



## ■ RESEARCH

# Robotic arm-assisted *versus* conventional unicompartmental knee arthroplasty

## EXPLORATORY SECONDARY ANALYSIS OF A RANDOMISED CONTROLLED TRIAL

**M. J. G. Blyth,  
I. Anthony,  
P. Rowe,  
M. S. Banger,  
A. MacLean,  
B. Jones**

Glasgow Royal  
Infirmary, Glasgow,  
United Kingdom

- M. J. G. Blyth, MBChB, FRCS(Tr&Orth), Orthopaedic Surgeon,
- I. Anthony, PhD, Orthopaedic Research Manager,
- A. MacLean, MBChB, FRCS(T&O), Orthopaedic Surgeon,
- B. Jones, MBChB, FRCS(Tr&Orth), Orthopaedic Surgeon, Department of Orthopaedics, Glasgow Royal Infirmary, Glasgow, G4 0SF, UK.
- P. Rowe, PhD, Professor of Rehabilitation Science,
- M. S. Banger, MEng, Research Associate, University of Strathclyde, Glasgow, G1 1XQ, UK.

Correspondence should be sent to M. Blyth;  
email: Mark.Blyth@ggc.scot.nhs.uk

doi: 10.1302/2046-3758.611.BJR-2017-0060.R1

*Bone Joint Res* 2017;6:631–639.

### Objectives

This study reports on a secondary exploratory analysis of the early clinical outcomes of a randomised clinical trial comparing robotic arm-assisted unicompartmental knee arthroplasty (UKA) for medial compartment osteoarthritis of the knee with manual UKA performed using traditional surgical jigs. This follows reporting of the primary outcomes of implant accuracy and gait analysis that showed significant advantages in the robotic arm-assisted group.

### Methods

A total of 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 the American Knee Society Score (AKSS), Oxford Knee Score (OKS), Forgotten Joint Score, Hospital Anxiety Depression Scale, University of California at Los Angeles (UCLA) activity scale, Short Form-12, Pain Catastrophising Scale, somatic disease (Primary Care Evaluation of Mental Disorders Score), Pain visual analogue scale, analgesic use, patient satisfaction, complications relating to surgery, 90-day pain diaries and the requirement for revision surgery.

### Results

From the first post-operative day through to week 8 post-operatively, the median pain scores for the robotic arm-assisted group were 55.4% lower than those observed in the manual surgery group ( $p = 0.040$ ).

At three months post-operatively, the robotic arm-assisted group had better AKSS (robotic median 164, interquartile range (IQR) 131 to 178, manual median 143, IQR 132 to 166), although no difference was noted with the OKS.

At one year post-operatively, the observed differences with the AKSS had narrowed from a median of 21 points to a median of seven points ( $p = 0.106$ ) (robotic median 171, IQR 153 to 179; manual median 164, IQR 144 to 182). No difference was observed with the OKS, and almost half of each group reached the ceiling limit of the score ( $OKS > 43$ ). A greater proportion of patients receiving robotic arm-assisted surgery improved their UCLA activity score.

Binary logistic regression modelling for dichotomised outcome scores predicted the key factors associated with achieving excellent outcome on the AKSS: a pre-operative activity level  $> 5$  on the UCLA activity score and use of robotic-arm surgery. For the same regression modelling, factors associated with a poor outcome were manual surgery and pre-operative depression.

### Conclusion

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 one year post-operatively. Although improved results favoured the robotic arm-assisted group in active patients (i.e.  $UCLA \geq 5$ ), these do not withstand adjustment for multiple comparisons.

**Cite this article:** *Bone Joint Res* 2017;6:631–639.

**Keywords:** Unicompartmental knee arthroplasty, Robotic, Randomised controlled trial

## Article focus

- Report on the exploratory analysis of the early clinical outcomes of a randomised control trial comparing robotic arm-assisted unicompartmental knee arthroplasty (UKA) with manual UKA performed using traditional surgical jigs.

