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Title: A Prospective Randomized Comparison of Patient Specific Instruments with Standard TKA Instrumentation

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Introduction:
Patient specific instruments (PSI), an alternative to standard total knee arthroplasty (TKA) technology, have shown mixed results regarding effectiveness in previous studies. This study evaluated the accuracy of the predicted PSI plan, compared incremental cost savings with PSI, and compared outcomes of PSI and standard TKA patients.

Patients and Methods:
This randomized, prospective feasibility study included 19 primary TKA patients receiving a cruciate-retaining cemented prosthesis from a single surgeon (DCA). 9 patients randomized to PSI received a pre-operative knee MRI for PSI fabrication using proprietary software. 10 standard TKAs were completed. Operative data collected included operating times, implant details, femoral (medial/lateral distal and posterior) and tibial (medial/lateral) resections, and instrument trays used. Hospitalization data collected included length of stay, blood loss, drain output, and transfusions. SF-36 and WOMAC scores, routine radiographic analysis, and femoral-tibial angles were collected pre- and post-operatively. Costs of operating room use and anesthesia, implants, and hospitalization were collected. Statistical analyses included t-tests and chi-square tests.

Results:
All implant sizes matched surgical team adjusted PSI software plans. Flexion gap resection (posterior medial/lateral femur) was extremely accurate (average <1 mm). Sagittal plane tibial component posterior slope was larger in PSI TKA (mean 7.3 degrees) than standard instrumentation (mean 4.2 degrees) (p<0.02). Coronal mechanical limb alignment was similar between the two cohorts (p>0.05). There were no differences in operating room times or hospitalization data, and there were no significant differences in functional outcomes between the two groups (p>0.05). PSI patients used 4 fewer instrument trays per case (p<0.0001).

Conclusion:
PSI TKA demonstrated outstanding accuracy in bone resection when compared with the pre-operative plan, and resulted in appropriate limb and component alignment with primary TKA. The number of instrument trays used in PSI TKA was significantly less than standard TKA, which led to less cost for instrument sterilization and assembly.