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Tibial Component Varus Alignment Does Not Affect Survivorship of Cementless Robotic-Assisted Total Knee Arthroplasty With Functional Knee Positioning

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ABSTRACT

Background: Cementless fixation is increasingly adopted in total knee arthroplasty (TKA). In parallel, robotic-assisted (RA) techniques have enabled personalized alignment strategies like functional knee positioning (FKP). However, evidence on survivorship for cementless robotic-assisted-TKA (RA-TKA) with FKP remains limited. This study evaluated revision risk and clinical outcomes after cementless RA-TKA with FKP at a minimum 2-year follow-up and explored whether tibial component varus alignment, age, sex, or body mass index (BMI) were associated with revisions.

Methods: This retrospective single-center study included all consecutive cementless cruciate-retaining or substituting RA-TKAs with FKP between November 2017 and September 2023. In total, 356 patients (381 RA-TKAs) who had a mean age of 70 years (range, 39.3 to 87.1) were analyzed at a minimum 2-year follow-up. The median follow-up was 3.5 years (95% confidence interval, CI: 3.3 to 3.8), and the follow-up rate was 94.9%. Survivorship was assessed using Kaplan–Meier analysis. Differences in survivorship stratified by tibial component coronal alignment (greater than 3° versus 3° or less varus), age greater than 75 years, sex, and BMI greater than 30 were evaluated using log-rank tests. The forgotten joint score-12 and a 5-level Likert satisfaction scale were collected at the last follow-up.

Results: Estimated survivorship at five years was 98.6% (95% CI: 97.4 to 99.8), with five revisions (four periprosthetic joint infections and one arthrofibrosis). There was no aseptic loosening that occurred. Tibial component varus greater than 3° was present in 35.6% of cases. Survivorship did not differ significantly between knees with and without tibial varus greater than 3°, nor for age greater than 75 years, sex, or BMI greater than 30 ($P > 0.05$). The mean forgotten joint score-12 and satisfaction were 85.2 (standard deviation 20.2) and 4.7 (standard deviation 0.7).

Conclusions: Cementless RA-TKA with FKP demonstrated excellent survivorship and high patient satisfaction at a minimum 2-year follow-up, with no aseptic loosening that occurred. There was no association between tibial component varus, age, sex, or BMI and revision detected, supporting the safety of cementless fixation in personalized robotic alignment; however, the low number of revision events limits the ability to identify predictors of failure.

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Cemented fixation has long been the gold standard for primary total knee arthroplasty (TKA) due to its reliable long-term outcomes. However, shifts in patient demographics – particularly the rise in younger, obese (body mass index (BMI) greater than 30), and more active individuals – have highlighted its limitations, including higher rates of aseptic loosening in these populations [1,2]. As a result, cementless fixation has gained increasing interest for its potential to provide more durable outcomes [3]. Although early cementless knee designs performed poorly due to technical limitations such as suboptimal coatings, weak locking mechanisms, and low-quality polyethylene [4,5], modern implants have addressed these issues. The introduction of metallic three-dimensional (3D) printing has enabled the development of cementless implants with highly porous surfaces, improving initial stability, and promoting reliable biological fixation [6–9]. Recent registry data show increasing trends for the use of cementless TKA designs. The recent American Joint Replacement Registry and Australian Orthopaedic Association National Joint Replacement Registry have shown increased adoption of cementless fixation [10,11].

In parallel with implant evolution, TKA has entered a new era of surgical precision. Image-based robotic assistance and 3D planning have facilitated the adoption of alignment philosophies focused on patient-specific knee phenotypes and individualized soft-tissue balancing. In particular, functional knee positioning (FKP) optimizes the balancing of both the patello-femoral and femoro-tibial joints, by tailoring component placement and prioritizing soft-tissue balance and joint line restoration [12–14]. Unlike mechanical alignment, FKP allows intentional deviation from neutral alignment within predefined “functional safe zones” [15] to better replicate the patient’s native anatomy.

