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No clinical and functional benefit after medial congruent compared to ultra congruent total knee arthroplasty at 1 year: A prospective randomized controlled study

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Abstract

Purpose: Various conforming bearing designs are used during total knee arthroplasty (TKA), yet their impact on clinical outcomes remains uncertain. In recent years, the use of medial congruent (MC) and ultra congruent (UC) onlays has gained popularity. Hence, this study aims to evaluate the clinical outcomes of MC onlays compared to UC onlays in TKA.

Methods: A prospective randomized controlled trial including 80 patients with advanced varus knee osteoarthritis undergoing primary TKA was conducted. Patients were randomly assigned to receive either a MC ($n = 40$) or UC insert ($n = 40$). Seventy-six patients (MC = 38; UC = 38) completed the 12-month follow-up. The primary outcome was the Knee Society Score (KSS), assessed preoperatively, at 6 weeks and 12 months postoperatively. Secondary outcomes included range of motion (ROM) and patient-reported outcome measures (PROMs): Oxford Knee Score (OKS), Forgotten Joint Score (FJS-12) and High-Activity Arthroplasty Score (HAAS) at 3, 6 and 12 months. Patient satisfaction, recommendation and willingness to undergo the procedure again were evaluated at 12 months. Radiographic alignment was assessed pre- and postoperatively.

Results: Both groups showed significant improvement in the primary outcome KSS (MC: 87.6 ± 24.9 to 172.2 ± 20.3; UC: 94.2 ± 20.6 to 174.0 ± 23.7; $p < 0.001$ within both groups), ROM and PROMs without significant intergroup differences at any time point (all $p > 0.05$). The overall satisfaction rate (very satisfied + satisfied) was 94.7% in the MC group and 92.1% in the UC group with no significant difference in the distribution of satisfaction responses between groups ($p = 0.994$).

Conclusion: Both MC and UC inserts provided excellent clinical and functional outcomes 1 year after TKA, with high patient satisfaction and no statistically significant differences between designs. Thus, MC or UC designs may be chosen according to surgeon preference.

Abbreviations: BMI, body mass index; CI, confidence interval; FJS/FJS-12, Forgotten Joint Score/Forgotten Joint Score-12; HAAS, High-Activity Arthroplasty Score; IRB, institutional review board; KSS, Knee Society Score; MC, medial congruent; MWU, Mann–Whitney *U* test; OKS, Oxford Knee Score; PE, polyethylene; PROMs, patient-reported outcome measures; RCT, randomized controlled trial; ROM, range of motion; SD, standard deviation; SEM, standard error of the mean; TKA, total knee arthroplasty; UC, ultra congruent; VAS, Visual Analogue Scale.

Daniel Schrednitzki and Jonas Sina share first authorship.

Level of Evidence: Level I.

KEYWORDS

congruency, kinematics, medial congruent (MC), total knee arthroplasty (TKA), ultra congruent (UC)

INTRODUCTION

Total knee arthroplasty (TKA) is a successful procedure for alleviating pain and restoring function in patients with severe knee osteoarthritis [20]. Despite its clinical success, patient satisfaction and subjective outcomes often fall short when compared to total hip arthroplasty [15]. The selection of the onlay during TKA might significantly influence outcomes, particularly regarding kinematics and patient satisfaction [6, 8, 14, 26]. In an effort to better reproduce native knee kinematics and thereby improve functional outcomes and patient satisfaction, increasing attention has been directed toward insert designs. Accordingly, TKA bearing surface design has evolved considerably in recent years, including the development of congruent polyethylene (PE) inserts such as the medial congruent (MC) and ultra congruent (UC) designs [10, 13, 18].

UC inserts are promoted for offering enhanced stability while maintaining the benefits of cruciate-preserving knees compared to posterior-stabilized (PS) designs, aiming to prevent paradoxical anterior femoral translation without reliance on a cam-post mechanism [13]. Medial pivot and lateral/dual pivot PE designs were introduced to more closely mimic natural knee kinematics, particularly with regard to femoral rollback [21]. Data from national registries and practice surveys have documented a substantial change in implant selection patterns, with MC and medial pivot bearings emerging as the most widely adopted designs, while the use of PS implants has declined considerably [1, 5]. While previous literature reports favourable surgical and kinematic outcomes for the MC onlay designs [23, 24], its clinical superiority over traditional designs remains uncertain. Although contemporary TKA designs achieve excellent overall functional outcomes, potentially limiting the detectability of intergroup differences, the theoretical biomechanical rationale for MC inserts warrants rigorous evaluation through a prospective randomized trial. Therefore, this study aimed to compare clinical and patient-reported outcomes between MC and UC PE inserts in patients undergoing primary TKA for advanced varus knee osteoarthritis. The primary outcome was the Knee Society Score (KSS). Secondary outcomes included ROM, patient-reported outcome measures (PROMs; OKS, FJS-12, HAAS), pain (Visual Analogue Scale [VAS]) and patient satisfaction at 12 months. We hypothesized that the MC design, which more closely replicates the physiological ball-and-socket kinematics of the medial compartment [19], would result in superior clinical and patient-reported outcomes compared to the UC design at 1-year follow-up.

