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# Early Functional Outcomes After Evolutionary Total Knee Arthroplasty

## A Randomized Controlled Trial. Is New Always Better?

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**Background:** Total knee replacement (TKR) designs continue to evolve with the aim of improving patient outcomes; however, there remains a significant patient dissatisfaction rate. We report the early functional outcomes of an evolutionary knee design in the context of a single-blinded, noninferiority, randomized controlled trial.

**Methods:** Patients were randomized to receive either the P.F.C. SIGMA or ATTUNE knee implant systems (DePuy Synthes). All implants were fixed-bearing, cruciate-retaining, and cemented constructs. Patients were assessed at baseline and 6 weeks, 3 months, and 1 year postoperatively using clinical and functional outcome measures, including range of motion, Oxford Knee Score (OKS), Oxford Knee Score-Activity and Participation Questionnaire (OKS-APQ), Patient Knee Implant Performance (PKIP) score, 5-Level EuroQol 5 Dimensions (EQ-5D-5L), and Short Form-36 outcome measures.

**Results:** There were 150 patients who underwent a surgical procedure (76 with the ATTUNE implant and 74 with the P.F.C. SIGMA implant), with 147 patients remaining at the final review. No differences were observed in any of the outcome measures between the groups at any time point. Tourniquet time was significantly shorter in the P.F.C. SIGMA arm ($p = 0.001$); however, this had no clinical impact on the OKS (analysis of covariance [ANCOVA] test) at the final review ($p = 0.825$). There was no difference in the numbers of patients achieving the minimal clinically important difference for the OKS between the groups ($p = 0.817$).

**Conclusions:** This trial did not show inferiority of the ATTUNE implant when compared with the P.F.C. SIGMA implant. The authors believe that implant innovation should continue and that modern implants should be introduced into the market following randomized controlled trials. Further work should assess the effect of non-implant-related factors on patient outcomes.

**Level of Evidence:** Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Total knee arthroplasty (TKA) successfully reduces pain and improves quality of life in patients with primary knee osteoarthritis[1]. In the United Kingdom in 2018, there were >90,000 TKAs performed, and this number is likely to rise over the coming years[2]. However, there still remains up to a 20% dissatisfaction rate in patients who have normal postoperative investigations and no detectable pain generator[3]. This has driven innovations in implant designs, materials, and knee kinematics understanding, with the hope of improving clinical outcomes[4].

The P.F.C. SIGMA system (DePuy Synthes) is the most widely used total knee replacement (TKR) design, with excellent survival and clinical outcomes[5]. In 2013, DePuy Synthes introduced the ATTUNE knee system. A gradual reduction of the femoral radius, a deeper trochlear notch, and an improved inventory of implant sizes were hypothesized to improve knee kinematics, knee stability, and early patient outcomes[6]. The aim of this study was to compare the early patient-reported functional and clinical outcomes between these 2 implant designs, with the null hypothesis that there was no inferiority of the ATTUNE knee system.

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A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJSOA/A295).

## Materials and Methods

Ethical approval was obtained (NRES Manchester South 14/NW/1330). The trial was designed as a single-center, single-blinded randomized controlled trial comparing the P.F.C. SIGMA and ATTUNE knee implants. The trial protocol was previously published and registered (ISRCTN10345709)[7]. Inclusion and exclusion criteria are illustrated in Table I.

### *Data Collection*

Demographic data included age, sex, body mass index, and medical comorbidities. Clinical data included tourniquet time, American Society of Anesthesiologists (ASA) classification, hospital length of stay, and preoperative and postoperative hemoglobin. Complications were recorded, such as superficial and deep infection, thromboembolic events, and return to the operating room for a procedure (e.g., a wound irrigation or joint manipulation) for the involved limb during the study.

### *Clinical and Functional Outcome Measures*

The primary outcome measure was the change in the Oxford Knee Score (OKS)[8] between baseline and 3 months; the time points of 6 weeks and 1 year were also examined. The secondary joint-specific outcome measures included the Oxford Knee Score-Activity and Participation Questionnaire (OKS-APQ) and the Patient Knee Implant Performance (PKIP) score. The secondary outcomes for general quality-of-life outcome measures included the Short Form-36 (SF-36) and the 5-Level EuroQol 5 Dimensions (EQ-5D-5L). The use of these questionnaires is well described in the literature, as are their validity and responsiveness to change[9-12]. All secondary outcomes were also evaluated at baseline, 6 weeks, 3 months, and 1 year.

