

# Improved Accuracy of Component Positioning with Robotic-Assisted Unicompartmental Knee Arthroplasty

## Data from a Prospective, Randomized Controlled Study

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**Background:** Higher revision rates have been reported in patients who have undergone unicompartmental knee arthroplasty compared with patients who have undergone total knee arthroplasty, with poor component positioning identified as a factor in implant failure. A robotic-assisted surgical procedure has been proposed as a method of improving the accuracy of component implantation in arthroplasty. The aim of this prospective, randomized, single-blinded, controlled trial was to evaluate the accuracy of component positioning in unicompartmental knee arthroplasty comparing robotic-assisted and conventional implantation techniques.

**Methods:** One hundred and thirty-nine patients were randomly assigned to treatment with either a robotic-assisted surgical procedure using the MAKO Robotic Interactive Orthopaedic Arm (RIO) system or a conventional surgical procedure using the Oxford Phase-3 unicompartmental knee replacement with traditional instrumentation. A postoperative computed tomographic scan was performed at three months to assess the accuracy of the axial, coronal, and sagittal component positioning.

**Results:** Data were available for 120 patients, sixty-two who had undergone robotic-assisted unicompartmental knee arthroplasty and fifty-eight who had undergone conventional unicompartmental knee arthroplasty. Intraobserver agreement was good for all measured component parameters. The accuracy of component positioning was improved with the use of the robotic-assisted surgical procedure, with lower root mean square errors and significantly lower median errors in all component parameters ( $p < 0.01$ ). The proportion of patients with component implantation within  $2^\circ$  of the target position was significantly greater in the group who underwent robotic-assisted unicompartmental knee arthroplasty compared with the group who underwent conventional unicompartmental knee arthroplasty with regard to the femoral component sagittal position (57% compared with 26%,  $p = 0.0008$ ), femoral component coronal position (70% compared with 28%,  $p = 0.0001$ ), femoral component axial position (53% compared with 31%,  $p = 0.0163$ ), tibial component sagittal position (80% compared with 22%,  $p = 0.0001$ ), and tibial component axial position (48% compared with 19%,  $p = 0.0009$ ).

**Conclusions:** Robotic-assisted surgical procedures with the use of the MAKO RIO lead to improved accuracy of implant positioning compared with conventional unicompartmental knee arthroplasty surgical techniques.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

**Peer review:** This article was reviewed by the Editor-in-Chief and one Deputy Editor, and it underwent blinded review by two or more outside experts. It was also reviewed by an expert in methodology and statistics. The Deputy Editor reviewed each revision of the article, and it underwent a final review by the Editor-in-Chief prior to publication. Final corrections and clarifications occurred during one or more exchanges between the author(s) and copyeditors.

**Disclosure:** This study was supported by an investigator-initiated research grant to all authors of this study from the MAKO Surgical Corporation, which is the manufacturer of the Robotic Interactive Orthopaedic Arm system used in this study. Also from MAKO Surgical Corporation, two authors of this study (B.J. and M.B.) received personal fees and three authors of this study (B.J., A.M., and M.B.) received surgical training. The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article.

Unicompartmental knee arthroplasty currently constitutes 8% to 10% of all knee arthroplasties performed in England and Wales and the United States<sup>1,2</sup>. The potential advantages of unicompartmental knee arthroplasty over total knee arthroplasty include improved functional outcome, proprioception, and gait; faster recovery; and less blood loss<sup>3-7</sup>. However, higher revision rates have been reported in patients with unicompartmental knee arthroplasty compared with total knee arthroplasty<sup>8,9</sup>. Several factors have been proposed for the higher failure rates in unicompartmental knee arthroplasty, including postoperative limb malalignment and poor implant positioning<sup>10-12</sup>. The accuracy and reproducibility of implant positioning appear to be important to the longevity of unicompartmental knee replacement, and, thus, techniques that improve accuracy may lead to improvement in unicompartmental knee replacement survival.

