Title: Robotic-Arm Assisted Versus Conventional Unicompartmental Knee Arthroplasty. The 2 year Results of a Randomised Controlled Trial.

Gilmour A, MacLean A, Rowe P, Banger M, Donnelly I, Jones B, Blyth MJ

Background:

Unicompartmental knee arthroplasty (UKA) for treatment of medial compartment osteoarthritis has many potential benefits over total knee arthroplasty but is recognised to have a higher revision rate. Robotic assisted UKA is increasingly common and offers more accurate implant positioning, improved alignment and lower early post-operative pain but there is little evidence on improved functional outcomes.

Methods:

The aim of this study was to compare the secondary outcome measures of a single centre, prospective, randomised controlled trial comparing robotic-arm assisted UKA with conventional 'manual' surgery. 139 participants were recruited and underwent either robotic-arm assisted or conventional UKA. At 2 years there were 58 patients in the robotic-arm assisted group and 54 in the manual group. The main outcome measures for this study were the Oxford Knee Score (OKS), American Knee Society Score (AKSS) and revision rate.

Results:

At 2 years, there were no significant differences between the cohorts for any of the outcome measures studied. Sub-group analysis (n=35) of participants with a pre-operative UCLA score >5 (more active) was performed. In this sub-group, the median OKS was 46 (IQR 6) for robotic-arm assisted and 41 (IQR 5.5) for the manual group (p=0.009). The median AKSS was 193.5 (IQR 14.0) for the robotic-arm assisted group and 174.0 (IQR 22.5) for the manual group. Survivorship was 100% in robotic-arm assisted group and 96.3% in the manual group. 29.3% of the robotic-assisted group were 'painfree' at 2 years, compared to 15.7% of the manual group (p=0.121).

Conclusions:

Overall, participants achieved an outcome equivalent to the "gold-standard" UKA in the UK. Sub-group analysis suggests that more active patients may benefit from robotic-arm assisted surgery but this study is not powered to substantiate this observation. The outcome scores are affected by ceiling effect and may lack the ability to identify any difference in functional outcome. The improved survivorship in robotic-assisted patients is promising, but long-term follow up is required.

Level of Evidence:

Level 1

INTRODUCTION

Unicompartmental knee arthroplasty (UKA) as a treatment for medial compartment osteoarthritis (OA) has many potential advantages over total knee arthroplasty (TKA), including restoration of normal knee kinematics (1), less blood loss (2), less post-operative morbidity (3) and accelerated recovery (4).

Despite these potential advantages, the long-term survivorship of UKA is not as good as that of TKA (5, 6). UKA is known to be technically challenging and errors of alignment and implant positioning (7-9), along with patient selection and thresholds for revision (10) may contribute to the lower recorded survivorship. Consistent with these observations is that high-volume units and surgeons have achieved improved survivorship in comparison to low-volume institutions (11, 12) .

In recent years, there has been a significant uptake of robotic-assisted surgery. Early evidence has suggested that robotic-assisted surgery delivers more accurate implant positioning (13-16), improved kinematic alignment (17, 18), improved soft tissue balancing (19), lower post-operative pain (20) and improved early survivorship (21), compared to conventional surgery. However, there is a lack of randomised controlled trial (RCT) evidence to support the potential benefits to patients of robotic-assisted UKA.

MATERIALS AND METHODS

Objectives

The aim of this study was to compare the secondary outcome measures of a RCT comparing robotic-arm assisted UKA with conventional surgery.

Trial Design

The trial was originally designed as prospective, randomised, parallel, single-centre study comparing surgical alignment in patients undergoing UKA for the treatment of medial compartment osteoarthritis (OA). Participants underwent surgery using either the robotic-arm assisted surgery or conventional manual instrumentation.

The primary outcome measure (surgical accuracy) has previously been reported (16), as has the 1 year secondary exploratory analysis (20). The 2-year analysis of secondary outcome measures and clinical follow-up is now presented.

