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Comparison of Patellofemoral Outcomes between Attune and PFC Sigma Designs: A Prospective Matched-Pair Analysis

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Background: Attune (DePuy Synthes) prosthesis was designed to overcome patellofemoral complications associated with PFC Sigma (DePuy Synthes) prosthesis. The aim of our study was to compare the incidence of anterior knee pain (AKP), patellofemoral crepitus (PCr), and functional outcome between them.

Methods: This prospective matched-pair study was conducted between January 2014 and June 2015, during which 75 consecutive Attune total knee arthroplasties (TKAs) were matched with 75 PFC Sigma TKAs based on age, sex, body mass index, pathology, and deformity. A single surgeon performed all the operations with aid of computer navigation, using a posterior-stabilized prosthesis with patellar resurfacing. Outcome was assessed by new Knee Society Score (NKSS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score. AKP and PCr were assessed by a patient-administered questionnaire till 2 years of follow-up. Three pairs were lost to follow-up and finally 72 pairs were analyzed.

Results: One patient in each group reported AKP and 1 patient from each group had PCr at 2 years postoperatively. None of these patients required additional surgery. The incidence of lateral retinacular release was higher with PFC Sigma (5/72) than Attune (2/72); however, this was statistically not significant (p = 0.4). The Attune group had a significantly greater range of motion (ROM) at 3 months postoperatively (p = 0.049). At final follow-up, ROM was comparable between two prosthesis designs. NKSS and WOMAC scores were also comparable between the groups.

Conclusions: We observed that both Attune and PFC Sigma had a low and comparable incidence of AKP and PCr up to 2 years of follow-up. The Attune group achieved a significantly greater ROM at 3 months postoperatively. At 2 years of follow-up, both prostheses had excellent and comparable clinical and functional results.

Keywords: *Knee, Prosthesis design, Patellofemoral joints, Arthroplasty, Anterior knee pain syndrome*

The incidence of anterior knee pain (AKP) with PFC Sigma (DePuy Synthes, Warsaw, IN, USA) design has been reported to be as high as 9% and that of patellofemoral crepitus (PCr) requiring surgery as high as 2%.[1] Such patellofemoral complications have been a drawback of the otherwise widely accepted and extensively used posterior-stabilized PFC Sigma design. One of the goals of the At-

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tune (DePuy Synthes, Warsaw, IN, USA) prosthesis design was to overcome this shortcoming by a closer recreation of trochlea-patellar anatomy and replication of normal patellar kinematics (Fig. 1A). Attune has low profile trochlear flanges with a trochlear groove that is 3° shallower than its PFC Sigma counterpart (Fig. 1B).[2] It also has a smoother transition from the notch to the trochlea. The box ratio is reduced with the Attune prosthesis to 0.7 compared to 0.8 with PFC sigma (Engineering data supplied by DePuy Synthes). The trochlea is funneled and has a laterally oriented groove to try and match the Q angle (Fig. 1). The patellar button was also changed to a medialized anatomic patella design unlike the dome design used in PFC Sigma.

The two designs have been compared with respect to their clinical outcomes,[3] risk of posterior tibial cortex injury,[4] and incidence of lateral retinacular release.[5] However, only three studies have focused on comparison of patellofemoral complications between the two prostheses. One of these was limited by the fact that it was retrospective and based on data pooled from multiple surgeons.[6] The other two were prospective matched-pair studies, but were limited by being multiple surgeon-based and having a significantly uneven distribution of fixed-bearing and mobile-bearing prostheses between two groups.[7,8]

To overcome these shortcomings, we designed a prospective, single surgeon-based, matched-pair study with the aim to compare the short-term results of Attune to PFC Sigma, with emphasis on patellofemoral results. Outcomes of these two prostheses were compared with respect to AKP, PCr, and function. Our hypothesis was that the newer Attune implant with a number of modifications in patellofemoral articulation will produce better patellofemoral results than its predecessor design PFC Sigma.

