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Primary Knee

## Minimum Five Years Follow-Up of Total Knee Arthroplasty Using Morphometric Implants in Patients With Osteoarthritis

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### ABSTRACT

**Background:** The use of morphometric implants in total knee arthroplasty (TKA) has shown better early clinical outcomes compared to conventional implants. The primary objective of this study is to evaluate the functional outcome and the implant survivorship of a morphometric TKA at a minimum of 5 years of follow-up.

**Methods:** From May 2012 to June 2015, all patients undergoing primary TKA with a single design of morphometric posterior-stabilized prosthesis (Persona; Zimmer) in a prospective observational single-center study were evaluated. The Knee Society Scoring System (KSS) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) were completed preoperatively, 1, 3, and 5 years postoperatively. Kaplan-Meier was used to calculate survivorship of the implants. The average follow-up was 75 months.

**Results:** In total, 237 TKAs were performed in 235 patients with a mean age of 73 years (49-90). The KSS Knee Score increased from 44.7 (13-64) preoperatively to 93.6 (71-100), the KSS Function Score from 45.8 (17-69) to 92.2 (51-98), and the KSS Satisfaction Score from 26.6 (16-51) to 41 (35-55) at 5 years of follow-up. Similarly, for the KOOS score, a significant improvement of all the subscales was observed at 5 years of follow-up. Implant survival without reoperation at 5 years of follow up was 98.72% (95% confidence interval 0.95-1.00).

**Conclusion:** This is the first study demonstrating that significant improvements of the functional scores with good survivorship can be achieved at a minimum of 5 years of follow-up with TKA using morphometric implants.

Investigation was performed at Aix Marseille University, APHM, CNRS, ISM, Sainte-Marguerite Hospital, Institute for Locomotion, Department of Orthopedics and Traumatology, Marseille, France.

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Local ethic committee approved our study protocol prior to investigation.

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Total knee arthroplasty (TKA) is considered as the gold standard to treat advanced global knee arthritis and is among the top 5 procedures most realized in the United States [1,2]. Patients who require knee replacement have considerably changed for the last decade as they are younger, involved in high physical activity, and therefore presenting more expectations [3,4]. Many factors are involved in the clinical results of TKA: adequate restoration of the patient anatomy, optimal component placement, ligament balance, and adequate perioperative management [5-7]. The frontal and sagittal positioning of the implants follows rather clear rules even if questions persist [8]. In the axial plane, positioning objectives are often more difficult to obtain intraoperatively for both the femur and the tibia, while axial positioning errors will have a significant impact on the knee flexion and function and on the survival of the implants [9-11].

The concepts of sexual dimorphism in humans and anatomic variations in various ethnic groups are well known and supported by anatomic and radiographic studies [12-14].

Developing more morphologic and personalized implants is a real challenge to improve both the functional outcome and the implant survivorship [15,16]. This recent anatomic approach led to the development of prosthesis design which tends to reproduce the kinematic chain of the native knee. Previous studies have demonstrated that morphometric tibial tray reduced prosthetic overhang, while improving implant positioning and thus potential survival of the implants [17–20]. The results at mid and long-term follow-up of this type of morphometric implants have not yet been evaluated in the literature.

Therefore, the hypothesis of this study is that the use of a morphometric tibial and medio/lateral (ML) adaptative femoral component can optimize implant positioning and consequently offers excellent clinical results and survival rate at a minimum follow-up of 5 years.

Therefore, the primary objective of this study is to determine survivorship of a morphological Knee system used in primary TKA, and the second objective is to determine functional outcome at a minimum of 5 years of follow-up.

## Materials and Methods

After review board approval, a cross-sectional study of a prospectively collected database was performed. All patients who underwent primary cemented TKA using morphometric implants between May 2012 and June 2015 were evaluated.

Inclusion criteria were: TKA performed for primary tri-compartmental arthritis of the knee and using a single design of morphometric prosthesis (Persona System; Zimmer Biomet, Warsaw, IN). This prosthesis includes both an asymmetric tibial tray to optimize rotational coverage ratios and also an ML adaptative femoral implant (narrow and standard for each size of femoral implant) with multiple ranges of sizes and shape offerings for improving the morphological fit in order to limit the potential conflicts with the soft tissue.

Exclusion criteria were patients with severe deformity with  $>20^\circ$  of valgus or varus, patients with post-traumatic knee osteoarthritis or with a history of prior ligament or osteosynthesis surgery on the ipsilateral knee, range of motion below  $0^\circ$  to  $100^\circ$  (extension to flexion), or personal history of trauma, sepsis, tumor, inflammatory or skeletal disease (that could influence functional outcomes), and patients with incomplete follow-up data.