139 patients were recruited at Glasgow Royal Infirmary (Glasgow, UK) between October 2010 and December 2012. All patients had been listed for a UKA to treat medial OA and were recruited by a research associate. Eligible patients were those deemed suitable for UKA surgery by a senior surgical author, could give informed consent and attend the prescribed follow-up. Exclusion criteria included those with ligament insufficiency, inflammatory arthritis, a deformity requiring augmentation, neurological movement disorders, pathology of the feet, ankles, hips or opposite knee causing significant pain or gait alterations and those who ultimately required a TKA.

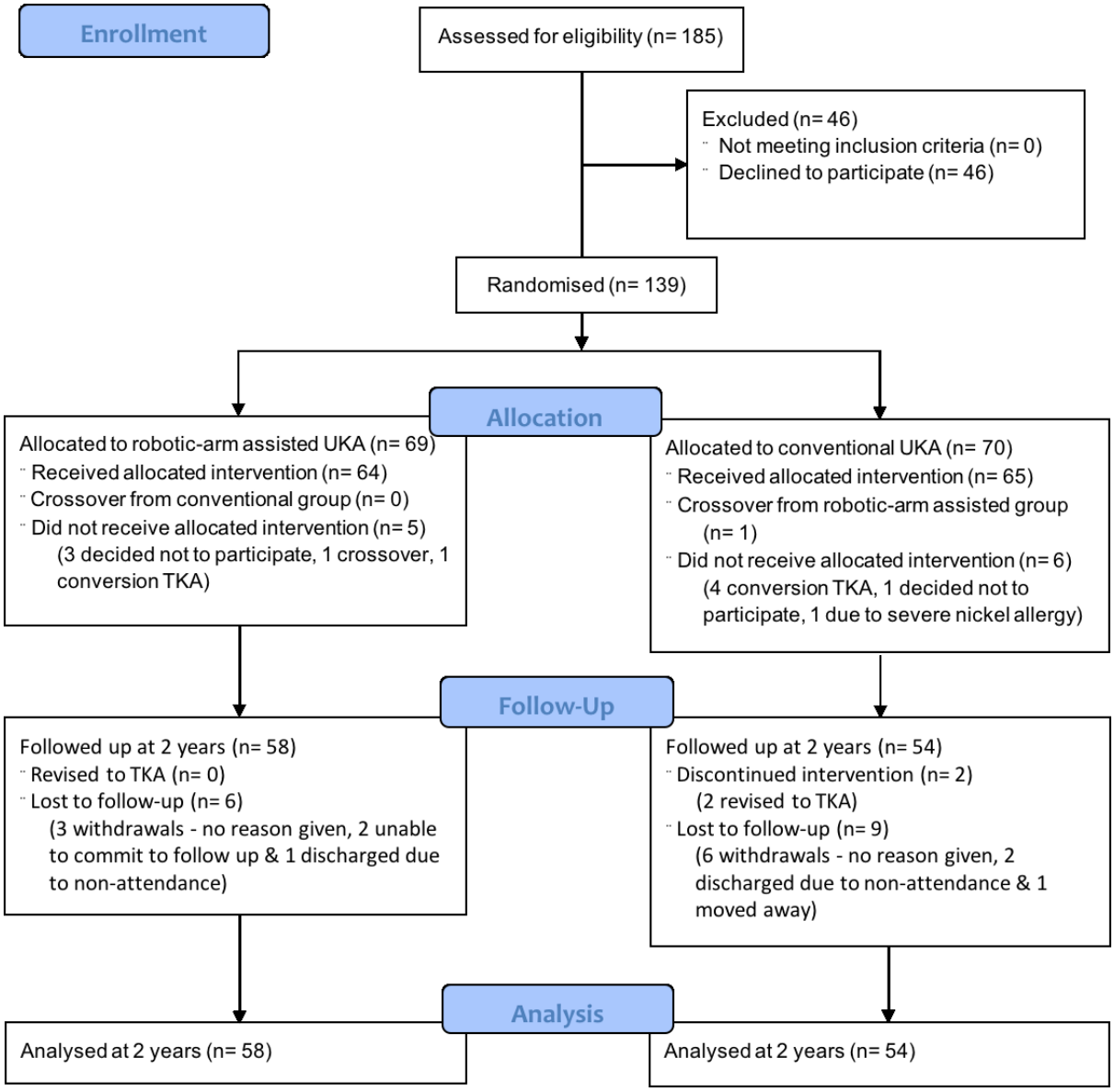

Figure 1. CONSORT flow diagram

Randomisation and blinding

The Robertson Centre for Biostatistics, University of Glasgow, facilitated online randomisation. The study was intended to be single blinded as participants and research staff were not informed of randomisation. Only the surgeon and operating team were aware. Staff assessing outcomes were also blinded.

Of the 185 patients eligible for the study, 69 were randomised to the robotic-arm assisted cohort and 70 to the manual cohort. 64 participants underwent robotic-arm assisted surgery and 65 manual surgery. At 2 years, follow up data were available for 58 participants in the robotic-arm assisted cohort and 54 in the manual cohort and all of those were included in the analysis (Figure 1).

Treatment

Patients received either an Oxford Phase 3 (Biomet, Warsaw, Indiana, USA), implanted using Phase 3 instrumentation or a Restoris MCK (Mako Surgical Corp., Fort Lauderdale, Florida, USA) using the Mako Robotic-Arm Interactive Orthopedic (RIO) system. Surgery was performed by one of the 3 senior surgical authors, all of whom are specialist knee surgeons with at least 5 years' experience in independent practice.

Surgical technique

Oxford Phase 3: The implant sizes were selected based on pre-operative templating. A paramedial quadriceps sparing incision and approach were utilised and UKA performed using the conventional instrumentation, in accordance with the operative technique. A vertical tibial cut was performed using a hand-held reciprocating saw, with reference to the tibial cutting guide and appropriate anatomical landmarks. The horizontal tibial cut was performed using an oscillating saw. An intramedullary reference was used to position the femoral cutting guide and the posterior femoral cut made using an oscillating saw. The distal femur was milled and the flexion/extension gaps balanced. The bone surfaces were prepared and the cobalt chrome implants cemented with a mobile polyethylene bearing inserted.

