Robotic-Arm Assisted Total Knee Arthroplasty Demonstrated Greater Accuracy and Precision to Plan Compared with Manual Techniques

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Abstract

This study determined if robotic-arm assisted total knee arthroplasty (RATKA) allows for more accurate and precise bone cuts and component position to plan compared with manual total knee arthroplasty (MTKA). Specifically, we assessed the following: (1) final bone cuts, (2) final component position, and (3) a potential learning curve for RATKA. On six cadaver specimens (12 knees), a MTKA and RATKA were performed on the left and right knees, respectively. Bone-cut and final-component positioning errors relative to preoperative plans were compared. Median errors and standard deviations (SDs) in the sagittal, coronal, and axial planes were compared. Median values of the absolute deviation from plan defined the accuracy to plan. SDs described the precision to plan. RATKA bone cuts were as or more accurate to plan based on nominal median values in 11 out of 12 measurements. RATKA bone cuts were more precise to plan in 8 out of 12 measurements ($p \leq 0.05$). RATKA final component positions were as or more accurate to plan based on median values in five out of five measurements. RATKA final component positions were more precise to plan in four out of five measurements ($p \leq 0.05$). Stacked error results from all cuts and implant positions for each specimen in procedural order showed that RATKA error was less than MTKA error. Although this study analyzed a small number of cadaver specimens, there were clear differences that separated these two groups. When compared with MTKA, RATKA demonstrated more accurate and precise bone cuts and implant positioning to plan.

Keywords
- robotic
- total knee arthroplasty
- accuracy
- precision
- alignment

Despite the overall success of total knee arthroplasty (TKA),[1,2] it can be difficult for orthopaedists to consistently achieve optimal component alignment. Malalignment may lead to less than optimal outcomes and implant survivorship.[3–8] Currently, the most adopted method of achieving coronal component alignment is through the use of an intramedullary femoral and extramedullary tibial guide. Even with the use of this method, surgeons may not always achieve optimal alignment, resulting in outliers.[9–13] In addition, axial component alignment has been shown to affect clinical and functional outcomes, and several studies have attempted to determine a safe range for component placement.[14–17] Computer-assisted surgery (CAS) has consistently demonstrated better alignment accuracy when compared with standard guides.[10,18–20] However, even though CAS was superior to the 32% outliers found in conventionally performed TKAs, a meta-analysis of component alignment still found mechanical axis malalignment of greater than 3 degrees in 9% of the CASs.[12]

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A robotic-arm assisted system is a technology designed to minimize the margin of error associated with bone cuts and component placement. Robotic tools, such as the Caspar (OrtoMaquet, Rastatt, Germany), Robodoc (Curexo Technology Corporation, Fremont, CA), and Mako (Stryker, Mahwah, NJ) systems, have been shown to have strong surgical and clinical patient outcomes.[21–26] One such robotic-arm assisted system has been shown to enhance the accuracy to plan and reproducibility of unicompartmental knee arthroplasties (UKAs)[27–30] as well as total hip arthroplasties (THAs).[31–34] For example, Lonner et al radiographically compared 31 consecutive patients who underwent robotic-arm assisted UKA with 27 patients who underwent manual UKA. The group found that the root mean square error of tibial slope was greater for the manual cases (3.1 vs. 1.9 degrees), the variance of the tibial component in manual cases was 2.6× greater ($p = 0.02$), and there was greater coronal plane error in the manual cohort (2.7 ± 2.1 vs. 0.2 ± 1.8 degrees of varus).[28] Domb et al performed a prospective study on a gender, age, and body mass index (BMI) matched cohort of 50 robotic and 50 manual THAs. They found that all robotic THA cups were in the "safe-zone" (inclination: 30–50 degrees; anteversion: 5–25 degrees), which was true for only 80% of the manual cohort.[32] Only a few studies have been performed to analyze robotic-arm assisted alignment,[35–38] and, to the best of the authors' knowledge, this type of analysis has not yet been performed for TKAs.

Therefore, the purpose of this study was to assess the accuracy and precision of implant alignment using a robotic-arm assisted TKA (RATKA), as measured against the preoperative plan, compared with manual TKA (MTKA). We hypothesized that RATKA would, in fact, allow for more accurate and precise bone cuts as well as component position when compared with MTKA. Specifically, we assessed the following: (1) final femoral and tibial bone cuts and (2) final femoral and tibial component position for RATKA versus MTKA performed on cadavers by a surgeon with extensive experience in MTKA and no experience with RATKA. An additional objective was to determine whether there was a learning curve associated with the use of RATKA.

Methods

Cadaver Characteristics

Six cadaver specimens (12 knees) were included in this study. The cadaver demographics included two females and four males, who had a mean age of 74 years (range: 53–93 years) and a mean BMI of 25 kg/m^2 (range: 17–40 kg/m^2). Paired knees from the same subjects were used to limit the potential baseline variability in the extent of osteoarthritis (OA) and deformity that can be present if knees from different subjects were compared.

Cadaver Osteoarthritis Assessment

For each cadaver knee, intraoperative assessment of OA based on a modification of the established Outerbridge Classification system[39] was performed. The classification system was modified so that in-between grades were assigned a half score. For the manual cohort, one knee was grade 1, one was grade 2, two were grade 2.5, one was grade 3.5, and one was grade 4. For the robotic cohort, one knee was grade 0, one was grade 2, one was grade 2.5, one was grade 3.5, and two were grade 4. No statistically significant difference was found between the mean OA grade for the manual (mean: 2.6; range: 1–4) versus robotic (mean: 2.7; range: 0–4) cohorts ($p > 0.05$) (►**Table 1**).

Table 1 Modified Outerbridge classification for knee osteoarthritis

	Cohort		*p*-Value
	Manual	Robotic	
Outerbridge classification grade	1	0	
	2	2	
	2.5	2.5	
	2.5	3.5	
	3.5	4	
	4	4	
Mean grade	2.6	2.7	**>0.05**

Robotic-Arm Assisted Total Knee Arthroplasty System

The robotic-arm assisted total knee arthroplasty Mako system (Stryker) was used in this study (►**Fig. 1**). This system is intended to assist the surgeon by providing robotic software defined spatial boundaries for orientation, and reference information for anatomical structures. This system included a robotic arm, camera stand, guidance module, and TKA application software, as well as dedicated instrumentation (►**Fig. 1**).

