

**Title:** Effect of Patient Specific Instrumentation on Kinematics in Total Knee Replacements

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**Structured Abstract:**

**Introduction:** Currently, the only treatment for end stage arthritis in the knee is total knee replacement (TKR). Even though TKR has improved over the years, with implants having greater longevity, patient satisfaction following TKR has not improved, with approximately 20% of patients recording dissatisfaction with their new knee joint. Manufacturers have attempted to solve this issue with patient specific instrumentation (PSI), custom surgical guides designed pre-operatively using MRI or CT scans. However, no consensus has been reached on the effectiveness of PSI. With the use of radiostereometric analysis (RSA), the current study aims to analyze the knee throughout flexion when PSI is used to determine whether PSI provides an improvement to TKR. We hypothesize that using PSI will provide a more stable knee consistent with more natural kinematics throughout flexion than conventional instrumentation (CI).

**Methods:** A cohort of 50 patients undergoing TKR were recruited to the study and randomized evenly to either PSI (Visionaire, Smith & Nephew, TN, USA) or conventional instruments. All patients received the same implant (Legion, Smith & Nephew) and postoperative care. At the 2-year follow-up, a series of RSA images were acquired at different knee flexion angles, ranging in 20° increments from 0° to 120°. Model-based RSA software (RSACore, Leiden, Netherlands) was used to obtain the 3D positions and orientations of the femoral and tibial implant components. Results from the model-based RSA software were used to attain kinematic measures for each condyle of magnitude of excursion, contact location, and stability, measured as the root mean square of the incremental anterior-posterior (AP) position change between mid-flexion angles (20° to 100°), and the incidence of condylar separation. Statistical analyses (t-test, Mann-Whitney test, and Fisher exact test) were performed for comparisons between PSI and CI.

**Results:** Preliminary results from 36 patients (16 PSI, 20 CI) suggest that there is no significant difference between PSI and CI groups with respect to magnitude of excursion on both medial (mean difference=0.58 mm,  $p=0.54$ ) and lateral (mean difference=0.42 mm,  $p=0.81$ ) condyles. There was also no difference in contact locations on both the medial and lateral condyles ( $p=0.28$  to  $0.91$ ) for all angles of flexion. Similarly, there was no significant difference present between PSI and CI groups when comparing the stability for both the medial (mean difference=0.82 mm,  $p=0.06$ ) and lateral (mean difference=0.19 mm,  $p=0.85$ ) condyles. Condylar separation was present in 3/20 CI patients and 0/16 PSI patients ( $p=0.24$ ).

**Discussion:** Early results suggest that PSI provides no substantial advantage for TKR surgery with respect to knee kinematics. Given its higher cost per case, it offers no benefit for routine primary TKR. Therefore, PSI may only be advantageous for cases with bone abnormalities that preclude the use of CI.