New instrumentation system for cementless mobile-bearing unicompartmental knee arthroplasty improves surgical performance particularly for trainees

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Introduction

Unicompartmental knee arthroplasty (UKA) is an effective treatment for end-stage medial compartment osteoarthritis of the knee [1]. In comparison to total knee arthroplasty (TKA), it has well-documented advantages which include quicker recovery, better patient-reported outcomes [2–4], as well as lower morbidity and mortality [5,6]. However despite these advantages, UKA remains underutilised, making up only 9.1% of primary knee arthroplasties in the UK [7]. The unpopularity of UKA persists for several reasons, which include relative unfamiliarity with the implants, perceived technical challenges and the resultant high revision rates particularly in low volume centres [8].

The Oxford© Partial Knee replacement (Zimmer Biomet, Bridgend, UK) has been under development since the 1970s [9], with Phase I and Phase II implants demonstrating excellent survivorship - around 98% at 10 years [10]. The Phase III implant was introduced in 1997, together with new instruments to support minimally invasive surgery (MIS) [11]. However, the learning curve for this instrumentation [12,13] was associated with component misalignment and difficulty optimising the tibial resection. Microplasty instrumentation was introduced in 2012 to address these problems, in particular to achieve a conservative and accurate tibial resection and to improve the accuracy of the femoral component sagittal plane alignment. Recent reports have suggested that it is associated with more accurate component placement [14] and a survival benefit at 5 years [15]. However, there have been no studies to investigate the use of Microplasty instrumentation by inexperienced surgeons (including orthopaedic trainees) who might be most likely to gain from its proposed advantages.

The primary aim of this study was to evaluate the technical performance of medial-UKA with reference to the design rationale of a new instrumentation system. The effect of instrumentation on surgical performance was evaluated independently within expert and trainee surgeon cohorts. Secondary aims were to evaluate functional outcomes, mid-term implant survivorship and re-operation rates.

Patients and methods

Institutional Review Board approval was obtained for this study.

Study population

A time-based comparative cohort study cohort study was performed for consecutive adult patients undergoing cementless mobile-bearing medial-UKA between January 2009 to January 2015 at a high-volume centre. Patients who underwent surgery prior to January 2012 received 'Phase III' instrumentation, whilst those undergoing surgery during or after this month received 'Microplasty' instrumentation. Whilst the design centre has used experimental instrumentation for many years, these were not available to non-designer surgeons. The differences between these instrumentation systems are described in Appendix 1. All operation notes were reviewed to confirm instrument usage. All patients provided informed consent and met the indications for surgery described by Pandit et al [17]. Patients who declined consent, underwent bilateral surgery or had a previous knee replacement on the contralateral side were excluded. Procedures were performed by one of two experienced, non-designer knee surgeons (AJP, WJ) or a trainee under their supervision. This was a pragmatic study where trainees were appropriately supervised. The amount of supervision required varied from trainee to trainee. To enrol in the trainee group, the procedure needed to be coded 'Supervised - Trainer Scrubbed' or a more independent coding in line with current UK guidance [18]. Orthopaedic trainees from the full spectrum of training grades (Specialty Trainee year 3 [ST3] to ST8) and senior clinical fellows rotated through this department for a period of 6 to 12 months and were enrolled in the study during their placements. Trainees rotating through the department routinely attended the instructional course for this mobile-bearing, unicompartment knee replacement. A planned, subgroup analysis to stratify by grade of operating surgeon (consultant or trainee) was included in the study protocol. Patients received the same pre- and post-operative instructions, which included rehabilitation in an Enhanced Recovery Programme. The electronic patient record (EPR) system was reviewed to extract data on patient demographics, operative details, and post-operative complications.

Outcome measures

The primary outcome measures were the technical performance of surgery judged by the proximal tibial resection depth and femoral component sagittal plane alignment, which are the design rationale of Microplasty instrumentation. Secondary outcome measures were patient-reported outcome measures (PROMs), implant survivorship and reoperation rate.

1. Technical performance

(a) Proximal tibial resection depth

The Microplasty instrumentation has the proposed advantage of enabling an accurate and conservative tibial resection. The appropriateness of the tibial resection was evaluated using the meniscal bearing thickness as a proxy measure. For each size of meniscal bearing, seven thicknesses are available ranging from 3mm to 9mm. The design rationale of the 3 G-clamp in the Microplasty instrumentation is to provide a 6mm proximal tibial resection for use with a 3mm bearing. Similarly, the 4 G-clamp is designed to provide a 7mm proximal tibial resection for use with a 4mm bearing. Bearing sizes 3mm and 4mm were therefore designated as 'optimal' in line with the planned resection depths.