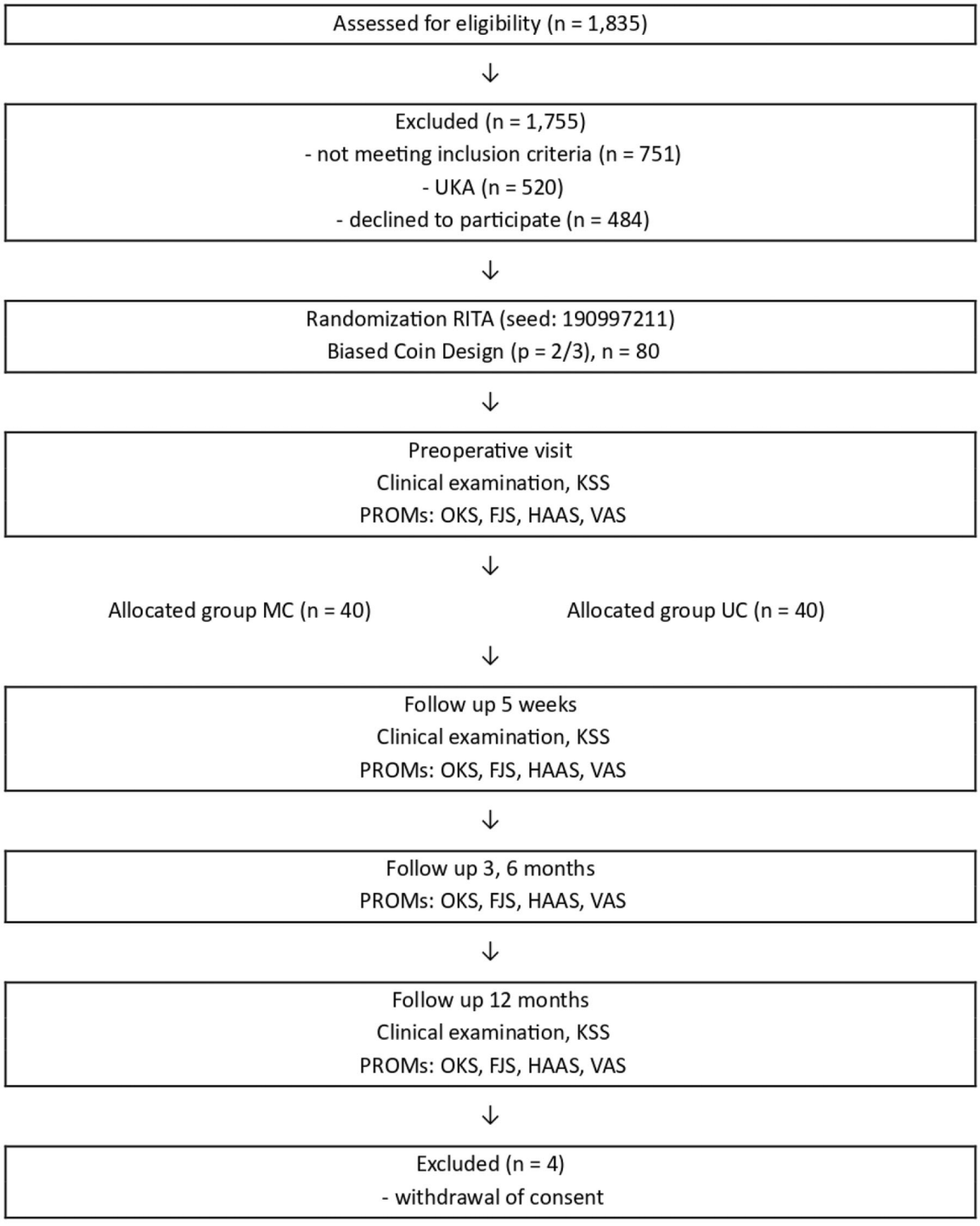
MATERIALS AND METHODS

We conducted a prospective, monocentric, randomized controlled trial (RCT) with two parallel study arms. Neither patients nor surgeons were blinded to the insert type, due to the nature of the surgical intervention. However, all clinical outcome assessments (KSS, ROM) were performed by an independent observer blinded to group allocation throughout the follow-up period. The study was approved by the Ethics review board of the Medical Association of Brandenburg (2021-2191-Bo-ff) and registered in the German Clinical Trials Register (DRKS00038345). Following approval, a total of 80 patients planned to undergo primary TKA between October 2020 and February 2021 were initially enroled, having met the inclusion and exclusion criteria. During the study interval, 1.835 knees were assessed for eligibility. Of these, 751 did not meet the inclusion and exclusion criteria, 520 underwent unicompartmental knee arthroplasty and 484 patients declined participation in this RCT (Figure 1). Among the initially enroled 80 patients, 4 withdrew their consent during the study interval (2 per group). All remaining 76 were followed for 1 year postoperatively and were available for the analysis.

Patients diagnosed with varus knee osteoarthritis, radiologically classified as Kellgren–Lawrence Grade 4, were eligible for inclusion. Exclusion criteria included a history of inflammatory arthritis, prior knee surgery, cruciate or collateral ligament instability, valgus deformity or a history of septic arthritis. All participants provided written informed consent prior to enrolment. Patients were then randomly assigned to either the MC or UC group using a software-based randomization method (RITA®—Randomization In Treatment Arms, Version 1.24). To ensure group balance, the Biased Coin Design was applied. A total of 80 patients were unblinded enroled using this algorithm. There were no significant differences in terms of age, height, weight, body mass index (BMI) and sex (all $p > 0.05$; Table 1).

Implant design and surgical technique

Participants received either a MC or UC PE onlay as part of the Persona Knee System (Fa. Zimmer Biomet;



Flow diagram illustrating patient screening, randomization, allocation to medial congruent (MC) and ultra congruent (UC) insert groups, follow-up, and exclusions throughout the study period.
Abbreviations: MC, medial congruent; UC, ultra congruent.

FIGURE 1 Patient enrolment and follow-up flowchart. FJS, Forgotten Joint Score; HAAS, High-Activity Arthroplasty Score; KSS, Knee Society Score; MC, medial congruent; OKS, Oxford Knee Score; PROMs, patient-reported outcome measures; RITA, Randomization In Treatment Arms; UC, ultra congruent; UKA, unicompartmental knee arthroplasty; VAS, Visual Analogue Scale.

TABLE 1 Baseline patient characteristics and preoperative clinical and patient-reported outcome measures.

	Group	*n*	Mean	Median	SD	SEM	Min	Max	Test	*p* Value
Weight (kg)	UC	38	92.29	91.00	15.49	2.513	61	138	*t*-test	0.152
	MC	38	98.18	100.50	19.75	3.203	66	158		
Height (cm)	UC	38	169.95	169.00	9.51	1.543	151	195	*t*-test	0.939
	MC	38	169.79	169.50	8.42	1.366	152	187		
BMI (kg/m^2)	UC	38	31.96	32.03	4.75	0.771	23.88	45.58	*t*-test	0.106
	MC	38	33.97	33.90	5.87	0.953	25.26	45.34		
Age (years)	UC	38	65.87	67.00	5.45	0.885	53	75	MWU	0.595
	MC	38	66.50	67.00	5.70	0.924	54	75		
Alignment (°)	UC	40	−7.88	−8	4.25	0.64	−21	−1	MWU	0.68
Preoperative	MC	40	8.18	−7	4.05	0.67	−17	1		
KSS—Knee	UC	38	37.24	40.00	14.02	2.275	− 21	80	*t*-test	0.348
Preoperative	MC	38	35.84	35.50	16.93	2.747	− 17	75		
KSS—Function	UC	38	56.97	60.00	13.63	2.212	3	100	MWU	0.051
Preoperative	MC	38	51.71	50.00	15.30	2.482	1	80		
KSS	UC	38	94.21	92.00	20.57	3.336	57	140	*t*-test	0.208
Preoperative	MC	38	87.55	85.50	24.92	4.042	40	139		
ROM (°)	UC	38	106.58	110.00	12.09	1.961	80	135	*t*-test	0.469
Preoperative	MC	38	106.18	105.00	15.00	2.433	70	135		
OKS	UC	38	23.74	24.00	7.44	1.207	9	26	*t*-test	0.129
Preoperative	MC	38	21.39	23.00	5.74	0.931	10	28		
HAAS	UC	38	5.87	5.50	2.13	0.346	3	11	MWU	0.085
Preoperative	MC	38	4.95	5.00	2.45	0.397	1	11		
FJS12	UC	38	13.25	9.37	12.04	1.954	0	50	MWU	0.400
Preoperative	MC	38	10.77	6.25	13.50	2.190	0	56		

