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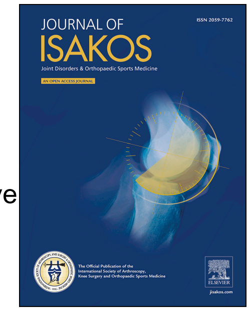

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Abstract

Objectives: This investigation aimed to evaluate if the modifications to prosthesis designs improve patients' clinical and functional outcomes after total knee arthroplasty (TKA), with a special focus on pain and kneeling ability.

Methods: Retrospective and comparative analysis of consecutive patients who were treated with posterior stabilized TKA using two different prostheses designs (single surgeon, single vendor). Group 1 received a traditional design TKA (PFC Sigma; DePuy, Inc., Warsaw, IN) with conventional dome-patella resurfacing and group 2 received a modern design implant (Attune; DePuy, Inc., Warsaw, IN), with medialised dome-patella resurfacing. Functional outcome (range of motion: ROM) and the Oxford Knee Score (OKS) were collected preoperatively, at 4-6 weeks and 12 months following surgery.

Results: Ninety-nine participants were included. Of these, 30 received traditional design implants, and 69 the modern design knee implants. The comparison between the two implants showed a statistically significant increased total OKS and kneeling ability in the modern design cohort at 1-year follow-up compared to the traditional design cohort ($p < 0.01$). In the modern design group, 53% (N=37) could kneel easily or with little difficulty, compared to 30% (N=9) in the traditional design group. No statistically significant differences in ROM or the OKS pain component were seen.

Conclusion: The incorporation of a medialized dome-patella in modern knee implant design may offer advantages over traditional designs, as seen in improved total OKS and kneeling ability at one-year follow-up. Further research with larger cohorts is needed to confirm these findings and explore the broader impact of implant design changes on patient outcomes.

Keywords: Total knee arthroplasty, kneeling, Posterior stabilized TKA, PFC Sigma knee implant, Attune knee implant, Medialized dome-patella resurfacing

Level of evidence

Clinical Study, Level III.

What are the new findings?

1. The modern design knee implant with medialized dome-patella resurfacing demonstrated statistically significant better outcomes in total Oxford Knee

Score and kneeling component ($p < 0.01$) compared to the traditional design knee implant, up to 1 year follow up.

2. An improvement in kneeling ability was evident in 53% of participants in the modern design cohort, surpassing the 30% observed in the traditional design group at 1-year follow-up.
3. No statistically significant difference in range of motion or the Oxford Knee Score pain component was seen between the two knee implants up to the 1-year follow-up

Introduction

In patients with severely degenerative knee joints, total knee arthroplasty (TKA) is a commonly used surgical procedure to relieve pain and improve functionality and quality of life [1, 2]. Despite the progress made in TKA, anterior knee pain continues to be a common issue, affecting 8-10% of patients and in some studies, even up to 30% [3, 4]. This is also related to functional limitations like kneeling, which is one of the most important and difficult activities in these cases [5]. Most patients expect to be able to kneel after TKA, but up to 65% of patients are unable to do so one year after surgery [6–8]. The ability to kneel also depends on knee flexion. The required degree for upright kneeling is 90 degrees, and >120 degrees for flexed kneeling [5, 9]. However, the factors that influence kneeling ability after TKA are still not well understood [10]. According to a recent meta-analysis, surgery-related predictors of kneeling ability in TKA include the incision type and TKA design [6].

The modern prosthesis design, as opposed to the traditional design, more accurately replicates the natural trochlea-patella anatomy (Figure 1). This aims to restore a more typical patellar movement, resulting in improved performance and reduced patellofemoral complications following surgery [11–13]. The primary objective of the present study was to compare a modern TKA design with a medialized dome-patella resurfacing and a traditional implant with a centralized dome-patella, with a special focus on pain and kneeling ability after 1 year of surgery. We hypothesise that the implementation of modern patellofemoral design modifications, particularly optimized patellar tracking in modern TKA with medialized dome patella resurfacing, would result in improved self-reported kneeling ability compared with conventional patella resurfacing. Additionally, clinical outcomes and knee function were analyzed.