Recently, the robotic-assisted surgical procedure has been introduced as a surgical technique to improve the accuracy of implant positioning. Cobb et al.<sup>13</sup> reported a prospective, randomized controlled trial using the Acrobot system (Acrobot) with the mobile-bearing Oxford unicompartmental knee replacement (Biomet), citing improved accuracy in the coronal plane compared with conventional techniques. The Acrobot system uses a statically referenced technique requiring rigid fixation of the patient's lower limb to a stereotactic frame. Initial studies using the first-generation MAKO Robotic Tactile Guidance System (MAKO Surgical) have also shown improved accuracy in the coronal and sagittal planes compared with conventional unicompartmental knee replacement controls<sup>14</sup>. To our knowledge, the accuracy of the second-generation RIO Robotic Arm Interactive Orthopedic System (MAKO Surgical) has not been investigated previously in a prospective, randomized controlled study. The MAKO RIO system uses a dynamic referencing guidance system and preoperative computed tomography (CT) data to facilitate preoperative surgical planning from a three-dimensional model of the patient's knee<sup>15</sup>. Our hypothesis was that the robotic-assisted surgical procedure would give increased accuracy of unicompartmental knee replacement implant positioning compared with the conventional surgical procedure.

The purpose of this study was to provide data from a prospective, randomized, single-blinded, controlled trial comparing the accuracy of component positioning assessed by two-dimensional CT scanning between robotic-assisted unicompartmental knee arthroplasty and conventional unicompartmental knee arthroplasty.

## Materials and Methods

One hundred and thirty-nine patients who were awaiting unicompartmental knee arthroplasty for medial compartment primary osteoarthritis were recruited to the trial from October 2010 to November 2012. Randomization was performed using an online web interface to either a conventional surgical procedure or a robotic-assisted surgical procedure, with stratification by surgeon. All procedures were performed at our institution by three high-volume unicompartmental knee arthroplasty surgeons who performed both the conventional and robotic-assisted procedures, and patients were blinded to their treatment.

The MAKO RIO system was used in the group who underwent robotic-assisted unicompartmental knee arthroplasty with implantation of the RESTORIS MCK (MAKO Surgical) fixed-bearing unicompartmental knee replacement. The conventional surgical arm of the trial used the Phase-3 Oxford mobile-bearing unicompartmental knee replacement implanted using standard manual instrumentation. The clinical trial was given prior approval by the local research ethics committee and was registered with the ISRCTN (International Standard Randomised Controlled Trial Number) Registry (ISRCTN77119437).

Patients were excluded if there was radiographic evidence of osteoarthritis affecting the lateral compartment or lateral facet of the patellofemoral compartment, the anterior cruciate ligament was deficient, or a fixed flexion or varus deformity of  $>10^\circ$  was present. The study Consolidated Standards of Reporting Trials (CONSORT) diagram is given in Figure 1. Of the 139 recruited patients, 120 patients (sixty-two who underwent a robotic-assisted surgical procedure and fifty-eight who underwent a manual surgical procedure) underwent postoperative CT scans and had data available for analysis in this accuracy study. Patient demographic characteristics are presented in Table I.

## Surgical Technique

Preoperative CT scans were performed in each of the patients randomized to the group receiving a MAKO unicompartmental knee replacement to facilitate preoperative surgical planning. These preoperative CT data then underwent a process of segmentation by a trained technician that was used to build a three-dimensional computer-aided design (CAD) model of the patient's knee to allow planning of the component position. The operating surgeon defined the size and position of the unicompartmental knee replacement components in the preoperative plan, optimizing bone coverage, restoring joint anatomy, and minimizing bone resection. Implant alignment was therefore tailored to each individual patient. Using the preoperative plan, the MAKO system calculated the volume of bone requiring resection and created a three-dimensional haptic

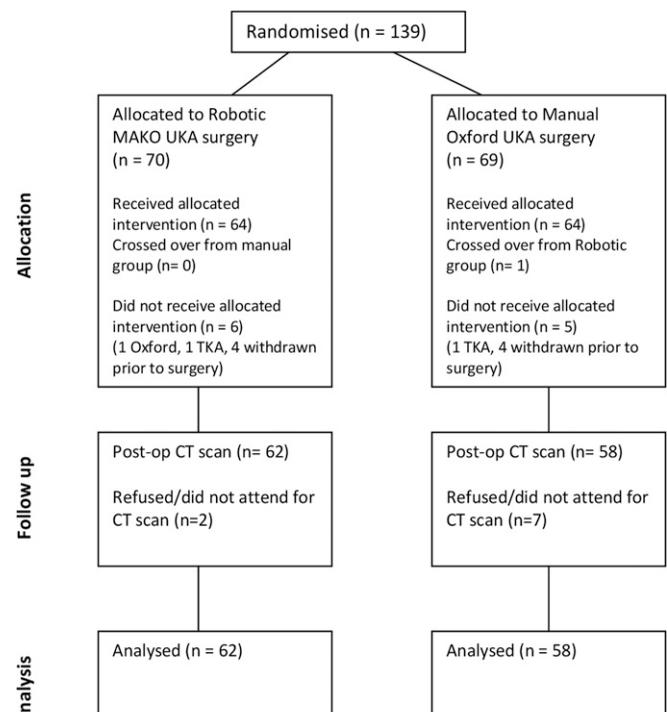


Fig. 1  
CONSORT diagram. UKA = unicompartmental knee arthroplasty, TKA = total knee arthroplasty.