A total of 251 patients met the inclusion and exclusion criteria. Sixteen (6.4%) patients had incomplete data. These 16 patients were excluded from the final clinical outcome and survivorship analysis.

A total of 235 patients were finally included. Two of these patients received bilateral implants and thus a total of 237 TKA procedures were analyzed (Fig. 1). All surgeries were performed by 2 senior surgeons who used the Persona Postero-Stabilized Knee Implant System (Zimmer Biomet) since 2012 and having a long experience with the NexGen Legacy Posterior-Stabilized (LPS) knee prosthesis (Zimmer Biomet).

Preoperative data including age, gender, American Society of Anesthesiologists classification, body mass index, and frontal deformity using the hip knee and ankle (HKA) angle were obtained. During surgery, data collection included size of the component tibial, femoral (narrow or not), patella, polyethylene insert thickness, and the necessity of a short tibial stem or not.

### Surgical Procedure

All TKAs were performed without a tourniquet using a medial parapatellar surgical approach. The tibial proximal resection was realized with an extramedullary guide and the distal femoral resection with an intramedullary guide in order to restore a frontal

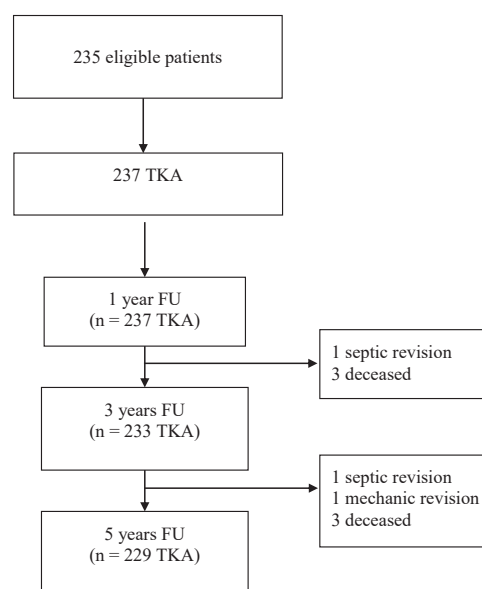


Fig. 1. Flowchart.

mechanical alignment. The external femoral component rotation was set at  $3^\circ$ , based on the posterior condylar axis, and was the same for every patient within the series [21].

Every patient received a morphometric posterior-stabilized knee prosthesis with anatomical tibial tray (Persona; Zimmer). The Persona Knee Implant system includes multiple ML offerings for a given anteroposterior (AP) femoral size with the standard and narrow femoral implants, finer increments in AP sizing (2 mm) which may contribute to a better fit and anatomical tibial tray right and left which is asymmetric. There are 11 sizes for the narrow femoral implant (size 1-11), 10 sizes for the standard femoral implant (size 3-12), and 9 sizes for the tibial tray (sizes A to I) right and left. A short cemented tibial stem was used for patients with body mass index  $>35$ . Femoral, tibial, and patella components were systematically cemented using an antibiotic-loaded cement.

Postoperative rehabilitation protocols included immediate weight bearing protected by crutches during the first 2 or 3 weeks according to patient tolerance, and exercises focused on passive and then active recuperation of range of motion. All patients received thromboprophylaxis with low-molecular-weight heparin preoperatively and postoperatively for 35 days.

### Clinical Evaluations

The clinical evaluations were performed by an independent observer preoperatively, at 1 year postoperatively, then at 3 and 5 years, during which a clinical evaluation was carried out. In addition, information regarding complications and range of motion was collected. The evaluation of functional outcomes was performed using the Knee Society Scoring System (KSS) [22] for TKA and the Knee Injury and Osteoarthritis Outcome Score (KOOS) [23]. The KSS has 2 components, an objective and a subjective one. The objective component (100 points) includes a clinical evaluation of the knee by the surgeon (axes, stability, joint motion) and 2 visual analog scales completed by the patient. The subjective component is a self-evaluation questionnaire with 3 domains: expectations (15 points), satisfaction (40 points), and functional activities (100 points).