Preoperative Cadaver Preparation

All six cadaver specimens (12 knees) were prepared by a single, high-volume TKA surgeon who had no prior clinical robotic experience. The surgeon was trained on a single robotic case prior to performing the procedure on the cadavers assessed in this study. For each cadaveric pair, a RATKA was prepared on the right leg and an MTKA was prepared on the left leg. This preparation helped minimize any potential variability with the setup and has not led to an apparent bias in robotic TKA alignment outcomes (see the Discussion section).

Preoperative Fiducial Cluster Mounting

Preoperatively, fiducial clusters were installed on each leg. These clusters were placed to measure the intraoperative bone cuts and component placement, and compare these to the preoperative plan. Four incisions were created on each specimen between muscle groups (two incisions on the femur and two on the tibia, each ~4 to 5 cm in length). The bone was cleared of all attached tissue, as would be done clinically. Pilot holes were drilled into the bone using a 4-mm SURGIBIT (Onyx Medical, Memphis, Tennessee) at each incision. Custom fiducial mounts were printed in three dimensions (3D) on an Objet machine (Stratasys, Eden Prairie, MN) using a rigid opaque photopolymer and were fixated to the bone using bone cement and a titanium screw. Prior to cementation, the bone was scored using a scalpel and an

Fig. 1 Robotic-arm assisted total knee arthroplasty system.

elevator to improve cement fixation. After the cement was cured, a custom aluminum fiducial kinematic base was secured to each fiducial mount with #4–40 5/16″ aluminum machine screws, and specimens were transported to a local facility for CT scanning. At the scanning facility, a custom fiducial cluster was mounted to each fiducial kinematic base using #6 ½″ aluminum screws. Fiducial clusters were 3D printed out of a rigid opaque photopolymer Somos NanoTool (DSM Functional Materials, Elgin, IL), and 21 Ti-6Al-4V heads were assembled to the 3D printed base.

Preoperative CT Scan

After the four fiducial clusters were properly fixed on each leg, preoperative CT scans were obtained from all knees. For each leg, the specimen was centered on the bed with clusters within the scanner's optimal CT field of view. The specimens were scanned using a Hitachi ECLOS 16 (Hitachi, Tokyo, Japan) slice CT in three regions (ankle, hip, and knee) using the following parameters: 0.625-mm slice thickness, 120- to 140-kVp tube potential, 200- to 400-mA tube current, and 0-degree tilt.

Fiducial Coordinate System

To establish the fiducial coordinate system, custom software was created to register clusters by allowing the intra-operative collection of the coordinates of each fiducial sphere (up to 21 spheres × 2 tibial or femoral mounts). From those coordinates, a fiducial registration transform was computed for the femur and tibia. Post-operatively, Mimics and 3-Matic (Materialise, Plymouth, MI) software were used to perform segmentation and 3D-to-3D registration of the pre- and postoperative CT scans for a visual assessment to confirm that the fiducials did not move during the study (►**Fig. 2A**).

Preoperative Implant Position Planning

Preoperative CTs were segmented to construct a 3D model of the knee for the planning of component position. The size and position were determined for each specimen by the operating surgeon. Prior to manual case planning, full-length coronal and sagittal CT scouts were reviewed to assess any joint deformity. Implant positions were planned relative to the femoral and tibial mechanical axes. The mechanical axis was identified from the femoral head center to the femur knee center for the femoral mechanical axis, and from the tibia knee center to the ankle center for the tibial mechanical axis.

Preoperative Planar Probe Preparation

A custom-navigated planar probe was used for all measurements (►**Fig. 2B**). The planar probe was inspected prior to the study using a coordinate measurement machine to determine the centroids and normals for each measurement surface, which was used in the bone cut and implant positional error calculations.

Operative Preparation and Measurements

Manual Bone Preparation and Surgical Technique

The manual cases were performed using a standard medial parapatellar approach with minimal medial release. Standard Triathlon cruciate-retaining TKA (Stryker) instrumentation was used to complete the manual preparation. Intramedullary alignment was used for femoral measurements, whereas

