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Comparative Analysis of Robotic-Assisted and Manual Total Knee Arthroplasty in Patients with Extra-Articular Deformities: A Propensity Score-Matched Prospective Cohort Study

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Abstract

Background: Total knee arthroplasty (TKA) in patients with extra-articular deformities (EAD) presents significant technical challenges. Robot-assisted TKA (RA-TKA) has the potential to provide more precise alignment and soft tissue balance. The primary aim of this study was to compare the rate of mechanical axis outliers (>3° deviation from target hip–knee–ankle angle) between RA-TKA and manual TKA in patients with EAD. Secondary aims included comparison of functional outcomes (KSS, FJS-12) at 12 months and exploratory subgroup analyses by deformity severity. **Methods:** This prospective, non-randomized, single-center cohort study included 80 patients with EAD undergoing primary TKA. Group allocation was based on the operating surgeon's clinical judgment considering deformity complexity. To minimize selection bias, propensity score matching (1:1, nearest-neighbor algorithm) was performed, yielding two comparable groups of 30 patients: RA-TKA (CUVIS system) and manual TKA. The primary outcome was the frequency of mechanical axis deviations > 3° (outliers) at 12 months. Secondary outcomes included KSS and FJS-12 scores at 12 months. All subgroup analyses were designated as exploratory. **Results:** After propensity score matching, the groups were comparable in baseline deformity severity (standardized mean differences < 0.1 for all covariates). The outlier rate was 6.7% in the RA-TKA group versus 23.3% in the manual group ($p = 0.03$). KSS Functional (84 vs. 74, $p = 0.008$) and FJS-12 (70 vs. 60, $p = 0.02$) scores were significantly higher after RA-TKA. In exploratory subgroup analyses, the advantage of the robotic technique appeared more pronounced for deformities with HKA > 10° and multiplanar deformities, though these analyses were underpowered and should be interpreted with caution. Surgery time was longer in the RA-TKA group (148 min vs. 110 min, $p < 0.001$), but the complication rate did not differ significantly. **Conclusions:** RA-TKA was associated with a significantly lower rate of mechanical axis outliers and higher functional outcome scores at 12 months compared with manual TKA in patients with EAD. Exploratory subgroup analyses suggest that the advantage may be most pronounced in severe and multiplanar deformities, but adequately powered studies are needed to confirm these findings. The longer operative time and higher cost of RA-TKA should be weighed against potential alignment benefits. Multicenter studies with longer follow-up are needed to assess implant survival and refine indications.

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Keywords: total knee arthroplasty; extra-articular deformity; robot-assisted surgery; propensity score matching; mechanical axis; alignment

1. Introduction

Total knee arthroplasty (TKA) is an effective treatment for end-stage osteoarthritis and aims to restore limb alignment, as well as soft tissue stability and balance [1,2]. However, in patients with extra-articular deformities (EAD) of the femur or tibia, performing TKA presents a significant technical and biomechanical challenge. EADs, which arise from malunion fractures, previous osteotomies, or congenital axial disorders, lead to changes in the anatomical axis, distortion of standard bone landmarks, and disruption of the physiological kinematics of the knee joint [3–5]. These changes increase the risk of inaccurate component positioning, residual deformity, and unsatisfactory functional outcomes.

The classic manual technique of TKA, based on the use of intramedullary and extramedullary guides, has significant limitations in conditions of deformed anatomy. Obstruction or sclerosis of the medullary canal, the presence of metal structures, and altered articular surface inclination angles limit the ability to perform precise resections [6,7]. In such situations, the manual technique is often accompanied by an increase in the number of deviations from the target mechanical axis (outliers > 3°), the requirement for non-standard techniques, an increase in the duration of the operation, and an increased likelihood of performing additional procedures, including corrective osteotomies. It is important to note that patients with EAD carry a higher risk of implant failure compared to standard primary TKA patients, which in turn reinforces and emphasizes the importance of scientific research in this area of orthopedics [2,8].

The development of computer navigation has improved the accuracy of mechanical axis reconstruction; however, the most significant progress in the correction of complex anatomical conditions is associated with the introduction of robot-assisted technologies. Robot-assisted TKA provides preoperative 3D planning and highly accurate resections, and eliminates the need for the development of intramedullary canals, which significantly complicates both planning and surgical intervention with a manual technique. There is a need to select implants of smaller sizes than necessary in order to reduce the intramedullary stem of the implant to prevent perforation of the bone cortices, and when installing more connected implants, this feature complicates the fixation of the modular stems of the prosthesis, which significantly affects the wear of the prosthesis. An equally important advantage is that robot-assisted TKA allows for intraoperative assessment of soft tissue balance in both phases of movement [9–12]. These advantages make robotic technology potentially more effective in conditions of significantly distorted anatomy. The less obvious disadvantages of the robotic system are the CT radiation risk and landmark registration error, which, if the surgeon is inexperienced, can affect the positioning of the implants.

An important consideration in TKA for EAD is the choice of alignment strategy. Mechanical alignment (MA), which targets a neutral hip–knee–ankle (HKA) axis, remains the most widely used approach [13]. This study emphasized mechanical alignment. The authors justify this decision primarily by the skills of the operating surgeons, who adopted robotic prosthetic systems after manual techniques, for which mechanical alignment is the "gold standard." Equally important is the absence of implants required for functional and kinematic alignment at the clinic where the study was conducted, which would have raised more questions and would have been unethical given the use of standard implants in the study groups. Furthermore, the authors of this study believe that the advantages of RA-TKA will be most evident in a simpler, well-known, and time-tested technique—mechanical

alignment. However, recent evidence suggests that applying strict MA in knees with severe EAD may generate unbalanced bone cuts and unstable joint gaps, often requiring extensive soft tissue releases that modify knee kinematics and balancing [2,14]. Alternative strategies such as functional alignment (FA) or kinematic alignment (KA) aim to achieve a more conservative joint line change through soft tissue balancing or intra-articular correction, potentially reducing the need for releases [14,15]. In the present study, the alignment target was a neutral mechanical axis (HKA $0° \pm 3°$), which was chosen as a standardized, reproducible target that allows objective comparison between techniques. The limitations of this approach in the context of EAD are acknowledged in the Discussion.