The KOOS score comprises a 42-item self-reported questionnaire of subscales that include pain (9 items), other symptoms (7

**Table 1**  
Preoperative Data.

Number of patients	235
Number of knees	237
Side (left/right)	163/74
Age (y)	73 (49-90)
Gender ratio (female/male)	151/84
BMI (kg/m <sup>2</sup> )	29
Follow-up (mo)	75 (60-96)
Flexion	111 (100/130)
HKA	177.4 ± 3.5

BMI, body mass index; HKA, hip knee and ankle.

items), function in daily living (17 items), function in sport and recreation (5 items), and knee-related quality of life (4 items), which are scored individually from 0 (extreme knee problems) to 100 (no knee problems).

The necessity of reoperation during the study time was also analyzed.

### Statistical Methods

Regarding our primary outcome, Kaplan-Meier was used to calculate survivorship of the implant. Confidence intervals (CIs) at the 95% level were determined.

Two end points were defined: (1) reoperation for any reason (including revision for septic and aseptic complications) and (2) implant revision for mechanical failure or aseptic loosening.

SPSS Software (IMB, Armonk, NY) was used to perform statistical analysis.

Concerning clinical evaluations and patient reported outcome measure tests, values were expressed as mean values with ranges. Two-sample (paired) *t*-tests were used to compare independent variables (functional scores).

## Results

### Patients

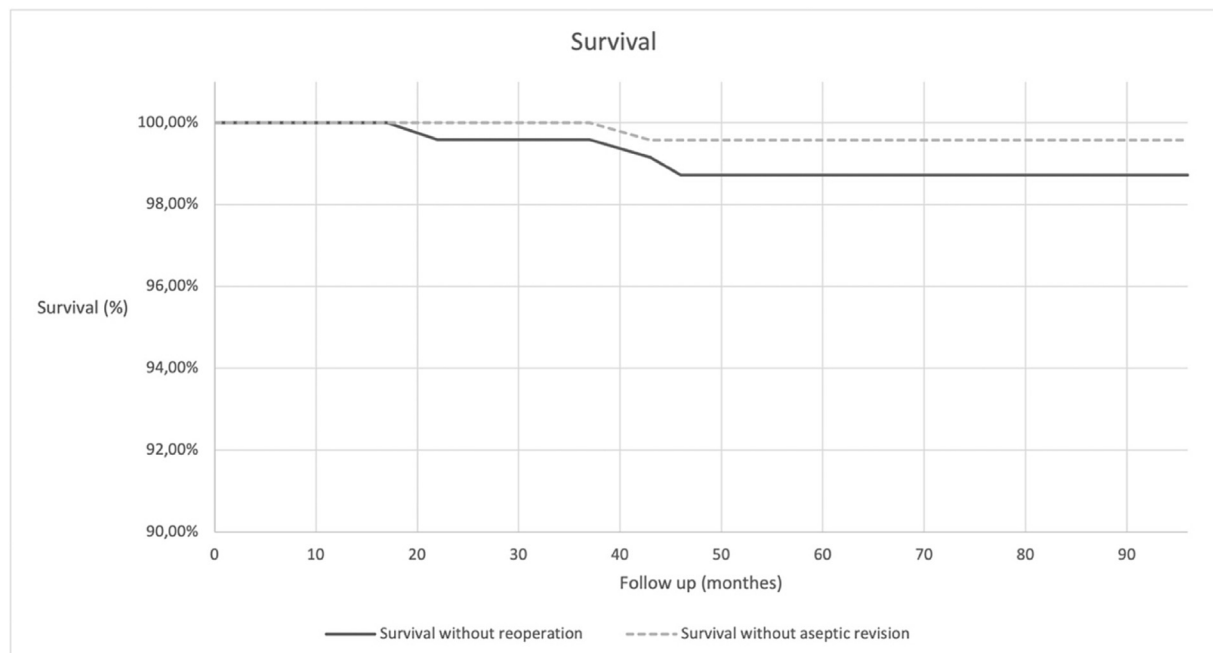
A total of 237 TKAs in 235 patients were included in the study with 151 females and 84 males, with an average age of 72.4 years (40-92). The mean follow-up was 75 months (range 60-96). For 54 patients (23 women and 31 men) the use of a narrow femoral implant was necessary, and a short tibial cemented stem was implanted in 45 patients. Patient characteristics are shown in [Table 1](#).

### Survivorship

Six patients died during this study before 5 years of follow-up, leaving 229 patients for survival analysis at). All patients died with their prosthesis in place. At last follow-up available, 3 knees required a reoperation and 1 knee an implant revision: 2 early reoperations for septic reasons were performed and treated by debridement lavage, polyethylene insert exchange, and antibiotic therapy and 1 tibial revision was performed at 4 years for tibial loosening and migration of the implant in a patient with severe osteopenia. Therefore, at 5 years of follow-up, the survival without reoperation was 98.72% (95% CI 0.95-1.00) and survival without implant revision for mechanical failure was 99.57% (95% CI 0.95-1.00) ([Fig. 2](#)).