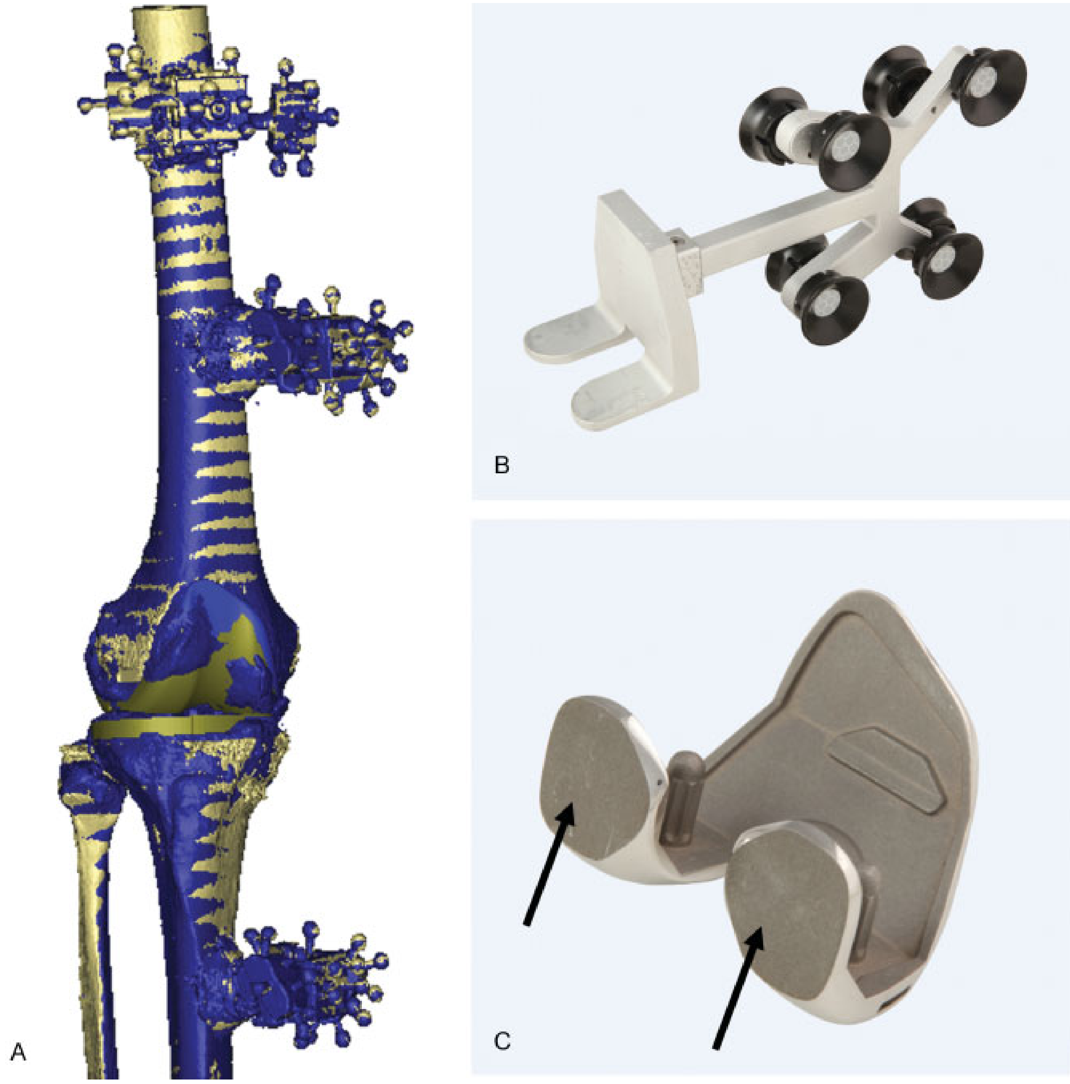

Fig. 2 Study materials showing (**A**) 3D-to-3D registration of segmented pre- and postoperative specimens with fiducial clusters, (**B**) planar probe, and (**C**) modified femoral component with posterior flats.

external alignment was used for tibial measurements. During the insertion of the femoral intramedullary rod, a fluoroscopy machine (SIREMOBIL Compact L, Siemens, Washington, DC) was used to ensure clearance of the rod with the fiducial mount, as any disturbance of the mount could compromise the measurements. Bone cuts were made in the following order: distal femur, anterior, posterior, posterior chamfer, anterior chamfer, and then proximal tibia. After placing implant trials, the knee was brought to full flexion and extension to confirm appropriate alignment and positioning. Patellar tracking was also checked. Any needed soft tissue balancing was then performed. The final femoral and tibial components were cemented using Simplex P bone cement (Stryker, Mawah, NJ). The wound was then closed, and final alignment of the bone cuts and implant positions were measured, as described later.

Robotic Surgical Technique and Implant Balancing

Preoperatively, the fiducial clusters were prepared as described previously. Using the robotic software and the preoperative CT scan, a 3D model for each cadaver's unique anatomy was generated. An intraoperative arthrotomy was performed using a standard medial parapatellar approach with minimal medial release. Tracking arrays and checkpoints were installed on the distal femur and proximal tibia using bicortical pins and stabilizing clamps. Another optical tracker was mounted on the robotic arm. The surgeon collected points on the specimen's anatomy using a probe, and the robotic-software registered the trackers to the 3D model generated from the pre-operative CT scan, which enabled the robotic-arm assisted system to track the bones in real-time. The surgeon then virtually planned the procedure using the robotic-arm assisted system (►**Fig. 1**). To do so, the knee was placed in full extension to virtually assess coronal alignment, as well as medial and lateral extension gaps. If any coronal deformity was present in extension, it was stressed to assess for correction. Then, the knee was put in 90 degrees of flexion to virtually assess medial and lateral flexion gaps. Based on these readings, the planned femoral and tibial bone cuts, as well as implant placements, were virtually adjusted (manipulated in the transverse, sagittal, and coronal planes) to achieve a balanced knee. A balanced knee consisted of equal medial and lateral gaps (as measured between the femur and tibia cuts) both in extension and flexion, to account for the prosthesis thickness. Once the knee was balanced, bone cuts were made.

Robotic Bone Cutting

The end of the robotic arm was equipped with a sawblade, which the surgeon used to make bony cuts (►**Fig. 1**). The robotic arm provided visual feedback, tactile resistance, an audible warning, and auto-turn-off feature if the robotic arm varied too far from the implant plan. With the robotic arm, bone cuts were made in the following order: distal femur, posterior chamfer, posterior, anterior, anterior chamfer, and then proximal tibia. The robotic arm aligned and constrained the cutting tool to the plane of each planned cut in real-time, such that if the trackers moved, the robotic arm adjusted in response. Intraoperatively, the surgeon was able to track the position of the blade in a 3D space relative to the bone on a screen. The bone cut surfaces were then measured for final alignment to plan (see below). After placing implant trials, the knee was brought to full flexion and extension to confirm appropriate alignment and positioning. Any necessary soft tissue balancing was then performed. The final femoral and tibial components were cemented using Simplex P bone cement (Stryker, Mawah, NJ). The wound was then closed, and final alignment of the bone cuts and implant positions were measured, as described in the following.