TABLE I Patient Demographic Characteristics

	MAKO Group (N = 70)	Oxford Group (N = 69)	P Value
Age* (yr)	62.5 ± 6.9	61.7 ± 7.9	0.548
Male:female ratio	1.17:1	1.29:1	0.860
Involved side†			0.605
Left	38	42	
Right	32	27	

\*The values are given as the mean and the standard deviation.  
†The values are given as the number of patients.

boundary defined by this volume, allowing the RIO robotic arm to resect bone to a high degree of accuracy using a high-speed, water-cooled burr. Any milling outside of the predetermined zone was resisted by the robotic arm using tactile resistive feedback and audio signals, with complete burr shutdown if the cutting tool was forced outside the zone.

The system used optical motion capture technology to dynamically track marker arrays fixed to the femur and tibia, which were mounted through separate stab incisions. This provided dynamic referencing of the femur and tibia and therefore allowed the three-dimensional haptic bone resection volume to move with the limb as it was moved by the surgeon. Visual feedback was given to the surgeon by the on-screen CAD images and tactile feedback was provided by the robotic arm. The RESTORIS MCK implant consists of a cobalt-chromium femoral component, a titanium tibial component, and a fixed-bearing polyethylene insert.

The conventional unicompartmental knee arthroplasties were performed using standard instrumentation and the Oxford Phase-3 unicompartmental knee replacement. The Oxford unicompartmental knee replacement consists of cobalt-chromium femoral and tibial implants and a fully congruent polyethylene mobile bearing.

The standard instrumentation jigs resulted in fixed target values for all patients, without the opportunity for tailoring of the implant position to each patient's anatomy. Target values for implantation were obtained from the Biomet Operating Technique manual (<http://www.biomet.nl/resource/5980/Oxford-Knee-Optec.pdf>) for the instruments and implants that were used.

### Postoperative CT Scans

All patients had a CT scan performed on a single scanner at three months postoperatively using a standard protocol (Table II). The postoperative CT scans were saved in DICOM (Digital Imaging and Communication in Medicine) format<sup>16</sup> before being loaded to Mimics software (Materialise) to render a two-dimensional model for calculation of the component position. Analysis was undertaken by an independent researcher who was based at the University

of Strathclyde. The conventional unicompartmental knee arthroplasty group had fixed targets that were identical for all patients and were determined by the manual instrumentation. The target values used were taken from the manufacturer's recommendations. In the robotic-assisted arthroplasty group, the target values for the component position varied among the individual patients. Fine-tuning of the implant position was performed by measuring the soft-tissue envelope with an intraoperative joint-balancing procedure.

The accuracy of component positioning was determined using postoperative CT by comparing the target positioning values in the preoperative plan with the actual values achieved postoperatively. Accuracy was therefore determined by the degree of deviation from the preoperative planned target values rather than by the absolute values of the component position. Effectively, it is therefore a measure of how well each technique delivers the preoperative surgical plan. This implantation error of component alignment was used as the primary outcome measure of accuracy of the techniques.

The component implant position was calculated in the sagittal, coronal, and axial planes. The individuals performing the measurements were not blinded as to treatment group because of the differences in the MAKO and Oxford implant designs. The mechanical axes of the femur and tibia were identified from the center of the hip and the center of the knee for the femoral mechanical axis and from the center of the knee and the center of the ankle for the tibial mechanical axis.

### Sagittal Alignment

The tibial sagittal alignment (tibial slope) was measured as the angle between the tibial implant or bone interface and the tibial mechanical axis. The femoral sagittal alignment (flexion) was measured as the angle between the femoral mechanical axis and the femoral implant peg axis.

### Coronal Alignment

The femoral coronal alignment was measured as the angle between the femoral mechanical axis and the medial to lateral axis of the condylar implant. The tibial coronal alignment was measured as the angle between the tibial mechanical axis and the medial to lateral axis of the tibial implant.