In robotic-assisted (RA)-TKA using FKP, the tibial component is frequently positioned in slight varus. Although tibial component varus alignment has been historically associated with increased risk of failure [16–18], these concerns do not appear to apply to modern FKP strategies combined with robotic assistance [19,20]. Nevertheless, there remains a need for focused studies specifically addressing cementless RA-TKA performed with personalized alignment strategies. Despite the growing adoption of both cementless fixation and FKP in RA-TKA, clinical data on their combined use remain scarce, and evidence specifically addressing cementless, image-based RA-TKA performed with FKP is still lacking. The purpose of this retrospective, observational study was therefore to determine the incidence of revision, patient satisfaction, and clinical performance in patients who had received a cementless RA-TKA with FKP at a minimum 2-year follow-up. It was hypothesized that tibial component varus greater than 3°, along with patients’ age, sex, and BMI, would not negatively impact cementless implant survivorship.

Materials and Methods

Study Design and Patient Selection

This retrospective, observational study included all consecutive primary TKAs performed with robotic assistance between November 1, 2017, and September 30, 2023, at a single high-volume academic center. All procedures were performed with the same TKA design, utilizing the Mako Robotic System (Stryker, Kalamazoo, Michigan, USA). Among all RA-TKA cases performed during the study period, a total of 356 patients undergoing cruciate-retaining (CR) and cruciate-substituting cementless implants (Triathlon Tritanium, Stryker, Kalamazoo, Michigan, USA) meeting the inclusion criteria were analyzed. Eligible patients who underwent cementless TKA presented with primary, secondary, or

post-traumatic end-stage osteoarthritis and disabling pain unresponsive to conservative therapy. Exclusion criteria were neuromuscular disorders, posterior cruciate or collateral ligament insufficiency, different or increased constraint, and poor bone quality, as determined intraoperatively. During the study period, cementless fixation represented the standard of care for RA-TKA. Bone quality was assessed intraoperatively via tactile and visual feedback after bone cuts; in some cases, cementless fixation was not performed in favor of cemented (112 RA-TKAs) or hybrid (10 RA-TKAs) fixation when intraoperative findings suggested inadequate bone quality to ensure reliable press-fit fixation or when increased implant constraint was required. These cases were excluded from the analysis (Figure 1).

Study Population and Demographic Data

A total of 356 patients underwent cementless RA-TKA with FKP, accounting for 381 procedures, as 25 patients received bilateral, staged implants. The mean age at surgery was 70 years (range, 39.3 to 87.1). A total of 123 patients (32.3%) were older than 75 years at surgery. The cohort included 138 men (38.8%) and 218 women (61.2%); 193 knees (50.7%) were operated on the left side and 188 knees (49.3%) on the right side. The mean BMI was 28.8. A CR polyethylene insert was used in 333 cases (87.4%), while a cruciate-substituting insert was used in 48 (12.6%).

Preoperative Planning

All patients underwent a preoperative computed tomography (CT) scan of the hip, knee, and ankle on the operative side. The CT data were processed using proprietary robotic software to generate a patient-specific 3D model. The joint line orientation of the femur and tibia in the coronal plane was evaluated in relation to their mechanical axes on CT slices. Surgical planning followed FKP principles, with component positioning tailored to native anatomy while correcting for cartilage wear and deformity [14]. Preoperatively measured CT-based mechanical medial proximal tibial angle (MPTA) and lateral distal femoral angle (mLDFA) were collected. The preoperative arithmetic hip-knee-ankle angle (preoperative aHKA) was calculated as preoperative MPTA – preoperative mLDFA, and knees were categorized as varus (aHKA less than -2°), neutral (aHKA $0^\circ \pm 2^\circ$), or valgus (aHKA greater than 2°).