Analysis of the available literature confirms that robot-assisted systems are used primarily in the most complex clinical scenarios. Robotic technology is typically chosen in the presence of multiplanar (coronal and sagittal planes) and severe deformities, especially with a mechanical axis deviation of $\geq 10°$ [3,6]. RA-TKA is considered the preferred method for antecurvatum, recurvatum, severe metaphyseal deformity, and in situations where standard intramedullary guidewires cannot be used due to deformity, sclerosis, or the presence of metal structures [6,9]. In contrast, manual TKA has been used by authors in cases of relatively simple, isolated deformities, predominantly uniplanar, where an experienced surgeon could achieve comparable accuracy of axial reconstruction [7].

Despite the obvious technological advantages of robot-assisted TKA in complex anatomical scenarios, a number of unresolved issues remain. The available literature lacks clear criteria for choosing a robotic or manual technique for extra-articular deformities of the femur or tibia. Existing studies do not allow determination of the threshold deformity values at which robotic technology provides a clinically significant advantage. There is insufficient data on the impact of robotic-assisted correction on mechanical axis restoration, component positioning accuracy, and early functional outcomes compared to manual techniques. Studies with adequate statistical correction for the initial incomparability of groups based on deformity severity are virtually nonexistent.

Therefore, the primary aim of this study was to compare the rate of mechanical axis outliers (>3° deviation from target HKA) between RA-TKA and manual TKA in patients with EAD in order to generate a hypothesis about the advantage of the robotic system in this patient group. Secondary aims included comparison of functional outcomes (KSS, FJS-12) at 12 months and exploratory subgroup analyses to generate hypotheses regarding indications for robotic technology.

2. Materials and Methods

2.1. Study Design

A prospective, non-randomized, single-center cohort study was conducted at the Orthopedics Department of City Clinical Hospital No. 31 Named After Academician G.M. Savelieva, with the support of the Department of Traumatology and Orthopedics of Peoples' Friendship University of Russia Named After Patrice Lumumba. All patients provided written informed consent prior to enrollment.

The conduct of this study was approved by the Ethics Committee of Academician G.M. Savelieva Clinical Hospital No. 31 (Protocol No. 37, dated 8 January 2025).

Clinical registration of the study was conducted retrospectively at https://clinicalstudy.ru/ (individual register code: NNADM310884). This is an observational cohort study and not an interventional clinical trial. Registration was performed for transparency purposes. The first patient was included in the study on 11 January 2025. The date of collection of the results of the last patient was 27 April 2026.

The study is reported in accordance with the STROBE guidelines for observational studies [16].

Given the non-randomized design, group allocation was based on the operating surgeon's clinical judgment considering deformity complexity. To minimize selection bias, propensity score matching was used for key prognostic factors. Follow-up was carried out for 12 months after surgery.

2.2. Inclusion and Exclusion Criteria

Inclusion and exclusion criteria are presented in Table 1.

Table 1. Inclusion and exclusion criteria for the study sample.

Inclusion Criteria	Exclusion Criteria
Age 40–80 years	Combined EAD of the femur and tibia simultaneously (two-segment deformities requiring two-level correction using highly constrained prostheses that do not allow the parameters studied in this work to be properly assessed)
Unilateral osteoarthritis grades III–IV (Kellgren-Lawrence) with severe pain	Active infection, highly active systemic inflammatory diseases
Presence of extra-articular deformity of the femur or tibia resulting from: malunion of a fracture, previous corrective osteotomy, or congenital/juvenile growth deformity	Inability to perform primary TKA (significant bone loss requiring a revision implant)
Uniplanar or multiplanar deformity (coronal and/or sagittal)	Contracture > 30° or severe instability requiring constrained implants
Planning for primary TKA	Prior TKA on the study side
Signed informed consent	Refusal to participate

2.3. Group Allocation

Patients were allocated to two groups based on the operating surgeon's clinical judgment. The surgeon's decision was guided by the following considerations, though strict adherence to predefined thresholds was not mandated:

Group 1—Robot-assisted TKA (n = 40 initially enrolled): Surgeries were performed using the CUVIS robot-assisted system (Curexo, Republic of Korea). The robotic technique was generally preferred for patients with more complex deformity patterns, including those with greater mechanical axis deviation, multiplanar deformities, canal sclerosis or obstruction, presence of metal structures, or significant sagittal deformities. The system provided preoperative CT planning with 3D reconstruction, intraoperative navigation guidance for resections, real-time assessment of soft tissue balance, and avoidance of intramedullary guides.

Group 2—Manual TKA (n = 40 initially enrolled): Surgeries were performed using traditional mechanical guides (intramedullary for the femur, extramedullary for the tibia). Due to the presence of deformation and for the purpose of adequate preoperative planning, CT scanning was also performed in this group of patients. The manual technique was generally chosen for patients with less complex deformity patterns, typically those with uniplanar deformities, patent intramedullary canals, and absence of metal structures.

All patients were informed about the type of intervention (manual or robotic-assisted arthroplasty) that would be performed on them.

It is important to note that the allocation was not based on rigid criteria but on the surgeon's overall assessment of deformity complexity. As a result, there is overlap between groups in individual deformity characteristics (e.g., some patients with HKA > 10° were

treated manually, and some patients with HKA $\leq 10^{\circ}$ were treated robotically). This overlap reflects real-world clinical decision-making, where multiple factors are weighed simultaneously. Propensity score matching was subsequently applied to balance the groups on key prognostic factors.

Both groups had a uniform protocol for anesthesia, antibiotic prophylaxis, and postoperative rehabilitation.

2.4. Surgeons

All surgeries were performed by 3 senior orthopedic surgeons with 7–15 years of experience in TKA. The lead surgeon had performed 117 robotic-assisted TKA procedures prior to the study period. Surgeon experience was not included as a covariate in the propensity score model, which is acknowledged as a limitation.

2.5. Surgical Technique

A standard medial parapatellar approach was used in all cases. Standard cemented posterior-stabilized implants were used, fixed according to the manufacturer's instructions. The alignment target in both groups was a neutral mechanical axis (HKA $0^{\circ} \pm 3^{\circ}$).

