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Full length article

A comparison of gait one year post operation in an RCT of robotic UKA versus traditional Oxford UKA

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Abstract

Robot-assisted unicompartmental knee surgery has been shown to improve the accuracy of implant alignment. However, little research has been conducted to ascertain if this results in a measureable improvement in knee function post operatively and a more normal gait. The kinematics of 70 OA knees were assessed using motion analysis in an RCT (31 receiving robotic-assisted surgery, and 39 receiving traditional manual surgery) and compared to healthy knees. Statistically Significant kinematic differences were seen between the two surgical groups from foot-strike to mid-stance. The robotic-assisted group achieved a higher knee excursion (18.0°, SD 4.9°) compared to the manual group (15.7°, SD 4.1°). There were no significant difference between the healthy group and the robotic assisted group, however there was a significant difference between the healthy group and the manual group ($p < 0.001$). Hence robotically-assisted knee replacement with Mako Restoris Implants appears to lead not only to better implant alignment but also some kinematic benefits to the user during gait.

Keywords: Kinematics; Gait; Robotic-assisted arthroplasty; Unicompartmental knee replacement; Walking

1 Introduction

Unicompartmental knee arthroplasty (UKA) has been re-emerging as a treatment for medial compartmental osteoarthritis (OA), and a popular alternative to total knee arthroplasty (TKA) when the disease is limited to the medial compartment and the soft-tissues remain intact [1,3,17].

The advantages of this procedure include reduced hospital time, faster recovery, better post-operative range of motion [4,5] and improved gait compared to TKA [36,37]. While UKA popularity waned in the 1980s due to high revision rates [33], current long term data show UKA is surviving into the second decade [18,19]. However performing UKA is technically demanding, and in some cases component malalignment has resulted in poor post-operative function and early revision [6–9].

To aid in component alignment, navigated and robotic-assisted UKA systems have been developed [12–14]. Using robot-assisted surgery the accuracy of implant alignment can be improved [11,15,20]. These systems also give the ability to make adjustments in implant placement during the procedure based on soft-tissue tension [10] and to use three dimensional curved implants which are claimed to better match knee joint anatomy and produce better function.

The aim of this study was to determine if the functional performance during gait of patients that have undergone robotic-assisted UKA (MAKO Surgical Corp., Ft Lauderdale, FL, USA) compared to manually implanted UKA (Biomet, Swindon, United Kingdom) showed a measureable improvement during walking in knee function and if the patients were returned to normal knee function post operatively (Tables 1 and 2).

Table 1 Mean participant demographic characteristics of the control group and the two surgical groups. Standard deviations in brackets.

alt-text: Table 1

	Control (n = 50)	Robotic-assisted (n = 31)	Manual (n = 39)
Age (years)	70.4 (6.6)	62.7 (7.0)*	64.6 (6.1)*
Gender (m/f)	28/22	19/12	24/15
Operated knee (left/right)	n/a	16/15	26/13
Height (cm)	167.2 (7.0)	168.3 (11.5)	168.8 (8.9)
Body Mass (Kg)	74.1 (12.7)	95.9 (22.4)*	87.9 (16.0)*

*Significantly different than the control group.

Table 2 Mean gait characteristics for the groups during walking. Standard deviations in brackets.

alt-text: Table 2

	Control (n = 50)	Robotic-assisted (n = 31)	Manual (n = 39)
Knee excursion from foot-strike to mid-stance (degrees)	19.5 (4.0)	18.0 (4.9)	15.7 (4.1)*,†
Knee excursion from mid-stance to terminal-stance (degrees)	15.8 (4.3)	12.9 (6.1)*	10.8 (4.7)*
Total knee excursion (degrees)	65.6 (5.1)	64.1 (6.6)	63.1 (7.2)
Average speed (metres per second)	1.17 (0.20)	1.16 (0.16)	1.11 (0.17)

*Significantly different thanfrom the control group.

†Significantly different form the robotic-assisted group.

2 Methods

2.1 Subjects

A total of 70 knees were assessed for this study taken from a larger randomised group of 129 participants. 31 were in the robotic-assisted UKA group, and 39 in the manual group. UKA surgery was performed at Glasgow Royal Infirmary from 2010 to 2013. Written informed consent was obtained from all patients. Patients were assessed one year post-operatively.

