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A novel patient-specific instrument design can deliver robotic level accuracy in unicompartmental knee arthroplasty

Gareth G. Jones [a,*], Susannah Clarke [a], Simon Harris [a], Martin Jaere [a], Thunayan Aldalmani [b], Patrick de Klee [a,c], Justin P. Cobb [a]

[a] MSk Lab, Imperial College London, 7th Floor Lab Block, Charing Cross Hospital, London W6 8RF, UK
[b] Royal College of Surgeons in Ireland, 123 St. Stephen's Green, Dublin 2, Ireland
[c] Embody Orthopaedic, MSk Lab, 7th Floor Lab Block, Charing Cross Hospital, London, W6 8RF, UK

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ABSTRACT

Background: A previous randomised controlled trial (RCT) by our group found that robotic assisted unicompartmental knee arthroplasty (UKA) surgery was significantly more accurate than conventional instrumentation. The aim of this study was to determine whether a low-cost novel PSI design could deliver the same level of accuracy as the robot in the same time efficient manner as conventional instruments.

Methods: Thirty patients undergoing medial UKA took part. Tibial component position was planned using a low dose CT-scan, and compared to a day 1 postoperative CT-scan to determine the difference between the planned and achieved positions. Operations were performed by one expert surgeon using PSI (Embody, London, UK).

Results: The mean absolute difference between planned and achieved tibial implant positions using PSI was 2.0° (SD 1.0°) in the coronal plane, 1.8° (SD 1.5) in the sagittal plane, and 4.5° (SD 3.3) in the axial plane. These results were not significantly different to the 13 historical robotic cases (mean difference 0.5°, 0.5°, and 1.7°, $p = 0.1907$, 0.2867 and 0.1049 respectively). PSI mean operating time was on average 62 min shorter than the robotic group ($p < 0.0001$) and 40 min shorter than the conventional instrument group ($p < 0.0001$). No complications were reported.

Conclusions: In conclusion, this clinical trial demonstrates that for tibial component positioning in UKA, a novel design PSI guide in the hands of an expert surgeon, can safely deliver comparable accuracy to a robotic system, whilst being significantly faster than conventional instruments. NIHR Clinical Research Network Reference: 16100.

1. Introduction

A caseload effect exists for unicompartmental knee arthroplasty (UKA), with revision rates for high volume surgeons, and high volume surgical centres, being superior to their low volume counterparts [1–3]. The technical difficulty of UKA is considered an

* Corresponding author.
E-mail addresses: ggjones@imperial.ac.uk, @MrGGJones (G.G. Jones), susannah.clarke05@imperial.ac.uk, (S. Clarke), s.harris@imperial.ac.uk, (S. Harris), martin.jaere11@imperial.ac.uk, (M. Jaere), t.aldalmani17@imperial.ac.uk, (T. Aldalmani), j.cobb@imperial.ac.uk. (J.P. Cobb).
@MrGGJones (G.G. Jones).

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important explanatory factor in this phenomenon. Aseptic tibial component loosening is the most common mode of failure, and finite element (FE) modelling, along with clinical studies, suggests a narrow tolerance for positioning of the tibial component in both the coronal and sagittal planes [4–6].

Assistive technology to improve component positioning is an attractive solution for low volume surgeons. Two randomised controlled trials (RCTs) have concluded that robotic assisted UKA is more accurate than conventional instruments [7]. However, robots remain expensive and time consuming, with a cost-effectiveness analysis suggesting a quality-adjusted life-year (QUALY) cost of $47,180, but only with a case volume of 100 *per annum* [8]. Patient specific instruments (PSIs) are an alternative, cheaper, technology with the potential of cost neutrality due to improved operating room efficiency [9]. A recent RCT comparing PSI and conventional UKA concluded that PSI did not improve component positioning in the coronal or sagittal plane [10]. However, the surgeons who conducted this study perform more than 200 UKAs *per annum*, therefore the results could equally be interpreted as a demonstration that PSI can replicate the accuracy of high volume surgeons.

