Hands-on robotic unicompartmental knee replacement

A PROSPECTIVE, RANDOMISED CONTROLLED STUDY OF THE ACROBOT SYSTEM

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We performed a prospective, randomised controlled trial of unicompartmental knee arthroplasty comparing the performance of the Acrobot system with conventional surgery. A total of 27 patients (28 knees) awaiting unicompartmental knee arthroplasty were randomly allocated to have the operation performed conventionally or with the assistance of the Acrobot. The primary outcome measurement was the angle of tibiofemoral alignment in the coronal plane, measured by CT. Other secondary parameters were evaluated and are reported.

All of the Acrobot group had tibiofemoral alignment in the coronal plane within 2° of the planned position, while only 40% of the conventional group achieved this level of accuracy. While the operations took longer, no adverse effects were noted, and there was a trend towards improvement in performance with increasing accuracy based on the Western Ontario and McMaster Universities Osteoarthritis Index and American Knee Society scores at six weeks and three months. The Acrobot device allows the surgeon to reproduce a pre-operative plan more reliably than is possible using conventional techniques which may have clinical advantages.

There is a considerable revision rate for total knee replacement and a slightly higher one for unicompartmental knee arthroplasty (UKA). There may be a number of reasons for this higher failure rate including poor patient selection, but it has been attributed to malpositioning by some authors. There may be a number of reasons for this higher failure rate including poor patient selection, but it has been attributed to malpositioning by some authors.7-5

A more conservative form of UKA, with the opportunity for a shorter hospital stay and superior function of the knee, can only be realised if the implant is inserted correctly, otherwise function is poor and the revision rate is increased.10

Computer-assistance devices have been developed to improve the accuracy of implantation using navigation by optical tracking and fully active robots. Surgical navigation has reduced the number of outliers as defined by radiological criteria, but improvement in outcome has been hard to document. The use of fully active robots has also been associated with problems which have prevented their acceptance.

One problem with computer assistance has been the quantification of their impact. A sufficiently sensitive measurement of the position of components, but CT is superior and allows accurate measurement of the correction obtained and the position of the implant. The dose of radiation and the cost of the scans have prevented this technique from being more widely adopted. Comparison of angular measurements taken from radiographs and CT scans has been made, revealing no systematic error between the two, with simply a greater scatter in radiological measurements.

The principal outcome measure in joint arthroplasty is still contentious. Knee scores, while extensively validated, are confounded by the variability between patients, and do not measure accuracy of alignment. A knee replacement may be inserted inaccurately in a number of ways, each of which will compromise function. Varus-valgus alignment is the variable which is reported most extensively as being both measurable and significant. Knees which are left in too much varus, or thrust into too much valgus, will be more likely to fail early.

We report a prospective, randomised, double-blind (patient and evaluator), controlled trial of minimally-invasive UKA using a new hands-on robotic assistant, the Acrobot System (The Acrobot Co. Ltd., London, UK).


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Patients and Methods

We recruited 31 patients who were awaiting medial UKA, and who fulfilled the entry criteria (inclusion and exclusion). All accepted and were blinded as to the type of treatment. In three patients, surgery was planned for both knees, in separate sessions, therefore the total number of knees involved in the study was 34.

Other than the operation all other aspects of pre- and post-operative care were standard practice. Randomisation and post-operative assessment were performed blind by independent parties. The clinical investigation was approved by the Ethics Committee and the Medicines and Healthcare Products Regulatory Agency.

Inclusion and exclusion criteria. Male and female subjects, aged over 18 years, requiring UKA on clinical and radiological grounds, who understood the requirements of the study and were willing to participate and to sign an informed consent form, fulfilled the general inclusion crite-

Figure 1a – CT scans showing the planned positions of the components. Figure 1b – Co-registration of the planned and achieved positions for both components. Figure 1c – Two close-up views of the joint illustrating the error of the tibiofemoral angle.
Knee-specific inclusion criteria were limitation of the disease to the medial compartment, an intact anterior cruciate ligament, a varus deformity which could correct fully in 10° of flexion and at most a minor fixed flexion contracture. Stressed radiographs were not taken pre-operatively by any of the contributing surgeons in routine practice, and therefore were not used in the study.

