Abstract:

Objectives: This study reports on a secondary exploratory analysis of the early clinical outcomes of a RCT comparing Robotic-arm Assisted Unicompartmental Knee Arthroplasty (UKA) for medial compartment osteoarthritis of the knee compared to Manual UKA performed using traditional surgical jigs. This follows reporting of primary outcomes of implant accuracy and gait analysis that showed significant advantages in the Robotic-arm assisted group.

Methods: 139 patients were recruited from a single centre. Patients were randomised to receive either a manual UKA implanted with the aid of traditional surgical jigs, or a UKA implanted with the aid of a tactile guided Robotic-arm Assisted system. Outcome measures included: American Knee Society Score (AKSS), Oxford Knee Score (OKS), Forgotten Joint Score (FJS), Hospital Anxiety Depression (HAD) Scale, UCLA Activity Scale, SF-12, Pain Catastrophising Scale (PCS), Somatic Disease (PRIME-MD score), Pain Visual Analogue Scale (VAS), Analgesic use, Patient Satisfaction, complications relating to surgery, 90 day Pain diaries and the requirement for revision surgery.

Results: From day 1 post-op through to week 8 post-op the median pain scores for Robotic-arm Assisted group were 55.4% lower than those observed in the Manual surgery group (p=0.040). A greater proportion of patients receiving Robotic-arm Assisted surgery improved their UCLA activity score.

At 3 months post-op, the Robotic-arm Assisted group had better AKSS scores (Robotic median 164 (Q1 131, Q3 178), Manual 143 (Q1 132, Q3 166)), although no difference was noted with the OKS.

At 1 year post-op, the observed differences with the AKSS had narrowed from 21 points to 7 points (p=0.106) (Robotic median=171 (Q1 153, Q3 179), Manual median=164 (Q1 144, Q3 182 No difference was observed with the OKS, and almost half of each group reached the ceiling limit of the score (OKS >43).

The key factors associated with achieving excellent outcome on the AKSS were a pre-operative activity level >5 on the UCLA activity score and use of Robotic-arm surgery. Factors associated with a poor outcome were manual surgery and pre-operative depression

Conclusions: Robotic-arm assisted surgery results in improved early pain scores and early function scores in some patient reported outcomes measures, but no difference was observed, at 1 year post operatively. Although improved results favoured the Robotic arm assisted group in active patients (i.e. UCLA>=5), these do not withstand more stringent multiplicity adjustments.

Keywords: UKA, Robotic, RCT

Article Summary:

Article focus:

- Report on the early clinical outcomes of a randomised control trial comparing Robotic-arm Assisted UKA with Manual UKA performed using traditional surgical jigs

Key messages:

- Early lower VAS pain scores in Robotic-arm Assisted group
- Positive predictive factors for good early clinical outcome after UKA include the use of Robotic-arm surgery and high patient pre-operative activity.

Strengths and limitations of this study:

- The study's strengths are the random allocation of participants, low dropout rate at follow-up at 1-year post-operatively and the comparison between current UK typical practice and a new emerging method.
- Limitations include the implants used varied between groups with a fixed bearing used in the Robotic-arm assisted group and a mobile bearing for the manual surgery group.
- This study is insufficiently powered to perform subgroup analysis

Robotic-arm assisted versus conventional unicompartmental knee arthroplasty – exploratory secondary analysis of a Randomised Controlled Trial

Introduction

The early 21st century has seen a proliferation of Robotic-assisted surgical technology. Over 50,000 procedures are reported to have been carried out to date with the Mako system, predominantly in the United States, and with the acquisition by Stryker Corporation of Mako Surgical Corp. at the cost of $1.65 Billion in December 2013; is an indication that Robotic Orthopaedic Surgery is about to enter mainstream medical care. Despite the rapid rise in Robotically Assisted procedures, randomised controlled trials directly comparing robotic and traditional surgery are rarely, if ever, undertaken.

Knee kinematics in TKA patients have consistently been shown to be worse than aged matched controls [1-3]. Poor knee kinematics, perceptible by patients, can influence satisfaction with surgery and the patients' ability to confidently undertake activities. High demand activities are even more likely to be severely limited by poor kinematics, and this is reflected in patient satisfaction surveys [4].

Although UKA offers potential functional advantages over TKA [5,6], one of the greatest challenges to both uptake of UKA by surgeons and the ultimate success of the surgery has been the technically demanding nature of that surgery. Poor prosthesis alignment has been associated with early failure of UKA and is likely to contribute to the higher revision rate observed with UKA in comparison to TKA (1.4% vs. 4.6% at 3 years) [7]. In addition, there is strong evidence emerging that surgeons undertaking low volumes of UKA have higher revision rates, reflecting the complexity of the surgery [8].

Both patient and surgical factors have been implicated as influences in those dissatisfied patients, such as malrotation of the implants and a history of depression or back pain [9-13]. Robotic-arm Assisted surgery using the Mako system has been previously reported to produce significantly more accurate implantation of both the femoral and tibial components in all three

planes (sagittal, coronal and axial) [14]. Similar results were reported for the Acrobot system by Cobb et al. and previous iterations of the Mako system (TGS) [15,16].

