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Radiological outcomes following manual and robotic-assisted unicompartmental knee arthroplasty

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Aims
The purpose of this study was to compare the radiological outcomes of manual versus robotic-assisted medial unicompartmental knee arthroplasty (UKA).

Methods
Postoperative radiological outcomes from 86 consecutive robotic-assisted UKAs (RAUKA group) from a single academic centre were retrospectively reviewed and compared to 253 manual UKAs (MUKA group) drawn from a prior study at our institution. Femoral coronal and sagittal angles (FCA, FSA), tibial coronal and sagittal angles (TCA, TSA), and implant overhang were radiologically measured to identify outliers.

Results
When assessing the accuracy of RAUKAs, 91.6% of all alignment measurements and 99.2% of all overhang measurements were within the target range. All alignment and overhang targets were simultaneously met in 68.6% of RAUKAs. When comparing radiological outcomes between the RAUKA and MUKA groups, statistically significant differences were identified for combined outliers in FCA (2.3% vs 12.6%; $p = 0.006$), FSA (17.4% vs 50.2%; $p < 0.001$), TCA (5.8% vs 41.5%; $p < 0.001$), and TSA (8.1% vs 18.6%; $p = 0.023$), as well as anterior (0.0% vs 4.7%; $p = 0.042$), posterior (1.2% vs 13.4%; $p = 0.001$), and medial (1.2% vs 14.2%; $p < 0.001$) overhang outliers.

Conclusion
Robotic system navigation decreases alignment and overhang outliers compared to manual UKA. Given the association between component placement errors and revision in UKA, this strong significant improvement in accuracy may improve implant survival.

Level of Evidence: III

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Introduction
Unicompartmental knee arthroplasty (UKA) offers many potential advantages compared to total knee arthroplasty (TKA) in the treatment of unicompartmental arthritis, including decreased pain, higher patient-reported satisfaction, shorter recovery times, and more functional knee kinematics.[1-12] Despite the clear advantages offered by UKA in terms of clinical outcomes, however, implant survival has been relatively poor compared to TKA. Aside from case series by the designing centres of the Oxford UKA, which have demonstrated ten-year UKA survival as high as 97%,[13-16] survival estimates from other case series and large national registry databases have ranged between 70% to 92% and 81% to 88%, respectively.[2,17-23]

Both patient- and surgeon-specific factors have been implicated as potential causes for the increased failure rates associated with UKA. Because patient-specific risk factors like lower age and higher BMI are largely beyond the surgeon's control and difficult or impossible to manipulate, they offer minimal opportunity for actionable strategies to improve outcomes.[24–26] Surgeon-specific factors, on the other hand, provide potential

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Table I. Patient demographic data.

Category	RAUKA	MUKA
Total, n	86	253
Mean age, yrs (SD)	62.6 (9.4)	62.9 (8.7)
Mean BMI, kg/m^2 (SD)	30.2 (4.2)	30.3 (5.4)
Sex, % male	60.0	44.0

MUKA, manual unicompartmental knee arthroplasty; RAUKA, robotic-assisted unicompartmental knee arthroplasty.

Table II. Implant alignment for robotic-assisted unicompartmental knee arthroplasty.

Angle	Aligned	Outliers	Far outliers	Any outliers
FCA, %	97.7	1.2	1.2	2.3
FSA, %	82.6	5.8	11.6	17.4
TCA, %	94.2	3.5	2.3	5.8
TSA, %	91.9	5.8	2.3	8.1

FCA, femoral coronal angle; FSA, femoral sagittal angle; TCA, tibial coronal angle; TSA, tibial sagittal angle.

modifiable targets to improve survivorship following UKA. As a result, these factors have become an important area of research in recent years.

Not surprisingly, surgeon-specific technical errors represent a considerable risk factor for UKA failure.[27-32] UKA is believed to be a more technically demanding procedure than TKA, as device implantation is performed through a smaller incision.[33] Due to the decreased viewing window, obtaining accurate implant alignment and positioning is often challenging. In a recent study by Kazarian et al,[23] a group of high-volume arthroplasty surgeons performing a moderate number of UKAs (> 14 UKAs/year) were found to only place implants within their target position and alignment ranges in 11.9% of knees. Concerningly, this study and others have demonstrated that implant malalignment and malpositioning are significant risk factors for early UKA failure and poor clinical outcomes.[22,23,27,33-38] Based on the demonstrated association between implant malpositioning/malalignment and poor clinical outcomes/survivorship, there is an outstanding need for efforts and technologies that decrease intraoperative surgical error and improve UKA alignment accuracy.