Clinical outcomes recorded included preoperative and postoperative range of motion of the affected knee joint as measured with a goniometer and a Pain Numeric Rating Scale (NRS) (not the visual analog scale [VAS] for pain that was listed in the registry data in error) on a scale of 0 (no pain) to 10 (worst pain)[13]. Table II illustrates the time points during the trial at which each patient-reported outcome measure and clinical outcome measure was recorded. Radiographic assessment using the Centricity Enterprise (GE Healthcare) Picture Archiving and Communication System (PACS) was utilized to document the severity of preoperative osteoarthritis as measured using the Kellgren-Lawrence grading[14].

### *Surgical Technique*

The operating surgeons were either consultants (n = 8) or senior fellows (n = 3) with extensive experience using the P.F.C. SIGMA system. Surgeons were asked to perform a minimum of 5 ATTUNE cruciate-retaining TKRs prior to operating on patients in the study to ensure familiarity with the system. It was planned for patients to undergo an enhanced recovery protocol per departmental guidelines (joint education classes, spinal anesthesia with local infiltration, and early mobilization). If patients declined spinal anesthesia or the spinal anesthetic was unable to be administered, the surgical procedure was performed under general anesthesia with local infiltration and with or without femoral nerve blockade. All patients received perioperative antibiotics and anticoagulation per departmental protocols.

Patients underwent TKA under a tourniquet, through a midline incision and medial parapatellar approach, with a cemented, fixed-bearing, cruciate-retaining implant. A measured resection technique was utilized and component cementation was performed in 2 independent mixes. All surgical procedures were planned to be undertaken without patellar resurfacing; however, surgeons were advised to resurface the patella if they believed that this was indicated. Wound closure was performed as per the operating surgeon's preferred technique, and the wound was dressed using AQUACEL dressings (ConvaTec) and a wool and crepe bandage. Patients were mobilized once the effects of regional anesthesia had subsided, and all patients underwent physiotherapy per departmental protocols.

**TABLE I Inclusion and Exclusion Criteria**

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| Male or female sex between 22 and 90 years of age, inclusive | Patient has a diagnosis of inflammatory or posttraumatic osteoarthritis |
| A diagnosis of primary osteoarthritis of the knee | Severe bone defects or deformity that will require augmentation with a bone graft, an augmented prosthesis, or a constrained device |
| Primary varus osteoarthritic deformity | Valgus osteoarthritis |
| Stable collateral ligaments at the time of the preoperative clinical examination | Previous patellectomy |
| Patient is a candidate for routine primary knee arthroplasty (cruciate-retaining with no patellar resurfacing) in line with the manufacturer's guidelines | Patient has a contralateral TKR that is a P.F.C. SIGMA or ATTUNE implant |
| Subject is able to give consent to procedure | Patient has a poorly functioning or symptomatic contralateral or ipsilateral total hip replacement |
| | Previous lower-limb amputation on either limb |
| | Previous fractures, osteotomy, or surgical procedure to the knee that required metal implantation and/or ligament reconstruction |
| | Neurogenic cause for arthritis in the knee or associated neurological symptoms in the lower limb referred from the spine |

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**TABLE II Time Points of Patient Assessments**

| Time Point in Trial | Assessments Recorded |
|---|---|
| Preoperative pack | OKS, OKS-APQ, PKIP, EQ-5D-5L, SF-36, Pain NRS, preoperative range of motion |
| Week 6 postoperative Pack A | OKS, OKS-APQ, PKIP, EQ-5D-5L, Pain NRS, postoperative range of motion |
| Week 12 postoperative Pack B | OKS, OKS-APQ, PKIP, EQ-5D-5L, Pain NRS, postoperative range of motion |
| Week 52 postoperative Pack C | OKS, OKS-APQ, PKIP, EQ-5D-5L, SF-36, Pain NRS, postoperative range of motion |