Surgical Technique

All surgeries were performed by three experienced arthroplasty surgeons who had a caseload of more than 50 TKAs per year or supervised arthroplasty fellows under the direct supervision of an experienced attending surgeon. RA-TKA was performed using the FKP technique for implant alignment and balancing, without tibial precut. A medial parapatellar approach was used in most cases; a lateral parapatellar approach was selectively adopted in a small number of cases with severe, uncorrectable valgus deformity [21]. Femoral and tibial tracking arrays were secured, and bone registration was completed through the robotic interface. Following femoral and tibial osteophyte removal, joint laxity assessment was conducted near extension (between 10° and 20° of knee flexion) to prevent false tight gaps caused by posterior capsule tension by a manual varus/valgus stress. At 90° flexion, the medial and lateral compartments were distracted with spoons to tension the collateral ligaments. Real-time intraoperative measurements, displayed by the robotic platform, reported the gap between virtual contact points of the prosthetic components. Implant positioning was adjusted, targeting a symmetric gap in

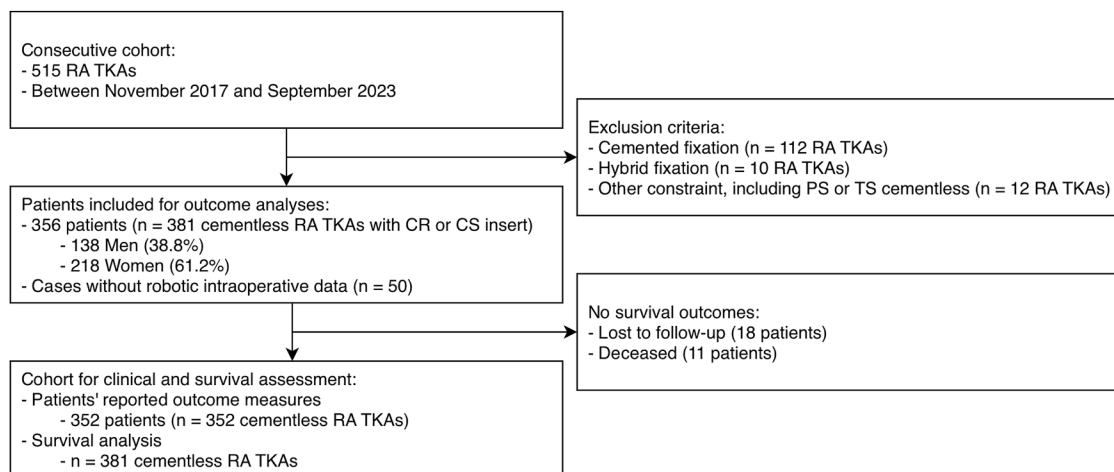


Figure 1. Flowchart of the inclusion process. RA, robotic assisted; TKA, total knee arthroplasty; CR, cruciate retaining; CS, cruciate substituting; PS, posterior stabilized; TS, total stabilized.

extension (0.5 to 1.5 mm) and an asymmetric gap in flexion, with a medial gap of 0.5 to 1.0 mm and a 1.0 to 2.0 mm larger gap laterally.

The coronal alignment of the tibial component was adapted to the patient's native MPTA, as measured on the preoperative CT scan, within 2° valgus to 4° varus, accounting for wear. In the sagittal plane, the native tibial slope was recreated within 0 to 7°. Femoral component coronal positioning was adjusted within a “safe zone” of 5° valgus/varus (mLDFA 85 to 95°), with sagittal positioning avoiding anterior notching and optimizing component sizing to both balance the flexion gap and restore posterior condylar offset. Axial femoral rotation, initially set parallel to the posterior condylar axis, was modified to optimize medio-lateral gap balance in flexion and adjusted to the trochlear morphology. Once final component positioning was established, all bone cuts were made at a single stage with the haptically-controlled robotic arm, preserving the posterior cruciate ligament insertion. Trial components were then inserted, and soft-tissue balance and joint congruency were reassessed. Intraoperatively, tibial component rotation was adapted to ensure congruency in extension. While patellar resurfacing was generally not performed, a lateral patellar facetectomy was routinely executed. In cases of suboptimal patellar tracking, reshaping of the patella was undertaken, reducing its thickness to prevent overstuffing and improving patello-femoral tracking [22]. Final cementless components were then impacted with the press-fit technique.