Bone Cut and Implant Alignment Measurements

Final alignment of the bone cuts and implant positions for RATKA and MTKA were measured in the sagittal, coronal, and axial planes using the navigated planar probe described previously. For sagittal measurements, the tibial anterior or posterior slope was defined by the angle between the tibial mechanical axis and the tibial implant or bone cut surface, whereas femoral flexion or extension rotation was defined by the angle between the femoral mechanical axis and the distal femoral implant or bone cut surface. For coronal measurements, the tibial varus or valgus rotation was defined as the angle between the tibial mechanical axis and the tibial implant or bone cut surface, whereas the femoral varus or valgus rotation was defined as the angle between the femoral mechanical axis and the distal femoral implant or bone cut surface. For transverse measurements, the femoral internal or external rotation was defined as the angle between the surgical transepicondylar axis (line connecting the center of the sulcus of the medial epicondyle and the most prominent point of the lateral epicondyle) and the posterior femoral implant or bone cut surface. The deviation to plan was the angular difference between the planned cut and the actual cut alignment.

Component Preparation

Implants were production-equivalent and pulled from finished goods. Femoral implants were machined using a wire electrical discharge machining with posterior flats (►**Fig. 2C**). The flats defined flexion/extension and internal/external orientation of the planar probe while measuring the final femoral component position. A puck was machined out of aluminum and assembled with the proximal face of the seated tibial component. The planar probe sat atop the puck to measure the anterior/posterior slope and the varus/valgus positioning of the tibial component. All machined components were inspected prior to use.

Accuracy and Precision Measurements

The accuracy of the system (RATKA or MTKA) considered several sources of error. The sources of final implant positioning error were assumed to be a sum of bone registration error (only applicable to RATKA), bone cut error, implant cementation error, and implant tolerance. Error from implant tolerance was accepted to be markedly smaller in comparison with the other sources of errors. Therefore, the three main procedural error sources that contributed to final implant positioning error were considered as follows:

$$\text{Final Implant Positioning Error} = \underbrace{\text{Bone Registration Error} + \text{Bone Cut Error}}_{\text{Final Bone Cut Error} = \text{Bone Registration Error} + \text{Bone Cut Error}} + \text{Implantation/Cementation Error}$$

Postoperative measurements were performed using an optical tracking navigation device. Final bone cuts to plan were measured relative to the fiducials, representing final bone cut error (sum of bone registration error and bone cut error). Final component position to plan was also measured relative to the fiducial clusters. The difference between the two measurements represented implantation/cementation error.

In addition, a gage assessment was performed for the planar probe to characterize variability of the measurement system and for a given user. To minimize variation in the measurements, a single, trained nonsurgeon operator made all of the measurements for both the manual and robotic cases using the same planar probe. The same planar probe was positioned on each cut surface or the cemented implant, as shown in ►**Fig. 3**, and angular error measurements were recorded from the custom screen.

Calculations

Median errors and SDs were compared between RATKA and MTKA for each planar bone cut and component position in the sagittal, coronal, and axial planes. Median values were used to assess the central tendency of the dataset. Medians were used to describe accuracy to plan and to represent the absolute deviation from plan. SD was used to describe the precision to plan. V/V represented varus or valgus deviation, F/E represented flexion or extension deviation, I/E represented internal or external deviation, and A/P represented anterior or posterior slope deviation.

Learning Curve

To analyze the learning curve associated with use of the robotic system, stacked error results from all cuts and implant positions for each specimen, in procedural order, were compared for RATKA and MTKA.

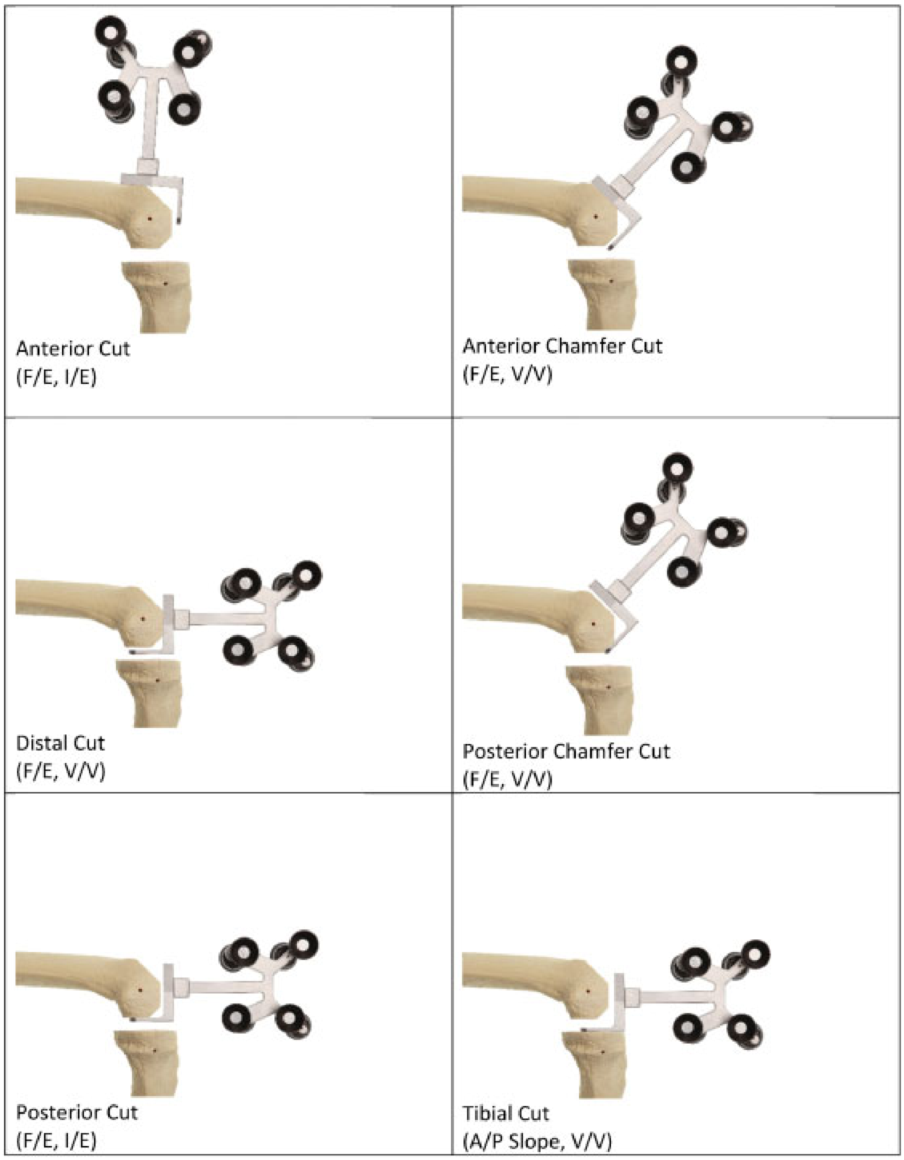

Fig. 3 Method of collecting final bone cut error with the planar probe.

