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Title

Improved accuracy of component positioning with robotic assisted unicompartmental knee arthroplasty: Data from a prospective, randomised controlled study.

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Introduction

Unicompartmental Knee Arthroplasty (UKA) currently comprises between 8 and 10% of all knee arthroplasty procedures performed in England and Wales and the United States of America ^{A B}. The potential advantages of UKA over total knee arthroplasty (TKA) include improved functional outcome, proprioception and gait, faster recovery and less blood loss ^{C D E H I}. However higher revision rates have been reported in patients with UKA compared to TKA ^{G J}. Several factors have been proposed for the higher failure rates in UKA including postoperative limb malalignment and poor implant positioning ^{K L M}. The accuracy and reproducibility of implant positioning appears to be important to the longevity of UKA and thus techniques that improve accuracy may lead to improvement in UKA survival.

Recently robotic assisted surgery has been introduced as a surgical technique to improve the accuracy of implant positioning. Cobb reported a prospective randomised control trial on 27 patients using the Acrobot system (The Acrobot Co. Ltd., London, UK) with the mobile bearing Oxford UKA, citing improved accuracy in

the coronal plane compared to conventional techniques^N. The Acrobot system is a statically referenced technique requiring rigid fixation of the patient's leg to a stereotactic frame throughout the procedure. Initial studies using the first generation MAKO Robotic Tactile Guidance System (TGS) system have also shown improved accuracy in the coronal and sagittal planes compared to conventional controls^O. The accuracy of the second generation MAKO Robotic Interactive Orthopaedic Arm (RIO) system (MAKO Surgical Corporation, Fort Lauderdale, FL, USA) has not been investigated previously in a prospective randomised controlled study. The MAKO RIO system uses a dynamic referencing guidance system and preoperative computerised tomography (CT) data to facilitate preoperative surgical planning from a 3D model of the patient's knee^F. Our hypothesis was that robotic assisted surgery would give increased accuracy of UKA implant positioning compared to conventional surgery.

We report data from a prospective, randomised, single blinded, controlled trial comparing the accuracy of component positioning assessed by 2 dimensional CT scanning between robotic assisted and conventional UKA.

Patients and Methods

139 patients who were awaiting UKA for medial compartment osteoarthritis were recruited to the trial between October 2010 and November 2012. Randomisation was performed using an online web interface provided by the Roberts Centre for BioStatistics (University of Glasgow). Patients were randomised to either conventional surgery or robotic assisted surgery, with stratification by surgeon.

The MAKO Robotic Interactive Orthopaedic Arm (RIO) system (MAKO Surgical Corporation, Fort Lauderdale, FL, USA) was used in the robotic assisted group implanting the Restoris MCK fixed bearing unicompartmental knee.

The conventional surgical arm of the trial used the Phase III Oxford mobile bearing UKA implanted with the standard manual instruments.

The clinical trial was given prior approval by the West of Scotland Research Ethics Committee. Patients were blinded to the treatment given and all operations were performed at our institution by one of three senior authors.

Patients were excluded if there was radiological evidence of osteoarthritis affecting the lateral compartment or lateral facet of the patellofemoral compartment, the anterior cruciate ligament was deficient, a fixed flexion deformity was present of more than 10 degrees or a fixed varus deformity of more than 10 degrees.

The study consort diagram is given in Figure 1. 139 patients were recruited, of these 120 patients (62 Robotic Assisted and 58 Manual Surgery) attended for post-operative CT scans and had data available for analysis in this accuracy study. Patient demographics are presented in Table I.

Surgical technique

Preoperative CT scans were performed in each of the patients randomised to a MAKO UKA as requisite to the preoperative surgical planning. This preoperative CT data then underwent a process of segmentation by a trained technician which was used to build a 3D CAD model of the patient's knee to allow planning of component position prior to surgery. The operating surgeon defined the size and position of the femoral and tibial components to be inserted in the preoperative plan, optimising bone

coverage, restoring joint anatomy and minimising bone resection. Implant alignment was therefore tailored to each individual patient. Using the preoperative plan, the MAKO system calculates the volume of bone requiring resection and creates a 3D haptic 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 pre-determined zone is resisted by the robotic arm using tactile resistive feedback and audio signals; with complete burr shut down if the cutting tool is forced outside the zone.

The system uses optical motion capture technology to dynamically track marker arrays fixed to the femur and tibia, which are mounted through separate stab incisions. This provides dynamic referencing of the femur and tibia and therefore allows the 3D haptic bone resection volume to move with the limb as it is moved by the surgeon.