Control group older adult data (n=50) were obtained from the University of Strathclyde normal archive. The data consisted of 50 typical gait cycles, recorded with the same system and protocol as for the knee RCT and with subjects from the Glasgow area. This data has been previously published in [41,42]

2.2 Test protocol

Three dimensional gait analysis was performed for both robotic-assisted and manual UKA groups. Subjects were asked to walk a total distance of 10 m across the biomechanics lab in order to reach steady speed, and their data were recorded within the middle 5–6 m camera capture measurement volume. The groups were asked to walk at a comfortable self-selected pace three times, during which their gait was recorded.

2.3 Data collection and processing

The subjects underwent their biomechanical gait assessment at the University of Strathclyde Biomedical Engineering Department. Kinematic data were obtained using the Vicon Nexus motion analysis system (Oxford Metrics Ltd. UK) with twelve infra-red cameras, powered by two MX Giganet servers and sampled at 100 Hz. The lower limb biomechanical model used was developed by Papi, [21] in which a combination of marker points and marker clusters were used to determine the anatomical model for each subject [35]. A single well-trained physiotherapist fixed the markers onto the lower limbs according to the protocol. Foot contacts were detected using four force plates (Kistler Instruments AG, Switzerland). The speed for each trial was calculated via the Vicon velocity function, whereby the pelvic segment was used as a reference across the entire length of the measurement volume, checked for irregularities, and averaged.

2.4 Data analysis

Data were extracted using the Vicon Nexus software (Oxford Metrics Ltd., UK) and further processing was performed in Matlab (MathWorks, Natick, MA).

Graphs were generated for each gait cycle, and observed for any errors such as dropout of markers, jumps in data or irregularities caused by mislabelling and if required reprocessed. Marker trajectories were filtered using a Woltring filter (MSE = 15). Each patient performed three walking tasks on their operated side. Each sagittal plane walking cycle was time-normalised from foot strike to foot strike. From these data three values for knee excursion were derived – total knee excursion, excursion from foot-strike to peak mid-stance, and excursion from peak mid-stance to minimum in terminal stance. The three values and the kinematic cycle were averaged for each subject. These same knee excursion values were obtained from the normal data, thus provided a baseline for normal older adult knee behaviour.

2.5 Statistical analysis

Each comparative test was first given an Anderson-Darling (AD) test in order to ascertain if the data were normally distributed. If the data were not normally distributed, the Mann Whitney (U) test was used to analyse any statistical differences. If the data were normally distributed then the comparison used a two tailed independent t-test. The alpha level was set at 0.05. The null hypothesis was H0 = no difference between the two groups. This hypothesis was rejected only when $p < 0.05$. Other group differences such as gender differences, knee, and age were evaluated by using the Chi Squared Test.

3 Results

Both patient groups that underwent UKA surgery were significantly younger than the healthy volunteer control group (both groups p-value <0.001), albeit by only six years on average (Table 1). However it is important to note that while the control group was significantly older than the UKA patients, they were given a health screening before taking part and were fit and able. This screening excluded subjects with pain during gait, arthritis, cardiovascular or neurological issues likely to affect gait. The subjects were therefore healthier individuals than a typical person of their age and hence their data can be considered a suitable comparison for UKA. They also weighed significantly less than the two surgical groups, however there was no statistically significant difference between the robotic-assisted and manual UKA groups in terms of weight ($p = 0.11$). The two surgical groups were also not significantly different in terms of height ($p = 0.85$), operated knee ($p = 0.20$), gender balance ($p = 0.98$) and age ($p = 0.25$). All data in each group were normally distributed, therefore independent t-tests could be used for analysis.

Statistically significant differences (Table 2) were seen in the knee joint kinematics during level walking between the robotic-assisted and manual UKA groups (Fig. 1). These differences were between foot-strike and mid-stance where the robotic-assisted group achieved a higher knee excursion (18.0°, SD 4.9°) compared to the manual group (15.7°, SD 4.1°). This difference was statistically significant at a p-value of 0.04. When compared to the control group no statistically significant differences were seen in the robotic-assisted UKA group ($p = 0.15$), however this difference was significant in the manual UKA group ($p < 0.001$). This implies the robotic assisted UKA knees behave normally in this region of the gait cycle whereas the manual UKA group do not.

