Are there functional biomechanical differences in Robotic arm-assisted bi-unicompartmental knee arthroplasty compared to conventional total knee arthroplasty? A prospective, randomised controlled trial.

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Word counts:

Word count: 6373
Abstract: 303
Main: 5001
Reference: 1066

Abstract:

Aims

The objective of this study was to compare any differences in the primary outcome (biphasic flexion knee moment during gait) of robotic-arm assisted bi-unicompartmental knee arthroplasty (bi-UKA) with conventional mechanically aligned total knee arthroplasty (TKA) at 1-year post-surgery.

Methods

76 patients (34 bi-UKA and 42 TKA patients) were analysed from a prospective, single-centre, randomised controlled trial. Flat ground, shod gait analysis was performed pre-operatively and one year post-operatively. Knee flexion moment was calculated from motion capture markers and force plates. The same setup determined proprioception outcomes during a joint position sense test and one-leg standing. Surgery allocation, surgeon and secondary outcomes were analysed for prediction of the primary outcome from a binary regression model.

Results

Both interventions were shown to be effective treatment options, with no significant differences shown between interventions for the primary outcome of this study (46% biphasic TKA patients vs 57% biphasic bi-UKA patients, $p=0.51$). All outcomes were compared to an aged-matched, healthy cohort that outperformed both groups indicating the residual deficits that exists post-surgery. Logistic regression analysis of primary outcome with secondary indicated that the most significant predictor of post-operative biphasic knee moments was pre-operative knee moment profile and trochlea degradation (Outerbridge) ($p=0.002$, 0.046 $R^2=0.381$). A separate regression of alignment against primary outcome indicated significant bi-UKA femoral and tibial axial alignment ($p=0.029$, 0.047 $R^2=0.352$) and TKA femoral sagittal alignment ($p=0.016$, $R^2=0.252$). The bi-UKA group showed a significant increased ability in the proprioceptive joint position test, but no difference was found in more dynamic testing of proprioception.

Conclusion

Robotic-arm assisted bi-UKA demonstrated equivalence to approach to OA showed equivalence to TKA in achieving a biphasic gait pattern after surgery for osteoarthritis (OA) of the knee. Both treatments are successful at improving gait, but both leave the patients with a functional limitation that is not present in healthy age-matched controls.

Introduction

Total knee arthroplasty (TKA) is a highly successful[1], cost effective[2] and frequently performed intervention[3] for osteoarthritis (OA) to alleviate pain and improve knee function. Patients with knee OA adopt different gait patterns for several reasons: unloading of diseased areas from pain[4], control of muscles around the knee[5], anatomical changes in the knee[6], weight gain[7], ageing[8] and walking speed[9]. Whilst function of the knee is often partially restored following surgery, TKA patients often report dissatisfaction[10] and exhibit deficits in function compared to aged-matched patients with normal knees[11–14].

Loading of the knee is an important factor in maintaining homeostasis of the mechanosensitive tissues in both pre-operative[15] and post-operative knees[6]. Individuals with OA or pain reduce the magnitude of the peak knee flexion moment[6,16]. Measuring the dynamic loading of the knee during walking is an accepted surrogate measure of the biomechanical function of the knee[17]. The use of motion capture systems and force plates offers an accurate, objective and non-invasive method of measuring the knee's pre- and post-operative biomechanical performance[18]. Prosthetic knee designs aim to recreate normal gait kinematics, and gait analysis studies with ground-to-foot force data can measure whether restoration has been achieved[19].

Figure 1 - Representative graphs of three knee flexion graphs. Quad avoidance, quad overuse and normal (Biphasic) knee moment

Normal sagittal plane knee moments show a biphasic (both flexion and extension) curve during the stance phase of gait. The most commonly seen deviation from this pattern in knee pathologies (OA, Anterior Cruciate ligament (ACL) rupture) is a flexor, quadricep overuse pattern[20] (Figure 1 – black line) which prevents knee extension moments. This gait pattern may result from fixed flexion deformities[20] or quad dysfunction (weakness[21] or inhibition[22]), leading to an inability to extend the leg fully. The reduced knee flexion excursions result in an overloading of the knee joint during walking that is associated with the progression of OA[23], a higher risk of tibial component loosening[24], anterior knee pain[25] and longer-term loss of function. The second much less commonly seen is a quadricep avoidance pattern (Figure 1 – red line) which involves a straight knee during the stance phase that avoids flexion moments. This dichotomous (biphasic, non-biphasic) classification of sagittal knee moments is an indicator of good biomechanical function of the knee and is the primary outcome of this study.

