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A new cementless tibial baseplate in kinematically aligned total knee arthroplasty has low migration and stabilizes at 3 months: A cohort study using radiostereometric analysis

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Abstract

Purpose: Introduction of new components in total knee arthroplasty (TKA) should be assessed for long-term stability. The primary objective was to determine whether migration of a new cementless tibial baseplate in kinematically aligned (KA) TKA is below the 6-month threshold where baseplates have a low incidence of long-term loosening. Other objectives were to determine when stability occurred, whether stability was associated with varus angles in knee and limb alignments, and whether a recut of the tibia affected migration.

Methods: New cementless components were implanted in 45 patients, of which 38% had a tibial recut. Baseplate migration was assessed using model-based radiostereometric analysis with radiographs obtained postoperatively and at 6 weeks, 3 months and 6 months. Mean maximum total point motion (MTPM) at 6 months was compared to a 6-month threshold where baseplates have low incidence of long-term loosening. An equivalence analysis determined when stability occurred. Correlation analyses related MTPM at 6 months to the medial proximal tibial angle (MPTA) and the hip–knee–ankle angle (HKAA). A two-sample *t* test determined whether mean MTPM differed between recut and non-recut groups.

Results: Mean 6-month MTPM of 0.93 mm was significantly below the 6-month stability threshold of 1.15 mm ($p = 0.015$), and stability was achieved by 3 months. There was no significant relationship between MTPM and MPTA ($\rho = 0.050$, $p = 0.77$) or HKAA ($\rho = 0.060$, $p = 0.72$). Mean MTPM did not differ between recut (0.85 ± 0.56 mm) and non-recut (0.97 ± 0.64 mm) groups ($p = 0.57$).

Conclusion: The new cementless tibial baseplate has migration significantly below the 6-month threshold where baseplates have a low incidence of long-term loosening and migration stabilizes early at 3 months.

Abbreviations: AP, anterior-posterior; CAD, computer-aided design; CI, confidence interval; FE, flexion-extension; HKAA, measured hip–knee–ankle angle; IE, internal-external; KA, kinematic alignment; LCL, lower 95% confidence limit; MA, mechanical alignment; MBRSA, model-based radiostereometric analysis; ML, medial-lateral; MPTA, medial proximal tibial angle; MTPM, maximum total point motion; PCL, posterior cruciate ligament; PD, proximal-distal; RSA, radiostereometric analysis; TKA, aligned total knee arthroplasty; TOST, two one-sided *t* test; UCL, upper 95% confidence limit; VV, varus-valgus.

Varus alignment of the baseplate and the limb as well as tibial recuts were not associated with increased migration.

Level of Evidence: N/A.

KEYWORDS

hip–knee–ankle angle, maximum total point motion, medial proximal tibial angle, six degree-of-freedom motion

INTRODUCTION

Although cementless components in total knee arthroplasty (TKA) are attractive alternatives to cemented components for a number of reasons [33], long-term stability should be assessed for new designs to ensure that they do not present increased risk of aseptic loosening, particularly for tibial baseplates. To assess long-term risk of tibial baseplate loosening, radiostereometric analysis (RSA) is a useful method where short-term baseplate migration is computed from biplanar radiographs of a patient's knee over time [25, 26]. Maximum total point motion (MTPM), defined as the largest displacement of a point on the baseplate between the surgery date and a subsequent time point, is the most commonly used metric to quantify migration and hence assess baseplate stability [25, 26].

A 2025 meta-analysis of RSA studies using cementless tibial baseplates showed that cohorts with a 6-month mean MTPM below a specified threshold of 1.15 mm had a low incidence of long-term baseplate loosening up to 15 years [26]. Hence, determining MTPM and comparing the mean value to the 6-month stability threshold is a viable method for evaluating the relative risk of subsequent aseptic loosening of a new tibial baseplate design when long-term safety is unknown.

Study of tibial baseplate stability is especially important for baseplates used in kinematic alignment (KA) TKA because no restrictions are placed on varus–valgus deformity and/or flexion contracture. Hence, the medial proximal tibial angle (MPTA) can be as high as 10° varus and the hip–knee–ankle angle (HKAA) as high as 8° varus [21]. Although long-term clinical studies [4, 11] and RSA studies of cemented tibial baseplates [21, 23] show low long-term incidence of aseptic loosening, concerns remain since baseplates in varus using mechanical alignment (MA) have been associated with greater migration [32]. More particularly, cementless baseplates aligned in varus in MA adversely impact the biomechanics of the bone–implant interaction [8].