Patients were excluded principally if they had any factors which would jeopardise their completion of the trial. Two CT scans were required, and the operation was predicted to take considerably longer than usual. In addition, prototype clamps to hold the knee were unsuitable for obese patients. Therefore, patients with a body mass index of 31 or more or conditions leading to osteoporosis or serious neurological disorders, women of childbearing age, and patients with an increased risk of deep-vein thrombosis were excluded from the trial.

Four patients (six knees) were withdrawn from the study. In the first withdrawn patient, an intra-operative decision was made to switch from UKA to total knee replacement. A second, having already undergone a UKA for one knee, had perforation of a duodenal ulcer in the post-operative period. The patient was reviewed at six weeks as per the protocol, but was not fit for the planned second operation. In three further patients, the reason for withdrawal was the unavailability of the Acrobot system because of a technical problem. Despite being randomised to the robotic arm these three patients had to be re-allocated to conventional surgery and were not included in the final analysis. All patients recruited were included, however, in the analysis of the safety data.

This left 27 patients (28 knees, since one patient had bilateral UKA) who were randomly allocated to receive either the Acrobot system or conventional surgery. Recruitment started in December 2003 and the last patient was assessed in July 2004. All 27 patients underwent their six- and 18-week post-operative assessment. The conventional (n = 14) and Acrobot groups (n = 13) had a mean age of 70.4 (62 to 79) and 69.8 (58 to 78) years, respectively. There were fewer women in the Acrobot group (5 of 13 patients) and left knees were more common in the conventional group (8 of 15 knees).

The primary hypothesis was that the Acrobot system would achieve more consistent angular alignment of the prosthesis and corresponding tibiofemoral alignment in the coronal plane than conventional instrumentation. Our review of the literature on UKA showed that there was a variety of tibiofemoral angles (2°, 3°, 5° and 10°) which had been used as the limit between accurate and inaccurate alignment. The proportion achieving the degree of accuracy within the limits accepted ranged from 48% to 92%.7,24-28

Our experience with previous devices and the ability to measure small differences enabled us to detect a change in alignment of 1°. Therefore, we expected to be able to measure within 2° of the angle planned in more than 99.9% of UKA patients compared with a predicted percentage of 48% achieving such accuracy of alignment in conventional surgery from the studies reported above.

Pre-operative planning. All patients had pre-operative CT, lying supine (Fig. 1). The affected leg was placed in a splint, with the foot pointing upwards. A bag of saline was placed against the lateral side of the knee to correct some of the varus and to avoid bone touching bone on the medial side which caused difficulty with segmentation. Slices were taken through the hips, knees and ankles. The scans were saved as Digital Imaging and Communications in Medicine files from which the bones were extracted using a semi-automated segmentation algorithm.29 The bone surfaces were then used to plan every case, with the surgeon defining the positioning of the components and test size for every case, whether robotic or conventional. The tibia was sized and positioned by the surgeon to recreate a joint line in keeping with the lateral compartment with a minimum thickness of 4 mm for the polyethylene insert. All patients had clinically, fully correctable varus deformities with the knee at 10° of flexion, but in each case, the surgeon chose the orientation of the tibial cut and the height of the joint...
Diagrams showing the planned position of the implant (white) and the actual position achieved (yellow) in a) the conventional and b) the Acrobot groups.
Based on a match with the lateral compartment and proximal tibia. This sometimes left the knee in slight varus (Fig. 1a). Each case was planned on its merits by each surgeon. The rotation of the component in relation to the shape of the proximal tibia, and the position relative to the tibial tubercle and the ankle were selected by the surgeon. The femoral component was positioned using the flexion facet of the condyle, which remains relatively preserved in anteromedial arthritis. The component was fitted to this curve in the sagittal plane by eye, having been aligned to the axis of the femur, and then translated and rotated at the discretion of the surgeon to the most appropriate position on the condyle (Fig. 1a). This differed from the manufacturer’s instructions in which the soft-tissue tension in both flexion and extension determined how much of the distal femur was resected. Our experience with CT-based planning in total knee arthroplasty in which varus deformity can be fully corrected led us to believe that retaining the centre of rotation of the femoral component at its pre-operative position was satisfactory. Additional increments of 0.5 mm could be taken from the extension gap if needed at operation. The plans were then printed and brought to the theatre on the operation day, for the surgeon to use as a visual aid.

