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Safe and reliable clinical outcomes at 2 years of a fixed-bearing partial knee arthroplasty with a morphometric tibial tray in a large worldwide population

Sébastien Parratte^{1,2} · Alexander Sah³ · Cécile Batailler⁴

Abstract

Purpose The purpose of this study was to evaluate: (1) improvement of functional and quality of life scores, (2) adverse events, (3) short-term implants survivorship of a newly designed fixed-bearing partial knee replacement (PKR) with a morphometric tibial tray in a large and multicentric population at a minimum follow-up of 2 years.

Methods From 2017 to 2019, 479 medial PKR were implanted by 16 non-developing surgeons from United States, Europe, and Japan. Eight patients were lost to follow-up (1.8%). Standardized follow-up procedures included patient-reported outcomes (Oxford Knee Society score, Forgotten Joint Score, EQ VAS, EQ 5D), patient satisfaction, radiographic assessments, adverse event at 2 years. Comparisons between the preoperative and postoperative values were performed using Student *t* test. Kaplan–Meier survivorship analysis was performed with knee revision as the endpoint.

Results The mean age was 65.6 ± 9.6 years. Mean body mass index was 29.5 ± 5.1 kg/m². Oxford Knee Society score and Forgotten Joint Score, respectively, improved from 23.7 ± 8 and 16 ± 15.8 preoperatively to 42.4 ± 6.5 and 74 ± 24.9 at 2 years ($p < 0.0001$). Satisfaction Score was 92.3 ± 13.4 at 2 years. Ten re-operations (2.1%) were reported including seven implant removals (1.5%). No other adverse event was reported. The causes of conversion to total knee arthroplasty were: nickel allergy ($n = 2$), patellofemoral osteoarthritis ($n = 1$), pain ($n = 1$), deep infection ($n = 3$). Two re-operations were performed due to infection, and one for internal fixation for a tibial plateau fracture. The 2-year Kaplan–Meier survival estimate was 98.4%, with implant removals as the endpoint.

Conclusion This prospective multicentric study reported safe and reliable clinical outcomes of a morphometric PKR, which optimized tibial coverage and femoral fit, in a large population of patients worldwide at 2 years.

Level of evidence Prospective cohort study–therapeutic study, Level II.

Keywords Unicompartmental knee arthroplasty · Patient reported outcome measure · Survivorship · Complications · Device removal

Abbreviations

BMI Body Mass Index

EQ 5D EuroQoL 5-Dimensions

EQ VAS EuroQoL Visual Analogic Scale

FJS Forgotten Joint Score

KSS Knee Society Score

OKS Oxford Knee Society score

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TKA Total Knee Arthroplasty
 UKA Unicompartmental Knee Arthroplasty

Introduction

Unicompartmental knee arthroplasty (UKA) continues to gain popularity and utilization [7]. UKA remains a demanding surgical procedure and optimal implant positioning is essential to obtain satisfactory outcomes [2, 18]. Some UKA have lateralized femoral implants, but the tibial implant is frequently not specific to the medial or lateral side and is called a symmetric tibial tray. In these cases, reaching optimal bone coverage is complex and surgeons have to compromise ideal coverage (maximum cortical support) while avoiding overhang. This is often not possible when using standard symmetric tibial components [26, 30]. A better theoretical positioning with an optimized rotation-coverage ratio has been reported with a morphometric tibial implant in UKA [12, 25]. Following the good results obtained in total knee arthroplasty (TKA) with morphometric and lateralized tibial implants [8], new morphometric tibial trays for UKA have been developed. It features optimized tibial coverage and femoral fit with morphometric implant design. Better early clinical outcomes of this morphometric implant compared to a symmetric fixed-bearing implant have been reported at 1 year in a small and single-center comparative series [10]. The validation of these results in a larger population of patients worldwide with a longer follow-up is still necessary.