### *Statistical Analysis*

The study was designed as a noninferiority study, with the primary outcome being the change in OKS between baseline and 3 months. A noninferiority margin in the OKS of 5.0 points was used to calculate the sample size[15]. Based on an estimated standard deviation of 11.6 points and a 2-sided alpha level of 0.05, a sample size of 150 patients was calculated. This was inclusive of a 10% loss of follow-up at each time point to maintain statistical power of 80%. Analyses were performed on an intention-to-treat basis, with missing data dealt with as per the recommendations for each outcome measure. We calculated the mean or median values and the accompanying 95% confidence intervals (CIs), and significance was set at $p < 0.05$. The primary outcome was analyzed using analysis of covariance (ANCOVA) techniques, which analyzed the 3-month outcome data and included the baseline data as an adjusting covariate. Further analyses were performed using longitudinal analysis methods using linear mixed modeling techniques with the patient identification included as a random effect and treatment included as a fixed effect nested within time, where time was included as a categorical variable. Differences between treatments were measured at each time point, and the results were presented as the difference between means and associated 95% CIs. Statistical analysis was performed using the R statistical package (version 3.6.2, R Foundation for Statistical Computing). Patients and the statistician were blinded as to the allocated treatment arm until all data had been analyzed.

## Results

### *Recruitment and Randomization*

A total of 162 patients were recruited and randomized to the study. The Consolidated Standards of Reporting Trials (CONSORT) diagram in Figure 1 illustrates the study progression. Twelve operations were cancelled for anesthetic reasons after randomization. These 12 patients were excluded from the study and their randomization numbers and allocations were discarded. This left a total of 150 patients who underwent a surgical procedure. Three patients declined continued participation in the trial after the 6-week review. Their data up to and including this point were included in the final analysis with their consent. There was no other loss to follow-up. However, 1 patient who was randomized to the ATTUNE arm received a P.F.C. SIGMA implant due to intraoperative instrumentation issues but was kept in the ATTUNE arm as part of an intention-to-treat analysis. In total, 76 patients were randomized to the ATTUNE arm (75 ATTUNE and 1 P.F.C. SIGMA), and 74 patients were randomized to the P.F.C. SIGMA arm. No patients underwent patellar resurfacing.

### *Demographic Characteristics*

There were no differences in preoperative parameters between the 2 groups with respect to all demographic characteristics, severity of osteoarthritis, hemoglobin levels, and the clinical, functional, and generic outcome measures (Table III). The median tourniquet time was shorter in the P.F.C. SIGMA group (66 minutes) compared with the ATTUNE group (75 minutes) ($p = 0.001$). There was no significant difference in the postoperative length of hospital stay ($p = 0.168$).

### *Postoperative Knee-Specific Clinical Outcome Measures*

There was no significant difference in the range of motion in knee extension or flexion between the groups at baseline or any of the postoperatively assessed time points (Table III and IV). Both groups showed comparable reductions in pain NRS levels after the surgical procedure.

### *Postoperative Disease-Specific, Patient-Reported Outcome Measures*

Preoperative and postoperative patient-reported outcome measure scores are presented in Tables III and IV. When assessing the primary outcome measure, the median (interquartile range [IQR]) change in OKS between baseline and 3 months was 15 points (9, 23 points) in the ATTUNE group and 13 points (8, 22.25 points) in the P.F.C. SIGMA group. An estimated mean difference (and standard error) between groups of $-1.748 \pm 1.547$ points was obtained, with a 95% CI of $-4.78$ to 1.28 points. The upper limit of the 95% CI was smaller than the noninferiority margin of 5 points, therefore showing noninferiority of the ATTUNE implant.

There were no significant differences between the 2 arms at baseline or at any postoperative time point when comparing the OKS and OKS-APQ. Both groups demonstrated increases in OKS scores above the minimal clinically important difference from baseline to 12 months postoperatively; the mean OKS was 18.2 points for the ATTUNE group compared with 18.07 points for the P.F.C. SIGMA group ($p = 0.929$) at baseline, and it was 38.03 points for the ATTUNE group compared with 36.28 points for the P.F.C. SIGMA group ($p = 0.254$) at 12 months postoperatively. There was no difference in the numbers of patients achieving the minimal clinically important difference from baseline to 1 year postoperatively for the OKS between the