Abbreviations: BMI, body mass index; FJS12, Forgotten Joint Score 12; HAAS, High-Activity Arthroplasty Score; KSS, Knee Society Score; MC, medial congruent; MWU, Mann–Whitney *U* test; OKS, Oxford Knee Score; ROM, range of motion; SD, standard deviation; SEM, standard error of the mean; UC, ultra congruent.

Figure 2). All procedures were performed by three senior orthopaedic surgeons, each performing more than 250 TKAs per year. Patients were distributed across the three senior orthopaedic surgeons as follows: Surgeon 1 (MC $n = 13$, UC $n = 13$), Surgeon 2 (MC $n = 12$, UC $n = 13$) and Surgeon 3 (MC $n = 13$, UC $n = 12$). All procedures were performed using conventional instrumentation without computer navigation or robotic assistance, following a measured resection technique with adapted mechanical alignment in both groups. An adapted mechanical alignment strategy was employed, targeting a neutral mechanical axis (0° ± 3°) while allowing for minor adjustments based on individual soft tissue balancing. Both the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) were resected in all cases. A medial parapatellar approach was used in all patients, with cemented fixation of both femoral and tibial components. None of the patellae were resurfaced, but denervation using electrocautery was performed in all cases. The surgical technique, alignment philosophy and ligament balancing principles were identical for both MC and UC insert groups. No modifications were made to the surgical approach, bone resection or soft tissue balancing based on insert type. Postoperatively, all patients were mobilized with full weight bearing and followed a standardized fast-track rehabilitation protocol.

Outcomes of interest

Clinical outcomes were measured using the original KSS as described by Insall et al. [11] at three time points: preoperatively, 5 weeks postoperatively and

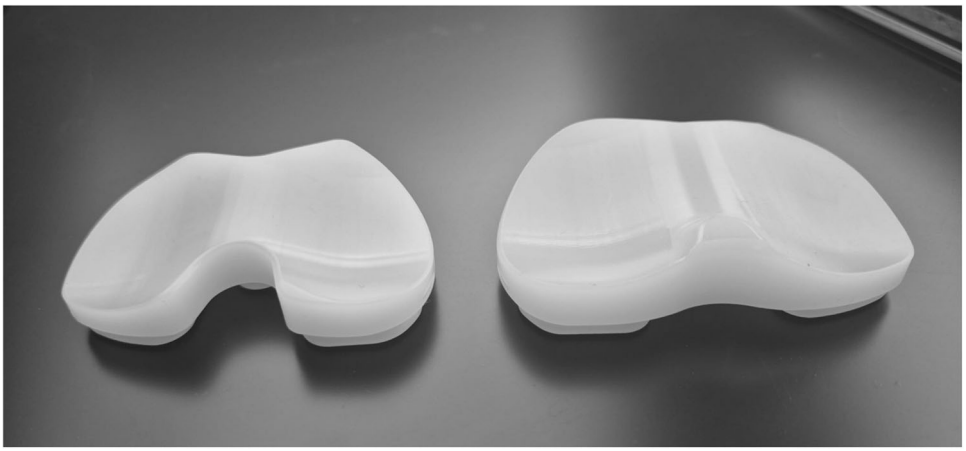


FIGURE 2 Polyethylene insert designs. Photograph of the medial congruent (MC, left) and ultra congruent (UC, right) polyethylene inserts of the Persona® Knee System (Zimmer Biomet), illustrating the asymmetric articular geometry of the MC design with a deeper medial concavity compared to the more uniform articulating surface of the UC insert.

1 year postoperatively, all assessed by the same investigator. Additionally, range of motion (ROM) was assessed preoperatively, 5 weeks postoperatively and 1 year postoperatively. Patient-reported outcomes were assessed preoperatively and at 5 weeks, 3 months, 6 months and 12 months postoperatively using the Forgotten Joint Score (FJS), Oxford Knee Score (OKS) and High-Activity Arthroplasty Score (HAAS). Pain was assessed using a VAS at 5 weeks, 3 months, 6 months and 12 months postoperatively. Furthermore, patient satisfaction with the surgery, willingness to recommend the procedure to others, and regret regarding having undergone the surgery were assessed at 12 months postoperatively.

Radiographic analysis

Standardized anteroposterior weight-bearing radiographs were obtained preoperatively and at 6 weeks postoperatively. Mechanical alignment was assessed by two independent observers blinded to group allocation using digital planning software (mediCAD; Hectec GmbH).

Power analysis

A priori power analysis was performed to determine the required sample size. Based on published minimal clinically important difference (MCID) values for the original KSS (Knee subscore: 5.3–5.9 points; Function subscore: 6.1–6.4 points) [16], we conservatively defined a clinically meaningful intergroup difference of 10 total KSS points, a threshold that exceeds the established MCID for both subscales. With an assumed standard deviation (SD) of 15 points, a two-sided significance level of $\alpha = 0.05$, and a statistical power of 0.80, a minimum of 36 patients per group was required (total $n = 72$). To account for potential dropouts, 40 patients per group were enroled (total $n = 80$).

Data analyses

To test for normality, the Shapiro–Wilk test was performed. In case of non-normal distribution, the Mann–Whitney *U* (MWU) test was used. Student's unpaired *t*-test was performed in case of normal distribution. Data are presented as boxplots with minimum, maximum, median, upper and lower quartile (box) and 5%–95% confidence interval (whiskers) and reported as means and SD. Chi-square tests of independence were applied to examine potential differences in response distributions between the UC and MC groups across all satisfaction-related questions. A p value of ≤0.05 was considered to be statistically significant. All analyses were performed using SPSS® (Version 27).