Data Analysis

Standard Deviation

Hypothesis testing was performed to assess MTKA and RATKA data using a two-sample standard deviation test. The α significance level for the test was 0.05 with a 95% confidence level. If the p-value was > 0.05, then the data provided insufficient evidence to reject the null hypothesis (Ho: $s1/s2 = p$) and accept the alternate hypothesis (Ha: $s1/s2 > p$), where $s1 =$ MTKA and $s2 =$ RATKA. This decision was reached because the calculated p-value for the test was more than the preselected α level.

If the p-value was ≤ 0.05, then the data provided sufficient evidence to reject the null hypothesis (Ho: $s1/s2 = p$) and accept the alternate hypothesis (Ho: $s1/s2 > p$) at a significance level of 0.05. This decision was reached because the calculated p-value for the test was less than the preselected α level.

Statistical power calculations were also included to assess the possibility of a type II error, the probability of correctly rejecting the null. This analysis was based on the sample size of $n = 6$ and assessed how much larger, or smaller, s1 was when compared with s2. Power level was based on 1-β, where $\beta = 0.02$ (power of 0.80) for all assessments.

Median Values: Graphical Analysis

Statistical methods to assess the central tendency of the data were considered. However, due to the small sample size, some assumptions could not be adequately assessed. It was decided to rely on a graphical analysis to evaluate. The median values were, therefore, used to compare MTKA with RATKA.

Results

Bone Cut Accuracy and Precision

Comparison of the medians shows that RATKA bone cuts were more or as accurate to plan than the MTKA control for 11 of 12 bone cut measurements: femoral anterior I/E (0.9 vs. 3.3 degrees), femoral anterior F/E (0.4 vs. 4.7 degrees),

Table 2 Measurement of bone cut medians and standard deviations for RATKA versus MTKA

Anatomical location	Median			SD			
	RATKA (degrees)	MTKA (degrees)	*p*-Value[a]	RATKA (degrees)	MTKA (degrees)	Two-sample SD test, *p*-value	Two-sample SD test, detectable difference (%)
Femoral anterior I/E	0.9	3.3	N/A	0.5	1.9	0.018	80.40
Femoral anterior F/E	0.4	4.7	N/A	0.4	2.3	0.001	74.90
Femoral anterior chamfer V/V	0.5	3.9	N/A	0.1	2.2	<0.001	77.90
Femoral anterior chamfer F/E	0.3	1.8	N/A	0.2	1.0	0.019	84.80
Femoral distal V/V	0.5	2.6	N/A	0.3	1.6	0.004	79.50
Femoral distal F/E	0.8	0.8	N/A	0.5	1.1	0.091	77.20
Femoral posterior chamfer V/V	1.1	2.6	N/A	0.4	2.0	<0.001	69.40
Femoral Posterior chamfer F/E	0.9	0.8	N/A	0.5	1.6	0.075	88.00
Femoral posterior I/E	1.0	2.5	N/A	0.6	1.6	0.043	73.70
Femoral posterior F/E	0.5	2.3	N/A	0.6	4.0	0.054	94.20
Tibial V/V	0.6	1.2	N/A	0.3	0.7	0.007	64.60
Tibial A/P	0.7	0.9	N/A	1.0	0.3	0.9	87.60

Abbreviations: A/P anterior or posterior slope deviation, F/E flexion or extension deviation, I/E internal or external deviation, MTKA, manual total knee arthroplasty; N/A, not applicable; RATKA, robotic-arm assisted total knee arthroplasty; SD, standard deviation; V/V varus or valgus deviation.
[a]Statistical method to assess the central tendency of the data was considered. However, due to the small sample size, some assumptions could not be adequately assessed, and evaluation was conducted based on graphical analysis.

femoral anterior chamfer V/V (0.5 vs. 3.9 degrees), femoral anterior chamfer F/E (0.3 vs. 1.8 degrees), femoral distal V/V (0.5 vs. 2.6 degrees), femoral distal F/E (0.8 vs. 0.8 degrees), femoral posterior chamfer V/V (1.1 vs. 2.6 degrees), femoral posterior I/E (1 vs. 2.5 degrees), femoral posterior F/E (0.5 vs. 2.3 degrees), tibial V/V (0.6 vs. 1.2 degrees), and tibial A/P (0.7 vs. 0.9 degrees) (►**Table 2**, ►**Figs. 4** and **5**). The posterior chamfer F/E bone cut median was slightly higher for RATKA than MTKA (0.9 vs. 0.8 degrees).

Similarly, when comparing the SDs, RATKA bone cuts were more precise to plan than the MTKA control on all femoral bone cuts: femoral anterior I/E (0.5 vs. 1.9 degrees), femoral anterior F/E (0.4 vs. 2.3 degrees), femoral anterior chamfer V/V (0.1 vs. 2.2 degrees), femoral anterior chamfer F/E (0.2 vs. 1 degree), femoral distal V/V (0.3 vs. 1.6 degrees), femoral distal F/E (0.5 vs. 1.1 degrees), femoral posterior chamfer V/V (0.4 vs. 2 degrees), femoral posterior chamfer F/E (0.5 vs. 1.6 degrees), femoral posterior I/E (0.6 vs. 1.6 degrees), and