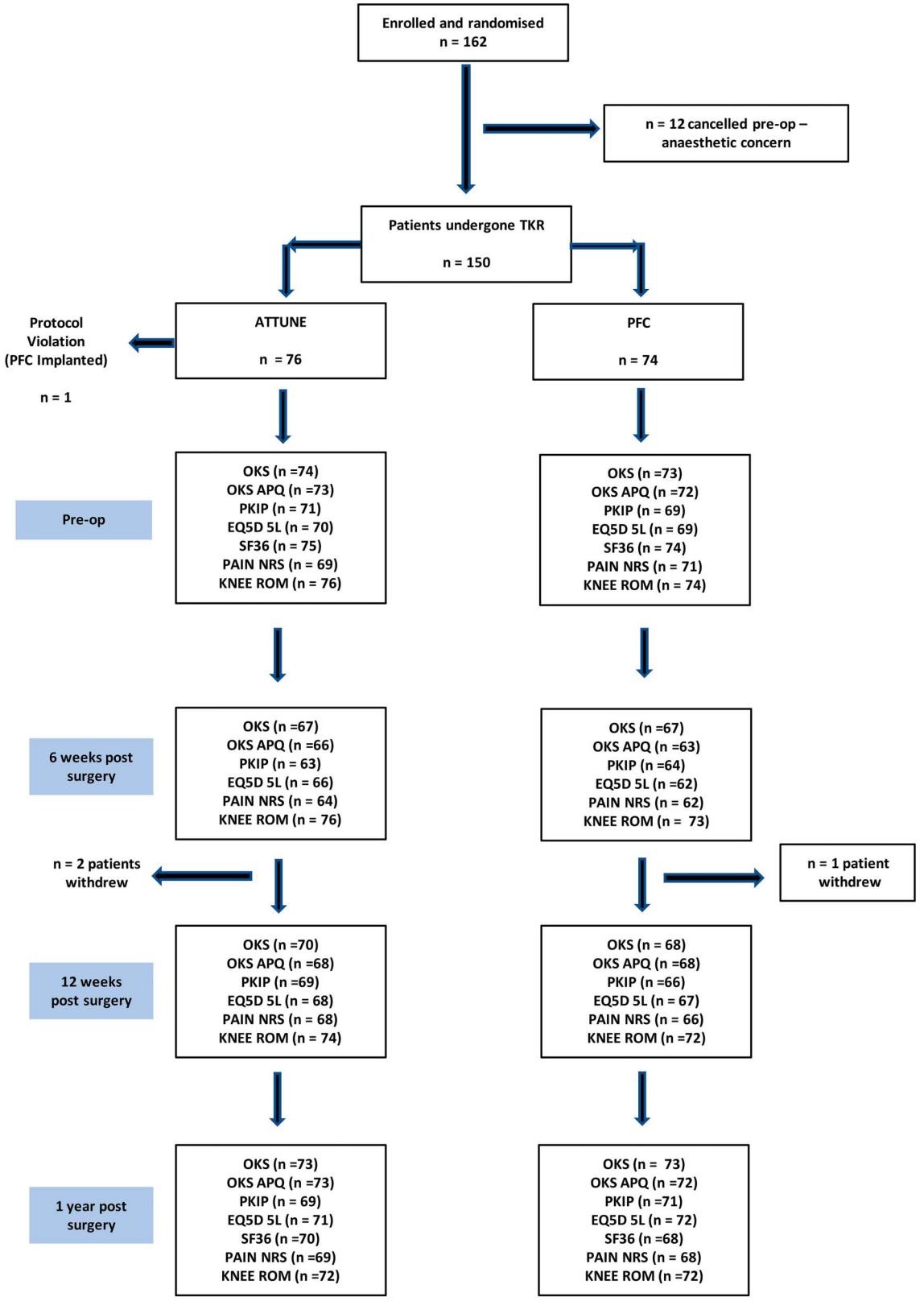


Fig. 1

CONSORT flow diagram. ROM = range of motion.