RESULTS

Clinical results

Both groups demonstrated significant improvement in total KSS over the follow-up period (Table 2, Figure 3). The KSS Function subscore was significantly higher in the MC group at 5 weeks ($p = 0.04$), but this difference was not maintained at 12 months ($p = 0.17$; Figure 4). KSS Knee scores at 12 months were comparable between groups ($p = 0.257$; Figure 5, Table 2). ROM improved comparably in both groups throughout follow-up, with no significant intergroup difference at any time point ($p = 0.746$; Table 2, Figure 6).

TABLE 2 Clinical and patient-reported outcomes over time.

Outcome	Group	Preoperative	5 weeks	3 months	6 months	12 months
FJS 12	UC	13.2 ± 1.95	23.5 ± 3.27	34.2 ± 4.03	47.2 ± 4.53	58.2 ± 4.08
	MC	10.8 ± 2.19	29.6 ± 3.39	37.4 ± 3.93	45.5 ± 4.24	55.8 ± 4.36
	p Value	0.400 (MWU)	0.913 (MWU)	0.728 (MWU)	0.392 (*t*-test)	0.344 (*t*-test)
OKS	UC	23.7 ± 1.21	27.5 ± 1.3	32.4 ± 1.3	37.0 ± 1.4	40.5 ± 1.1
	MC	21.4 ± 0.93	26.7 ± 1.1	32.2 ± 1.3	37.5 ± 1.5	41.3 ± 1.0
	p Value	0.13 (*t*-test)	0.3 (*t*-test)	0.46 (*t*-test)	0.48 (MWU)	0.58 (MWU)
HAAS	UC	5.9 ± 2.1	5.3 ± 1.8	8.6 ± 2.6	10.5 ± 2.9	11.7 ± 2.6
	MC	5.0 ± 2.5	5.5 ± 2.1	8.1 ± 2.3	9.8 ± 2.4	10.9 ± 2.0
	p Value	0.09 (MWU)	0.636 (*t*-test)	0.204 (MWU)	0.188 (MWU)	0.052 (*t*-test)
KSS—Knee	UC	37.2 ± 14	55.9 ± 21.1			86.8 ± 12.6
	MC	35.8 ± 16.9	62.7 ± 14.6			87.4 ± 10.3
	p Value	0.348 (*t*-test)	0.947 (*t*-test)			0.257 (MWU)
KSS—function	UC	57.0 ± 13.6	52.8 ± 16.5			87.2 ± 14.6
	MC	51.7 ± 15.3	55.1 ± 14.4			84.7 ± 13.5
	p Value	0.051 (MWU)	0.83 (MWU)			0.17 (MWU)
KSS	UC	94.2 ± 20.6	108.7 ± 31.9			174.0 ± 23.7
	MC	87.6 ± 24.9	117.9 ± 24.4			172.2 ± 20.3
	p Value	0.21 (*t*-test)	0.92 (*t*-test)			0.36 (*t*-test)
ROM	UC	106.6 ± 12.1	99.5 ± 12			116.2 ± 10.7
	MC	106 ± 15	102 ± 10.4			118 ± 8.1
	p Value	0.45 (*t*-test)	0.846 (*t*-test)			0.746 (*t*-test)
VAS	UC		32.8 ± 20.5	26.5 ± 22.5	15.3 ± 14.7	12.2 ± 14.1
	MC		29.3 ± 16.3	22.0 ± 12.5	17.6 ± 13.2	10.7 ± 9.6
	p Value		0.25 (MWU)	0.58 (MWU)	0.84 (MWU)	0.50 (MWU)

Note: Values are presented as mean ± SD unless otherwise indicated.

Abbreviations: FJS-12, Forgotten Joint Score-12; HAAS, High-Activity Arthroplasty Score; KSS, Knee Society Score; MWU, Mann–Whitney *U* test; OKS, Oxford Knee Score; ROM, range of motion; SD, standard deviation; VAS, Visual Analogue Scale.

Patient-reported outcomes

All PROMs improved significantly in both groups from baseline to 12 months, with no significant differences in the magnitude of improvement between groups (Table 2). The HAAS showed a trend toward higher scores in the UC group at all time points, without reaching statistical significance at 12 months ($p = 0.052$; Figure 7). The OKS improved significantly in both groups with no statistically significant intergroup difference at any time point ($p = 0.58$; Figure 8). FJS-12 scores were numerically higher in the MC group at all postoperative time points, but converged by 12 months without reaching statistical significance at final follow-up ($p = 0.344$; Figure 9). VAS pain scores decreased in both groups throughout follow-up, without significant intergroup difference at any time point (12-month $p = 0.50$; Figure 10).

Patient-reported 'satisfaction—recommendation—repeat'

At 12 months, overall satisfaction rates were high and comparable between groups, with only a few patients expressing dissatisfaction in either group (≤2.6%; $\chi^2(4) = 0.24$, $p = 0.994$). The willingness to recommend the procedure and to undergo the same surgery again was similarly high in both groups, with no statistically significant differences in response distribution

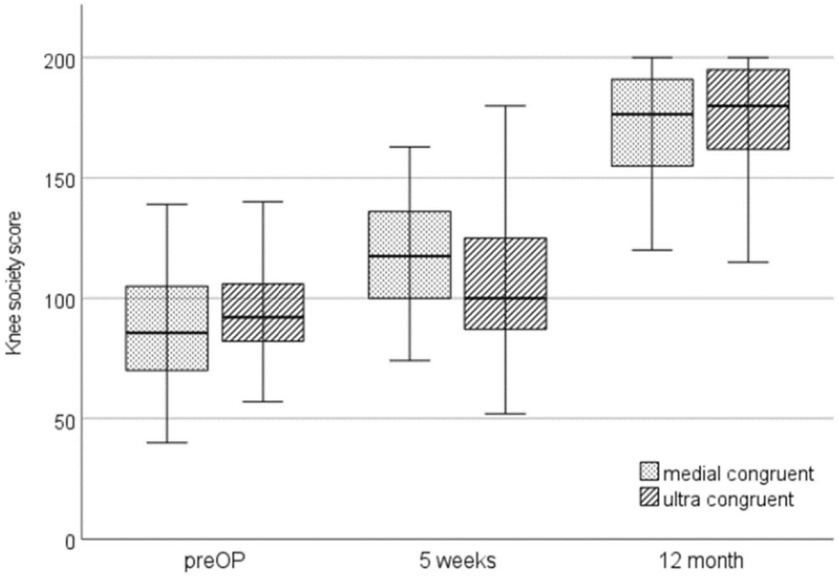


FIGURE 3 Total Knee Society Score (KSS) over time. Boxplots of the total KSS for the medial congruent (MC) and ultra congruent (UC) groups at the preoperative assessment, 5 weeks and 12 months postoperatively. Boxes represent the interquartile range with the median indicated; whiskers represent the 5th to 95th percentiles.