### Functional Outcome

Functional outcomes are described in [Table 2](#). The KSS Knee Score increased from 44.7 (13-64) preoperatively to 93.6 (71-100) at 5 years of follow-up ([Fig. 3](#)). The KSS Function Score increased from 45.8 (17-69) preoperatively to 92.2 (51-98) ([Fig. 4](#)). Furthermore, satisfaction of patients beside their expectations was improved in the subjective KSS, from 26.6 (16-51) to 41 (35-55) at 5 years of follow up ([Fig. 5](#)). Similarly, a significant improvement was



**Fig. 2.** Survival.

**Table 2**  
Results.

Follow-up	Preop	1 y	3 y	5 y
Patients	235	235	231	227
Knee	237	237	233	229
HKA (°)	177.4 ± 3.5	180.4 ± 1.7		
ROM (°)	111 ± 9.9	123 ± 10.8	130 ± 10.3	132 ± 8.4
KSS Knee score	45 ± 9 (13-64)	75 ± 14 (46-100)	94 ± 13 (71-100)	94 ± 14 (71-100)
KSS Function score	46 ± 13 (17-69)	78 ± 14 (36-99)	92 ± 15 (49-98)	95 ± 16 (51-98)
KSS Satisfaction	26 ± 7 (16-51)	38 ± 9 (32-55)	41 ± 13 (35-55)	43 ± 13 (35-55)
KOOS				
KOOS Symptom	44 ± 11 (5-70)	69 ± 16 (36-100)	83 ± 17 (62-100)	85 ± 16 (66-100)
KOOS Pain	46 ± 12 (5-70)	71 ± 13 (24-100)	86 ± 16 (67-100)	87 ± 17 (65-100)
KOOS ADL	49 ± 13 (5-70)	62 ± 17 (24-100)	78 ± 20 (39-100)	82 ± 19 (43-100)

HKA, hip knee and ankle; ROM, range of motion; KSS, Knee Society Scoring System; KOOS, Knee Injury and Osteoarthritis Outcome Score; ADL, function in daily living.

observed for all the subscales of the KOOS score between preoperative scores and postoperative scores at 5 years (Fig. 6).

Statistical significant difference was found between KSS scores and KOOS score ( $P < .05$ ) before surgery and at 1 year postoperative. Furthermore, a global improvement of the scores between 1 year and 5 years was observed, but no significant difference was shown.

Range of motion was improved from 111° to 123° at 1 year postoperatively, and until 132° after 5 years of follow up (Fig. 7).

## Discussion

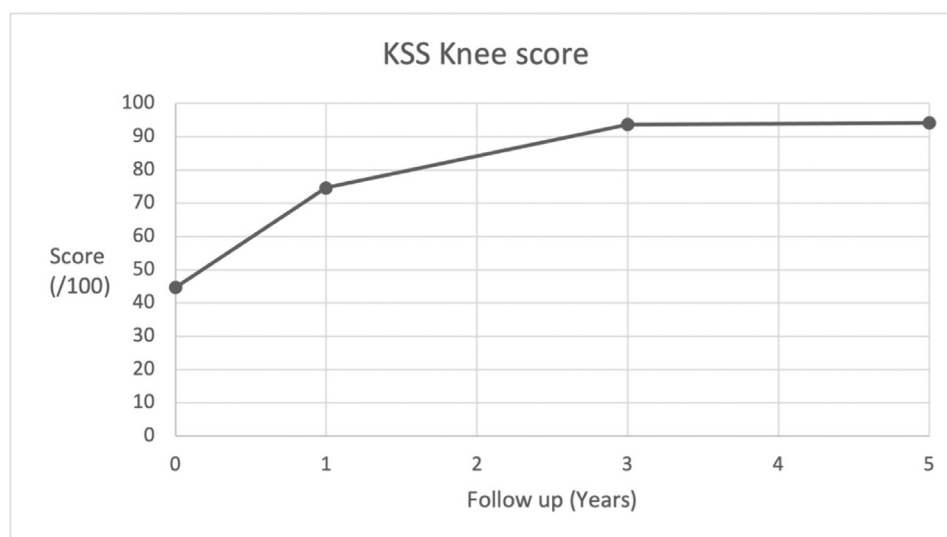
Tibial component malrotation and femoral component oversizing can be a cause of pain and limited flexion after TKA in the absence of infection or aseptic loosening [24,25]. Poor rotation of the tibial component can result in aberrant patellar tracking, limited range of knee flexion, and early revision surgery [24,26]. Optimal rotational positioning of the tibial component remains challenging [27] using symmetrical tibial tray; implant axial positioning often requires a compromise between optimal rotation and bone coverage [28,29]. Similarly, the use of standard femoral component without ML adaptation (narrow component) and with large size increments can result in an oversizing of the implant especially in female patients and can be a cause of pain [30].