## Key messages

- Early lower visual analogue scale 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

- The study's strengths are the random allocation of participants, low dropout rate at one-year post-operative follow-up and the comparison between current United Kingdom typical practice and a new emerging method.
- Limitations include the variation in implants used 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 and the study itself represents a secondary exploratory analysis separate from the primary analysis of the original 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. The acquisition by Stryker Corporation (Kalamazoo, Michigan) of Mako Surgical Corporation (Fort Lauderdale, Florida) at the cost of \$1.65 billion in December 2013<sup>1</sup> 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 total knee arthroplasty (TKA) patients have consistently been shown to be worse than aged matched controls.<sup>2-4</sup> Poor knee kinematics, perceptible to patients, can influence a patient's satisfaction with surgery and their ability to undertake activities with confidence. High-demand activities are even more likely to be severely limited by poor kinematics, and this is reflected in patient satisfaction surveys.<sup>5</sup>

Although unicompartmental knee arthroplasty (UKA) offers potential functional advantages over TKA,<sup>6,7</sup> 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 the 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 with TKA (1.4% *versus* 4.6% at three years).<sup>8</sup> In addition, there is strong evidence emerging that surgeons undertaking low volumes of UKA have higher revision rates, reflecting the complexity of the surgery.<sup>9</sup>

Both patient and surgical factors have been implicated as contributing to the dissatisfaction of patients; factors such as malrotation of the implant and a history of depression or back pain.<sup>10-14</sup> 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).<sup>15</sup> Similar results were reported for the Acrobot system (Acrobot Company Ltd., London, United Kingdom) by Cobb et al<sup>16</sup> and for previous iterations of the Mako system (Tactile Guidance System; Mako Surgical Corporation).<sup>17</sup>

Having demonstrated the accuracy of robotic-arm UKA,<sup>15</sup> the challenge for surgical robotics is to demonstrate sufficient improvements in clinical outcome to offset the additional costs of these systems.

## Materials and Methods

**Trial design.** The original trial was designed as a prospective parallel equally randomised single-centre study to compare alignment in two groups of patients undergoing unicompartmental knee arthroplasty for treatment of osteoarthritis of the medial compartment of the knee. The Mako robotic arm-assisted system was used for one group and a manual UKA was performed using traditional surgical jigs in the other.

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

**Patients.** A total of 139 patients were recruited from a single centre (Glasgow Royal Infirmary, Glasgow, United Kingdom) between October 2010 and December 2012 (Fig. 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 (MJGB, BJ, AM), who gave written informed consent and who could comply with the study follow-up regime.

Patients were excluded if they had any of the following: any contraindications detailed by the device manufacturer; any tibial deformity requiring tibial component augmentation; requirement for a total knee prosthesis; inflammatory polyarthritis; a disorder of the contralateral knee, feet, ankles, hips or spine causing significant abnormal gait or significant pain; a neurological condition affecting movement; or any other pre-existing condition that would, in the opinion of the investigator (MJGB),