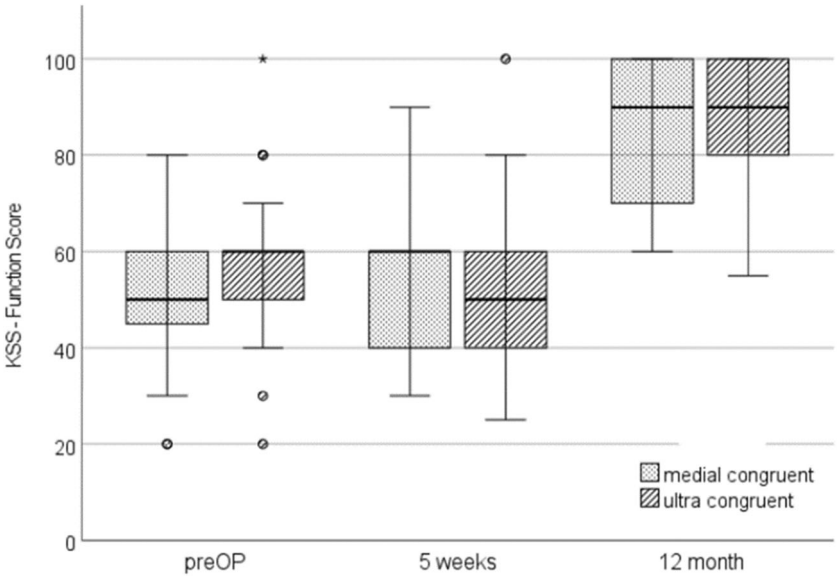


FIGURE 4 Knee Society Score (KSS)—Function over time. Boxplots of the KSS—Function subscore for the medial congruent (MC) and ultra congruent (UC) groups at the preoperative assessment, 5 weeks and 12 months postoperatively. Boxes represent the interquartile range with the median indicated; whiskers represent the 5th to 95th percentiles.

($p = 0.918$ and $p = 0.824$, respectively; Figure 11, Table 3).

Radiographic outcomes

There were no significant differences between groups regarding preoperative or postoperative alignment, and the magnitude of correction was comparable between groups ($p = 0.74$; Table 4).

DISCUSSION

Contemporary TKA designs have evolved to more closely reproduce patient anatomy, with two prominent concepts being the MC and UC bearing designs. However, the impact on outcomes and the extent to which these designs differ remains insufficiently studied. As such, the present RCT compared clinical outcomes, PROMs, implant survivorship and complications between TKAs with MC and UC PE designs. At

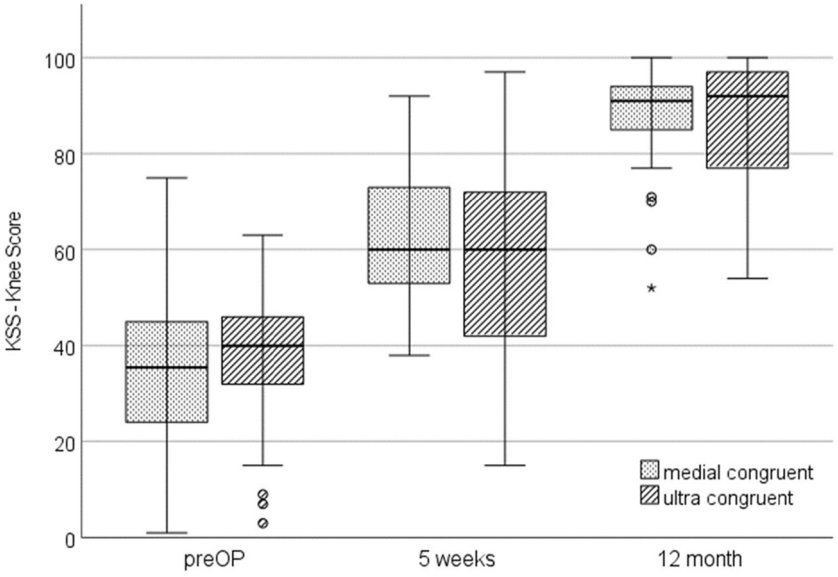


FIGURE 5 Knee Society Score (KSS)—Knee over time. Boxplots of the KSS—Knee subscore for the medial congruent (MC) and ultra congruent (UC) groups at the preoperative assessment, 5 weeks and 12 months postoperatively. Boxes represent the interquartile range with the median indicated; whiskers represent the 5th to 95th percentiles.

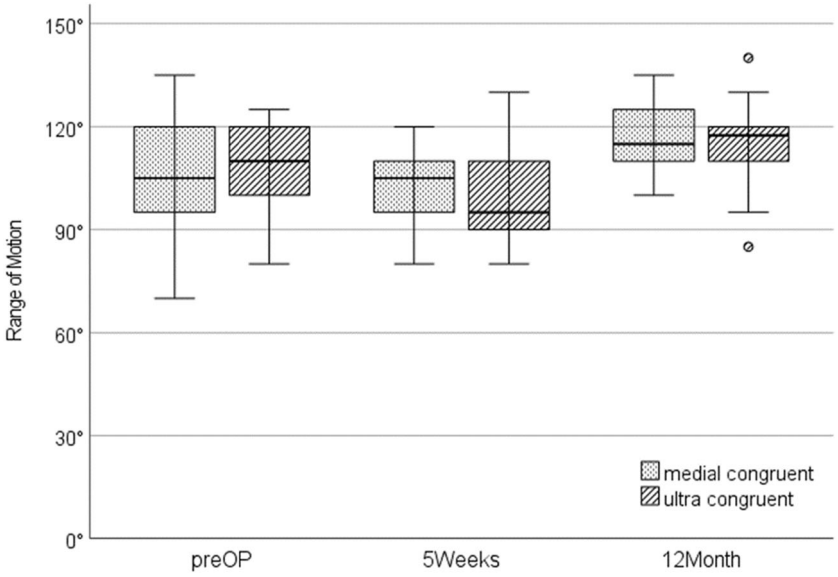


FIGURE 6 Range of motion (ROM) over time. Boxplots of knee ROM for the medial congruent (MC) and ultra congruent (UC) groups at the preoperative assessment, 5 weeks and 12 months postoperatively. Boxes represent the interquartile range with the median indicated; whiskers represent the 5th to 95th percentiles.

the 1-year follow-up, both insert designs demonstrated substantial improvements in all assessed outcome measures, with no statistically significant differences between groups for any outcome.