Operative procedure. The Acrobot system is a novel hands-on robotic device for orthopaedic surgery. It consists of a high-speed cutter which is mounted on a robotic device. The latter actively prevents the surgeon from cutting bone away from outside the area defined in the pre-operative plan, but servo-assists the surgeon when the drill is within the area of bone to be milled away (Fig. 2). One surgeon (JC) performed the operation in the 13 robotic cases and four others performed the 15 conventional cases. The potential conflict of interest of the first author determined that he should not undertake all the control operations. All surgeons whose patients were entered into the trial were familiar with the Oxford UKA (Biomet, Swansea, UK).

Method of measurement. For the purpose of the study, we defined the angle of tibiofemoral alignment as the angle between the femoral axis and the tibial axis in the coronal plane. The angles (mechanical, tibial component, femoral component) and mechanical axes (of the femur and the tibia) were measured from CT scans.

Numbers were calculated for a level of significance of 0.05 and a power of 80% ($\beta = 0.20$), based on a two-sample test of proportions and a two-sided test hypothesis using SPSS software (SPSS Inc, Chicago, Illinois). Yates’s correction for continuity was applied. A total of 26 completed subjects (13 per group) would be sufficient to detect a difference, in support of the hypothesis.

The primary outcome measure was the change in the tibiofemoral angle, defined as the difference between the planned and achieved angles in the coronal plane. The measured values were transformed into dichotomous data (i.e. an angle of $\leq 2^\circ$ into 0; a difference $> \pm 2^\circ$ into 1). These two groups were compared by Fisher’s exact test.

To test this hypothesis, involving the confident measurement of angles and translations to less than one degree, the method had to be sufficiently accurate. The post-operative CT scan was co-registered with the pre-operative plan (Fig. 1) by a medical physicist who was blinded as to which group the patient belonged. The resulting change in varus-valgus alignment was calculated from the proximal-distal translation error (achieved vs planned), obtained in millimetres, for both the femoral and the tibial components. These measurements were transformed into angular values using the inverse tangent generated by the width of the joint and the translation error. This was reproducible, based upon a software analysis of position. Every other variable was also measured but, since they have not been described by other authors, comparison is not possible. After the co-registration, the bone was subtracted, allowing visualisation of the two positions, planned and achieved (Fig. 3).

![Bar chart showing the difference in tibiofemoral alignment between planned and achieved in the coronal plane. One of the Acrobot cases has a value of 0˚.](image-url)
Figure 5a – Bar charts showing the absolute value of alignment error in the varus-valgus direction. Acrobot cases range between 0.2° and 4.8° with a mean of 1.5° (SD 1.4°) vs 0.1°, 9.8° and 3.4° (SD 2.4°) in the conventional group. Figure 5b – Bar charts showing the absolute value of alignment error in the flexion-extension direction. Acrobot cases range between 0° and 4.1° with a mean of 1.3° (SD 1.1°) vs 0°, 14°, and 4.9° (SD 3.4°) in the conventional group. Figure 5c – Bar charts showing the absolute value of alignment error in the axial direction. Acrobot cases range between 0.1° and 8.4° with a mean of 2.8° (SD 2.5°) vs 0.7°, 13.1°, and 5.1° (SD 3.7°) in the conventional group. Figure 5d – Bar charts showing the absolute value of the alignment error in the medial-lateral direction. Acrobot cases range between 0.1 and 2.3 mm with a mean of 0.8 (SD 0.6) vs 0.1, 7 and 1.9 (SD 1.7) in the conventional group.
Secondary outcome parameters included measurement of the American Knee Society (AKS) score and Western Ontario and McMaster Universities Osteoarthritis (WOMAC) index (pre-operatively and at six and 18 weeks), all adverse events and, specifically, device- and procedure-related complications, and the operating times.