The current investigation set-out to be the first clinical study to directly compare the accuracy of medial UKA tibial component positioning using a PSI design which incorporates a novel personalised ankle clamp (Embody, London, UK), with a robot (Acrobot), and conventional instruments (Oxford Phase III, Zimmer Biomet, Bridgend, UK). Accuracy data for the Acrobot and conventional instruments exists from a previous study by our group [7]. By replicating the experimental conditions of this study, including the use of preoperative and postoperative Computed Tomography (CT) Scans, a prospective clinical trial of PSI was conducted for comparison with this historical cohort. The primary outcome measures were accuracy of component positioning compared to the 3D preoperative plan, and duration of surgery, with the hypothesis that a novel PSI would achieve the same level of accuracy as the robot in a time comparable to conventional instruments.

2. Patients and methods

Between May 2015 and February 2016, a total of 27 patients were prospectively recruited to undergo medial UKA using a novel PSI. Five of these patients were scheduled for simultaneous bilateral surgery, making a total of 32 knees. One patient, who underwent bilateral UKA, did not have a post-operative CT scan due to an administrative error, and was withdrawn.

The previous study by our group recruited 31 patients for medial UKA, three of whom were scheduled for staged bilateral procedures, making a total of 34 knees [7]. Four patients (six knees) were withdrawn: one knee deemed unsuitable for UKA at operation, one patient medically unfit for surgery, and three due to the unavailability of the Acrobot due to technical issues. This left 28 knees, which were randomised to the Acrobot (n = 13) or conventional instrument (Oxford Phase III, Zimmer Biomet, Bridgend, UK) group (n = 14). Demographic data for the present prospective PSI cohort, and the historical robotic and conventional cohorts, is contained in Table 1.

Inclusion criteria were the same for both studies: (1) any patient with medial tibiofemoral compartment arthrosis considered suitable for medial UKA by the operating surgeon (2) medically fit for surgery and (3) over 18 years of age. Exclusion criteria were: (1) patients lacking capacity and (2) patients who did not understand written and verbal English. All patients who met the stated criteria were invited to participate in this PSI study. Participants gave written informed consent, and ethical approval was granted by the National Research Ethics Service (Stanmore, London, UK, REC Reference: 13/LO/1639). Neither patients nor the surgeon were blinded to the use of PSI. The trial took place at King Edward VII's Hospital, London, UK. All PSI cases were performed by the same surgeon who performed the Acrobot cases (JPC), and performs more than 100 UKAs each year. These cases did not form part of the learning curve for either technology. Surgery for the historical conventional instrument group was performed by four surgeons familiar with the procedure.

Preoperative planning and postoperative analysis for the PSI study replicated the methodology used in the previous RCT [7]. Each patient underwent a low-dose preoperative CT scan of the hips, knees, and ankles, according to an established protocol [11]. Slice thickness at the knee was one millimetre. The CT scan was segmented using Mimics software (Materialise NV, Leuven, Belgium) to produce a three-dimensional (3D) bone model. Acrobot UKA planning software (Acrobot, London, UK), validated for clinical use with an accuracy of 0.5°, was then used to plan the position of a medial Oxford UKA tibial component (Figure 1). The software aligns the tibial bone model in 3D space using established frames of reference: the tibial mechanical axis in the Z plane, and the posterior femoral condylar axis in the X and Y planes [12]. Each plan was patient specific. In the coronal plane, the implant position was matched to the native medial proximal tibial angle (MPTA), with a maximum varus limit set at three degrees. In the sagittal plane, the implant was matched to the native tibial slope. In the axial plane, the implant was aligned parallel to the tibial spines. All plans were approved by the operating surgeon (JPC). A CT scan performed on postoperative day one was co-registered with the preoperative plan, and the difference between the planned and achieved implant positions was

Table 1
Demographic data.

	n	Age	Gender (M:F)	Left:right
PSI	30	71 (52–84)	20:10	13:7
Acrobot	13	70.4 (58–78)	8:5	7:6
Conventional instruments	14	69.8 (62–79)	7:7	8:7

Demographic data for the Acrobot and conventional instrument groups taken from the study by Cobb et al. [7].