### Axial Alignment

To measure the axial alignment of the femoral component, the surgical transepicondylar axis was first identified as a line connecting the center of the sulcus of the medial epicondyle and the most prominent point of the lateral epicondyle. Femoral rotation was calculated as the angle between the surgical transepicondylar axis and the posterior condylar axis of the implant<sup>17</sup>. This method was used to calculate femoral rotations of both MAKO and Oxford implants. The MAKO system software algorithm uses the surgical transepicondylar axis to determine femoral rotation, and the rotation of the Oxford component is controlled using the mechanical axis of the tibia with the knee in 90° of flexion. Although there are no specific target values set for rotation of the Oxford components, the surgical transepicondylar axis is effectively perpendicular to the tibia when the knee is flexed to 90°, allowing us to use this measure for the Oxford implant also.

TABLE II Imaging Protocol of Three Regions: Hip, Knee, and Ankle

	Hip	Knee	Ankle
Tube potential	100 kV	100 kV	100 kV
Tube current-time product	80 mAs	100 mAs	45 mAs
Scan length	~ 50 mm	~ 200 mm	~ 50 mm
Collimation	4 mm	1 mm	4 mm
Field of view	Includes femoral head	Must include 100 mm above and below the joint line between the femur and the tibia	Must include the talus and distal part of the tibia

**TABLE III Intraclass Correlation for Individual Component Alignment Measurements**

Measurement	Intraclass Correlation*
Femoral sagittal	0.974 (0.889 to 0.997)
Femoral coronal	0.982 (0.924 to 0.998)
Femoral axial	0.750 (0.457 to 0.993)
Tibial sagittal	0.764 (0.584 to 0.989)
Tibial coronal	0.836 (0.727 to 0.993)
Tibial axial	0.959 (0.832 to 0.995)

\*The values are given as the mean, with the 95% confidence interval in parentheses.

**TABLE IV Component Root Mean Square (RMS) Implantation Errors**

	Robotic-Assisted Arthroplasty Group*	Conventional Arthroplasty Group*
Femoral sagittal	3.35	6.87
Femoral coronal	2.09	5.09
Femoral axial	2.70	5.78
Tibial sagittal	1.64	4.43
Tibial coronal	2.58	3.71
Tibial axial	2.97	7.95

\*The values are given as the degrees.

The measurement of the MAKO tibial rotation was calculated from the angle between the anteroposterior axis of the tibial implant and the line connecting the posterior cruciate ligament and the medial third of the tibial tu-

bercle. Oxford tibial rotation is controlled by the manual instruments to match the femoral mechanical axis with the knee flexed to 90°. Again, this is effectively perpendicular to the surgical transepicondylar axis and so tibial rotation was calculated as the angle between the anteroposterior axis of the tibial implant and the surgical transepicondylar axis.

### Power Calculation

The minimum detectable difference using our measurement methodology was 1°. Based on previous CT accuracy studies carried out by the same authors in a study of total knee arthroplasty<sup>18</sup>, the mean deviation from the target value for tibial sagittal positioning was 4°. Assuming similar levels of accuracy for unicompartmental knee arthroplasty, we would have required 126 patients to detect a difference of 1° with a power of 80% ( $\alpha = 0.05$ ). The detection of larger differences would have required a smaller sample size or would have had >80% power with the given sample size. To allow for loss to follow-up, we allowed an additional twenty-four patients, giving a total target recruitment of 150 patients (seventy-five in each group).

### Statistical Analysis

Statistical analysis was carried out using Prism 5 (GraphPad Software). The Fisher exact test and the chi-square test were used to compare categorical data. The Mann-Whitney test was used to compare continuous variables that were not normally distributed. Significance was set at  $p < 0.05$  for all analyses. Intraclass correlation coefficients were calculated using SPSS version 20 (IBM).

### Results

The intraclass correlation coefficient for intraobserver agreement with regard to the measurements of the component alignment parameters was checked (Table III). The intraclass correlation coefficient ranged from 0.750 to 0.982, indicating good agreement for all parameters. The root mean square (RMS) errors were lower in all six component alignment parameters in the robotic-assisted arthroplasty group compared with the conventional arthroplasty group (Table IV).

Robotic assistance resulted in significantly lower component median implantation errors ( $p < 0.01$ ) for all three femoral and tibial component parameters (sagittal, coronal, and axial).