Objectives:

Having demonstrated the accuracy of Robotic-arm UKA [14], the challenge for surgical robotics is to demonstrate sufficient improvements in clinical outcome to offset the additional costs of these systems.

Methods

Trial design

The original trial was designed as a prospective, parallel, equally randomised, single centre study to compare alignment in 2 groups of patients undergoing unicondylar knee replacement using the Mako Robotic-arm assisted system for treatment of osteoarthritis of the medial compartment of the knee, comparing this technology against Manual UKA performed using traditional surgical jigs.

The present study reports a secondary exploratory analysis of whether the increased accuracy provided by Robotic-arm technology influences clinical outcomes.

Patients

139 patients were recruited from a single centre (Glasgow Royal Infirmary, Glasgow, UK) between October 2010 to December 2012 (Figure 1) who were awaiting unicompartmental knee arthroplasty for medial compartment primary osteoarthritis. Enrolment was carried out by a research associate.

Patients included in the study were those considered suitable for UKA by the surgical authors, were able to give written informed consent and were able to comply with the study follow-up regime.

Patients were excluded if they had a pre-existing condition that would compromise their participation and follow-up in the study, if they had any tibial deformity requiring tibial component augmentation, required a total knee prosthesis, had inflammatory polyarthritis, had disorders of the contralateral knee, feet, ankles, hips or spine causing significant abnormal gait or significant pain, or had neurological conditions affecting movement.

Randomisation and blinding

The randomisation was performed by the Robertson Centre for Biostatistics (University of Glasgow) via a web interface, with stratification by surgeon. The treatment team were blinded

to the sequence, and patients and researchers were not informed of the outcome of the randomisation.

Treatment

Patients were randomised to receive either an Oxford Phase 3 UKA (Biomet, Warsaw, Indiana) implanted with the aid of traditional surgical Phase 3 jigs, or a Restoris MCK UKA (Mako Surgical Corp, Fort Lauderdale, Florida) implanted with the aid of the Mako System – a tactile guided Robotic-arm Assisted system. Three specialist knee surgeons with a minimum of 5 years independent practice as an orthopaedic surgeon performed the surgery. The unit performs approximately 100 UKAs per annum.

Surgical technique

Robotic-arm assisted UKA

Preoperative CT scans and segmentation by a trained technician built a 3D model of the patient's knee to allow planning of individualised component positioning prior to surgery. The operating surgeon defined the size and position of the femoral and tibial components in the preoperative plan, optimising bone coverage, restoring joint anatomy and minimising bone resection. Implant alignment, therefore, was tailored to each patient. Using the preoperative plan the Mako system calculates the 3D volume of bone requiring resection, allowing the Robotic-arm to resect bone using a high speed, saline-cooled burr. Any burring outside of the pre-determined zone is resisted by the Robotic-arm using tactile feedback and audio signals; with complete burr shut down if the arm is forced outside of the zone.

The system uses optical motion capture technology to track photoreflective marker arrays fixed to the femur and tibia through separate stab incisions. This technique allows dynamic referencing of the femur and tibia. As a result, the 3D bone resection volume moves with the limb in real time as the surgeon moves the limb. Visual feedback is given to the surgeon by the on screen CAD images and tactile feedback is provided by the Robotic-arm restricting the burr to stay within the resection volume.

The Restoris MCK implant consists of a cobalt chrome femoral component and a titanium tibial component with a fixed bearing polyethylene insert.

Conventional UKA

Conventional UKA operations were carried out using standard manual instrumentation and the Oxford Phase 3 UKA. Standard instrumentation involved pinning a tibial cutting guide to the tibia providing a flat surface to guide manual resection of the bone using a hand held reciprocating saw for the vertical cut and an oscillating saw for the horizontal. This guide is

aligned using visual and palpable anatomic landmarks. On the femoral side, an intramedullary rod is inserted into the distal femur to align the femoral cutting guide, again using visual landmarks. The standard instrumentation jigs and accompanying operating technique manual provide fixed target values for all patients, without the opportunity for tailoring of implant position to each patient's anatomy.

The Oxford UKA consists of a cobalt chrome femoral and tibial implant and a fully congruent polyethylene mobile bearing.

Follow-up

Data was collected at 3 months and 1-year post-operatively. All trial data was collected by a blinded independent Research Nurse or Research Associate at the Glasgow Royal Infirmary, UK.

Power Calculation

The primary outcome required 126 patients to detect a difference of 1° in tibial sagittal positioning with a power of 80% (a=0.05). To allow for loss to follow-up, a total target recruitment of 150 patients (seventy-five in each group). Completion of recruitment was regarded as the primary stopping point for the surgical stage, and completion of follow-up at 1 year after surgery for all patients defined the stopping point for this study of secondary outcomes.

