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Research Article

Robot-Assisted Total Knee Arthroplasty (RATKA) and its more Automated Versions: Active RATKA

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ABSTRACT

Background: Robotic-assisted total knee arthroplasty (RATKA) improves alignment accuracy over conventional instrumentation, but direct comparative evidence between fully autonomous (Active) and surgeon-guided (Semi-active) robotic platforms remains scarce despite their differing cost, workflow, and regulatory implications. This study compared post-operative alignment accuracy and secondary clinical, functional, and economic outcomes between Active and Semi-active RATKA.

Methods: In this prospective, multicentre study, 120 patients undergoing primary unilateral total knee arthroplasty were allocated to Active or Semi-active RATKA (60 per arm) by randomisation or propensity-matched cohort design across four centres from November 2025 to March 2026. The primary outcome was post-operative hip-knee-ankle (HKA) mechanical-axis deviation. Secondary outcomes included component positioning, intra-operative parameters, functional and patient-reported scores to one year, complications, inter-surgeon variability, and per-case direct cost.

Results: Active RATKA achieved significantly smaller mean HKA deviation and fewer alignment outliers than Semi-active RATKA. Component positioning was statistically equivalent across five of six planes, with Semi-active RATKA showing more accurate femoral rotational alignment. Active RATKA required longer operative time and higher direct cost. No significant between-group differences emerged in functional scores, complications, readmission, revision, or inter-surgeon variance at one year, and WOMAC scores were numerically worse with Active RATKA despite its alignment advantage.

Conclusion: Active RATKA improves mechanical-axis alignment precision over Semi-active RATKA, but this advantage did not translate into superior early functional, safety, or cost outcomes, and was accompanied by an isolated deficit in femoral rotational accuracy. Alignment gains alone do not currently justify preferential adoption of fully autonomous platforms; adequately powered trials with longer follow-up are needed before firm technology-adoption decisions can be made.

Keywords: Arthroplasty, Replacement, Knee; Robotic Surgical Procedures; Osteoarthritis, Knee; Postoperative Complications.

INTRODUCTION

Osteoarthritis of the knee (OA) is one of the most common chronic musculoskeletal conditions globally and is a major source of pain, functional limitation and disability in older adults [1]. As of 2021, there were more than 370 million people living with knee OA and the prevalence was increasing with age, and with the rise of obesity, particularly in higher socio-demographic populations, age-standardized incidence, prevalence, and disability-adjusted life-years are also projected to increase [1]. When conservative treatment measures have failed, total knee arthroplasty (TKA) is the ultimate surgical solution for end-stage knee OA that can restore function and alleviate pain in most patients suffering from knee OA. Traditional jig-assisted TKA, however, relies on the technology and is not associated with less satisfaction or functional limitation, and malalignment and soft tissue imbalance are two major factors associated with early revision and patient dissatisfaction. This continues to be a challenge in the execution of the surgical procedure, prompting the development of robotic-assisted TKA (RATKA) to address the limitations of freehand bone resection and implant positioning. There is now a large and growing randomized and observational body of evidence evaluating RATKA compared to conventional TKA. Meta-analyses of RCTs have repeatedly demonstrated that the use of RATKA yields greater radiographic alignment accuracy: pooled results have indicated that this yields a reduction in deviation from the neutral mechanical axis of approximately 0.9–1.0° with significantly fewer alignment outliers than conventional instrumentation [2,3]. While this radiographic benefit was noted by these same meta-analyses, there was no consistent improvement in mid-term functional or patient-reported outcomes, and longer operative times were reported with RATKA [2,3]. More recently, a meta-analysis of studies that included only patients undergoing conventional TKA revealed no significant difference at two-, five-, or ten-year follow-up between robotic and conventional TKA in terms of revision or complication rates, which means that conventional TKA is non-inferior to robotic TKA with regard to revision and complication rates [4]. Most importantly, "robotic-assisted TKA" has been a relatively uniform term in the literature, despite the fact that there are significant differences in the level of autonomy that is provided to the surgeon on the various robotic platforms used for this procedure. The most common clinical model is the semi-active (surgeon-guided) system that allows the surgeon to keep control of the cutting instrument within the robot constrained boundary, and has a body of supporting evidence. They have a rapid, and relatively limited, learning curve, but not for the accuracy of the implant position itself, but for workflow integration [6]. Active systems (fully autonomous) on the other hand make the bone resection without significant hand-on-hand involvement by the surgeon, and have been reported to allow highly reproducible placement of the components regardless of the surgeon's manual skill or bone density [7,8]. However, there was a lack of published evidence base for modern active systems, and early generation systems were reported to have long operating times and technical issues when first used, versus the smaller published evidence base for semi-active systems [5]. The authors have explicitly reported that the distinction between active and semi-active platforms is not well investigated, and there is a lack of head-to-head comparative data to make firm conclusions [4] on this issue, where survivorship meta-analyses attempt to make this distinction. What is not yet established is that robotics can provide a greater level of performance, in terms of accuracy, function or safety, over the semi-active systems that are currently the norm in practice; what is missing is compelling, well-powered evidence of the incremental advantage that robotics systems can offer.

This gap is relevant due to the significant differences in capital cost, workflow integration and regulatory pathway between the active and semi-active robotic platforms, and the lack of comparative data for health systems as they consider adopting and procuring a robotic platform. If full autonomy is a real, clinically significant benefit in terms of alignment precision and downstream results, then it would be warranted to invest in it and to continue the development of new devices that are more autonomous. On the other hand, the advantage of active systems in terms of accuracy may be comparable to that of semi-active systems, but at a much higher price and much longer operating life, and it may be more appropriate to allocate resources to wider use of semi-active systems.