Visual feedback is given to the surgeon by the on screen CAD images and tactile feedback is provided by the robotic arm (Fig 2). The Restoris MCK implant consists of a cobalt chrome femoral component, a titanium tibial component with a fixed bearing polyethylene insert.

The conventional UKA operations were carried out using standard instrumentation and the Oxford Phase 3 UKA (Biomet). The Oxford UKA consists of a cobalt chrome femoral and tibial implant and a fully congruent polyethylene mobile bearing.

The standard instrumentation jigs result in fixed target values for all patients, without the opportunity for tailoring of implant position to each patient's anatomy. Target values for implantation were obtained from the Biomet Operating Technique manual for the instruments and implants that were used.

Post-operative CT scans

All patients had a CT scan at 3 months post-surgery, using the protocol specified below. All CT scans were performed on a single scanner at the Nuffield Hospital (Glasgow).

CT scan protocol:

Imaging of three regions: hip, knee and ankle as detailed below.

	Hip	Knee	Ankle
kV	100	100	100
mAs	80	100	45
Scan length	~ 50 mm	~200mm	~ 50 mm
Collimation	4 mm	1 mm	4 mm
FOV	Includes femoral head	Must include 100mm above and below the joint-line between the femur and the tibia	Must include the talus and distal tibia

The postoperative CT scans were saved as Digital Imaging and Communication in Medicine (DICOM) format ^S before being loaded to the Mimics software (Materialise NV, Belgium) to render a 2D model for analysis and calculation of component position. Analysis was undertaken by an independent researcher based at the University of Strathclyde. The conventional UKA group had fixed targets which were identical for all patients and which were determined by the manual instrumentation. The target values used were taken from the manufacturer's recommendations. In the robotic assisted group the target values for the component position varied between the individual patients and were dependent on optimising bone coverage, restoring joint anatomy and minimising bone resection.

Accuracy of component positioning was determined on the post-operative CT scan by comparing the target positioning values in the pre-operative plan with the actual

values achieved post-operatively. Accuracy was therefore determined by the degree of deviation from the preoperative planned target values rather than the absolute values of the component position. Effectively it is therefore a measure of how well each technique delivers the pre-operative surgical plan.

The implant position was calculated for the femoral and tibial components in the sagittal, coronal and axial planes. The mechanical axes of the femur and tibia were identified from the centre of the hip and the centre of the knee for the femoral mechanical axis and centre of the knee and the centre of the ankle for the tibial mechanical axis.

Sagittal Alignment

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

Coronal Alignment

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

Axial Alignment

To measure the axial alignment of the femoral component the surgical transepicondylar axis (STEA) was first identified as a line connecting the centre 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 STEA and the posterior condylar axis of the implant. This method was used to calculate femoral

rotations of both MAKO and Oxford implants. The MAKO system software algorithm uses the STEA to determine femoral rotation, whilst the rotation of the Oxford component is controlled using the mechanical axis of the tibia with the knee at 90 degrees of flexion. Although there are no specific target values set for rotation of the Oxford components, the STEA is effectively perpendicular to the tibia when the knee is flexed to 90 degrees allowing us to use this measure for the Oxford implant also.

The MAKO tibial rotation measured again replicated the software algorithm and was calculated from the angle between the AP axis of the tibial implant and the line connecting the posterior cruciate ligament and the medial third of the tibial tubercle.

Oxford tibial rotation is controlled by the manual instruments by the femoral mechanical axis with the knee flexed at 90 degrees. Again this is effectively perpendicular to the STEA and so tibial rotation was calculated as the angle between the anteroposterior (AP) axis of the tibial implant and the STEA.

Power Calculation

The minimum detectable difference using our measurement methodology is 1 degree. Based on previous CT accuracy studies carried out by the same authors in Total Knee Arthroplasty, the mean deviation from target value for tibial sagittal positioning is 4 degrees. Assuming similar levels of accuracy for Unicompartamental Knee Replacement we would require 126 patients in order to detect a difference of 1 degree with a power of 80% ($\alpha 0.05$). Detection of larger differences would require a smaller sample size or would have >80% power with the given sample size. In order to allow for loss to follow-up we have allowed an additional 24 patients, giving a total target recruitment of 150 patients (75 in each group).

Statistical analysis. Statistical analysis was carried out using Graph Pad Prism 5 (GraphPad Software Inc). Fisher's Exact test and the Chi square test were used to compare categorical data. Mann Whitney Test was used to compare continuous variables that were not normally distributed. The level of significance was set as a p-value of <0.05 for all analyses.

