Do Customized Implants Yield Superior Clinical and Functional Outcomes Compared to Off-the-Shelf Implants in Primary Total Knee Arthroplasty? A Propensity-Matched Analysis

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INTRODUCTION:

Customized implants have been developed to optimize functional outcomes in patients undergoing primary total knee arthroplasty (TKA). However, utilization remains limited in clinical practice; one study reported that only 2.3% of procedures employed customized implants. Customized implant systems require preoperative computed tomography (CT) imaging to design individualized femoral and tibial components. This tailored approach aims to enhance coronal and sagittal mechanical alignment, improve implant fit, optimize bone coverage, and restore the joint line with greater precision. However, customized implants are typically more expensive and involve complex ordering and manufacturing processes compared to off-the-shelf (OTS) implants. Additional challenges include the necessity for customized instrumentation. Despite the promising biomechanical and perioperative metrics, there is a lack of long-term evidence on clinical and functional outcomes in patients who receive customized implants. This study aims to evaluate whether these theoretical benefits translate into improved patient-reported outcome measures (PROMs) and whether they affect overall rates of readmission, reoperation, or revision following primary TKA.

METHODS:

A retrospective cohort study was conducted at a single institution to evaluate clinical and patient reported outcome measures following primary TKA using either customized or OTS implants. 11,210 consecutive primary TKA cases were reviewed. Of these, 2,477 patients with complete preoperative and postoperative PROMs met our inclusion criteria. Patients who received customized implants (n = 260) were matched to those who received OTS implants (n = 780) using 1:3 nearest-neighbor propensity score matching based on age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) classification, and Charlson Comorbidity Index (CCI). PROMs assessed included the SF-10 Physical Function (SF-10a), Patient-Reported Outcome Measure Information Systems (PROMIS) Global-Physical, PROMIS Global-Mental, and the knee disability and osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS). Delta scores were calculated as the difference between postoperative and preoperative scores. Minimal clinically important difference (MCID) thresholds were defined as one-half of the standard deviation of the delta score distribution for each PROM. Patients were categorized as improved (MCID-I), worsened (MCID-W), or unchanged based on these thresholds.

RESULTS:

Baseline demographics, including age, BMI, and gender, were comparable across both cohorts. Patients who received customized implants were more frequently discharged home compared to those in the OTS cohort (96.5% vs 87.2%, $p < 0.0001$) and experienced a shorter length of stay (38.02 ± 21.22 vs 43.01 ± 28.62 hours, $p = 0.0029$). No differences were observed in rates of readmission (7.3% vs 5.8%, $p = 0.4806$), reoperation (7.2% vs 5.8%, $p = 0.5229$), or revision surgery (5.1% vs 4.2%, $p = 0.6785$). While differences were identified in absolute mean preoperative and postoperative scores for SF-10a, PROMIS Mental, PROMIS Physical, and KOOS-PS between the two cohorts, no differences were observed in the corresponding delta scores. The proportion of patients achieving MCID-I did not differ between groups in any of the four surveys. Fewer patients who received a customized implant reached MCID-W based on the SF-10a (9% vs 14%; $p = 0.034$) and PROMIS Global Physical (7% vs 17%; $p < 0.001$) scores. No differences in MCID-W rates were observed between cohorts for PROMIS Mental (27% vs 31%; $p = 0.202$) or KOOS-PS scores (9% vs 9%; $p = 0.100$).

DISCUSSION AND CONCLUSION:

This is one of the first propensity-matched studies that compared various PROMs of patients who received customized or off-the-shelf implants using MCID thresholds. The customized implants cohort had a shorter length of stay and more frequent home discharge. While significant differences were observed in the absolute mean preoperative and postoperative PROM scores across multiple domains, no significant differences were found in the delta scores. Likewise, rates of achieving MCID-I did not differ significantly between groups for any PROM domain. Together, these findings indicate that patients experienced similar clinically meaningful improvements in PROMs regardless of implant type.