The aim of this study was to evaluate: (1) the patient-reported outcome measurements over a 2-year follow-up (Oxford Knee Score (OKS), EuroQoL Visual Analogic Scale (EQ VAS), EuroQoL 5-Dimensions (EQ 5D), Forgotten Joint Score (FJS) and Derived Patient Satisfaction Score), (2) the adverse events as measured as any complication related to the implant, and (3) implants survivorship as measured using the Kaplan–Meier survivorship. The hypothesis was that the use of this would provide safe and reliable results, with low revision rate due to this device, in a large and multicentric population at a minimum follow-up of 2 years.

Materials and methods

Approval of the ethics committee of each participating country was obtained before the start of the study (Appendix 1). All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee, the 1964 Helsinki Declaration, and its later amendments, or comparable ethical standards. All included patients have signed an informed consent. In this prospective

multicentric study, 479 medial fixed-bearing morphometric partial knee replacements (Persona Partial Knee System, Zimmer Biomet, Warsaw Indiana) were included [10]. The inclusion criteria were all patients, at least 18 years of age, with an indication of medial UKA for medial femorotibial osteoarthritis or osteonecrosis, operated from March 2017 to January 2019 by 16 non-developing surgeons from the United States, Europe, and Japan. The exclusion criteria were the fixed varus deformity ($> 15^\circ$) and fixed flexion deformity ($> 15^\circ$), the associated diagnosis of infection, osteomyelitis, osteomalacia, rheumatoid arthritis or other forms of inflammatory joint disease, the insufficiency of the collateral, anterior or posterior cruciate ligaments, the full thickness damage to the weight bearing area of the contralateral compartment, the rapid joint destruction and the insufficient bone stock to provide adequate fixation to the prosthesis, the metabolic disorders which may impair bone formation, the vascular insufficiency, muscular atrophy, neuromuscular disease. Eight patients were lost to follow-up (1.8%) (Fig. 1). The primary preoperative diagnosis was osteoarthritis in 94.3% of knees. Further preoperative diagnoses were avascular necrosis in 4.9% of knees and post-traumatic arthritis in 0.8% of knees. 81.3% of the patients had a grade 4 of medial femorotibial osteoarthritis (Kellgren Lawrence [17]), 14.9% had a grade 3 of medial femorotibial osteoarthritis, 3.8% had a grade 2 of medial femorotibial

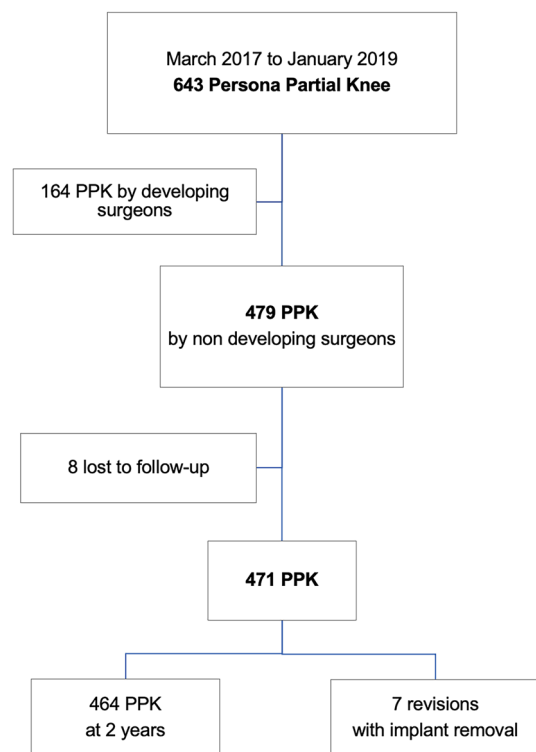


Fig. 1 Flowchart

osteoarthritis or less. The preoperative knee status and the preoperative clinical scores are described in Table 1.