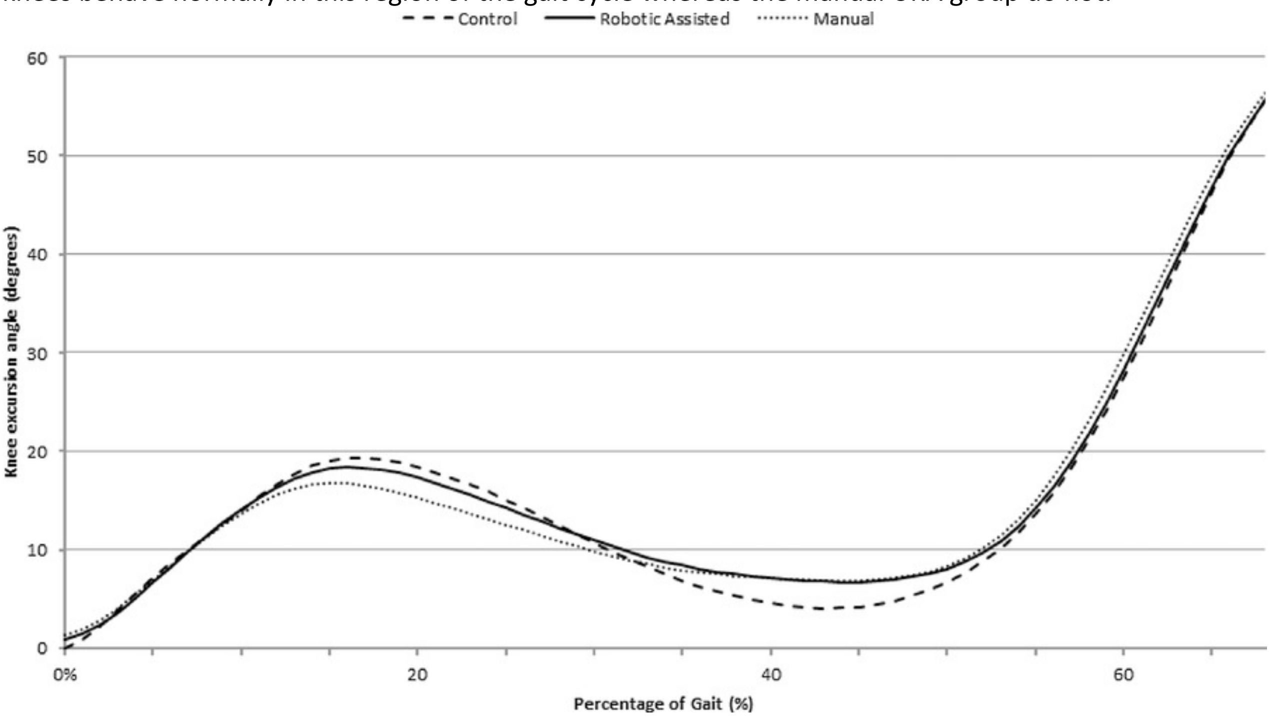

Fig. 1 Mean knee excursion angles of the control group, the robotic-assisted and manual UKA groups during the stance phase of gait.

Neither UKA group managed to achieve comparable levels of knee excursion between mid stance and the minima in terminal stance when compared to the control group between mid-stance and terminal stance(robotic-assisted UKA group $p = 0.03$, manual UKA group $p < 0.001$). While the robotic-assisted UKA group showed a higher knee excursion in this phase (12.9°, SD 6.1°) compared to the manual UKA group (10.8°, SD 4.7°) this difference was not statistically significant with a p-value of 0.11.

Both UKA groups had comparable total knee excursion values when taken over the whole gait cycle and neither were statistically different from the control group.

There were no statistically significant differences seen in the average walking speeds between the surgical groups, or the control group. A marginal correlation between speed and flexion during stance was seen ($R2 = 0.21$)

4 Discussion

The 1 year post-operative gait data showed that overall the robotic-assisted UKA group had normal knee flexion during loading response whereas the manual UKA group continued to show statistically significant loss of this gait variable post-operatively. From foot-strike to mid-stance on average they robotic UKA group achieved a knee excursion of 18.0° (SD 4.9°) compared to the manual UKA group 15.7° (SD 4.1°). The control group achieved knee excursion values of 19.5° (SD 4.0°) – not significantly different from the robotic-assisted UKA group (p-value = 0.15), but significant in the manual UKA group ($p < 0.001$). The literature suggests that 18–20° is the normal range for knee flexion for healthy patients at this stage of gait [22] indicating the robotic-assisted group showed normal knee kinematics during weight acceptance while the manual group did not. Neither group achieved similar knee excursion during push off from mid-stance to terminal stance, however both achieved comparable overall knee excursion indicating similar and normal amounts of excursion during swing.