Component positioning data, including coronal, sagittal, and axial orientation, was recorded via the robotic platform, and digital screenshots were archived. Postimplant aHKA was computed as the difference between tibial and femoral component coronal alignment. Cases with incomplete intraoperative robotic data — defined as missing records for component positioning parameters — were excluded from implant positioning analysis (Figure 1).

Clinical Outcomes and Implant Survivorship

Postoperative clinical follow-up was conducted at three, six, and 12 months and annually thereafter. At final follow-up, patients completed the forgotten joint score-12 (FJS-12) [23] and rated satisfaction using a 5-point Likert scale (“very satisfied” to “strongly not satisfied”). Revision surgeries and reoperations were recorded, with causes for revision classified as aseptic loosening,

instability, arthrofibrosis, chronic or acute periprosthetic joint infection (PJI), periprosthetic fracture, unexplained pain, or other.

Patients lost to follow-up were contacted by telephone; non-responders after three attempts were classified as unavailable. Deceased patients were included in survivorship analyses when implant status could be verified through chart review or family interview. The primary endpoint for survivorship was all-cause revision. The median follow-up was 3.5 years (95% confidence interval, CI: 3.3 to 3.8). The follow-up rate was 94.9%, as 18 patients were lost to follow-up. There were 11 patients who were deceased for reasons unrelated to surgery.

Ethics Statement

The present study adheres to the principles outlined by the Declaration of Helsinki and follows Good Clinical Practice guidelines for each step performed during the study, including data collection, analysis, and reporting. Institutional review board approval was obtained (441/2025/OSS/AOUMO RA-TKA MO) and transmitted with protocol number 35281/2025.

Data Analyses

Descriptive statistics were computed for all variables. Categorical data are presented as absolute and relative frequencies; continuous variables are reported as means with standard deviations (SDs) or medians with interquartile ranges, as appropriate. Implant survivorship was estimated using the Kaplan–Meier estimator and reported as revision-free survivorship, with 95% CI. Differences in survival probability between groups stratified by tibial component coronal alignment (greater than 3 versus 3° or less varus), age greater than 75 years, sex, and BMI greater than 30 were assessed using log-rank tests. Patients' characteristics associated with high satisfaction were investigated using univariable Poisson regression models to estimate rate ratio. Univariable linear regression models estimated associations with respect to FJS-12, and the obtained results were expressed as mean differences. All tests were two-sided, with a significance level set at $\alpha = 0.05$. Analyses were performed using R software, version 4.3.2 (The R Foundation for Statistical Computing, Vienna, Austria, 2023).

Table 1
Mean Implant Alignment Variables and Standard Deviations Stratified by Preoperative aHKA.

Variable (°)	Varus (n = 154)	Neutral (n = 138)	Valgus (n = 89)	Overall (n = 381)
Tibial coronal alignment	2.5 (1.0)	2.1 (1.1)	0.5 (1.1)	2.1 (1.3)
Tibial sagittal alignment	4.5 (1.3)	4.0 (1.0)	3.8 (1.2)	4.3 (1.5)
Femoral coronal alignment	0.3 (1.6)	-1.1 (1.8)	-3.0 (1.8)	-0.9 (2.1)
Femoral transverse alignment (relative to PCA)	3.5 (2.3)	2.5 (2.3)	1.2 (1.9)	2.5 (2.3)
Postimplant aHKA	2.8 (1.7)	1.0 (2.0)	-2.5 (2.3)	1.2 (2.7)

Positive values are expression of varus alignment, posterior slope, and external rotation. PCA, posterior condylar axis; aHKA, arithmetic hip-knee-ankle angle.