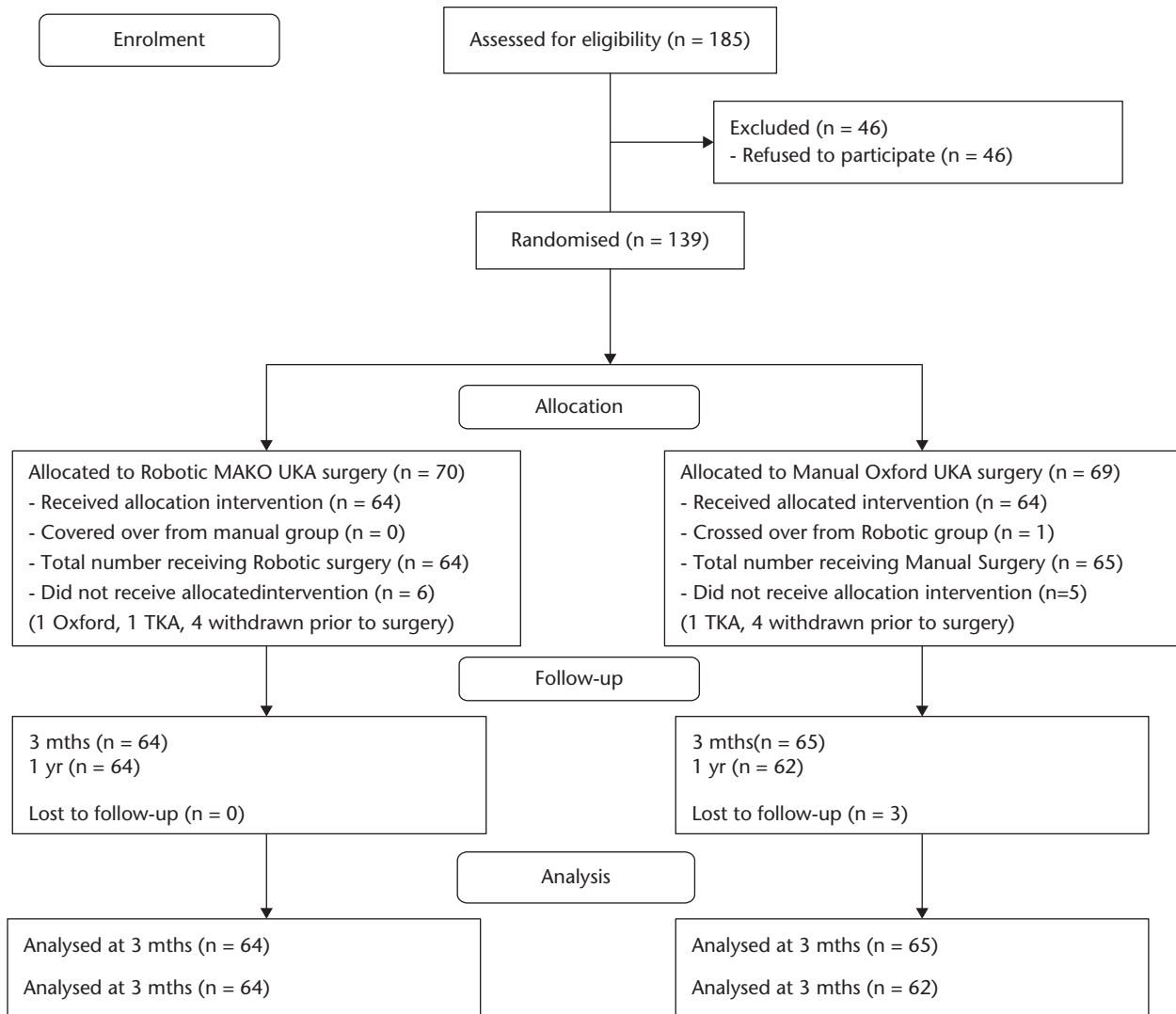


Fig. 1

Consolidated Standards Of Reporting Trials diagram showing the flow of participants through each stage of the randomised trial (UKA, unicompartmental knee arthroplasty; TKA, total knee arthroplasty).

compromise their participation and follow-up in the study.

**Randomisation and blinding.** The randomisation was performed by the Robertson Centre for Biostatistics (University of Glasgow) via a bespoke web-based randomisation portal and S-Plus (TIBCO Software Inc, Palo Alto, California), with stratification by surgeon (MJGB, BJ, AM). 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 Corporation) implanted with the aid of the Mako System, a tactile guided robotic arm-assisted system. Three specialist knee surgeons (MJGB, BJ, AM) with a minimum of five years

independent practice as an orthopaedic surgeon performed the surgery. The clinical unit performs approximately 100 UKAs per annum.

**Surgical technique: robotic arm-assisted UKA.** A pre-operative CT scan was segmented by a trained technician to construct a 3D model of the patient's knee. This allows planning of individualised component positioning prior to surgery. The operating surgeon (MJGB, BJ, AM) defined the size and position of the femoral and tibial components in the pre-operative plan, optimising bone coverage, restoring joint anatomy and minimising bone resection. Implant alignment, therefore, was tailored to each patient. Using the pre-operative 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 predetermined zone is resisted by the robotic arm using

tactile feedback and audio signals, with complete shut-down of the burr if the arm is forced outside of the zone.

The system uses optical motion capture technology (Polaris Spectra, NDI, Northern Digital Inc. Ontario, Canada) 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. Thus, 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 computer aided design 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.

**Surgical technique: 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 handheld 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 were collected at three months and one year post-operatively. All trial data were collected by a blinded independent research nurse or research associate at the Glasgow Royal Infirmary, United Kingdom.

**Power calculation.** The primary outcome required 126 patients to detect a difference of 1° in tibial sagittal positioning with a power of 80% ( $\alpha = 0.05$ ). To allow for loss to follow-up, the total target of recruitment was 150 patients (75 in each group). Completion of recruitment was regarded as the primary stopping point for the surgical stage, and completion of follow-up at one year post-operatively for all patients was defined as 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 the American Knee Society Score (AKSS), Oxford Knee Score (OKS), Forgotten Joint Score (FJS), Hospital Anxiety Depression (HAD) Scale, University of California, Los Angeles (UCLA) Activity Scale, Short Form-12 (SF-12), Pain Catastrophising Scale (PCS), somatic disease (Primary Care Evaluation Of Mental Disorders 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 post-operatively.

**Statistical analysis.** Student's *t*-test was used to compare continuous variables with a normal distribution of data. The Mann-Whitney U test was used to compare continuous variables without normal distribution. A chi-squared test or Fisher's exact test was used to compare categorical data. These analyses were performed using GraphPad Prism 5.04 (GraphPad Software Inc., La Jolla, California).