Another factor potentially adversely affecting the stability of cementless baseplates in KA is tibial recuts [37]. Since KA is a femur-first technique, tibial recuts are common to balance the knee. Since recuts are made preferentially in one compartment or the other, the possibility of an uneven resected surface arises, leaving a gap between implant and bone. A gap in excess of 50–150 μm between implant and bone can lead to fibrous tissue formation instead of bony ingrowth, thus compromising stability [34].

The objectives were several. The primary objective was to determine whether a new cementless tibial baseplate used in conjunction with KA-optimized components has mean MTPM at 6 months significantly below the 6-month threshold where baseplates have a low incidence of aseptic loosening. Other objectives were to determine when stability occurred, whether increased MTPM was associated with increased varus angles in knee and limb alignments, and whether migration was affected by tibial recuts. The hypotheses were that the new cementless tibial baseplate is safe (i.e., low incidence of long-term aseptic loosening), that stability would occur as early as 3 months, that MTPM is unrelated to varus angles, and that recuts would not adversely affect migration evidenced by greater mean MTPM.

METHODS

Patients

Of the 142 patients assessed for eligibility, this study enroled 45 patients who underwent caliper-verified KA TKA. Inclusion criteria were patients with symptomatic osteoarthritis of the knee aged 52–81 years, who were able to give informed consent, who did not have a prior joint implant in the treated limb, who did not have a history of neurological disorder, who did not have a history of rheumatoid arthritis, who were not pregnant, and who were not currently involved in healthcare litigation. No restriction was placed on the severity of preoperative varus–valgus or flexion-contracture deformity. All patients were enroled at one site between February 2025 and September 2025 (Table 1).

Surgical technique

Surgeries were performed by a single experienced surgeon using manual instruments. KA TKA is a personalized approach to aligning components where resections are made to restore the patient's pre-arthritic limb alignment and joint lines without collateral ligament release. The accuracy with which this is accomplished using manual instruments has been described previously [12, 17, 19, 30]. Patients received cementless components optimized for KA (GMK SpheriKA, Medacta). This component set includes a femoral component with spherical condyles and a 20° trochlear groove, an anatomic tibial baseplate, and an insert with medial ball-in-socket conformity, a flat lateral articular surface, and posterior cruciate ligament (PCL) retention. In this component set, the titanium tibial baseplate was manufactured from direct metal laser sintering for both the solid bulk and porous layer (Figure 1). The porous layer was 1.4 mm thick with a pore size of 620 μm and porosity of 65% [1]. After resecting the tibia, proper ligament balance in extension was determined with a spacer block during a varus–valgus stress test. Recuts were performed in 38% (17 out of 45) of patients. Insert thickness, which maximized internal tibial rotation between 0° and 90° flexion in passive motion, was determined using an insert goniometer [29]. During surgery, eight tantalum markers were implanted into the cancellous bone of the proximal tibia using a bead inserter (Halifax Bead Set and Inserter; Halifax Biomedical Inc.) to create a bone reference for measuring migration.

TABLE 1 Preoperative patient demographics and clinical characteristics ($N = 45$).

	Mean ± SD	Median (range)
Demographics		
Age (years)	69 ± 9	68 (52–81)
Sex (male) *N* (%)	21 (47%)	-
Body mass index (kg/m^2)	31.5 ± 6.1	30 (21.5–56)
Preoperative motion and deformity		
Extension (°)	4.4 ± 4.8	3 (0–18)
Flexion (°)	113 ± 11.3	115 (55–135)
Deformity type, *N* (%)		
Varus	33 (73%)	-
Valgus	9 (20%)	-
Patellofemoral	3 (7%)	-

Abbreviation: SD, standard deviation.

Post-operative limb and implant alignment

Post-operatively on the day of surgery, non-weightbearing, anteroposterior, rotationally controlled, long-leg CT scanograms were acquired and used to measure MPTA and HKAA (Table 1). Reliability of these measurements has been evaluated previously, where intraclass correlation (ICC) values for inter-observer and intra-observer variability were 0.76–0.97, indicating good to excellent agreement, and repeatability was 0.3° and 0.2° for MPTA and HKAA, respectively [18].