Results

Component Positioning

There were 50 cases with incomplete intraoperative robotic data. Overall, the tibial component was implanted at a mean 2.1° varus (SD 1.3) and 4.3° posterior slope (SD 1.5). Tibial component varus greater than 3° occurred in 118 RA-TKAs (35.6%), whereas 213 RA-TKAs (64.4%) were 3° or less of varus. The femoral component was implanted at a mean of -0.9° valgus (SD 2.1) and 2.5° external rotation (SD 2.3) relative to the posterior condylar axis. The mean postimplant aHKA was 1.2° varus (SD 2.7) overall, whereas in cases with a tibial component implanted at greater than 3° varus, it was 3.3° varus (SD 2.1). There were 66 RA-TKAs (19.9%) with a combined tibial component varus greater than 3° and residual postimplant aHKA greater than 3° in varus. Postoperative aHKA outliers exceeding $\pm 5^\circ$ were observed in 43 cases. The mean implant alignment parameters stratified by preoperative aHKA are reported in Table 1.

Survivorship Data

The estimated survivorship at five years was 98.6% (95% CI: 97.4 to 99.8) (Figure 2). There were five revisions (1.3%): two patients were revised for acute PJI treated with debridement, antibiotics, and implant retention at 0.5 and 1.0 months, respectively; two patients reported chronic PJI, treated with two-stage revision at four and 11 months postoperatively. There was one patient who developed knee arthrofibrosis and was treated with open arthrolysis and polyethylene insert exchange at one year. A total of five nonrevision reoperations occurred, including two patients treated for periprosthetic fractures, one for traumatic quadriceps tendon rupture, and two secondary patellar resurfacings for anterior knee pain. There were no failures due to aseptic loosening reported (zero of 381 RA-TKAs). A single case of early tibial component subsidence was reported radiographically 45 days postoperatively. This occurred in an 82-year-old woman who had a BMI of 17.4. Intraoperative robotic data demonstrated tibial component positioning at 2° of varus and 3° of posterior slope, within the predefined FKP alignment range. The patient remained asymptomatic, required no reoperation, and follow-up radiographs showed no progression of subsidence or loosening. The patient subsequently died four years after surgery for reasons unrelated to the surgical procedure. This case was therefore not classified as a failure for survivorship analysis.

Survival analysis stratified by tibial coronal alignment (greater than 3 versus 3° or less varus) showed no significant differences in revision-free survivorship (log-rank $P = 0.930$). Similarly, age greater than 75 years (log-rank $P = 0.551$), women (log-rank $P = 0.930$), and obesity (BMI greater than 30, log-rank $P = 0.484$) were not significantly associated with increased revision risk.

Patients' Reported Outcome Measures

The mean FJS-12 was 85.2 (SD, 20.2), and satisfaction was 4.7 (SD, 0.7) at the latest follow-up. Univariable logistic regression showed no association of postoperative FJS-12 or satisfaction with patients' age or BMI. Men had marginally higher satisfaction scores compared with women (rate ratio = 1.04, 95% CI: 1.00 to 1.07, $P = 0.045$) (Table 2).

Discussion

This study demonstrated that 3D-printed cementless RA-TKA with FKP achieved an overall survivorship of 98.7% at a mean follow-up of 3.6 years, with 100% survivorship when aseptic loosening was considered the endpoint. These results were achieved in a population including a tibial component varus greater than 3°, age greater than 75 years, and BMI greater than 30 – all factors that have traditionally raised concern for cementless fixation. These findings support modern cementless TKA designs as capable of providing durable fixation and satisfactory clinical outcomes at follow-ups ranging from four to 10 years [9,24,25]. The absence of failures for aseptic loosening underscores the reliability of contemporary porous implant surfaces, promoting osseointegration [26]. In addition, the presented results showed that cementless fixation can be safely applied within patient-specific alignment philosophies and that RA FKP, allowing controlled deviations from neutral alignment, did not compromise