Due to the exploratory nature of the study, a standard alpha level of 0.05 was adjusted for multiplicity to 0.005, given the ten secondary outcomes presented, following a 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 from which to perform an intention-to-treat analysis for those who had withdrawn or had been discharged, or those who were converted to TKA on the table or those who were revised.

**Proposed additional secondary outcome analysis.** A *post hoc* power calculation was carried out on the population means, sample deviations and sample numbers to determine the power ( $(1-\beta) \times 100\%$ ) of the study at three months and one year to detect the minimally important clinical difference<sup>18</sup> for the AKSS and OKS (supplementary material). This showed that the study was powered for OKS but otherwise underpowered for AKSS.

**Factors predictive of excellent and poor clinical outcomes analysis.** The ceiling limitations of the current standard patient-reported outcome measures are well recognised<sup>19,20</sup> and render them incapable of differentiating between degrees of excellence in clinical outcomes. For further analysis, outcome scores were dichotomised due to the 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 who 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 percentile value was used as the ceiling effect of this score is minimal.<sup>21</sup>

The HAD score can be divided into an anxiety score and a depression score; a score of greater than eight is generally accepted as being indicative of depressive or anxious traits.<sup>22</sup>

For the UCLA Activity Scale, a cutoff value of five 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, as previously been used by Riddle et al.<sup>23</sup>

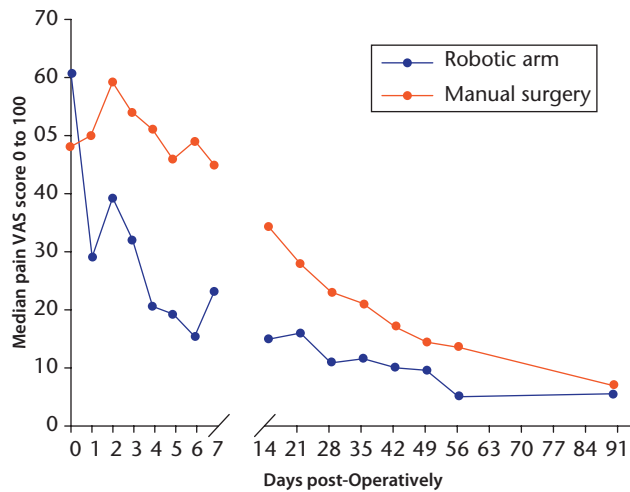


Fig. 2

Graph showing early post-operative pain. Visual analogue scale (VAS) pain scores were recorded by the patient daily for the first seven days, and then subsequently weekly.

Patients who report more than three 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 five reported symptoms was used. 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 was used to denote severe pain. This value has previously been used by Kelly<sup>24</sup> to denote patients with severe pain.

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

**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) and registered with the ISRCTN (International Standard Randomised Controlled Trial Number) Registry (ISRCTN77119437).

## Results

**Follow-up.** A total of 139 patients underwent randomisation (Fig. 1); 64 of 70 (91%) in the robotic arm-assisted group and 62 of 69 (90%) in the manual surgery group completed the 12-month follow-up. The mean three month and one year follow-up times for the robotic arm-assisted group was 3.2 months and 13.0 months, and for the manual surgery group it was 3.2 months and 13.0 months.

**Pre-operative demographics.** Pre-operative demographics (supplementary material) were well balanced for all

variables other than pre-operative anxiety. Although the difference in pre-operative anxiety between the groups reached statistical significance ( $p < 0.05$ ), the higher anxiety in the manual group is unlikely to be a clinically relevant difference (0.5).

**Early post-operative pain.** Pre-operative pain levels were not significantly different between the two groups (supplementary material). However, from the first post-operative day through to week 8 post-operatively, the median pain scores for the robotic arm-assisted group were 55.4% lower than those observed in the manual surgery group (Fig. 2) ( $p = 0.040$ ). However, by three months and one year post-operatively, there was no difference in pain scores between the groups (supplementary material). All patients were offered the same analgesic pathways (supplementary material), demonstrating no difference in the overall analgesic use for either patient group.

**Clinical outcomes.** At three months post-operatively, the robotic arm-assisted group had better AKSS (Fig. 3, and supplementary material), although no difference was noted in OKS. The 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 (15% versus 8%,  $p = 0.265$ ).