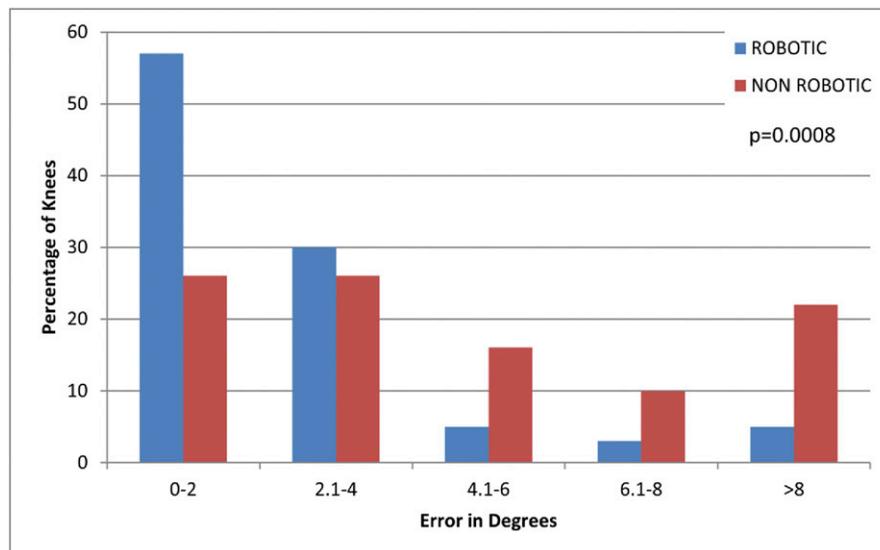


Fig. 2-A  
Implantation error of the femoral component in the sagittal plane.

**TABLE V Component Median Implantation Errors**

	Robotic-Assisted Arthroplasty Group*	Conventional Arthroplasty Group*	P Value
Femoral sagittal	1.9 (0.8, 2.9)	3.9 (2.0, 7.8)	0.0001
Femoral coronal	1.4 (0.6, 2.3)	4.1 (1.8, 5.8)	0.0001
Femoral axial	1.9 (1.1, 3.3)	3.6 (2.0, 5.9)	0.0001
Tibial sagittal	1.0 (0.7, 1.8)	3.7 (2.3, 5.6)	0.0001
Tibial coronal	1.6 (0.8, 3.0)	2.7 (1.6, 3.7)	0.0089
Tibial axial	2.2 (1.1, 3.4)	5.4 (2.8, 9.3)	0.0001

\*The values are given as the median error in degrees, with the first and third quartiles given in parentheses.

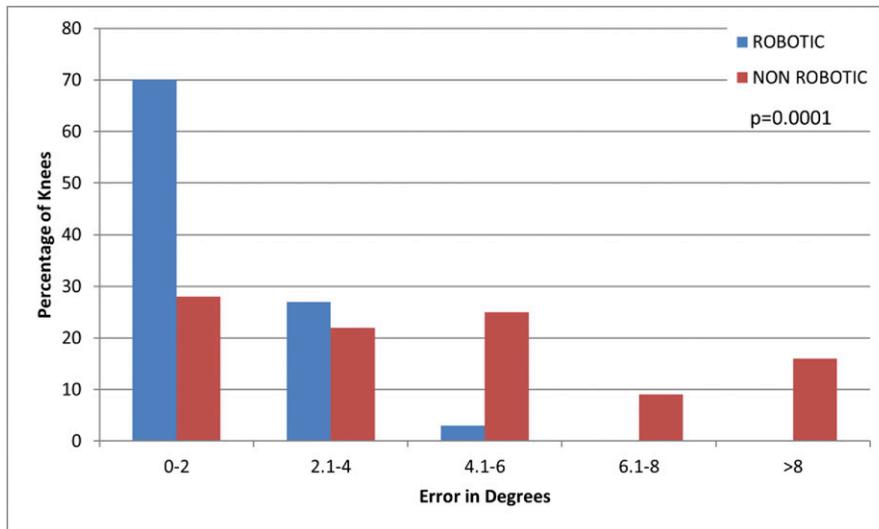


Fig. 2-B  
Implantation error of the femoral component in the coronal plane.