Biplanar imaging and migration analysis

Biplanar radiographs were acquired post-operatively and at 6-week, 3-month and 6-month follow-up time points. At each time point, including post-operatively,

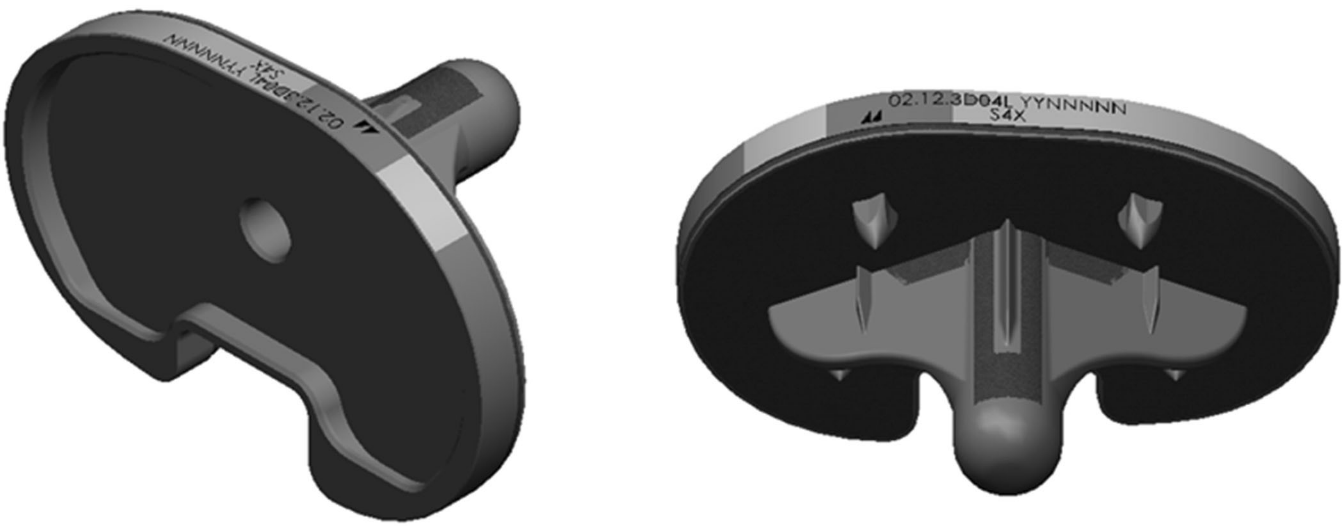

FIGURE 1 Top (left) and bottom (right) views of the new uncemented baseplate under study. Surfaces contacting the underlying bone are largely porous to promote osseointegration.

two independent biplanar knee radiographs (i.e., double examinations) were obtained within minutes of each other. A biplanar calibration cage (Model 10, Tilly Medical Products AB) was used to define the laboratory coordinate system. The calibration cage and patient were repositioned under no weight-bearing conditions between imaging. Imaging was performed using two portable X-ray machines (HF100H+, MinXray) positioned at 90° relative to each other, with radiographs acquired at 76 kVp and 3.5 mAs and a source-to-image distance of approximately 90 cm. During imaging, the patients' knees were slightly flexed and positioned to have minimal superimposition of the femoral and tibial components. Because double examinations were performed on the same day, no actual tibial baseplate migration occurred, allowing quantification of artifactual migration due to registration error.

Model-based RSA (MBRSA) was performed using RSAcore software (version 4.2). The implant manufacturer supplied CAD models of all sizes. Migration was computed in six degrees of freedom consistent with ISO16087 [13]. Because the baseplate was not oriented consistent with the anatomic coordinate system defined by the calibration cage, the migration computation was based on a local baseplate coordinate system [20]. The coordinate system origin was the point where the central axis of the baseplate stem intersected the lower surface of the baseplate tray, and the axes were as follows: positive *x* pointing medial for a right tibial baseplate, positive *y* pointing proximal, and positive *z* pointing anterior. MTPM was computed using 5 standardized feature points around the perimeter of the baseplate. The points were the most anterior point, the most medial and lateral points, and the two most posterior points. The maximum condition number was 79, and the mean error for rigid-body fitting was 0.08 mm, which are within acceptable limits [13].

Bias (mean error) and precision (standard deviation of error) of artifactual migration were quantified using double examinations at each time point, including post-operative [22]. For each pair of same-day radiographs, one image was defined as the reference and the other as the scene. This yielded a single artifactual MTPM value per image pair. Because no actual migration occurred between same-day radiographs, these values represent artifactual migration due to registration errors. Bias was computed as the mean artifactual MTPM, and precision was computed as the standard deviation of artifactual MPTM [22]. Bias was 0.16 mm and precision was 0.06 mm.

Actual tibial baseplate migration was quantified by calculating MTPM across follow-up time points, relative to the post-operative radiographs as reference. For each follow-up time point, all combinations between the two post-operative and the two follow-up biplanar images were analyzed. This generated four actual MTPM values per patient, which were averaged to obtain one actual MTPM value per patient at each time point.

