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Original research

Posterior-stabilized total knee arthroplasty: a matched pair analysis of a classic and its evolutional design

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ABSTRACT

Background: Total knee arthroplasty (TKA) designs continue to be modified to optimize patient's outcome. This study was designed to compare clinical and radiological results of classic worldwide used TKA posterior-stabilized (PS) design to those of its recent evolution.
Methods: A consecutive group of 100 patients undergoing TKA using a classic cemented fixed-bearing PS TKA system was matched by age, gender, body max index to 100 patients having the newer cemented fixed-bearing PS design, both by the same manufacturer. Patients were assessed preoperatively, at 12 months and at 24 months minimum follow-up (range, 24-46) in a standard prospective fashion. The outcome assessments used were the Oxford Knee Score, the Knee Society Score, range of motion, and a satisfaction survey. A 2-sample *t* test comparing the 2 groups was performed.
Results: No patients were lost at follow-up. At 2-year follow-up, differences in clinical and radiological Knee Society Score ($P = .09$), Oxford Score ($P = .08$), and overall satisfaction rate did not reach statistical significance. Implant group 2 showed a statistically significant decrease in postoperative anterior knee pain ($P = .006$). At final follow-up, 16% of group 1 knees achieved > 130° flexion compared with 37% in group 2 ($P = .0009$). There were 2 revisions for any reason in group 1 and none in group 2.
Conclusions: Design modifications applied to the newer TKA system allowed greater flexion and lower patellofemoral complications but did not appear to achieve better overall clinical scores.

Introduction

Although current results are excellent, total knee arthroplasty (TKA) is not a “perfect” operation. One recent study showed that posterior-stabilized (PS) TKA implants demonstrated survivorship greater than 94% at 16 years [1], yet the Ontario Joint Registry showed that only 70% of patients met their expectations one year after TKA [2]. Twenty percent of patients report persistent knee pain at 5 years from surgery [3], with anterior knee pain related to the patellofemoral joint representing a frequent cause for revision surgery [4]. Particularly in younger individuals, TKA is associated with higher rates of revision and decreased patient satisfaction [5]. Because of these reports, several manufacturers have recently implemented major design modifications to their classic PS design in an attempt to improve patient outcomes. However, many surgeons and patients wonder if these modifications translate into improved clinical results.

The Press-Fit Condylar (PFC) Sigma TKA (DePuy Orthopaedics Inc., Warsaw, IN) was introduced in 1996 based on the manufacturer's previous PFC implant design (Johnson & Johnson, Raynham, MA). New design features included modularity to increase intraoperative adaptability, an updated femoral coronal geometry, and a deeper and prolonged trochlear groove to improve patellar tracking

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beyond 90° of flexion. In recent years, a number of studies have investigated the functional outcome of the PFC and PFC Sigma knee systems [6-8], showing satisfactory midterm results. Unfortunately, anterior mechanism-related complications have been reported with an incidence up to 21% by many authors [9,10]. Largely because of these issues, the PFC Sigma femoral component was redesigned, becoming available in 2009 with the name of PFC Sigma PS (DePuy Synthes, Warsaw, IN). The new principal design largely focused on changes to the femoral sagittal and coronal profiles as well as changes to the trochlear groove. The authors of the present study reviewed a consecutive series of 100 PFC Sigma PS TKA at 3-year follow-up, reporting satisfactory clinical results in 94%, although 9% of the patients had extensor mechanism-related complications [11].

More recently in 2013, Depuy Synthes launched the Attune prosthesis (DePuy Synthes). The most notable difference in the PS femoral component of this system is a multiradius transition at the distal component to posterior condyle region. This has been attributed to conferring greater mid flexion stability as the implanted knee moves from extension to flexion as a result of the more gradual change in the femoral component radius of curvature [12] (Fig. 1). Currently, this system has 14 femoral sizes, 10 tibial sizes, and 5 patella options.

This study was designed to compare clinical and radiological results of the Attune PS design to those of its PFC Sigma PS predecessor. We performed a matched pair analysis of the 2 prostheses with 2-year follow-up. We hypothesized that the patient-reported outcomes of the newer design would be comparable or better than the old design. Specifically, we compared the Oxford Knee Scores (OKSs) [13], the clinical and radiological results according to the Knee Society scoring system [14] and the complication and revision rates. The authors paid particular attention to the differences in terms of range of motion (ROM), patellofemoral joint symptoms, incidence of manipulation, and overall revision rates. To our knowledge, this is the first clinical and radiological study with a 2-year follow-up comparing the PFC Sigma PS and the Attune PS TKA systems.