Intraclass Correlation Coefficients were calculated using SPSS vs 20 (IBM Corporation).

Results

The intraclass correlation coefficients (ICC) for intra-observer agreement regarding the measurements of the component alignment parameters was checked; see Table II. The ICC 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 group compared to the conventional group (Table III).

Robotic assistance resulted in statistically significantly lower median errors for all three femoral component parameters (Sagittal, Coronal and Axial) and all three tibial components. The greatest difference between errors was identified in the tibial component axial alignment of 3.2 degrees ($p=0.0001$). The results are presented in Table IV.

The distribution of the errors for the component alignment parameters are presented as categorical data graphically (Figure 3 a-f). The proportion of patients with component implantation errors within two degrees of the target position was significantly greater in the robotic surgical group in all of the alignment parameters other than the Coronal plane for the Tibial implant (Table V).

Discussion

We have demonstrated improved accuracy of implant positioning in UKA using robotic assisted surgery with the MAKO RIO system compared with conventional surgery.

In our study we have used the Phase III Oxford UKA implant with the standard manual instrumentation in the conventional surgery 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 UKA was used as the comparator because the senior authors have experience using this implant technique and because it is the most commonly used UKA implant in the UK National Joint Registry ^A.

Postoperative limb malalignment and poor implant positioning have been implicated as a cause of early failure in UKA surgery. In our study, the bearing types differ between the two implants with MAKO using a fixed bearing and Oxford a mobile bearing. The mobile bearing has a more conforming surface than the fixed bearing with theoretically improved wear characteristics. The conforming geometry of the bearing might also suffer less from the edge loading effects which can be observed with fixed bearing designs that are poorly implanted ^T. Accurate component alignment is important however in the prevention of mobile bearing dislocation ^U. It is

not clear at this stage whether the improved accuracy of the surgery seen in the robotically assisted group will translate into improved joint survivorship in the longer term.

This study shows that robotic assisted surgery with the MAKO RIO system had greater accuracy of component positioning with significantly less deviation from the target pre-operative plan in all three parameters (sagittal, coronal and axial) for both the tibial and femoral components.

The finding of increased accuracy with robotic assisted UKA surgery is consistent with the findings of a smaller RCT comparing a different robotic assisted system, the Acrobot robotic assisted system ^N. This study found that robotic assisted surgery achieved greater accuracy compared to conventional surgery using the Oxford UKA with all patients studied achieving coronal tibiofemoral alignment within two degrees of the planned position. The methodology for the measurement of the component error using pre and postoperative CT scan data differed to that employed in our study. They measured the distance of error (translation error) between the preoperative plan and the postoperative component position and mathematically converted this to an angular value. Our methodology differed in that we measured the angle of the component position with respect to the mechanical axes of the femur and tibia respectively and compared this to the preoperative planned 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 ^N and Dunbar et al ^O. is that the latter two studies used each post-operative CT to facilitate a surface shape match of the 3D CAD files of the implanted components and the 3D image of the actual implanted components. Our technique essentially used each post-

op CT to create 2D images projected on anatomic axes that were defined from the 3D CT. Despite these differences in the measurement of error and the differences in the robotic systems utilised, all three studies showed improved accuracy with robotic assisted surgical techniques.

Improved accuracy using the MAKO system has been reported in a previous case series of 20 patients⁹. They reported RMS errors within 3 degrees for all the femoral component alignments and mean tibial and femoral RMS errors of 1.5 and 2.6 degrees respectively.

In our study, despite the overall improved accuracy of implantation achieved using robotic assistance, there were a small number of outliers with implant positions beyond that which would have been anticipated using this system. Post-operative 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 has not been possible to identify with certainty the source of these errors, but we hypothesise that they may have resulted from either small movements in the optical trackers attached to the tibia or femur during surgery, or alternatively it is possible that small errors in initial segmentation of the pre-operative CT images and identification of bony landmarks may have resulted in small errors in implant positioning. The pre-operative CT images used in this study were segmented and bony landmarks identified by a member of the research team (a non-MAKO employee). This work was undertaken by three individuals over the course of the study, on average each individual performed just 1 case per month during the recruitment phase of the study. **The MAKO system is currently predominantly used**

in the United States where segmentation and landmark identification is undertaken by MAKO employees who carry out significantly more cases per month and are therefore potentially less likely to generate errors. Also, our measurement methodology assumes that the evaluator of the post-operative CT chose the same 3D dimensional position of the bony landmarks defining the 2D anatomic axes upon which the errors are measured as the operator who performed the initial pre-operative segmentation. Similar occasional outliers have been noted with the Acrobat Robotic UKA system reported by Cobb et al^N.