Over the years, multiple technologies have been introduced in order to increase the accuracy of implant alignment and mitigate the potential risk of implant failure, such as customized patient-specific instrumentation (PSI) and robotic technology. While PSI has shown minimal impact in improving the accuracy of implant alignment in UKA,[39] the overwhelming majority of studies assessing the influence of robotic systems have demonstrated noticeably improved implant accuracy across multiple different robotic system platforms.[40-45]

The primary goal of the current study was to assess the proportion of radiological alignment and overhang outliers following robotically assisted UKA, and compare these results to historic controls from manual UKA at our institution (which used the same indications). We hypothesized that robotic system assistance would significantly decrease the number of alignment and overhang outliers.

Methods

Study design. Institutional Review Board approval was attained prior to the initiation of this study. This was a single-centre retrospective cohort study comparing the clinical outcomes and radiological results between primary medial UKAs performed using robotic assistance (RAUKA, n = 86) and manual instrumentation (MUKA, n = 253). RAUKAs represented a consecutive series of robotic-assisted UKAs performed between February 2019 and February 2020. RAUKAs were performed by one of three fellowship-trained senior arthroplasty surgeons (RLB, RMN, CML) using the Mako Robotic Arm System (Stryker, USA) and the Restoris MCK implant (Stryker), and included surgeons' learning curves (initial training cases) with the robotic system.

The control group of MUKAs was drawn from a cohort of patients that were previously described in a case series by Kazarian et al[23] assessing alignment and clinical survival following MUKA in a series that included both fixed- (Journey UKA; Smith & Nephew, USA) and mobile-bearing (Oxford Phase 3 UKA; Zimmer-Biomet, USA) UKAs. MUKAs were performed between January 2008 and December 2017 by one of two fellowship-trained senior arthroplasty surgeons (RLB, RMN) using standard instrumentation without the assistance of custom-cutting guides, PSI, or fluoroscopy. The MUKA cohort did not include each surgeon's MUKA learning curve.

The decision to perform robotic system versus manual UKA was not based on clinical decision-making or surgeon/patient preference, and there were no specific inclusion/exclusion criteria that differentiated the use of these surgical methods. The use of RAUKA versus MUKA was determined by the availability of the Mako Rio System at our institution. Prior to the acquisition of the robotic system in February 2019, all UKAs were performed using standard manual instrumentation. After its acquisition, all UKAs were performed using robotic system assistance.

Consecutive series of male and female patients aged ≥ 18 years who underwent RAUKA or MUKA were included in our analysis. In the current study, patients' ages ranged between 40.5 and 83.6 years. Patients were excluded from undergoing UKA if they had knee instability, posterior tibial translation, fixed varus (> 10°) or valgus (> 5°) deformity, or grade IV patellofemoral compartment chondrosis. Patient demographics for the UKA groups are shown in Table I.

Our sample size of RAUKAs was calculated in order to detect a difference in percent outliers of roughly 15% compared to the MUKA group, which would require 71