Differences in the pre- and post-operative AKS and WOMAC scores were compared by the Mann-Whitney U test.

**Results**

The mean overall pre-operative AKS score was 101.4 (SD 13.93). This was higher in the conventional group than in those treated by the Acrobot system (104.9 (SD 13.43) vs 97.3 (SD 13.90)). The overall mean operating time was 95 (SD 18.1) minutes, but was greater in the Acrobot-treated patients (104 (SD 16.6) vs 88 (SD 16.3) minutes). The difference in the mean operating time between the two groups was not significant.

The differences between the tibiofemoral angles planned and achieved were transformed into dichotomous data (angles ≤ 2° or > ± 2°) and a cross-tabulation, angles vs type of surgery, was performed. In all the patients in the Acrobot group the tibiofemoral alignment in the coronal plane was within 2° of the planned position with a mean of 0.65° (SD 0.59; -1.6° to 0.3°) while in the conventional group only six of 15 knees achieved this level of accuracy with a mean of -0.84° (SD 2.75; -4.2° to +4.2°) (Fig. 4). These results were significant (Fisher’s exact test; p = 0.001) thus confirming the primary hypothesis that the use of an active constraint robotic assistant improved the positioning of the prosthesis in the coronal plane.

This difference in accuracy was further illustrated by images showing the planned and achieved positions of the implants after the bones have been superimposed on one another and then subtracted (Fig. 3) by a blinded assessor.

Differences between the pre- and post-operative AKS scores in both groups were calculated for all 28 knees and the data analysed by the Mann-Whitney U test at six and 18 weeks. The scores for patients treated by conventional surgery showed a wider spread, ranging from 3 to 83, than those in the Acrobot group which ranged between 38 and 107. The mean increase in the AKS score was twice as large in the Acrobot system group (65.2 (SD 18.36) vs 32.5 (SD 27.46)) and the median values were more than three times higher in the Acrobot group (62 vs 19). The difference
between the type of surgery was statistically significant (non-parametric test, p = 0.004).

There was no significant difference (p = 0.06) between WOMAC scores of the two groups for pain, stiffness and physical function. The results are presented in Table I.

The deviations of position from the pre-operative plan were measured in all six degrees of freedom (three degrees of translation, in the medial-lateral, anterior-posterior, and proximal-distal directions and three degrees of rotation, in the varus-valgus, flexion-extension and axial directions). The variations from the planned position are shown graphically (Fig. 5). They showed that the Acrobot-assisted group had consistently more accurate results in each degree of freedom.

The translational and rotational errors have been combined to form measures of compound translational and rotational errors, for both the femur and tibia. Plots of improvements in the AKS scores at 6 weeks were plotted against these errors (Fig. 6). They showed the difference between the two groups with the Acrobot group having higher scores and lower errors, with closer clustering of results.

During the course of the study, four minor adverse events were registered, three in the Acrobot group and one in the conventional group. In no case did the adverse event lead to the patient’s withdrawal (Table II). Three serious adverse events occurred in three subjects, one in the Acrobot group.
and two in the conventional group (Table III). While all adverse events are likely to be related to the procedure, none was considered to be directly related to the study itself.

**Discussion**

This prospective, randomised controlled trial has confirmed that computer assistance improves the accuracy and consistency of placement of the implant in UKA. All of the Acrobot group achieved angles of tibiofemoral alignment on the coronal plane within the target zone of ± 2°, while only six of 15 knees in the conventional group were within this zone (p = 0.001). The operations took longer but the clinical outcome as shown by the functional scores at six and 18 weeks did not reveal any detrimental effect.

Before the trial there had been concern that the four extra stab wounds in the skin for the introduction of the bone clamps, together with the extended operating time, would result in poorer function in the short term. These concerns proved to be unfounded.