Methods

Study Design

After obtaining approval from the local Institutional Review Board (St John of God Health Care Human Research Ethics Committee, Reference 1430/2020), we conducted a retrospective and comparative analysis. The inclusion criteria for this study were all participants over 18 years old who underwent primary cemented, posterior stabilized (PS) TKA for osteoarthritis at two centres (St. John of God Murdoch Private Hospital and Fremantle Hospital, Western Australia). Implant choice in our study was determined based on consecutive cohorts. This means that as patients were enrolled in the study, the choice of the implant was made sequentially without any predetermined selection criteria and was not influenced by any bias or temporal considerations. This study was exclusively conducted using the implant employed by a single surgeon, and this constitutes the dataset available for analysis).

Implant types

Modern Total Knee Arthroplasty Design

All prosthesis types were manufactured by DePuy Synthes (Warsaw, IN, USA).

Differences in the design can be found in Table 1 and visualized in Figure 1 [11–13].

Table 1 Comparison of Design Features between Traditional and Modern Design Total Knee Arthroplasty Implants. [11–13]

	Traditional design implant	**Modern design implant**
Implant type	P.F.C. Sigma	Attune
Femoral component	Greater width and thickness	Reduced width and thickness and gradually reducing radius
Patellofemoral Design	Conventional patellar dome design	By 3mm medialized dome patellar
Patella component thickness (mm)	8.0 (Size 29), 8.5 (Size 32, 35 and 38), 11 (Size 41)	8.5 (Size 29), 9.0 (Size 32), 9.5 (Size 35), 10 (Size 38), and 10.5 (Size 41)
Trochlear Shape	More proximal trochlear groove	Funneled trochlear groove, extended distally, 3° shallower
Box ratio	0.8	0.7

Surgical Technique

All procedures were done by a single surgeon with over 10 years of experience. The surgery was performed through a medial parapatellar approach. Using conventional instrumentation (intramedullary femur, extramedullary tibia), we aimed for mechanical alignment. No lateral retinacular release had to be performed in this series.

We routinely perform patellar resurfacing in all posterior stabilized knees as a standard practice. In our surgical technique for patellar resurfacing, we used the Attune cutting guide to achieve a total thickness of 22-26mm for the patellar bone resection, taking into consideration the preoperative thickness of the patella. Our surgical approach ensured that the residual thickness of the patella was never less than 12mm. Our goal was to ensure complete coverage of the cut surface with the patellar component implant.

In terms of femoral component rotation, our default reference was set at 3 degrees external rotation. However, we always double-checked the femoral rotation using spacer blocks before making the definitive cut to ensure optimal patellofemoral alignment. To evaluate the patellofemoral tracking, we performed a thorough assessment during the trial component phase of the surgery. We observed the patella throughout the range of motion to ensure it sat flat and maintained balanced tracking. This evaluation was done before any repair of the quadriceps tendon to eliminate any potential confounding effects.

Rehabilitation protocol

Immediate mobilization with physiotherapy assistance on the day of surgery aimed to prevent complications and facilitate a swift return to functional activities. Patients underwent frequent physiotherapy sessions twice daily, focusing on improving joint range of motion and strengthening knee muscles. Typically, participants were discharged from the hospital on either day 2 or 3 after surgery, indicating close monitoring. Follow-up physiotherapy sessions commenced at 3 to 4 weeks post-surgery to sustain rehabilitation progress. Notably, Continuous Passive Motion was not part of this protocol.

Outcome measures and follow-up

Demographic data, including age, gender, and the side of the operation, were collected for all participants. These variables were included to assess potential differences in patient characteristics that might influence postoperative outcomes, such as kneeling ability and pain levels. Patient-reported outcomes were assessed using the OKS reported by patients. This questionnaire is routinely given to patients before TKR and for each follow-up visit. The OKS ranges from 0 to 48, with a higher score representing a better functional outcome. The published minimal clinical important difference (MCID) for the OKS is 5 [14, 15]. Given that pain and kneeling are particularly important outcomes for patients who undergo TKA, the OKS scores for pain (question 1) and kneeling ability (question 7) in the last 4 weeks, were analyzed separately [10, 16]. ROM data (active flexion and extension) were measured preoperatively and during each postoperative control using a goniometer. Data were obtained from participant's medical charts. Participants data (OKS, ROM) were collected at baseline, 4-6 weeks, and 12 months following surgery. Missing data from the participant's medical charts or incomplete questionnaire responses were excluded from the analysis. Specifically, for ROM measurements and questionnaire data, any instances of missing data were not included in the analysis to ensure the integrity and accuracy of the results.