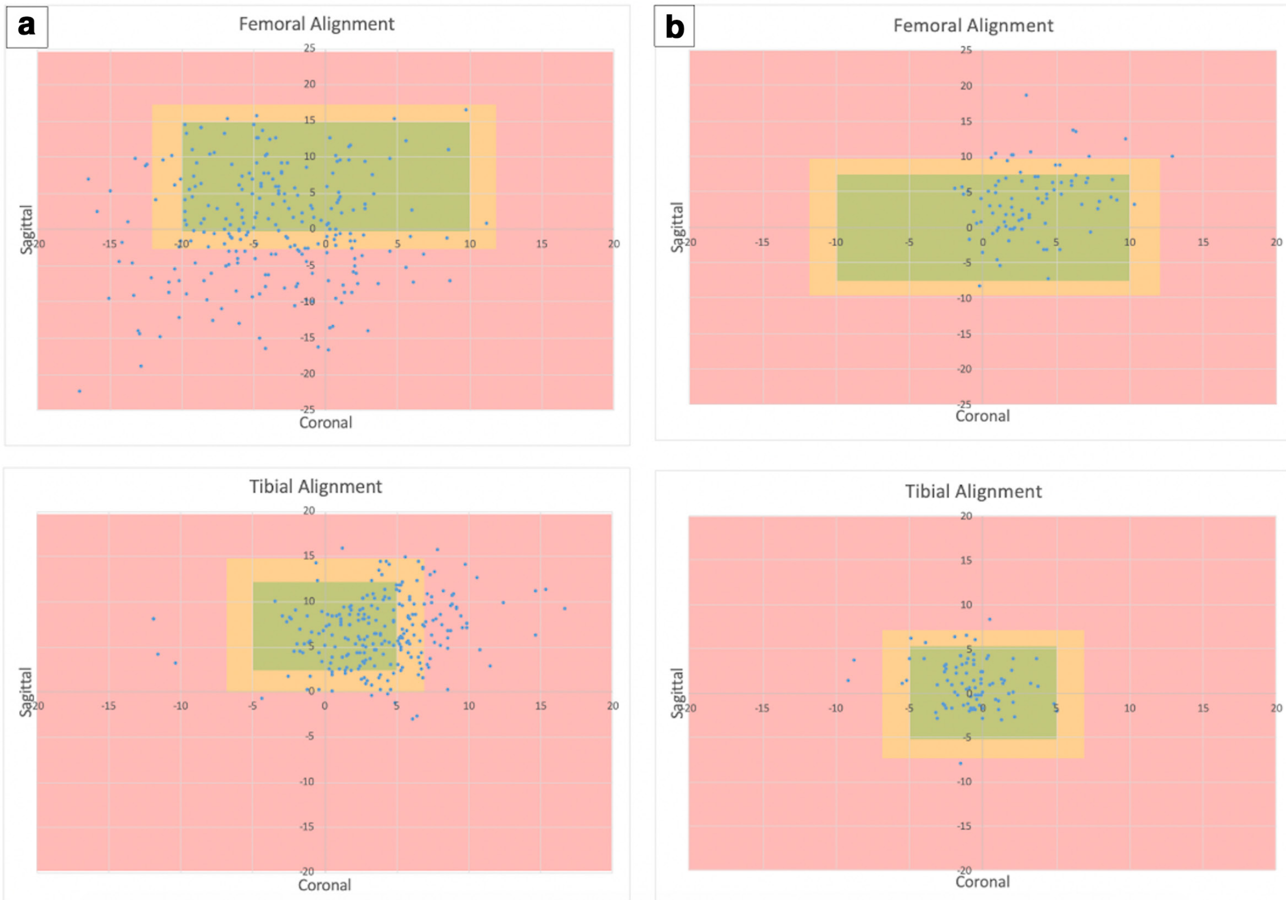

Fig. 1

Comparison of femoral and sagittal alignment in the manual unicompartmental knee arthroplasty (MUKA) and robotic-assisted unicompartmental knee arthroplasty (RAUKA) groups. a) For the MUKA group, green shading indicates the region of optimal femoral coronal angle ((FCA) ≤ 10° deviation from the neutral axis and femoral sagittal angle (FSA) < 15° flexion) and sagittal (tibial coronal angle (TCA) ≤ 5° deviation from the neutral axis and tibial sagittal angle (TSA) ≤ 5° deviation from 7°) alignment based on preoperative targets. b) For the RAUKA group, green shading indicates the regions of optimal femoral and tibial alignent based on deviation from intraoperative targets. In both instances, outliers that remain within approximately 2° of the optimal alignment targets are indicated with yellow shading. "Far" outliers, which are ≥ 2° outside of optimal alignment, are indicated with red shading.

patients. In order to account for a possible 20% attrition rate, we enrolled a total of 86 patients.

Radiological and clinical outcomes. Radiological outcomes included digital measurements of femoral coronal angle (FCA), femoral sagittal angle (FSA), tibial coronal angle (TCA), and tibial sagittal angle (TSA), as well as assessments of medial, anterior, and posterior overhang. All measurements were performed on post-anesthesia care unit (PACU) non weight-bearing AP and lateral short-leg radiographs. The use of short-leg radiographs in lieu of long-leg radiographs for the assessment of implant alignment has been previously validated.[23,46–52] A description of the methodology used to assess implant alignment and positioning has been detailed in prior studies.[23,53] The accuracy of non-weight-bearing short-leg radiographs in assessing implant alignment was assessed by comparing 45 non-weight-bearing short-leg radiographs to the standing weight-bearing radiographs from the same patients at the four- to six-week postoperative visit.