Robot-assisted technique: (1) Preoperative CT scanning with construction of a 3D model of the femur and tibia. (2) Determination of the magnitude and plane of the extra-articular deformity (coronal, sagittal, multiplanar). (3) Planning the level and extent of resections, taking into account anatomical constraints, preventing notching of the anterior femoral cortex, and soft tissue tension. (4) Intraoperative registration of anatomical landmarks. (5) Performing resections under robotic arm control. (6) Intraoperative assessment of medial and lateral gaps in extension (0°) and flexion (90°) using the CUVIS system. (7) Real-time plan adjustment to achieve symmetrical gaps.

Manual technique: (1) Orientation of resections along intramedullary (femur) and extramedullary (tibia) guidewires. (2) In case of partial canal deformity, use of shortened intramedullary rods. (3) Mechanical axis control using standard alignment rods. (5) Subjective gap check using test components and spacers in extension and midflexion during valgus-varus test.

2.6. Outcome Measures

Primary outcome: The proportion of patients with postoperative HKA deviation > 3° from the target (0°)—outliers—assessed on lower extremity teleradiographs at 12 months.

Secondary outcomes (assessed preoperatively and at 12 months):

- Radiographic parameters: HKA angle, lateral distal femoral angle (LDFA), medial proximal tibial angle (MPTA), tibial slope, femoral component flexion, incidence of anterior femoral cortex notching, need for additional interventions (osteotomies).
- Clinical and functional outcomes: Knee Society Score (KSS)—clinical and functional components; Forgotten Joint Score-12 (FJS-12); VAS pain score; ROM (range of motion)—flexion and extension; subjective satisfaction on a Likert scale (1–5); complication rate (deep vein thrombosis, surgical site infection, stiffness).

Radiographic measurements were performed by two independent observers blinded to group allocation. Blindness in the X-ray evaluation was ensured by randomizing the images and presenting them sequentially to each expert. Each X-ray was anonymized and assigned its own unique code. The experts sequentially completed a special form, indicating the X-ray code and noting the radiographic parameters mentioned above in the study. In the second stage, the images were recoded and presented to the same experts using a similar methodology.

Intra-observer and inter-observer reliability were assessed using Interclass correlation coefficient (ICC) with 95% confidence interval (CI).

Soft tissue balance (intraoperative, for the robotic group only): medial and lateral gaps (mm) in extension (0°) and flexion (90°); gap symmetry (difference between medial and lateral gaps $\leq$ 2 mm). This parameter was measured only in the RA-TKA group using the robotic system's built-in sensors and is reported descriptively. It is not intended for between-group comparison and is acknowledged as a limitation.

Exploratory subgroup analyses were performed to generate hypotheses regarding potential indications for robotic technology. Subgroups were formed after propensity score matching based on: EAD with HKA $\leq 10^{\circ}$ vs. HKA $> 10^{\circ}$; coronal vs. multiplanar deformities; presence vs. absence of metalwork; sclerosis of the medullary canal vs. patent canal; isolated femoral vs. tibial deformity.

2.7. Sample Size Calculation

Based on published data reporting outlier rates of approximately 6–8% for RA-TKA and 20–25% for manual TKA in complex primary TKA, a sample size of 30 patients per group was estimated to provide approximately 70% power to detect a difference of 17 percentage points in outlier rates (6.7% vs. 23.3%) using McNemar's test at a two-sided alpha of 0.05 [17,18]. This power is below the conventional 80% threshold, which limits the ability to detect smaller differences and renders the subgroup analyses exploratory. A post-hoc power analysis confirmed that the study was adequately powered for the primary outcome (observed > 50%]) but underpowered for subgroup comparisons.

2.8. Statistical Analysis

Statistical analysis was performed using SPSS 26.0 and R 4.2.1. Normality of distribution was tested using the Shapiro–Wilk test. To ensure comparability of groups based on baseline prognostic factors, propensity score matching (PSM) with the nearest-neighbor algorithm was used (caliper = 0.2 standard deviations of the propensity score logit function). The PSM model included age, sex, BMI, preoperative HKA, deformity type (uniplanar/multiplanar), presence of metal structures, and intramedullary canal patency. PSM only accounted for observed covariates, but not latent factors.

After matching, balance was assessed using standardized mean differences (SMD) for all covariates included in the propensity score model. An SMD < 0.1 was considered indicative of adequate balance. SMD values for all covariates are reported in Table 1.

Comparisons between matched groups were performed using: paired Student's *t*-test (normally distributed continuous variables); Wilcoxon signed-rank test (non-normally distributed continuous variables); and McNemar's test (paired binary outcomes). The specific test used for each comparison is indicated in the footnotes of each table.

The primary outcome (outlier rate) was analyzed using McNemar's test. All secondary outcomes are reported with 95% confidence intervals. No adjustment for multiple comparisons was applied to secondary outcomes, which are therefore considered exploratory.

To quantify the effect size, Cohen's d was calculated for continuous outcomes. Clinical scales were compared with published minimum clinically important difference (MCID) thresholds: KSS Knee Score—5.3–8.9 points; KSS Function Score—6.1–10.3 points; FJS-12—13.7–16.6 points [11,12,19]. Rather than comparing the between-group median difference against MCID, the proportion of patients in each group achieving the MCID was calculated and compared using McNemar's test.

Differences were considered statistically significant at $p < 0.05$.

3. Results

3.1. Patient Flow

The study enrolled 80 patients (40 per group). After propensity score matching, 30 matched pairs (n = 60) were formed. Twenty patients were excluded from the matched analysis: 10 in the RA-TKA group and 10 in the manual group could not be matched within the specified caliper due to refusal to participate (13 patients) and inability to perform primary TKA (significant bone loss requiring a revision implant) (7 patients) (Table 2). No patients were lost to follow-up during the 12-month observation period (Figure 1A–C).

Table 2. Baseline characteristics of excluded patients.