Statistical Analysis

The normal distribution of the data was assessed using the Shapiro-Wilk test, which indicated that all data showed a normal distribution. Descriptive statistics were then used to summarize the data, including the calculation of the mean and standard deviation (SD). Univariate differences in baseline demographics by implant type were explored using analysis of variance (ANOVA). Differences in outcomes were explored using repeated-measures 2-way ANOVA followed by multiple comparisons corrected by the Holm-Šídák method. P-values <0.05 were considered statistically significant. Cohen's d was computed, and interpretation was based on effect sizes categorized as small (d = 0.2), medium (d = 0.5), and large (d = 0.8), following the benchmarks suggested by Cohen [17]. All analyses were performed using GraphPad Prism version 8.0.0 for Windows, GraphPad Software, San Diego, California USA.

Results

We included a total of 99 participants, with a follow-up of one year. Sixty-nine participants received the modern design (posterior stabilized with medialized dome patella resurfacing), and 30 patients received the traditional design implant (posterior stabilized with conventional dome patella resurfacing;Figure 2). The post hoc power analysis revealed that with a significance level (alpha) of 5% and a power (1-beta) exceeding 80%, the sample size of 69 in the modern design group and 30 in the traditional design group was adequate to detect a statistically significant difference in kneeling ability based on the OKS after one year. The overall Total OKS, encompassing various aspects of knee function, demonstrated a power of 80.3%. The OKS kneeling exhibited a power of 83.6%. The OKS pain component displayed a substantial power of 76.5%.

No intraoperative or major complications were reported, furthermore, none of the participants in our study experienced complications following their total knee arthroplasty that required Manipulation Under Anesthesia or prolonged physiotherapy post-operatively. One patient in the modern design group with a rotating platform required reoperation to remove a posterolateral cement leak that caused localized pain. Following surgery, the patient's pain was relieved.

Patient Demographic Data

No statistically significant difference in age, sex, or operation side were found between the modern and traditional design cohorts (Table 1).

Table 2 Patient Demographics between Traditional and Modern Design Total Knee Arthroplasty (TKA).

Variable	Traditional design TKA	Modern design TKA	P value
Patients, n	30	69	-
Age, y	69.7 ± 7.2	65.4 ± 9.3	.120
Female, n (%)	19 (63)	47 (68)	>.999
Left side operation, n (%)	18 (60)	42 (61)	>.999

Analyzed using 2-way ANOVA with subsequent multiple comparisons correction by the Holm-Šídák method. Statistically significant differences were denoted by P-values <0.05

Range of motion

Both modern and traditional design participants demonstrated statistically significant improvements in flexion from baseline to the 12-month postoperative assessment (p

<.001, Supplementary Table 1). At the 1-year postoperative mark, there were no discernible differences between the two implant designs (Table 3).

Table 3 Functional Analysis of Range of Motion (mean ± SD) in Traditional and Modern Design Total Knee Arthroplasty (TKA) at Baseline (preoperative), 4-6 weeks, and 1 year postoperatively.

Variable	Traditional design TKA	Modern design TKA	P value *
Participants (n)	30	69	-
Extension			
Baseline extension (°)	5 ± 6	4 ± 4	*>.999*
Postoperative extension, 4-6 weeks (°)	3 ± 7	4 ± 6	>.999
Postoperative extension, 1 year (°)	0.5 ± 3	1± 2	>.999
Flexion			
Baseline flexion (°)	106 ± 20	108 ± 15	.979
Postoperative flexion 4-6 weeks (°)	105 ±13	107 ± 14	.995
Postoperative flexion 1 year (°)	118 ± 11	117 ± 12	>.999

*2-way ANOVA followed by multiple comparisons corrected by the Holm-Šídák method. P-values <0.05 were considered statistically significant.