Material and methods

This study is a retrospective review of 2 cohorts of patients receiving different designs of a PS TKA from the same manufacturer (DePuy Synthes, Warsaw, IN). A matched pair analysis was performed. All patients gave their informed consent before their inclusion in the study. The first study group included 100 patients (100 knees) who underwent TKA with a classic PS TKA system (PFC Sigma PS, 2009 design). Another cohort was matched by gender, preoperative ROM, preoperative patient-reported outcome measurements and body mass index to 100 patients (100 knees) that underwent TKA using the newer PS TKA design (Attune PS, 2013 design) (Table 1). The surgeries were performed at 2 surgical centers (University of Florence School of Medicine—CESAT, Florence, Italy and Villa Regina Hospital—Uniludes University, Bologna, Italy). Patient surveys were evaluated by a third-party surgeon, not involved in the original surgery (Angelo Graceffa, Umberto I Hospital, Enna, Italy). Each center had an active joint replacement registry, and all surgeons were fellowship trained, performing more than 200 TKAs per year. Before initiation of the study, institutional review board approval was obtained at the University of Florence, School of Medicine to serve as the coordinating center, and each participating center obtained approval from its institutional review board.

Exclusion criteria were the following: diagnosis of inflammatory osteoarthritis of the knee, severe bony defects or deformity which might require augmentation with bone graft or a constrained device, previous patellectomy, body mass index greater than 40, symptomatic hip pathology, previous lower extremity fractures, previous high tibial osteotomy, previous knee ligament reconstruction, and neurogenic causes of knee arthritis.

A total of 3 surgeons from 2 centers contributed patients to this study. Two surgeons at a single center (University of Florence, School of Medicine) contributed all patients to the PFC Sigma PS cohort and zero patients to the remaining cohort. One surgeon at a single center (Villa Regina Hospital—Uniludes University) contributed all patients to the Attune PS cohort and zero patients to the remaining cohort.

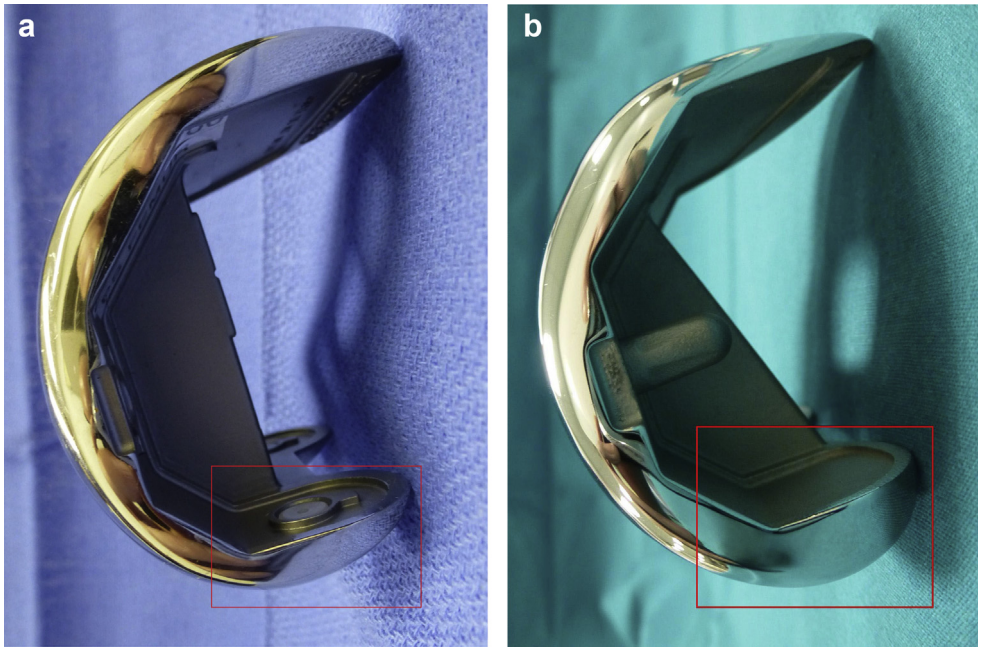

Figure 1. DePuy Synthes PFC Sigma PS (a) and Attune (b) TKA systems. The posterior femoral condyles gradual change of curvature between the 2 femoral designs can be noted in the highlighted rectangular spaces.