Indicator	RA-TKA (n = 10)	Manual TKA (n = 10)
Sex (m/f)	4/6	2/8
Age, years, median [IQR]	62 [58 to 66]	64 [55 to 70]
BMI, kg/m^2, median [IQR]	27.4 [26.5 to 33.3]	28.0 [26.2 to 30.9]
Preoperative HKA, ° varus, median [IQR]	8.7 [6.6 to 10.2]	8.2 [6.1 to 10.3]
Multiplanar deformity, n (%)	4 (40.0%)	2 (20.0%)
Metal implants, n (%)	1 (10.0%)	0 (0%)
Canal sclerosis, n (%)	5 (50.0%)	2 (20.0%)
Previous operations, n (%)	7 (70.0%)	6 (60.0%)

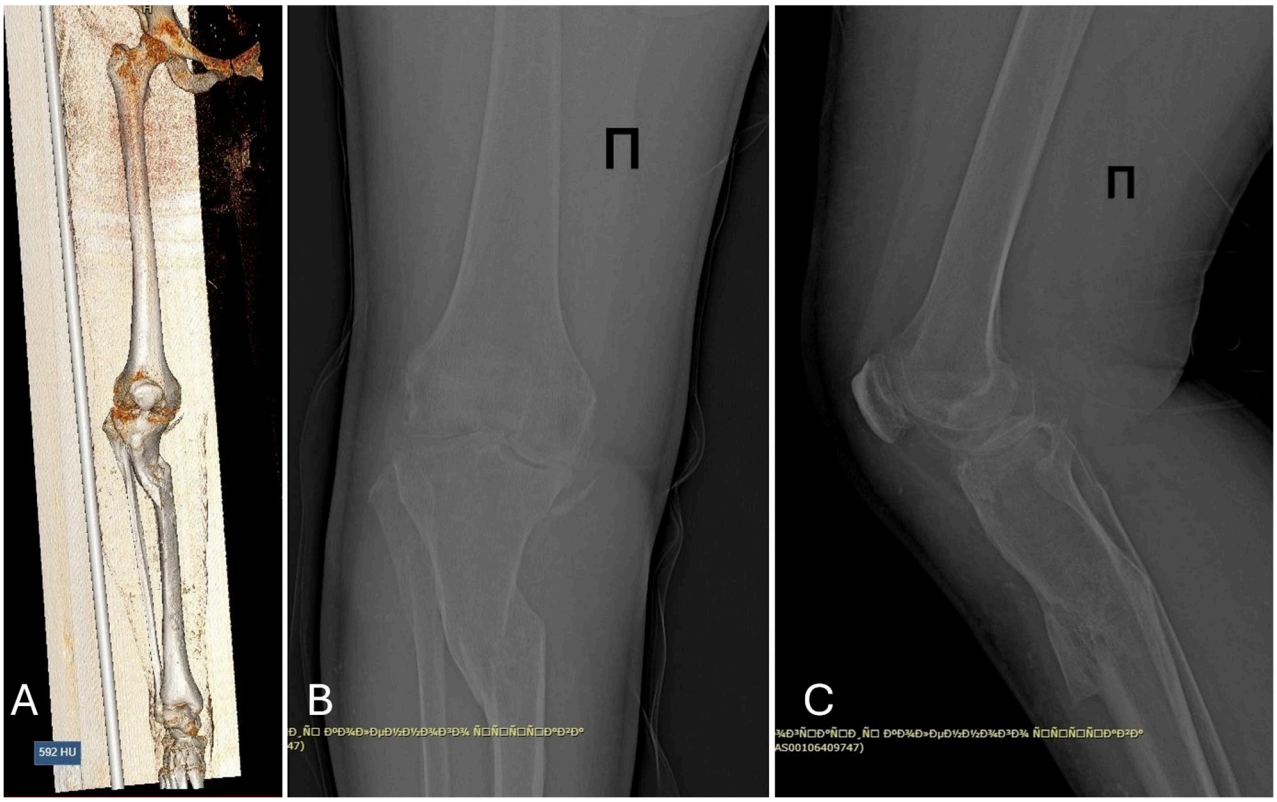


Figure 1. An example of a clinical case of one of the patients included in the RA-TKA group. Patient L., 70 years old, extra-articular deformity of the tibia due to conservative treatment of a fracture with displacement more than 10 years ago. (**A**) Preoperative CT scan of the lower extremity for planning robotic-assisted prosthetics. (**B**) X-ray of the knee joint in the frontal and (**C**) lateral projections.

3.2. Baseline Characteristics After Propensity Score Matching

Analysis of baseline characteristics after matching confirmed comparability between the groups for all key prognostic factors (Table 3). All standardized mean differences were <0.1, indicating adequate balance.

Table 3. Baseline Characteristics After Propensity Score Matching.

Indicator	RA-TKA (*n* = 30)	Manual TKA (*n* = 30)	*p*-Value	SMD
Sex (m/f)	11/19	12/18	0.79 [a]	0.07
Age, years, median [IQR]	67 [63 to 72]	66 [62 to 71]	0.61 [b]	0.08
BMI, kg/m^2, median [IQR]	29.2 [26.8 to 32.1]	29.0 [26.3 to 31.8]	0.68 [b]	0.05
Preoperative HKA, ° varus, median [IQR]	8.4 [6.8 to 11.2]	8.1 [6.2 to 10.8]	0.59 [b]	0.09
Multiplanar deformity, *n* (%)	8 (26.7%)	7 (23.3%)	0.77 [a]	0.08
Metal implants, *n* (%)	3 (10.0%)	3 (10.0%)	1.00 [a]	0.00
Canal sclerosis, *n* (%)	5 (16.7%)	4 (13.3%)	0.72 [a]	0.10
Previous operations, *n* (%)	6 (20.0%)	7 (23.3%)	0.76 [a]	0.08

[a] McNemar's test. [b] Wilcoxon signed-rank test. SMD = standardized mean difference. IQR = interquartile range.

3.3. Radiographic Results

The ICC of intra- and inter-examiner agreement in evaluation of the median in radiographic parameters: HKA angle, LDFA, MPTA, tibial slope, femoral component flexion, incidence of anterior femoral cortex notching, need for additional interventions (osteotomies) in the RA-TKA group is 0,94, which, in accordance with 95% CI, corresponds to a high correlation strength and reliability of the examination.

The ICC of intra- and inter-examiner agreement in evaluation of the median in radiographic parameters: HKA angle, LDFA, MPTA, tibial slope, femoral component flexion, incidence of anterior femoral cortex notching, need for additional interventions (osteotomies) in the Manual TKA group is 0.97, which, in accordance with 95% CI, corresponds to a high correlation strength and reliability of the examination.