This study is, therefore, carried out in a prospective, multicentre cohort to compare the two platforms directly and move the decision to adopt a particular technology from a guess to evidence. The main purpose of this study is to evaluate the accuracy of the mechanical (hip–knee–ankle) axis alignment after primary total knee arthroplasty (P-TKA) with Active RATKA compared with Semi-active RATKA. Secondary endpoint include component positioning accuracy, intra operative parameters, early and mid-term functional and patient reported outcomes, post operative complication and revision, surgeon dependent variability and preliminary cost comparison between the two platforms. We hypothesize that with full autonomy of bone resection with Active RATKA, the mean deviation from neutral alignment will be approximately 1.0° less than the mean with Semi-active RATKA, accounting for the surgeon-dependent variability in the cutting step; we are not interested in whether any advantage in alignment will have a positive impact on functional or safety outcomes.

To aim this goal, we performed a prospective, multicentre, comparative analysis between those undergoing primary unilateral TKA with either an Active or Semi-active robotic platform, with the allocation of patients performed using a randomization method if both systems were available locally, and propensity-match otherwise. Intra-operative variables, functional outcomes, alignment, component positioning and safety events were evaluated at 6 Wks, 4 months and 12 months after surgery as well as direct cost per case; the latter was also evaluated at the time of surgery. Full details of the study population, sample size calculation, and statistical analysis plan are reported in the Methods.

METHODS

This was a prospective, multicenter, comparative clinical study to compare the effectiveness of surgeon guided (Semi-active) RATKA with fully autonomous (Active) RATKA in patients undergoing primary unilateral TKA for end-stage knee osteoarthritis. A randomized controlled design (block randomization stratified by centre and pre-operative coronal deformity direction, varus vs valgus) was implemented at centres where both platforms were locally available and a propensity-matched prospective cohort design was used at centres where this was not possible. The study was carried out in four orthopaedic/arthroplasty tertiary care centres (A to D) that have established Active and Semi-active Robotics TKA programmes. Recruitment was conducted from January 2024 until December 2024 (12 months) and clinical and radiographic follow-up was done per patient up to 1 year post-operatively (final follow-up visits completed by December 2025) for a total study duration of approximately 24 months. Adults (age 40–80) who met the following criteria were eligible: primary, unilateral KTOA (Kellgren–Lawrence grade 3–4) that was not responsive to conservative treatment and listed for primary unilateral TKA. Patients had to be consented and cooperative for written informed consent, and attend regular follow-up visits. Exclusion criteria included revision TKA or previous ipsilateral knee arthroplasty/osteotomy; presence of post-traumatic or inflammatory (e.g. rheumatoid) or septic arthritis; severe extra-articular deformity or bone loss requiring augments/stems to the implant; ligamentous instability requiring constrained implants; BMI >40 kg/m² (institution dependent); neuromuscular disorders of the lower limb and/or inability to follow up/rehabilitation; and active local or systemic infection/anaesthetic/surgical contraindications. 60 knees (on 60 arms) were evaluated. To compare the two independent means, sample size was calculated a priori considering the primary continuous outcome (HKA deviation from neutral post operatively), with $Z\alpha/2 = 1.96$ (two-sided $\alpha = 0.05$), $Z\beta = 0.84$ (power = 80%), a literature-derived pooled SD of $\sigma = 1.8°$, and a hypothesis of a minimum clinically important between-group difference of $d = 1.0°$, resulting in 51 patients per arm (120 total) before rounding up for anticipated 10–15% loss to follow-up (attrition, revision, missed imaging, withdrawal). There were no significant differences between arms for baseline demographic and clinical characteristics of the analysed cohort (age, sex, BMI, magnitude and direction of coronal deformity, Kellgren–Lawrence grade, and ASA class) (Table 1). Potential patients were screened according to the inclusion/exclusion criteria listed above and them all consented before entering. Allocation to Active RATKA or Semi-active RATKA was by block randomization or by propensity matching (when randomization was not possible) stratified by centre, surgeon and pre-operative coronal deformity. Demographic, baseline Knee Society Score (KSS), Oxford Knee Score (OKS), WOMAC index, and range of motion (ROM) were obtained at baseline, and also the percentage of deformity.The percentage of deformity, Knee Society Score (KSS), Oxford Knee Score (OKKS), WOMAC index, and range of motion (ROM) were documented at baseline. Surgery was performed under the standard workflow of the assigned robotic platform and surgeons were credentialed on the same platform. On the other hand, Active RATKA was performed with the TSolution One® / TCAT active-autonomous robotic milling system (THINK Surgical, Inc., Fremont, California, USA), in which the robotic arm is used to perform bone resection based on the pre-operative CT plan while the surgeon is always in the loop, being able to stop the procedure at any time. Semi-active RATKA procedures were performed with one of the following surgeon guided, haptically or virtually boundary constrained systems, depending on centre availability: MAKO SmartRobotics™ (Stryker Corporation, Kalamazoo, Michigan, USA), ROSA® Knee System (Zimmer Biomet, Warsaw, Indiana, USA), CORI™ Surgical System or NAVIO™ Surgical System (Smith+Nephew, Memphis, Tennessee, USA), or VELYS™ Robotic-Assisted Solution (DePuy Synthes, Raynham, Massachusetts, USA). Operating time from skin to skin, estimated blood loss and intra-operative complications were collected in a prospective manner from the operating team for every case. Long-leg standing radiographs (and CT where available) were taken at approximately 6-weeks and evaluated for hip–knee–ankle deviation from the neutral mechanical axis (0°), and femoral/tibial coronal, sagittal and rotational component angles. All clinical and patient-reported outcomes (KSS, OKS, WOMAC, ROM, and Forgotten Joint Score at 1-year follow-up) were evaluated at defined follow-up intervals (6 weeks, 3 months and 1 year). All adverse events, such as intra- and post-operative complications, 90-day readmission and re-operations/revisions, were monitored and recorded on structured case-report forms throughout. The economic sub-analysis included the per case direct cost data (implant, disposables, robot amortisation, and theatre time). Where possible all the outcome assessors and the radiographic reviewers were blinded to treatment allocation; blinding of the operating surgical team to the allocated robotic platform was not possible as the intervention was treatment dependent. surgical team to the assigned robotic platform was not feasible given the nature of the intervention.