Outcome measures

We report within this paper the secondary clinical outcomes from the randomised controlled trial. Outcome measures included: American Knee Society Score (AKSS), Oxford Knee Score (OKS), Forgotten Joint Score (FJS), Hospital Anxiety Depression (HAD) Scale, UCLA Activity Scale, SF-12, Pain Catastrophising Scale (PCS), Somatic Disease (PRIME-MD score), Pain Visual Analogue Scale (VAS), Analgesic use, Patient Satisfaction, complications relating to surgery, the requirement for revision surgery and a 90 day diary to catalogue early pain and functional recovery after surgery.

Statistical Analysis

Student's T-test was used to compare continuous variables with a normal distribution of data. Mann-Whitney Test was used to compare continuous variables whose distribution was not normally distributed. Chi-square test or Fisher's Exact Test was used to compare categorical data. These analyses were performed using Graph PadPrism 5.04.

Due to the exploratory nature of the study a standard alpha level of 0.05 was adjusted for multiplicity to 0.005, given the 10 secondary outcomes presented following Bonferroni correction. Given the exploratory approach of the study and the conservative nature of the Bonferroni approach, both levels were used to highlight key results.

The study was analysed on a per protocol basis due to a lack of available data to perform an intention to treat analysis for those withdrawn/been discharged or those who were converted to TKR on the table/those who were revised.

Proposed addition secondary outcome analysis

A post hoc power calculation was carried out on the population means, sample deviations and sample numbers to determine the power of the study at 3 months and 1 year to detect the Minimally Important Clinical Difference (MICD)[17] for the AKSS and OKS (Table 1). This shows the study was powered for OKS but otherwise underpowered for AKSS.

(1-β)*100	MICD	Power Analysis 3 months	Power Analysis 1 year
AKSS Function	6.1-6.4	35.6%	23.2%
AKSS Knee	5.3-5.9	50.8%	36.3%
OKS	5	99%	100%

Table 1. Post hoc power calculation

Factors predictive of excellent and poor clinical outcomes analysis

The ceiling limitations of the current standard patient-reported outcome measures are well recognised [18,19] and render them incapable of differentiating between degrees of excellence in clinical outcomes. For the purpose of further analysis, outcome scores were dichotomised, due to this non-linear nature of many of the scores used.

For the AKSS and OKS the 90th centile was used to differentiate patients with an excellent outcome that may be limited by the ceiling limits of the respective scores; for the AKSS this value was 180 out of 200 and for the OKS it was 43 out of 48. For the FJS a less stringent 80th centile value was used as the ceiling effect of this score is minimal. The HAD score can be divided into an anxiety score and a depression score, a score of greater than 8 is generally accepted as being indicative of depressive or anxious traits [20]. For the UCLA activity scale a cutoff value of 5 was used, this represents patients who are able to undertake all of the basic daily activities of life such as housework, shopping and simple exercise. The PCS cutoff level

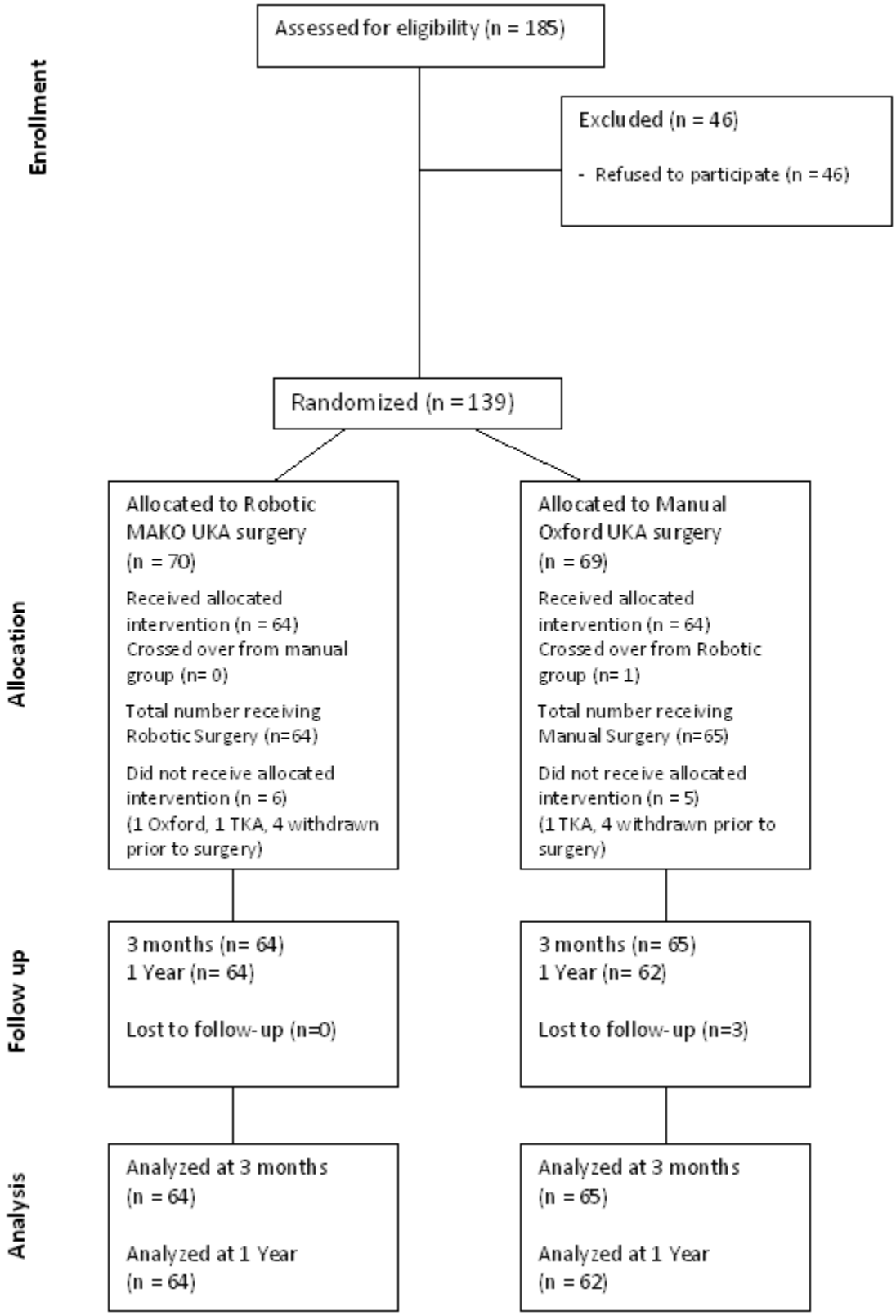
was set at 20 out of 54 which represents the cutoff point for the bottom tertile of the patient cohort. This methodology has previously been used by Riddle et al. [21]. Patients who report more than 3 somatic type symptoms on the Somatic Disease Scale, for which a cause cannot be identified, are considered to be at risk of somatic disease. Without access to General Practitioner records, the ability to assess and verify all patient symptoms other than joint pain was restricted and therefore a more stringent level of 5 reported symptoms was utilised. This level also allows for the fact that all patients in the cohort, by default of indication, report joint pain as a symptom. Finally, for the pain VAS a cutoff value of 70 out of 100 to denote severe pain, this value has previously been used by Kelly et al. to denote patients with severe pain [22].