An accepted shortcoming of most TKA procedures is the loss of one or both of the cruciate ligaments. These structures provide restraint to motion and sensory input to the perception of joint position, control and balance. Retention of the cruciate ligaments may lead to better functional outcomes, proprioception metrics and more natural knee motion[26]. The modular or multi-compartmental approach treats only the affected compartments with individual implants in a single or staged approach. The concept involves minimal bone and cartilage removal and conservation of the knee ligaments, including the cruciates[27]. Alongside gait analysis, proprioception metrics are reviewed to compare cruciate-retaining bi-UKA with a cruciate sacrificing TKA approach. Wada et al.[28] have reviewed the sparse literature on simultaneous bi-unicompartmental knee arthroplasty (bi-UKA) and concluded that there was a need for further studies, such as this one, to determine the efficacy of two UKAs as an alternative treatment option to TKA with isolated degeneration in the condyles and an intact ACL.

This study reports on the functional biomechanical results of an explanatory randomised controlled trial to compare a novel robotic-assisted surgical technique, bi-UKA, against a standard surgical technique, TKA, in patients with OA of both the medial and lateral compartments of the knee. The primary outcome was the proportion of patients achieving biphasic gait, with proprioception assessments of the two groups as a secondary outcome measure.

Patients and methods

Trial design:

The treating clinician screened patients on the waiting list for TKA for possible recruitment to the **T**otal versus **R**obotic assisted bi-**U**ni**C**ompartmental **K**nee (TRUCK) trial (ISRCTN 12151461). Eligible participants were suitable for a standard TKA to treat medial and lateral compartment OA with clinically intact cruciate and collateral ligaments. Participants were excluded from the recruitment if they had inflammatory arthropathies, varus or valgus deformities greater than 15°, a fixed flexion contracture greater than 10°, single-compartment OA suitable for an isolated UKA procedure, or patellofemoral OA (Merchant skyline x-ray) greater than Kellgren and Lawrence grade III. Eligible participants were consented and recruited to the study by research nurses or members of the research team.

The study design was a prospective, randomised, double-blinded, controlled study comparing two surgical techniques: a standard TKA or robotic-assisted bi-UKA surgery. Patients receiving TKA received a fixed bearing, cruciate sacrificing posterior stabilised Zimmer NexGen LPS TKA. Patients randomised to bi-UKA received two unicondylar fixed bearing MAKO Restoris MCK implants, one implanted on the medial side of the knee and the other on the lateral side. These implants were inserted with the aid of robotic-arm assistance using the MAKO RIO Robotic System. Neither group received patella resurfacing. All patients received inpatient physiotherapy and home exercise programs, with further formal outpatient rehabilitation only if required.

Randomisation and Blinding

Of the 209 participants screened, a total of 80 patients were eligible and willing to be recruited to the study (Figure 2 and Table 1). Surgical treatment randomisation was stratified to one of three surgeons with extensive experience with the new robotic technology. Randomisation led to similar patient demographics in both treatment groups, with the exception of significantly more bi-UKA patients using walking aids before surgery than TKA patients (Table 1). Two additional intraoperative assessments of the knee led to cross overs from participants randomised to bi-UKA receiving TKA. The ACL was assessed to ensure that the main structure was intact, with superficial fraying was accepted and ignored. All joint surfaces, including the PFJ, were assessed and graded according to Outerbridge.