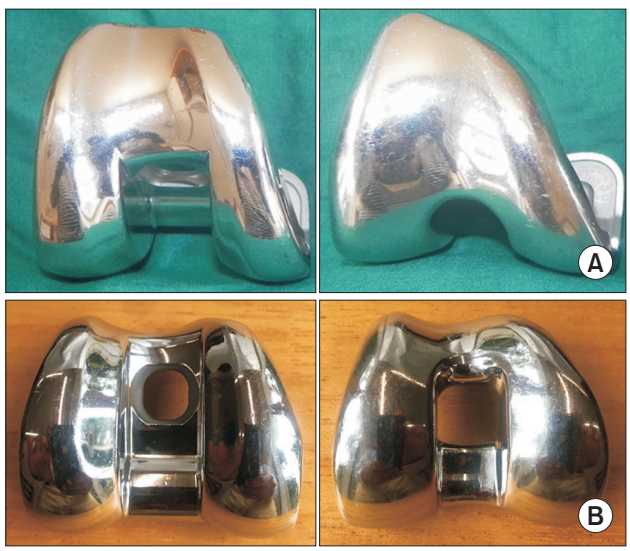

Fig. 1. Posterior-stabilised versions of PFC Sigma and Attune femoral components placed side by side for comparison: anterior view (A) and distal view (B).

METHODS

This prospective matched-pair study was conducted between January 2014 and June 2015 after obtaining Lilavati Hospital and Research Center Institutional Review Board and Ethics Committee approval (IRB No. ECR/606/Inst/MH/2014/RR-17). A written informed consent was obtained from all patients authorizing radiological examination, photographic documentation, and surgery.

During this period, 343 patients (417 knees) underwent primary total knee arthroplasty (TKA). Preoperatively, each patient had been offered a choice between Attune and PFC Sigma prosthesis. Attune was higher priced than PFC Sigma, hence the patients were asked to choose the prosthesis based on their individual financial preference.

The minimum sample size required for such a study was calculated with the level of significance (α) taken as $p = 0.05$, and the power of study being 80%. Using the incidence of AKP reported by Ranawat et al.[7] with Attune and PFC Sigma as the outcome measure, we arrived at a minimum sample size of 73 for the study group. The first 75 consecutive knees (43 patients), in whom Attune prosthesis was implanted, were considered for inclusion. The control group of 75 knees was selected from 302 consecutive patients (344 knees) in whom PFC Sigma was implanted during the same period. Each Attune TKA was matched manually with PFC Sigma TKA based on age (± 5 years), sex, diagnosis (primary osteoarthritis or rheumatoid arthritis), deformity (varus or valgus), body mass index (± 5 kg/m^2), and type of implant (fixed-bearing or mobile-bearing).

The mean age of the study population was 65.8 years (range, 49–85 years) and mean body mass index was 31.9 kg/m^2 (range, 22.8–45.1 kg/m^2). The majority of the patients were women (87.5%). Only 4 patients in each group (5.5%) had rheumatoid arthritis, the rest had primary osteoarthritis (Table 1). The majority of the knees had a varus deformity (138 knees, 95.8%) and the rest were in valgus. The Attune and PFC Sigma groups were comparable in all demographic aspects (Table 1). The mean deformity, as measured by computer navigation, was 10.6° varus in the PFC Sigma group and 8.8° varus in the Attune group. Although this difference was statistically significant, we believe a difference of less than 2° in their means did not make a significant clinical difference. The sizes of the patellar buttons used in the two groups were

Table 1. Comparison of Demographic Variables and Intraoperative Characteristics between the Two Groups

Variable	Attune	PFC Sigma	*p*-value
Demographics			
Age (yr)	65.9 (7.7)	65.6 (6.8)	0.83
Body mass index (kg/m^2)	31.9 (5.1)	31.9 (5)	0.99
Sex			
Female	63	63	-
Male	9	9	-
Diagnosis			
Osteoarthritis	68	68	-
Rheumatoid	4	4	-
Intraoperative parameter			
Alignment (°)	8.8 (4.3)	10.6 (5.9)	0.04
Patella button size (mm)	33.5 (2.1)	34.1 (2.6)	0.10
Soft-tissue release			
Lateral retinacular	2	5	0.40
Posteromedial	0	3	0.20

Values are presented as number (%).

also comparable.