Statistics

To determine the sample size, a prospective power analysis based on a one-sample *t* test was performed for the primary objective. A single-sided analysis was used because the objective was to determine whether mean MTPM was less than the 6-month stability threshold. Using an effect size of 0.4, significance level of 0.05, and power of 0.80, 41 patients were required. Hence, with 45 subjects to allow for dropout, the study was amply powered.

To test the first hypothesis, a one-sample *t* test was used to determine whether mean MTPM was significantly less than the 6-month stability threshold of 1.15 mm. To test the second hypothesis, an equivalence analysis using two one-sided *t* tests (TOST) was performed using the difference in the 3-month to 6-month mean MPTM with equivalence boundaries of ±0.1 mm. To test the third hypothesis, Spearman's correlation coefficient together with upper (UCL) and lower (LCL) 95% confidence limits were computed to assess how strongly the MPTA and the HKAA were associated with MTPM. A two-sample *t* test was used to test the fourth hypothesis that tibial recuts would not adversely affect migration, as evidenced by an increase in mean MTPM.

RESULTS

A total of 142 patients were considered for eligibility during the period of enrollment. Of these, 97 were excluded for the main reasons that they did not meet the inclusion criteria ($n = 37$), did not respond ($n = 18$) or declined to participate ($n = 16$). Hence, 45 patients provided informed consent and participated (Figure 2).

Mean 6-month MTPM of 0.93 mm (1.09 mm with one-sided 95% confidence interval) was significantly below the 6-month stability threshold ($p = 0.015$) (Figure 3). Six degree-of-freedom migration patterns at 6 months revealed that migration occurred predominantly in flexion and compression (i.e., distal translation) (Figure 4).

The TOST result for the 3 month-to-6 month difference in mean MTPM revealed that stability occurred at 3 months. Means were not only equivalent (90% CI: −0.090 to +0.026 mm) but also not significantly different ($p = 0.028$ at ±0.1 mm).

Although 95% and 50% of patients had varus MPTA and HKAA, respectively (Figure 5), there was no significant relationship between MPTA and HKAA and MTPM at 6 months (MPTA: $\rho = 0.050$ (LCL/UCL = −0.27/0.36), $p = 0.766$; HKAA: $\rho = 0.060$ (LCL/UCL = −0.26/0.37), $p = 0.721$) (Figure 5). The most frequent

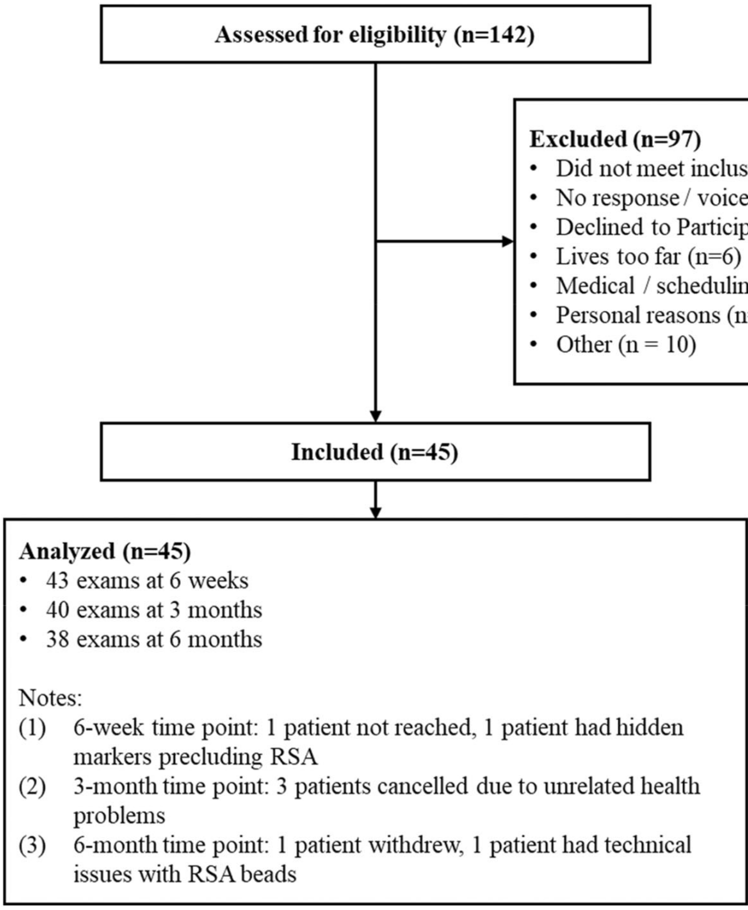

FIGURE 2 STROBE diagram. RSA, radiostereometric analysis.