Gait analysis:

The primary outcome measure for the study was the proportion of patients in each group with a biphasic sagittal knee moment pattern during gait. Biomechanical gait analysis was conducted pre-operatively and at 1-year post-operatively in our human performance lab at Glasgow Royal Infirmary and the University of Strathclyde. Three-dimensional gait analysis was performed using a lower limb cluster-based marker model and a 12 camera Vicon Bonita (Oxford Metrics Ltd. UK) optical motion tracking system, operated using Vicon Nexus 2.9.0 capturing at 100Hz, and two AMTI force plates (AMTI©, Massachusetts, USA) embedded in the floor. A physiotherapist, who was familiar with the bespoke marker set, attached the markers for all participants. Participants repeated shod, 10m overground walking trials at a self-selected, comfortable pace using walking aids if necessary, until three clean strikes of the force plate were recorded for each leg. Data were processed and analysed using MATLAB (MathWorks Inc). All gait data were normalised to 100% of the gait cycle.

Our system reports external flexion moments with a positive value and external extension moments with a negative value. For a patient to be classified as having a "biphasic gait", the patient must produce a moment pattern with both flexion (positive) moment at any point of stance and extension (negative) moment in the second half of stance. This classification was assessed from the timings of maximum and minimum moment values, verifying that the maximum value has a positive value and the minimum is negative. Patterns with either all positive or all negative max and min values were defined as non-biphasic without subjective inference from the researchers carrying out the test. Additionally, spatiotemporal walking parameters, including speed, stride length, stride width, cadence, and percentage of gait cycle in stance, were measured.

Further contextual comparisons were made against existing data from 17 healthy age-matched controls from a previous study in the same lab and by the same researchers. This healthy group were determined from medical histories, excluding any arthritis or functionally impairing conditions. Secondary outcomes (CT, PROMs) were not captured in this group, and hence analysis is limited to gait parameters.

Proprioception

Participant proprioception was tested through a joint position test and a single leg stand with eyes closed[30]. Whilst seated and with eyes closed, joint positions were taught to the participant by a physiotherapist passively moving the leg to a position 20 degrees from full extension. These passive movements were repeated three times, after which the participant was instructed to actively place their leg at the same position and hold it there for 3 seconds. This cycle was repeated three times. The motion capture system measured all joint angles.

A 30-second dynamic sway test was performed with eyes closed alternating between both legs. Following familiarisation with the protocol, the test was repeated three times for each leg. The centre of pressure (COP) was calculated from two force plates. The trajectory of the COP movements was analysed for area and length of COP trajectory, which measures the amount of movement and time spent balancing on a single leg.

Alignment

We have shown in a parallel CT alignment study on the patients involved in this study that the difference between pre-operative anatomy and post-operative implant alignment was significantly lower in the bi-UKA group[31]. The CT outcomes were analysed by treatment stratified binary regression to predict whether smaller pre-- to post-operative anatomy changes were associated with post-operative biphasic sagittal knee moments.

Clinical outcomes

Patients were followed in the first 6 weeks post-surgery using patient diaries to track patient Pain and Stiffness Visual Analogue Scales (VAS) and activity questions. Research staff performed physical assessments and assisted patients in completing PROMs at Pre-op, 3 months and 1 year following surgery. These included Oxford Knee Score (OKS), New Knee Society Score (NKSS), Forgotten Joint Score (FJS), EQ5D-3L, UCLA activity score, Hospital Anxiety and Depression (HAD) Scale, Pain and Stiffness VAS, Satisfaction, Range of motion (ROM), Quadriceps Strength, Timed Up and Go and Stair Climb Test. These outcomes have been reported at 1 year[32] and analysed in this study by binary regression to predict whether clinical outcomes scores predict the presence of biphasic gait.

Statistical analysis

The sample size was calculated for the primary outcome measure of the proportion of patients with a biphasic knee flexion moment (normal) during gait. TKA patients achieved biphasic gait in 23% of cases after surgery compared to 70% of UKA patients[33]. It was hypothesised that bi-UKA surgery would be unlikely to achieve the same level as UKA. Nevertheless, it was anticipated that a substantial proportion of this effect would be achievable[34]. We, therefore, based our assumptions that 60% of bi-UKA patients might have a biphasic gait after surgery. To detect a difference of this size with a power of 90% at a 5% level of significance using a chi-squared test a study of 36 patients per group would be needed (calculated using 'sampsi' in Stata 11.2 without continuity correction). An additional 10% for loss to follow up at 1 year created sample sizes of 40 patients per group (80 in total) which were recruited over a 41-month period.