**TABLE III Baseline Demographic Characteristics and Preoperative Outcome Scores by Group**

| Covariate and Level | ATTUNE (N = 76) | P.F.C. SIGMA (N = 74) | Total (N = 150) | P Value |
|---|---|---|---|---|
| Side* | | | | |
| Left | 34 | 34 | 68 | |
| Right | 42 | 40 | 82 | 1 |
| Sex* | | | | |
| Male | 36 | 30 | 66 | |
| Female | 40 | 44 | 84 | |
| Grade of surgeon† | | | | 0.171 |
| Consultant | 46 (61%) | 53 (72%) | 99 | |
| Fellow or registrar | 30 (39%) | 21 (28%) | 51 | |
| Body mass index‡ *(kg/m²)* | 30.6 (27, 34.5) | 30.5 (27, 35.3) | | 0.5 |
| ASA classification† | | | | 0.546 |
| I | 13 (17%) | 9 (12%) | 22 | |
| II | 52 (68%) | 50 (68%) | 102 | |
| III | 11 (15%) | 15 (20%) | 26 | |
| Anesthetic type† | | | | |
| General anesthesia only | 0 (0%) | 1 (1%) | 1 | |
| General anesthesia and femoral block | 2 (3%) | 1 (1%) | 3 | |
| Spinal | 74 (97%) | 72 (97%) | 146 | |
| Preoperative hemoglobin‡ *(g/dL)* | 13.7 (12.78, 14.6) | 13.7 (13, 14.5) | | 0.649 |
| Kellgren-Lawrence grade† | | | | 1 |
| 3 | 23 (30%) | 22 (30%) | 45 | |
| 4 | 53 (70%) | 52 (70%) | 105 | |
| Knee extension§ *(deg)* | 7.11 (6.09 to 8.12) | 6.96 (5.94 to 7.98) | | 0.843 |
| Knee flexion§ *(deg)* | 106.71 (103.75 to 109.67) | 103.31 (100.31 to 106.31) | | 0.116 |
| Pain VAS§ (0 to 10) | 7.27 (6.69 to 7.84) | 7.18 (6.62 to 7.75) | | 0.842 |
| OKS Total§ *(points)* | 18.2 (16.1 to 20.31) | 18.07 (15.96 to 20.17) | | 0.929 |
| OKS-APQ§ *(points)* | 9.33 (3.15 to 15.5) | 12.73 (6.55 to 18.91) | | 0.446 |
| PKIP Total§ *(points)* | 26.56 (22.9 to 30.22) | 24.54 (20.83 to 28.25) | | 0.447 |
| PKIP Confidence§ *(points)* | 2.81 (2.22 to 3.41) | 2.57 (1.96 to 3.17) | | 0.572 |
| PKIP Stability§ *(points)* | 2.64 (2.02 to 3.26) | 2.45 (1.82 to 3.08) | | 0.673 |
| PKIP Modify Activities§ *(points)* | 5.04 (4.29 to 5.8) | 4.89 (4.13 to 5.66) | | 0.784 |
| PKIP Satisfaction§ *(points)* | 1.7 (1.13 to 2.26) | 1.34 (0.77 to 1.91) | | 0.390 |
| EQ-5D-5L Index§ | 0.44 (0.39 to 0.5) | 0.42 (0.37 to 0.47) | | 0.550 |
| SF-36 PCS‡ *(points)* | 33.69 (28.735, 38.415) | 33.5 (28.645, 37.23) | | 0.679 |
| SF-36 MCS‡ *(points)* | 44.795 (39.442, 54.015) | 43.815 (36.193, 53.89) | | 0.368 |

*The values are given as the number of patients. †The values are given as the number of patients, with the percentage in parentheses. ‡The values are given as the median, with the IQR in parentheses. §The values are given as the mean, with the 95% CI in parentheses.

groups: 66 patients (87%) in the ATTUNE group and 64 patients (86%) in the P.F.C. SIGMA group (p = 0.817). There were also increases in the OKS-APQ scores in both groups from baseline to 12 months postoperatively; the mean OKS-APQ was 9.33 points in the ATTUNE group compared with 12.73 points in the P.F.C. SIGMA group (p = 0.446) at baseline, and it was 56.16 points in the ATTUNE group compared with 58.94 points in the P.F.C. SIGMA group (p = 0.533) at 12 months postoperatively. There was an increase in the overall and subset PKIP scores from baseline but no significant difference between the groups.

### *Generic Health Outcome Measures: EQ-5D-5L and SF-36*

There was no difference between the 2 groups at baseline when comparing the EQ-5D-5L index scores. The increase in the EQ-5D-5L scores in both groups indicated overall improvement in quality of life; however, there were no significant differences at

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**TABLE IV Postoperative Surgical Data and Outcome Scores by Group**