Robotic-arm assisted: A pre-operative CT was performed and a 3D computer (CAD) model of the knee was constructed by a trained technician. Implants were then positioned on the CAD model pre-operatively aiming to minimise bone resection and restore the joint anatomy. The system calculates the 3D bone resection volume or haptic required. A similar paramedial quadriceps sparing incision and approach were utilised. Reflective marker arrays were positioned on the tibia and femur via separate stab incisions. Anatomical landmarks were recorded using optical motion capture technology to map the CT data to the surgical field and allow dynamic referencing of the tibia and femur. Joint balancing with re-tensioning of the medial collateral ligament was then carried out, before final orientation of the position of the implants on the CAD model. The robotic-arm was fitted with a high-speed, saline cooled burr, directed by the surgeon, removing planned areas of bone. Tactile, visual and audio feedback are provided to prevent bone resection beyond the predetermined haptic volume. The joint surfaces were prepared and implants cemented. The Restoris MCK consist of a titanium tibial component, fixed polyethylene bearing and a cobalt chrome femoral component.

Follow-up

Data was collected at 3 months, 1 year and 2 years post-operatively. All trial data were collected by a blinded independent Research Associate/Research Nurse at Glasgow Royal Infirmary.

Power Calculation

The original study was powered to detect a 1° difference in tibial sagittal positioning with 80% power (a=0.05), based on 126 patients. The target recruitment was 70 patients in each group, allowing a loss to follow-up rate of 10%. As this study represents exploratory analyses of secondary outcomes, a post-hoc power calculation has been performed (a=0.05). With the AKSS (SD 26.4), 56 patients per group would have a power of 51% detect a difference of 10 points. With the OKS (SD 8.2), 56 patients per group would have a power of 89% to detect a difference of 5 points.