In addition, the robotic system converts the planned implant position to bony 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 are controlled, tracked or measured by the robotic system.

We have demonstrated that robotic assisted surgery provides more accurate implantation compared to manual surgery using traditional surgical jigs. Although this is an intuitive result, it is important to verify the manufacturer's claims. Increased accuracy of implantation brings theoretical benefits to patient outcome and longevity of implants. While we have demonstrated increased accuracy, further follow-up of the study cohort is required to determine if this results in improved clinical outcomes.

Table I - Patient demographics

	MAKO (n=70)	Oxford (n=69)	p value
Age, mean, (stdev)	62.5 ± 6.9	61.7 ± 7.9	0.548

Gender	1.17:1	1.29:1	0.860
Side	38L:30R	42L:27R	0.605
Diagnosis of osteoarthritis	100%	100%	1.0

Table II - Intraclass correlation for individual component alignment measurements

	Intraclass Correlation	95% Confidence Intervals
Femoral Sagittal	0.974	(0.889-0.997)
Femoral Coronal	0.982	(0.924-0.998)
Femoral Axial	0.750	(0.457-0.993)
Tibial Sagittal	0.764	(0.584-0.989)
Tibial Coronal	0.836	(0.727-0.993)
Tibial Axial	0.959	(0.832-0.995)

Table III - Root Mean Square (RMS) Errors

	Robotic Assisted MAKO RIO UKA	Conventional Oxford UKA
Femur Sagittal	3.35	6.87
Femur 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

Table IV - Component Median Implantation Errors

	Robotic Assisted Median Error (Degrees)	Conventional Median Error (Degrees)	P Value
Femur Sagittal	1.9	3.9	0.0001
Femur Coronal	1.4	4.1	0.0001
Femoral Axial	1.9	3.6	0.0001
Tibial Sagittal	1.0	3.7	0.0001
Tibial Coronal	1.6	2.7	0.0089
Tibial Axial	2.2	5.4	0.0001

Table V – Proportion of patients with implants positioned within 2 degrees of the target value

	Robotic Assisted	Conventional	P Value
Femur Sagittal	57%	26%	0.0008
Femur Coronal	70%	28%	0.0001

Femoral Axial	53%	31%	0.0163
Tibial Sagittal	80%	22%	0.0001
Tibial Coronal	58%	41%	0.097
Tibial Axial	48%	19%	0.0009