Demographic data, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and new Knee Society Score (NKSS) were recorded preoperatively. These outcome measures were chosen since their validity and reliability have been established in our population.[9,10] Presence of AKP and PCr was ascertained by a validated patient-administered questionnaire that asks the patient to localize the site of pain and incidence of any noise from the joint.[11]

All TKAs, irrespective of the prosthesis being implanted, were performed by the same senior surgeon (RNM), under tourniquet control, using the medial parapatellar approach, with the aid of computer navigation, by the tibial-cut first technique. For all cases, cemented, cruciate-substituting implants were used and the patella was resurfaced. Operative details of limb alignment (as per computer navigation), implant size, and ligament releases were recorded. Patellar tracking was recorded, and if required, a step-wise outside-in lateral retinacular release was performed as described by Maniar et al.[12] The surgeon has performed over 4,000 TKAs using PFC Sigma and has hence refined surgical techniques with respect to PFC Sigma. This included maintaining patellar bone thickness between 13 and 15 mm and avoiding tilt in the mediolateral or cephalocaudal directions. The placement of patellar button was matched with the medial and proximal edges of the patella and lateral patellar osteophyte/spur was excised. Synovial fold at the quadriceps tendon-patella junction was completely excised. Ensuring flush fit of femoral component on the anterior cortex prevented overstuffing of the patellofemoral joint. An outside-in lateral retinacular release was performed as and when indicated to correct patellar maltracking.[12] For Attune prosthesis, synovial fold at the quadriceps tendon-patella junction was completely excised just as in PFC sigma cases. However, placement of patella was central since the patellar design has a medialized anatomic dome.

A 100-mL cocktail of ketorolac (30 mg, 1 mL), bupivacaine (0.5%, volume in mL calculated as 40% of bodyweight), epinephrine (5 μg/mL, 0.01 mL per kg of body weight), and normal saline was used for periarticular injection. Out of this, 70 mL was injected into the deeper structures (posterior capsule, around collateral ligaments and extensor apparatus) and 30 mL into superficial structures (subcutaneous tissue). Patient-controlled analgesia (PCA) with an infusion pump containing morphine 1mg/ml, was used for pain management. Apart from this, oral paracetamol (1 g, thrice a day) and diclofenac suppositories (100 g, twice a day) were used for all patients.

A uniform postoperative rehabilitation protocol was followed, consisting of in-home physiotherapy for a period of around 4–6 weeks. After removal of sutures at 2 weeks postoperatively, patients were re-evaluated at 3 months, 1 year, and 2 years from the surgery. At these follow-up visits, the senior author (RNM) examined the patients and used a hand-held goniometer for measuring range of motion (ROM) in supine position. WOMAC and NKSS were readministered and presence of AKP and/or PCr was also noted at each of these visits. Weight-bearing anteroposterior, lateral, and skyline radiographs of the knees were obtained at each of these visits. All radiographs were scrutinized using Knee Society radiographic scoring system by the senior author (RNM) for signs of loosening or patellar maltracking.[13]

One patient from the Attune group expired within 1 year from the surgery, from causes unrelated to the knee. Two more patients from the Attune group were not available for follow-up at 1 and 2 years postoperatively due to their distant geographical location. These patients along with their PFC Sigma matched pair were excluded from final analysis. All other patients were followed up actively to ensure that no other patients (72 Attune TKAs and 72 PFC

Sigma TKAs) were lost. Asymptomatic, painless, or mildly painful patellar crepitus was treated conservatively by non-steroidal anti-inflammatory drugs, quadriceps strengthening and restricting activities that involve extreme knee bending. Patients not responding to conservative measures, those with painful crepitus or patellar clunk, were considered for arthroscopic debridement and scar tissue excision.

SPSS ver. 18.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Data were given as mean and standard deviation for quantitative data and number (percentage, %) for qualitative data. Student unpaired *t*-test was applied to compare means between two groups. Chi-square test and Fisher-exact test were applied to compare qualitative data. All statistical tests were two-tailed.