Outcome measures

This paper reports the two year secondary outcome measures, which includes the Oxford Knee Score (OKS), American Knee Society Score (AKSS), Forgotten Joint Score (FJS), Pain Catastrophising Scale (PCS), Pain Visual Analogue Scale (PVAS), Stiffness Visual Analogue Scale (SVAS), patient satisfaction, range of motion (ROM), UCLA Activity Scale, complications and revision rates. The main outcomes for this secondary study were the OKS, AKSS and revision rate.

Statistical Analysis

Data were assessed for normality. Normally distributed continuous variables were compared using Student's T-test. Continuous variables without a normal distribution were analysed using the Kruskal-Wallis test. Chi-square test was used to compare categorical data. These analyses were performed using Minitab 16 (State College, Pennsylvania, USA).

A per protocol analysis was conducted. Patients converted to TKR did not continue in the trial, nor those who were revised. Therefore, intention to treat analysis was not feasible.

Study Oversight

The study complied with the principles of the Declaration of Helsinki and was approved by the local ethics committee of the West of Scotland research ethics service (10/S0704/12).

SOURCES OF FUNDING

This study was funded with an institutional support grant from Stryker Mako, who had oversight of the trial but no influence of data analysis nor the publication of the findings.

RESULTS

The CONSORT diagram in Figure 1 explains the outcome for those patients not included in the 2 year analysis. Two patients in the manual surgery group were revised to a TKA between 1 and 2 years, with no revisions in the robotic-arm assisted group during this period. One revision for persistent symptoms, the other for aseptic loosening with no positive microbiological culture. Both patients were treated with revision to a TKA.

	Robotic-assisted (n=58)	Manual (n=54)	
Age Mean (SD)	61.8 (7.84)	62.6 (7.13)	p=0.599
Sex M/F Ratio	1.23:1	1.08:1	-
AKSS (0-200) Mean (SD)	105.5 (27.4)	102.8 (24.6)	p=0.581
OKS (0-48) Median (IQR)	19.50 (11.3)	21.0 (8.5)	p=0.986
Pain VAS (0-100) Mean (SD)	52.7 (24.6)	55.1 (18.7)	p=0.575
Stiffness VAS (0-100) Mean (SD)	45.7 (24.66)	60.0 (20.15)	p=0.001*
HAD Depression (0-100) Median (IQR)	5.0 (5.3)	4.0 (4.3)	p=0.468
HAD Anxiety Median (IQR)	6.0 (5.3)	6.0 (5.3)	p=0.089
Pain Catastrophizing ScaleMedian (IQR)	13.5 (16.8)	11.0 (13.5)	p=0.984
UCLA Activity Score Median (IQR)	3.0 (1.5)	4.0 (3.0)	p=0.130
Range of Motion Median (IQR)	110.0 ^{O} (20.0)	115.0 ^{O} (20.0)	p=0.166

Table 1. Pre-operative demographics and outcome scores

There were no differences between the groups pre-operatively (Table 1), other than Stiffness VAS, which was significantly greater in the manual group. At 2 years, Stiffness VAS remained significantly higher in the manual group. The change in ROM pre to post-operatively was significantly greater in the robotic-arm assisted group. However, there were no significant differences between either group in any of the principal patient reported outcome measures. (Table 2).

	Robotic-assisted (n=58)	Manual (n=54)	
AKSS (0-200) Median (IQR)	168.0 (40.0)	173.0 (23.3)	p=0.951
OKS (0-48) Median (IQR)	39.0 (12.3)	40.0 (8.3)	p=0.965
FJS Median (IQR)	55.2 (58.5)	54.1 (42.2)	p=0.937
Pain VAS (0-100) Median (IQR)	3.0 (25.0)	5.0 (14.8)	p=0.533
Stiffness VAS (0-100) Median (IQR)	3.5 (24.3)	14.5 (27.2)	p=0.043*
Pain Catastrophizing Scale Median (IQR)	0.5 (7.25)	0.0 (2.0)	p=0.196
Range of Motion Median (IQR)	130.0^{O} (17.5)	125.0 ^{O} (10.0)	p=0.333
ROM Change Pre-operatively > 2years	+15 ^{O} (20.0)	+10 ^{O} (20.0)	p=0.040*
Revisions	0	2	-

Table 2. Year 2 clinical results for all participants

A sub-group analysis was performed of patients with a pre-operative UCLA activity score > 5 (Figure 2). There were 14 patients in the robotic-arm assisted and 21 in the manual groups. More active patients had significantly better outcomes at 2 years in the AKSS, OKS, FJS and Stiffness VAS, if they had undergone robotic-arm assisted surgery. There was no difference in median Pain VAS or PCS.