Figure 1: CONSORT Diagram

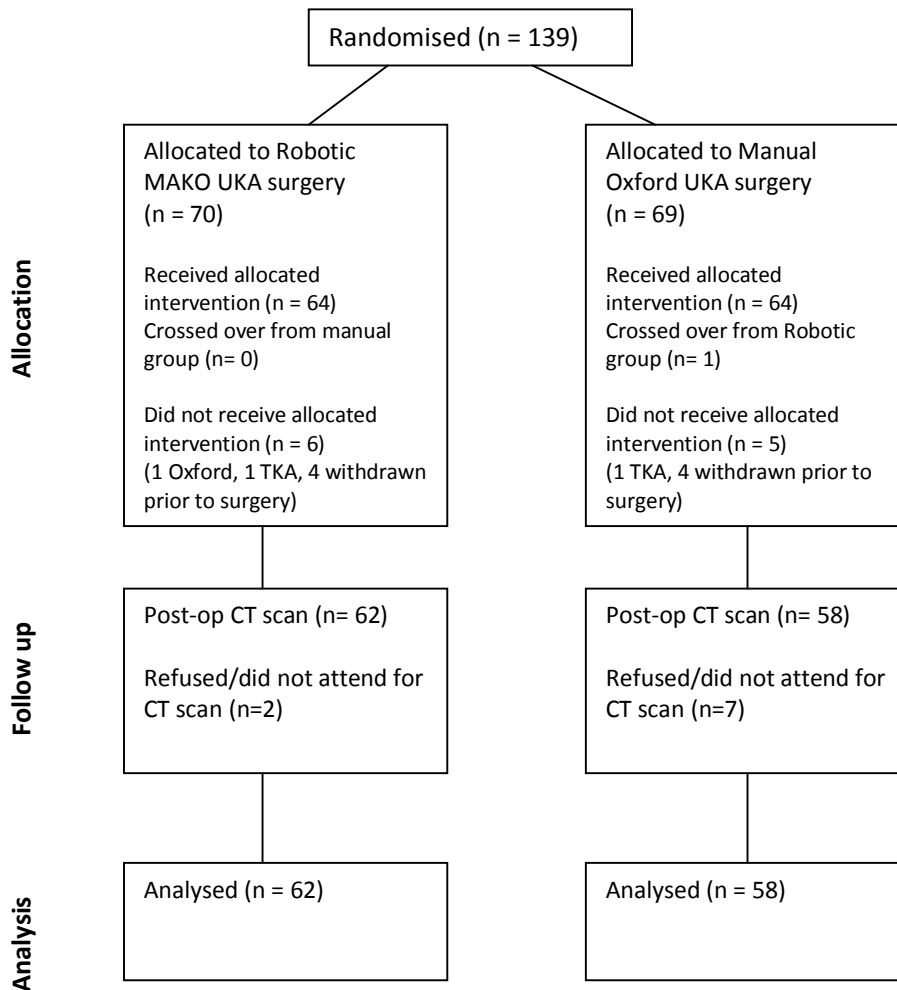


Figure 2 CAD image screen shot (left) from the RIO system (right); bone still to be resected is identified in green on the screen shot.