Our study had a number of limitations. It used the AKS score at six and 18 weeks as the clinical end-point which, while repeatable, and blinded, has been shown to have substantial inter- and intra-observer errors. No long-term follow-up is available as yet but we are continuing to follow these patients, although the assessment is no longer blinded. The series is small, governed by the power calculation performed and at the outset it had been agreed for ethical and regulatory reasons, that no more Acrobot procedures than those strictly necessary would be performed until the device had received regulatory approval. All the Acrobot operations were performed by the first author, while the conventional operations were performed by four colleagues who were regularly performing UKAs. It was felt that this would minimise potential bias from an interested party. Learning curves are well documented within arthroplasty in general and UKA in particular. All the surgeons performing the UKAs in the conventional group had undertaken more than ten UKAs previously, while the Acrobot had been proven with extensive laboratory tests before the study to demonstrate that the system worked satisfactorily. The variations in the short-term clinical outcome may be due to surgeon bias, but the correlation between accuracy and function implies that there is a real association. If the joint line and orientation can be planned and reproduced accurately, the chances of a good clinical result are higher.

The introduction of robotic devices such as this may shorten the learning period for surgeons in training for acquiring a new technique, and reduce the risk of error. This may be particularly valuable in minimal access arthroplasty.

The use of CT in the assessment of the accuracy of insertion of the implant has allowed a more detailed inspection of the impact of the operative technique to be undertaken. It has also shown that each degree of freedom can be measured. How accurate the surgeon needs to be to obtain reliably good results remains unknown. While it is suspected that there is a relationship between accuracy and outcome in arthroplasty, it has been difficult to prove radiologically. The post-operative CT protocol which we have developed allows the precise position of any implant to be determined. A joint which is functioning poorly will frequently be shown to have some significant technical error, whether in angular positioning, translation, or sizing of component, or a combination of these. The use of an active constraint device should reduce the chances of a patient being exposed to the risk of poor function, and possibly early joint failure. The Acrobot system has been shown to be both accurate and reliable. By permitting the creation of bone surfaces that can be machined by means other than an oscillating saw, this system paves the way for novel implant

### Table II. Details of non-serious adverse events

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Days after surgery</th>
<th>Event</th>
<th>Severity</th>
<th>Cause</th>
<th>Relationship of the patient</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrobot</td>
<td>21</td>
<td>Swollen leg</td>
<td>Mild</td>
<td>Probably related to surgical procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acrobot</td>
<td>4</td>
<td>Skin blister in peri-scar area</td>
<td>Mild</td>
<td>Certainly related to surgical procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acrobot</td>
<td>21</td>
<td>Swollen ankle</td>
<td>Mild</td>
<td>Possibly related to surgical procedure and condition of the patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conventional</td>
<td>2</td>
<td>Bilateral swollen legs</td>
<td>Intermediate</td>
<td>Unlikely to be related to the condition of the patient</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table III. Details of serious adverse events

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Days after surgery</th>
<th>Event</th>
<th>Severity</th>
<th>Relationship of the patient</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrobot</td>
<td>1</td>
<td>Acute urinary retention</td>
<td>Intermediate</td>
<td>Possibly related to the condition of the patient</td>
<td>Resolved by TURP*</td>
</tr>
<tr>
<td>Conventional</td>
<td>1</td>
<td>Perforated peptic ulcer</td>
<td>Severe</td>
<td>Probably related to the condition of the patient and the surgical procedure</td>
<td>Laparotomy</td>
</tr>
<tr>
<td>Conventional</td>
<td>9</td>
<td>Myocardial infarction</td>
<td>Intermediate</td>
<td>Possibly related to the condition of the patient</td>
<td>Recovered well</td>
</tr>
</tbody>
</table>

* TURP, transurethral section of prostate
designs to be developed. These may facilitate bone conserving arthroplasty in the knee, hip and spine, with a new generation of even less invasive and more conservative procedures.

Supplementary Material

A further opinion by Mr Christopher Ackroyd is available with the electronic version of this article on our website at www.jbjs.org.uk

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References