Table 1
Patients demographic distribution.

	PFC Sigma PS		Attune PS	
	Mean	Range	Mean	Range
Age	73	55-87	69	45-85
BMI	28.17	21.11-39.97	29.79	22.07-41.66
	Number	Percent	Number	Percent
Gender				
Male	67	67	71	71
Female	33	33	29	29
Side				
Right	73	73	68	68
Left	27	27	32	32
Diagnosis				
OA	100	100	100	100

The standard anesthesia technique used in all cases was regional anesthesia (spinal), which combined intrathecal opioids (ie, 0.2-0.3 mg of morphine) and a local anesthetic. The surgical approach in all cases included a standard midline skin incision and a medial peripatellar capsulotomy, avoiding lateral patellar retinacular releases. The chosen surgical technique was a combination of the "balanced gaps technique" [15] and the "measured resection technique" [16]: first, a rectangular extension gap was created; second, the rotation of the femoral component was oriented according to the surgical transepicondylar axis (Fig. 2). All implants were aligned on the coronal plane, reproducing the patient's neutral mechanical axis. Cemented PS femoral components from each group were aligned rotationally according to the patient's surgical transepicondylar. The rotational alignment of all cemented symmetric tibial components was set matching the contour of the tibial anterior cortex, following author's previously published surgical technique [17]. All patellae were replaced using a "free hand technique" without cutting guides, and tracking of the patella was checked using the "no thumb technique" [18]. A release of the deep lateral patellofemoral ligament without capsulotomy was performed when the operating surgeon thought necessary: 27 times in the PFC Sigma PS group and 7 times in the Attune PS group. All patients followed identical postoperative rehabilitation protocol, including weight bearing as tolerated with crutches and the use of a continuous passive motion machine beginning on postoperative day 1.

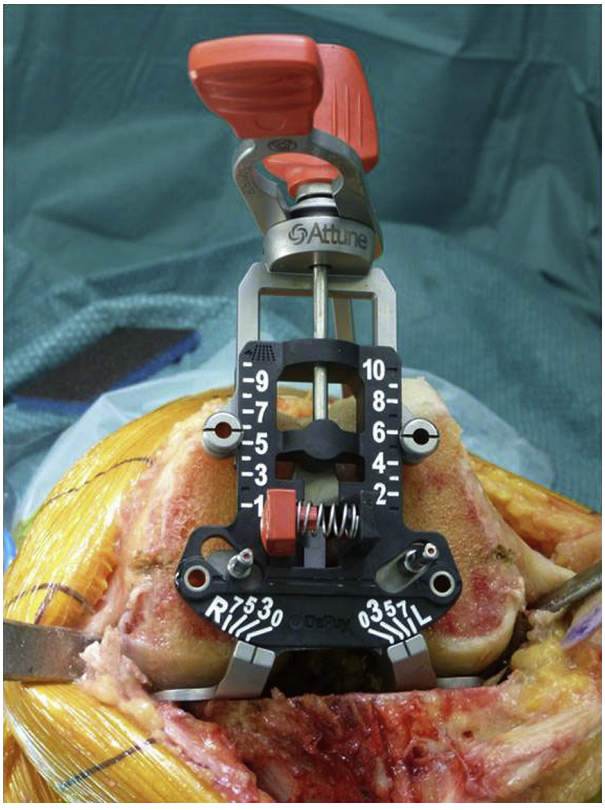

Figure 2. Left knee. De Puy Synthes Attune TKA system: sizing and rotational alignment guide for the femoral component. In this case the external rotation of the femoral component was set at 3° of external rotation.

Patients were assessed at 12 months and at 24 months minimum follow-up (range, 24-46) using the OKS as a patient reported outcomes measurement system and the Clinical and Radiological Knee Society Score (KSS) as an overall validated measurement instrument. A pangonogram of the affected lower extremity, standard anteroposterior weight bearing, and lateral and bilateral axial radiographs were performed in all patients at the time of final follow-up. All radiographs were reviewed by an external evaluator (Angelo Graceffa) according to the Knee Society criteria for radiolucency; change in the position of the components; femorotibial alignment; and evidence for loosening, wear, and osteolysis. ROM was measured with a goniometer preoperatively and at the latest follow-up. A pain-relief satisfaction survey questionnaire (A. satisfied; B. partially satisfied; C. not satisfied) was administrated by an independent, third-party evaluator (Angelo Graceffa) blinded to the treatment arm.