Oxford Knee Score

MCID (>5) at 12-month follow-up was achieved in the postoperative OKS total score compared to baseline in all three groups (Supplementary Table 1). At 4-6 weeks postoperative, no statistically significant difference was observed between the traditional and modern design TKA groups. However, at the 1-year follow-up, the modern design cohort displayed a statistically significant increase in total OKS score ($p < 0.01$) with a medium-large effect size of dCOHEN = 0.73 compared to the traditional design group (Table 4).

Oxford Knee Score - Kneeling

At the 12-month follow-up, a substantial and statistically significant improvement ($p < 0.01$) was observed in the OKS kneeling component. The effect size, as indicated by Cohen's d ($d = 0.68$), falls within the medium-large range, demonstrating a notable difference in scores between the modern design and traditional design groups (Table 4).Specifically, 53% (N=37) of participants in the modern design group reported easy or little difficulty in kneeling, while only 30% (N=9) of traditional design group participants did (reported by OKS, Figure 3).

Oxford Knee Score - Pain

The OKS pain component score improved in all groups from the preoperative assessment to the 1-year follow-up. Although a higher pain score was observed in the modern design cohort compared to the traditional design group 1 year after surgery, this difference was not statistically significant ($p=0.16$; Table 4). Specifically, 79% (N=55) of participants who received the modern design TKA reported no or very mild pain, while 63% (N=19) of participants who received the traditional design TKA reported the same. Additionally, only

21% (N=14) of participants in the modern design cohort experienced mild to severe pain, compared to 37% (N=11) in the traditional design group (Figure 4, Table 4).

Table 4 Results of the Oxford Knee Score (OKS). Baseline (preoperative), after 4-6weeks and 1 year postoperatively

Variable	Traditional design TKA	Modern design TKA	P value *	Effect size (d_{COHEN}) #
Participants (n)	30	69		
Total OKS				
OKS Baseline	19.4 ± 7.3	20.4 ± 8.7	>.999	
OKS total score (4-6 weeks)	29.5 ± 8.2	30.2 ± 8.4	*>.999*	
OKS total score (1 year)	35.8 ± 10.4	41.6 ± 6.7	***<.01***	***0.73***
OKS pain component				
OKS pain (Baseline)	0.8 ± 0.6	0.7 ± 0.6	>.999	
OKS pain (4-6 weeks)	1.8 ± 1.2	1.8 ± 1.0	*>.999*	
OKS pain (1 year)	2.6 ± 1.3	3.3 ± 0.9	*0.16*	
OKS kneeling component				
OKS kneeling (Baseline)	0.5 ± 0.8	1.1 ±1.1	*>.999*	
OKS kneeling (4-6 weeks)	0.9 ± 1.3	1.1 ± 1.4	*>.999*	
OKS kneeling (1 year)	1.4 ± 1.4	2.3 ± 1.4	***<.01***	***0.68***

*2-way ANOVA followed by multiple comparisons corrected by the Holm-Šídák method. P-values <0.05 were considered statistically significant.
Effect size (d_{COHEN}) # d = 0.2 “small”, 0.5 “medium”, and 0.8 a “large” effect size

Discussion

In this comparative study of 99 participants, a modern design knee implant with medialized dome-patella resurfacing exhibited advantages over a traditional knee implant in terms of total Oxford Knee Score and kneeling ability up to one year post-implantation. Specifically, in the modern design cohort we saw an improvement in kneeling ability in 53% (N=37) of participants, outperforming the 30% (N=9) observed in the traditional design group, while there were no statistically significant differences in ROM or the pain component of the Oxford Knee Score between the two implant types over the one-year follow-up period.

Patellofemoral complications account for 6-11.6% of knee implant revisions, particularly in PS implants [18–20]. Over the past two decades, TKA implant designs have improved with changes to the femoral component and patella to enhance kinematics, postoperative function, and pain reduction [21, 22]. The modern design prosthesis is an example of an implant with innovative design changes compared to the traditional model. For instance, the anterior part of the femoral component is smaller in width and thickness, to avoid overhanging and increasing the anterior offset in the patellofemoral side [23, 24]. Moreover, it has a medialized dome-patella component for better tracking [25, 26], and a gradually reducing radius of curvature to prevent abrupt transitions [27].