The hypothesis of this study was that the use of a morphometric tibial and ML adaptative femoral component can improve the

prosthetic positioning and consequently offers excellent clinical results and survival rate at a minimum follow-up of 5 years.

This hypothesis was confirmed as regarding our endpoint, at 5 years survivorship of the components without implant revision for mechanical failure was 99.57% (95% CI 0.95-1.00) with excellent clinical outcome regarding the KOOS and KSS score.

An optimally implanted TKA tibial component would be one that can flush with all edges of the tibia. This is often not possible, partly because current traditional tibial components may not be of ideal shape and often require a compromise between optimal rotation and bone coverage [28,29]. To optimize rotational-coverage ratios and limit the potential conflicts with the soft tissues, new designs of tibial implants have been developed using large anatomical databases and specific software simulating bone cuts [17]. Thus, morphometric trays have been designed to adapt not only to the morphology of the proximal tibial plateau, but also to its dimensions. In vitro studies, using positioning simulations of the tray on the basis of computed tomography scans, demonstrated that a morphometric tray allows an optimum rotational positioning, while optimizing the tibial coverage without causing any posterolateral conflict with the soft tissues [31,32]. An in vivo prospective matched controlled study comparing morphometric and symmetric tibial tray conducted by Bizzozero et al [17] using the same design as evaluated in the present study demonstrated that bone coverage (90% vs 88%,  $P = .07$ ) and rotation (mean difference  $0.7^\circ \pm 3^\circ$ ;  $P = .69$ ) were not different between the 2 groups.



**Fig. 3.** KSS Knee Score. KSS, Knee Society Scoring System.

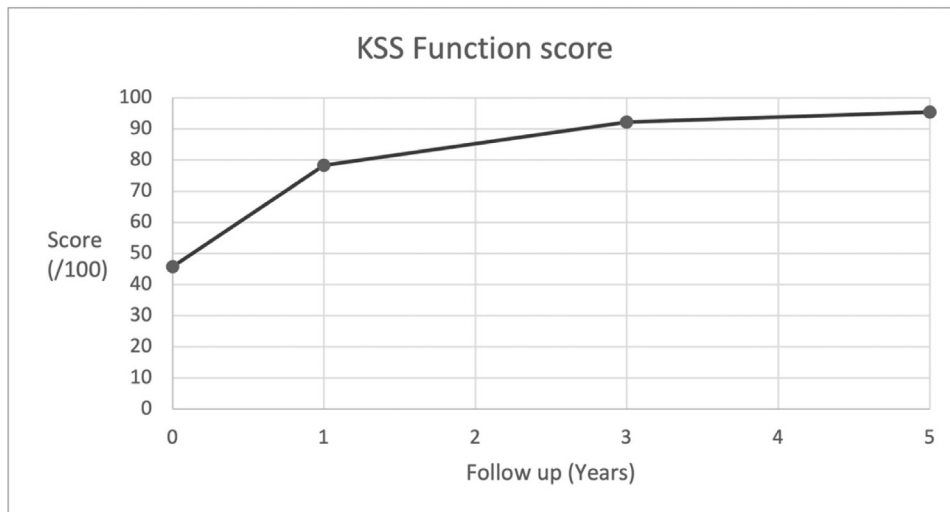


Fig. 4. KSS Function Score. KSS, Knee Society Scoring System.

But the percentage of patients with a posterior overhang was lower in the morphometric group (2/33 vs 14/33,  $P = .01$ , odds ratio 10.3 [2.12-50.24]). They also observed that functional scores were superior in the morphometric group: KSS (mean difference  $20 \pm 21$  points;  $P = .0005$ ) mainly due to a difference in the KSS pain subscore (mean difference  $11 \pm 15$  points;  $P = .0002$ ) at a mean follow-up of 44 months. In the present study, at a mean follow-up of 75 months, same excellent outcomes were observed concerning KSS score and the KOOS score.