The clinical outcomes at final follow-up were similar between groups, as were the mean improvements. Our findings align with recent comparative studies suggesting that differences between contemporary TKA designs may be less pronounced than theoretical considerations would suggest.

Strait et al. [25] conducted a large retrospective cohort study comparing 2883 TKAs with medial-congruent, ultracongruent and cruciate retaining inserts. They found no differences in early complications, revision rates or implant survivorship. Although PROMs Physical and Mental scores were slightly higher in the medial-congruent group after 1 year, these differences were small and within the MCID range. These results are consistent with those of the present trial, which also showed no significant

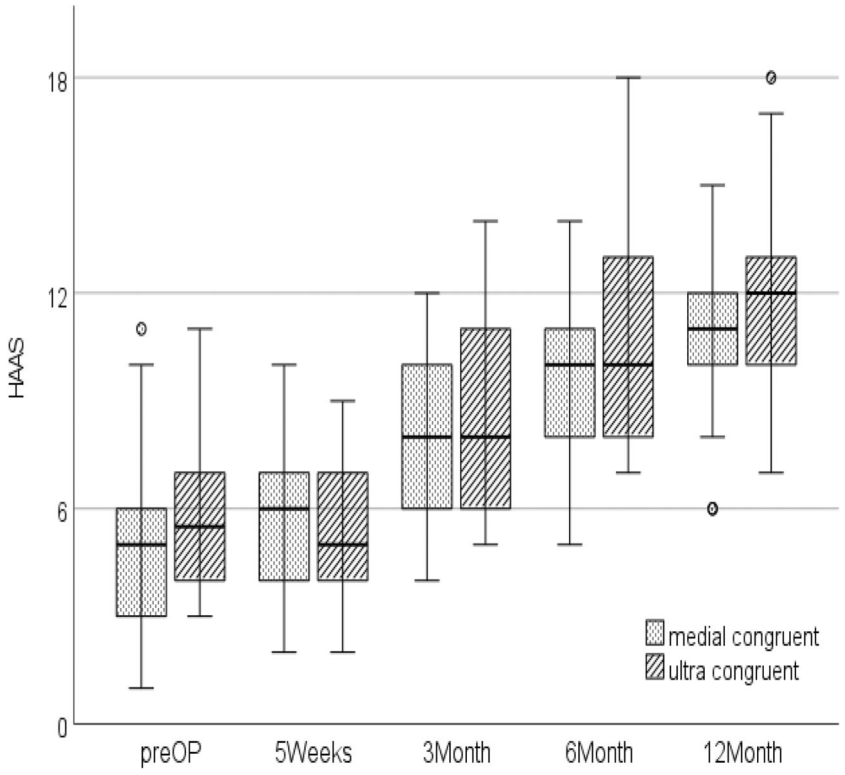


FIGURE 7 HAAS High-Activity Arthroplasty Score (HAAS) over time. Boxplots of the HAAS for the medial congruent (MC) and ultra congruent (UC) groups at the preoperative assessment, 5 weeks, 3 months, 6 months and 12 months postoperatively. Boxes represent the interquartile range with the median indicated; whiskers represent the 5th to 95th percentiles.

differences in clinical outcomes, patient-reported outcomes or survivorship between the two insert designs.

Alesi et al. [2] compared in vivo kinematics of a TKA using either medial-congruent or ultracongruent inserts and found largely comparable kinematical patterns. Their results align with the present study, although Alesi et al. reported greater flexion in the MC group, whereas no flexion differences were observed in our cohort. Given the relevance of kinematics for function and satisfaction, these findings support the notion that similar kinematics may translate into similar clinical outcomes.

Faschingbauer et al. [7] conducted an in vitro biomechanical investigation comparing CR, ultracongruent and medial-congruent inserts in combination with a single CR femoral component. In contrast to the in vivo findings of Alesi et al. [2], the medial-congruent insert demonstrated the greatest degree of constraint, with reduced femoral rollback and tibiofemoral rotation, whereas the ultracongruent design allowed more freedom of motion. These biomechanical differences were not reflected in the clinical outcomes of the present randomized trial, in which no differences in ROM, functional improvement or patient-reported outcomes were observed at 1 year. This supports the notion that measurable mechanical or kinematic distinctions between insert geometries do not necessarily translate into clinically relevant advantages.

PROMs further corroborated these findings, as there were similar between groups for all PROMs reported. The comparable FJS scores observed in our study are particularly noteworthy, as this outcome measure specifically assesses patients' awareness of their artificial joint during daily activities. Higher FJS scores indicate better joint awareness, or rather, the ability to 'forget' the joint replacement [3]. While the MC group showed numerically higher FJS scores at early timepoints, the convergence of scores by 12 months suggests that both designs ultimately achieve similar levels of joint awareness and functional integration. Patient satisfaction and clinical outcomes have been demonstrated to be associated with several factors, including patient expectations, age, function, ROM, axis alignment and disability. Knee kinematics are among the most significant factors associated with clinical outcomes following TKA [4, 12, 17, 22].

Most importantly, patient satisfaction remained high and comparable between groups, with overall satisfaction rates of 94.7% (MC) and 92.1% (UC). Similarly, 97.4% of patients in both groups indicated they would recommend the procedure, and the willingness to undergo the surgery again was high in both groups.