Binary logistic regression modelling was used to predict factors that are important in the surgical outcomes, and this was performed using Minitab vs12.

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).

Figure 1 CONSORT diagram showing the flow of participants through each stage of the randomised trial.



Results

Follow-up

139 patients underwent randomisation (Figure 1); 64 of 70 (91%) in the Robotic-Arm assisted group and 62 of 69 (90%) completing to 12-month follow-up. The mean follow-up time for the Robotic-Arm assisted group was 3.2 and 13.0 months, and the manual surgery was 3.2 and 13.0 months.

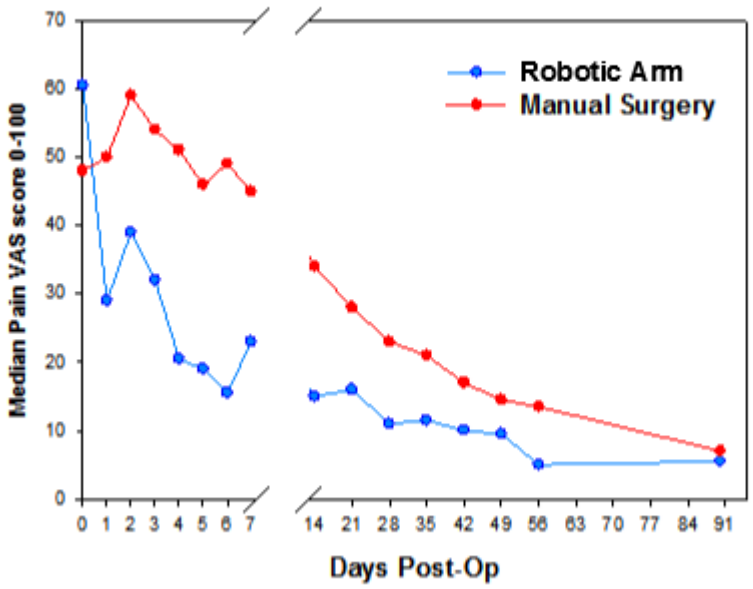
Pre-operative demographics

Pre-operative demographics (Table S1) were well balanced for all variables other than pre-op anxiety. Although the difference in pre-op anxiety between the groups reached statistical significance ($p<0.05$), the difference is unlikely to be clinically relevant.

Early post-operative pain

Pre-operative pain levels were not significantly different between the two groups (Table S1). However from day 1 post-op through to week 8 post-op the median pain scores for Robotic-arm Assisted group were 55.4% lower than those observed in the Manual surgery group (Figure 2, $p=0.040$). However, by 3 months and 1 year post-op there was no difference in pain scores between the groups (Table S6 and Table S2). All patients were offered the same analgesic pathways, (Figure S1) demonstrates no difference in the overall analgesic use for either patient group.