KSS score also improved by more than the minimal clinically important difference (MCID) at 3 and 5 years after surgery in the present study. An increase by more than the MCID is more important than a significant difference since it reflects the clinical relevance of the increase. The MCID of the KSS function is 34.5 points [33] and the mean improvement of KSS in the present study was 46 and 49 points, respectively. But this difference was not reached at 1 year post-operatively (mean difference: 32 points).

According to the study of Monticone et al [34], the MCID of KOOS for patients who underwent a TKA was 16.7 for Pain, 10.7 for Symptoms, 18.4 for function in daily living, 12.5 for Sports, and 15.6 for quality of life. However, Collins et al [35] concluded in a review that a change of at least 20 for all subscales represents a true change in older patients. This difference was systematically reached for all the subscales of the KOOS in the present study at 3 and 5 years postoperatively.

These excellent results might be explained first by the small amount of prosthesis with posterolateral overhang. Conflicts between prosthetic components and soft tissues have been advocated to be responsible for pain after primary TKA [36]. They may involve the popliteal tendon [37,38], the patellar tendon [39], the iliotibial band [40], or the medial collateral ligament [30]. The knowledge of this potential conflict allowed Kazakin et al to pay particular attention to it intraoperatively [38]. For Bonnin et al [41], a non-overhang tibial component was associated with lower pain score

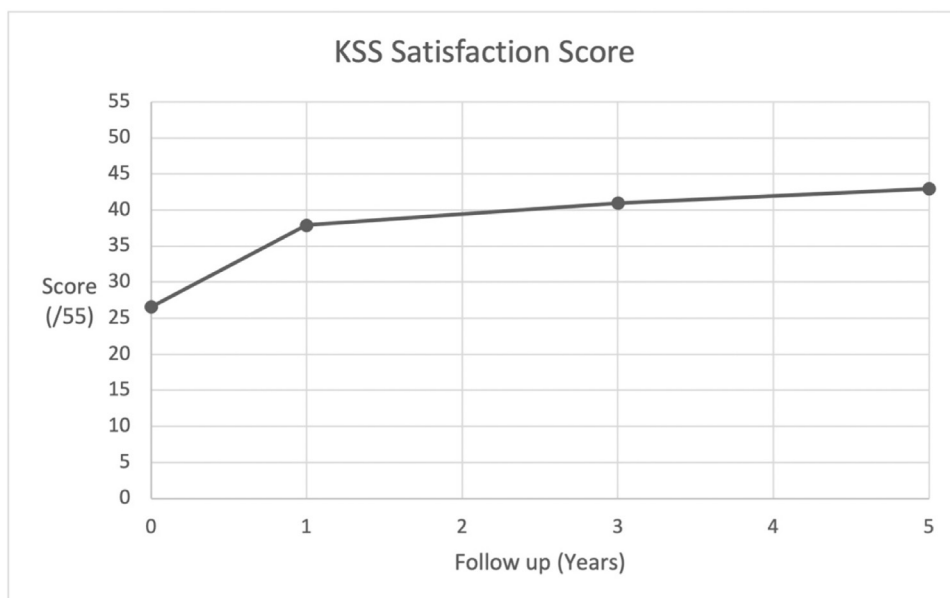
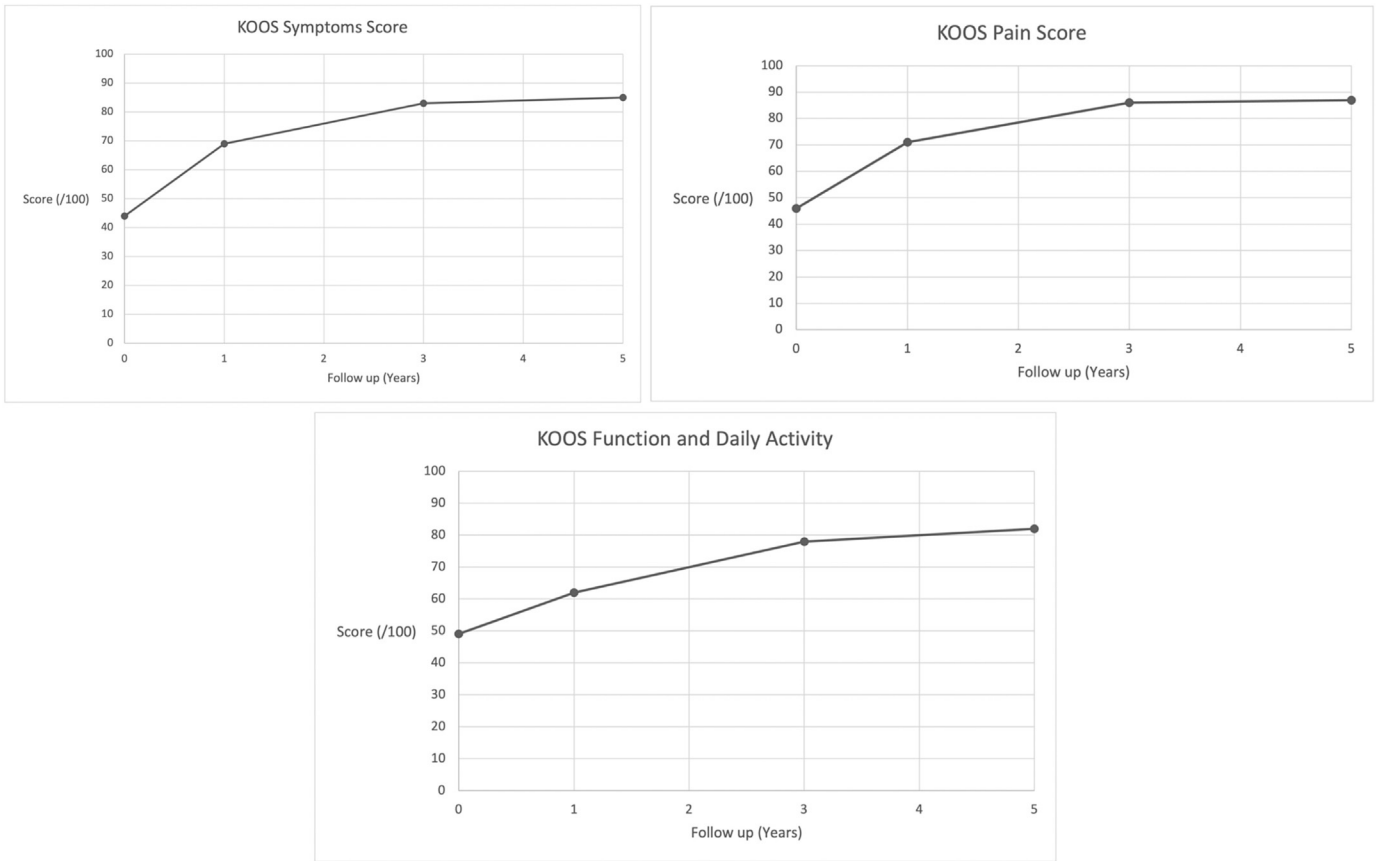


