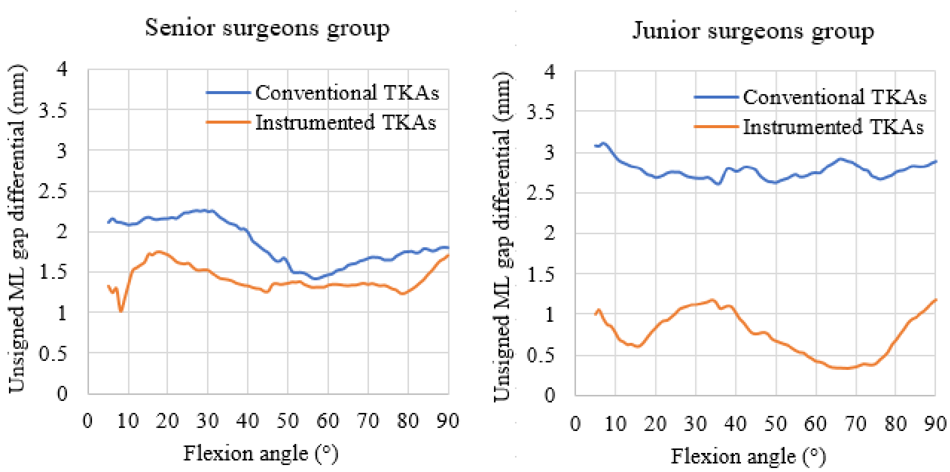


Figure 2B: Impact of the instrumentation on the unsigned ML gap differential as a function of the flexion angle for the senior and the junior groups

4 Discussion

Historically, soft tissue balancing during TKA has been reported as an art rather than a science (Held, et al., 2021). 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 (Held, et al., 2021) (Elmallah, et al., 2016). 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 (Risitano & Indelli, 2017).

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 (Nielsen, et al., 2018) (Keggi, et al., 2021), 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 (Manning, et al., 2020), the present study established that the usage of instrumented CAOS led to significantly lower ML gap differences than conventional instrumentation.

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