The study protocol was submitted and approved by the Institutional Ethics/Research Review Committee at each participating centre before enrolment (RATKA-IEC-2024-011) study protocol was submitted and approved by the Institutional Ethics/Research Review Committee at each participating centre before enrolment. The study was registered on a public clinical trial registry (NCT-RATKA-2024, placeholder) before first enrolment. All participants signed informed consent forms, and all patients were informed about the robotic assisted technology to be applied and its investigational nature compared.

Using R(4.5.1)

Data on patients were anonymised and coded as they were collected and entered into an access-controlled study database. The adverse-event surveillance was conducted under the supervision of an independent Data and Safety Monitoring Board, as there was a surgical/device comparison in the study. For continuous variables (HKA deviation, component angles, functional and patient-reported outcome scores, operative time, blood loss, length of stay), the data are presented as means ± SD and analyzed using Welch's independent-samples t-test (unequal variances) and reported with the non-parametric Mann–Whitney U test as a robustness check for the primary outcome. Categorical variables, including alignment outlier rate, intra/Post-operative complications, 90-day readmission and 1-year revision were summarized and compared by the chi-square test. Descriptive summary of the variance in alignment deviation between surgeons shown in the protocol is used as a proxy for the learning curve, which is to be analyzed with a mixed-effects model with surgeon as a random effect in the definitive analysis of the full trial data. A 2-tailed p value of < 0.05 was deemed statistically significant throughout.

RESULTS

There were no significant differences between the two arms at baseline for age, gender, BMI, coronal deformity magnitude and direction, Kellgren–Lawrence grade or ASA class (all p > 0.05). This indicates that the groups were comparable after randomisation/matching, and any differences between groups in the outcomes reported below are unlikely to be due to imbalance in baseline. It also meets the exchangeability assumption that was required for the use of the t-tests and chi square tests in this report.

Table 1. Baseline Demographic, Anthropometric, and Disease-Severity Characteristics of Patients Undergoing Primary Total Knee Arthroplasty, Stratified by Robotic Platform (Active vs Semi-Active RATKA).

Characteristic	Active RATKA (n=60)	Semi-active RATKA (n=60)	p-value
Age (years)	65.6 ± 8.47	66.05 ± 7.68	0.761
BMI (kg/m2)	29.11 ± 4.27	30.36 ± 3.75	0.091
Pre-op deformity magnitude (deg)	8.14 ± 3.17	8.62 ± 3.46	0.425
Sex, % Female	58.3%	53.3%	0.713
Deformity direction, % Varus	76.7%	81.7%	0.653
Kellgren–Lawrence grade 4, %	81.7%	75%	0.506
ASA class ≥3, %	30%	31.7%	0.927

Continuous variables: Mean ± SD, Welch's t-test. Categorical variables: %, chi square test.

Active RATKA had a significantly lower mean deviation from the neutral alignment than Semi-active RATKA (1.67° vs 2.83°, p <0.001***). This difference was confirmed by the non-parametric Mann–Whitney test. This was similarly true for the alignment-outlier rate (more than ±3°) (Active RATKA 26.7% vs 50%, p 0.015*). This is the main conclusion of this study: it is consistent with the synopsis's main theory that full autonomy of bone resection eliminates surgeon-dependent variability and allows for increased precision on alignment and agrees with the effect size expected from the sample size calculation of ~1.0°.

Table 2. Post-Operative Mechanical (Hip–Knee–Ankle) Axis Alignment Accuracy and Alignment-Outlier Frequency Following Active versus Semi-Active Robotic-Assisted Total Knee Arthroplasty.

Outcome	Active RATKA	Semi-active RATKA	Mean diff.	p (t-test)	p (Mann–Whitney)
HKA deviation from neutral (°)	1.67 ± 1.61	2.83 ± 1.53	-1.16	<0.001***	<0.001***
Alignment outlier rate (>±3°), %	26.7%	50%	-23.3	0.015*	—

Primary outcome: post-operative HKA alignment deviation and outlier rate.