Fig. 5. KSS Satisfaction Score. KSS, Knee Society Scoring System.

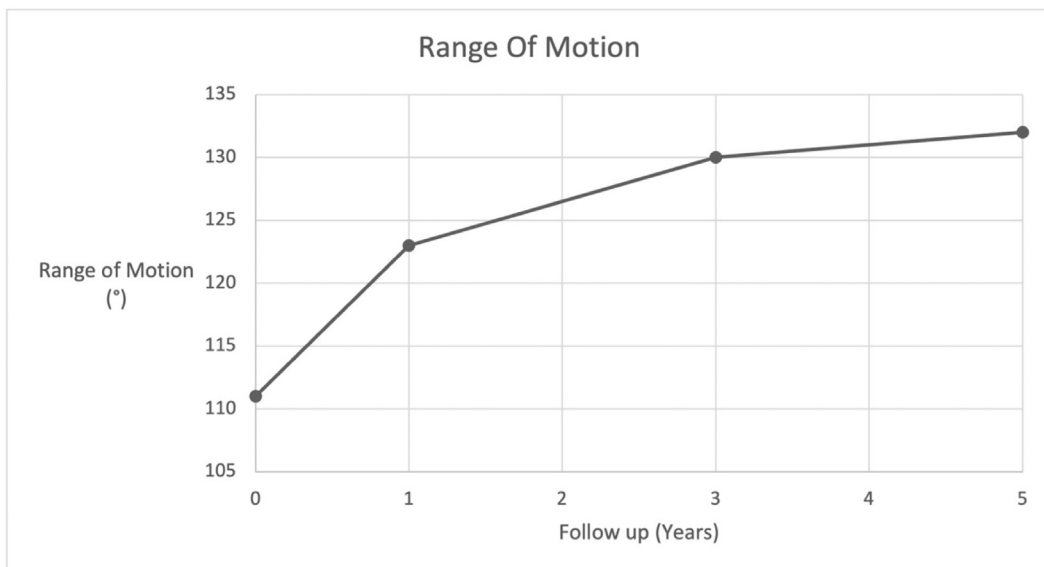


**Fig. 6.** KOOS scores (Symptoms, Pain, Function, and Daily Activity). KOOS, Knee Injury and Osteoarthritis Outcome Score.

compared to an overhang component, which corroborates with the results from Bizzozero et al and Dai et al study [42]. It is then possible that the morphometric design of the tibial component contributed to these excellent results at 5 years.

