

Posterior-stabilized (PS) total knee arthroplasty: a matched pair analysis of a classic and its evolutionary design.

Pier Francesco Indelli, MD, PhD^{*}, Gennaro Pipino, MD[†], Angelo Graceffa, MD[‡]
and Massimiliano Marcucci, MD[§]

From the ^{*} Department of Orthopaedic Surgery, Stanford University School of Medicine, Stanford, USA, the [†] Villa Regina Hospital, Bologna, Italy – Uniludes University, Lugano, Switzerland, the [‡] Umberto I Hospital, Enna, Italy and the [§] Clinica Ortopedica Università di Firenze – CESAT, Firenze, Italy

Reprint requests:
Pier Francesco Indelli, MD, PhD

Abstract

Introduction: Total Knee Arthroplasty (TKA) designs continue to be modified to optimize patient's outcome. This study showed that patient outcome was only partially influenced by design modifications applied to a classic posterior-stabilized (PS) TKA system.

Methods: A consecutive group of 100 knees (group 1: 100 patients) undergoing TKA using a classic cemented fixed-bearing PS TKA system was matched by age, gender, BMI to 100 knees (group 2: 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 (KSS), range-of-motion (ROM) and a satisfaction survey. A two-sample *t*-test comparing the two groups was performed.

Results: No patients were lost at follow-up. At 2-year follow-up, implant group 2 showed a statistically significant decrease in postoperative anterior knee pain ($p=0.006$), greater ROM ($p=0.0009$) and revision rate for any reason; differences in clinical and radiological KSS ($p=0.09$), Oxford Score ($p=0.08$) and overall satisfaction rate did not reach statistical significance. At follow-up, 16 % of group 1 knees achieved $> 130^\circ$ flexion compared with 37% in group 2. There were two revisions for any reason in group 1 and none in group 2.

Conclusion: Design modifications applied to the newer TKA system allowed greater flexion and lower anterior-mechanism complications but not appeared to achieve better overall clinical scores.

Keywords: Total knee arthroplasty, TKA, posterior-stabilized, knee, outcome, patients

INTRODUCTION

Although current results are relatively good, total knee arthroplasty (TKA) is not a “perfect” operation. Although posterior-stabilized (PS) TKA demonstrates survivorship above 94% at 16 years [1], 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 five years from surgery [3], where anterior knee pain related to the patello-femoral joint represent a frequent cause for revision surgery [4]. Particularly in younger individuals, TKA is associated with higher rates of revision and with decreased patient satisfaction [5]. Because of these reports, several manufacturers have implanted major design modifications to their classic PS design in an attempt to improve patient outcomes. Therefore, concerns remain regarding both the necessity and clinical use of these design modifications and whether patients perceive improved outcomes with their use.

The PFC Sigma TKA (DePuy Orthopaedics Inc., Warsaw, USA) TKA was introduced in 1996 as a development of the Press-Fit Condylar (PFC) implant (Johnson & Johnson, Raynham, Massachusetts, USA). Design features included modularity to increase intra-operative adaptability, an updated femoral coronal geometry and a deeper and prolonged trochlear groove to improve patellar tracking 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, 7, 8], showing satisfactory midterm results. Unfortunately, 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]. Because of these and other issues on patello-femoral complications, the PFC Sigma femoral component was re-designed, becoming available in 2009 with the name of

PFC Sigma PS (DePuy Orthopaedics Inc., Warsaw, USA). The new principal design features included a “J curve” femoral design, three different tangential radius curves in the sagittal profile, and a single radius curve in the coronal profiles. The femoral box edge and the thrclear groove edges were refined too in order to provide a better patellar route during ROM. A new specific TKA instrumentation (High Performance: HP; DePuy Orthopaedics Inc., Warsaw, USA) was introduced too. This system had originally 8 femoral sizes, 7 tibial sizes and 4 symmetric patella options. The authors of the current study reviewed a consecutive series of 100 PFC Sigma PS TKA at three years follow-up, reporting satisfactory clinical results in 94% but extensor mechanism related complications in 9% of the patients [11].