Statistical analysis of all data was performed by one institution's biostatisticians (University of Florence, School of Medicine) to compare each variable to look for significant differences on any of the outcomes measures between the 2 groups of patients. *P*-values for ROM were obtained from a 2×2 chi-square test with multiple testing adjustments using the Bonferroni-Holm method. *P*-values for outcomes score of the OKS [13] and the Knee Society Scoring system [14] were obtained with a 2-sample *t* test comparing the 2 groups.

Results

At 2-year minimum follow-up, all patients were available for evaluation. Average follow-up for PFC Sigma PS group was 32.4 months (range, 28-36) and for the Attune PS group was 28.3 months (range, 24-31).

Patient-reported outcome measurements

The OKS improved in both groups: average OKS improved from preoperative 18 (females 17, males 20) to 36 (females 34, males 38) at final follow-up in the classic PS design group; average OKS improved from preoperative 19 (females 18, males 21) to 38 (females 34, males 38) at final follow-up in the newer PS design group. The difference between the 2 groups at final follow-up was not statistically significant ($P = .08$).

Knee Society Scores

At the final follow-up, all patients were available for analysis according to the KSS. Average KSS improved in both groups, but the Attune PS group did show higher scores at the final follow-up at 169 ± 32 vs the PFC Sigma PS group at 165 ± 35. Anyway, the difference between the 2 groups at final follow-up was not statistically significant ($P = .09$). Good to excellent clinical results according to the KSS were achieved in 94% of the knees in the PFC Sigma PS group and in 98% in the Attune PS group.

Range of motion

Preoperative average ROM was similar in both groups: 106° in the Attune PS group and 104° in the PFC Sigma PS group. The average ROM at final follow-up visit in the Attune PS group reached 123° (range, 98°-135°), whereas the PFC Sigma PS group reached 115° (range, 97°-132°). The difference between the 2 groups at final follow-up was statistically significant ($P = .0009$). At final follow-up, 16% of PFC Sigma PS group knees achieved >130° compared with 37% in the Attune PS group knees ($P = .0008$). Loss of full extension at final follow-up was present in 7 knees in the PFC Sigma PS group (average 3°) comparing to 8 knees in the Attune PS group (average 5°).

Postoperative complications

There were no intraoperative complications in either of the 2 groups. There were 2 revisions in the PFC Sigma PS group: both patients required reoperation with removal of fibromatous intra-rticular tissue ("Clunk Syndrome") without revision of any of the original prosthetic components. However, there were no revisions in the Attune PS group. Mild anterior knee pain was present in 9% of the knees in the PFC Sigma PS group and in 2% in the Attune PS group ($P = .006$). Severe painful patellofemoral crepitations were noted in 5% of the knees in the PFC Sigma PS group and in 1% in the Attune PS group ($P = .007$).