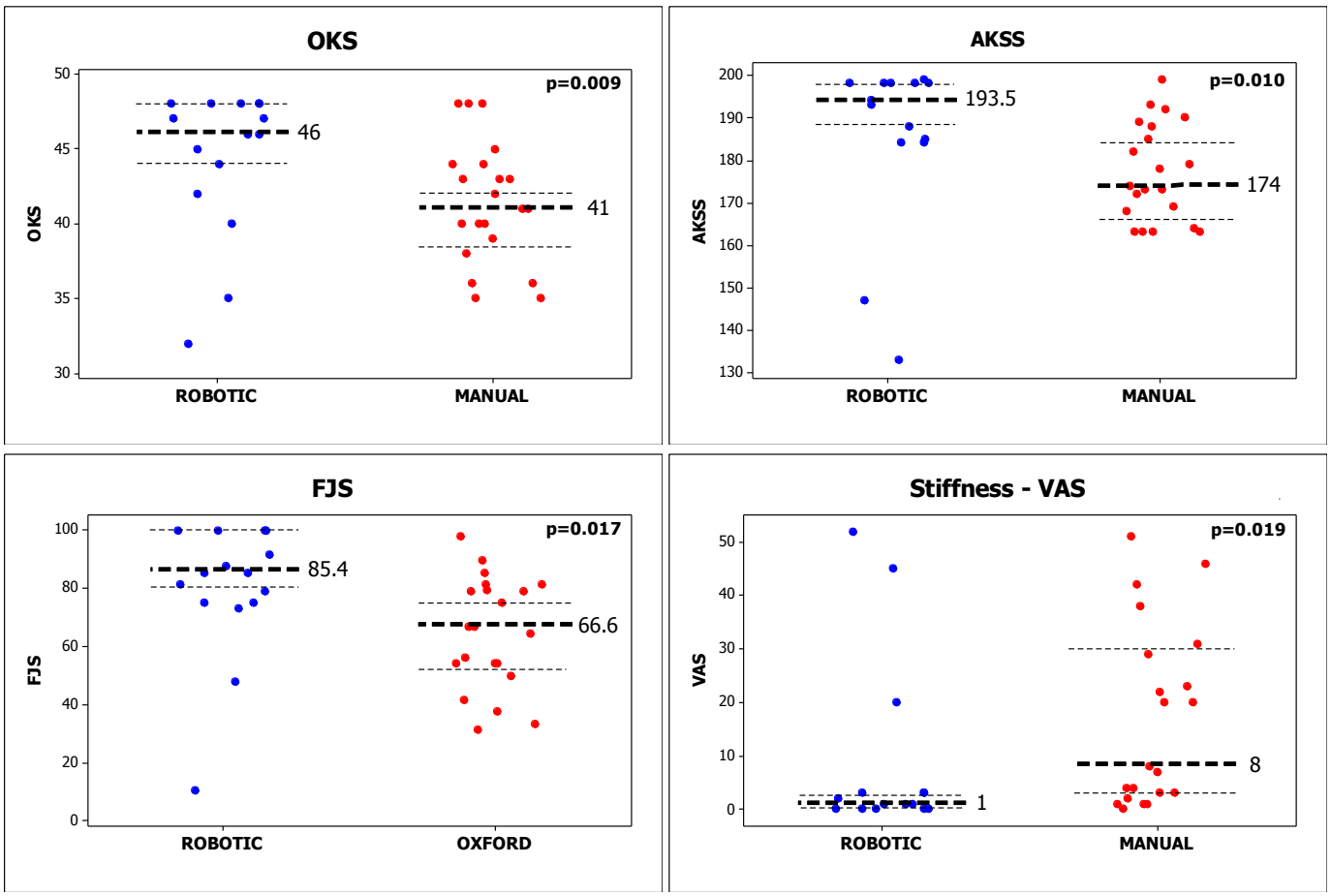

Figure 2. Year 2 median values and interquartile ranges for patients with pre-operative UCLA activity score >5.