More recently in 2013, Depuy Synthes launched the Attune™ prosthesis (DePuy Synthes, Warsaw, USA). The most notable difference in the femoral component of this system is a multi-radius 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]. This system has 14 femoral sizes, 10 tibial sizes and 5 patella options.

This study was designed to compare the new cemented, fix-bearing PS TKA design to that of its predecessor in a matched pair analysis evaluating a minimum of two years of follow-up of both types of implants. It was hypothesized that the patients reported outcomes according to the Oxford Knee Score [13], the clinical and radiological results according to the Knee Society Scoring system [14] and the complication and revision rates of the newer design would be comparable or better respect to the previous design from the same manufacturer. 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 at 2 years minimum follow-up comparing the PFC Sigma PS and the Attune PS TKA systems.

MATERIALS AND METHOD

This study is a retrospective review of two cohorts of patients receiving different designs of a posterior-stabilized TKA from the same manufacturer (DePuy Synthes, Warsaw, USA). A matched pair analysis was performed. All patients gave their informed consent prior to their inclusion in the study. The first study group included 100 patients (100 knees) that underwent total knee arthroplasty with a classic posterior-stabilized (PS) TKA system (PFC Sigma PS). This consecutive series cohort was matched by gender and body mass index (BMI) to 100 patients (100 knees) that underwent total knee arthroplasty using the newer PS TKA design (Attune PS) (Table 1). Two total joints centers (University of Florence School of Medicine – CESAT, Florence, Italy; Villa Regina Hospital- Uniludes University, Bologna, Italy) and an independent third-party survey evaluator (Umberto I Hospital, Enna, Italy). Each center had an active joint replacement registry, all surgeons were fellowship-trained performing more than 200 TKAs per year and each contributed patients meeting the inclusion criteria. 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 diagnosis of inflammatory osteoarthritis of the knee, severe bone defects or deformity which might require augmentation with bone graft or the use of augments or a constrained device, previous patellectomy, BMI over 40, poorly

functioning or symptomatic contra-or ipsilateral hip, previous fractures, high tibial osteotomy or knee ligament reconstruction and finally neurogenic causes for knee arthritis.

A total of three surgeons from two 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.

The standard anesthesia technique used in all cases was regional anesthesia (spinal), which combined intrathecal opioids (i.e. 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; secondarily, the rotation of the femoral component was oriented according to the surgical transepicondylar (sTEA) axis. All implants were aligned on the coronal plane reproducing patient’s neutral mechanical axis. All cemented PS femoral components (Designs 1 and 2) were aligned rotationally according to the patient’s surgical TEA. The rotational alignment of all cemented tibial components (Designs 1 and 2) was set matching the contour of the tibial anterior alignment [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 if necessary. All patients followed identical

postoperative rehabilitation protocol, including weightbearing as tolerated with crutches and the use of a continuous passive motion machine beginning on postoperative day one.

Patients were assessed preoperatively, at 12 months and at 24 months minimum follow-up (range, 24-46) using the Oxford Knee Score as a patient reported outcomes measurement system (PROM) and the Clinical and Radiological Knee Society Score (KSS) as an overall validated measurement instrument. A pangonogramm of the affected lower extremity, standard antero-posterior weight-bearing, 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 (AG) 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 (A.G.) blinded to the treatment arm.

Statistical analysis of all data was performed by one institutions' biostatisticians (University of Florence School of Medicine) to compare each variable to look for significant differences on any of the outcomes measures between the two groups of patients. *p* values for ROM were obtained from a 2x2 chi-square test with multiple testing adjustments using the Bonferroni-Holm method. *p* values for outcomes score of the Oxford Knee Score [13] and the Knee Society Scoring system [14] were obtained with a two-sample t-test comparing the two groups.

RESULTS

At 2-year minimum follow-up, all originally included patients were available for evaluation. Average follow-up was 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).

PROMs

The Oxford Knee Score (OKS) improved in both groups: average OKS improved from pre-op 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 pre-op 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 two groups at final follow-up was not statistically significant ($p=0.08$).