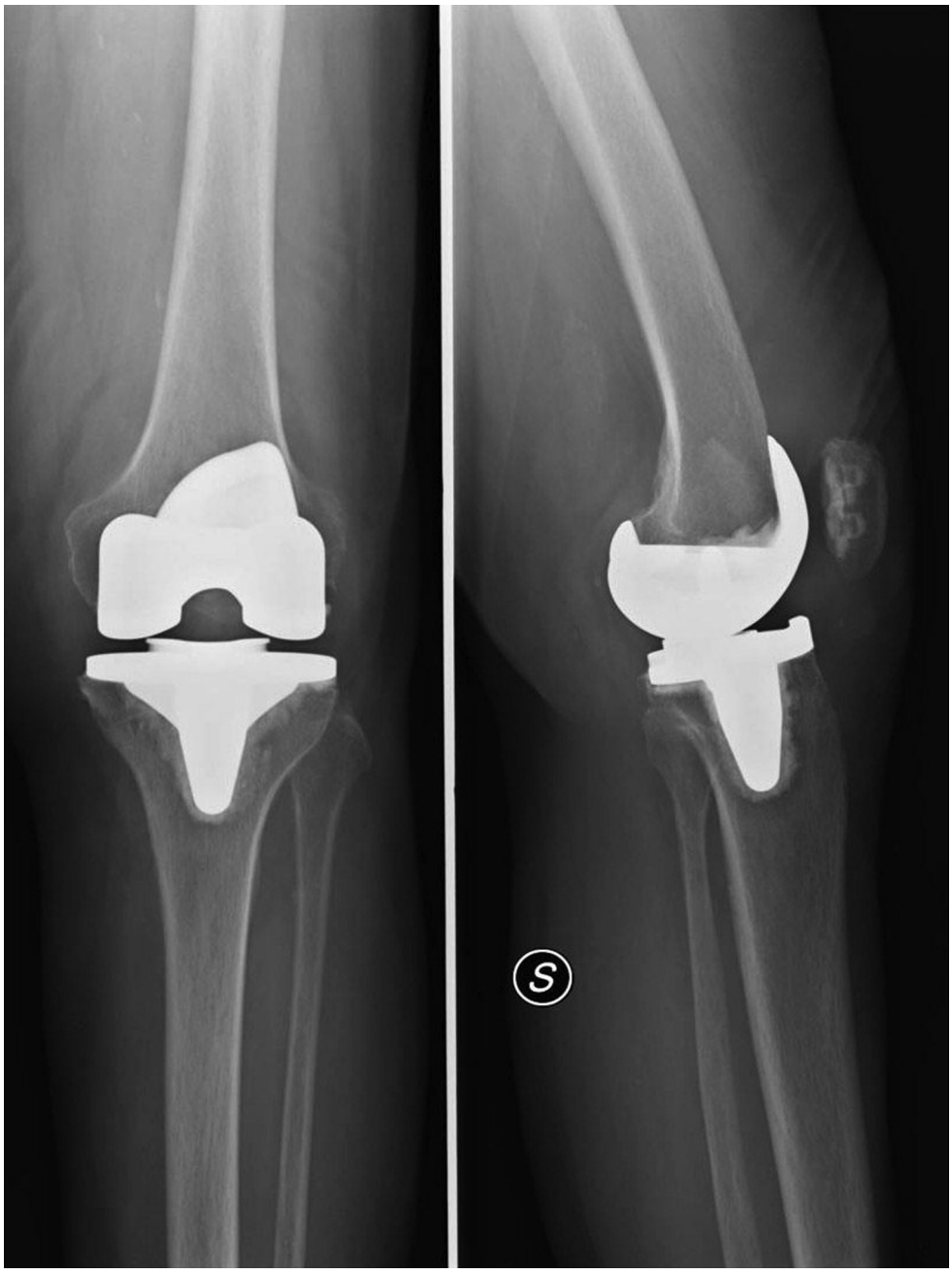

Figure 3. A 76-year-old female patient. Anteroposterior and lateral weight-bearing views at 27 months follow-up. Left TKA (Attune, DePuy Synthes, Warsaw, IN).

Satisfaction questionnaire

There was no statistical difference in the degree to which the satisfaction survey scores changed in either group: 94 % of the patients in the PFC Sigma PS cohort and 97% of those in the Attune PS cohort were satisfied or partially satisfied with their degree of pain relief at final follow-up.

Radiological results

There were no statistically significant differences between the 2 cohorts in terms of postoperative anatomic knee alignment ($P = .178$), overall incidence of radiolucent lines ($P = .217$), incidence of isolated femoral radiolucent lines ($P = .824$), and incidence of isolated tibial radiolucent lines ($P = .229$). The radiological assessment at follow-up showed that the anatomical femorotibial alignment, in respect to a desired anatomical axis of 5° of valgus, averaged 5.3° of valgus (range from 6° of valgus to 4° of varus) in the PFC Sigma PS group and 4.7° of valgus (range from 5° of valgus to 3° of varus) in the Attune PS group. There was no evidence of osteolysis in all knees. None of the components were found to be radiologically loose at the final follow-up evaluation (Fig. 3).

Discussion

With the orthopaedic community and industry striving to improve outcomes following knee arthroplasty surgery, newer implants with distinct design features have been introduced into the market. However, little is known of the safety and functionality of these newer designs. Some surgeons may have the tendency to assume that "newer is better". A recent study from Australia demonstrated that this is not always the case, and that, in fact, newer designs may result in worse outcomes [19]. Surgeons will not have the time or means to test every single implant. For this reason, objective analyses of available products become important as surgeons attempt to choose the right implant for their patients. The present study aimed to assess for potential patient-reported functional benefits and report short-term outcomes of the newer Attune PS TKA design when compared with its predecessor.

Overall, we found few differences between the 2 implants. The most significant differences detected (mainly in function, none in satisfaction) favored the new design. At 2-year follow-up, the Attune PS group showed a statistically significant decrease in postoperative anterior knee pain, improved ROM, and decrease in revision rate when compared to the PFC Sigma PS group; however, no statistically significant differences were found in the Oxford Score, the KSS, and the satisfaction rate at final follow-up.