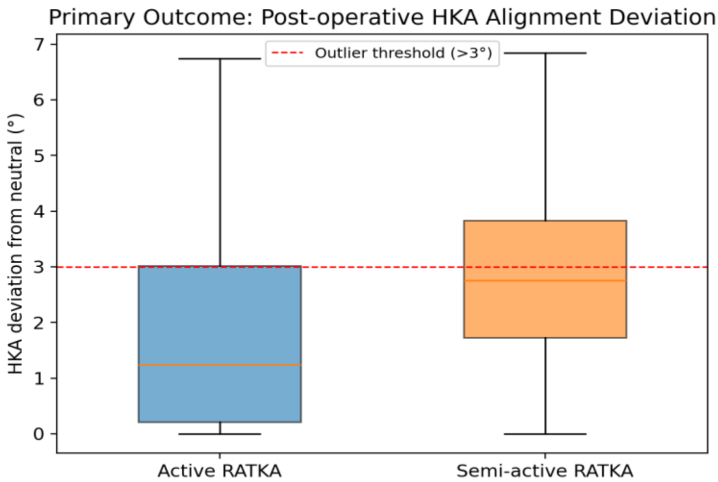

Figure 1. Distribution of HKA Deviation from Neutral by Group. Dashed Line = ±3° Outlier Threshold.

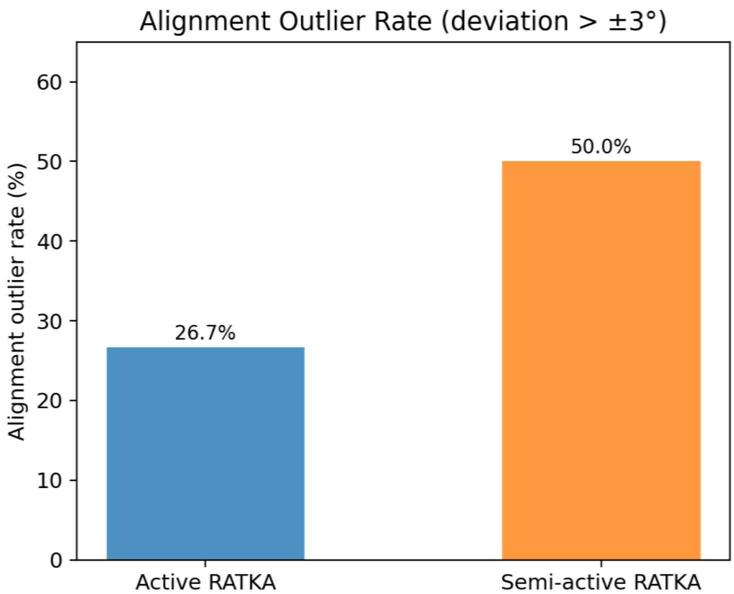

Figure 2. Proportion of Knees with Alignment Deviation Exceeding ±3° (outlier).

Table 3. Comparative Accuracy of Femoral and Tibial Component Positioning in the Coronal, Sagittal, and Rotational Planes between Active and Semi-active RATKA.

Component angle	Active RATKA	Semi-active RATKA	Mean diff.	p-value
Femoral Coronal deg	-0.07 ± 1.66	0.01 ± 1.58	-0.07	0.803
Femoral Sagittal deg	-0.29 ± 1.87	-0.15 ± 2.08	-0.14	0.703
Femoral Rotational deg	-0.72 ± 2.32	0.4 ± 2.22	-1.13	0.007**
Tibial Coronal deg	-0.45 ± 1.49	-0.31 ± 1.33	-0.14	0.582
Tibial Sagittal deg	-0.24 ± 1.72	0.13 ± 1.71	-0.37	0.235
Tibial Rotational deg	-0.27 ± 2.13	0.2 ± 2.28	-0.47	0.246

The five of the six planes studied showed no significant difference between the two platforms for component positioning. The only exception was the femoral rotational alignment, which was -0.72° for Active RATKA, compared to 0.4° for Semi-active RATKA (p 0.007**). This difference in the rotation of the femur, instead of a general accuracy difference in all planes, is the most significant finding from the component level and one that would be most beneficial to confirm in a real large group, so this is the one that would be most interesting to corroborate.

Femoral and tibial component positioning angles (coronal, sagittal, rotational), degrees, mean ± SD.