The robot-assisted technique provided significantly more accurate restoration of the mechanical axis and component positioning (Table 4) (Figure 2A,B). The proportion of outliers > 3° was significantly lower in the robot-assisted group (6.7% vs. 23.3%, $p = 0.03$).

Table 4. Postoperative Radiographic Parameters at 12 Months.

Indicator	RA-TKA, Median [IQR]	Manual TKA, Median [IQR]	*p*-Value	Cohen's d
HKA, °	0.3 [−0.2 to 0.9]	1.7 [0.5 to 3.8]	0.008 [b]	0.71
LDFA, °	87.1 [86.2 to 87.9]	85.8 [84.5 to 88.4]	0.04 [b]	0.52
MPTA, °	89.4 [88.8 to 90.1]	87.2 [86.0 to 89.3]	0.01 [b]	0.64
Tibial slope, °	3.1 [2.5 to 3.6]	4.8 [3.1 to 6.9]	0.02 [b]	0.58
Femoral component flexion, °	2.3 [1.5 to 3.2]	3.9 [2.1 to 6.2]	0.04 [b]	0.51
Outliers > 3°, *n* (%)	2 (6.7%)	7 (23.3%)	0.03 [a]	—
Notching, *n* (%)	0 (0%)	3 (10.0%)	0.08 [a]	—

[a] McNemar's test. [b] Wilcoxon signed-rank test.

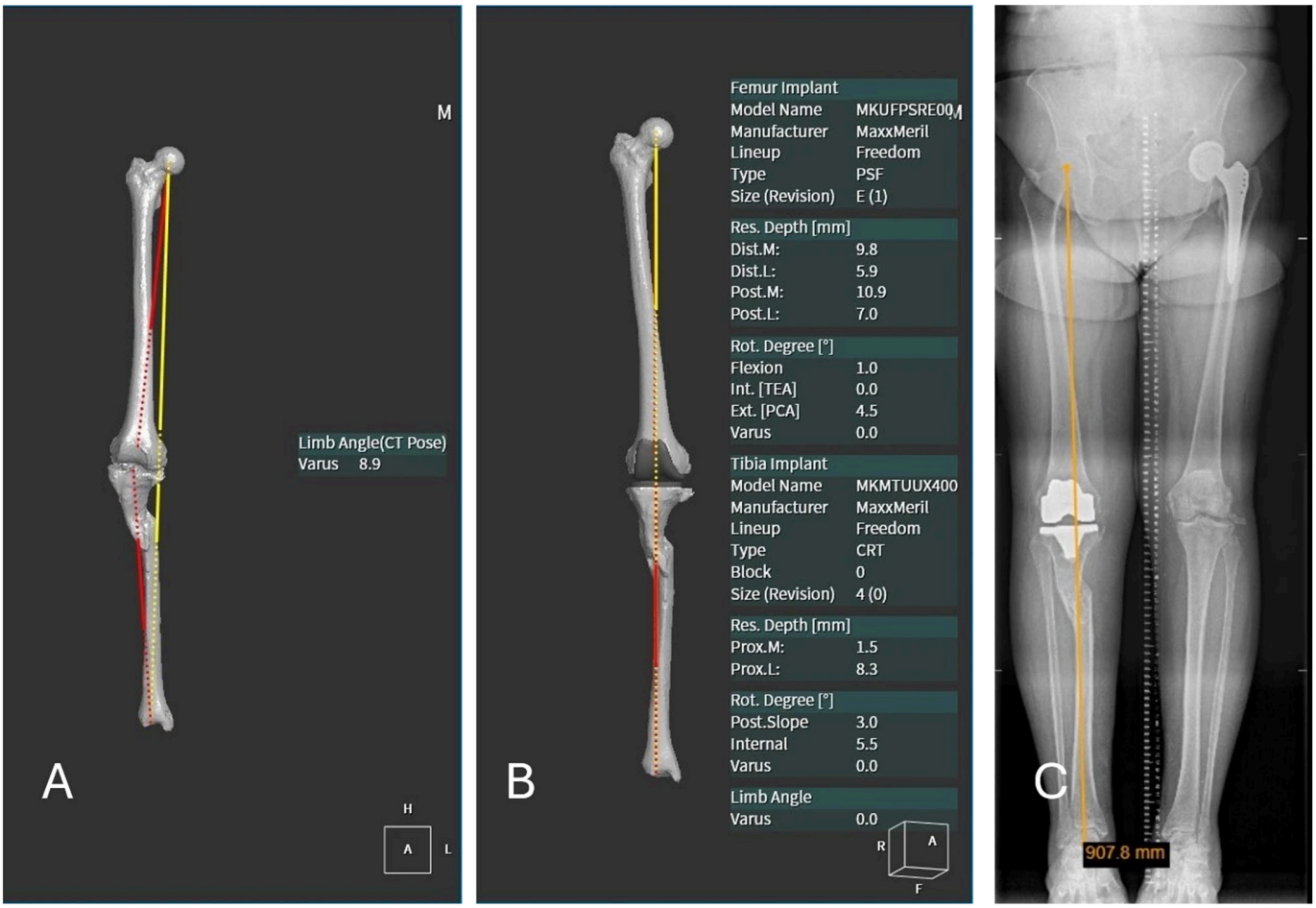


Figure 2. An example of the result of total knee arthroplasty in patient A with extra-articular deformity: (**A**) preoperative CT image in the planning program, (**B**) result of preoperative planning, (**C**) postoperative X-ray.

3.4. Soft Tissue Balance (RA-TKA Group Only)

For the RA-TKA group, intraoperative gap assessment revealed symmetrical balance in extension and flexion (Table 5). In the manual group, quantitative gap assessment in real time was not performed, precluding direct comparison. This parameter is reported descriptively for the RA-TKA group only (Figure 3A,B).

Table 5. Intraoperative Soft Tissue Balance (RA-TKA Group Only).