Table 2. Comparison of Incidence of Anterior Knee Pain and Patellofemoral Crepitus between the Two Groups

Variable	Attune	PFC Sigma	*p*-value
Anterior knee pain			
Preoperative			0.7
Yes	59	57	
No	13	15	
3 Months			0.9
Yes	25	23	
No	47	49	
12 Months			0.8
Yes	8	7	
No	64	65	
2 Years			1.0
Yes	1	1	
No	71	71	
Patellofemoral crepitus			
Preoperative			0.7
Yes	27	24	
No	45	48	
3 Months			0.8
Yes	9	7	
No	63	65	
12 Months			1.0
Yes	3	3	
No	69	69	
2 Years			1.0
Yes	1	1	
No	71	71	

RESULTS

AKP and PCr

Preoperatively, 116 knees (80.5%) had AKP and 51 knees (35.4%) had PCr. Both groups had a comparable distribution of AKP and PCr preoperatively (Table 2). The incidence of both AKP and PCr declined steadily postoperatively (Fig. 2). There were no significant differences in their incidence at 3 months and 12 months follow-up visits. At final follow-up, 2 years postoperatively, 1 patient in each group reported AKP. Similarly, only 1 knee from each group had PCr. None of the patients that had postoperative AKP or PCr required additional surgical intervention. They were managed successfully nonoperatively. The patients with PCr persisting at 2 years did not report it to be a hindrance in activities of daily living.

Range of Motion

The mean ROM improved from 118° preoperatively to 132° at 2 years in the Attune group and from 114° to 132° in the PFC Sigma group (Fig. 3). This improvement in ROM was statistically significant ($p < 0.001$) in both groups. Although preoperative ROM was comparable between the groups, at 3 months postoperatively, patients with Attune prosthesis had a significantly better ROM than their PFC Sigma counterparts (Table 3). However, at 1 year and 2 years postoperatively, the ROM was again comparable between the two prosthesis designs. The im-

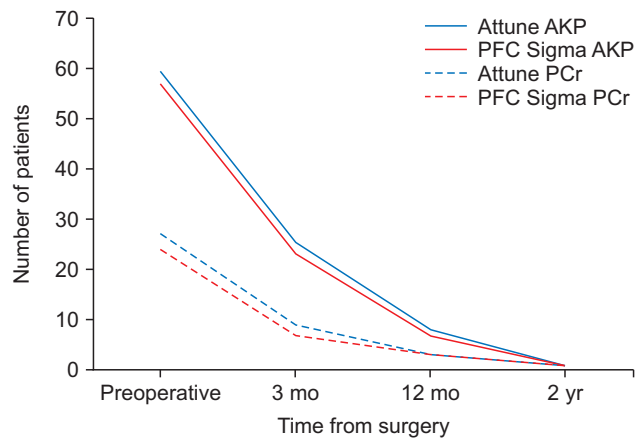

Fig. 2. Trend of decline of anterior knee pain (AKP) and patellofemoral crepitus (PCr) in the Attune and PFC Sigma groups.

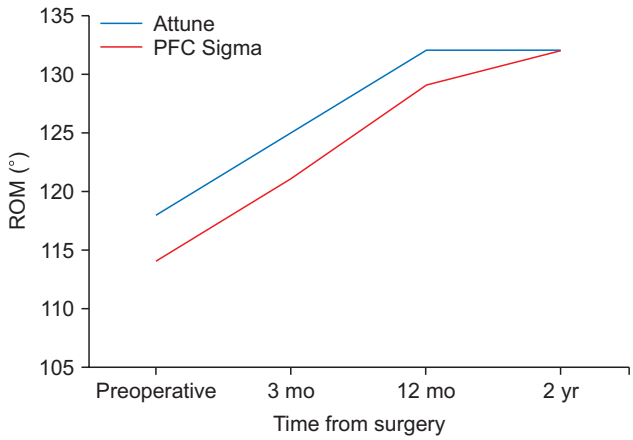

Fig. 3. Trend of improvement of range of motion (ROM) in the Attune and PFC Sigma groups.

provement in ROM from the preoperative value to 2-year follow-up was also comparable between the groups. None of the patients required manipulation under anesthesia or any surgical intervention to improve ROM.