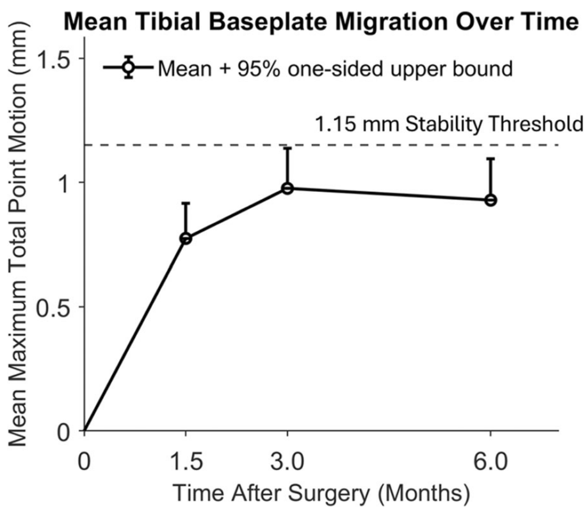

FIGURE 3 Mean MTPM over time and comparison to the 6-month stability threshold. MTPM, maximum total point motion.

location of MTPM was the lateral point (36.8%), but the highest magnitudes of MTPM occurred at the posterolateral point (mean 1.66 mm). Of the 11 patients whose MTPM occurred at the posterolateral point, 9 had MTPM values greater than 1.10 mm.

There was no difference in mean MTPM between tibial recut (0.85 ± 0.56 mm) and non-recut (0.97 ± 0.64 mm) groups ($p = 0.57$).

DISCUSSION

The most important finding of this study was that mean 6-month MTPM was significantly below the 6-month stability threshold where baseplates have a low incidence of long-term aseptic loosening. Other important findings were that early stability was achieved by 3 months, MTPM was unrelated to the MPTA and the HKAA, and MTPM was unaffected by tibial recuts.

To assess long-term baseplate stability at the group level, mean MTPM was computed and compared with a 6-month stability threshold determined from a recently reported meta-analysis [26]. The finding that mean MTPM is significantly below the 6-month stability threshold indicates a high probability of a low incidence of long-term baseplate loosening for KA TKA using a KA-optimized component system. This finding holds notwithstanding that (1) almost all patients (95%) had varus baseplate alignment with 42% exceeding 3° (Figure 5); (2) the medial ball-in-socket conformity of