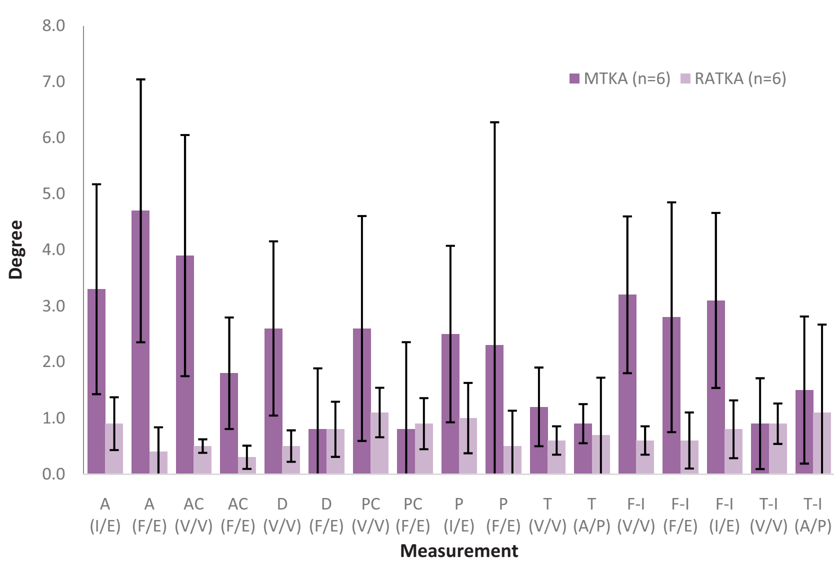

Fig. 4 Comparison of manual total knee arthroplasty (MTKA) and robotic-arm assisted total knee arthroplasty (RATKA) median cuts and implant position for all six matched pairs, where A = anterior, AC = anterior chamfer, D = distal, PC = posterior chamfer, P = posterior for the femur. T = tibia, F-I = femoral implant, and T-I = tibial implant. Error bars indicate standard deviations.

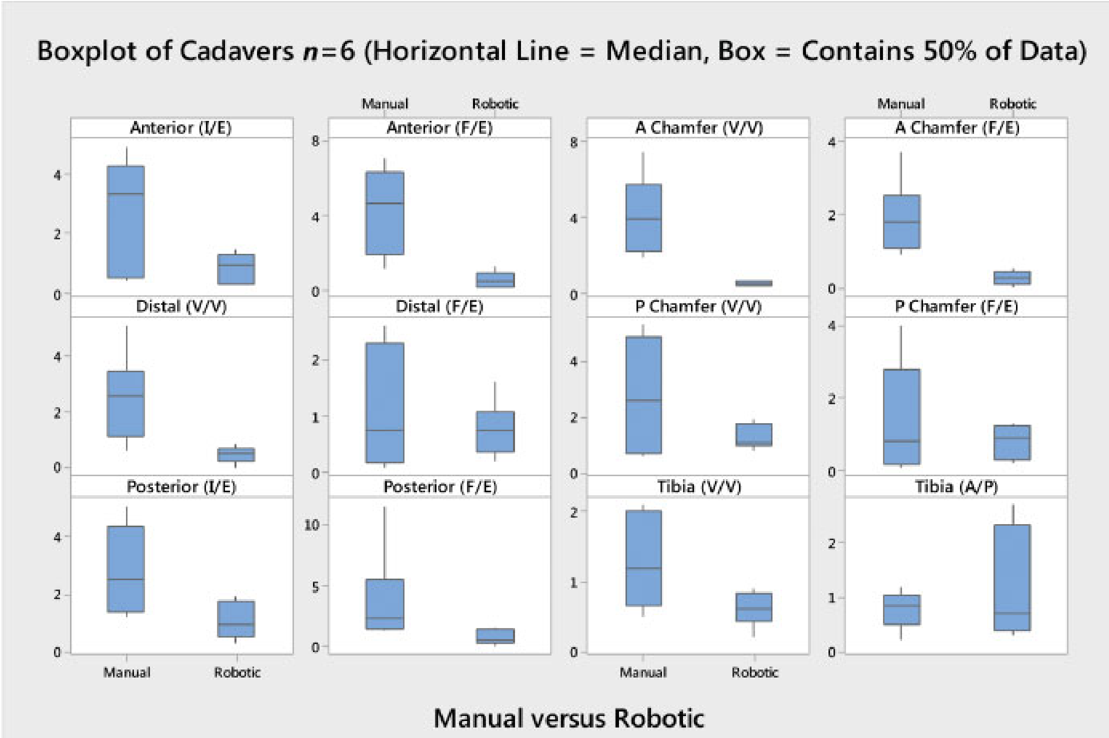

Fig. 5 Boxplots assessing accuracy and precision of bone cuts to plan for robotic versus manual total knee arthroplasty.

femoral posterior F/E (0.6 vs. 4 degrees).The tibial V/V bone cut was more precise for RATKA (0.3 vs. 0.7 degrees), but the tibial A/P cut was less precise for RATKA (0.3 vs. 0.9 degrees).

Based on a power analysis and the ability to detect a difference, the SD of RATKA was smaller for 8 out of 12 bone cut measurements (at the $p = 0.05$ level of significance based on the detectable difference). Additionally, three of the four sets that failed to reject the null were near the significance level of 0.05, at 0.091, 0.075, and 0.054 for the femoral distal F/E, femoral posterior chamfer F/E, and femoral posterior F/E measurements, respectively.

Component Position Accuracy and Precision

Comparison of the medians showed RATKA final component positions were as or more accurate to plan than the MTKA control for all measurements: femoral V/V (0.6 vs. 3.2 degrees), F/E (0.6 vs. 2.8 degrees), I/E (0.8 vs. 3.1 degrees), tibial V/V (0.9 vs. 0.9 degrees), tibial A/P (1.1 vs. 1.5 degrees) (►**Table 3**).