Questionnaire-Based Outcomes

In the Attune group, the mean WOMAC score improved from 43 preoperatively to 10 at 2 years (Table 4). In the PFC Sigma group, the mean WOMAC score improved from 42 preoperatively to 11 at 2 years. WOMAC score improved consistently at each of the follow-up visits in both groups (Fig. 4). The WOMAC score was comparable between the two groups preoperatively, as well as at each of the subsequent visits. The mean preoperative NKSS was 97 in Attune group and 94 in PFC Sigma group, which improved at 2 years to 201 and 199, respectively (Table 4). There was no significant difference in these scores between the two groups. NKSS and its subcomponents also showed consistent improvement at each of the intermediate follow-up visits (Fig. 4). The scores of the two groups were comparable at all of these visits.

Soft-Tissue Releases

Lateral retinacular release for patellofemoral maltracking was required in 5 knees with PFC Sigma, as compared to 2 in the Attune group; however, this difference was not statistically significant ($p = 0.4$). The incidence of posteromedial corner release was also higher in the PFC Sigma group than in the Attune group although the difference was not statistically significant (Table 1).

Revision Surgery and Radiographic Analysis

None of the patients in either of the groups required revision surgery for any cause during the 2-year follow-up period. Radiographs did not show any osteolytic changes or signs of loosening in any of the patients.

Table 3. Comparison of ROM between the Two Groups

Variable	ROM (°)		*p*-value
	Attune	PFC Sigma	
Preoperative	118.0 ± 24.0	113.9 ± 17.2	0.200
3 Months	125.1 ± 10.8	121.5 ± 11.0	0.049
12 Months	131.7 ± 10.1	129.1 ± 9.0	0.100
2 Years	131.9 ± 12.8	132.1 ± 9.6	0.900
Improvement in ROM	14.5 ± 22.3	18.1 ± 17.3	0.300

Values are presented as mean ± standard deviation.
ROM: range of motion.

DISCUSSION

The most important finding of this study is that the incidence of postoperative AKP and PCr was comparable between the two groups. This is in contrast to the results described in recent literature (Table 5), wherein AKP and painful/symptomatic crepitus were observed to be significantly less frequent with Attune prosthesis in comparison to PFC Sigma prosthesis.[6-8] At 1 year postoperatively, in our study, AKP was present in 11% of knees in Attune group and in 9% of knees in PFC Sigma group. At 2 years postoperatively, 1 knee (1.4%) in each group had AKP. In contrast, other matched pair studies have reported AKP at 2-year follow-up to be 2%–13% in Attune group and 9%–26% in PFC Sigma group.[7,8] We observed symptomatic crepitus in 4% of knees in both Attune and PFC groups at 1 year postoperatively. Most of these resolved with nonoperative management. Symptomatic crepitus persisted in only 1 knee (1.4%) in each group at 2 years of follow-up. This is in tune with observations of the other two matched-pair studies, which also reported 1% incidence of symptomatic crepitus at 2 years in the Attune group.[7,8] However, the contrast is stark at 2 years in the PFC Sigma group, where only 1 of our patients (1.4%) had PCr as compared to the 5% and 4% incidence reported by Indelli et al.[8] and Ranawat et al.,[7] respectively. The operating surgeon (RNM) previously reported the incidence of PCr to be 1.1% and AKP to be 3.4% with PFC Sigma prosthesis in patients operated by him.[12] However, this was amongst patients that underwent lateral retinacular release for patellar maltracking.

The deviation of our results, as compared to that of existing literature can be explained by three factors. Firstly,

Table 4. Comparison of Questionnaire-Based Outcome Measures between the Two Groups