The second explanation of these results may probably be linked to the inclusion of multiple ML/AP femoral shape offerings and the

increased number of available sizes resulting in improved femoral component fit [43]. The additional use of adaptative ML size of the femoral component with the possibility of a “narrow” femoral implant for each AP size, as well as the finer increments in AP sizing (2 mm), has also permitted to better match the component to each distal femoral anatomy. This hypothesis agrees with a recent study,



**Fig. 7.** Range of motion.



which concluded that designs with multiple ML offerings for a given component AP size may improve component-to-bone fit and reduce the propensity of greater than 2-mm component overhang/underhang in Chinese patients [44]. The use of this type of implant in the present cohort could probably explain a decrease in the pain induced by an ML oversizing of the femoral component. Indeed, the concepts of sexual dimorphism in humans and anatomic variations in various ethnic groups are well known and supported by anatomic and radiographic studies [12–14]. Traditional knee implants have been designed “down the middle” based on the combined average size and shape of male and female knee anatomy. The need for both additional shape and size offerings led to the introduction of “narrow” femoral implant for each AP size as well as to a reduced increment between sizes in order to better match distal femoral anatomy.

The second objective of this study is to evaluate the mid-term survivorship of a knee arthroplasty system using morphometric implants. The survival without reoperation at 5 years of follow-up was 98.72% (95% CI 0.95–1.00) and survival without revision for aseptic reason was 99.57% (95% CI 0.95–1.00). In the 2020 annual report of the national joint registry (UK), reporting results of the same implant at a comparable follow-up, the risk of revision was 3.99 at 5 years [45]. Survival rates of TKAs have improved in the last decades; the Swedish Knee Arthroplasty Register showed an improvement in 10-year survival from 89% for TKAs performed during 1985 to 1994 to 96% during 2005 to 2014 [46]. Furthermore, from the Norwegian Arthroplasty Register it was concluded that the 10-year survival had improved to 94% in the period 2005–2015 [47]. The explanation for these increasing survival rates is multifactorial, with adjusted patient selection, improved implant designs, and altered education. In their study using the Persona knee system for 146 knees, Mathijssen et al [18] observed that the Kaplan-Meier survival estimate at 2 years was 0.99 (95% CI 0.95–1.00). The results of the present study at 5 years confirm the promising observation of Mathijssen et al concerning the survival at mid-term follow-up of Persona knee system with a larger cohort. The survivorship of a different model of an asymmetrical tibial tray was also described by Bourne et al [48]. They observed that the survivorship with any reoperation at 12 years was 96% ( $\pm 2\%$ ).

Several limitations of this study need to be addressed. First, since this is an observational cohort study, comparison with other prosthesis is difficult. Regarding a previous study performed in the same center using another design of TKA with symmetric tibial tray (NexGen LPS-Flex System), no clinical difference was observed concerning the KSS score (KSS function score: 94 vs 95 previously and KSS knee score: 94 vs 96 previously). But the mean follow-up of the previous study was 3 vs 6.2 years in the present study, and this difference can influence the results. Second, all the procedures were performed by 2 experienced surgeons specializing in knee surgery arthroplasty. The results obtained may not be extrapolated to all surgery centers. Third, for all the patients, a neutral final alignment was targeted. It is therefore also not possible to extrapolate the functional results and survivorship of this cohort to other types of knee arthroplasty alignment (kinematic, hybrid, functional). Furthermore, all the patients in this cohort had optimal conditions preoperatively: flexion of at least 100° preoperatively, no major deformity or previous surgery. It might contribute to the good results found in this study. Despite those limitations, this study contains the largest cohort in the literature, to our knowledge, that evaluates the functional outcome and the survival of the Persona knee system from a single institution at a minimum follow-up of 5 years. However, longer follow-up and further studies are needed to determine long-term survival and long-term clinical performance of the Persona knee implant system.

## Conclusion

Morphometric implants for TKA showed survival reliability and function restoration at minimum 5 years of follow-up. Pain level might be durably decreased possibly related to reduction of prosthetic overhang and optimization of the component fit.

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