At one year post-operatively, the reported differences with the AKSS had narrowed from a mean of 21 points to a mean of 7 points ( $p = 0.106$ ) (Fig. 4, and supplementary material), with 44% of the robotic arm-assisted group 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 group 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) (supplementary material).

A greater proportion of patients receiving robotic arm-assisted surgery improved their UCLA Activity Score from pre-operatively to one year post-operatively 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 there 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 (supplementary material), 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 ( $p = 0.07$ ) (supplementary material). Additionally, three months post-operatively, primary care utilisation calculated from

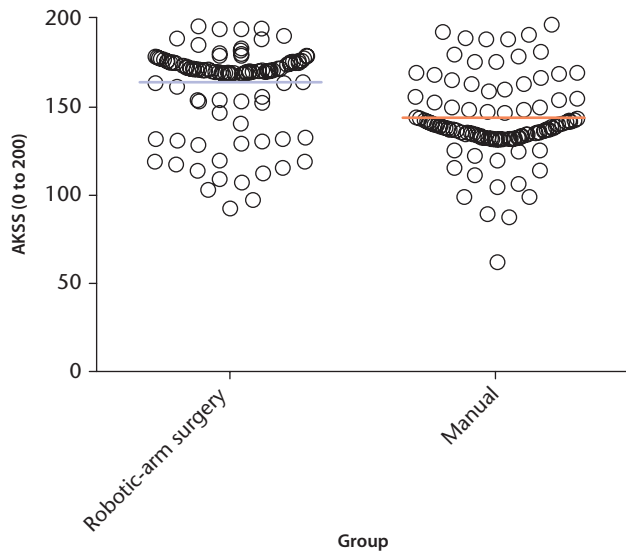


Fig. 3

Graph showing three-month post-operative American Knee Society Score (AKSS) ( $p = 0.0405$ ).

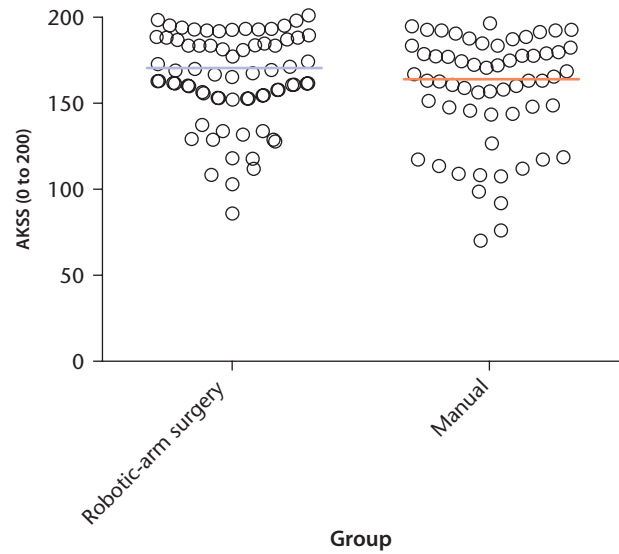


Fig. 4

Graph showing one-year post-operative American Knee Society Score (AKSS) ( $p = 0.1056$ ).

the group proportions visiting their GPs, was 15% lower ( $p = 0.092$ ) (supplementary material) 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 three outcome measures; AKSS, OKS, FJS), use of robotic-arm surgery (two outcome measures; AKSS, FJS), and not having pre-operative depression (one outcome measure; AKSS) (supplementary material).

Subanalysis 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 ( $p = 0.0346$ ) (Figs 5 and 6, and supplementary material).

Factors associated with poor outcome were pre-operative depression (three outcome measures; AKSS, OKS, FJS) and pre-operative anxiety (one outcome measure; OKS) (supplementary material).

## 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 those of TKA surgery. Different soft-tissue balancing based on implant positioning affects the kinematics of the knee *in vitro*.<sup>25</sup>

While for standard significance levels ( $\alpha = 0.05$ ) the use of robotic arm-assisted surgery for UKA results in

better early post-operative clinical outcomes (at three months) based on the AKSS and lower early post-operative pain scores (over the first eight weeks), these didn't reach significance with adjustment for multiple comparisons. By one year, the difference between the groups had narrowed, with most 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 timepoint. 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-operative and post-operative disease in TKA patients. They are inadequate for UKA patients who start with smaller burden of disease and are generally younger, fitter and healthier. In the cohort, 43% of patients had a one-year post-operative Oxford score > 42, which is generally acknowledged as being an excellent score. With so many patients scoring so highly, the restrictive ceiling limits of the OKS make it impossible for the score to differentiate between 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 between good and excellent, statistical methods were sought to examine the factors that are associated with good (and poor) outcomes. Positive predictive factors ( $\alpha = 0.05$ ) for good early clinical outcome after UKA include the use of robotic-arm surgery (for two of three outcome measures; AKSS, FJS) and high patient