Defining postoperative radiological outliers. Postoperative radiological outliers for both RAUKA and MUKA were assessed using the parameters described in Kazarian et al[23] For the MUKA group, outliers were defined as follows: FCA ≥ 10° deviation from the neutral axis, FSA > 15° flexion, TCA ≥ 5° deviation from the neutral axis, and TSA ≥ 5° deviation from 7°. During RAUKA, target alignment is not pre-defined, but is calculated and customized intraoperatively after the robotic system calculates the ideal implant placement to optimize soft tissue balancing. Therefore, for RAUKA, implant alignment outliers were defined as follows: FCA ≥ 10° deviation from the intraoperative target, FSA > 15° flexion from the intraoperative target, TCA ≥ 5° deviation from the intraoperative target, and TSA ≥ 5° deviation from the intraoperative target. This method allowed us to determine how accurately the robotic system was able to execute its intraoperative plan. Measurements that fell ≥ 2° outside of these ranges were defined as far outliers.[52] Medial/posterior overhang

Table III. Radiological outcomes between the robotic-assisted unicompartmental knee arthroplasty (n = 86) and manual unicompartmental knee arthroplasty (n = 253) groups.

Measure	RAUKA, %	MUKA, %	Difference, %	p-value
FCA outlier	1.2	5.1	3.9	0.113
FSA outlier	5.8	14.6	8.8	0.033
TCA outlier	3.5	22.1	18.6	< 0.001
TSA outlier	5.8	13.0	7.2	0.069
FCA far outlier	1.2	7.5	6.3	0.032
FSA far outlier	11.6	35.6	24.0	< 0.001
TCA far outlier	2.3	19.4	17.1	< 0.001
TSA far outlier	2.3	5.5	3.2	0.230
FCA any outlier	2.3	12.6	10.3	0.006
FSA any outlier	17.4	50.2	32.8	< 0.001
TCA any outlier	5.8	41.5	35.7	< 0.001
TSA any outlier	8.1	18.6	10.4	0.023
Anterior fit	0.0	4.7	4.7	0.042
Posterior fit	1.2	13.4	12.2	0.001
Medial fit	1.2	14.2	13.0	0.001
All perfect	68.6	11.9	-56.7	< 0.001

FCA, femoral coronal angle; FSA, femoral sagittal angle; MUKA, manual unicompartmental knee arthroplasty; RAUKA, robotic-assisted unicompartmental knee arthroplasty; TCA, tibial coronal angle; TSA, tibial sagittal angle.

outliers were defined as > 2 mm of overhang, while anterior overhang outliers were defined as > 3 mm of overhang.

Statistical analysis. The statistical analysis for this study was performed using SAS version 9.4 (SAS Institute, USA). Outcomes scores and the proportion of radiological alignment/overhang outliers between the RAUKA and MUKA groups were compared. Categorical variables were compared using Fischer's exact tests, while continuous variables were compared using independent-samples *t*-tests. The threshold for statistical significance was p < 0.05.

Results

Radiological outcomes in RAUKA. We found that 91.6% of all FCA, FSA, TCA, and TSA angles measured in this study were within alignment targets, while 4.1% and 4.4% represented outliers and far outliers, respectively (Table II). Additionally, when assessing anterior, posterior, and medial overhang, 99.2% of all measurements were within target overhang ranges, while only 0.8% represented outliers. Femoral and tibial implant alignment results from the RAUKA and MUKA groups are demonstrated in scatterplots in Figure 1.

When comparing the use of short-leg non-weight-bearing PACU radiographs to standing weight-bearing radiographs at four to six weeks postoperatively, each method identified 16 total close and far outliers when assessing FCA, FSA, TCA, and TSA from 45 patients, with 93.3% agreement between these methods.

Comparing radiological outcomes in RAUKA versus MUKA. When comparing radiological outcomes between the RAUKA and MUKA groups, statistically significant differences (all calculated using Fisher's exact test) were identified between the proportion of FSA outliers (5.8% vs 14.6%; p = 0.033) and TCA outliers (3.5% vs 22.1%; p < 0.001), as well as far FCA (1.2% vs 7.5%; p = 0.032), FSA (11.6% vs 35.6%; p < 0.001), and TCA (2.3% vs 19.4%; p < 0.001) outliers. Differences in anterior (0.0% vs 4.7%; p = 0.042), posterior (1.2% vs 13.4%; p = 0.001), and medial (1.2% vs 14.2%; p < 0.001) overhang outliers were also statistically significant. When assessing the number of combined close and far outliers, statistically significant differences were identified for combined outliers in FCA (2.3% vs 12.6%; p = 0.006), FSA (17.4% vs 50.2%; p < 0.001), TCA (5.8% vs 41.5%; p < 0.001), and TSA (8.1% vs 18.6%; p = 0.023) (Table III).