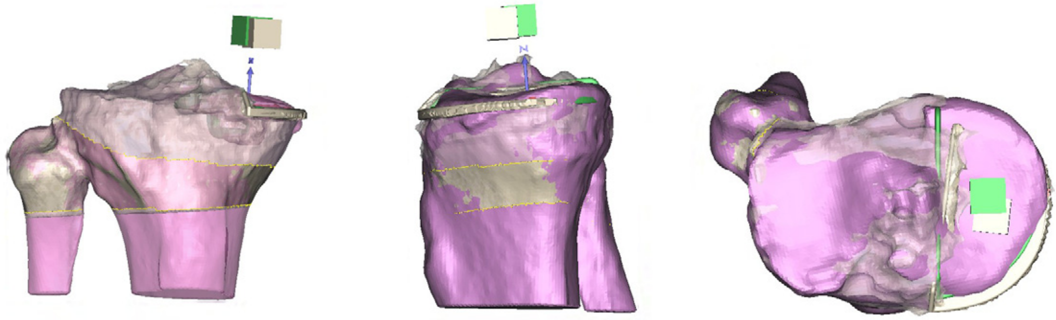

Figure 1. Postoperative analysis. Example of how the postoperative CT derived bone model (purple) was co-registered with the 3D preoperative plan (grey bone model). Identical cubes positioned in identical positions above their respective tibial components illustrate the difference between the planned and achieved implant positions.

calculated (Figure 1). This measuring process was performed by the lead author (GGJ). Intra- and inter-rater reliability was assessed by an independent observer using a random sample of eight cases.

PSI guides (Embody, London, UK) were 3D printed in medical grade Nylon (PA 2200) using an EOS P110 printer. This novel guide could be used through a standard minimally invasive skin incision, and incorporated local bony references to match the morphology of the proximal tibia, as well as distant references in the form of a personalised ankle clamp to match the

Figure 2. The PSI guide incorporated a personalised ankle clamp to match the morphology of the patient's malleoli (red) and local patient specific referencing of the proximal tibia (blue). Interchangeable cutting shims (black) with captured saw slots allowed the surgeon to choose the depth of resection.

morphology of the patient's malleoli (Figure 2). These distant references are unique to this PSI, and are designed to assist the surgeon in guide positioning, and to deliver the posterior slope determined in the pre-operative plan. Once positioned and secured with a headed pin, interchangeable cutting shims allow the surgeon to choose the depth of resection, with captured saw slots guiding both sagittal and coronal cuts. A sterilised 3D printed model of the proximal tibia, incorporating the planned bone cut, was used intra-operatively to check the initial bone resection (Figure 3). Any intra-operative adjustments to the PSI saw cuts following this check were recorded.

For both studies, operative time was recorded from skin incision to skin closure. Postoperative complications, and any adverse events were recorded.

2.1. Statistical methods

An *a priori* sample size calculation of 32 patients was determined assuming a five percent significance level, a power of 80%, a five percent dropout rate, and a desire to detect a one degree difference from the planned correction, with an estimated measurement of variability of one degree based on a preliminary sawbone study.

SPSS v22 (IBM Corp, New York, USA) was used for statistical analysis. Descriptive statistics are presented as mean standard deviation (SD) unless otherwise stated. Unpaired t-tests were used to compare the mean absolute error in implant position between the groups. Paired t-tests were used to compare pre- and post-operative PROMS. Statistical significance was set at $p < 0.05$.

3. Results

3.1. Planned versus achieved implant position

For PSI, the mean absolute difference between planned and achieved implant positions was 2.0° (SD 1.0°) in the coronal plane, 1.8° (SD 1.5°) in the sagittal plane, and 4.5° (SD 3.3°) in the axial plane (Figure 4). These results are comparable to the error observed with the Acrobot: 1.5° (SD 1.4°) coronal plane, 1.3° (SD 1.1°) sagittal plane, and 2.8° (SD 2.5°) axial plane ($p = 0.1907$, 0.2867 and 0.1049 respectively). Conventional instruments were significantly less accurate than both PSI and the Acrobot in the coronal plane (3.4° (SD 2.4°), $p = 0.0087$ and 0.0199 respectively), and sagittal plane (4.9° (SD 3.4°), $p = 0.0001$ and 0.0012 respectively), but not the axial plane (5.1° (SD 3.7°), $p = 0.5916$ and 0.0722 respectively) (Table 2).