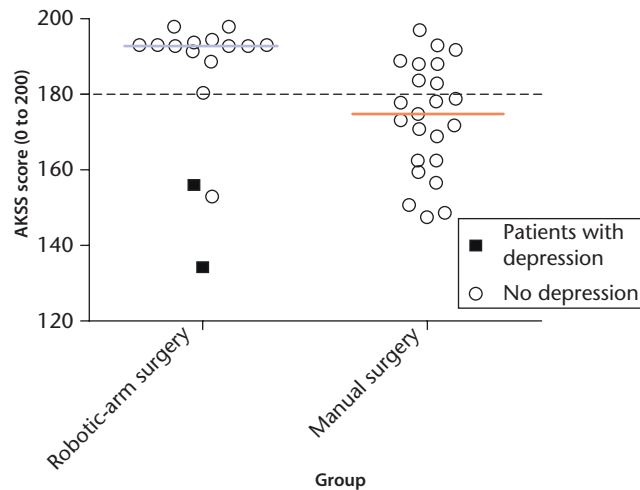


Fig. 5

Graph showing one-year post-operative American Knee Society Score (AKSS) for patients with pre-operative University of California, Los Angeles Activity Scale score > 5. The lack of depressed patients in this higher functioning group further represents association of depression and poor clinical outcomes. Two depressed patients in the robotic arm group achieved higher levels of activity ( $p = 0.0064$ ).

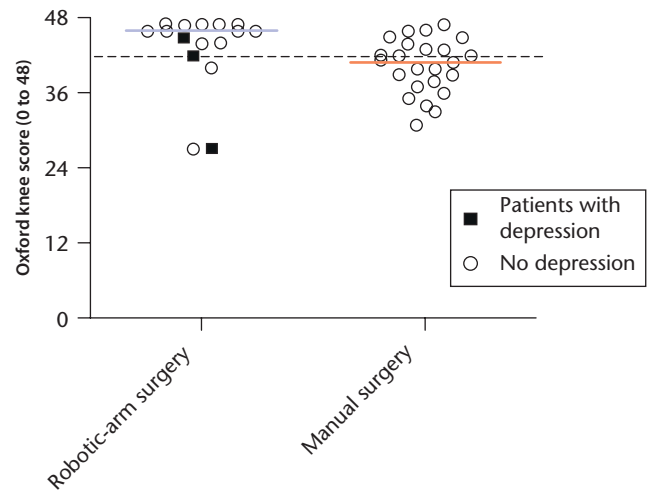


Fig. 6

Graph showing one-year post-operative Oxford Knee Score for patients with pre-operative University of California, Los Angeles Activity Scale score > 5. The lack of depressed patients in this higher functioning group further represents association of depression and poor clinical outcomes. Three depressed patients in the robotic arm group achieved higher levels of activity ( $p = 0.0106$ ).

pre-operative activity (all outcome measures; AKSS, OKS, FJS). Poor results were universally associated with pre-operative depression, which has been previously reported by a number of authors.<sup>12,13,26-28</sup>

Outcome following joint arthroplasty 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 demonstrated in favour of robotic-arm surgery.

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 show quite marked differences in post-operative pain from day 1 through to week 8 post-operatively. Although definitive explanations for these differences could not be provided, there are several key distinctions between the two surgical philosophies that may potentially provide an explanation. 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 use a femoral intramedullary rod thereby 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 may lead to less post-operative pain. Alternatively, there may be a

placebo effect if patients determine that they have 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 discover this themselves as sham procedures (such as stab wounds on the limbs of patients receiving manual surgery to mimic the entry of bone pins) were not performed.

There are several limitations to the study. The sample size is relatively small, as the study was originally devised to determine the accuracy of the robotic-arm system. Without correction for multiple comparisons, statistically significant findings may be spurious (Type I error). Similarly, adjustment for multiple comparisons 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 differed between the two groups in the study: fixed bearing for the robotic arm-assisted group and mobile bearing for the manual surgery group. There are recognised differences in kinematics between these implant designs.<sup>29</sup> 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 benchmark treatment for UKA, which, in the United Kingdom at least, is the Biomet Oxford Unicompartmental Knee System (Zimmer Biomet, Warsaw, Indiana). This limitation in the study design makes it impossible to determine if the differences observed are due to the differences in the implants or due to the robotic-arm surgical technique.