The results of the original PFC TKA design (DePuy Orthopaedics Inc.) have been previously reported as excellent with a 93% survival rate at 15 years [20]: unfortunately, the revision rate for patellofemoral-related problems was reported up to 5.2% [21]. The PFC Sigma implant, introduced in 1996, has been extremely successful, but anterior mechanism complications have still been reported. Painless and painful patellar crepitations, general anterior knee pain, and patellar clunk syndromes have been reported with an incidence up to 21% by many authors, including the implant's designers [9,10]. In 2009, the same manufacturer (DePuy Orthopaedics Inc.) introduced a new femoral "J curve" design (PFC Sigma PS) with 3 different tangential radii in the sagittal profile and a single radius curve in the coronal profile. In addition, this design implemented a prolonged anterior flange and a "smoother" transition from trochlea to the box. The system included 8 femoral sizes, 7 tibial sizes, and 4 symmetric patella options, and the system was accompanied by new surgical instrumentation (high performance; DePuy Orthopaedics Inc.). The authors of the present study reported the results from a series of 100 PFC Sigma PS TKA at 3-year follow-up, showing satisfactory clinical results in 94% but extensor mechanism complications in 9% of the patients [11].

The most recent design evolution, the Attune Primary Total Knee System (DePuy Synthes Joint Reconstruction, Warsaw, USA), was released in 2013. This system claimed to have several design innovations, including an extreme modularity (14 left and right femoral sizes, 10 tibial sizes), cruciate retaining and PS implant variants, 1-mm tibial insert increments, and several characteristics to improve the patellafemoral tracking (a femoral component characterized by an anatomically angled trochlear groove, a funnel capture between 0° and 30°, a medialized dome and anatomic patella options, and a reduction on the dimension of the femoral flange and shoulders in respect to the PFC Sigma PS design). In the present study, the clinical outcomes of this updated design have been reviewed and matched with those one of the PFC Sigma PS implant.

One of the most important findings of the present study was the statistically significant improvement in ROM in the Attune PS knees. Theoretically, the design features in the posterior femoral condylar radius might have improved the physiological femoral rollback compared to the PFC Sigma PS. On the other hand, although certain studies have demonstrated improved results regarding the degree of flexion achieved using other high-flex designs, whether or not patients perceive this increase to be clinically significant remains controversial [22-24]. In the present study, there was no significant difference in overall satisfaction rate between the 2 tested designs, questioning the relevance of this degree of improved flexion.

Another important finding of the present study was the lower rate of complications, related to the extensor mechanism, in the Attune PS group compared to the PFC Sigma PS group. The Attune PS knee system incorporated a few design alterations that may have contributed to the decreased incidence of anterior knee pain: the medialized anatomic patella, a trochlear groove angle that changes according to the femoral size, the high modularity of the femoral components (14 left and right sizes), a reduced femoral component sagittal profile, and a patellar component characterized by 0.5-mm increments. Interestingly, these design characteristics are similar to those of gender-specific implants, which have failed to demonstrate any superiority vs conventional implants [24-26]. It must be recognized that the PFC Sigma knee implant has been historically related to a higher incidence of extensor mechanism complications if compared to different systems [9], and the design modifications to the patella-femoral compartment in the Attune PS system might have affected the postoperative development of anterior knee pain.

The present study has several limitations. Our greatest study limitation is that all the procedures utilizing the Attune PS implant were performed by one surgeon, whereas all of the PFC sigma PS implants were placed by 2 separate surgeons. Selection bias was obviously a factor. In addition, one must consider the possible variation in outcomes that could result from separate operating centers, nursing staff and rehabilitation professionals. However, each surgeon had independently excellent clinical results at these institutions with the PFC sigma PS implant before this study [11]. In addition, postoperative rehab protocols and follow-up care were standardized for each institution. Finally, with only 2-year follow-up, future studies will be necessary to ascertain any significant differences in long-term results.

Conclusions

It is critical for orthopaedic surgeons to understand the implants they choose to use and how they may compare with other implants. Although surgeons may form their opinions through personal

experience, it is helpful to have some objective data to help the decision-making process. Although our study possesses several clear limitations, it provides some objective data regarding the PFC Sigma design series and the possible improvement in outcome measures with the new Attune design.

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