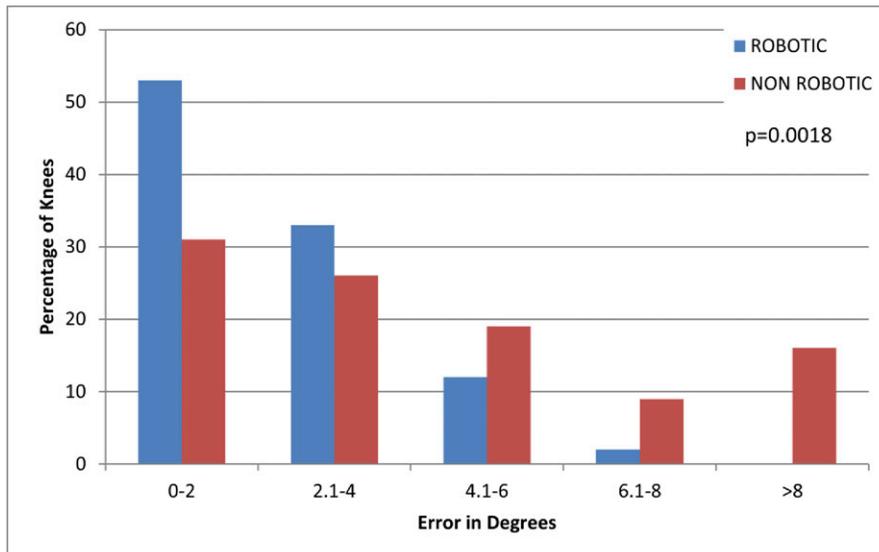


Fig. 2-C  
Implantation error of the femoral component in the axial plane.

**TABLE VI Percentage of Patients with Implants Positioned within 2° of the Target Value**

	Robotic-Assisted Arthroplasty Group	Conventional Arthroplasty Group	P Value
Femoral sagittal	57%	26%	0.0008
Femoral coronal	70%	28%	0.0001
Femoral axial	53%	31%	0.0163
Tibial sagittal	80%	22%	0.0001
Tibial coronal	58%	41%	0.0970
Tibial axial	48%	19%	0.0009

The greatest difference between errors was identified in the tibial component axial alignment and was 3.2° ( $p = 0.0001$ ). The results are presented in Table V.

The distribution of the errors for the component alignment parameters is presented graphically as categorical data (Figs. 2-A through 2-F). The proportion of patients with component

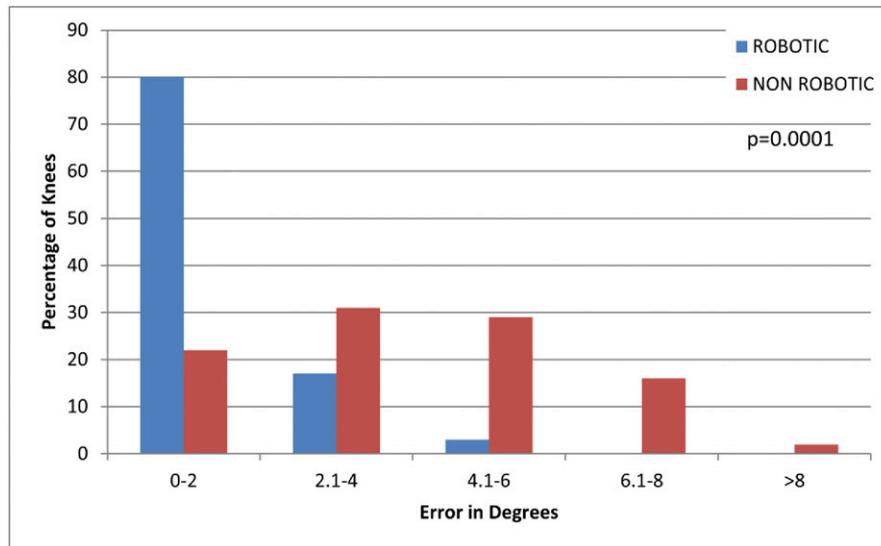


Fig. 2-D

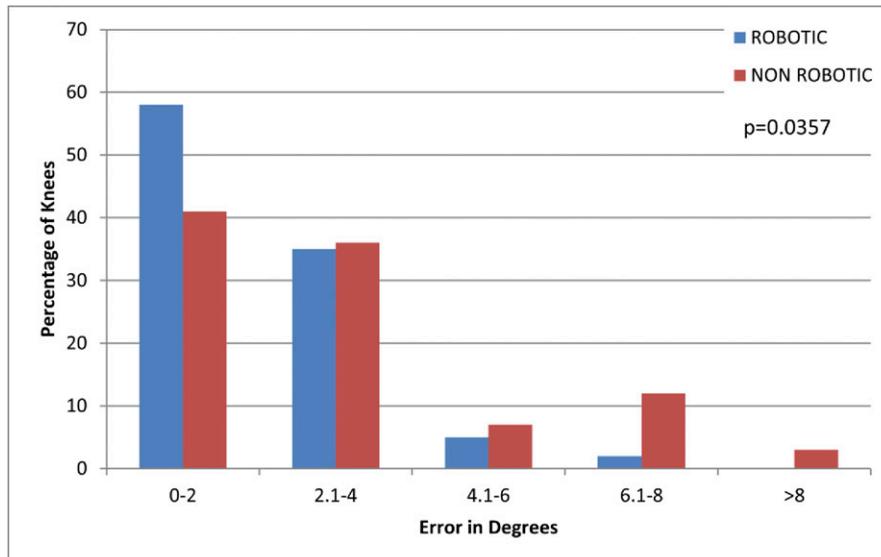


Fig. 2-E

**Fig. 2-D** Implantation error of the tibial component in the sagittal plane. **Fig. 2-E** Implantation error of the tibial component in the coronal plane.