A third limitation is that the cohort of patients has not yet reached the relevant timepoint at which to assess the impact on implant survivorship that may develop due to the increased accuracy that robotic-arm technology affords.

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


Ensuring surgical equipoise is difficult in trials which involve new technologies are compared against current standards of care. Surgical experience among 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. To explore further the influence of surgeon experience on the results, a much larger trial would have to be conducted incorporating an expertise-based design.

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.

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 multicentre 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 multicentre randomised trials, in addition to studying clinical effectiveness, should also include a full health economic assessment of the cost-effectiveness of the technology.

### Supplementary material

 Tables and figures showing detailed patient demographics, three-month and one-year clinical results, all results for predictive factors of excellent and poor outcomes, analgesic use, in-patient stay, post-operative primary care utilisation and patient satisfaction are available alongside the online version of this article at [www.bjr.boneandjoint.org.uk](http://www.bjr.boneandjoint.org.uk).

### References

1. No authors listed. <http://www.stryker.com/en-us/products/Orthopaedics/MakoRobotic-ArmAssistedSurgery/index.htm> (date last accessed 17 August 2017).

2. Rowe PJ, Myles CM, Nutton R. The effect of total knee arthroplasty on joint movement during functional activities and joint range of motion with particular regard to higher flexion users. *J Orthop Surg (Hong Kong)* 2005;13:131-138.
3. Saari T, Tranberg R, Zügner R, Uvehammer J, Kärrholm J. Total knee replacement influences both knee and hip joint kinematics during stair climbing. *Int Orthop* 2004;28:82-86.
4. Saari T, Tranberg R, Zügner R, Uvehammer J, Kärrholm J. Changed gait pattern in patients with total knee arthroplasty but minimal influence of tibial insert design: gait analysis during level walking in 39 TKR patients and 18 healthy controls. *Acta Orthop* 2005;76:253-260.
5. Mahomed N, Gandhi R, Daltroy L, Katz JN. The self-administered patient satisfaction scale for primary hip and knee arthroplasty. *Arthritis* 2011;2011:591253.
6. Patil S, Colwell CW Jr, Ezzet KA, D'Lima DD. Can normal knee kinematics be restored with unicompartmental knee replacement? *J Bone Joint Surg [Am]* 2005;87-A:332-338.
7. Laurencin CT, Zelicof SB, Scott RD, Ewald FC. Unicompartmental versus total knee arthroplasty in the same patient. A comparative study. *Clin Orthop Relat Res* 1991;273:151-156.
8. Collier MB, Eickmann TH, Sukezaki F, McAuley JP, Engh GA. Patient, implant, and alignment factors associated with revision of medial compartment unicompartmental arthroplasty. *J Arthroplasty* 2006;21(Suppl 2):108-115.
9. Badawy M, Espehaug B, Indrekvam K, Havelin LI, Furnes O. Higher revision risk for unicompartmental knee arthroplasty in low-volume hospitals. *Acta Orthop* 2014;85:342-347.
10. Nicoll D, Rowley DI. Internal rotational error of the tibial component is a major cause of pain after total knee replacement. *J Bone Joint Surg [Br]* 2010;92-B:1238-1244.
11. Bell SW, Young P, Drury C, et al. Component rotational alignment in unexplained painful primary total knee arthroplasty. *Knee* 2014;21:272-277.
12. Brander VA, Stulberg SD, Adams AD, et al. Predicting total knee replacement pain: a prospective, observational study. *Clin Orthop Relat Res* 2003;416:27-36.
13. Wylde V, Dieppe P, Hewlett S, Learmonth ID. Total knee replacement: is it really an effective procedure for all? *Knee* 2007;14:417-423.
14. Boyle JK, Anthony IC, Jones BG, Wheelwright EF, Blyth MJ. Influence of low back pain on total knee arthroplasty outcome. *Knee* 2014;21:410-414.
15. Bell SW, Anthony I, Jones B, et al. Improved Accuracy of Component Positioning with Robotic-Assisted Unicompartmental Knee Arthroplasty: Data from a Prospective, Randomized Controlled Study. *J Bone Joint Surg [Am]* 2016;98A:627-635.
16. Cobb J, Henkel J, Gomes P, et al. Hands-on robotic unicompartmental knee replacement: a prospective, randomised controlled study of the acrobot system. *J Bone Joint Surg [Br]* 2006;88-B:188-197.
17. Dunbar NJ, Roche MW, Park BH, et al. Accuracy of dynamic tactile-guided unicompartmental knee arthroplasty. *J Arthroplasty* 2012;27:803-808.
18. Lee WC, Kwan YH, Chong HC, Yeo SJ. The minimal clinically important difference for Knee Society Clinical Rating System after total knee arthroplasty for primary osteoarthritis. *Knee Surg Sports Traumatol Arthrosc* 2016 June 21. (Epub ahead of print)
19. Dowsey MM, Choong PF. The utility of outcome measures in total knee replacement surgery. *Int J Rheumatol* 2013;2013:506518.
20. Jenny JY, Diesinger Y. The Oxford Knee Score: compared performance before and after knee replacement. *Orthop Traumatol Surg Res* 2012;98:409-412.
21. Thomsen MG, Latifi R, Kalleose T, et al. Good validity and reliability of the forgotten joint score in evaluating the outcome of total knee arthroplasty. *Acta Orthop* 2016;280-285.
22. Carroll BT, Kathol RG, Noyes R Jr, Wald TG, Clamon GH. Screening for depression and anxiety in cancer patients using the Hospital Anxiety and Depression Scale. *Gen Hosp Psychiatry* 1993;15:69-74.
23. Riddle DL, Wade JB, Jiranek WA, Kong X. Preoperative pain catastrophizing predicts pain outcome after knee arthroplasty. *Clin Orthop Relat Res* 2010;468:798-806.
24. Kelly AM. The minimum clinically significant difference in visual analogue scale pain score does not differ with severity of pain. *Emerg Med J* 2001;18:205-207.
25. Heyse TJ, Slane J, Peersman G, et al. Balancing mobile-bearing unicompartmental knee arthroplasty in vitro. *Knee Surg Sports Traumatol Arthrosc* 2016 July 19. (Epub ahead of print)
26. Judge A, Arden NK, Cooper C, et al. Predictors of outcomes of total knee replacement surgery. *Rheumatology (Oxford)* 2012;51:1804-1813.
27. Scott CE, Howie CR, MacDonald D, Biant LC. Predicting dissatisfaction following total knee replacement: a prospective study of 1217 patients. *J Bone Joint Surg [Br]* 2010;92-B:1253-1258.