(b) Femoral component sagittal plane alignment

One of the proposed advantages of Microplasty is to improve femoral sagittal plane alignment by linking the drill guide to the intramedullary rod. To evaluate this, all patients received standardised post-operative radiographs, where the anteroposterior (AP) image was fluoroscopically aligned to the tibial component and the lateral image to the femoral component. Femoral component flexion-extension angle was measured as the angle subtended between the femoral peg and the posterior femoral cortex on the lateral radiograph [19]. Radiographs were exported as image files from the Picture Archiving and Communication System (PACS) and analysed using a custom MATLAB script developed in-house (MATLAB. 9.7.0.1190202 (R2019b). Natick, Massachusetts: The MathWorks Inc.; 2018). Optimal position was defined as 15° flexion to 0° extension based on recommendations made by the developers of the implant and instrumentation [20]. Implants outside this range were considered to be misaligned.

2. Patient-reported outcome measures (PROMs)

All patients completed the Oxford Knee Score [21,22] pre-operatively and at 1 year post-operation. This is a 12-Likert item instrument that measures pain and function over a 4-week period. Each item is scored from 0 (worst) to 4 (best) to provide a total score out of 48 points. Phase III and Microplasty groups were compared with a minimal important difference (MID) of 5 points set to represent a clinically-relevant difference [23].

3. Survival analysis

Revision surgery was defined as any procedure to add, modify or replace a component of an existing mUKA. This included addition of a lateral UKA, exchange of a mobile bearing, or conversion to a total knee replacement. Patients were followed-up in-person at 1 year, and by telephone at 3 years and 5 years. A further follow-up was performed when writing this manuscript by reviewing our local arthroplasty database, the National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man Clinician Feedback system, and NHS Spine to evaluate mortality records. Where revision procedures were identified, the date of these procedures and the indication for surgery were obtained.

4. Reoperation rate

Any further surgery to the operated knee that did not meet criteria for revision was recorded. Procedures to be classified in this category included manipulation under anaesthesia (MUA) or knee washout without component exchange.

Statistical analysis

The study population was described using frequencies, means and standard deviations or medians and ranges. Descriptive statistics were prepared using Stata (StataCorp. 2019. *Stata Statistical Software: Release 16*. College Station, TX: StataCorp LLC.). The main analysis compared Microplasty versus Phase III for the entire cohort. The study cohort was then stratified by grade of surgeon (consultant or trainee) to analyse differences between instrumentation systems *within* these groups. Group differences were evaluated using the Wilcoxon rank-sum test for continuous variables and Fisher's Exact Test to compare differences in observed frequencies between groups. The log-rank test was used to test for differences in survival estimates. A p-value <0.05 was considered statistically significant.

Results

Study population

273 patients (273 knees, 49.5% female) were recruited. The mean age at primary surgery was 67.8 (standard deviation 10.1) years. The indications for surgery were anteromedial osteoarthritis (AMOA) in 268 patients (98.2%) and spontaneous osteonecrosis of the knee (SONK) in 5 patients (1.8%). 120 patients (44.0%) underwent surgery with Phase III instruments, and 153 (56.0%) with Microplasty instruments. Among these procedures, 155 (56.8%) were performed by a consultant surgeon and 118 (43.2%) by a trainee under supervision. Patient demographics and outcomes are provided in *Table 1* and stratified by grade of surgeon in *Table 2*.

Outcome measures

1. *Technical performance*

(a) Proximal tibial resection depth

Fewer non-optimal bearings were used in the Microplasty cohort (Phase III 27.5% versus Microplasty 15.7%, p=0.024) (Table 1). For consultant surgeons, there was no difference in non-optimal bearing usage between Phase III and Microplasty instrumentation (p=0.53). However, for trainee surgeons, fewer non-optimal bearings were used (p=0.017) (Table 2).

(b) Femoral component sagittal plane alignment

There was no statistically significant difference in the incidence of sagittal plane misalignment of the femoral component between patients who received Phase III or Microplasty instrumentation (10.8% versus 5.9%, p=0.18) (Table 1). No group differences were identified after stratifying by surgeon grade (Table 2).