Knee Society Scores

At the final follow-up, all patients were available for analysis according to the Knee Society Scores (KSS). Average KSS improved in both groups, but the Attune PS group did show higher scores at the final follow-up at 169 ± 32 versus the PFC Sigma PS group at 165 ± 35 . Anyway, the difference between the two groups at final follow-up was not statistically significant ($p=0.09$). 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.

ROM

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 two groups at final follow-up was statistically significant ($p=0.0009$). At final follow-up, 16% of PFC Sigma PS group knees achieved $>130^\circ$ compared with 37% in the Attune PS group knees ($p=0.0008$). 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 two groups. There were two revisions in the PFC Sigma PS group: both patients required reoperation with removal of fibromatous intrarticular 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 ($p=0.006$). Severe painful patello-femoral crepitations were noted in 5% of the knees in the PFC Sigma PS group and in 1% in the Attune PS group ($p=0.007$).

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 PD 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 two cohorts in terms of postoperative anatomic knee alignment ($p=0.178$), overall incidence of radiolucent lines ($p=0.217$), incidence of isolated femoral radiolucent lines ($p=0.824$) and incidence of isolated tibial radiolucent lines ($p=0.229$). The radiological assessment at follow-up showed that the anatomical femoro-tibial 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.

DISCUSSION

With the orthopaedic community and industry striving to improve outcomes following arthroplasty surgery by introducing newer implants and adjusting design features of current implants, little is known on the safety and functionality of these newer designs. The current study aimed to assess for potential patients reported functional benefits and report short-term outcomes of a newer PS TKA design when compared with his highly successful predecessor. We found overall few differences among the two tested implants, and, where differences were detected (mainly in function, none in satisfaction) they favored the newer design over the older implant. In fact, at 2-year minimum follow-up, the Attune PS group showed only a statistically significant decrease in postoperative anterior knee pain, greater ROM and absence of revisions when compared to the PFC Sigma PS group; no statistically significant differences were found in the Oxford Score, the KSS and the satisfaction rate.

The results of the Press-Fit Condylar (PFC) TKA (DePuy Orthopaedics Inc., Warsaw, USA), improvement of the Total Condylar Knee Implant, were overall satisfactory with a 93% survival rate at 15 years [...]: unfortunately, the revision rate for patello-femoral related problems was reported up to 5.2% [...]. The PFC Sigma implant, introduced in 1996 and having an updated femoral coronal geometry and a deeper trochlear groove to improve patellar tracking in respect to predecessor, has been

extremely successful, but anterior mechanism complications have still been reported by many authors, including the implant's designers [..., ...]. In 2009, the same manufacturer (DePuy Orthopaedics Inc., Warsaw, USA) introduced a new femoral design evolution (PFC Sigma PS) characterized by having a "J curve" design with 3 different tangential radii in the sagittal profile and a single radius curve in the coronal profile; a prolonged anterior flange and a "smoother" transition from trochlea to the box are innovative to this design too. The clinical outcomes of this updated design have been reviewed in the current study.

In the attempt to decrease patient's dissatisfaction after primary TKA, the Attune Primary Total Knee System (De Puy Synthes Joint Reconstruction, Warsaw, USA) was released in early 2013 as an improvement of the PFC Sigma PS knee system. This system claimed to have several design innovations, including an extreme modularity (14 left and right femoral sizes, 10 tibial sizes), CR (cruciate retaining) and PS implant variants, 1 mm tibial insert increments and several characteristics to improve the patella-femoral tracking (a femoral component characterized by an angled trochlear groove with anatomic geometry with 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). The clinical outcomes of this updated design have been reviewed and matched with the PFC Sigma PS implant in the current study.

One of the most important findings of this study was the statistically significant improvement in ROM in the Attune PS knees. Theoretically, the design features in of the posterior femoral condylar radius might have improved the physiological femoral rollback compared to the PFC Sigma PS. On the other side, although certain studies

have demonstrated improved results regarding the degree of flexion achieved using other high-flex designs, whether patients perceive this increase to be clinically significant remains controversial [...]. However, there was no difference in satisfaction rate between the two tested designs, questioning the relevance of this degree of improved flexion.