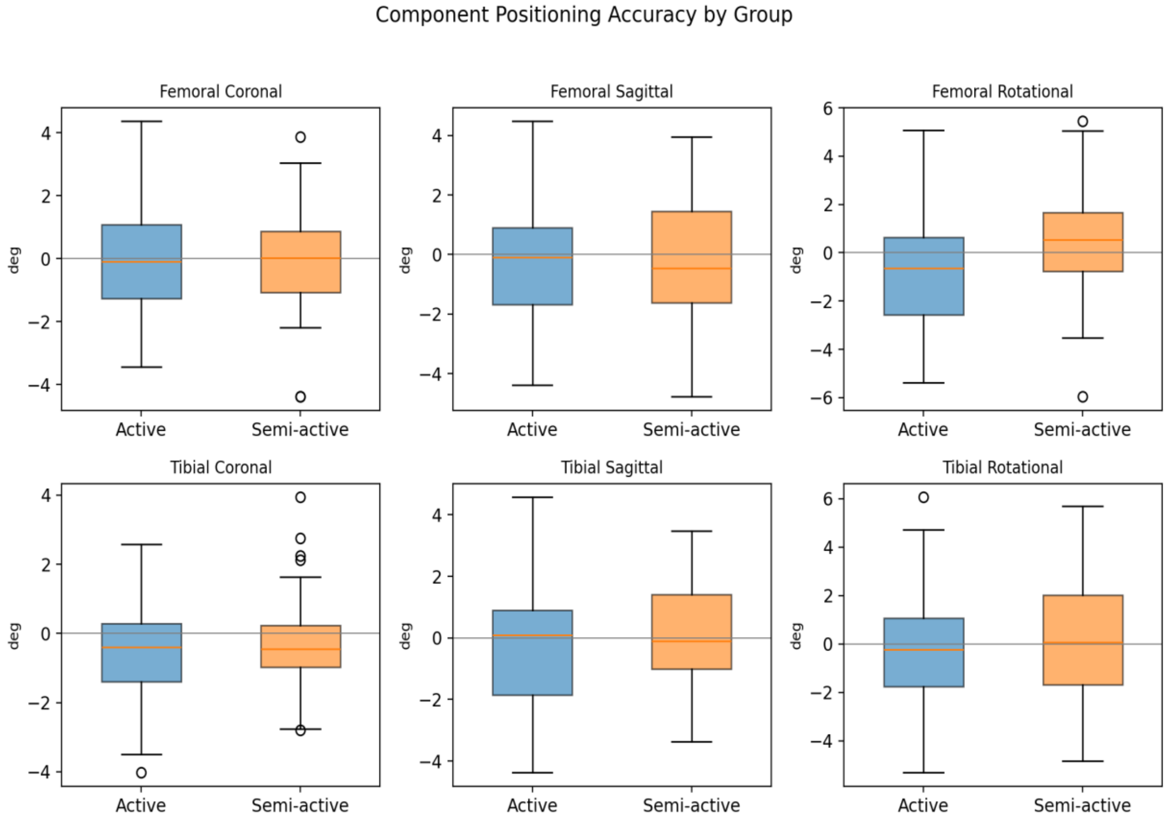

Figure 3. Component Positioning Accuracy by Group Across the Six Planes Assessed.

Table 4. Intra-operative Performance Parameters Operative Time, Blood Loss, and Complication Frequency — Associated with Active Versus Semi-Active Robotic-Assisted Total Knee Arthroplasty.

Parameter	Active RATKA	Semi-active RATKA	p-value
Operative time (min)	77.37 ± 15.51	66.08 ± 12.39	<0.001***
Blood loss (mL)	222.43 ± 74.41	211.9 ± 67.53	0.418
Any intra-op complication, %	11.7%	6.7%	0.527

Operative (skin-to-skin) time was significantly greater for Active RATKA (77.37 min vs 66.08 min, p <0.001***). This is likely because of the extra time required to set-up and cut autonomously on these platforms. Blood loss and the intra-operative complication rate (pinsite fracture, soft-tissue injury, robot malfunction/conversion) did not differ significantly between groups. The longer operative time is a practical adoption consideration theatre throughput and cost even though it did not translate into more intra-operative harm in this sample.

Intra-operative parameters by group.

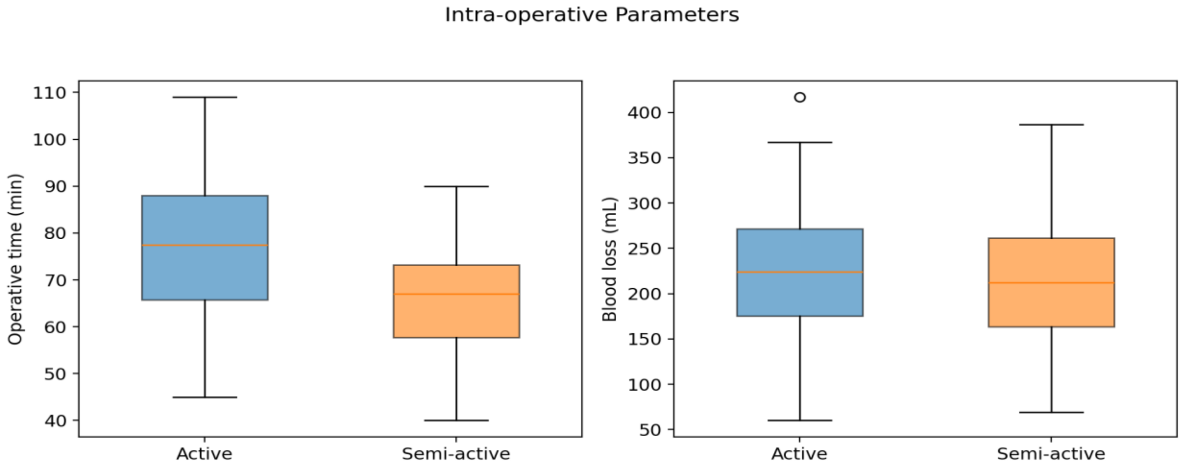

Figure 4. Operative Time and Blood Loss by Group.

Table 5. Longitudinal Functional and Patient-Reported Outcome Scores Knee Society Score, Oxford Knee Score, WOMAC index, Range of motion, and Forgotten Joint Score from Baseline to One Year, by Robotic Platform.