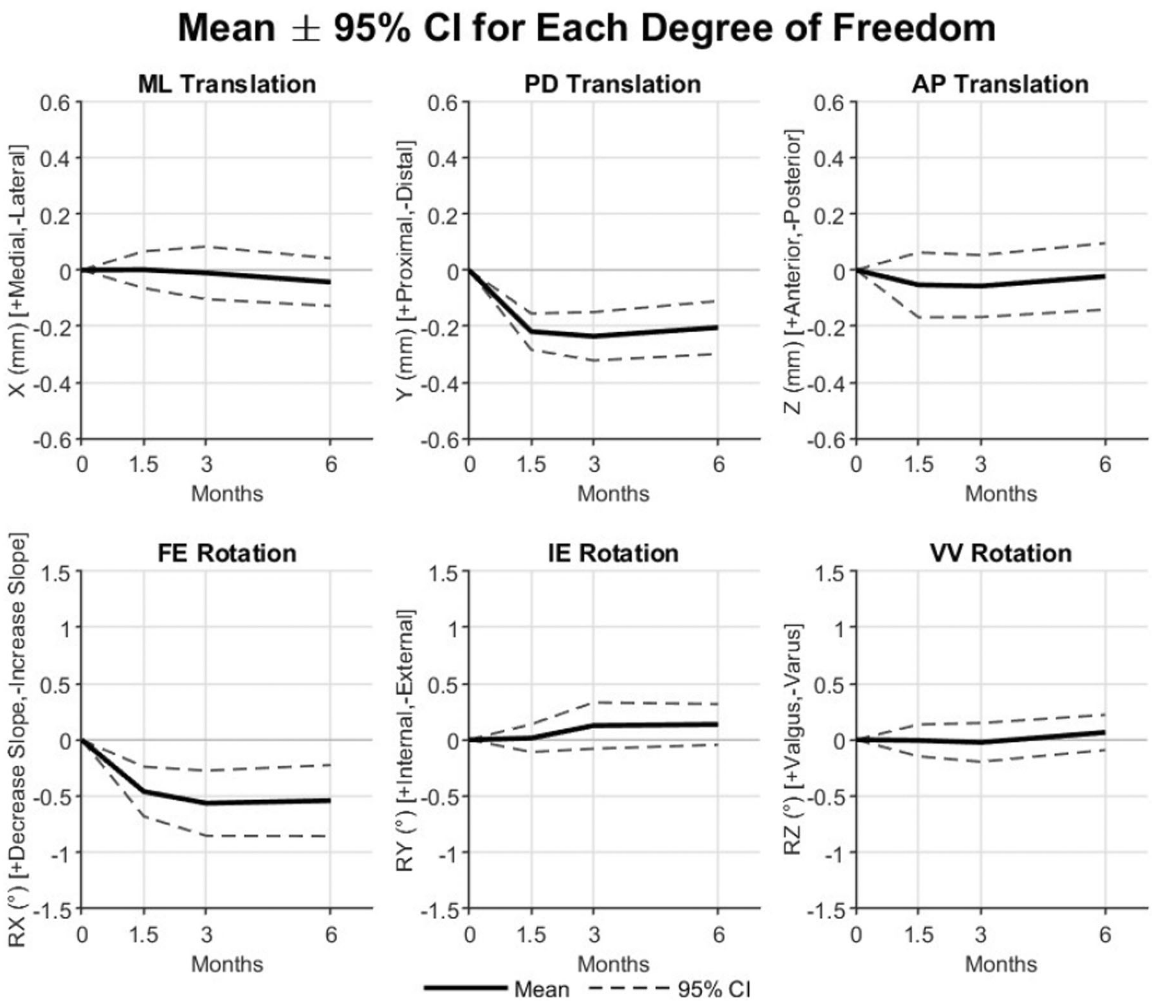

FIGURE 4 Six degree-of-freedom migrations. Positive *x* is medial for a right knee, positive *y* is proximal, and positive *z* is anterior. AP, anterior-posterior; CI, confidence interval. ML. medial-lateral; FE, flexion-extension; IE, internal-external; PD, proximal-distal; VV, varus-valgus.

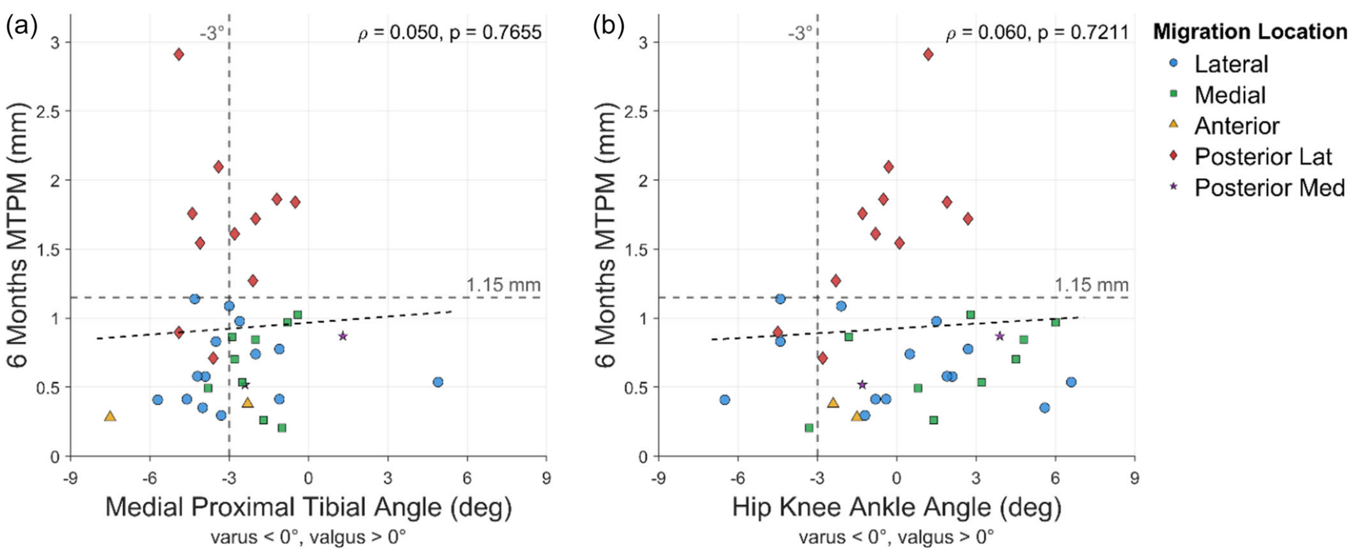

FIGURE 5 Plots showing results of correlation analysis relating the MPTA and the HKAA of 38 patients to MTPM at 6 months for each patient. Also shown is the location of MTPM for each patient. HKAA, hip–knee–ankle angle; MPTA, medial proximal tibial angle; MTPM, maximum total point motion.

the insert provided maximum A–P constraint of the medial femoral condyle thus transmitting shear loads at the baseplate-bone interface which could have inhibited osseointegration [34], and (3) the flat lateral surface of the insert together with PCL retention allowed unconstrained posterior movement of the lateral femoral condyle.