	Robotic-assisted (n=25)	Manual (n=20)	
AKSS (0-200) Median (IQR)	174.0 (28.0)	178.0 (23.25)	p=0.697
OKS (0-48) Median (IQR)	40.0 (10.0)	40.5 (7.0)	p=0.553
FJS Median (IQR)	43.75 (55.21)	65.63 (38.75)	p=0.937
Pain VAS (0-100) Median (IQR)	2.0 (15.0)	5.0 (16.0)	p=0.568
Stiffness VAS (0-100) Median (IQR)	3.0 (21.5)	10.0 (29.0)	p=0.288

Table 3. Subgroup analyses of young patients (≤60 years of age).

Further subgroup analyses of younger patients (≤60) was performed but did not reveal any significant differences between the two cohorts. This is demonstrated in table 3. The number of "pain free" patients was calculated from the OKS using the methodology described by Dosset et al (22). 29.3% of the robotic-arm assisted cohort were classified as pain free versus 15.7% of the manual cohort but this was not statistically significant (p=0.088). Satisfaction was assessed using a 4-point scale (very satisfied, satisfied, unsatisfied or very dissatisfied), with respect to the participants return to recreational activities and their activities of daily living (ADL). 32.8% of robotic-arm assisted participants were 'very satisfied' with recreation vs 20% in the manual group (p=0.121). 46.6% of robotic-arm assisted participants were 'very satisfied' with ADLs vs 41.2% in the manual group (p=0.573).

Data were available for 12 participants who were included in the 1 year analysis but subsequently lost to follow up. There were no statistically or clinically significant differences in any outcome measure at 1 year in these patients compared to those who remained in the study. This is demonstrated in table 4.

	Study Participants (n=112)	Dropouts (n=12)	
AKSS (0-200) Median (IQR)	169.0 (40.0)	165.0 (53.3)	p=0.633
OKS (0-48) Median (IQR)	40.0 (12.0)	39.0 (21.25)	p=0.563
FJS Median (IQR)	56.25 (50.0)	40.63 (52.61)	p=0.179
Pain VAS (0-100) Median (IQR)	5.0 (17.75)	16.0 (61.75)	p=0.213
Stiffness VAS (0-100) Median (IQR)	8.5 (22.75)	22.5 (54.75)	p=0.122

Table 4. 1 year clinical outcomes of study participants at 2 year follow up and those who dropped out after 1 year.

DISCUSSION

This paper presents the secondary outcomes of a prospective RCT comparing robotic-arm assisted UKA with conventional, manual surgery. There was no overall difference between the two groups at 2 years, in terms of patient reported outcome measures (PROMs) or any other clinically significant outcome measure. The median OKS at 2 years was 39 for the robotic-arm assisted group and 40 for the manual, with preoperative medians of 19.5 and 21.0, respectively. Overall, many patients in each group have achieved a good result, but it is difficult to differentiate between those who achieve a good outcome and those who achieve an excellent outcome. Furthermore, patients in the robotic-arm assisted group achieved a significantly greater improvement in ROM, although this could be influenced by differences in implant design. Stiffness VAS was noted to be significantly higher in the manual group, but this was also the case pre-operatively and is unlikely to be of clinical significance. 29% of the robotic-arm assisted group were deemed to be 'pain free' at 2 years vs 15.7% of the manual group. This may reflect the previous findings of lower early pain in the robotic-arm assisted group (20).