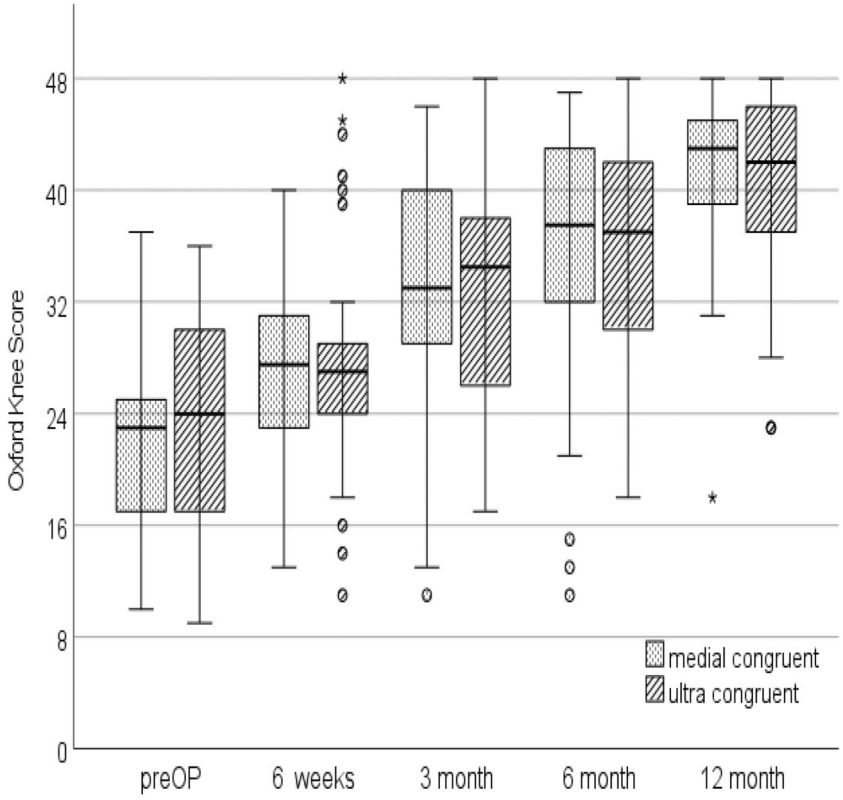


FIGURE 8 Oxford Knee Score (OKS) over time. Boxplots of the OKS for the medial congruent (MC) and ultra congruent (UC) groups at the preoperative assessment, 5 weeks, 3 months, 6 months and 12 months postoperatively. Boxes represent the interquartile range with the median indicated; whiskers represent the 5th to 95th percentiles.

The theoretical advantages of MC and UC designs are based on different biomechanical principles. MC designs aim to replicate the medial pivot kinematics of the natural knee, where the medial femoral condyle remains relatively stationary while the lateral condyle rolls back during flexion [9]. This design philosophy suggests that mimicking natural kinematics should lead to improved proprioception, reduced PE wear and enhanced patient satisfaction. UC designs, conversely, prioritize conformity and stability across the entire articulating surface, potentially reducing contact stresses and improving load distribution [21]. However, our results suggest that these theoretical differences may not translate into clinically detectable outcome differences at 1 year. Several factors may explain this finding. First, contemporary TKA designs have reached a level of refinement where multiple design philosophies can achieve excellent clinical outcomes. The selection of appropriate component alignment, soft tissue balancing and surgical technique may be more critical determinants of outcome than specific insert geometry [24]. Second, the outcome measures used in this study, while comprehensive and validated, may not be sensitive enough to detect subtle differences in kinematics or proprioception that might exist between designs. Third, the 1-year follow-up period, while adequate for assessing early clinical outcomes, may be insufficient to detect differences in long-term implant survivorship or PE wear that could potentially differ between designs.

For this, several limitations must be acknowledged. First, the study was limited to patient-reported clinical outcome measures and implant survivorship and did not include kinematic analysis. Advanced imaging techniques such as fluoroscopy, dynamic radiostereometric analysis (RSA) or inertial measurement units could provide objective data on differences in knee kinematics between insert designs that may not be captured by PROMs. Second, the 1-year follow-up period is insufficient to evaluate long-term implant survivorship, PE wear or late complications. The biomechanical differences between MC and UC designs may only become clinically relevant after longer follow-up periods. Third, all patients in this study had varus knee osteoarthritis classified as Kellgren–Lawrence Grade 4, and the results may not be applicable to patients with different deformity patterns, less severe osteoarthritis or other etiologies of knee pathology. In addition, the study may have been underpowered to detect small but clinically meaningful differences between groups, though the observed effect sizes were generally small and unlikely to be clinically significant

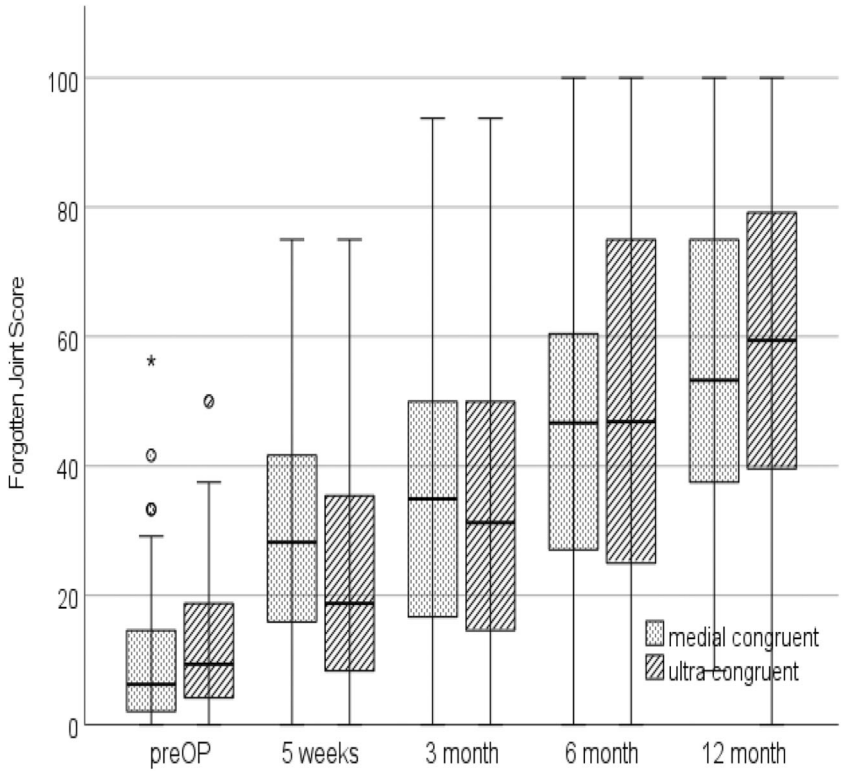


FIGURE 9 Forgotten Joint Score (FJS) over time. Boxplots of the FJS-12 for the medial congruent (MC) and ultra congruent (UC) groups at the preoperative assessment, 5 weeks, 3 months, 6 months and 12 months postoperatively. Boxes represent the interquartile range with the median indicated; whiskers represent the 5th to 95th percentiles.