The function of the lower limb during stance is to resist collapse during weight acceptance, and to extend sufficiently to achieve the required push-off [23]. The muscular activity is greatest during weight acceptance and push off since demands in all three planes must be controlled [24]. Possible clinical factors that could account for these differences are, the implant design, implant alignment and surgical technique.

Excursion during weight acceptance is a commonly reported gait variable, and has often been used in gait analysis studies of Arthroplasty as a key biomechanical outcome measure [37–40]. McClelland et al. highlighted this outcome measure in their systematic review of gait analysis of patients following TKR (where the knee excursion values during loading response is referred to as the K3 angle).

Table 3 highlights these studies and their use of the knee excursion values during loading response. Smith et al. reported K3 values rising from 5.6 to only 6 ° in patients following TKA who continued to suffer from anterior knee pain post operatively. Both time points in this study were significantly lower than their control group ($P < 0.01$). John Insall's Group (Bolanos et al.) reported post operative values of 6.9° in PCL sacrificing TKA patients and 8.3° degrees in PCL retaining and again these K3 results were significantly different from their control group ($P < 0.01$). Additionally Wilson et al. reported a value of 7.6° in a group of posterior stabilised total knees which was again significantly different from their control group (P < 0.01). These results show that excursion during weight acceptance is limited by OA and Pain and while improved by TKA excursion during weight acceptance remains limited postoperatively.

Table 3 Comparison of knee excursion values during loading phase of gait comparing to TKA studies. Standard deviations in brackets.

	This Study			Bolanos et al. [38]			Smith et al. [39]			Wilson et al. [40]	
	Control	Mako	Oxford	Control	PCLS	PCLR	Control	Pre-surgery	Post-surgery TKA	Control	TKA group
Knee excursion from foot-strike to mid-stance (degrees)	19.5 (4.0)	18.0 (4.9)	15.7 (4.1) *	12.5 (4.8)	6.9 (3.9) *	8.3 (6.1) *	11 (3)	6 (5)*	7 (4)*	12.5 (4.1)	7.6 (3.3) *

*Significantly different than the control group.

Similarly our results for UKA show a much greater excursion during weight acceptance in UKA (15.7° and 18°) compared to TKA (approximately 8°). They also show that the difference in knee excursion during loading response for the patients receiving the manually implanted UKA intervention compared to the control group was statistically significant (p < 0.001). However there was no statistically significant difference between the robotic-assisted UKA and the control group implying normal knee excursion during weight acceptance had been restored for this group.

The manually implanted UKA (Oxford Biomet) consists of 2 congruent joint surfaces that do not allow any relative mobility, but which sit on the flat tibial implant which may slide. The femoral implant is a single radius component in order to be perfectly congruent with the polyethylene bearing and to spread load transmission [25]. However due to the bi-spherical nature of the medial femoral condyle, the Oxford UKA femoral implant does not reproduce the anterior aspect of the femoral condyle [26]. This design is to allow for surgical inaccuracies, as some varus/valgus implant malalignment can be accommodated and should not affect knee motion as the spherical femoral components can rotate in the coronal plane, but still have the ability for angular movements in the saggital plane [27]. Some fluoroscopic studies have shown they can restore normal knee kinematics [28,29].

The robotic-assisted UKA femoral implant surface (Restoris, Mako) was designed to mimic the surface of the natural femur. This can be achieved due to the enhanced bone sculpting ability offered by the burr cutting tool within the Mako RIO robotic arm which facilitates the cutting of curved surfaces on the bone.

Both designs should allow the ligaments to be restored to normal function [2,32], but the robotic-assisted system gives feedback to the surgeon to aid this process.

Implant alignment shouldn't influence the manually implanted Oxford UKA as long as it fits within the specified radiographic criteria of component position. Indeed studies have shown that there is no correlation between component alignment and outcomes in correctly positioned implants due to the spherical femoral component [30,31].

As the robotic-assisted UKA implants are fixed bearings and anatomical in shape [32] they have shown poor tolerance to misalignment in the past [33]. However as previously shown by ourselves when implanted with robotic-assistance their positioning is consistently well aligned [34].