2. *Patient-reported outcome measures (PROMs)*

For the entire study cohort, the pre-operative OKS was approximately normally distributed and the post-operative OKS had a left-sided tail. Given relatively small numbers within each group, non-parametric statistics were calculated. For the Phase III cohort, the pre-operative OKS was median 19 (interquartile range (IQR) 14 – 23.5) points. The pre-operative OKS was similar for the Microplasty cohort: median 19 (IQR 16 – 25) points (p=0.47). The post-

operative OKS was significantly higher in the Microplasty cohort (p=0.023), but the difference was less than a threshold that could be considered clinically meaningful.

3. Survival analysis

No patients were lost to follow-up. Latest follow-up was performed at a mean of 7.7 (sd 1.8) years which found 232 mUKA (85.0%) remained viable, 36 patients (13.2%) were deceased and 5 patients (1.8%) had undergone revision surgery. The 5-year Kaplan-Meier (KM) survival estimate was 99.3% (95% CI 97.0-99.8%). The 5-year KM survival estimate for Phase III was 99.1% (95% CI 94.0-99.9%) and Microplasty 99.3% (95% CI 95.4-99.9%). This is illustrated in *Figure 1*. None of the observed patient deaths were related to surgery, with the earliest death at 8 months post-operation. The indications for revision surgery were progressive osteoarthritis (n=4) and prosthetic joint infection (PJI, n=1). These are described further in *Table 3*.

4. Reoperation rate

Overall, three patients (1.1%) underwent re-operation. Two patients from the Microplasty group were treated with MUA for stiffness. One patient from the Phase III group underwent a debridement, antibiotics and implant retention (DAIR) procedure at 6 days post-operation. This was followed by revision for PJI at 30 months as described above.

Discussion

This study has demonstrated that use of Microplasty instrumentation was associated with more bone-conserving proximal tibial resection than Phase III instrumentation, with improvement in the performance of trainee surgeons responsible for this difference. There was no difference in femoral component sagittal plane alignment between groups. PROMs were statistically significantly better in the Microplasty cohort compared to Phase III, but this difference was small and below a threshold that patients would recognise as clinically meaningful. This series has excellent survivorship of cementless mobile-bearing medial-UKA, whether performed by expert surgeons or trainees, with newer Microplasty or older Phase III instrumentation.

Mohammad et al [15] recently reported improved five-year survivorship for Microplasty UKA (Overall Survival (OS) 96.7% (95% CI: 96.0%–97.2%)) compared to Non-Microplasty UKA (OS 94.5% (95% CI: 93.8–95.1%) using data from the National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man. Since the NJR does not record instrumentation, this analysis was based on a date cut-off where surgeons were assumed to have changed over to newer instrumentation. Sub-analysis was performed based on caseload, where no differences were found. However, performance was not investigated within trainee and consultant cohorts. Further support for the advantages of Microplasty instrumentation was provided by Gaba et al [24] who reported excellent survivorship, accurate component alignment and low rates of tibial re-cut with the new instruments. Koh et al [14] also compared the new instrumentation with Phase III instruments and demonstrated reduced risk of bearing dislocation with Microplasty instrumentation. The improved radiographic alignment using Microplasty instrumentation has also been reported by in previous studies [25,26], with Walker et al demonstrating more accurate tibial bone resection.

However, the current study is the first to report more predictable implantation of the mUKA when performed by trainee surgeons, and expert surgeons switching to new instrumentation. There are some limitations that should be considered. We acknowledge that some of the features of our study design are susceptible to bias. First, trainee surgeons were supervised by expert surgeons, which may have resulted in improved performance. Second, this was a

pragmatic study with different trainees receiving different amounts of supervision, as found in any training practice. Third, instances of selection bias where more difficult cases were triaged to the consultant surgeon rather than the trainee are possible with this design. However, these would not have biased results *within* trainee and consultant groups which were the comparisons presented. Fourth, this study was performed in the design centre, which has reported better outcomes than other centres [17,27] but no designer surgeons were present on the study team. Due to the time-based study design, the follow-up for the Microplasty group is shorter than for the Phase III group. However, presentation of Kaplan-Meier survival curves allows equivalent time-points to be compared. No a priori power calculation was performed, which limits the interpretation of study power.