Indicator	Medial Gap (mm)	Lateral Gap (mm)	Difference (mm)
Extension (0°)	10.2 [9.5 to 11.0]	10.4 [9.8 to 11.2]	0.2 [−0.5 to 0.8]
Flexion (90°)	10.5 [9.8 to 11.3]	10.6 [10.0 to 11.4]	0.1 [−0.4 to 0.7]

Symmetry of gaps (≤2 mm) was achieved in 28 patients (93.3%).

In two cases after RA-TKA, the gap symmetry was greater than 2 mm. In both cases, the deformity was associated with post-traumatic tibia deformity with valgus deviation of the joint axis. The gap difference was within 2.2 mm with widening in the medial part. The final postoperative results obtained in these patients indicate a satisfactory outcome of the operation (Table 6).



Figure 3. An example of an intraoperative gap check in patient with extra-articular deformity in the tibia: (**A**) Final gap balance in extension and (**B**) flexion.

Table 6. Postoperative results of patients with a gap difference of more than 2 mm.

Indicator	Patient 1	Patient 2
KSS Clinical	87	89
KSS Functional	84	86
FJS-12	72	70
VAS pain	1	1
Satisfaction (1–5)	5	5

3.5. Clinical and Functional Results

After 12 months, the RA-TKA group demonstrated statistically higher scores on the KSS and FJS-12 scales (Table 7). The proportion of patients achieving the MCID threshold is reported for each outcome (Figure 4).

Table 7. Clinical and Functional Results at 12 Months.

Indicator	RA-TKA, Median [IQR]	Manual TKA, Median [IQR]	*p*-Value	Cohen's d	Patients Achieving MCID: RA-TKA vs. Manual, *n* (%)	*p*-Value (MCID Comparison)
KSS Clinical	88 [83 to 91]	80 [75 to 85]	0.01 [b]	0.67	28 (93%)	$p < 0.05$
KSS Functional	84 [78 to 89]	74 [68 to 79]	0.008 [b]	0.72	29 (97%)	$p < 0.05$
FJS-12	70 [62 to 77]	60 [52 to 67]	0.02 [b]	0.61	26(86%)	$p < 0.05$
VAS pain	1.5 [1.0 to 2.5]	2.5 [1.5 to 3.5]	0.04 [b]	0.55	28 (93%)	$p < 0.05$
Satisfaction (1–5)	4.2 [3.8 to 4.6]	3.8 [3.2 to 4.4]	0.10 [b]	0.38	—	—

[b] Wilcoxon signed-rank test. MCID thresholds used: KSS Clinical, 5.3–8.9 points; KSS Functional, 6.1–10.3 points; FJS-12, 13.7–16.6 points; VAS, 2 points [11,12,19].

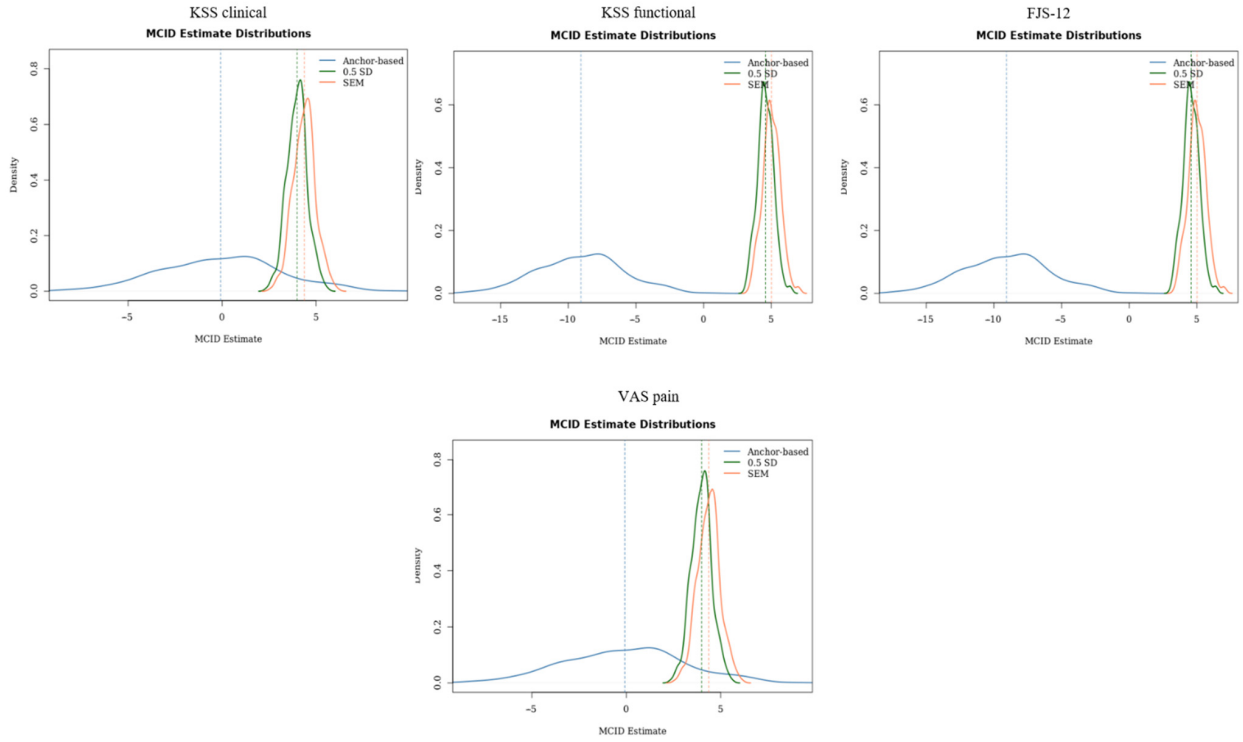


Figure 4. MCID report for each outcome. SD: standard deviation, SEM: standard error of the mean.

3.6. Range of Motion

Both groups achieved improvements in flexion; the difference of 6° was statistically significant but did not reach the MCID (Table 8).

Table 8. Range of Motion (ROM) Before Surgery and at 12 Months.