There was as might be expected a correlation between increased walking speed and increased knee flexion in stance phase. However the Coefficient of Determination was only 21% (R2 = 0.21) leaving 79% of the improvement in knee flexion unexplained by the increase in walking speed. However walking speed was higher in the robotic group. Both an increased walking speed and an increased and more normal knee kinematic pattern can be considered improvements in function due to the robotic-assisted surgery.

Many knee replacement patients have high BMI values hence locating anatomical points on their hips and placing markers on them can be more challenging that in people with lower BMIs. Should pelvic marker misplacement occur it would lead to an error in the position of the hip joint centre location. This would give a constant offset throughout the data and not affect the excursion values. Further, if it occurred randomly it would likely caused some knees to have exhibited hyper-extension. None of the data exhibited hyper-extension so we can be confident that our hip joint centre calculations were correct despite the BMIs of the patients

The findings of this study should be interpreted with a number of limitations in mind. Firstly this was a single blind study. The patients were electronically randomised into their groups, however due to the procedure of the robotic-assisted UKA [32] they would have received an additional CT scan, and had the potential to see the Mako System in theatre. However the assessors were blinded and their gait data could not have been biased because it was recorded and analysed automatically.

Additionally in the complete clinical trial 63 patients were recruited into the robotic-assisted UKA group, and 66 into the manual. A few patients were excluded due to technical errors with the Vicon system, but mostly patients didn't want to take part in the additional voluntary biomechanical assessment at 1 year and hence a sub-group of 70 of the original 129 participants were available. To ascertain that the data for this sub-group was a representative sample of the larger group of patients that were recruited to the trial their American Knee Society Scores (AKSS) and Oxford Knee Scores (OKS) were compared, and there was no significant difference between the two groups. The median AKSS for the overall robotic-assisted group and sub-group were 171 and 184 respectively (p-value 0.26). For the manual group both median AKSS values were 164 (p-value 0.96). In addition the OKS for the robotic-assisted group and sub-group were 21 and 20.5 respectively (p-value 0.47), and the manual group 19.5 and 18 respectively (p-value 0.86). We can conclude that the two sub groups reported in this paper are representative of the trial groups as a whole.

Overall this study has found a difference between the two operative groups in knee flexion during loading response. Whether this difference is clinically meaningful is open for debate. For the authors the data are indicative of a return to normal gait during loading response in the robotic-assisted UKA group, and in our opinion such a finding is likely to be of value to the patient. However knee excursion during push off remained less than normal in both groups. It would appear that robotically assisted UKA combined with the Restoris Implant leads to a better gait outcome than the current UK standard procedure. Whether this benefit in gait is of sufficient value to the patient to warrant the adoption of the robotic technology and implant remains to be decided and will need to include other important issues such as implant longevity, complication rates and cost.

5 Conclusion

Robotically-assisted fixed bearing UKA implantation has been shown to produce more normal knee motion during the early stance phase of gait when compared to a manually implanted mobile bearing UKA. There may be many variables that could potentially cause this difference, such as the implants, surgical differences (such as using a cutting burr instead of a saw), the navigation element, or the fact that the bone resection is robotically-assisted. It can be argued that the Oxford knees can tolerate some surgical inaccuracies. The Mako implants using the robotic system were implanted precisely and reproducibly. The previous published data have shown that the Mako implants are put in more accurately and lead to less postoperative pain [34]. In this paper we have shown that the robotic-assisted group also achieve better results during walking than the conventional group. However the multi-factorial differences between the two types of procedures, their approach to UKA, and the limitations of this study make it difficult to identify the underlying cause of this difference.

6 Future work

While there was a difference seen between the robotic-assisted and manual UKA groups during walking, overall relatively modest benefits have been seen. A multi-centre study should be the next step for the use of robotics in UKA. The current study was done at a single, centre of excellence hospital with three experienced surgeons. This is not necessarily generalisable to a less experienced surgeon in a general hospital. We hypothesise that the differences seen would increase with robotic assistance in such circumstances. Having multiple centres including a larger pool of surgeons with different experience levels would determine if these functional benefits from robotic-assisted surgery could be generalised to all UKA surgery.

Conflict of interest

The authors have no conflict of interest to disclose.

Uncited reference

[16].

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