Another important finding of the current study was the lower rate of extensor mechanism related complications in the Attune PS group respect to the PFC Sigma PS group. Theoretically, few design factors inherent to the Attune PS knee system might have impacted 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 profile and a patellar component characterized by 0.5 mm increments. However, these design characteristics are similar to those of gender-specific implants: few studies assessing the outcome of gender-specific designs have failed to demonstrate any superiority versus conventional implants [...]. On the other side, the PFC Sigma knee implant has been historically related to a high incidence of extensor mechanism related complications [Ranawat-Ranawat-Orthopedics 2006] and the design modifications to the patella-femoral compartment in the Attune PS system might have affected the postoperative development of anterior knee pain.

Study limitations.....

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%

1) Table 1.

REFERENCES

- 1) PS results
- 2) Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD (2010). Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? . Clin Orthop Relat Res.; 468(1):57-63.
- 3) Hofmann S, Seitlinger G, Djahani O, Pietsch M (2011). The painful knee after TKA: a diagnostic algorithm for failure analysis. [Knee Surg Sports Traumatol Arthrosc.](#); 19(9):1442-52.
- 4) [Patel J](#), [Ries MD](#), [Bozic KJ](#) (2008). Extensor mechanism complications after total knee arthroplasty. Instr Course Lect 2008; 57:283-94.
- 5)
- 6) Kim YH, Choi Y, Kim JS (2010). [Comparison of a standard and a gender-specific posterior cruciate-substituting high-flexion knee prosthesis: a prospective, randomized, short-term outcome study.](#) J Bone Joint Surg Am.; 92(10):1911-20.
- 7) [Zihlmann MS](#), [Stacoff A](#), [Romero J](#), [Quervain IK](#), [Stüssi E](#) (2005). Biomechanical background and clinical observations of rotational malalignment in TKA: literature review and consequences. [Clin Biomech.](#); 20(7):661-8.
- 8) Benjamin J (2006). Component alignment in total knee arthroplasty. [Instr Course Lect.](#) 2006; 55:405-12.
- 9) Dalury DF, Gonzales RA, Adams MJ, Gruen TA, Trier K (2008). Midterm results with the PFC Sigma total knee arthroplasty system. J Arthroplasty; 23(2):175-81.
- 10) Zaki SH, Rafiq I, Kapoor A, Raut V, Gambhir AK, Porter ML (2007). Medium term results with the Press Fit Condylar (PFC) Sigma knee prosthesis. The Wrightington experience. Acta Orthop Belg.; 73, 55-59
- 11) Hanusch B, Lou TN, Warriner G, Hui A, Gregg P (2010). Functional outcome of PFC Sigma fixed and rotating-platform total knee arthroplasty. A prospective randomized controlled trial. Int Orthop; 34: 349-354.
- 12) Ranawat AS, Ranawat CS, Slamin JE, Dennis DA (2006). Patellar crepitation in the P.F.C. sigma total knee system. Orthopedics; 29 (9 Suppl): 68-70.
- 13) [Meftah M](#), [Ranawat AS](#), [Ranawat CS](#) (2011). Safety and efficacy of a rotating-platform, high-flexion knee design three- to five-year follow-up. J Arthroplasty; 27(2): 201-6.
- 14) Indelli PF, Marcucci M, Cariello D, Poli P, Innocenti M (2012). [Contemporary femoral designs in total knee arthroplasty: effects on the patello-femoral congruence.](#) Int Orthop.; 36(6):1167-73.
- 15) Fulkerson JP, Schutzer SF, Ramsby GR, Bernstein RA (1987). Computerized tomography of the patellofemoral joint before and after lateral release or realignment. Arthroscopy; 3(1):19-24.
- 16) Aglietti P, Insall JN, Cerulli G (1983). Patellar pain and incongruence: I. Measurements of incongruence. Clin Orthop Relat Res; 176: 217-224.