Figure 3a

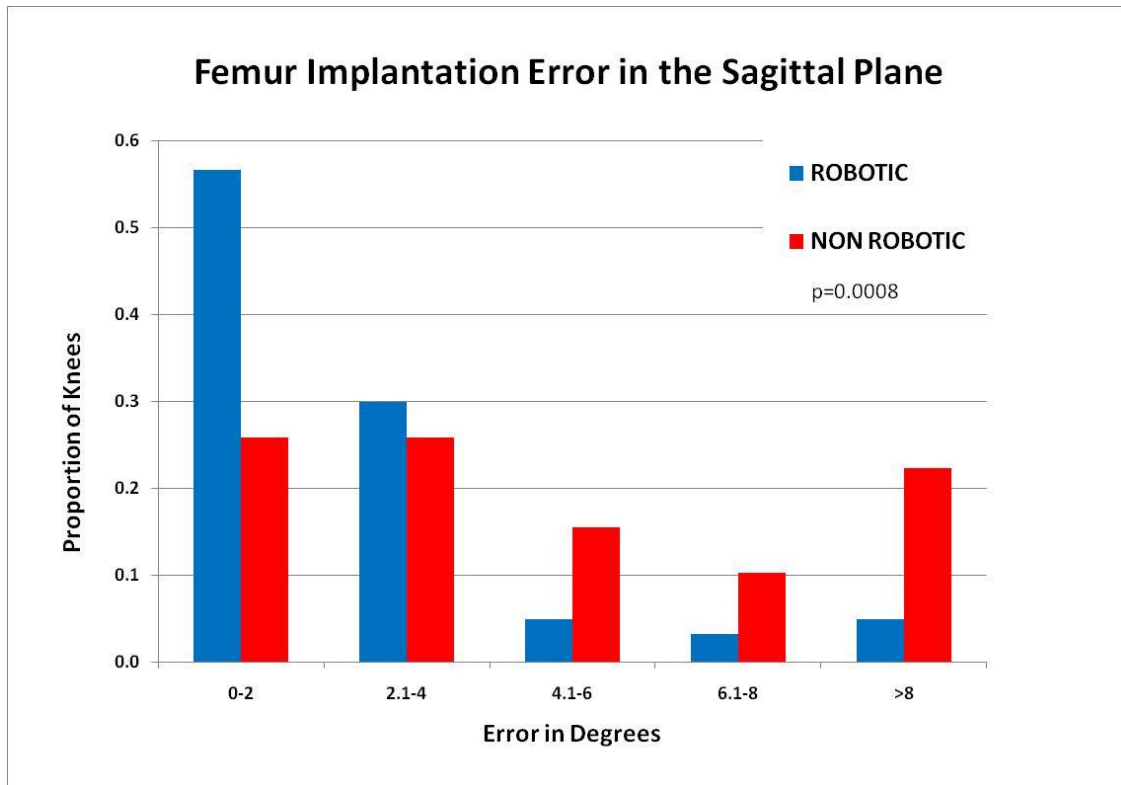


Figure 3b

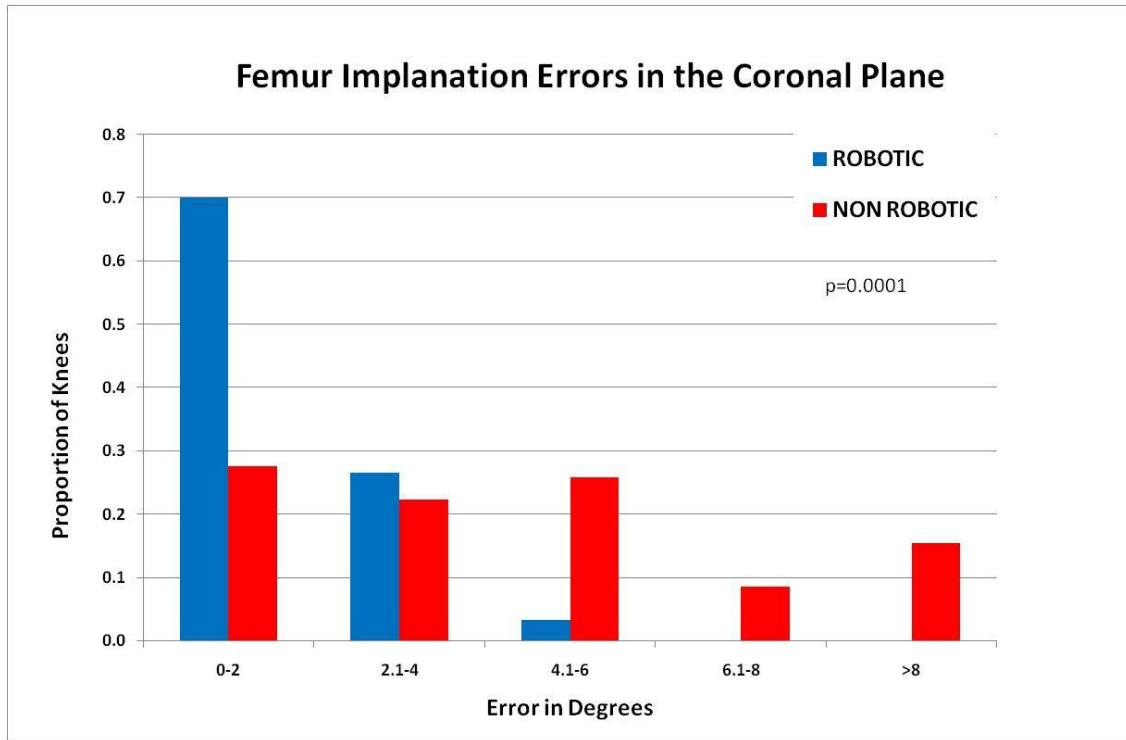


Figure 3c

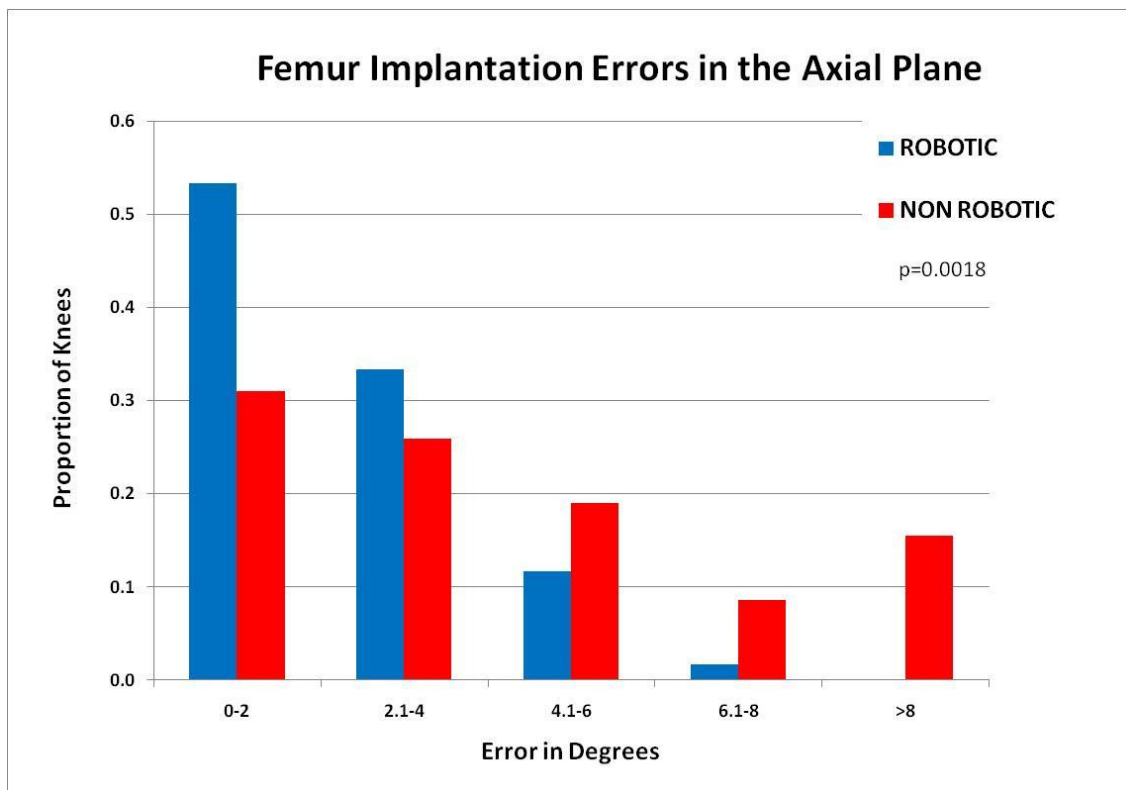