Subgroup analysis has demonstrated that patients who were more active pre-operatively, with a UCLA score >5, achieve significantly better outcomes with robotic-arm assisted surgery. Within this sub-group, a greater median improvement in the AKSS of 19 points exceeded the minimally important clinical difference (MICD) for this PROM (23). The greater median improvement in OKS was 5 points, which is equivalent to the MICD (24). Subgroup analyses of patients <60 years of age did not reveal any differences. UKA patients are usually younger and have a higher level of pre-operative function(25). A pre-operative UCLA>5 indicates a higher level of function and provided the rationale for sub-group analyses.

At 2 years, 80.6% of the original trial population remain enrolled within the study. 3.6% of those randomised were converted to a TKA on the table, which is a recognised factor in UKA surgery. Although the drop-out rate of 15.8% is higher than we would have liked, 1 year data were available for 12 of these patients and there were no significant difference in their clinical outcome vs the trial group at the 1 year time point. To our knowledge, there have been no revisions in these lost to follow-up patients, confirmed on scrutiny of our national imaging database.

In terms of survivorship, patients in the robotic-arm assisted group have a 100% survivorship at 2 years, compared to 97% of those in the manual group. A low revision rate has been described by multiple other studies featuring robotic-arm assisted UKA (21), although further longer term follow-up is required.

The authors are aware of several limitations with the secondary analyses presented in this report. Firstly, this study was originally powered to assess surgical accuracy (20) and these analyses were mainly exploratory in nature. If a Bonferroni correction were applied to exclude bias associated with multiple hypothesis testing, then there would be no significant results, even in the more active sub-group of patients.

Secondly, the PROMs used may not detect the differences between our two cohorts due to the ceiling effects observed. The OKS, AKSS and FJS were selected due to their widespread acceptance and use in assessing both TKA and UKA, but other PROMs are available. It has been recognised that patients undergoing UKA have a higher pre-operative function, and also achieve a higher post-operative function compared to TKA patients (25). However, there is little evidence that these PROMs, or any other outcome measure, have been validated specifically for use in the assessment of UKA (26). The OKS and AKSS have been shown to have high ceiling effects mainly following TKA (26-29). Assessing outcome of UKA by these PROMs is therefore particularly limited by ceiling effect (25).

The ceiling has been defined as the proportion of patients within 15% of the maximum possible score (28). Our overall ceiling rate for the AKSS was 51.4% and 36.61% for the OKS, which is comparable with previous studies (30). The ability of these outcome scores to differentiate between patients achieving a good outcome following UKA surgery is therefore questionable. Perhaps more discriminatory scores for high functioning patients, such as the HAAS (High Activity Arthorplasty Score), may be used in the future (31).

Intrinsic differences in the design of the implants (mobile bearing implant vs a fixed bearing) may well influence the results, as the in vitro kinematics have been demonstrated to differ (32), however the purpose of this study was to compare robotic-arm assisted technology with the existing gold standard treatment. At least in the UK this means a mobile bearing Oxford implant. The study therefore compares two treatment types (surgical technique and implant) rather than surgical technique alone.

Finally, only a per protocol analysis is available. Ideally, patients converted to TKA should have remained in the trial to allow for an intention to treat comparison to be carried out. We believe that it is unlikely that this would have had an effect on the results due to the small numbers of patients involved, but this will be noted for further work.

In conclusion, we have demonstrated that at two years post-operatively, robotic-arm assisted technology delivers a clinical outcome that is at least equivalent to the current 'gold-standard' in UKA surgery and may be superior in more active patients. However, the ceiling effect of our outcome measures may well make it difficult to identify a difference in functional outcome. Nonetheless, we have encouraging early results that suggest improved survivorship and lower post-operative pain in patients undergoing robotic-arm assisted surgery. We will continue to follow the trial participants in the future to assess whether long-term revision rates differ between the two groups, as revision rates may have major implications for the cost-effectiveness of the technology (21). Our trial is based on relatively small numbers and we believe a larger multi-centre trial using appropriate outcome measures is required. This would provide sufficient power to perform a sub-group analysis to determine which patients may benefit from robotic-arm assisted UKA.

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