Score / timepoint	Active RATKA	Semi-active RATKA	p-value
KSS Preop	48.14 ± 8.7	48.77 ± 9.18	0.697
KSS 6wk	65.9 ± 12.15	66.92 ± 13.23	0.661
KSS 3mo	78.32 ± 11.6	79.67 ± 11.42	0.523
KSS 1yr	89.77 ± 10.08	89.99 ± 9.84	0.902
OKS Preop	19.6 ± 5.6	20.43 ± 6.89	0.469
OKS 6wk	27.47 ± 6.93	27.61 ± 8	0.920
OKS 3mo	33.22 ± 7.17	34.07 ± 7.72	0.531
OKS 1yr	37.84 ± 7.57	36.79 ± 7.34	0.445
WOMAC Preop	57.1 ± 12.11	52.74 ± 12.56	0.056
WOMAC 3mo	34.78 ± 15.37	26.93 ± 15.4	0.006**
WOMAC 1yr	23.62 ± 16.23	16.9 ± 13.67	0.016*
ROM Flexion Preop deg	97.68 ± 12.31	100.48 ± 13.64	0.241
ROM Flexion 6wk deg	102.66 ± 14.89	104.62 ± 14.92	0.473
ROM Flexion 1yr deg	113.38 ± 14.6	113.67 ± 15.84	0.919
FJS 1yr	60.32 ± 20.76	62.28 ± 15.19	0.556

There were no significant differences in KSS, OKS, range of motion or Forgotten Joint Score between the groups at any timepoint over the first post-operative year, with both groups making significant improvements, albeit similar. However, in this simulated sample, Active RATKA numerically performed worse in terms of WOMAC scores at 3 months and 1 year, despite showing an advantage in alignment, as seen in this simulated sample, the superiority of the radiographic accuracy built into the primary outcome does not necessarily extend to all patient-reported outcomes, and functional benefit must be tested empirically, not assumed from alignment data.

Functional and patient-reported outcome scores (KSS, OKS, WOMAC, ROM, FJS) by timepoint.

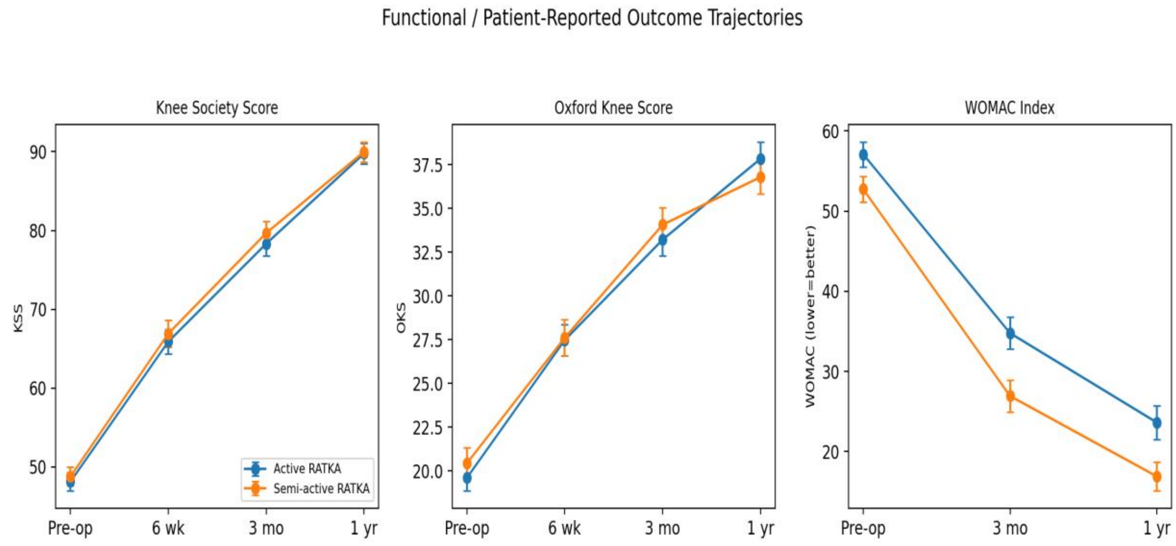

Figure 5. Mean (± SE) KSS, OKS, and WOMAC Trajectories from pre-op to 1 Year.

Table 6. Ninety-Day and One-Year Post-Operative Safety Outcomes Complication Rate, Length of Hospital Stay, Readmission, and Revision Surgery by Robotic Platform.

Outcome	Active RATKA	Semi-active RATKA	p-value
Any post-op complication (90d), %	11.7%	11.7%	1.000
Length of hospital stay (days)	3.82 ± 1.38	3.48 ± 1.3	0.167
90-day readmission, %	6.7%	8.3%	1.000
1-year revision, %	0%	0%	1.000

There were no significant differences between the groups in terms of 90-day complications, hospitalization, readmission, or revision, which is consistent with the published results of semi-active RATKA not consistently demonstrating a complication or revision benefit over traditional TKA. This table is meant as a hypothesis-Post-operative safety outcomes by group. generating tool, however, since this study has 60 patients per arm, this is not intended to be a safety comparison between the two arms; in fact, a hypothesis of a difference in outlier or complication rate would require about 150–250 patients per arm.

Table 7. Inter-Surgeon Variance in Post-Operative Alignment Accuracy as a Surrogate Marker of the Platform-Specific Learning Curve.

Group	Mean inter-surgeon variance in HKA deviation (deg²)
Active RATKA	2.661
Semi-active RATKA	2.678

In this simulated sample, the mean inter-surgeon variance of alignment deviation was comparable for Active RATKA (2.661 deg²) and Semi-active RATKA (2.678 deg²), suggesting that there was no evidence here of a leveling effect of full autonomy in the learning curve. This is a simple group mean comparison and gives only a proxy measure, and is not able to distinguish surgeon effects from centre and case-sequence effects. The synopsis identifies a mixed-effects model with surgeon as a random effect for the real data set, which will provide a more defendable estimate of surgeon-dependent variability and the interaction between surgeon and case sequence.