Figure 3d

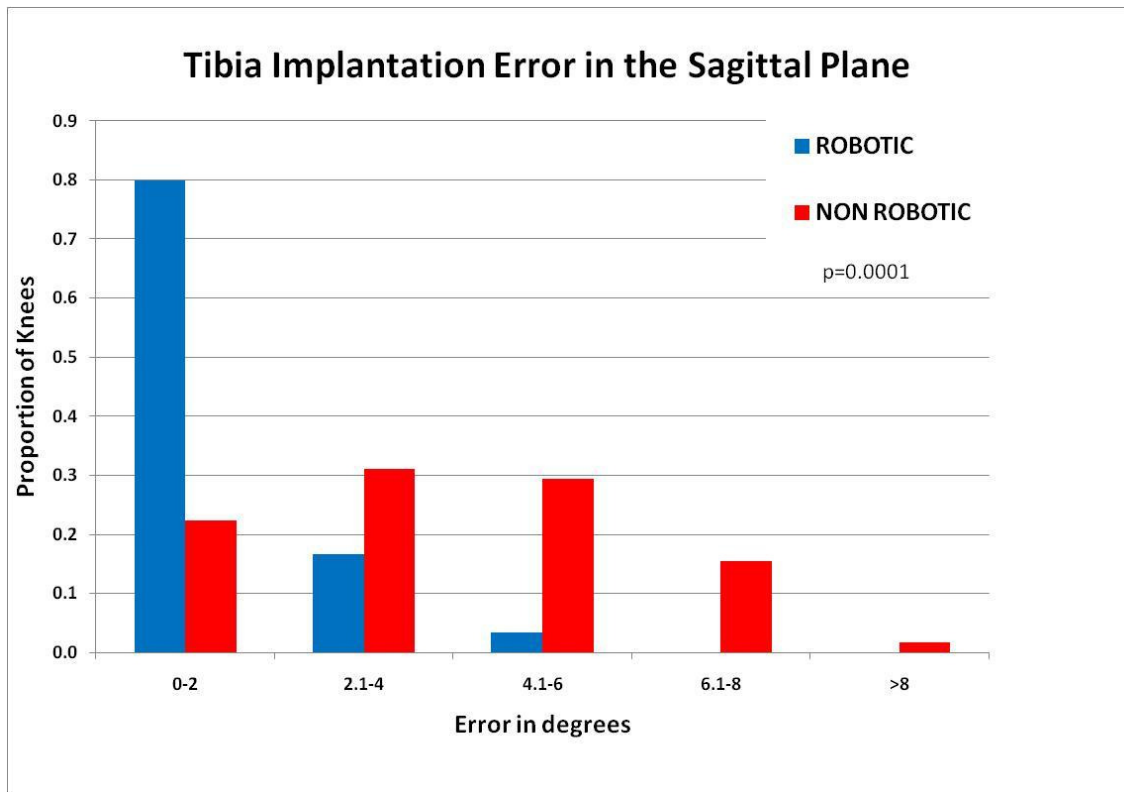


Figure 3e

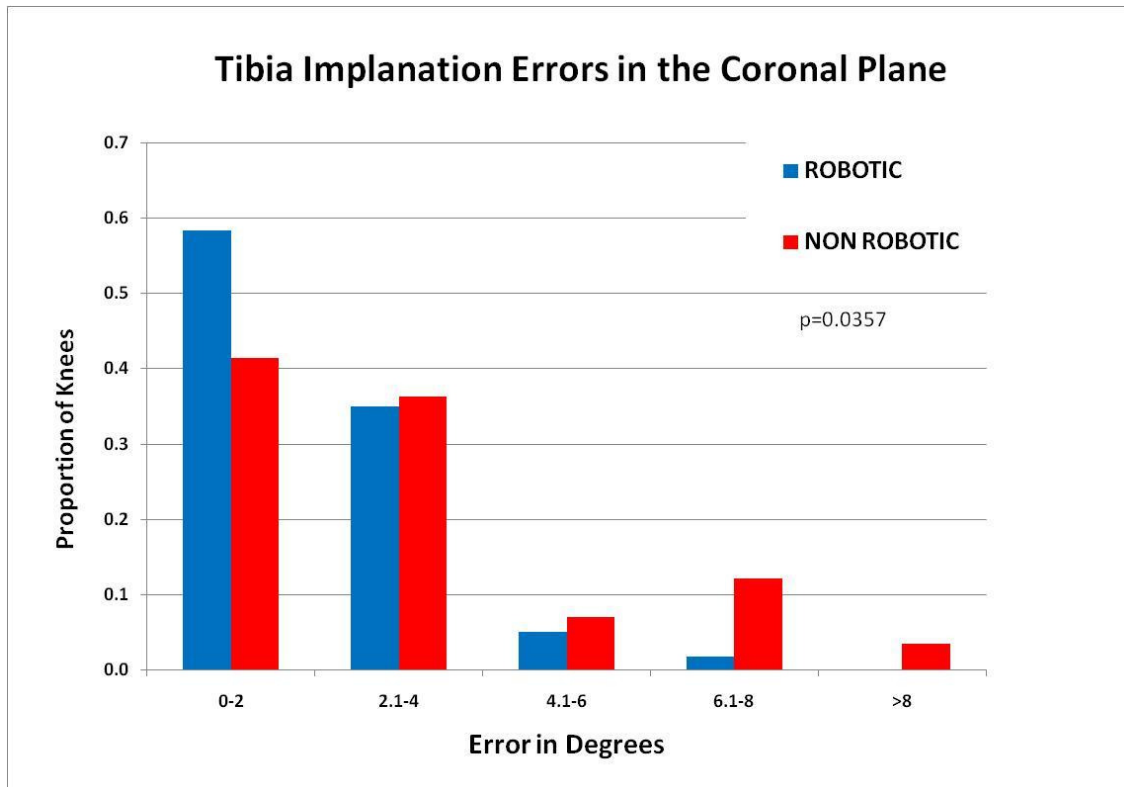