Surgeons were trained on the conventional technique with cadaver labs and educational sessions. All surgeons were experienced (experience of more than 300 UKA by surgeon). This system is a tibia-based technique using the spacer-block technique for the femoral preparation. The implant was a morphometric tibial tray and femoral component UKA (Persona Partial Knee; Zimmer-Biomet, Warsaw, IN). This cemented metal-backed prosthesis consists of cobalt-chromium-molybdenum (Co–Cr–Mo) alloy femoral components, titanium alloy (Ti-6Al-4V) tibial baseplates, and Vivacit-E® highly crosslinked polyethylene tibial articular surfaces. It features optimized tibial coverage and femoral fit with morphometric implant design based on the Zibra Technology (Fig. 2). The tibial polyethylene articulating surface is flat and unconstrained.

All the patients were followed according to the same protocol in all the participating centers. For each visit, the follow-up included a clinical evaluation, radiographic assessments, and adverse events reporting. Pre-operative clinical evaluation and clinical follow-up were completed at 3 months, 1 year, and 2 years. Functional outcomes were measured using the OKS [21]. Patient quality of life scores were measured using the EQ VAS [11], the EQ 5D score [9], the FJS [3] and patient satisfaction using the Derived Patient Satisfaction Score [27]. The range of motion was recorded preoperatively, during the follow-up, and at the final evaluation. The radiographic assessment searched for early radiological complications (fracture, loosening, secondary displacement). The adverse events were recorded during follow-up and at the final assessment and categorized according to the protocol as implant related or not. The implant-related adverse events were all the mechanical and painful adverse events of the operated knee. The



Fig. 2 Morphometric tibial tray of medial persona partial knee system

surgery-related adverse events were all the adverse events concerning the operated knee secondary to a surgical procedure. All re-operations and revisions were also recorded and the reason for the re-operation or the revision documented.

Comparisons between the preoperative and postoperative values for the different scores were performed using Student t test for linked samples considering a p value < 0.05 as significant. Continuous variables were averaged and reported with standard deviations. The adverse events were described in percentages. Kaplan–Meier survivorship analysis (with a 95% confidence interval (CI)) was performed with knee revision as the endpoint, defined as a knee revision with metal component removal. The statistical analysis was performed with SAS Enterprise Guide version 12 (SAS Institute Inc, Cary, NC, USA).

A post hoc power analysis has been performed on the revisions rate with implant removal compared to the rate

Table 1 Clinical scores preoperatively and at 2 years of follow-up

Variables mean \pm SD [min; max]	Pre-operative data $N=471$	Postoperative data $N=464$	p value
Flexion	123.9 \pm 10.4 [90;150]	128.4 \pm 7.9 [100;150]	< 0.0001
Flexion contracture ($> 5^\circ$)	35 (7.4%)	11 (2.4%)	< 0.001
OKS	23.7 \pm 8 [1; 45]	42.4 \pm 6.5 [18; 48]	< 0.0001
EQ VAS	65.6 \pm 20.8 [0; 100]	82.2 \pm 15.9 [5; 100]	< 0.0001
EQ 5D Index	0.5 \pm 0.3 [– 0.2;1]	0.9 \pm 0.2 [0.1;1]	< 0.0001
FJS	16.0 \pm 15.8 [0; 85]	74.0 \pm 24.9 [2; 100]	< 0.0001
Derived patient satisfaction score	–	92.3 \pm 13.4 [25; 100]	–
Patient satisfaction			
Very satisfied	–	79.1%	–
Somewhat satisfied		17.9%	
Somewhat dissatisfied		1.8%	
Very dissatisfied		1.2%	

OKS Oxford Knee Score, VAS Visual Analogic Scale, DS deviation standard, min minimum, max maximum, FJS Forgotten joint score

described in the literature [24, 28]. This post hoc power analysis found a power superior to 90%.

Results

The mean age at the time of surgery was 65.6 ± 9.6 years (range 40–89). 51.2% were male patients, and 53% of the patients were operated on the left knee. Mean BMI was 29.5 ± 5.1 kg/m² (range 19–47). The average duration of surgery was 57.3 ± 15 min (range 21–125). The average length of hospital stays varied between 0.5 ± 0.9 days and 7.3 ± 2 days (range 0–24), according to the country (USA and European countries). Outpatient (including same day or 23-h discharge) surgeries were conducted in 21.7% of the patients.