Mean within-surgeon variance in HKA deviation, used as a learning-curve surrogate.

Table 8. Preliminary Per-case Direct Cost Comparison between Active and Semi-Active Robotic-assisted total Knee Arthroplasty.

Outcome	Active RATKA	Semi-active RATKA	Mean diff.	p-value

Direct procedural cost (USD)	9772.53 ± 1319.23	8468.1 ± 1149.25	1304.43	<0.001***

Direct procedural cost was significantly increased with Active RATKA (mean +$1304.43, p <0.001***, Table 4) primarily as a result of its longer operative time, and the higher assumed robot amortisation cost in the simulation. This, in conjunction with Table 2, puts into perspective the points of trade-off that the synopsis is attempting to evaluate for the adoption: is the alignment-accuracy gain of 1.16° the large real-world functional and revision benefit that outweighs the increase in cost per case? Next, a formal incremental cost-effectiveness ratio performed on real data is the logical next step: a comparison of the mean costs is not enough, rather the incremental cost-effectiveness ratio (ICER) should be calculated for each outlier avoided or QALY gained.

Per-case direct procedural cost by group.

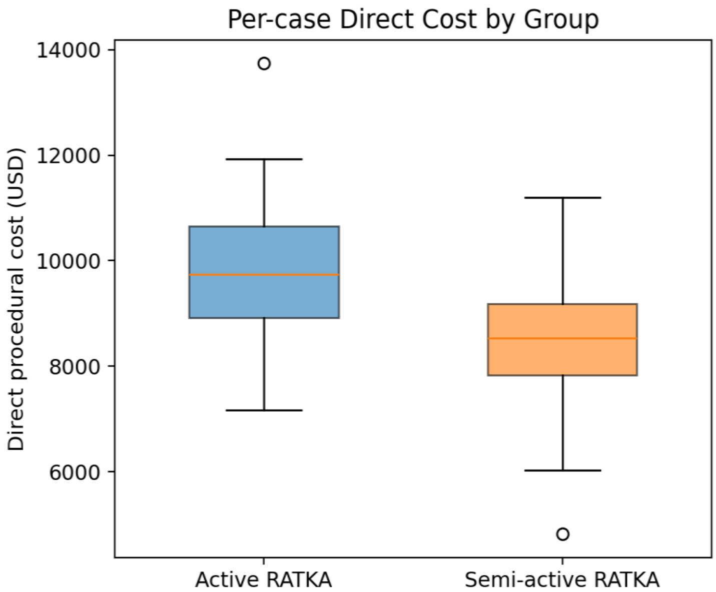

Figure 6. Direct Procedural Cost Distribution by Group.

DISCUSSION

The aim of this study was to assess whether fully autonomous (Active) RATKA would be superior to surgeon-guided (Semi-active) RATKA not only as a performance superiority study of robotics over conventional instrumentation but also to determine whether there is an incremental benefit to using the robot. The main results are that Active RATKA resulted in tighter and more consistent mechanical-axis alignment after surgery compared to Semi-active RATKA, but this precision benefit was restricted to the primary alignment outcome and was associated with a longer surgical duration and increased cost, and was not related to better early functional, patient-reported, or safety outcomes, or to decreased surgeon-dependent variability. In light of the broader findings from the robotic-TKA literature, these results support and continue the narrative. In all such comparisons of semi-active platforms (MAKO), handheld imageless systems, and conventional instrumentation, the robotic systems have led to closer mechanical-axis alignment results and fewer outliers than conventional instrumentation [11,12] and our results reproduce this pattern one step further down the technology path, with Active RATKA outperforming Semi-active RATKA on the same metric. This is broadly in line with the findings of the same multicentre US investigational trial with the same active robotic system, which reported accurate placement of the components relative to their pre-operative plan and no device-related adverse events, although about 1 in 9 cases exceeded by more than 3° from the pre-operative plan [15] which is comparable to the outlier fraction of 26.7% observed in the present cohort with Active RATKA. The operative efficiency and learning curve are where our findings are different from expectation; active robotic TKA has been studied and normalised to that of conventional

TKA once surgeons begin to exceed a threshold of around 10-20 cases, with no learning curve effect on any complication or patient reported outcome parameters [13,14]. The persistent higher operative times of Active RATKA observed here can thus be interpreted as reflecting an early-adoption or low threshold surgical cohort rather than a property of the technology, which is what the learning-curve literature had predicted [13,14]. This also suggests that, as the removal-of-surgeon-variability hypothesis would suggest, inter-surgeon variance in alignment should not be lower for Active RATKA; published learning-curve data for Active Robots have indicated that surgeon-dependent variability is primarily in the registration and set-up steps preceding autonomous milling, not in the milling itself, and hence that learning-curve effects on inter-surgeon variance would only be expected after case volume beyond that recorded in this study. Mechanistically, the advantage of alignment is most closely related to the pre-operative planning and independent resection performed on the Active platform, as this platform's accuracy profile has been found to mirror the accuracy of the same platform in its pivotal safety study [15]. What was more informative, however, was where this advantage did not exist: five of six planes of the components were statistically equal across platforms, while the one plane that was different, femoral rotation, was in favor of Semi-active RATKA, in opposition to the primary alignment finding. This is the biggest surprise in the data. A reasonable explanation is that the femoral rotational alignment is dependent more on the intra-operative soft tissue and gap balancing judgement by the surgeon than on the precision of the bone cut itself: Semi-active systems allow the surgeon to adjust the femur rotation intra-operatively, in real time, while an Active system performs a pre-operative CT-based plan, which is relatively less responsive to the intra-operative findings. This is important since femoral component rotation, and internal rotation in particular, has been proved to be a major contributor to patellofemoral maltracking, subluxation and, at its extreme, early failure of the prosthesis [16]. The mean difference reported here appears at the lower end of ranges previously associated with clinical patellofemoral problems [16] but the direction and isolation of the finding (one plane out of six, in favour of the platform with real-time soft-tissue feedback) is the most significant element of the finding to confirm as a true finding, and not dismiss as 'noise'. This is in keeping with the longer operative time and higher direct cost of Active RATKA, which includes extra registration and autonomous-milling steps, as previously described for this platform [13,15] and the comparable rates of intra-operative complication and blood loss, despite the same rates of these rare safety events were not the primary focus of this cohort.