3.2. Operative time

Mean operative time using PSI was significantly less than the Acrobot (48 min (SD 6) *versus* 104 min (SD 6), $p = 0.0001$), and conventional instruments (48 min (SD 6) *versus* 88 min (SD 16.3), $p = 0.0001$). The Acrobot was also significantly slower than conventional instruments ($p = 0.0161$) (Table 1).

3.3. Adverse events

For PSI, there were no operative complications or adverse events at one year follow-up. PSI was successfully used in every case. Sagittal recuts were performed in three cases after comparing the excised bone with the 3D printed tibial bone model. The previous RCT reported four adverse events for the Acrobot group, two of which (swollen leg, and skin blisters) were felt likely

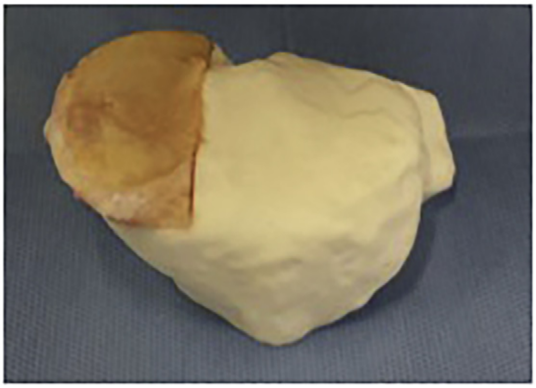

Figure 3. The saw cut is checked intraoperatively by placing the cut tibia on a sterile 3D printed bone model.

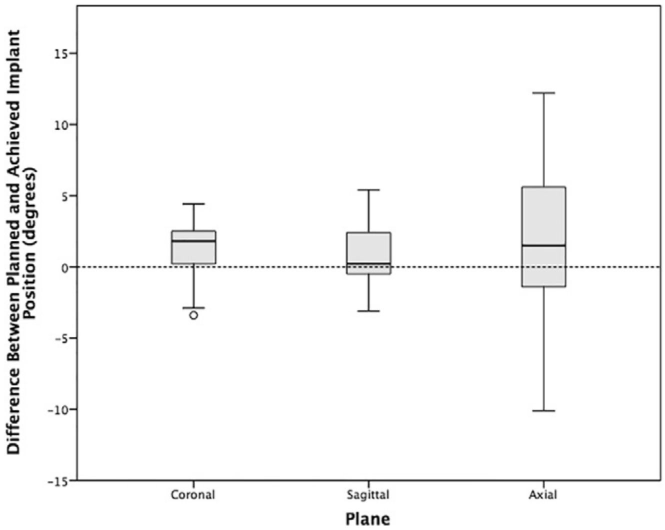

Figure 4. Box-plots of the difference between planned and achieved implant positions using PSI.

to be related to the operative technique [7]. Three adverse events were reported for the conventional instrument group, none of which were considered likely to be related to the operative technique.

3.4. Error and reliability

After matching the preoperative and postoperative bones, the mean absolute difference between fixed points was 0.5 mm (SD 0.05) *i.e.* less than the one millimetre CT slice thickness. The absolute intra-rater measurement error was 0.4° (SD 1.3°) in the coronal plane, 0.1° (SD 1.0°) in the sagittal plane, and 0.2° (SD 0.8°) in the axial plane. Similarly, inter-rater measurement error was 0.3° (SD 1.0°) in the coronal plane, 0.2° (SD 0.9°) in the sagittal plane, and 0.1° (SD 0.8°) in the axial plane. Inter-rater (3,1) and intra-rater (1,1) intra-class correlation coefficients for all three measurements indicated almost perfect agreement using the Landis and Koch criteria [13].

4. Discussion

Malpositioning of the tibial component in UKA is associated with an increased risk of component migration and loosening, and may contribute to the higher revision rates seen in low volume surgical centres [14]. Assistive technology has the potential to improve component positioning, but it is unclear which technology is best suited to this task. This study is the first to compare the achieved accuracy between a PSI and a robot in the positioning of a UKA tibial component. It found no difference between the technologies, both of which were more accurate than conventional instrumentation in the coronal and sagittal planes. However, operative time using PSI was significantly shorter than both the robot and conventional instruments.