The OKS improved significantly from 23.7 ± 8 preoperatively to 42.4 ± 6.5 at 2-year follow-up ($p < 0.0001$) (Fig. 3). The EQ-5D Index improved significantly from 0.5 ± 0.3 preoperatively to 0.9 ± 0.2 at 2-year follow-up ($p < 0.0001$). The EQ VAS improved significantly from 65.6 ± 20.8 preoperatively to 82.2 ± 15.9 at 2-year follow-up ($p < 0.0001$). FJS improved significantly from 16 ± 15.8 preoperatively to 74 ± 24.9 at 2-year follow-up ($p < 0.0001$) (Fig. 4). The derived Patient Satisfaction Score was 92.3 ± 13.4 (range 25–100) at 2-year follow-up. The mean total range of knee flexion improved significantly from 123.9 ± 10.4

preoperatively to 128.4 ± 7.9 at 2-year follow-up ($p < 0.0001$) (Table 1). The 2-year radiographic results showed no complication, loosening sign, or secondary displacement.

There was no adverse event related to the device or to the surgery without re-operation. Ten re-operations (2.1%) were reported at 2 years with seven revisions with implant removal (1.5%) and three re-operations without implant removal (0.6%) (Table 2).

The 2-year Kaplan–Meier survival estimate was 98.4% (CI95% 0.9649–0.9929) with knee revisions with metal component removal as the endpoint (Fig. 5).

Discussion

The most important finding of this study was that early outcomes of this newly released prosthesis in non-developing group of surgeons were satisfactory at a minimum of 2 years follow-up with a significant improvement of the functional and quality of life scores and a low rate of adverse events related to this device.

Only one study has reported the early clinical outcomes of a morphometric fixed-bearing UKA at 1 year minimum in a small and single-center comparative series [10]. In this study, better clinical outcomes have been described with the morphometric tibial tray compared to a symmetric tibial tray. The early outcomes of UKA reported in this study were also