Additionally, comparison of the SDs showed that RATKA final component positions were as or more precise to plan than MTKA for all femoral implant positions as well as for the tibial V/V implant positions, as demonstrated by SDs:

Table 3 Measurement of component position medians and standard deviations for RATKA versus MTKA

Anatomical location	Median			SD			
	RATKA (degrees)	MTKA (degrees)	p-value[a]	RATKA (degrees)	MTKA (degrees)	Two-sample SD test, *p*-value	Two-sample SD test, detectable difference (%)
Femoral distal V/V	0.6	3.2	N/A	0.3	1.4	0.003	79.10
Femoral distal F/E	0.6	2.8	N/A	0.5	2.1	0.009	77.10
Femoral I/E	0.8	3.1	N/A	0.5	1.6	0.045	83.60
Tibial V/V	0.9	0.9	N/A	0.4	0.8	0.022	83.50
Tibial A/P	1.1	1.5	N/A	1.6	1.3	0.093	79.10

Abbreviations: A/P anterior or posterior slope deviation, F/E flexion or extension deviation, I/E internal or external deviation, MTKA, manual total knee arthroplasty; N/A, not applicable; RATKA, robotic-arm assisted total knee arthroplasty; SD, standard deviation; V/V varus or valgus deviation.
[a]Statistical method to assess the central tendency of the data was considered. However, due to the small sample size, some assumptions could not be adequately assessed, and evaluation was conducted based on graphical analysis.

femoral V/V (SD: 0.3 vs. 1.4 degrees), F/E (SD: 0.5 vs. 2.1 degrees), I/E (SD: 0.5 vs. 1.6 degrees), and tibial V/V (SD: 0.4 vs. 0.8 degrees), but not for tibial A/P.

Based on a power analysis and the ability to detect a difference, the SD of RATKA was smaller for four out of five implant positions (at the $p = 0.05$ level of significance based on the detectable difference). Additionally, one set that failed to reject the null was close to the significance level of 0.05 at 0.093 (tibial A/P).

Learning Curve

►**Fig. 6** shows an area plot of the stacked error results from all cuts (►**Fig. 6A**) and implant positions (►**Fig. 6B**) for each specimen in procedural order. As seen in ►**Fig. 6**, the overall MTKA cut error to plan was greater, when comparing specimen pairs and procedural order, than RATKA. Similarly, the overall MTKA component positional error to plan was greater, when comparing specimen pairs and procedural order, than RATKA. Thus, when assessing the total stacked error, there did not appear to be a learning curve in the RATKAs.

When considering individual cut error to plan, for RATKA, it was evident that the greatest deviation from plan for tibial slope cut and implant position occurred in the first two RATKA cases (►**Figs. 6A** and **6B**, respectively), and can be attributed to the learning curve for tibial bone registration due process of bone registration. After the third robotic case, the tibial registration procedure was reviewed and the accuracy for tibial slope to plan improved.

Discussion

Currently, the most commonly used methods for achieving coronal component alignment in TKA are through the use of intramedullary femoral and extramedullary tibial guides. Even with the use of manual instrumentation and navigation, studies have shown that surgeons may not always achieve optimal alignment.[9–13,18–20,40] Therefore, this study assessed RATKA,