The primary outcome at 1 year was analysed according to a per-protocol chi-squared test and a mixed-effects logistic regression model against surgeon and treatment type[35]. An explorative stepwise logistic regression model analysed all secondary outcomes and CT alignment previously published[32] as a random effect.

Ethics and Approvals

The study complied with the principles of the Declaration of Helsinki and received ethical approval from the West of Scotland Research Ethics Committee (14/WS/0134).[35] The bi-UKA technique, simultaneously replacing both medial and lateral sides of the joint, was an off-label use of the Mako System at the time of registration of the trial. Permission for this specific use of the robotic arm-assistance system was obtained via a Clinical Trials Notification (CI/2014/0032) with the Medicines and Healthcare products Regulatory Agency (MHRA). This study was registered with the International Standard Randomised Controlled Trial Number Registry (ISRCTN 12151461).

Results:

Figure 2 – CONSORT (Consolidated Standards of Reporting Trials) diagram demonstrating the flow of patients through the randomised clinical study.

*Table 1 – Pre-op participant characteristics from bi-UKA, TKA and Healthy Controls. * = bi-UKA versus TKA; p = 0.01.*

	bi-UKA (n = 34)	TKA (n = 42)	Healthy Controls (n=17)
Age (y), Mean (SD)	70.4 (7.1)	68.7 (7.7)	70.3 (2.9)
Gender m/f	21/21	17/17	4/13
Height (m), Mean (SD)	1.63 (0.11)	1.62 (0.11)	1.65 (0.09)
Weight (kg), Mean (SD)	86.8 (15.7)	83.8 (14.5)	79.4 (18.5)
BMI, Mean (SD)	32.6 (5.5)	32.4 (6.7)	28.9 (6.4)
Walking with Aids	44%*	19%	0 %
Outerbridge: (Median)			
Medial femoral compartment	4 (0.729)	4 (0.722)	-
Lateral femoral compartment	2 (1.256)	2 (1.352)	-
Medial tibial compartment	4 (0.626)	4 (0.976)	-
Lateral tibial compartment	1 (1.141)	1 (1.376)	-
Trochlea	3 (1.036)	3 (1.204)	-
Medial patella facet	2 (1.173)	2 (1.061)	-
Lateral patella facet	1 (1.067)	1 (1.234)	-

Biphasic Gait

Table 2 – Comparison of gait vs spatiotemporal biomechanical outcomes in pre- and post-op bi-UKA and TKA patients, and healthy controls.

	Pre-Op			Post-Op				
	bi-UKA (n=33)	**TKA (n=39)**	**p value**	**bi-UKA (n=31)**	**TKA (n=40)**	**p value**	**Healthy (n=17)**	**p value healthy vs post-operative**
Proportion of patients with biphasic gait (%)	41.9	46.0	0.74	64.5	56.8	0.51	88.2	p < 0.001
Walking speed Normalised with leg length (m/ms)	1.15	1.18	0.212	1.37	1.34	0.046	1.73	p < 0.001
Stride Length Normalised with leg length (m/m)	1.16	1.27	<0.001	1.36	1.37	0.933	1.61	p < 0.001
Step Width Normalised with leg length (m/m)	0.14	0.12	<0.001	0.13	0.12	<0.001	0.11	p < 0.001
Stride Time (Cadence – secs)	1.19	1.22	<0.001	1.09	1.13	<0.001	0.97	p < 0.001
Percentage of stride in stance (%)	65.07	64.06	<0.001	64.3	64.67	0.004	0.62	p < 0.001

There were no significant differences in the proportion of patients with biphasic gait between bi-UKA and TKA either pre-operatively (p=0.74) or at 1-year post-op (p=0.51) (Table 2). However, both treatment groups demonstrated an increase in the number of patients with biphasic knee flexion moment from pre-operative to post-operative. Compared to healthy controls, both TKA and bi-UKA patients had a lower percentage of the cohort achieving biphasic gait. The healthy control group were aged-matched with no reported joint disease, and only two of the seventeen participants had non-biphasic gait.