Score (range)	Attune	PFC Sigma	*p*-value
WOMAC (0–96)			
Preoperative	43.4 ± 13.2	41.7 ± 13.2	0.4
3 Months	19.6 ± 16.7	19.6 ± 13.9	0.9
12 Months	13.6 ± 13.5	14.8 ± 10.2	0.6
2 Years	10.4 ± 9.9	10.6 ± 10.4	0.9
New Knee Society Score (0–255)			
Preoperative	96.9 ± 24.1	94.3 ± 25.4	0.5
3 Months	174.8 ± 34.2	176.9 ± 24.0	0.6
12 Months	195.2 ± 27.8	188.6 ± 23.3	0.1
2 Years	200.9 ± 27.8	198.5 ± 32.7	0.6
Objective Knee Score (0–100)			
Preoperative	42.5 ± 10.4	42.2 ± 13.4	0.9
3 Months	90.5 ± 8.6	91.8 ± 6.0	0.3
12 Months	96.4 ± 6.1	96.1 ± 4.8	0.7
2 Years	96.5 ± 5.7	96.5 ± 6.2	0.9
Subjective Knee Score (0–155)			
Preoperative	54.7 ± 17.8	52.8 ± 17.1	0.5
3 Months	86 ± 24.1	82.7 ± 22.7	0.4
12 Months	98.7 ± 24.0	92.5 ± 21.0	0.1
2 Years	103.8 ± 25.1	105.6 ± 25.4	0.7
Function Score (0–100)			
Preoperative	29.4 ± 12.3	30.1 ± 11.7	0.7
3 Months	47.7 ± 14.0	45.7 ± 15.1	0.4
12 Months	56.1 ± 17.6	51.4 ± 16.4	0.1
2 Years	61.3 ± 19.4	63.8 ± 21.2	0.5

Values are presented as mean ± standard deviation.
WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

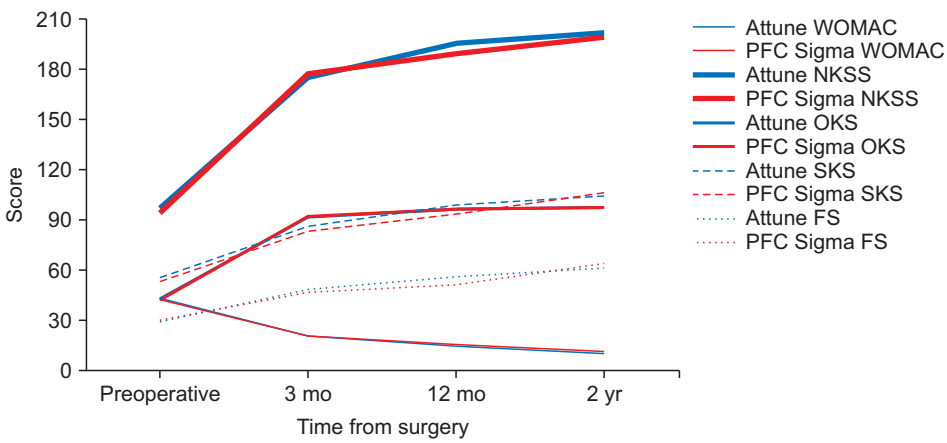

Fig. 4. Trend of improvement of questionnaire-based outcome measures in the Attune and PFC Sigma groups. WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index, NKSS: new Knee Society Score, OKS: Objective Knee Score, SKS: Subjective Knee Score, FS: function score.

Table 5. Summary of Recent Studies Comparing the Patellofemoral Outcomes of Attune and PFC Sigma Prostheses

Study	Study design and patients	Patellofemoral outcome				Other outcome	Remark
		Outcome	Attune (%)	PFC Sigma (%)	*p*-value		
Current study	Prospective 72 matched pairs	AKP	1.4	1.4	1.000	No significant difference in ROM, questionnaire-based outcomes	Single surgeon study, who had substantial experience with PFC Sigma; these were his first cases of Attune. Groups were comparable
		Painful crepitus	1.4	1.4	1.000		
		Patellar clunk surgery	-	-	-		
		Manipulation	-	-	-		
Indelli et al. (2016)[8]	Prospective 100 matched pairs	AKP	2	9	0.006	Significantly better ROM in Attune group	PFC Sigma surgeries done by two surgeons, whereas Attune surgeries done by a third surgeon
		Painful crepitus	1	5	0.007		
		Patellar clunk surgery	-	2	-		
Ranawat et al. (2017)[7]	Prospective 100 matched pairs	AKP	13	26	0.02	No significant difference in function, ROM, and satisfaction between groups	PFC Sigma surgeries done by two surgeons; the groups were not comparable with respect to distribution of mobile-bearing and fixed-bearing tibial components
		Painless crepitus	18	31	0.03		
		Painful crepitus	1	4	0.37		
		Manipulation	2	2	-		
		Peripatellar scar excision	1	-	-		
Martin et al. (2017)[6]	Retrospective 1,165 PFC Sigma; 728 Attune	Total crepitus	0.5	6.3	0.001	Significantly better ROM but lower KSS in Attune	Two surgeon-based study; groups not comparable in sex, BMI, follow-up, and preoperative scores
		Symptomatic crepitus	0.1	2.7	0.001		
		Patellar clunk surgery	0.1	1.6	0.002		
Webb et al. (2017)[5]	Retrospective 397 PFC; 1,403 Sigma; 191 Attune	Significantly higher chances of lateral release in PFC and Sigma as compared to Attune (odds ratio of 6.3 and 2, respectively)			< 0.001	No other outcome measure investigated	Surgeries were done over a period of 30 years, hence introducing variations in techniques and instruments