This is an important publication in the context of new guidelines from the National Institute for Clinical Excellence (NICE) to offer eligible patients the choice of either UKA or TKA [28]. The adoption of modern indications for UKA suggests that around half of all patients with end-stage knee osteoarthritis may be candidates [29]. At our institution, around 55% of primary knee replacements are UKAs. The Danish Knee Arthroplasty Register (DKAR) reports an increase in UKA utilisation from <2% in 1997 to around 20% in 2017, with 91% mobile-bearing medial-UKA from the same brand as the present study [30]. However, surgeons within the UK have demonstrated little change in UKA utilisation over the past decade [7] and it remains to be seen whether the new guidance will change this. One potential barrier to this is the requirement for more trainee surgeons to be trained in the surgical technique. This study provides encouraging results to suggest that new instrumentation is associated with reliable component orientation and bone-conserving tibial resection both for expert surgeons and trainees under supervision. Previous work from our unit has suggested a learning curve of 10 cases for surgeons performing UKA using Phase III instrumentation [31]. Further research is warranted to investigate whether Microplasty instrumentation shortens this learning curve. New technologies such as patient-specific instrumentation (PSI) and surgical robots have also been proposed in order to improve outcomes from surgery. Previous research from our group found no improvement in performance and surgical outcome using PSI [32] and similar conclusions were drawn from a recent systematic review of robotic-assisted UKA [33]. However, this evidence-base is still relatively immature and requires further study.

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279 Conclusions

280 This study demonstrated that new instrumentation improved the reliability of the proximal
281 tibial resection in trainees. Further research is warranted to investigate whether Microplasty
282 instrumentation shortens the learning curve for medial UKA. Patients receiving a UKA in this
283 study had excellent mid-term functional outcomes, and implant survivorship whether surgery
284 was performed by a consultant surgeon or a trainee, or with newer or older instrumentation.

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Table 1 – Patient demographics and outcomes stratified by instrumentation

	Phase III ***(n=120)***	**Microplasty** ***(n=153)***	**p-value**
Age at primary surgery *Median (IQR)*	67.2 (60.1-73.4)	69.0 (63.5-76.6)	0.093
Female *No. (%)*	54 (45%)	81 (52.9%)	0.22
Pre-operative OKS *Median (IQR)*	19 (14-23.5)	19 (16-25)	0.47
Post-operative OKS at 1 year *Median (IQR)*	39.5 (33-44)	42 (38-44)	0.023*
Change in OKS *Median (IQR)*	18 (12-25)	21 (16-26)	0.087
Sagittal plane femoral misalignment *No. (%)*	13 (10.8%)	9 (5.9%)	0.18
Non-optimal bearing usage *No. (%)*	33 (27.5%)	24 (15.7%)	0.024*
Outcome at 5-year follow-up			
Deceased	23 (19.2%)	13 (8.5%)	
Revised	2 (1.7%)	3 (2.0%)	0.78
Viable	95 (79.2%)	137 (89.5%)	

*statistically significant difference

Table 2 – Patient demographics and outcomes stratified by grade of operating surgeon

	Consultant			Trainee
	Phase III ***(n=67)***	**Microplasty** ***(n=88)***	**p-value**	**Phase III** ***(n=53)***
Age at primary surgery *Median (IQR)*	68.0 (60.1-75.4)	68.0 (62.0-74.7)	0.91	65.3 (60.0-73.3)
Female *No. (%)*	36 (54%)	43 (49%)	0.63	18 (34%)
Pre-operative Oxford Knee Score *Median (IQR)*	19 (14-23)	18 (14-25)	0.66	19 (14-24)
Post-operative OKS at 1 year *Median (IQR)*	39 (30-44)	41.5 (34.5-44)	0.076	40 (36-44)
Change in OKS *Median (IQR)*	18 (9-25)	21.5 (13-26)	0.15	20 (14-25)
Sagittal plane femoral misalignment *No. (%)*	6 (9%)	3 (3%)	0.18	7 (13%)
Non-optimal bearing usage *No. (%)*	14 (21%)	14 (16%)	0.53	19 (36%)
Outcome at 5-year follow-up				
Deceased	11 (16%)	7 (8%)		12 (23%)
Revised	1 (1%)	3 (3%)	0.46	1 (2%)
Viable	55 (82%)	78 (89%)		40 (75%)