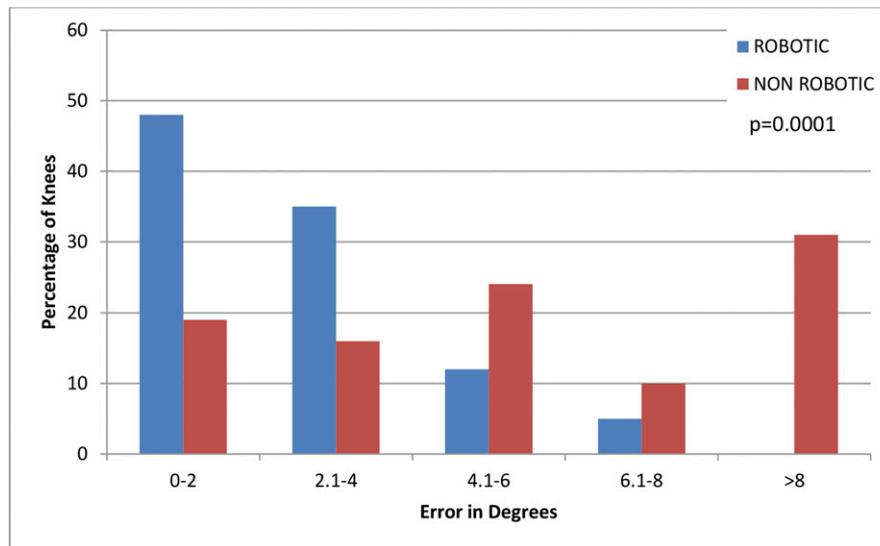


Fig. 2-F  
Implantation error of the tibial component in the axial plane.

implantation within  $2^\circ$  of the target position was significantly greater using the robotic-assisted technique for the femoral component sagittal position (57% compared with 26%,  $p = 0.0008$ ), femoral component coronal position (70% compared with 28%,  $p = 0.0001$ ), femoral component axial position (53% compared with 31%,  $p = 0.0163$ ), tibial component sagittal position (80% compared with 22%,  $p = 0.0001$ ), and tibial component axial position (48% compared with 19%,  $p = 0.0009$ ) (Table VI).

### Discussion

We have demonstrated improved accuracy of implant positioning in unicompartmental knee arthroplasty using a robotic-assisted surgical procedure with the MAKO RIO system compared with that using a conventional surgical procedure. In our study, we used the Oxford Phase-3 unicompartmental knee arthroplasty implant with standard manual instrumentation in the conventional arthroplasty group. The MAKO implant is not designed to be implanted using conventional surgical methods, and, therefore, a direct comparison using the same implant design was not possible. The Oxford unicompartmental knee replacement was used as the comparator because the senior authors (A.M., B.J., and M.B.) have had experience using this implant technique and because it is the most commonly used unicompartmental knee arthroplasty implant in the U.K. National Joint Registry<sup>1</sup>.

Postoperative limb malalignment and poor implant positioning have been implicated as causes of early failure in unicompartmental knee arthroplasty. In our study, the bearing types differed between the two implants, with the MAKO implant using a fixed bearing and the Oxford implant using a mobile bearing. The mobile bearing has a more conforming surface theoretically associated with improved wear characteristics. The conforming geometry of the mobile bearing may also protect against the edge-loading effects that can be observed with fixed-bearing designs that are poorly implanted<sup>19</sup>. Thus, mobile-bearing unicompartmental

knee replacement may better tolerate minor degrees of malalignment; however, accurate component alignment has been shown to be important in the prevention of mobile-bearing dislocations<sup>20</sup>. The degree of tolerance to malalignment afforded by the mobile-bearing geometry was not investigated by this study design, but we would have expected there to be limits to its effect. It was not clear at this stage whether the improved accuracy of the surgical procedure seen in the robotically assisted group would translate into improved joint survivorship.