AKP: anterior knee pain, ROM: range of motion, KSS: Knee Society Score, BMI: body mass index.

ours is a single surgeon-based study; hence, a standard surgical technique was used in all patients. The studies by Ranawat et al.[7] and Indelli et al.[8] pooled their data from operations done by multiple surgeons and hence may have inevitably introduced variations in surgical techniques and postoperative evaluation. Secondly, all operations in our study were done with the aid of computer navigation, whereas the other two studies used the conventional surgical technique. Computer navigation is proven to improve coronal alignment and rotational orientation of components.[14-16] Component positioning plays a key role in influencing patellofemoral kinematics.[17,18] Hence, we believe that by improving the accuracy of component positioning by the use of computer navigation, the risk of postoperative patellofemoral complications can be reduced. Lastly, the preoperative varus alignment amongst the 69 pairs that had varus deformity showed a statistical difference between them. However, the mean difference between the two groups was less than 2° and therefore clinically irrelevant and is unlikely to influence the patellofemoral outcome.

Surgical scar excision for patellar clunk has been reported to be significantly lower in Attune TKAs (0.14%) as compared to PFC Sigma TKAs (1.6%).[6] However, the rate of surgery for patellar clunk was discordant between the two matched pair studies by Indelli et al.[8] and Ranawat et al.[7] Peripatellar scar excision was performed in 2% of PFC Sigma TKAs and in none of the Attune TKAs by Indelli et al.[8] whereas it was performed in 1% of Attune TKAs and in none of the PFC Sigma TKAs by Ranawat et al.[7] We did not encounter any case of patellar clunk syndrome warranting surgery.

The incidence of lateral retinacular release is an indirect indicator of patellofemoral kinematics and maltracking. The need for lateral release is significantly higher with PFC Sigma than Attune.[5] We also observed a higher incidence of lateral release in the PFC Sigma group, but the difference was not statistically significant. Questionnaire-based outcome measures (WOMAC and NKSS) were also comparable between the two types of prosthesis at each stage of follow-up.

The Attune femoral component is designed with a gradually reducing femoral radius in higher degrees of knee flexion.[2] This allows for a gradual reduction in tibiofemoral conformity, which in turn allows greater freedom of rotation. This feature has been designed to increase knee flexion without sacrificing stability. However, clinical results comparing ROM with the older PFC designs are divided. Significantly better ROM in Attune groups was reported by Indelli et al.[8] and Martin et al.[6] However, Ranawat et al.[7] reported no significant differences in ROM between the two designs. We observed significantly better ROM in the Attune group at 3 months postoperatively, but the difference evened out at 1 year postoperatively.

The primary limitation of the study is the selection bias and observer bias due to lack of randomization and blinding, respectively. Such a bias is inherent to matched-pair studies and could not be excluded. This study also had a relatively smaller study population (72 pairs) as compared to other recent matched-pair studies (100 pairs).[7,8] However, we minimized loss to follow-up by actively ensuring that the patients report for their postoperative visits.

The strengths of this study are that this is a single surgeon-based study and has minimal loss to follow-up. Another strength is that both the Attune and PFC Sigma groups were comparable in terms of demographics and intraoperative variables. We observed that both Attune and PFC Sigma had a low and comparable incidence of AKP and PCr up to 2 years of follow-up. Attune group achieved significantly better ROM at 3 months postoperatively. At 2 years of follow-up, both prostheses had excellent and comparable clinical and functional results.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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