Figure 2 Early post-operative pain



Clinical Outcomes

At 3 months post-op, the Robotic-arm Assisted group had better AKSS scores (Table S6 and Figure 3), although no difference was noted with OKS. The Forgotten Joint Score (FJS) is a measure of a patient's awareness of their joint. Although there was no overall statistical difference between the two groups, the proportion of patients achieving a forgotten joint (FJS>80%) was almost double in the Robotic-arm Assisted group.

At 1 year post-op, the observed differences with the AKSS had narrowed from 21 points to 7 points (p=0.106) (Table S2, Figure 4), with 44% of the Robotic Assisted and 26% of the Manual surgery group reaching the ceiling limit of the score (AKSS> 180/200). The proportion of patients with a forgotten joint had increased proportionately in both groups to 26% in the Robotic-arm Assisted and 13% in the Manual surgery group (p=0.067). No difference was observed with the OKS, and almost half of each group reached the ceiling limit of the score (OKS >43) (Table S2).

A greater proportion of patients receiving Robotic-arm Assisted surgery improved their UCLA activity score from pre-op to post-op by more than one level, 69% versus 52% (p=0.06).

There were no significant differences between the two groups using the general health outcome measure SF-12, nor were any significant differences in complications noted. No revision surgery was performed on any patient within the first 12 months after surgery. There were a number of minor wound complications which were more common in the Manual surgery group (Table S2), but there were no deep infections in either group.

Inpatient length of stay was shorter in the Robotic-arm surgery group, with a difference of 0.54 days (P=0.07) (Figure S2). Additionally, 3 months post-op Primary care utilisation, here calculated from the group proportions visiting their GPs, was 15% fewer (p=0.092) (Figure S3) in the Robotic-arm group.

Factors predictive of excellent and poor clinical outcome

Using AKSS>180, OKS>43 and FJS>80% as markers of excellent clinical outcome, the key factors associated with achieving excellent outcome were a pre-operative activity level >5 on the UCLA activity score (all 3 outcome measures), use of Robotic-arm surgery (2 outcome measures) and not having pre-operative depression (1 outcome measure) (Table S3).

Sub-analysis of patients with pre-operative UCLA activity scores >5 revealed differences in the outcome between Robotic-arm Assisted and Manual surgery for the AKSS (p=0.0064), the OKS (p=0.0106) and the FJS (p=0.0346) (Figure 5 and Figure 6, Table S7).

Factors associated with poor outcome were pre-operative depression (3 outcome measures) and pre-operative anxiety (1 outcome measure) (Table S4).

