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 implants require preoperative computed tomography imaging to design individualized components. This tailored approach aims to enhance 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 potentially promising biomechanical and perioperative metrics, there is a lack of evidence on clinical and functional outcomes in patients who receive customized implants. Therefore, this study aims to evaluate whether these theoretical benefits translate into improved patient-reported outcome measures (PROMs) and clinical outcomes following primary TKA.

METHODS: This study was conducted at a single institution with IRB approval. 11,210 consecutive primary TKA cases were reviewed. A 1:3 nearest-neighbor propensity score matching based on age, sex, body mass index, diabetes, chronic kidney disease, heart failure, osteoporosis, and American Society of Anesthesiologists classification. The PROMs of interest included the SF-10 Physical Function (SF-10a), Patient-Reported Outcome Measure Information System (PROMIS) Physical, PROMIS Mental, and the Knee Injury 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. Ninety-day and one- and two-year postoperative complication rates were recorded for both groups.

RESULTS SECTION: After propensity-matching, 258 custom and 774 OTS patients were available for analysis, with no observed differences in demographics (p>0.05). Similar 90-day and one-year complication rates occurred in the two groups (p>0.05). Custom implants were associated with a higher two-year reoperation rate than OTS implants (6.6% vs 10.9%, p = 0.030). Absolute preoperative scores were higher in the custom implant group for the SF10-a (37.38 vs 38.19, p = 0.0355), PROMIS Mental (51.15 vs 52.22, p = 0.0401), PROMIS Physical (42.23 vs 43.04, p = 0.0294), and KOOS-PS (56.73 vs 59.60, p = 0.0184). Postoperative scores were higher in the custom group for the SF10a (43.44 vs 44.61, p = 0.0448), PROMIS Mental (52.22 vs 53.54, p = 0.0274), and PROMIS Physical (47.81 vs 49.69, p = 0.0005). However, there were no differences in delta scores or proportions of clinically significant improvement, no change, and worsening between groups in any PROMs (p>0.05).

DISCUSSION: 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. 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.

SIGNIFICANCE/CLINICAL RELEVANCE: There is no significant difference in Patient-Reported Outcome Measures between patients that undergo primary total knee arthroplasty with customized or off-the-shelf implants.

Variable	Off-the-shelf (N = 774)	Custom (N = 258)	P-value
Age (years)	68.5 ± 8.8	68.5 ±8.8	0.945
Body mass index (kg/m^2)	29.8 ± 5.5	29.6 ± 5.5	0.593
Female	377 (48.7%)	131 (50.8%)	0.183
Diabetes	95 (12.3%)	31 (12.0%)	1.000
Chronic kidney disease	36 (4.7%)	10 (3.9%)	0.728
Heart failure	17 (2.2%)	7 (2.7%)	0.811
Osteoporosis	122 (15.8%)	46 (17.8%)	0.496

Table 1. Demographic data of off-the-shelf and custom total knee arthroplasty patients following propensity-matching.

Patient-Reported Outcome Measure	Off-the-shelf	Custom	P-value
SF10-a	N = 721	N = 236	
Preoperative score	37.38 ± 5.23	38.19 ± 4.71	0.0355
Postoperative score	43.33 ± 7.69	44.61 ± 7.43	0.0448
Delta score	5.95 ± 7.10	6.42 ± 6.74	0.6102
PROMIS Mental	N = 731	N = 255	
Preoperative score	51.15 ± 8.61	52.22 ± 8.16	0.0401
Postoperative score	52.22 ± 8.86	53.54 ± 8.44	0.0274
Delta score	1.06 ± 6.40	1.32 ± 5.69	0.5856
PROMIS Physical	N = 731	N = 255	
Preoperative score	42.23 ± 7.13	43.06 ± 6.80	0.0294
Postoperative score	47.81 ± 8.32	49.69 ± 7.71	0.0005
Delta score	5.59 ± 7.12	6.63 ± 6.31	0.0989
KOOS-PS	N = 617	N = 116	
Preoperative score	56.73 ± 13.49	59.60 ± 13.44	0.0184
Postoperative score	70.95 ± 14.90	71.29 ± 15.19	0.8264
Delta score	14.22 ± 16.40	11.69 — 15.97	0.0841

Table 2. Patient-Reported Outcome Measures for patients undergoing primary total knee arthroplasty with off-the-shelf and custom implants.