28. **Sullivan M, Tanzer M, Stanish W, et al.** Psychological determinants of problematic outcomes following Total Knee Arthroplasty. *Pain* 2009;143:123-129.
29. **Ettinger M, Zoch JM, Becher C, et al.** In vitro kinematics of fixed versus mobile bearing in unicompartmental knee arthroplasty. *Arch Orthop Trauma Surg* 2015;135:871-877.

**Funding Statement**

- None declared

**Author Contribution**

- M. J. G. Blyth, Conception or design of the work, Data collection, Data analysis and interpretation, Drafting the article, Critical revision of the article, Final approval of the version to be published.
- I. Anthony, Conception or design of the work, Data collection, Data analysis and interpretation, Drafting the article, Critical revision of the article, Final approval of the version to be published.
- P. Rowe, Conception or design of the work, Data collection, Data analysis and interpretation, Drafting the article, Critical revision of the article, Final approval of the version to be published.
- M. S. Banger, Data analysis and interpretation, Drafting the article, Critical revision of the article, Final approval of the version to be published.

- A. MacLean, Conception or design of the work, Data collection, Data analysis and interpretation, Drafting the article, Critical revision of the article, Final approval of the version to be published.
- B. Jones, Conception or design of the work, Data collection, Data analysis and interpretation, Drafting the article, Critical revision of the article, Final approval of the version to be published.

**Acknowledgements**

- We would like to thank Sister Pauline May, Sister Rachael Halifax, Miss Sinead O'Donnell, Dr Arman Motesharei (Trained technician), Dr Julie Smith (Research Associate) and Miss Iona Donnelly for their support of this study.

**Conflicts of Interest Statement**

- Funding has been received in the form both of a grant and personal fees from Mako Surgical Corporation which is related to this paper. Funders of the study were given oversight of the study by means of reports on the trials progress, but otherwise had no influence on the analysis and reporting of the data.
- The author M. Banger was supported for his DEng studies by the EPSRC Doctoral Training Centre in Medical Devices Grant (number EP/F50036X/1).

© 2017 Blyth et al. This is an open-access article distributed under the terms of the Creative Commons Attribution licence (CC-BY-NC), which permits unrestricted use, distribution, and reproduction in any medium, but not for commercial gain, provided the original author and source are credited.