Figure 3 3 month post-op AKSS score

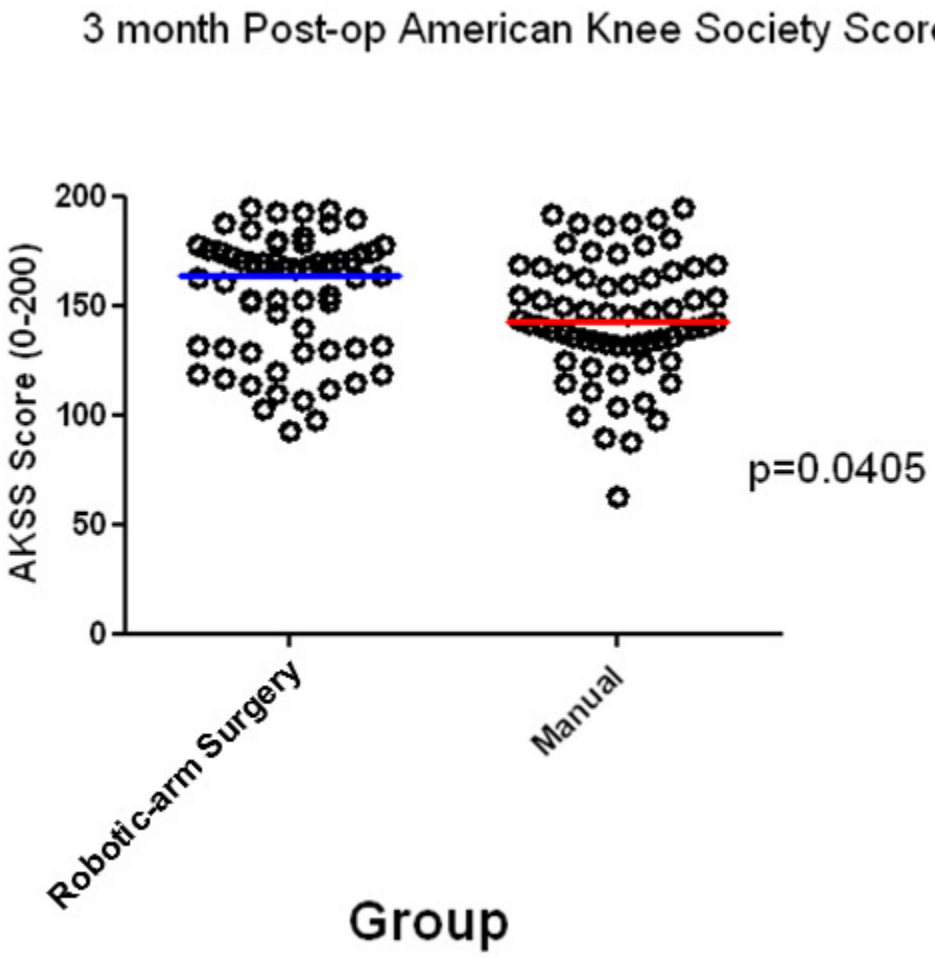


Figure 4 1 Year post-op AKSS score

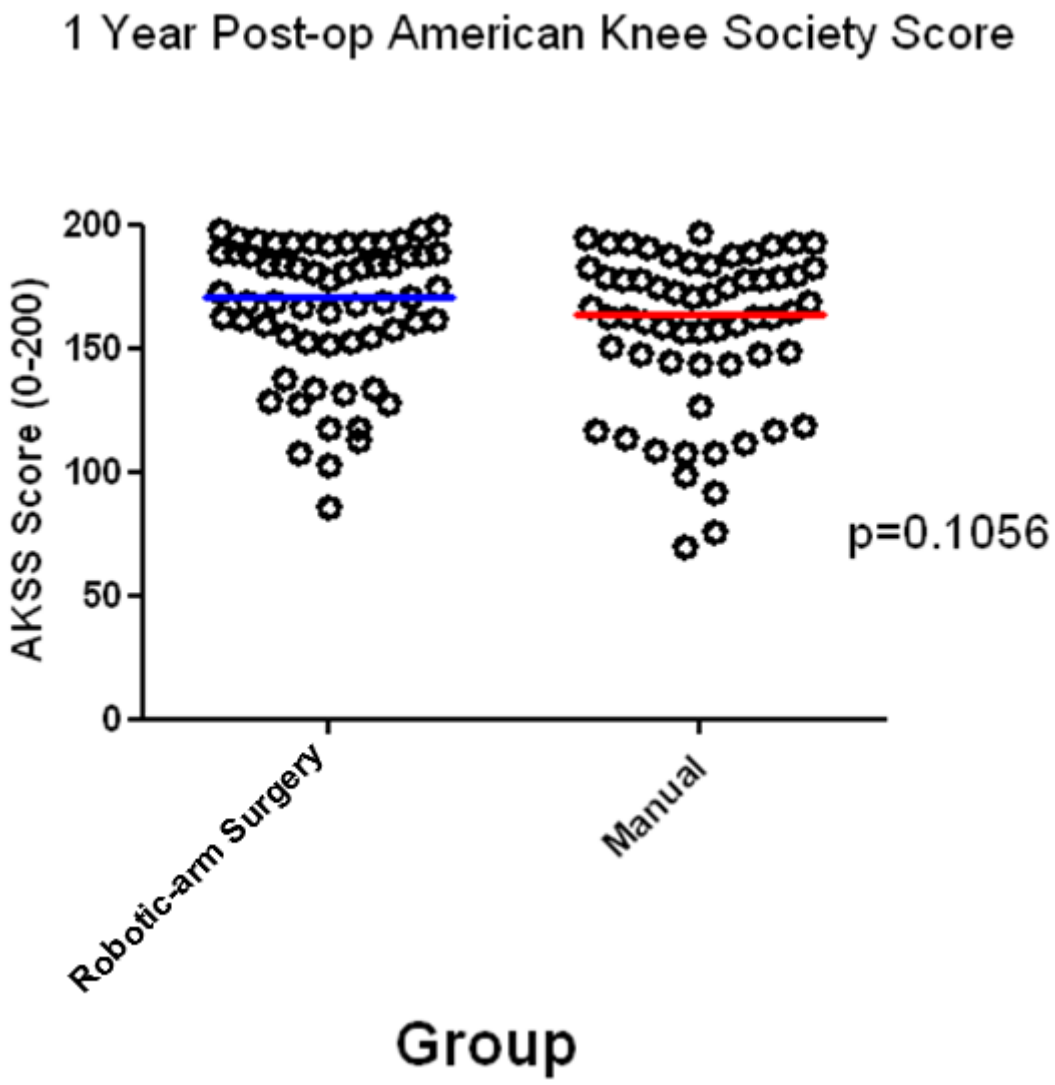


Figure 5 1 Year post-op AKSS score for patients with pre-op UCLA score >5

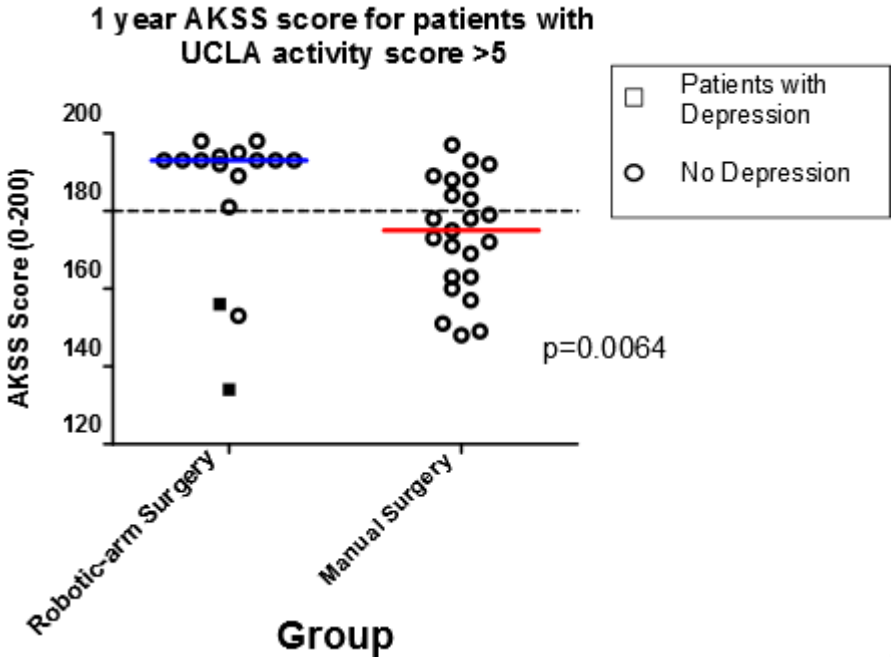
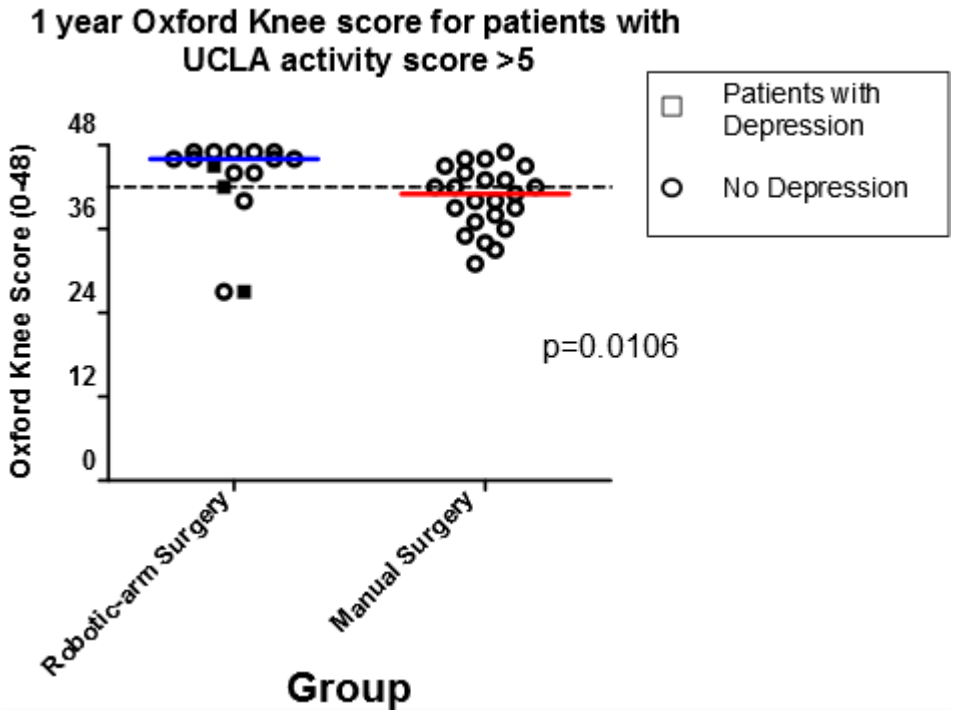


Figure 6 1 Year post-op Oxford Knee score for patients with pre-op UCLA score >5



Discussion

By its very nature, UKA surgery is more complex and with the ability of the robotic system to tailor implant position to individual patient's anatomy and adjust component position intra-operatively, the potential benefits of this advanced technology, in theory, should be greater than TKA surgery. Different soft tissue balancing based on implant positioning affects the kinematics of the knee in vitro [23].

While for standard significance levels (α=0.05) the use of Robotic-arm Assisted surgery for UKA results in better early postoperative clinical outcomes (at 3 months) based on the AKSS and lower early postoperative pain scores (over the first 8 weeks), these didn't reach significance with multiplicity adjustments. By 1 year the difference between the groups had narrowed, with the majority of patients in both surgical groups reaching towards the ceiling level of the AKSS with no difference observed in the scores. The OKS was noted to have no difference with either standard or adjusted significance levels at any time point. Although the proportion of patients achieving a forgotten joint (FJS >80%) was more than double in the Robotic-arm group, this did not reach standard or adjusted statistical significance.

The currently available knee outcome measures are designed to measure differences between pre-op and post-op disease in TKA patients. They are inadequate for UKA patients who start with less disease burden and are generally younger, fitter and healthier. In the cohort, 43% of patients had a 1-year post-op Oxford score greater than 42, which is generally acknowledged as being an excellent score. With so many patients scoring so highly, the restrictive ceiling limits of the OKS, in particular, make it impossible for the score to differentiate degrees of excellence. The FJS is a more discriminatory scoring system, but does not adequately tackle patients function, only awareness or feeling of the knee joint.