Discussion

In the current study, we assessed the radiological and clinical outcomes of RAUKA and compared them to MUKA control groups for implant accuracy. Overall, 8.4% of alignment measurements were outliers, with only 4.4% representing far outliers. Additionally, only 0.8% of overhang measurements were outliers. A total of 68.6% of knees simultaneously met optimal alignment and overhang targets. When comparing alignment accuracy between the RAUKA and MUKA groups, RAUKA was associated with a highly significant decrease in the proportion of FSA and TCA outliers, FCA, FSA, and TCA far outliers, and combined outliers for all alignment measures. Furthermore, RAUKA was associated with significant decreases in the proportion of anterior, posterior, and medial overhang outliers.

The results of the current study are best understood when compared to the results of a prior study at our institution that assessed the accuracy of implant alignment following manual UKA and its impact on implant survival.[23] In the first study, FCA, FSA, TCA, and TSA outliers were found to significantly increase the risk of failure, as did far outliers, posterior overhang outliers, and medial overhang outliers. By demonstrating that robotic-arm assistance during medial UKA can diminish the risk of FSA and TCA outliers, FCA, FSA, and TCA far outliers, and posterior and medial overhang outliers, it is possible that this technology can significantly decrease the high risk of premature implant failure associated with UKA.

Over the years, multiple technologies have been introduced in order to increase the accuracy of implant alignment and mitigate the potential risk of implant failure, such as custom instrumentation and robotic technology. The overwhelming majority of studies assessing the influence of robotic systems, including randomized controlled trials (RCTs), have demonstrated significantly improved implant accuracy associated with the use of robotic system technology across multiple different robotic platforms.[40-45,54] Though the notion that robotic system technology improves alignment in UKA and TKA is generally accepted, this has been called into question in a recent study of 128 manual UKAs performed by Bush et al.[55] While this study did not have an internal control group, it demonstrated that a high-volume surgeon could out-perform historic robotic-assisted UKA controls in terms of implant accuracy. Importantly, this study commented only on differences in root-mean square (RMS) error from preoperative targets and did not comment on the number of alignment outliers. Studies assessing outliers to compare RAUKA and MUKA, on the other hand, have demonstrated that the use of robotic system technology significantly decreases the frequency of implant alignment outliers.[44,45]

While the evidence appears clear that robotic system technology improves implant alignment following UKA, what remains controversial is what impact, if any, this has on long-term outcomes. Though results from "designer series" and early studies assessing the survival of UKA have demonstrated excellent long-term survival,[13,14,56,57] other studies from a wide variety of surgeons have demonstrated much poorer long-term survival.[2,16-21,53,58,59] It is yet unclear whether this increased failure rate compared to TKA is related to the patient demographic details associated with UKA, implant design, or implant placement. However, a growing body of indirect[33,60-64] and direct[22,23,27,33-38] evidence has implicated the accuracy of implant placement as a major cause for this increased rate of failure. Future studies must validate this theory through RCTs and cost-effectiveness analyses to better understand whether these presumed trends can withstand more rigorously controlled analyses, and if so, whether these improvements justify the high costs associated with the use of robotic system technology in orthopaedics.

This study had many limitations. Firstly, it relied on short-leg radiographs rather than CT scans for the assessment of implant alignment. While we have demonstrated precision with this measurement technique, the accuracy of this method may be variable due to human error, image quality, or image rotation, especially in the assessment of FSA. This may explain the higher-than-expected proportion of outliers and far outliers identified. Secondly, our comparison of RAUKA to historic MUKA controls is an imperfect comparison, and the lack of randomization introduces a potential risk of bias. Thirdly, while the surgeon learning curve for the RAUKA group was included in our analysis, it was not for the MUKA group. This may bias the results of this study to show poorer outcomes for the RAUKA group. Finally, it is important to highlight that historic MUKA controls were performed by senior surgeons who fall below the high-volume standards for UKA recommended by the Oxford group, which may have influenced implant accuracy[55]

In conclusion, RAUKA was associated with significant improvements in implant placement accuracy compared to MUKA. Further studies are needed to assess the durability of these early postoperative outcomes, as well as to assess whether the improved alignment associated with RAUKA leads to meaningful improvements in implant survival.

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