Although mean MTPM was significantly below the 6-month stability threshold, a group of patients experienced MTPM above the threshold (Figure 5), and MTPM occurred at the posterolateral location for all patients in this group. One possible explanation is traced to the design of the insert, which allows unconstrained posterior movement of the lateral femoral condyle. This movement could lead to compression of the underlying bone as a result of repeated posterolateral edge loading exacerbated by PCL retention. While retaining the PCL increases internal tibial rotation in flexion to restore knee function closer to native [7] and offers additional posterior stability [9], at the same time PCL retention promotes increased posterior movement of the lateral femoral condyle to allow the increased tibial rotation, hence repeatedly loading the posterolateral region of the insert. Accordingly, it will be important to assess continuous migration particularly for this group, and this will be reported in a future paper.

A second important finding was that the cementless baseplate stabilized early with equivalent migration at 3 and 6 months (Figure 3). Evidently, this occurred because osseointegration was well developed. Since many factors, as dictated by the baseplate design and surgical technique, affect osseointegration, it is worth elaborating on each factor in the context of our study.

The baseplate was designed to promote rapid osseointegration. Titanium was used as the material, which has low toxicity and is inert in a physiologic environment. This inertness indirectly promotes bone ingrowth because it avoids an inflammatory local tissue response that can lead to failure of peri-implant osteogenesis [16]. In addition, the surfaces which contact trabecular bone were largely coated with a porous layer. The porosity of 620 μm and density of 65% of this layer are both well above minimums necessary to promote rapid osseointegration [3].

Regarding the surgical technique, KA TKA was performed without restrictions on varus–valgus deformity and/or flexion contracture. As KA is a personalized alignment approach where the goal is to restore prearthritic limb and knee alignments, tibial baseplates are often aligned in varus as herein and the hip-knee-ankle angle likewise often is in varus as herein. Although concern has been expressed regarding increased risk of aseptic loosening because of varus alignment in KA [10], in fact the biomechanics suggest otherwise. Restoring limb and knee alignments in KA creates a joint line parallel to the ground and a moment arm which reduces knee adduction moments compared to MA [24]. Furthermore, tibial contact forces are significantly lower, and the balance between tibial contact forces is closer to native [27]. Accordingly, it is not surprising that long-term clinical studies [4, 11] and RSA studies [15, 21, 23] using cemented components show an incidence of long-term loosening similar to or better than MA. These biomechanical results also explain why MTPM was unrelated to varus knee and limb alignments, which is consistent with RSA studies of cemented baseplates used in KA [21, 23].

The final important finding that migration was unaffected by tibial recuts is likely explained by the method used to make the recuts. When asymmetry is observed, ligament balancing calls for additional resection in the under-resected compartment. Rather than shaving the under-resected compartment preferentially to correct asymmetry, the surgeon always used a tibial cutting guide. As such, the guide maintained a relatively flat cutting plane over the full area of the tibial resection, thus avoiding an uneven resected surface which can compromise baseplate stability [34, 37].

In comparing our results to those of other studies using cementless tibial baseplates, this comparison could be a review paper in its own right since approximately 30 RSA studies have been conducted [26]. Accordingly, the comparison will be to a limited number of recent studies. Noting that no study known to the authors has used RSA to analyze cementless baseplate stability in KA, these comparisons are necessarily limited to MA. This comparison reveals that the KA-optimized cementless baseplate and insert stabilized as early as or earlier than other cementless baseplates and that mean MTPM at 6-months was comparable (Table 2).

In considering limitations, the generalizability of results should be considered. Results apply to a single cementless baseplate using KA TKA. Other designs may experience different migration magnitudes using different alignment methods. Next, a single experienced surgeon performed the KA TKA procedure. Although migration may differ for other surgeons, this is unlikely because caliper-verified KA TKA uses intraoperative verification checks to ensure alignment targets are met [19] and recent studies demonstrate that surgeon experience has a negligible effect on the accuracy of the femoral resections [12, 17]. Next, this study evaluated migration using KA performed with manual instruments in which the accuracy of the caliper-verified technique has been evaluated thoroughly. Results may not apply to other types of instrumentation, which achieve different accuracy. However, use of other types of instrumentation is unnecessary in performing KA TKA because alignment targets are achieved consistently and efficiently with manual instruments.