In the absence of outcome measures that are truly able to differentiate good and excellent, statistical methods were sought to examine the factors that are associated with good (and poor) outcomes. Positive predictive factors (α=0.05) for good early clinical outcome after UKA include the use of Robotic-arm surgery (for two of 3 outcome measures) and high patient pre-operative activity (all outcome measures). Poor results were universally associated with pre-operative depression, which has been previously reported by a number of authors [11,12,24-26].

Outcome following joint replacement surgery is affected by both patient and surgical factors. The analysis of the results in patients who are more active pre-operatively effectively allows us to focus on the influence of surgical factors, with a clinically important difference in outcome in favour of Robotic-arm surgery demonstrated.

Although the ability to assess clinical outcomes has been limited by the available outcome measures, change in pain over time is easier to quantify and stratify reliably. The data shows quite marked differences in post-op pain from day one through to week 8 post-op. Although definitive explanations for this difference could not be provided, there are several key differences between the two surgical philosophies that may potentially explain the difference in post-op pain. The Robotic-arm system allows surgery to be tailored to the patient's anatomy, with more accurate reconstruction of the joint surfaces and the potential for more natural knee kinematics. Robotic-arm assisted surgery does not utilise a femoral intramedullary rod, avoiding additional surgical trauma. This benefit may be offset, however, by the additional use of bone pins, inserted into the femur and tibia, during surgery for the navigation trackers. The use of a Robotic-arm mounted irrigated burr rather than a traditional high-speed saw blade may prevent excessive heat associated bone necrosis and might facilitate more minimal bone resection, both of which might lead to less post-operative pain. Alternatively, there may be a placebo effect if patients were able to determine that they had received Robotic-arm assisted surgery. Patients were not specifically informed of what type of surgery they would receive, but it would have been possible for an inquisitive patient to determine this themselves as sham procedures were not performed, such as stab wounds on the limbs of patients receiving manual surgery to mimic the entry of bone pins.

There are several limitations to the study. The sample size is relatively small, the study having originally been devised to determine the accuracy of the Robotic-arm system. Given the exploratory nature of the study and the lack of correction for multiplicity, statistical significance differences found run the risk of type I errors (false positive where an apparent statistically significance difference is found where no difference exists). Similarly, multiplicity adjustments can introduce type II errors (false negatives, where true differences are not observed due to the more stringent test to detect significant differences $p<0.005$).

In addition the implants used in both groups in the study differed; fixed bearing for the Robotic-arm assisted group and mobile bearing for the manual surgery group. There are recognised differences kinematics between the implants[27]. The pragmatic decision to use these implants was based on the lack of availability of a mobile bearing implant for use with the Mako system and a desire to compare the Robotic-arm technology with the current gold standard treatment for UKA, which, in the United Kingdom at least, is the Biomet Oxford Unicompartmental Knee System. This limitation in the study design makes it impossible to determine if the differences observed are due to the differences in the implants or the Robotic-arm surgical technique, and are, therefore, in effect, comparing two types of care rather than two implants.

A third limitation is that the cohort of patients has not yet reached the relevant time point to assess the impact on implant survivorship of the increased accuracy that Robotic-arm technology affords.

Only per-protocol data was available for analysis as patients who were treated with total knee arthroplasty were not followed up. There is therefore risk to the integrity of the randomised groups from attrition bias.

Ensuring surgical equipoise is difficult in trials involve new technologies against current standards of care. Surgical experience amongst the investigators favoured the traditional Oxford procedure with all surgeons experienced in this surgical technique. Experience with the Robotic-arm to date however suggests that the technology is easily adopted and this is underlined by the improved implant accuracy shown in an earlier study. In order to further explore the influence of surgeon experience on the results a much larger trial would have to be conducted which corporates an expertise-based design. This limitation also affects the ability of the study to assess the generalisability to the wider surgical community of the results shown here for surgeons less familiar with UKA surgery.

The final limitation of the study relates to the use of standard outcome measures that are ineffective at differentiating degrees of excellence in clinical outcome. The decision to use the AKSS and OKS was based on both scores being widely accepted in the Orthopaedic community. Differences in outcome might yet be demonstrated by a quantitative assessment of kinematics using gait analysis.

Funders of the study were given oversight of the study, but otherwise has no influence on the analysis and reporting of the data.

Although improved outcomes were seen in favour of Robotic-arm assisted surgery in active, healthy patients (i.e. UCLA>5) this outcome does not withstand more stringent multiplicity adjustments. A much larger scale multi-centre study is required to determine whether the technology is effective for patients presenting with OA of the knee who require a UKA.

Currently, the fundamental barrier to adoption of this technology, particularly in the public health sector, remains the cost of Robotic-arm systems. Any future multi-centre randomised trials in addition to studying clinical effectiveness should also include a full health economic assessment of the cost-effectiveness of the technology.

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