The differences in spatiotemporal gait characteristics from pre to post-op for TKA and bi-UKA patients show similar improvements that fall short of those seen in healthy controls (Table 2). From these post-operative gait characteristics, TKA and bi-UKA participants walked slower, had shorter stride lengths, wider step widths, lower cadence and spent more time in stance than healthy controls (Table 2).

Figure 3 - Change in biphasic gait from pre-operative status between bi-UKA and TKA patients. bi-UKA patients; Gained biphasic gait (27.7%, n = 10), retained biphasic gait (38.8%, n = 14), never achieved biphasic gait (27.7%, n = 10), lost biphasic gait (5.5%, n = 2). TKA patients; Gained biphasic gait (17.5%, n = 7), retained biphasic gait (35.0%, n = 14), never achieved biphasic gait (40.0%, n = 16), lost biphasic gait (7.5%, n = 3).

Biphasic gait was present in some patients pre-operatively, but there was no difference between the two groups. Although most retained or gained biphasic gait, a few patients lost this gait pattern following surgery (Figure 3).

Figure 4 - Knee flexion moment during stance as a percentage of the overall gait cycle. The trial groups: bi-UKA (n=31) and TKA (n=40) and a healthy control group (n=17).

The data presented in Figure 4 demonstrates grouped mean profiles of weight and height normalised sagittal knee moment through the stance of the gait cycle. Expressed as a percentage; heel strike is initiated at 0% through toe-off at 100%. This method can be used to show differences in gait cycle beyond a binary biphasic or non-biphasic classification. Statistical parametric mapping analysis showed no significant differences between the bi-UKA and TKA groups at any point in the gait cycle. However, comparison of either bi-UKA and TKA patients to the healthy control cohort demonstrates significantly lower peak moments during the stance phase (the first 10-35% of gait). In contrast, during late stance (83-93%), only TKA patients have significantly lower peak extension moments than healthy controls.

Regression Analysis

Table 3- Logistic regression analysis for post-operative biphasic gait based on treatment allocation.

Model: Primary outcome	β	SE β	Wald's χ^2	Df	p
Constant	-1.070	0.959	1.244	1	0.265
Surgeon	0.337	0.337	1.458	1	0.263
Treatment	0.493	0.496	0.991	1	0.319
Overall model eval			χ^2	Df	P
Likelihood ratio test			2.321	2	0.313
Hosmert & Lemeshow			5.936	4	0.204
Accuracy	67.6%				

Nagelkerke R^2	0.043				
Model: Secondary outcomes: TKA+BiUKA	β	SE β	Wald's χ^2	Df	p
Constant	1.848	0.921	4.062	1	0.044
PreBiphasic	1.965	0.625	9.887	1	0.002
Trochlear	-0.584	0.293	3.969	1	0.046
StiffnessVASPostOp1Yr	-0.274	0.139	3.899	1	0.048
Overall model eval			χ^2	Df	P
Likelihood ratio test			23.683	3	<0.001
Hosmert & Lemeshow			5.958	8	0.652
Accuracy	71.8%				
Nagelkerke R^2	0.381				
Model: Secondary outcomes: BiUKA Alignment	β	SE β	Wald's χ^2	Df	p
Constant	0.823	0.485	2.876	1	0.090
Femoral Axial Angle	-0.480	0.220	4.772	1	0.029
Tibial Axial Angle	-0.135	0.068	3.952	1	0.047
Overall model eval			χ^2	Df	P
Likelihood ratio test			9.659	2	0.008
Hosmert & Lemeshow			4.954	8	0.762
Accuracy	75.0%				
Nagelkerke R^2	0.352				
Model: Secondary outcomes: TKA Alignment	β	SE β	Wald's χ^2	Df	p
Constant	1.004	0.546	3.385	1	0.066
Femoral Sagittal Angle	-.387	0.161	5.807	1	0.016
Overall model eval			χ^2	Df	P
Likelihood ratio test			7.946	1	0.005
Hosmert & Lemeshow			4.951	8	0.763
Accuracy	68.4%				
Nagelkerke R^2	0.252				