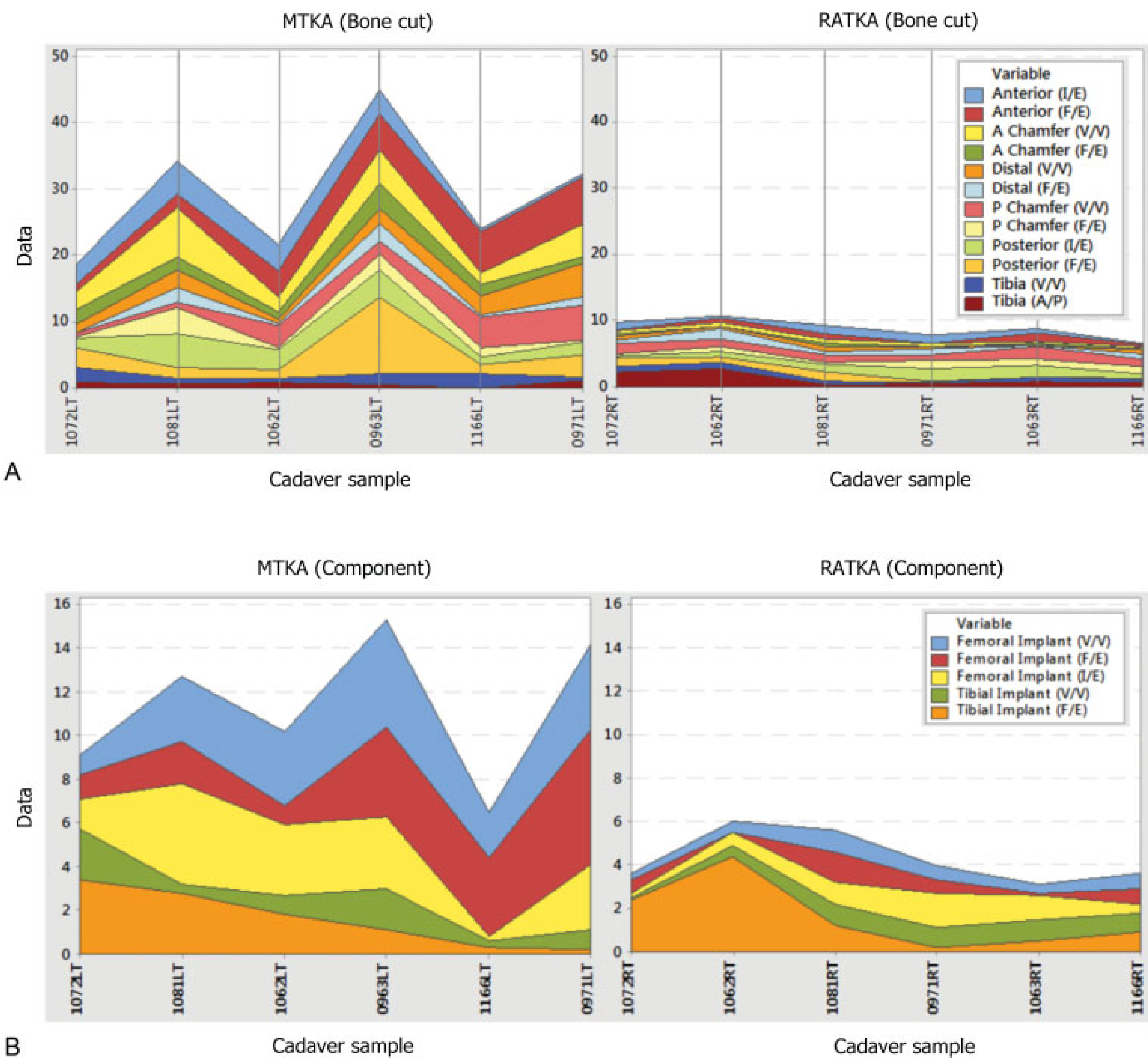

Fig. 6 Area plot showing stacked results of all final (A) bone cut and (B) component positional errors to plan for manual and robotic total knee arthroplasties. Left to right, cadaver samples are presented in procedural order.

which has been introduced to potentially minimize the margin of alignment error associated with component placement. The operating surgeon had over 25 years of manual TKA experience, and following a single cadaver training with no previous robotic experience, the surgeon's first six RATKA demonstrated greater accuracy and precision of bone cuts and component placement to plan, compared with MTKA in this cadaver study.

There were some limitations to this study. Although the sample size was small, the results revealed clear differences in between these two groups. Additionally, using one knee for RATKA and the other for MTKA on the same cadaver introduces a potential bias as one procedure was always performed with the dominant hand of the surgeon. However, the primary surgeon from this study has since performed more than 40 robotic-arm assisted TKAs and has not found any considerable differences in coronal alignment between right and left knees (less than 0.5 degrees) on postoperative surgical evaluation that would bias the substantial differences found in this study. Additionally, a recent study analyzing a single surgeon's robotic-arm assisted TKA postoperative coronal alignment of 157 left and 173 right knees found that neutral alignment (0 ± 3 degrees) could be achieved on both sides, even in 100% of severe valgus deformity cases.[41] Another study, analyzing a single surgeon's robotic-arm assisted UKA alignment of 56 right and 38 left knees, also found that no differences attributable to laterality as significant pre- to postoperative mechanical axis alignment correction could be achieved on both sides using the robotic-assisted device (5 ± 3 degrees of varus vs. 3 ± 2 degrees of varus; $p < 0.0001$).[42] In a large retrospective study on 6,070 left and right knees with varying degrees of coronal alignment, it was found that 4,236 (70%) patients were corrected to normal alignment within 1 SD from the mean (mean: 4.8 ± 2.5 degrees; range: 2.4–7.2 degrees of valgus), with no distinct differences mentioned regarding joint laterality and outcomes.[43] The successful outcomes of these studies evaluating both the left and right knees further highlight that hand-dominance and joint laterality play a minimal role in influencing surgical outcomes.

Another limitation of this study was that the results of the gage assessment showed that certain bone cuts were more difficult than other cuts to measure with the planar probe. This was true for the posterior chamfer F/E measurement, which was the cut with the least surface area and where the median was slightly higher for RATKA than MTKA. However, a single, trained nonsurgeon operator was used to collect all of the measurements for both robotic and manual to minimize this variation.

Although we were able to consistently demonstrate large statistically significant differences in SD of bone cut and component placement errors to plan between robotic-arm assisted and manual TKA, we cannot comment on the clinical relevance of these findings because it is still debated as to what amount of error is considered clinically relevant in TKA. In addition, this study used cadavers instead of live patients, which may not allow for results to be translated in vivo.

Robotic technology was introduced in the operating room more than 30 years ago and has continued to evolve and become part of daily medical practice. Even in the early stages, it was known that this technology could provide accurate and reproducible results.[44] Additionally, due to the reliability of robotic technology, the economic benefits have become clear in many different surgical fields.[45] For many of these reasons, robotics have become an integral part of medicine. In addition to use in orthopaedics, robotic technology is also used in neurosurgery, gynecology, cardiothoracic surgery, urology, and general surgery.[46,47]

Specific to orthopaedics, robotic technology has been used in the operating room since the early 1990s.[48] One of the first robotic devices was the ROBODOC (Curexo Technology Corporation). This device was primarily used for THA, and was found to achieve significantly improved fit, fill, and alignment when compared with manual techniques.[48] Another commonly used robotic system was the Caspar device (OrtoMaquet). An early report on this system also highlighted potential advantages with TKA alignment. The study also reported on a learning curve in which the first 70 robotic cases (mean: 135 minutes; range: 80–220 minutes) had significantly longer operating times compared with the manual cases ($p < 0.01$), whereas the last set of robotic cases had similar operating times compared with the manual cases (mean: 90 minutes).[22] Using the same robotic-arm assisted device analyzed in this study, but applied for UKA, Pearle et al found the overall mean operative time for 10 cases to be 35 minutes (range: 18–50).[49] However, the first five cases had a mean operative time of 43 minutes, whereas the last five cases had a mean of 27 minutes, further indicating a learning curve. Although this study did not find a learning curve based on stacked error differences between MTKA and RATKA for all bone cuts, a learning curve of a 2 RATKA cases was found for tibial slope cuts and implant positions.

Conclusion

In conclusion, this study evaluated alignment outcomes using a robotic-arm assisted system for TKA. Following a single cadaver training with no previous RATKA experience, the surgeon's first six RATKAs demonstrated greater accuracy and precision of bone cuts and component placement, based on the preoperative plan, compared with MTKA. This cadaveric study provides preliminary evidence supporting the use of robotic-arm assisted systems in TKA. Ongoing clinical studies will hopefully show that this novel technology will result in enhanced clinical outcomes.

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Conflict of Interest
E.L.H.: Stryker; M.C.: DJ Orthopaedics, Sage Products, Stryker; L.Y.S.: Stryker; M.B-S.: Stryker; D.J.J.: Biomet, Stryker, Smith-Nephew, Arthrex, Journal of Arthroplasty, Journal of Hip Surgery, Secure Independence, SLACK

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