| Covariate and Level | ATTUNE (N = 76) | P.F.C. SIGMA (N = 74) | P Value |
|---|---|---|---|
| Tourniquet time* *(min)* | 75 (65, 86) | 66 (55, 77) | 0.001† |
| Postoperative hemoglobin* *(g/dL)* | 11.55 (10.68, 12.33) | 11.00 (10.40, 12.10) | 0.102 |
| Length of stay* *(day)* | 3.00 (2.75, 4.00) | 3.00 (3.00, 4.00) | 0.168 |
| Knee extension† *(deg)* | | | |
| 6 weeks | 3.55 (2.54 to 4.56) | 3.69 (2.66 to 4.72) | 0.851 |
| 12 weeks | 2.18 (1.17 to 3.20) | 2.15 (1.12 to 3.19) | 0.968 |
| 1 year | 0.31 (−0.73 to 1.34) | 1.03 (−0.01 to 2.07) | 0.333 |
| Knee flexion† *(deg)* | | | |
| 6 weeks | 99.80 (96.84 to 102.76) | 99.41 (96.40 to 102.43) | 0.856 |
| 12 weeks | 106.30 (103.33 to 109.28) | 104.89 (101.86 to 107.92) | 0.516 |
| 1 year | 109.01 (105.99 to 112.03) | 108.09 (105.06 to 111.12) | 0.673 |
| Pain VAS† (0 to 10) | | | |
| 6 weeks | 3.80 (3.20 to 4.39) | 3.89 (3.29 to 4.48) | 0.837 |
| 12 weeks | 3.23 (2.65 to 3.82) | 3.29 (2.71 to 3.87) | 0.896 |
| 1 year | 2.48 (1.90 to 3.06) | 1.97 (1.40 to 2.55) | 0.224 |
| OKS Total† *(points)* | | | |
| 6 weeks | 27.39 (25.22 to 29.57) | 27.05 (24.88 to 29.22) | 0.826 |
| 12 weeks | 33.85 (31.71 to 36.00) | 32.23 (30.07 to 34.39) | 0.298 |
| 1 year | 38.03 (35.91 to 40.14) | 36.28 (34.16 to 38.40) | 0.254 |
| OKS-APQ† *(points)* | | | |
| 6 weeks | 28.60 (22.15 to 35.04) | 29.74 (23.20 to 36.28) | 0.807 |
| 12 weeks | 47.46 (41.09 to 53.82) | 43.14 (36.81 to 49.47) | 0.347 |
| 1 year | 56.16 (49.99 to 62.33) | 58.94 (52.76 to 65.13) | 0.533 |
| PKIP Total† *(points)* | | | |
| 6 weeks | 50.73 (47.07 to 54.39) | 51.00 (47.29 to 54.70) | 0.920 |
| 12 weeks | 57.00 (53.34 to 60.66) | 56.83 (53.12 to 60.53) | 0.948 |
| 1 year | 60.63 (56.95 to 64.30) | 61.00 (57.30 to 64.71) | 0.888 |
| PKIP Confidence† *(points)* | | | |
| 6 weeks | 4.96 (4.36 to 5.55) | 5.28 (4.68 to 5.89) | 0.451 |
| 12 weeks | 5.96 (5.36 to 6.55) | 5.88 (5.28 to 6.49) | 0.866 |
| 1 year | 6.57 (5.97 to 7.17) | 6.72 (6.12 to 7.33) | 0.726 |
| PKIP Stability† *(points)* | | | |
| 6 weeks | 5.45 (4.82 to 6.07) | 5.65 (5.01 to 6.28) | 0.659 |
| 12 weeks | 6.18 (5.56 to 6.80) | 6.19 (5.56 to 6.82) | 0.978 |
| 1 year | 6.80 (6.18 to 7.42) | 7.18 (6.54 to 7.81) | 0.408 |
| PKIP Modify Activities† *(points)* | | | |
| 6 weeks | 5.40 (4.64 to 6.16) | 5.32 (4.55 to 6.08) | 0.883 |
| 12 weeks | 5.79 (5.04 to 6.55) | 5.68 (4.92 to 6.45) | 0.836 |
| 1 year | 5.58 (4.83 to 6.34) | 5.28 (4.51 to 6.04) | 0.581 |
| PKIP Satisfaction† *(points)* | | | |
| 6 weeks | 5.61 (5.05 to 6.18) | 5.64 (5.06 to 6.21) | 0.959 |
| 12 weeks | 6.52 (5.96 to 7.09) | 6.36 (5.79 to 6.94) | 0.702 |
| 1 year | 6.71 (6.15 to 7.28) | 6.83 (6.26 to 7.40) | 0.769 |
| EQ-5D Index† *(points)* | | | |
| 6 weeks | 0.67 (0.62 to 0.72) | 0.63 (0.57 to 0.68) | 0.279 |
| 12 weeks | 0.73 (0.67 to 0.78) | 0.67 (0.62 to 0.73) | 0.164 |