The factors influencing kneeling ability in TKA are not yet fully understood, and the findings regarding the association between prosthesis types and kneeling ability have been inconsistent across studies. In a recent systematic review, surgical factors such as the incision type and TKA design were identified as predictors of kneeling ability in TKA [6]. The review suggested that anterolateral and shorter incisions were associated with greater odds of kneeling ability, also a transverse incision was found to improve kneeling ability, but this was based only on one study [6, 28]. In our study, a medial parapatellar incision was utilized.

We found that over half of the participants in the modern design group reported being able to kneel easily or with little difficulty, whereas only about a third of the participants in the traditional design group reported the same. It is worth noting that a study on the traditional design implant reported a slightly higher proportion (39%) of participants being able to kneel easily or with little difficulty, compared to our cohort (30%), despite using the same implant and having similar patients demographics [29]. Our study did not directly investigate the factors leading to greater difficulty kneeling, and further research is needed to explore these factors in more detail. We found a statistically significant higher total OKS score in the modern compared to the traditional design group ($p < 0.01$). Since the OKS heavily relies on pain scores, we further examined the pain and kneeling questions [30, 31]. We showed that 79% of participants in the modern design group had no or mild pain versus 63% in the traditional design group. Our results are in line with some studies, which also report less anterior knee pain and fewer patellofemoral complications with the modern design implant [32–34]. However, in other studies comparing the patellofemoral outcomes of modern versus traditional design TKAs, the authors could not show a statistically significant difference in pain or questionnaire-based outcomes [32, 35, 36]. Regarding the ROM between modern and traditional design implants, we could not show any statistically significant differences. Improvements in knee flexion to a mean of 120°, and extension to a mean of 0° across all groups were similar to those reported by other authors. Values range between 110–123° flexion for the modern design group and 110–117° for traditional design TKAs. [32, 34, 37]. However, a recently published study could show a higher total ROM of 132° for both implant systems [35].

Several studies have highlighted the advantages of the modern design in comparison to traditional TKAs; however, this study is the first to specifically investigate its impact on pain and kneeling abilities [10]. Nonetheless, we acknowledge that our study has certain limitations. Firstly, it was conducted retrospectively, which inherently carries the limitations associated with this study design. Additionally, as the participants were not randomized, it is challenging to ascertain whether differences in outcomes are solely attributed to intrinsic patient characteristics or influenced by the surgeon's choice of knee system. Although our sample size was small, the surgeries were highly standardized and performed by the same surgeon, ensuring high comparability and minimizing variability. However, it is important to note that the subgroup analysis was underpowered, and therefore, caution should be exercised when interpreting the results. Furthermore, the assessment of kneeling ability was solely based on the kneeling question of the OKS, which is commonly used in this type of research [6, 10, 16, 38, 39]. We chose a 12-month follow-up period based on the fact that 94% of patients expect to regain the ability to kneel after this time frame [8], which is consistent with findings from the literature where kneeling ability typically does not show statistically significant improvement beyond one year [6, 40, 41]. Furthermore, we acknowledge that conducting an expanded investigation encompassing factors such as different surgical techniques, radiographic parameters, and different implant design options would provide valuable insights into the factors influencing outcomes in TKA. Nevertheless, it is important to note that the scope of our current research study was specifically focused on comparing the functional outcomes (kneeling ability), ROM, and pain levels between two specific TKA designs.

The objective of future research should focus on developing innovative interventions and rehabilitation strategies specifically targeting the restoration and improvement of kneeling ability in the long term. This may involve exploring alternative surgical techniques, implant designs, postoperative rehabilitation protocols, and patient-centred interventions aimed at optimizing functional outcomes and facilitating a successful return to kneeling activities. By addressing this ongoing challenge, we can strive to enhance the overall functional outcomes and quality of life for patients undergoing TKA.