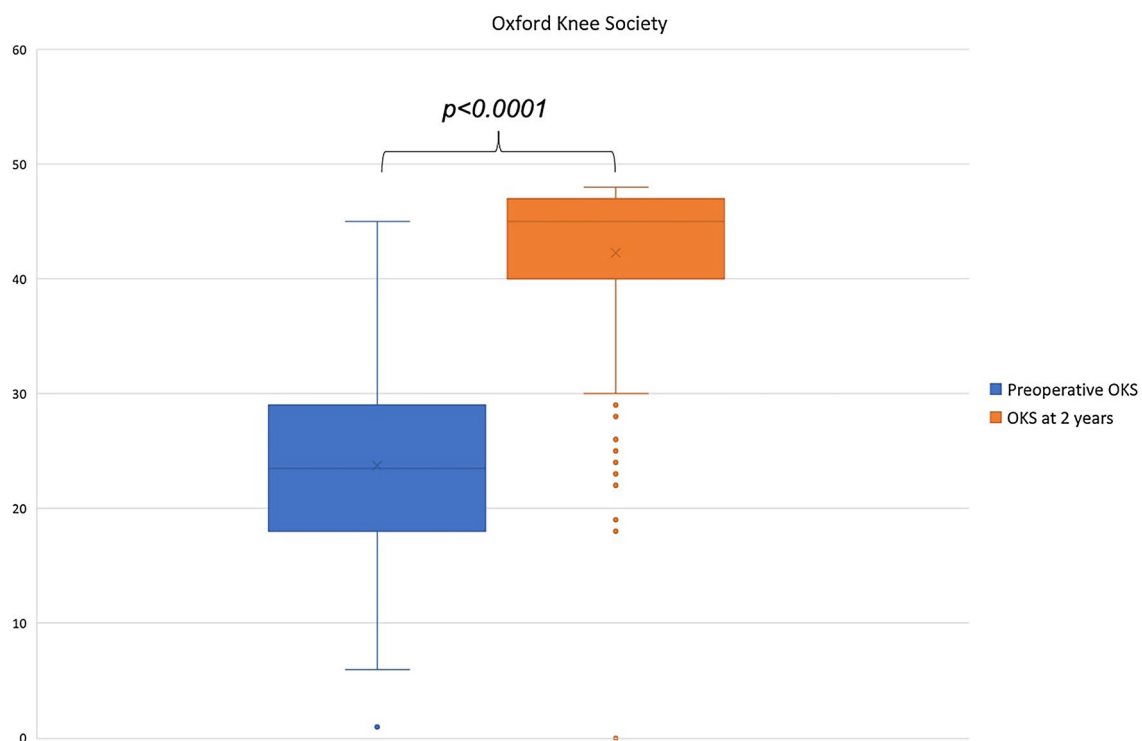


Fig. 3 Boxplots of preoperative OKS and OKS at 2 years of follow-up [significant improvement from 23.7 ± 8 to 42.4 ± 6.5 ($p < 0.0001$)]

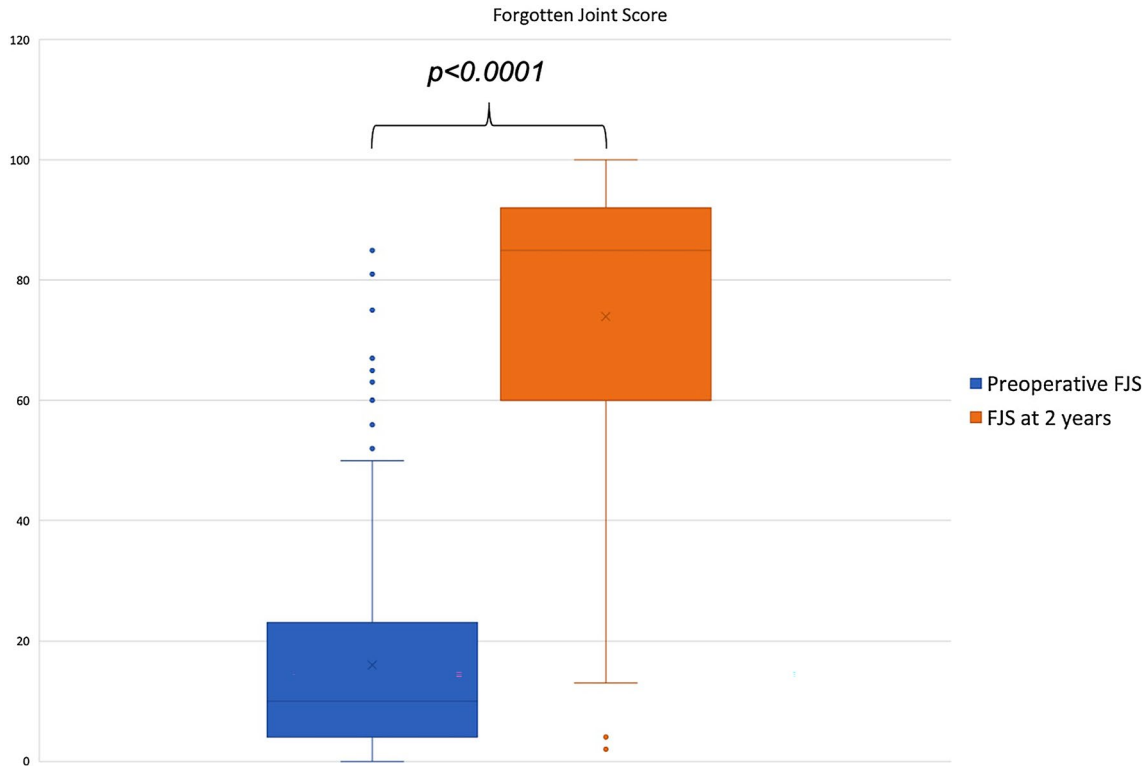


Fig. 4 Boxplots of preoperative FJS and FJS at 2 years of follow-up [significant improvement 16 ± 15.8 to 74 ± 24.9 ($p < 0.0001$)]