- 17) [Brossmann J](#), [Muhle C](#), [Schröder C](#), [Melchert UH](#), et al (1993). Patellar tracking patterns during active and passive knee extension: evolution with motion-triggered Cine MR imaging. *Radiology*; 187 (1): 205-212.
- 18) Boisgard S, Moreau PE, Descamps S, Courtalhiac C, Silbert H, Moreel P, Michel JL, Levai JP (2003). Computed tomographic study of the posterior condylar angle in arthritic knees: its use in the rotational positioning of the femoral implant of total knee prostheses. *Surg Radiol Anat.*; 25: 330-4.
- 19) Ranawat CS, Rose HA, Rich DS (1984). Total condylar knee arthroplasty for valgus and combined valgus-flexion deformity of the knee. *Instr Course Lect.* 1984; 33:412-6.
- 20) Rodricks DJ, Patil S, Pulido P and Colwell Jr CW (2007). Press-Fit Condylar Design Total Knee Arthroplasty Fourteen to Seventeen-Year Follow-up. [J Bone Joint Surg Am.](#); 89 (1): 89-95.
- 21) Dalury DF, Barrett WP, Mason JB, Goldstein WM, et al (2008). Midterm survival of a contemporary modular knee replacement. A multicentre study of 1970 knees. *JBJS (Br)*; 90-B: 1594-6.
- 22) Dalury DF, Mason JB, Murphy JA, Adams MJ (2009). Analysis of the outcome in male and female patients using an unisex total knee replacement system. *JBJS (Br)* 91-B: 357-360.
- 23) Pagnano MV, Trousdale RT (2004). Rotating platform knees did not improve patellar tracking: a prospective, randomized study of 240 primary TKA. *Clin Orthop Relat Res.*; (428):221-7.
- 24) [Meftah M](#), [Ranawat AS](#), [Ranawat CS](#) (2011). The natural history of anterior knee pain in 2 posterior-stabilized, modular total knee arthroplasty designs. [J Arthroplasty](#); 26(8):1145-8.
- 25) Meijerink HJ, Barink M, Van Loon CJ, et al. (2007). The trochlea is medialized by total knee arthroplasty: an intraoperative assessment in 61 patients. *Acta Ortop*; 78 (1): 123-127.
- 26) Barink M, Van de Groes S, Verdonschot N, et al (2006). The difference in trochlear orientation between the natural knee and current prosthetic knee designs: towards a truly physiological prosthetic groove orientation. *J Biomech*; 39: 1708-1715.
- 27) Kulkarni SK, Freeman MAR, Poal-Manresa JC, Asencio JI, Rodriguez JJ (2000). The patellofemoral joint in total knee arthroplasty. Is the design the critical factor ?. *J Arthroplasty*; 15 (4): 424-429.
- 28) D'Lima DD, Steklov N, Patil S, Colwell CW (2008). [The Mark Coventry Award: In Vivo Knee Forces During Recreation and Exercise After Knee Arthroplasty](#). *Clin Orthop Relat Res.*; 466 (11): 2605-2611.
- 29) Ostermeier S, Hurschler C, Stukenborg-Colsman C (2004). Quadriceps function after TKA—an in vitro study in a knee kinematic simulator. *Clin Biomech*; 19 (3): 270-276.
- 30) Winemaker MJ (2002). Perfect balance in total knee arthroplasty: the elusive compromise. *J Arthroplasty*; 17(1): 2-10.

- 31) Parratte S, Pagnano MW, Trousdale RT, Berry DJ (2010). Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. [J Bone Joint Surg Am.](#); 92(12): 2143-9.
- 32) Lachiewicz PF (2004). Implant design and techniques for patellar resurfacing in total knee arthroplasty. Instr Course Lect 2004; 53: 187-191.
- 33) Chonko DJ, Lombardi AV Jr, Berend KR (2004). Patella baja and total knee arthroplasty (TKA): etiology, diagnosis, and management. Surg Technol Int.; 12: 231-238.
- 34) Schindler OS (2012). The controversy of patellar resurfacing in TKA: Ibisne in medio tutissimus? Knee Surg Sports Traumatolog Arthrosc; 20: 1227-1244.