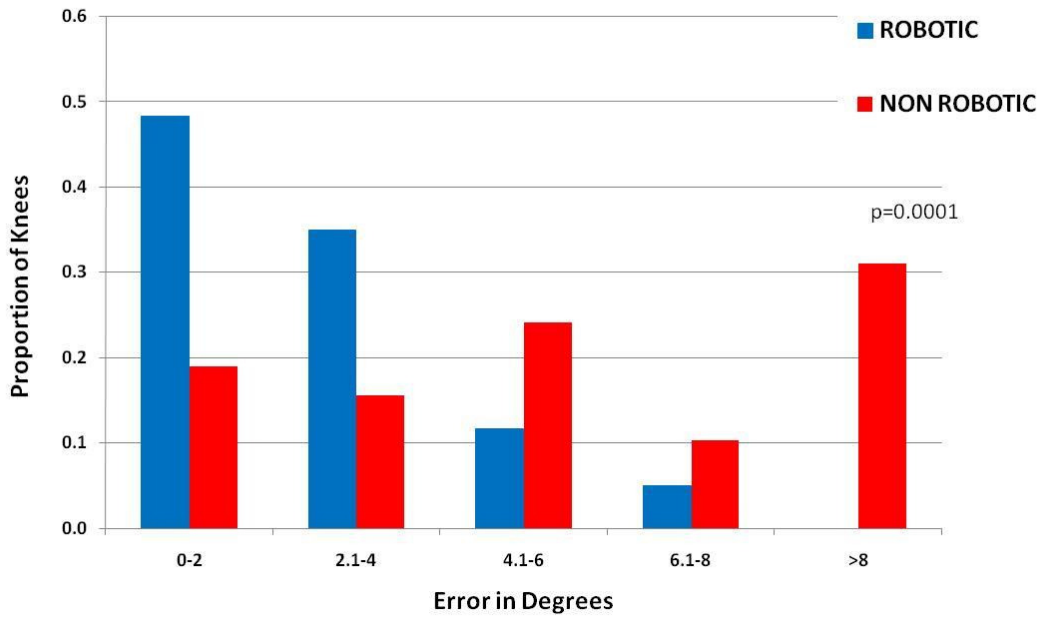


Figure 3f

Tibia Implantation Errors in the Axial Plane



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