Conclusion

This retrospective study focused on a single surgeon's experience with a specific implant design within a single-vendor context. Notable improvements in both overall knee function, as indicated by the OKS, and kneeling ability after one year of follow-up were revealed. The modern design TKA includes a medialized dome-patella, potentially contributing to these outcomes. Although these were statistically significant differences, the clinical significance is uncertain as there are no established MCID values for the OKS components. Despite promising results, study limitations include its retrospective nature and small sample size, necessitating future research with larger cohorts and comprehensive assessments.

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Figures

Figure 1 The design features of the modern (Attune) versus traditional design (PFC Sigma) implant. (A) The trochlear groove of the modern design implant is more distally elongated than that of the traditional design, leading to a decreased intercondylar box ratio. (B) Narrower width and thickness of the modern design implant (inner dimension; solid line) than that of the traditional design (outer dimension; dotted line). (C) The modern design implant features a medialized dome-patella component to provide optimization of patellofemoral conformity. *[Image source: Sang Jun Song et al., Knee Surgery & Related Research 2018;30:334~340* [11] *]*

Figure 2 Flowchart illustrating the process of participant selection for the study.

TKA, Total Knee Arthroplasty

PROMs, Patient-reported outcome measures

Figure 3 Comparison of Oxford Knee Score (OKS) kneeling component scores at 12 months postoperatively between traditional and modern implant types, illustrating the distribution and differences in kneeling ability outcomes.

Figure 4 Comparison of Oxford Knee Score (OKS) Pain Component Scores at 12 months postoperatively among participants with modern and traditional design total knee arthroplasty implant. In the modern design group, 79% (N=55) reported no or very mild pain, contrasting with 63% (N=19) in the traditional design group. Moreover, only 21% (N=14) of the modern design cohort experienced mild to severe pain, as opposed to 37% (N=11) in the traditional design group.

List of abbreviations

ANOVA	Analysis of variance
MCID	Minimal clinical important differences
OKS	Oxford Knee Score
PFC	Press-Fit Condylar
PS	Posterior stabilized

ROM	Preoperative range of motion
TKA	Total knee arthroplasty

Declarations

Ethics approval

Ethical approval was obtained by the St John of God Health Care Human Research Ethics Committee (Reference 1430/2020).

Consent for publication

Not applicable

Availability of data and material

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests

PY: consulting work (DePuy/Synthes), Presentations/Travel costs (DePuy/Synthes)

LH: no competing interests

SH: no competing interests

MF: no competing interests

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Authors' contributions

SH: Formal analysis, Investigation, Methodology, Visualization, Writing

LH: Conceptualization, Data curation, Investigation, Methodology, Project administration, Visualization, Writing – original draft, Writing – review & editing

MF: Methodology, Writing – review & editing

PY: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Writing – review & editing.

All authors discussed the results, and corrected and approved the final version of the manuscript.