A previous study, by Trong et al. [15] investigated PSI accuracy in 25 medial UKA, with postoperative CT scan analysis of implant position. Interestingly, they reported saw-cut error in addition to implant error, which we found impossible to do using the same software due to metal artefact. They reported a mean implant error of 0.3° (SD 1.7°) in the coronal plane, 1.1° (SD 2.6°) in

Table 2
Surgical accuracy and operative time.

	Absolute error (°)			Operating time (min)
	Coronal plane	Sagittal plane	Axial plane	
PSI	2 (1)	1.8 (1.5)	4.5 (3.3)	42 (6)
Acrobot	1.5 (1.4)	1.3 (1.1)	2.8 (2.5)	104 (16.6)*
Conventional instruments	3.4 (2.4)*,Ψ	4.9 (3.4)*,Ψ	5.1 (3.7)	88 (16.3)*,Ψ

Values are mean (SD).
* Denotes a significant difference to the PSI group ($p < 0.05$).
Ψ Denotes a significant difference to the Acrobot group ($p < 0.05$).

the sagittal plane and 1.6° (SD 3.5°) in the axial plane. These errors appear smaller than those observed in the current study, but represent mean error, rather than absolute mean error, and are therefore not directly comparable.

Kerens et al. [16] used magnetic resonance imaging (MRI) based PSI for 30 medial UKA, and recorded a mean error of one degree in the coronal plane (range −3° to 7°), and 5° in the sagittal plane (range 1° to 10°), which is more variability than we observed. Ollivier et al. [10] also used MRI based PSI for 30 medial UKA, with a mean error of 1° (range −2° to 3°) in the coronal plane and 1° (−3° to 2°) in the sagittal plane. Neither of these two studies reported absolute mean error. They also relied on postoperative two dimensional (2D) radiographs to determine component positioning, which can introduce measurement errors due to variability in limb positioning [17,18].

For the robotic group, a more recent RCT by Bell et al. [19] compared a 2nd generation MAKO robot (Stryker Surgical, Michigan, USA) with conventional instruments. The robotic group comprised 62 patients, and accuracy was assessed using postoperative CT scans. Median error was 1.6° (1st and 3rd quartiles −0.8°, 3.0°) in the coronal plane, 1.0° (0.1°, 1.8°) in the sagittal plane, and 2.2° (1.1°, 3.4°) in the axial plane, which is comparable with the Acrobot results from our RCT [7]. An earlier study consisting of a sample of 20 UKAs performed with the MAKO robot also concluded that the observed errors in component positioning were similar to the Acrobot [20].

Bell et al.'s RCT [19] also provides an excellent comparison group for conventional instrument accuracy: 58 medial UKA, using Oxford Phase III instruments (Zimmer Biomet, Bridgend, UK), performed by three experienced UKA surgeons, with postoperative CT analysis. They observed a median error of 2.7° (1st and 3rd quartiles 1.6°, 3.7°) in the coronal plane, 3.7° (2.3°, 5.6°) in the sagittal plane, and 5.4° (2.8°, 9.3°) in the axial plane. Again, these are similar to the results from the previous RCT conducted by our group [7].

In the current study using PSI, the operating surgeon chose to redo the sagittal saw cut (determining axial plane orientation) in three cases after visually comparing the excised bone with the sterile 3D printed bone model (Figure 2), suggesting that in these cases the vertical saw slot in the PSI may not have been sufficiently rigid to prevent the reciprocating saw blade from deflecting during use. However, the inclusion of a sterile model of the planned resection is an advantage of PSI, providing the surgeon with a simple intraoperative check. It should also be noted that axial alignment accuracy was not improved with the use of assistive technology, but this is an area of significant controversy, with no 'ground truth' or 'gold standard', beyond the anatomical tibial axis proposed by earlier work from our lab [21]. In comparison, Ollivier et al. [10] recut the tibia in 10% of their PSI cases, although this was for depth only, whilst Kerens et al. [16] reported no tibial recuts in their series.