TABLE 2 Recent comparison studies.

Study	Baseplate	Insert	Mean MTPM at 6 months	Follow-up for stability
Present	SpheriKA, keel, four pegs	KA-optimized, CR	0.93 mm	3 months
Altun [2]	Persona, no keel, two pegs	CR	0.80 mm	3 months
Dyreborg [6]	Vanguard, with Regenerex, keel with four pegs	CR	1.5 mm	12 months
Dyreborg [6]	Vanguard with plasma spray, keel with no pegs	CR	1.3 mm	12 months
Williams [36]	Triathlon, keel with four pegs, peri-apatite coated	CR condylar stabilizing	0.83 mm	3 months
Dunbar [5]	Triathlon, keel with four pegs, peri-apatite coated	CS posterior stabilized	0.84 mm	6 months
Van Ooij [35]	Implant cast advanced-coated system, long keel with no pegs	CS mobile bearing	1.03 mm	NA
Koster [14]	Low contact stress, keel with four pegs	CR mobile bearing	1.18 mm	6 months
Koster [14]	Attune, keel with no pegs	CR mobile bearing	1.13 mm	6 months
Sporer [31]	Triathlon Tritanium, keel with 4 pegs	CR	0.72 mm	6 months

Notes: Follow-ups for stability of comparison studies were estimated from graphs rather than determined statistically.
Abbreviations: CR, cruciate-retaining; CS, cruciate-substituting; KA, kinematic alignment; MTPM, maximum total point motion.

Additional limitations concern methods of analysis. Although the study was appropriately powered for the primary outcome variable (i.e., MTPM), analyses examining the association between migration and MPTA, HKAA, and tibial recuts involved substantially smaller effective sample sizes. Therefore, the absence of statistically significant associations should not be interpreted as proof of absence of an effect. However, even if the effects were significant, then these effects would be clinically unimportant given the correlation coefficients <0.1 and the mean MTPM difference between recut and non-recut groups of 0.12 mm with mean MTPM being lower for the recut group. Next, early stability at the group level should not be understood to indicate that all baseplates at the individual patient level are immune to continuous migration. Analysis of migration at the patient level between 1 and 2 years is necessary to diagnose patients at risk of aseptic loosening [28]. Finally, the method used to evaluate stability, comparing mean MTPM to a 6-month stability threshold, was based on a recent meta-analysis [26]. Since the studies on which the analysis was based generally were performed with MA, caution should be exercised in applying the threshold to KA TKA considering the systematic differences in baseplate alignment between KA and MA.

CONCLUSION

Our findings indicate that a new cementless tibial baseplate has migration significantly below the 6-month threshold where baseplates have a low incidence of long-term aseptic loosening up to 15 years and becomes stable as early as 3 months. Varus alignment of the tibial baseplate and the limb was not associated with increased migration, suggesting no increased risk of loosening. Finally, tibial recuts did not adversely affect stability.

AUTHOR CONTRIBUTIONS

Rubiana Monteiro redesigned the frame for mounting the biplanar portable x-ray machines, coordinated patient imaging, processed images, performed statistical analyses and drafted sections of the original manuscript. Ali Mohammadi consulted on statistical analyses. Alexander J. Nedopil performed surgeries including implantation of markers. Stephen M. Howell provided oversight. Maury L. Hull conceived the study, applied for the funding and was the principal investigator, coordinated project personnel, provided oversight of all aspects including finances, wrote the original manuscript and revised the manuscript.

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The study was funded by Medacta USA, Inc. The funder had no role in study design, data collection, data analysis, interpretation of results or the decision to submit for publication.

CONFLICT OF INTEREST STATEMENT

Alexander J. Nedopil is a paid consultant and receives royalties from Medacta. He is also on the editorial board for *Knee Surgery, Sports Traumatology, Arthroscopy*. Stephen M. Howell is a paid consultant, a paid speaker and receives royalties from Medacta. Maury L. Hull is a paid speaker and receives research funding from Medacta. He is also on the editorial boards for *Knee Surgery, Sports Traumatology, Arthroscopy* and the *Journal of Biomechanics* and is an

Associate Editor for *Bioengineering*. The other authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data available by contacting the corresponding author.

ETHICS STATEMENT

The Institutional Review Board of the University of California Davis approved the study (IRB No. 1251807-10). The authors received financial support from Medacta USA, Inc. The funder had no role in study design, data collection, data analysis, interpretation of results or the decision to submit for publication.

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