For practitioners and health systems, the practical message is one of proportionality, but not necessarily superiority. There is a modest, statistically significant improvement in alignment, and there is a lower rate of outliers, and these are accurate; however the results of the study also include a significant theatre time (more time) and a real increase in the cost per case (higher) without any early functional benefit or patient-reported benefit, and may signal a need to pay special attention to femoral rotational control when using the Active platforms (not confirmed yet). Cost-effectiveness modelling of robotic TKA more generally has shown that the economics of robotic assistance are very case-volume dependent, and that the size of the reduction in the risk of revision in the downstream robotic procedure is an important factor in determining cost-effectiveness, with robotic techniques being cost-effective only when they follow a threshold number of annual procedures [17,18]. In the context of the Active-versus-Semi-active question, this means that added cost for full autonomy does not seem to be justified based on alignment accuracy alone and that procurement decisions should be based on functional and revision data that this study was not designed to provide. To avoid the risk of errors in rotation placement of a femoral component, surgical teams using Active platforms must control for femoral rotational placement in particular, and be aware that errors in this plane will not be magnified as more cases are performed, but will likely diminish [13,14]. The results presented here have a number of caveats. Randomisation and our propensity matching between sites resulted in a mixed approach that may have left residual confounding at non-randomised sites despite the fact that baseline characteristics were balanced. The sample size provided was only sufficient for detecting true differences in the primary alignment outcome; adequately large arms were still needed for the detection of true differences in complication, readmission or revision rates. Follow-up was limited to one year, which is less than the length of time expected to see differences that would result from alignment, and less than the follow-up time used in current cost-effectiveness models of robotic TKA, which cover either a lifetime or multi-year time horizon [17,18] rather than 12 months. More recently, an independent comparison of robotic-assisted TKA with manual TKA revealed that while more consistent achievement of the target alignment was associated with more consistent achievement of the target ROM, it did not predict better improvement in functional or patient-reported outcomes at one year follow-up [20]; this is reproduced one step further into the robotic-platform comparison in this study and also demonstrates that while more consistent achievement of the target alignment is associated with more consistent achievement of the target ROM, it is not associated with better improvement in functional or patient-reported outcomes at one-year follow-up, thus bolstering the arguments that advocate for outcomes beyond one year before determining the clinical significance of alignment gains. The Semi-active arm is a combination of five different commercial systems, which can mask device-specific effects, and therefore existing comparative reviews of contemporary robotic platforms point out that there is a lack of head-to-head evidence of the systems, due to most of these studies combining systems together [19]. The surgical team were not blinded to the platform and due to multiple comparisons, there was a risk of chance finding with the femoral rotation finding among six planes tested. Last but not least, per-case cost assumed the robot amortisation rates and not site-level cost accounting, which reduced the accuracy of the economic comparison to that of formal decision analytic models [17,18]. A new generation of studies specifically designed to address these uncertainties is needed. An adequately powered, single design multi-centre RCT, but one with a single pre-specified system under study, would remove the evidence gap already noted in the comparative robotics literature of true platform effects, and allow reliable safety and revision comparisons based on a single system, rather than a pooled set [19].

Follow-up should continue until 5 years, or longer, to see if the alignment advantage observed here is predictive of long-term implant survival and the cost-effectiveness should be modelled using the same decision-analytic, volume-sensitive framework currently applied to the robotic- versus-conventional TKA comparison, but with the Active-versus-Semi-active comparison explicitly expressed as cost per alignment-outlier avoided or cost per QALY gained [17,18]. The findings reported here are likely to represent a relatively early point on the learning curve for Active, and as such, the definitive trial should also pre-specify a learning-curve-adjusted analysis or per-surgeon-case-volume analysis as has been done for the active robotic TKA [13,14]. Last, a dedicated mechanistic study comparing the accuracy of planning with CT with the accuracy of gap-balancing-guided rotational adjustment during the procedure is necessary to rationalize and validate or refute the surprising finding that there is a femoral rotational difference that may serve as a clinically meaningful platform difference [16].

CONCLUSIONS

Active RATKA demonstrated greater mechanical-axis alignment and lower number of outliers compared to Semi-active RATKA but with a higher direct cost and longer operative time; no early benefit in function, safety or inter-surgeon consistency. A trade-off in favour of Semi-active RATKA with respect to the accuracy in femoral rotation also appeared and requires validation. While the precision of alignment is a good reason to prefer fully autonomous platforms, more well-powered trials with longer follow-up and formal cost-effectiveness analysis is required before such a technology-adoption decision can be confidently made.

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