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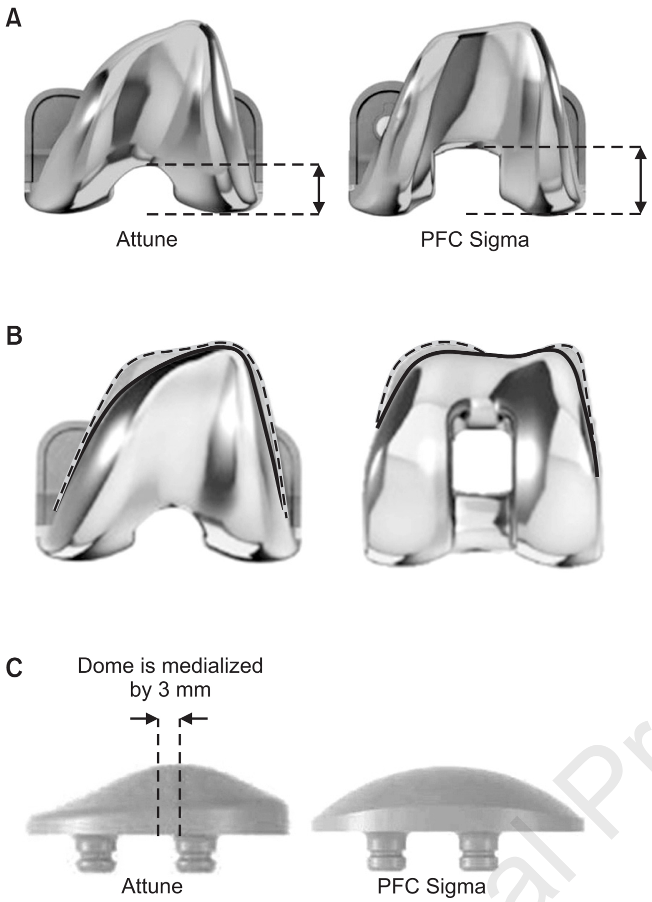
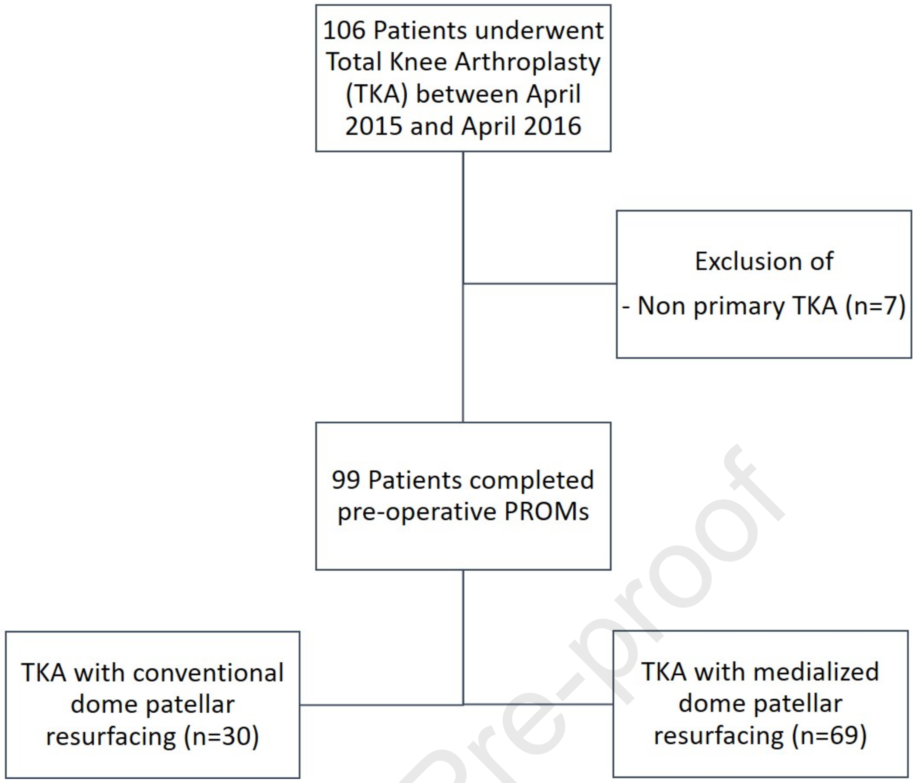
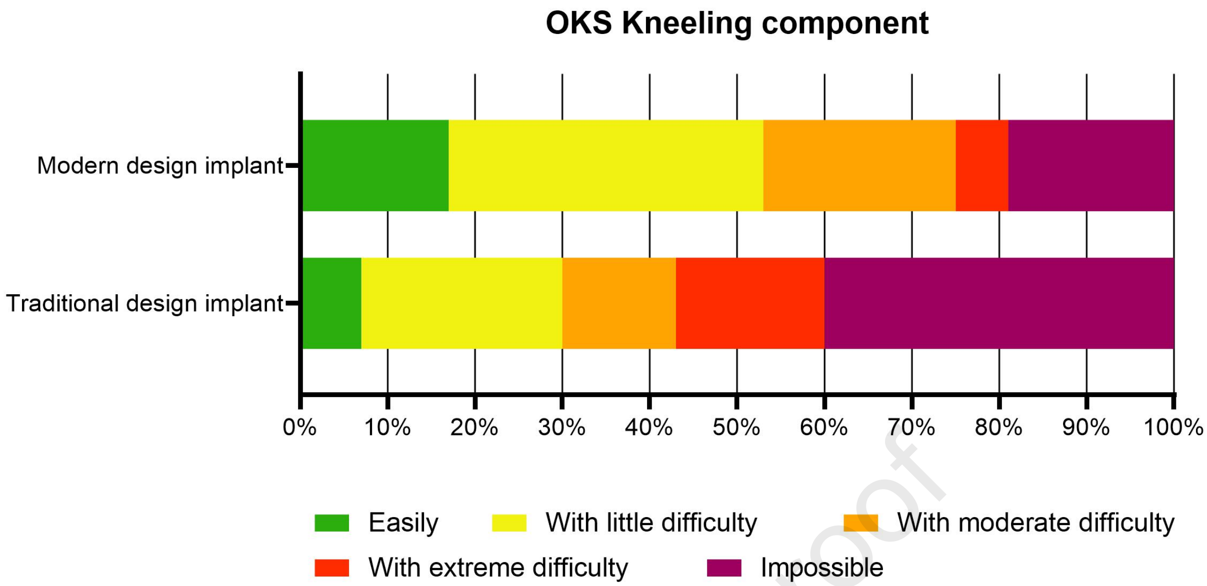
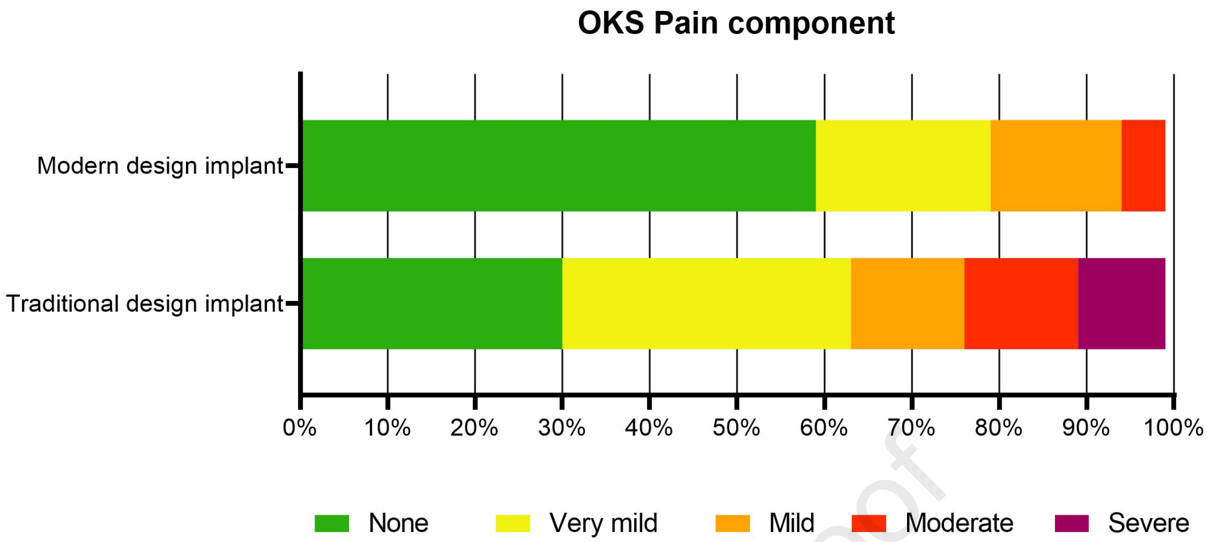

A
Attune
PFC Sigma
B
C
Dome is medialized
by 3 mm
Attune
PFC Sigma


106 Patients underwent Total Knee Arthroplasty (TKA) between April 2015 and April 2016
Exclusion of
- Non primary TKA (n=7)
99 Patients completed pre-operative PROMs
TKA with conventional dome patellar resurfacing (n=30)
TKA with medialized dome patellar resurfacing (n=69)


OKS Kneeling component
Modern design implant
Traditional design implant
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
Easily
With little difficulty
With moderate difficulty
With extreme difficulty
Impossible


OKS Pain component
Modern design implant
Traditional design implant
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
None
Very mild
Mild
Moderate
Severe

Declaration of interests

☐ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☒ The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Piers Yates did consulting work (DePuy/Synthes), Presentations/Travel costs (DePuy/Synthes)