*continued*

**TABLE IV (*continued*)**

| Covariate and Level | ATTUNE (N = 76) | P.F.C. SIGMA (N = 74) | P Value |
|---|---|---|---|
| 1 year | 0.77 (0.71 to 0.82) | 0.71 (0.66 to 0.76) | 0.112 |
| SF-36 PCS* *(points)* | | | |
| 1 year | 44.795 (39.442, 54.015) | 43.815 (36.193, 53.89) | 0.529 |
| SF-36 MCS* *(points)* | | | |
| 1 year | 54.835 (44.46, 59.6) | 53.845 (44.39, 59.325) | 0.490 |

*The values are given as the median, with the IQR in parentheses. †Significant. ‡The values are given as the mean, with the 95% CI in parentheses.

any time point. SF-36 outcome scores again showed improvements in the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores; however, no differences were seen between the groups.

### *Complications*

Complications observed during the study are outlined in Table V. In the ATTUNE group, there were 2 cases of thromboembolic events, compared with 1 case in the P.F.C. SIGMA group. All cases were treated with anticoagulation as per trust guidelines. One patient in the ATTUNE group required a hematoma irrigation at 4 days postoperatively. There were 3 superficial infections (1 with the ATTUNE implant and 2 with the P.F.C. SIGMA implant), all treated with oral antibiotics with no subsequent antibiotic or surgical treatment required. Three patients with progressive stiffness (2 with the ATTUNE implant and 1 with the P.F.C. SIGMA implant) underwent a manipulation under anesthesia within 3 months of the index procedure and recovered knee flexion to a satisfactory level. One patient in the ATTUNE group sustained an intraoperative popliteal artery injury that required vascular repair within 24 hours of the index procedure. Despite the complications, 9 of 10 patients (1 patient in the P.F.C. SIGMA group developed a pulmonary embolism) had achieved the minimal clinically important difference for the OKS at the final review; the mean OKS increase was 15.4 points (range, 2 to 26 points).

**TABLE V Complications Observed During the Study Period***

| Complication | ATTUNE | P.F.C. SIGMA |
|---|---|---|
| Deep venous thrombosis | 1 | 0 |
| Pulmonary embolism | 1 | 1 |
| Hematoma irrigation | 1 | 0 |
| Superficial infection | 1 | 2 |
| Deep infection | 0 | 0 |
| Vascular injury | 1 | 0 |
| Stiffness requiring manipulation under anesthesia | 2 | 1 |

*The values are given as the number of patients.

## Discussion

This study did not show any inferiority of the ATTUNE implant compared with the P.F.C. SIGMA implant at 3 months postoperatively and did not show any differences at any other time point. Patient recruitment and retention met the target set by the power analysis and there was minimal loss to follow-up. Both groups showed significant and comparable improvements in all outcome measures in the first year postoperatively, with no significant implant-related complications. Both the EQ-5D-5L and SF-36 generic health measures showed consistent patient satisfaction and health improvements in both groups, further highlighting the success of the knee replacement. Tourniquet time was found to be significantly lower in the P.F.C. SIGMA group ($p = 0.001$); however, an ANCOVA performed to assess the 12-month follow-up data while adjusting for the baseline OKS showed that tourniquet time had no measurable impact on the OKS ($p = 0.825$).

Surgeon and industry-led collaborations have led to many advancements in the understanding of knee arthroplasty with respect to biomechanics and material science, with subsequent implant evolution. Early studies following the launch of the ATTUNE prosthesis in 2013 demonstrated improved patient-reported outcome measures, greater range of motion, reduced pain scores, and a shorter length of stay compared with other leading knee systems[16]. However, these studies were nonrandomized and had significant bias and small sample sizes.

Several studies have previously shown improved results when using the ATTUNE knee implant. Ranawat et al.[17] reported on 100 consecutive ATTUNE knee implants that were matched to 100 P.F.C. SIGMA implants. At the 2-year follow-up, there were no differences found in the Knee Society Scores (KSS) or patient satisfaction; however, there was a reduced incidence of anterior knee pain and patellofemoral joint crepitation in the ATTUNE group, postulated to be a result of improved implant patellofemoral kinematics and trochlear design. Martin et al.[18] compared 2 cohorts of patients with the P.F.C. SIGMA implant (n = 1,165) and patients with the ATTUNE implant (n = 728) and found that cases with a posterior-stabilized ATTUNE TKR had significantly less patellofemoral crepitus; however, the retrospective design of the study and the nonstandardized method of diagnosing patellofemoral crepitus were significant limitations. Indelli et al.[19] compared 100 matched patients with a posterior-