Indicator	RA-TKA, Median [IQR]	Manual TKA, Median [IQR]	*p*-Value	Cohen's d
Flexion preoperative, °	103 [94 to 111]	102 [93 to 112]	0.72 [b]	—
Flexion at 12 months, °	120 [115 to 128]	114 [108 to 122]	0.045 [b]	0.48
Extension preoperative, °	−5 [−9 to −3]	−6 [−10 to −3]	0.54 [b]	—
Extension at 12 months, °	−1 [−3 to 0]	−2 [−4 to 0]	0.31 [b]	0.22

[b] Wilcoxon signed-rank test.

3.7. Exploratory Subgroup Analysis

Subgroup analyses are presented in Table 9. These analyses are exploratory and underpowered; the results should be interpreted as hypothesis-generating only. Subgroup sizes are unequal because matching was performed on the overall propensity score, not within individual subgroups; therefore, matched pairs may differ on individual covariates despite overall balance.

Table 9. Exploratory Subgroup Analysis: Frequency of Outliers > 3°.

Subgroup	RA-TKA, *n*/N (%)	Manual TKA, *n*/N (%)	*p*-Value
HKA ≤ 10° (*n* = 42)	1/21 (4.8%)	3/21 (14.3%)	0.15 [c]
HKA > 10° (*n* = 18)	1/9 (11.1%)	4/9 (44.4%)	0.04 [c]
Multiplanar (*n* = 15)	1/8 (12.5%)	4/7 (57.1%)	0.03 [c]
Uniplanar (*n* = 45)	1/22 (4.5%)	3/23 (13.0%)	0.21 [c]
Metal implants (*n* = 6)	0/3 (0%)	1/3 (33.3%)	0.31 [c]
Canal sclerosis (*n* = 9)	0/5 (0%)	2/4 (50.0%)	0.07 [c]

[c] Fisher's exact test (used due to small expected cell counts). Note: Unequal subgroup sizes (e.g., multiplanar 8 vs. 7) reflect the fact that propensity score matching was performed on the overall score, not within individual subgroups. Matched pairs may therefore differ on individual covariates.

3.8. Surgical Time, Learning Curve, and Complications

The operative time in the RA-TKA group was 148 min [135 to 168] versus 110 min [95 to 124] in the manual group ($p < 0.001$, Wilcoxon signed-rank test). The learning curve analysis was performed on all 40 allocated (pre-matching) RA-TKA cases: the median time for the first 10 surgeries was 168 min, while for the last 10 surgeries it was 128 min ($p = 0.002$, Mann–Whitney U test). This is consistent with published learning curves for robotic TKA systems, which report proficiency at 15–40 cases [20–22]. Complications were not statistically different between groups (Table 10). Absolute counts are reported given the small sample size.

Table 10. Complications Through 12 Months.

Complication	RA-TKA (*n* = 30)	Manual TKA (*n* = 30)	*p*-Value
Deep vein thrombosis	1 (3.3%)	2 (6.7%)	0.55 [a]
Surgical site infection	0 (0%)	1 (3.3%)	0.31 [a]
Stiffness (flexion < 90°)	1 (3.3%)	3 (10.0%)	0.30 [a]
Total complications	2 (6.7%)	6 (20.0%)	0.13 [a]

[a] McNemar's test.

3.9. Surgical Technique Selection Algorithm

Based on the data obtained, a structured algorithm was developed reflecting the main considerations for choosing a robotic-assisted or manual technique for extra-articular deformities. The algorithm visualizes the sequence of key diagnostic steps—from assessing the magnitude and plane of the deformity to analyzing technical limitations and alignment principles. This framework is intended as a practical guide and requires validation in larger cohorts.

4. Discussion

This study demonstrates that robotic-assisted knee arthroplasty was associated with a lower rate of mechanical axis outliers and higher functional outcome scores at 12 months

compared with manual TKA in patients with extra-articular deformities. A key methodological feature of this study is the use of propensity score matching, which minimized selection bias and allowed comparison of the two techniques in groups balanced for severity of pathology.

After matching the groups for key prognostic factors (all SMD < 0.1), the outlier rate was 6.7% versus 23.3% (p = 0.03). This is consistent with the findings of recent meta-analyses and large cohort studies demonstrating lower outlier rates with robotic-assisted TKA [10,17,18]. A recent systematic review of randomized clinical trials confirmed that RA-TKA was associated with fewer outliers in HKA angle, femoral component angle, and tibial component angle compared with conventional TKA [10].

Functional outcomes at 12 months (KSS, FJS-12) were statistically higher in the RA-TKA group. However, interpretation of clinical significance requires caution. Published MCID values for the KSS vary considerably depending on the method used: 5.3–5.9 points for KSS Knee Score and 6.1–6.4 points for KSS Function Score using anchor-based methods, versus 8.9 and 10.3 points respectively using ROC analysis [11,19]. The MCID for the FJS-12 has been reported as 13.7 points using a distribution-based method and 16.6 points using an anchor-based method [12]. The observed between-group median difference of 10 points for both KSS Functional and FJS-12 falls within the lower range of published MCID estimates for KSS Functional but below the MCID threshold for FJS-12. The median difference of 10 points for the FJS-12 is below the established MCID (13.7–16.6). To provide a more robust assessment of clinical significance, the proportion of patients achieving the MCID in each group was compared (Table 7), as recommended for paired designs [11,19].

In exploratory subgroup analyses, the advantage of the robotic technique appeared more pronounced in patients with HKA > 10° (outlier rate 11.1% vs. 44.4%, p = 0.04) and multiplanar deformities (12.5% vs. 57.1%, p = 0.03). However, these findings must be interpreted with considerable caution for several reasons. First, the subgroup sample sizes were very small (n = 6 to n = 45), resulting in insufficient statistical power. Second, comparing a statistically significant result in one subgroup against a non-significant result in another does not constitute evidence of a differential treatment effect; a formal test of interaction would be required to support such a claim [7,8]. Third, no adjustment for multiple comparisons was applied. These subgroup results should therefore be regarded as hypothesis-generating only.

It is important to note that functional outcomes were not analyzed by subgroup. Therefore, the claim that positioning accuracy contributes to functional improvement specifically in complex anatomical scenarios cannot be directly supported by the present data and remains a hypothesis for future investigation.

