Extramedullary Guides versus Portable Navigation for Tibial Component Alignment: A Randomized, Controlled Trial

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Introduction: Conventional, extramedullary (EM) tibial alignment guides are only 65% to 88% accurate in creating a resection within 2° of perpendicular to the mechanical axis in total knee arthroplasty (TKA). The purpose of this study was to compare the tibial component alignment, and the ability to achieve a specific goal for alignment between a portable, accelerometer-based navigation device, and EM guides.

Methods: Five fellowship-trained, attending orthopaedic surgeons specializing in adult reconstruction participated in this prospective, randomized controlled study. Patients received a TKA using either the navigation device (navigation cohort; Figure 1), or an EM guide (EM cohort) to perform the tibial resection. Intraoperatively, surgeons recorded their alignment goal, and an intramedullary (IM) femoral guide was used for all TKAs. Standing AP hip-to-ankle radiographs and lateral knee-to-ankle radiographs were performed at the first, postoperative visit. Two, independent observers in a blinded fashion measured the tibial component varus/valgus and posterior slope (Figure 2), femoral component varus/valgus, and lower extremity alignment.

140 total patients were required to detect a 20% improvement in accuracy with appropriate power (beta level = 0.80, alpha level = 0.05). A mid-term analysis after the enrollment of 100 patients revealed a statistically significant difference with adequate power (minimal effect size of a 24% difference), and enrollment was discontinued. A Student’s two-tailed t-test was used to compare continuous variables, and a Fischer’s exact test was used to compare the number of “outliers” in each cohort (p<0.05=significant). Based on prior studies assessing the accuracy of component alignment, an “outlier” was considered a tibial or femoral component outside of 2° of perpendicular to the coronal mechanical axis, and a tibial component alignment outside of 3° + 2° of posterior slope relative to the sagittal mechanical axis(1). Interclass correlation coefficients were calculated between the two, blinded observers.

Results: 95.7% of tibial components in the navigation cohort were within 2° of perpendicular to the coronal, tibial mechanical axis, versus 68.1% in the EM cohort (p<0.001). 95.0% of the tibial components were within 2° of a 3° posterior slope, versus 72.1% in the EM cohort (p=0.007). The difference between the surgeon’s goal and postoperative alignment for varus/valgus was 0.9° + 0.7° in the navigation cohort, versus 1.5° + 1.1° in the EM cohort (p<0.001). For posterior slope, the difference was 0.9° + 1.2° in the navigation cohort, versus 1.8° + 1.7° in the EM cohort (p=0.01).

Only 70.2% of femoral components in the navigation cohort and 66.0% in the EM cohort were within 2° of perpendicular to the coronal, femoral mechanical axis, and a tibial component alignment outside of 3° + 2° of posterior slope relative to the sagittal mechanical axis(1). Interclass correlation coefficients were calculated between the two, blinded observers.

The mean time to perform the tibial resection was significantly increased in the navigation cohort versus the EM cohort (290.0 + 125.3 seconds versus 70.6 + 28.1 seconds, p<0.001). The blinded, interobserver correlation coefficients were good to excellent for all measurements (r=0.84 to 0.97).

Discussion: This randomized, controlled study demonstrates a portable, accelerometer-based navigation device to significantly improve tibial component alignment, and the surgeon’s ability to achieve a specific, intraoperative goal, versus conventional, EM guides in TKA.

Significance: This randomized, controlled study demonstrates that a portable, accelerometer-based navigation device significantly improves tibial component alignment versus EM guides in TKA.

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