stabilized ATTUNE implant and 100 patients with a posterior-stabilized P.F.C. SIGMA implant. Despite significant increases in knee flexion and reduced anterior knee pain in the ATTUNE group, no other clinical or patient-reported outcome measurement showed any significant difference. It should be noted that only 1 surgeon performed the ATTUNE knee implantations compared with 2 surgeons in the P.F.C. SIGMA group, with no crossover, and there was an increased use of a lateral release in the P.F.C. SIGMA group, which could have had a significant bearing on the clinical outcomes and subsequent comparison, especially when comparing the rates of anterior knee pain. Carey and Harty[20] retrospectively reviewed 21 patients who underwent bilateral TKA (with 1 ATTUNE implant and 1 P.F.C. SIGMA implant) performed in staged procedures. The authors reported a significant increase in the patient-reported outcome measures in the ATTUNE group; however, different patient-reported outcome measure assessments were utilized for the P.F.C. SIGMA and ATTUNE groups, and this, coupled with the small sample size, presented significant limitations. Giaretta et al.[21] reported on 228 primary cemented ATTUNE TKRs, showing improvements on the Knee injury and Osteoarthritis Outcome Score (KOOS) and OKS; however, there was no comparator group in this study. Song et al.[22] compared 300 patients with the ATTUNE implant with 300 matched patients with the P.F.C. SIGMA implant in a retrospective study in patients with a posterior-stabilized design with patellar resurfacing. Significant improvements were reported in the postoperative Knee Society Knee Score and range of motion; however, no difference was reported in the Knee Society Function Score.

In contrast, several studies have found no improvements in outcomes with the ATTUNE implant. Kaptein et al.[23] performed a randomized controlled trial that did not show any difference in postoperative patient-reported outcome measures; however, these were secondary outcome measures, as the study was primarily powered for radiographic assessment and not patient-reported outcome measure assessment. Furthermore, this study included patients with inflammatory arthritis, patellar resurfacing was performed, and preoperative severity and alignment were not discussed. Behrend et al.[24] found no differences in clinical outcomes or patient-reported outcome measures at 1 year postoperatively when comparing the ATTUNE implant with the LCS implant (DePuy Synthes). Molloy et al.[25] and Chua et al.[26] found no difference in outcome measures between the ATTUNE group and the P.F.C. SIGMA group.

There were several limitations to this study. This study involved a single, high-volume institution, which may limit the generalizability of the results to other orthopaedic departments in other hospitals. However, multiple surgeons performed the procedures and surgeons used their own techniques in performing the surgical procedure, albeit using a measured resection technique. The study only assessed patients with varus-pattern osteoarthritis, and all patients underwent a surgical procedure with a cruciate-retaining, fixed-bearing design with no patellar resurfacing. Although this is the most common indication and construct in our institution, the results cannot be extrapolated to other fixed-bearing, cruciate-retaining implants or types of osteoarthritis. The goal of the trial was to assess early functional results, and we cannot comment on longer-term results or revision rates without longer follow-up. Given that the focus of our study was early functional outcomes, we believe that the calculated sample size and follow-up duration were appropriate. The 5-year cumulative revision rates for the ATTUNE implant are in line with those of the P.F.C. SIGMA implant[2,27], and proving any marginal differences in revision rates would require longer follow-up studies with thousands of patients and arguably would not be an appropriate use of public health funding resources.

With multiple studies showing no significant advantage of one implant over another, the question remains as to how patient satisfaction can be improved following TKA. A recent review highlighted that improved kinematics of a knee implant does not necessarily correlate with improved clinical outcomes in the short to medium term[28]. This further highlights the multifactorial nature of knee replacement recovery and that implant design is only one of a multitude of factors that need to be addressed along with the soft-tissue component, postoperative rehabilitation, and the psychosocial aspects of the patient. Further studies looking at these factors would be valuable in helping to improve patient outcomes following TKA.

In conclusion, this study showed no inferiority of the ATTUNE implant following TKA when comparing early function with that of the P.F.C. SIGMA implant. The results only reflect short-term outcomes; however, we recommend that implant innovation should continue, with the implantation of new devices being performed within the context of randomized controlled trials to ensure their safety and efficacy. Further studies into TKA outcomes should examine the influence of patient characteristics, psychosocial factors, and rehabilitation modalities. ■

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