To determine which pre-operative characteristics, treatment allocation, and post-operative outcomes were associated with biphasic gait, logistic regression analysis was carried out across clinical and imaging variables, with the 4 models presented in Table 3. As per the primary outcome (Model: Primary outcome), there was no association between allocated treatment or surgeon and the presence of biphasic gait ($p>0.05$ Nagelkerke $R^2=0.043$).

An additional regression analysis was carried out on the 1-year post-operative patient-reported outcome measures from this trial. These were assessed against the presence of post-operative biphasic knee moment, irrespective of treatment. This stepwise forward entry model defined from likelihood ratios showed pre-operative biphasic knee flexion moment as significant ($p=0.002$, Nagelkerke $R^2=0.381$) and positively correlated influence on the model's prediction of post-operative biphasic knee moment (Model: Secondary outcomes: TKA+BiUKA). This suggests that if a patient had a biphasic gait pre-operatively, they were significantly more likely to maintain a biphasic gait post-operatively. Lower Outerbridge grade scores, indicating less trochlear degeneration, were a significant predictor of those patients that went on to achieve post-operative biphasic gait (p=0.046, Nagelkerke R^2=0.381). Finally, post-operatively lower stiffness VAS were associate with biphasic knee moments (p=0.048, Nagelkerke R^2=0.381). No other patient-reported outcome measures demonstrated a significant association with the primary outcome.

The change in pre-operative anatomy to post-operative implant alignment showed limited prediction on post-operative biphasic knee moments. In the bi-UKA allocated group, femoral and tibia axial angle change was a predictor of the post-operative biphasic moment (Model: Secondary outcomes: bi-UKA Alignment p=0.029, p=0.047, Nagelkerke R^2=0.352). In the TKA group, femoral sagittal angle change was a predictor of post-operative biphasic knee moment (Model: Secondary outcomes: TKA Alignment p=0.066, Nagelkerke R^2=0.252).

Proprioception

Figure 5 – Joint position sense testing proprioception. Seated, eyes closed, participants were taught a knee flexion angle 20° from full extension. Error is the difference between the taught angle and the participants' perceived joint position.

In contrast to bi-UKA, proprioception in TKA patients worsened after surgery (Figure 5; p=0.006) and resulted in a significant difference between the treatment allocations at 1 year following surgery (Figure 5; p=0.005).

Table 4 - Proprioception sway analysis. COP; centre of pressure.

	Pre-op			Post-op		
Outcome	**bi-UKA (median)**	**TKA (median)**	**p-value**	**bi-UKA (median)**	**TKA (median)**	**p-value**
Area of COP (mm^2)	1920	1896	0.94	2179	2093	0.49
Length of COP trajectory (mm)	2217	2304	0.75	2545	2635	0.84
Length of COP trajectory time normalised (mm/s)	175	163	0.08	181	172	0.19
Time (secs)	13	14	0.47	15	15	0.90

Our participants in the bi-UKA and TKA groups demonstrated no significant differences in the eyes closed, single-leg sway test for any of the calculated outcomes (Table 4). However, at 1 year following surgery, both groups showed a significant increase in the total time spent on one leg during a 30-second eyes closed, one leg sway test (p=0.01), showing an increased ability to perform this test and an overall improvement in function pre to post-surgery.

Discussion

Both TKA and robotic arm-assisted bi-UKA are effective treatment options for knee OA showing significant improvements in the number of patients achieving biphasic knee moments and secondary outcomes. However, when using biphasic knee moment as an indicator of normal knee function, neither group achieved the same level of function after knee arthroplasty as a healthy aged-matched target group and no significant difference was noted between the two treatment allocations.