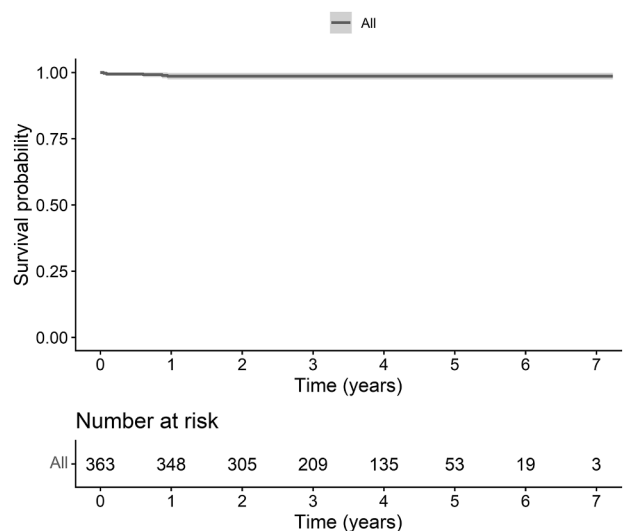


Figure 2. Kaplan–Meier revision-free survival probability of cementless robotic-assisted total knee arthroplasty, considering implant revision as the endpoint. Faded areas represent 95% confidence intervals.

Table 2

Univariable Associations Between Patients' Reported Outcome Measures and Sociodemographic Characteristics.

Parameter	FJS-12			5-Level Likert Scale		
	MD	95% CI	P-Value	RR	95% CI	P-Value
Age	0.03	−0.24 to 0.30	0.829	1.00	1.00 to 1.00	0.816
Sex (Men)	1.53	−3.09 to 6.14	0.518	1.04	1.00 to 1.07	0.045 ^a
BMI	−0.53	−1.09 to 0.02	0.060	0.99	0.99 to 1.00	0.062

FJS-12, forgotten joint score-12; MD, mean difference; RR, rate ratio; CI, confidence interval.

^a Statistically significant association. FJS-12 and patient's satisfaction, assessed through 5-level Likert scale, were analyzed using generalized linear regression models.

fixation stability. These results suggest that the combination of robotic assistance, personalized alignment, and cementless fixation can provide a reliable strategy for a broad spectrum of patients, including those traditionally considered at higher risk for fixation failure.

While cemented TKA remains the predominant fixation method in many institutions, long-term registry data and recent clinical series have reported equivalent [27] or superior [2] outcomes for cementless implants when component placement and soft-tissue balance are accurate. Robotic-arm assistance may contribute to these outcomes [20,28] by enabling accurate execution of the surgical plan and reproducible soft-tissue balancing, thereby reducing surgical variability and minimizing asymmetric loading, even in the presence of tibial component varus. This may be particularly relevant for cementless tibial components, where initial press-fit stability is essential for osseointegration. Within this cohort, tibial varus greater than 3° was not associated with an increased risk of aseptic loosening. This finding appears to contrast with historic literature on failure mechanisms [18,29] and with finite element modeling studies, demonstrating that tibial varus alignment increases micromotion at the bone-implant interface in cementless designs, raising concerns about compromised fixation [30]. Radiostereometric analyses have demonstrated cementless tibial component migration during the first years in the presence of excessive varus of the lower limb [31], likely because of continued asymmetric loading conditions [32]. In the present series, 19.9% of RA-TKAs exhibited a combined tibial varus greater than 3° and residual postimplant aHKA greater than 3° varus, yet no aseptic loosening was observed. Deviations from neutral alignment were achieved as part of the FKP strategy and guided by individualized soft-tissue balancing. Within this workflow, tibial component positioning primarily followed the native tibial epiphyseal alignment (MPTA), resulting in tibial baseplate orientation close to perpendicular to the predominant trabecular architecture and promoting a more physiological load transfer. When the native MPTA was excessive, tibial coronal alignment was mitigated within predefined FKP boundaries. Accordingly, this approach should not be interpreted as supporting extreme or uncontrolled alignment strategies. Implant design may also play a protective role: biomechanical studies have demonstrated that tibial baseplates incorporating a keel and cruciform pegs provide superior initial stability and reduced micromotion compared to peg-only designs [33]. Moreover, no increased aseptic failure risk was observed in patients who were older than 75 years, a group historically considered less suitable for cementless fixation due to concerns regarding bone quality and underdiagnosed osteoporosis [34]. While cement may provide a theoretical advantage in osteoporotic bone for stronger primary fixation, cementless fixation has been confirmed to be reliable even in older patients [35–38]. Sex