Flexion range was slightly higher in the RA-TKA group (120° vs. 114°, p = 0.045, Cohen's d = 0.48), but the 6° difference did not reach the MCID (10°) and is within the standard error of goniometer measurement. This is consistent with most meta-analyses, which have not found a clinically significant advantage of robotic systems in terms of ROM [10]. Stiffness (flexion < 90°) was more common in the manual group (10.0% vs. 3.3%), although the difference did not reach statistical significance (p = 0.30), which may be due to insufficient sample power.

Intraoperative assessment of soft tissue balance in the RA-TKA group demonstrated a high level of gap symmetry (93.3% of patients with a difference of ≤2 mm, 6,7% of patients with a difference within 2.2 mm (widening of the medial part of the gap)). However, since this parameter was measured only in the RA-TKA group using the robotic system's built-in sensors, no between-group comparison is possible. It remains unclear whether gap symmetry, as measured by the robotic system, directly drives functional gains. The absence of comparable quantitative gap data in the manual group is a significant limitation, and the

relationship between intraoperative gap balance and patient-reported outcomes warrants further investigation in studies where both groups undergo standardized gap assessment.

Operative time was significantly longer in the RA-TKA group (148 vs. 110 min), which is typical for robotic-assisted procedures. The observed learning curve effect, with a 40-min reduction in time by the end of the series, indicates potential for optimization with experience and is consistent with published learning curves reporting proficiency at 15–40 cases [20–22]. The incidence of complications between groups was not statistically different, consistent with data from registry studies.

5. Cost Considerations

The higher cost of RA-TKA is an important factor that was not formally assessed in this study. Robotic systems entail significant capital expenditure, maintenance costs, and the cost of disposable components and preoperative CT scanning. These costs must be weighed against the potential benefits of improved alignment accuracy and functional outcomes, particularly in the context of healthcare systems with limited resources. Future studies should incorporate formal cost-effectiveness analyses to determine whether the alignment and functional advantages of RA-TKA justify the additional expense, especially in the subgroup of patients with severe and multiplanar deformities where the benefits appear most pronounced.

6. Alignment Strategy Considerations

The present study used a neutral mechanical axis (HKA $0^\circ \pm 3^\circ$) as the alignment target in both groups. While this approach provides a standardized, reproducible benchmark for comparing techniques, it has important limitations in the context of EAD. Recent evidence suggests that applying strict mechanical alignment in knees with severe extra-articular deformities may generate unbalanced bone cuts and unstable joint gaps, often necessitating extensive soft tissue releases that alter knee kinematics [2,13]. Alternative alignment strategies—including functional alignment, kinematic alignment, and restricted kinematic alignment—aim to achieve a more conservative joint line change, either through soft tissue balancing or intra-articular correction, potentially reducing the need for releases and improving patient-reported outcomes [1,3–5,15]. Robotic-assisted technology may be particularly well suited to implementing these personalized alignment strategies, as it enables precise intraoperative adjustment of component positions relative to soft tissue balance. Future studies comparing RA-TKA and manual TKA in patients with EAD should consider evaluating alternative alignment targets, as the choice of alignment strategy may significantly influence both the magnitude of the robotic advantage and the clinical outcomes achieved.

7. Limitations

This study has several important limitations that should be considered when interpreting the results. First, despite the use of propensity score matching, the study remains non-randomized, which does not allow for the complete exclusion of unmeasured confounding factors. The propensity score model included key prognostic variables, but surgeon experience—a potentially important confounder—was not included as a covariate. Second, the sample size (30 matched pairs) limits the statistical power, particularly for subgroup analyses. The study was estimated to have approximately 70% power for the primary outcome, which is below the conventional 80% threshold. All subgroup results should be considered exploratory and hypothesis-generating. Third, radiographic assessments were performed by observers blinded to group allocation, but clinical outcome assessments (KSS, FJS-12, VAS) were not blinded, introducing the possibility of assessment

bias. Fourth, the observation period of 12 months does not allow for assessment of medium- and long-term implant survival. Claims regarding long-term superiority cannot be made based on these data, and longer follow-up is essential. Fifth, quantitative assessment of soft tissue balance was performed only in the robotic group using the system's built-in sensors, precluding direct between-group comparison for this parameter. It should be noted that direct comparison of soft tissue balance between groups is limited by the lack of quantitative intraoperative gap measurements in the manual group. Sixth, the study was conducted on a single robotic platform (CUVIS), which limits the generalizability of the findings to other robotic systems. Seventh, functional outcomes at 6 weeks and 3 months were collected but are not reported in this analysis due to decision to focus on the primary 12-month endpoint. Similarly, VAS scores at rest versus with activity were not reported separately. These data will be presented in a subsequent analysis. Eighth, the alignment target of neutral mechanical axis may not be optimal for all patients with EAD, as discussed above.

Another important limitation of the study is that the group assignment based on clinical judgment and surgeon experience may introduce systematic errors, despite PSM. Due to the rarity of this category of patients in our clinic, the authors took into account primarily the orthopedic status, which can affect the final result, which also depends on the general somatic condition of the patient. Non-randomized group allocation based on surgeon's judgment may introduce unmeasured confounding factors that PSM cannot fully address.

Last but not least, a limitation is related to the fact that while a higher proportion of patients in the RA-TKA group achieved MCID, the between-group median difference did not meet the FJS-12 MCID threshold.

The authors acknowledge all the shortcomings and limitations of this study, but sincerely believe that it can serve as a basis for developing greater interest among orthopedic surgeons in addressing extra-articular knee deformities using a robotic system and will serve as a basis for the publication of more papers in this area.

8. Conclusions

Robot-assisted knee arthroplasty was associated with a significantly lower rate of mechanical axis outliers and higher functional outcome scores at 12 months compared with manual TKA in patients with extra-articular deformities. Exploratory subgroup analyses suggest that the advantage may be most pronounced in patients with severe deformities (HKA > 10°) and multiplanar deformities, but these findings are hypothesis-generating and require confirmation in adequately powered studies. For moderate uniplanar deformities (HKA $\leq$ 10°), the manual technique provided comparable accuracy and functional outcomes. The longer operative time and higher cost of RA-TKA should be weighed against the potential alignment and functional benefits. Multicenter randomized studies with longer follow-up, formal cost-effectiveness analyses, and evaluation of alternative alignment strategies are needed to refine indications for robotic technology in this challenging patient population.

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