The initial power calculation for the study was based on the assumption that 25% of TKAs and 60% of the bi-UKA patients would achieve biphasic gait. Although our estimate of the bi-UKA group was remarkably accurate, our outcomes for the TKA patients at 57% did not match historical data. Based on the bi-phasic outcomes achieved at 1-year post-surgery, our cohort would require a sample size of 500 per group at 80% power to determine a difference. The lack of power in this study means that we have failed to recognise that a difference does exist. A similar assessment during more challenging tasks, e.g. slope, stairs and treadmill walking, may lead to a diversion of outcome between the groups. Large scale profiling of gait is a preferred approach but is limited by the extensive resources required.

Many factors affect gait, including knee stiffness and mobility after surgery[20], type of implant[19], surgical technique[19], residual swelling[36], poor exercise regimes[37] and proprioception deficits[30]. These have all been shown to influence how patients walk after knee replacement surgery. Often historical compensations of neighbouring joints to the pain and other deficits in the knee remain post-operatively[18]. This study replicated these findings, with pre-operative biphasic knee moment significantly predicting post-operative biphasic gait. This suggests that while there were significant gains of normal gait patterns in both groups (Figure 3), a majority of patients would maintain their pre-operative gait pattern post-operatively. In total, only 5 patients lost biphasic knee moments, all scoring highly for pain and stiffness post-operatively.

Gait velocity is a factor in the magnitude of knee flexion moments due to angular motions and inertial effects. In patients with higher walking speeds, the peak knee flexion moment seen is higher due to the greater deceleration at weight acceptance[7]. It is not clear whether the trough knee flexion moment is also greater in patients with higher walking speeds, which is important as walking speed on its own could influence the presence of biphasic gait. However, in our binary regression analysis, pre-operative ($p= 0.935$) and post-operative ($p= 0.187$) gait speed did not affect biphasic gait. This would suggest that slower walkers can still achieve biphasic knee moments; alternatively, faster walkers cannot rely on speed alone to achieve biphasic knee moments. Although the first peak knee flexion moment is known to increase with speed[7], the trough is governed more by the amount of knee extension achieved during mid- to late-stance of gait. By definition, in order to achieve biphasic knee gait, the trough knee flexion moment has to become extensor (Figure 1). This is achieved by extension of the leg in late stance positioning the ground reaction force in front of the knee creating the knee extension moment. Levinger et al. [20] also confirmed that the abnormal (non-biphasic) flexor in TKA patients' moment pattern is likely due to restriction in knee extension rather than spatiotemporal parameters such as walking speed. This justifies our use of a more natural self-paced walking rather than mandating a predetermined or maximal walking speed.

Trochlear degeneration was a significant, negatively correlated (odds ratio <1) predictor of post-operative biphasic knee moment. This suggests that pre-operative disease involving the extensor mechanism was associated with worse outcomes (higher Outerbridge, lower biphasic). Biphasic gait relies on adequate knee extension in late stance, and interestingly neither surgical treatment allocation nor post-operative rehabilitation appears to have overcome this pre-operative deficit of the knee in all cases. Additionally, the significant predictor of post-operative biphasic knee moment in the TKA group of increased implant flexion would also indicate an extensor mechanism sensitivity to the primary outcome. Further studies are required to understand how best we address trochlear degeneration and extensor mechanism deficits with either a bespoke modular trochlear implant or as part of a mono-block femoral implant.

Post-operative stiffness VAS was associated with poor gait outcomes. Whilst stiffer knees were less likely to have a biphasic knee moment, no differences were seen between the treatment groups. We are unable to determine a single mechanism by which stiffness influenced the failure to achieve an extensor knee moment.

Proprioception is thought to be a factor in knee control and movement. Retaining the cruciate ligaments in bi-UKA surgery may help preserve kinematic function and proprioception of the knee. Although more accurate joint position sense was seen in the bi-UKA group, there was no difference between the groups in sway testing. This suggests that although cruciate retention does lead to better proprioception, this does not necessarily aid sway control or walking, which are more complex functional tasks with additional elements such as balance, joint stability and muscle control. Interestingly although improvements in the sway test were seen in both treatment allocations from pre- to post-operatively, neither achieved the minimum 20-second accepted minimum standard for this test. This underlines the fact that patients following knee arthroplasty have poorer function than age-matched controls.