The clinical implications of component malalignment are still unknown in unicompartmental knee arthroplasty, and further studies will be required to establish this. The measurement of axial component alignment after unicompartmental knee arthroplasty requires a postoperative CT scan; thus, it is infrequently reported and hence its importance is not fully understood. Axial component positioning was the least accurate for any of the measured tibial parameters, for both conventional and robotic-assisted techniques. The relative position of the components to each other is an important concept but is difficult to directly compare, as the conventional tibial component should lie in the same axial rotational plane as the conventional femoral component (in line with the surgical transepicondylar axis). However, in the MAKO planning, components were also placed to give maximal bone coverage, and, therefore, the axial position of each component was specific to each individual patient.

The finding of increased accuracy with robotic-assisted unicompartmental knee arthroplasty was consistent with the findings of a smaller randomized controlled trial comparing a different robotic-assisted system in which all robotic-assisted unicompartmental knee arthroplasties achieved a coronal tibiofemoral alignment within  $2^\circ$  of the planned position<sup>15</sup>. Improved accuracy using the MAKO system has been reported in a previous case series of twenty unicompartmental knee arthroplasties<sup>14</sup>. Dunbar et al. reported RMS errors within  $3^\circ$  for all femoral component alignments, a mean tibial RMS error of  $1.5^\circ$ , and a

mean femoral RMS error of 2.6°. The method for the measurement of the component error differed from that employed in our study, as it involved measuring the distance error (translation error) between the preoperative plan and the postoperative component position and mathematically converting this to an angular value. We measured the angle of the component position with respect to the mechanical axes of the femur and the tibia, compared this with the preoperative planned component position or manufacturers' recommendations, and used the difference as the error. Another difference between our measurement methodology and the shared methodology of both Cobb et al.<sup>13</sup> and Dunbar et al.<sup>14</sup> was that those two studies each used postoperative CT to facilitate a surface shape match of the three-dimensional CAD files of the implanted components and the three-dimensional image of the actual implanted components. Our technique essentially used each postoperative CT to create two-dimensional images projected on anatomic axes that were defined from the three-dimensional CT. Despite these differences in the measurement of error and the differences in the robotic systems utilized, those two studies and our current study all showed improved accuracy with robotic-assisted surgical techniques.

In our study, despite the overall improved accuracy achieved using robotic assistance, there were a small number of outliers with implant positions beyond that which would have been anticipated. Postoperative CT measurements for outlier cases in both groups were verified by a second observer to ensure that they had not resulted from measurement errors. Both observer measurements were consistent, suggesting that the errors were not related to measurement methodology. It was not possible to identify with certainty the source of these errors, but we hypothesized that they may have resulted from small movements in the optical trackers attached to the tibia or the femur during the surgical procedure, or, alternatively, it was possible that small errors in initial segmentation of the preoperative CT images and identification of osseous landmarks may have resulted in small errors in implant positioning. The preoperative CT images used in this study were segmented and osseous landmarks were identified by a member of the research team. Our measurement method assumed that the evaluator of the postoperative CT chose the same osseous landmarks as the operator who performed the initial preoperative segmentation. Similar occasional outliers have been reported previously<sup>13</sup>. In addition, the robotic system converted the planned implant position to osseous preparation through the haptic guidance of the cutting tool. We did not directly measure the accuracy of the cut

surfaces, but instead measured the final placement of the cemented components. Neither final component placement nor cementing is controlled, tracked, or measured by the robotic system.

We acknowledge that there were limitations in our study. Although, intuitively, improvement in the accuracy of component positioning in unicompartmental knee arthroplasty would have been expected to be beneficial, improved accuracy of component implantation has not yet been shown to lead to improved clinical performance or survivorship. Although we found good intraobserver agreement in the measurement of the component alignment parameters using postoperative CT scans, the potential for error existed between the identification of anatomic landmarks in the preoperative and postoperative CT scans by the research engineer and investigators. Additionally, with the observers being aware of the treatment group assignment, a substantial potential for detection bias existed.

In summary, we demonstrated that the robotic-assisted surgical procedure provided more accurate implantation compared with a conventional surgical technique. Although this was an intuitive result, it was important to verify the manufacturer's claims. The potential for detection bias limited the strength of this conclusion. Although we demonstrated increased accuracy, further follow-up of the study cohort is required to determine if the improved accuracy of component positioning results in improved clinical outcomes. ■

NOTE: The authors acknowledge the contribution of Dr. Julie Wells, Arman Moteshareh, and Sister Rachael Halifax. They also thank Gavin Douglas and the illustration department at Glasgow Royal Infirmary for assistance with the figure illustrations.

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