Table 2 Adverse events and revisions in the cohort at 2 years of follow-up

Complications	Treatment	Implant removal	Number of knees
Nickel allergy	Conversion to TKA	Yes	2 (0.4%)
Patellofemoral OA	Conversion to TKA	Yes	1 (0.2%)
Chronic deep infection	Conversion to TKA	Yes	3 (0.6%)
Persistent pain	Conversion to TKA	Yes	1 (0.2%)
Acute infection	DAIR, PE exchange	No	2 (0.4%)
Medial tibial plateau fracture (at 2 weeks)	Open reduction, Internal fixation	No	1 (0.2%)

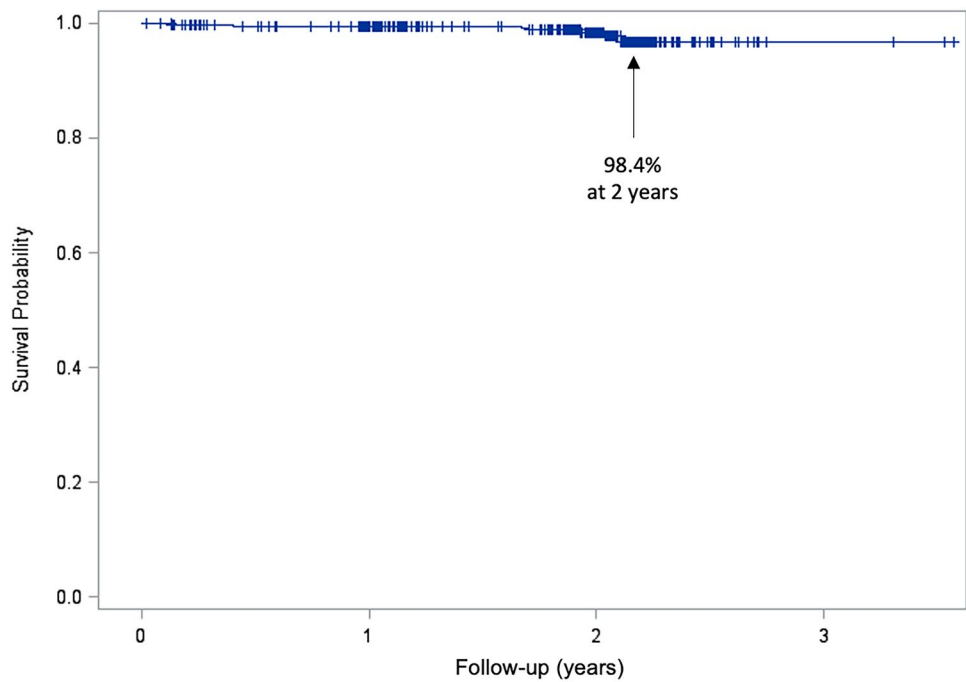
TKA total knee arthroplasty, OA osteoarthritis, DAIR debridement, antibiotics and implant retention, PE polyethylene

promising, with a significant improvement of the functional scores. These results were comparable to those reported in the literature concerning the fixed-bearing or mobile-bearing UKA [10, 19, 31]. More discriminant scores, such as the FJS or the patient satisfaction score, were also high at 2 years in this study, attesting to encouraging early outcomes. The

FJS was comparable to those reported in previous studies on UKA [16, 29]. The advantages of the morphometric tibial implant in the UKA positioning are, among others, to optimize the rotational-coverage ratio, maximizing the cortical support while limiting overhangs. This optimal ratio could overcome the potential risks coming with over or under-sizing as described in the previous study [10]. Over-sizing risks poorer functional results and pain due to impingement with soft tissues or the patella [6]. Under-sizing may cause loosening and premature wear due to insufficient bone coverage [20].