The alignment philosophy differed in the two treatment groups. In the TKA group the target was for a neutral mechanical axis with the joint line perpendicular to the mechanical axis. In the robotic – arm assisted group, alignment was determined by retensioning the collateral ligament on the more involved side of the joint (e.g. medial collateral for medial disease) with resurfacing of the joint surfaces. Driven by a soft tissue approach, the robotic approach retains the natural alignment of the knee. A previous paper from this clinical trial has shown that the TKA approach significantly increased the changes (delta) in pre to post-operative joint anatomy and overall alignment, with a smaller delta seen in the bi-UKA group[38]. This relative change in joint alignment was analysed to see whether smaller pre- to post-operative changes in joint anatomy were associated with the presence of biphasic gait knee moment post-operatively (Figure 3). Of the six alignment variables studied a smaller femoral and tibial axial rotation delta for the bi-UKA and a smaller femoral sagittal angle delta for the TKA were the only variables associated with post-operative biphasic knee moments. This implies that the presence of biphasic gait is not simply driven by maintaining joint anatomy following surgery, but instead is a more complex phenomenon that may include a need for gait retraining as part of post-operative rehabilitation, given the strong association between the presence of biphasic gait pre-operatively and its presence post-operatively.

There are some limitations to this study. The main limitation remains the number of patients and this has been raised in the discussion of the power calculation. We were unable to perform a subgroup analysis to look at patient factors and local factors within the knee, such as trochlear dysplasia, with any certainty. The difficulty with sample size is not limited to this clinical trial with cost and practicality often restricting the scope of many studies. Additionally, a dichotomous outcome measure was chosen (biphasic vs non-biphasic) over one which analysed continuous variables. The risk of using this approach is that it is sensitive to errors, and those patients close to the threshold may influence the outcome. To validate our choice of analysis, we analysed the data using a continuous variables method and found no difference in our results.

All surgeons had experience using the robotic-arm assisted system used in the study; however, all had much greater experience implanting TKAs using traditional methods. As the bi-UKA arm of the study was an off-label use of the robotic-arm none had any prior experience of using the technology in this specific way. Although a learning curve analysis failed to show any difference in surgical time in the early bi-UKA cases it is unrealistic to expect that surgeons had equipoise between the two techniques given their previous experience. There may also be intrinsic differences in robotic-arm assisted and manual approaches in implanting TKA and it would be preferable to eliminate this potential source of bias[39]. However, the robotic TKA platform was not available at the start of this study. Regarding the clinical assessment of patients, whilst the status of the ACL and Outerbridge classification of the joint surfaces are routinely recorded and assessed in this unit by the treating clinician, inter- or intra-observer variation was not carried out in this study.

The pre-operative higher rate of walking aids in the bi-UKA group was thought not to significantly affect pre-operative or post-operative biphasic knee moment through a person chi-square test ($p=0.408$). However, this does indicate a difference in the mobility between the groups pre-operatively.

The robotic-arm assisted group received the same tibial components on the medial and lateral sides as no specific lateral sided component is available. Although the shorter relative dimension of the lateral tibial plateau in the AP direction than the medial, good cortical coverage on the lateral side was achieved by manipulating the components at the time of pre-operative planning. This followed the standard MAKOplasty procedure for a lateral UKA.

Conclusion

A bi-unicompartmental approach to knee OA replaces both medial and lateral sides of the joint and retains both cruciate ligaments is not superior to a cruciate sacrificing TKA to achieve a biphasic gait pattern. Both treatments successfully improve gait, but both leave the patients with a functional limitation that is not present in healthy age-matched controls. Although better proprioception in terms of joint position sense was observed in the bi-UKA group, this benefit was not maintained in a sway test or self-paced walking. Similarly, the alignment of the implants had limited prediction on the biphasic outcome of the surgery, indicating that gait outcomes are sensitive to more than just bony reconstruction of the joint.

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