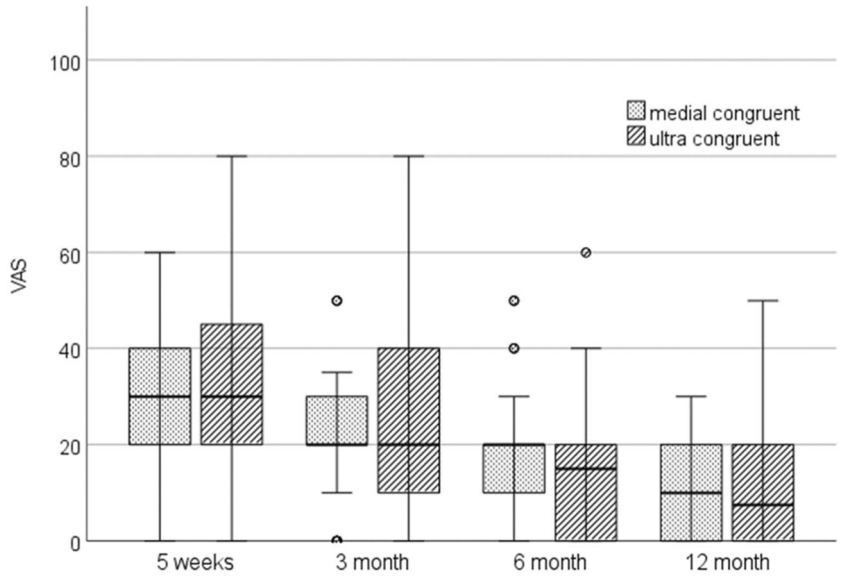


FIGURE 10 Pain scores over time. Boxplots of Visual Analogue Scale (VAS) pain scores for the medial congruent (MC) and ultra congruent (UC) groups at the preoperative assessment, 5 weeks, 3 months, 6 months and 12 months postoperatively. Boxes represent the interquartile range with the median indicated; whiskers represent the 5th to 95th percentiles.

even if statistically significant with larger sample sizes. Finally, the outcome measures used, while comprehensive and validated, may suffer from ceiling effects that limit their ability to detect differences in high-functioning patients. This is particularly relevant in the context of contemporary TKA, where overall outcomes are excellent and intergroup differences between implant designs are expected to be small.

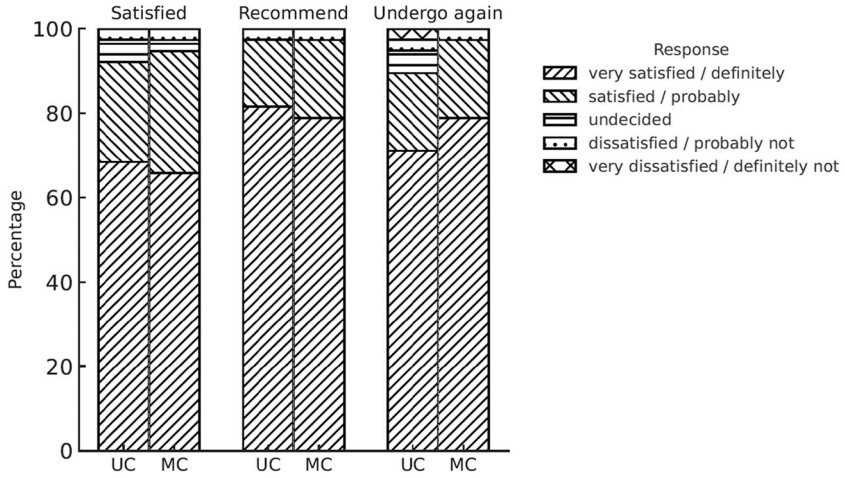


FIGURE 11 Satisfaction—recommendation—repeat. Stacked bar charts showing patient-reported satisfaction with surgery, willingness to recommend the procedure and willingness to undergo the surgery again for the MC and UC groups at 12 months postoperatively. MC, medial congruent; UC, ultra congruent.

TABLE 3 Patient satisfaction, recommendation and willingness to undergo surgery again at 12 months.

Question	Response	UC (%)	MC (%)	χ^2 (df = 4)	*p* Value
I am satisfied with the surgery.	Very satisfied	68.4	65.8	0.24	0.994
	Satisfied	23.7	28.9		
	Undecided	5.3	2.6		
	Dissatisfied	2.6	2.6		
	Very dissatisfied	0.0	0.0		
I would recommend the surgery.	Definitely	81.6	78.9	0.17	0.918
	Probably	15.8	18.4		
	Undecided	0.0	0.0		
	Probably not	2.6	2.6		
	Definitely not	0.0	0.0		
I would undergo the surgery again.	Definitely	71.1	78.9	1.51	0.824
	Probably	18.4	18.4		
	Undecided	5.3	0.0		
	Probably not	2.6	2.6		
	Definitely not	2.6	0.0		

Note: Values are presented as percentages. *p* values were calculated using the χ^2 test of independence.
Abbreviations: df, degrees of freedom; MC, medial congruent; UC, ultra congruent.

TABLE 4 Radiographic outcomes.

	Group	Preoperative	Postoperative	Δ Preoperative/postoperative
Alignment (°)	UC	−7.88 ± 0.64 (min −21; max −1)	−1.23 ± 0.35 (min −9; max 3)	+6.95 ± 0.53 (min +1; max +14)
	MC	−8.18 ± 0.67 (min −17; max 1)	−1.18 ± 0.27 (min −5; max 2)	+6.70 ± 0.49 (min +1; max +15)
	p Value	0.68 (MWU)	0.91 (MWU)	0.74 (*t*-test)

Note: Values are presented as mean ± SEM (minimum; maximum). *p* values were calculated using the Mann–Whitney *U* test (MWU) or unpaired *t*-test as appropriate.
Abbreviations: MC, medial congruent; MWU, Mann–Whitney *U* test; SEM, standard error of the mean; UC, ultra congruent.

In conclusion, this RCT demonstrated that MC and UC PE designs provide comparable clinical outcomes, PROMs, satisfaction rates and implant survivorship at 12 months postoperatively. These findings suggest that surgeons can confidently use either insert design with the expectation of excellent outcomes. However, long-term follow-up with kinematic analysis is needed to determine whether subtle differences exist that may influence long-term implant performance and durability.

AUTHOR CONTRIBUTIONS

Daniel Schrednitzki: Conceptualization; methodology; writing—review and editing. **Jonas Sina**: Formal analysis; writing—original draft; writing—review and editing. **Alexander Lamarche**: Investigation. **Nils Meissner**: Writing—review and editing; writing—original draft. **Andreas M. Halder**: Conceptualization; methodology; supervision.

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DATA AVAILABILITY STATEMENT

The data are not publicly available due to privacy and ethical restrictions.

ETHICS STATEMENT

The study was approved by the Ethics review board of the Medical Association of Brandenburg (Landesärztekammer Brandenburg) (2021-2191-Boff). Informed consent was obtained from all participants included in the study.

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