The complications reported in this study were not specific of this newly designed implant. The infections and the tibial fracture were secondary to the surgery but not specifically to this implant. In the literature, similar rates of infection and fracture of medial UKA were reported [4, 13, 22]. In the Australian registry, there was a 0.5% of UKA revision for infection and 0.3% for fracture [24]. The incidence of tibial plateau fracture related to UKA is low, without correlation between the type of implant and the risk of tibial fracture [5]. Only the two revisions for nickel allergy were due to the device. The UKA revision for nickel allergy is usually classified as "unexplained pain" in the registries [24]. The revision rate for unexplained pain represented 1% in the Australian registry [24]. In other registries, the revisions for "unexplained pain" does not exist [22]. These unexplained

Fig. 5 The Kaplan–Meier survival curve of the morphometric UKA performed by non-developing surgeons, with knee revision with metal component removal as the endpoint



pains are difficult to manage. The understanding of the pain causes, such as metals allergy, is essential to decide a revision. In national registries or previous studies, the main causes of UKA revision were implants loosening, progression of osteoarthritis, and malpositioning [1, 14, 22, 24]. These complications were not reported in this study, probably due to the short follow-up. The risk of malpositioning should decrease with the morphometric tibial tray, allowing fewer compromises in size and rotation positioning [10].

The survivorship of this morphometric UKA at 2 years was high (98.4%) with knee revisions with metal component removal as the endpoint. This was comparable to the survivorship presented by the national registries for the medial UKA in short term [15, 23, 24] [28]. In the national registry of England, Wales, and Northern Ireland, the cumulative revision rate at 3 years varied from 2.06 (ZUK) to 6.07% (AMC/Uniglide), with a mean of 4.01% [28]. In the Australian registry, the medial fixed-bearing UKA had a cumulative revision rate at 3 years of 5.1% [24]. Currently, only two national registries reported revisions for this morphometric implant at 1 year {(0.14% (on 1990 knees) in the national registry of England, Wales, and Northern Ireland [28] and 2% (on 763 knees) in the German Arthroplasty Registry [15]} [23, 24]. These results were also similar to the previous studies on conventional medial UKA [4, 13, 22]. The mean time for revision to TKA or addition of a patellofemoral arthroplasty was 13 years (3 months–21 years) and essentially for implants loosening or progression of osteoarthritis [1]. The evaluation of the fixation of this morphometric UKA would need the results of this prospective worldwide multi-center study in the long term.

Several limitations should be outlined in this study. First, the mean follow-up was short. Nevertheless, early evaluations are primordial to assess adverse events and early implant outcomes before full market release. Second, there was no direct comparison with a matched series of UKAs with a symmetric tibial plateau. However, the aim was to assess the early results and the lack of early complications of a new implant; and not demonstrate its superiority compared to the previous implants. Third, this study did not report the alignment and implant positioning as it was not among the goals of this study.

This study reported the results and complications in a large and multicentric population of a newly designed UKA with a morphometric tibial tray at a minimum follow-up of 2 years. These results were encouraging for future users concerning the safety and reliability of this new implant.

Conclusion

This prospective multicentric study reported safe and reliable early clinical outcomes of a newly designed fixed-bearing morphometric partial knee replacement, without fixation complication, in a large population of patients worldwide at 2-year follow-up.

Author contributions SP (MD, PhD orthopaedic surgeon): study design, data collection, literature review and manuscript writing. AS (MD, PhD orthopaedic surgeon): study design, data collection, and

manuscript editing. CB (MD, PhD orthopaedic surgeon): statistical analysis, literature review and manuscript writing.

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Declarations

Conflict of interest SP: Royalties from Zimmer Biomet and Newclip; Consultant for Zimmer Biomet; Treasurer for European Knee Society. AS: Research support from Zimmer Biomet. CB: Grant from SoFCOT.

Ethical approval Approval of the ethics committee of each participating country was obtained before the start of the study. All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee, the 1964 Helsinki Declaration, and its later amendments, or comparable ethical standards.

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