The degree of accuracy required for UKA longevity is of course germane to this study. A retrospective review by Chatellard et al. [5] of 559 medial UKAs identified orientation of the tibial component more than three degrees from the native joint line in the coronal plane as being associated with decreased prosthesis survival. Whilst Innocenti et al.'s FE modelling predicted that stress in the underlying cancellous bone is lowest when the tibial implant is positioned between neutral and three degrees varus in the coronal plane [6]. As well as component loosening, increased bone stresses can lead to pain, which might also result in revision surgery [22]. In the sagittal plane, composite bone [23] and FE model [24] studies found that a posterior tibial slope greater than five degrees results in significantly increased bone strain. These findings are consistent with clinical data from Chatellard et al.'s study which identified a posterior slope greater than five degrees, or a change in the native tibial slope of more than two degrees, as risk factors for decreased prosthesis survival [5]. In our study, mean absolute error in tibial component positioning was significantly less than three degrees in the coronal and sagittal planes for both the PSI ($p < 0.0001$ for both) and Acrobot ($p = 0.002$ and $p < 0.0001$ respectively), but not for the conventional instruments ($p = 0.5437$ and $p = 0.0567$ respectively). Long term follow-up is required to confirm whether this improved accuracy translates to a reduction in revision rates.

The Acrobot robot was a first generation servo-assisted orthopaedic robot, and it is reasonable to expect gains in reliability and operating room efficiency with subsequent hardware and software improvements. Whilst the Acrobot robot was unavailable for 10% of cases due to technical problems in our historical cohort, a MAKO robot was successfully used in 116 consecutive cases reported by Marcovigi et al. [25] and available for all 139 cases in the RCT by Bell et al. [19]. With regard to operating room efficiency, for the conventional instrument group, operative time was consistent with the mean of 81.4 min (SD 25.5 min) in a retrospective review of 64 consecutive UKAs performed by a high volume surgeon [27]. Interestingly, we found PSI to be significantly faster than the conventional instruments, with most time saving noted during guide positioning. However, the fact that different surgeons performed the PSI and conventional instrument procedures might also have contributed to this observation. Using a second generation (MAKO) robot, Marcovigi et al. [25] recorded a mean operative time of 76.5 min (SD 13.3 min) for their first 72 consecutive patients undergoing UKA. A separate analysis of the last 37 operations in their series revealed a mean total operative time of 70 min (SD 10.9 min). These operative times are shorter than were recorded for the Acrobot, but remain significantly longer than those recorded with PSI in the current study. Interestingly, a recent time analysis study, by the same group who performed the MAKO robot RCT, concluded that the robot takes on average 27 min longer than Oxford Phase III instruments [26], which is consistent with results from the Acrobot RCT.

There are limitations to our study. Although the protocol for the original RCT was replicated as far as possible, the PSI group was not randomised, which of course introduces the potential for bias. The same surgeon performed all robotic and PSI cases, but the operations using conventional instrumentation were undertaken by four different surgeons, which must be considered when evaluating the results. For the conventional instrument group, Oxford Phase III instruments were used (Zimmer Biomet, Bridgend, UK). A newer instrumentation set (Oxford Microplasty®) has been developed by the same manufacturer, but uses the same instrument to guide tibial resection in the coronal, sagittal and axial planes. Finally, it was impossible to measure the actual saw cuts due to metal artefact on the postoperative scans, hence implant position was used as a surrogate, which may have introduced error.

5. Conclusion

In conclusion, this study has demonstrated that a novel PSI can safely deliver the same level of accuracy as a robot for tibial component positioning in medial UKA whilst being significantly faster, even when compared to conventional instruments. The technology is also potentially much cheaper, and hence deliverable at a cost point suitable for the low volume centres and surgeons who arguably might benefit the most. Future studies will need to determine whether PSI can deliver a similar level of accuracy for low-volume surgeons.

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Declaration of competing interest

G. Jones declares grants from The Michael Uren Foundation, activity relating to the submitted work.

S. Clarke declares provision of equipment from Embody Orthopaedic, activity relating to the submitted work; board membership, royalties and stocks/stock options from Embody Orthopaedic, activity outside the submitted work.

S. Harris declares consultancy for Embody Orthopaedic, activity outside the submitted work.

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