*statistically significant difference

406 *Table 3 – Characteristics of patients undergoing revision surgery*
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ID	Group	Age at primary	Gender	Time to revision	Revision diagnosis	Revision implant
1	Phase III-Trainee	64	Male	85 months	Lateral progression of OA	Bi-uni
2	Microplasty-Consultant	66	Male	72 months	Lateral progression of OA	Bi-uni
3	Microplasty-Consultant	63	Female	25 months	Lateral progression of OA	TKA
4	Microplasty-Consultant	74	Female	72 months	Lateral progression of OA	Bi-uni
5	Phase III-Consultant	72	Male	DAIR on day 8 Revision at 30 months	Prosthetic joint infection	2-stage revision to varus-valgus constrained knee

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411 *Figure 1 – Kaplan Meier Survival Analysis for Phase III instrumentation versus Microplasty*
412 *instrumentation*

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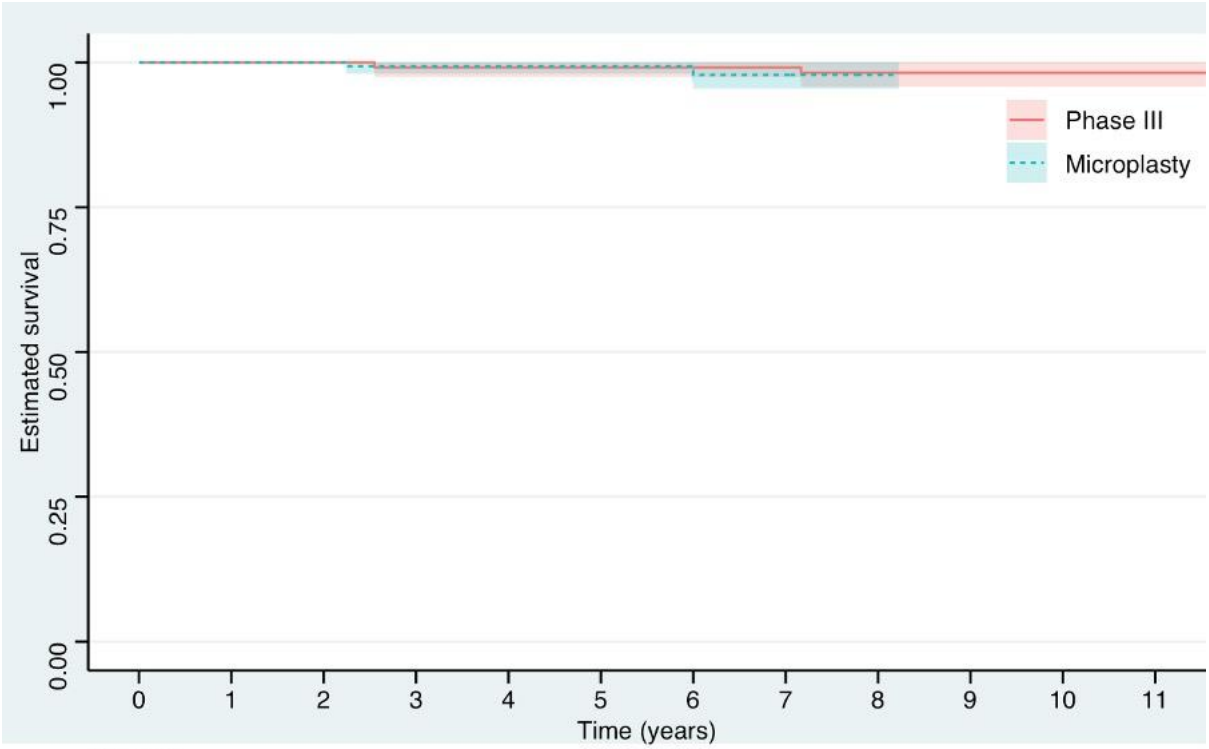

Phase III												
At risk	120	119	118	115	113	109	107	106	104	54	27	3
Censored	0	1	2	4	6	10	12	13	14	64	91	115
Events	0	0	0	1	1	1	1	1	2	2	2	2

Microplasty												
At risk	153	153	152	149	145	143	132	99	16	0	0	0
Censored	0	0	1	3	7	9	18	51	134	150	150	150
Events	0	0	0	1	1	1	3	3	3	3	3	3

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