and BMI were likewise not predictors of failure, aligning with prior literature [2,36]. These findings are particularly relevant given concerns regarding decreased bone mineral density in postmenopausal women and the growing prevalence of obesity. In this context, a single case of early radiographic tibial component subsidence was observed without clinical symptoms, progression, or need for reoperation. This suggests that early, nonprogressive subsidence does not necessarily indicate mechanical failure or compromised fixation.

The patients' reported outcome measures (PROMs) were favorable, consistent with or superior to other RA-TKA series [20,39] and confirm that controlled deviations from neutral alignment do not compromise patient-perceived results.

This study has several potential limitations. Its retrospective and observational design is subject to selection bias, as patients who had severely compromised bone stock may have been excluded from cementless fixation at the surgeon's discretion. The absence of a cemented control group limits direct comparison between fixation methods and prevents definitive conclusions regarding the relative superiority of cementless fixation. In addition, the mean follow-up of three years is sufficient to capture early failures but not to evaluate long-term survivorship and fixation. However, consistency with the 10-year follow-up series [25] is reassuring that favorable fixation observed at a minimum of 2-year follow-up is likely to persist. Also, PROMs were limited to the FJS-12 and a satisfaction scale, without baseline scores or additional validated scores assessing knee function. However, the FJS-12 and satisfaction scale directly reflect the patient's perception of the implant, and the FJS-12 offers the advantage of a low ceiling effect compared to other PROMs [40]. In addition, although all procedures were performed using the same robotic workflow, the involvement of multiple surgeons introduces potential inter-operator variability. Another limitation was that the study was conducted at a single high-volume academic center. This may limit generalizability to other settings. In addition, no systematic post-operative radiographic assessment was performed to evaluate component fixation, osseointegration, or radiolucent lines; implant fixation was inferred indirectly from the absence of revision, which may fail to detect subclinical loosening or early migration. Consequently, the absence of aseptic loosening in the present series should be interpreted with caution and may not fully reflect radiographic fixation status. Another limitation was that the low number of revisions limited the statistical power to identify meaningful predictors of failure, raising the possibility of type II error; therefore, analyses evaluating the association between tibial component varus and revision should be interpreted as exploratory, reflecting an absence of a detected association rather than evidence of no effect. Nevertheless, the large overall cohort and high follow-up rate strengthen the robustness of the survival estimates. Also, several relevant factors such as preoperative expectations, radiographic severity of osteoarthritis, and knee phenotype were not evaluated, though they may influence outcomes. Their absence, however, does not compromise the primary aim of the study, which was to evaluate early survivorship and patient-reported outcomes after cementless RA-TKA with a personalized approach to implant positioning.

Conclusions

Cementless, CR image-based RA-TKA performed with FKP achieved excellent survivorship (98.7% at 3.6 years), with no cases of aseptic loosening. In this cohort, no association between tibial varus greater than 3°, age greater than 75 years, sex, or BMI greater than 30, and early revision was detected; however, the low number of revision events limits the ability to identify predictors of

failure. The findings of this study reinforce the growing consensus that cementless TKA is safe in most patients. Robotic systems may expand the applicability of cementless fixation by enhancing precision and reproducibility during TKA.

CRedit authorship contribution statement

Francesco Zambianchi: Writing – review & editing, Writing – original draft, Visualization, Methodology, Data curation, Conceptualization. **Mattia Clò:** Validation, Methodology, Formal analysis, Data curation. **Sebastiano Clemenza:** Writing – review & editing, Validation, Investigation. **Riccardo Cuoghi Costantini:** Writing – review & editing, Methodology, Formal analysis. **Vincenzo Iorio:** Writing – review & editing. **Fabio Catani:** Writing – review & editing, Supervision, Methodology, Data curation, Conceptualization.

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