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Short Term Patient Outcomes After Total Knee Arthroplasty: Does the Implant Matter?

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Abstract

Background—Newer implants for total knee arthroplasty (TKA) often gain market share at higher cost with little patient-reported and long-term clinical data. We compared outcomes after TKA using two different implants: Depuy PFC Sigma and Attune.

Methods—Using a prospective data repository from an academic tertiary medical center, we analyzed 2116 TKAs (1603 Sigma and 513 Attune) from April 2011 through July 2016. Outcomes included length of surgery, length of stay, facility discharge, 90-day reoperation, range of motion (ROM) change, and patient-reported physical function (PCS).

Results—There was no difference in length of surgery (Attune –2.87 minutes, $P=0.143$). Implant type was not associated with extended LOS (>3 days) (OR 0.80, $P=0.439$). There was no difference in facility discharge (OR 0.65, $P=0.103$). Unadjusted 90-day reoperations were 0.3% for

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Sigma and 1.0% for Attune cohorts ($P=0.158$). Sigma implants were associated with more ROM improvement in unadjusted analyses (+ 2.1 degree improvement $P=0.031$). 59% of the Sigma cohort and 49% of the Attune cohort achieved the minimal clinically important (MCID) change for PCS improvement, although there was no adjusted difference in achieving MCID (Attune OR 0.84, $P=0.435$). There was no adjusted difference in absolute PCS improvement (Attune +0.12 score, $P=0.864$).

Conclusions—Our data show no difference in physical function and most outcomes between Sigma and Attune. Attune implants had shorter absolute LOS, but there were no differences in extended LOS.

Keywords

total knee arthroplasty; implant; Attune; patient-reported outcome measures; physical function

1. Introduction

Total knee arthroplasty (TKA) is an effective treatment of end-stage arthritis [1-3], with survivorship as high as 90% at 12 years after surgery [4]. As the US population ages, experts anticipate that the need for TKA will increase dramatically, with primary TKAs performed in the US predicted to reach almost 1.4 million by 2020 [5]. With the growing TKA market, companies are continuously providing innovative and personalized total knee systems that focus on the unique needs of the patient [6]. DePuy Synthes, a Johnson & Johnson Professional manufacturer of artificial knee implants, released the Press-Fit Condylar (PFC) Sigma in 1996 (Depuy Synthes, Warsaw, IN), with a modified femoral component for improved patellar tracking [7]. In 2013, DePuy released the Attune (Depuy Synthes, Warsaw, IN), a TKA implant designed to have a more anatomic trochlear groove and patella [8]. In two recent studies, the new system produced improved patella tracking with decreased incidence of patellar crepitus when compared to the PFC Sigma [9, 10].

Implant expense is one of the costlier parts of the hospital bill for total knee arthroplasty, and new implants tend to have a higher price tag [11, 12]. Efforts have been made to minimize cost with TKA surgery and hospitalization with decreasing Medicare reimbursements and an emphasis on national healthcare reform[13]. Although we do not directly report on cost, it would be reasonable to weigh price considerations against the desire to use new technology that may not be superior to implants already on the market.

Current literature lacks direct comparison of PFC Sigma and Attune implants for patient-reported outcome measures (PROMs). PROMs assess patient health status directly through the patient's perspective and can be used to evaluate general patient function before and after surgery [14]. PROM can improve the quality of care delivery, while assessing the effect of TKA on physical function, pain, and depression [15].

The purpose of our study was to compare two different TKA implants using patient-reported outcomes. We looked at postoperative Patient-Reported Outcomes Measurement Information System (PROMIS®-10) global physical function score (PCS) after PFC Sigma and Attune TKA. Secondary outcomes included the effect of implant on length of surgery,

length of stay (LOS), discharge disposition, reoperation rates, and knee range of motion (ROM) change between the two designs.

2. Materials and Methods

2.1 Setting

We performed a retrospective analysis of prospectively collected data on patients undergoing primary unilateral and bilateral TKAs from April 2011 through July 2016 at an academic tertiary medical center in northern New England. Prospective data collection within the electronic health record is a routine part of daily practice for all patients. Our institutional review board waived the requirement for individual informed consent. Apart from the use of other implants (n=192, 8.3%), there were no exclusions among completed surgeries. We identified 2116 applicable TKAs (1603 Sigma and 513 Attune) conducted by 10 surgeons. The Attune implant was introduced to the Orthopaedic practice in 2014, with both Sigma and Attune implants used from 2014 to 2016. The peri-operative protocols were not exactly the same for the two implants, with some variation occurring between the surgeons. To help account for the variation, we controlled for the outcomes by surgeon.

2.2 Variables

We used the established, standardized PROMIS-10 and Veterans RAND 12-item health survey to determine physical function score (PCS) with time. During the study period, we collected both, prioritizing the PROMIS-10. If PROMIS-10 scores were not available, the Veterans RAND-12 PCS was converted to the PROMIS-10 scale using a validated crosswalk [16]. A conservative minimal clinically important change score (MCID) for the PCS is an improvement of 5 points of greater [17-19]. All data were obtained from our prospective repository except for the implant information, which we obtained through our institution's department of purchasing.

As part of routine clinical care, patients completed PROMs at least once preoperatively and at multiple postoperative time points. The repeated measures of PROMs were captured at 6 periods relative to the surgery for the purposes of this report. These were defined as an early PROM well before surgery (46+ days before surgery), baseline preoperative (1-45 days before surgery), 1-month postoperative (1-46 days after surgery), 3-months postoperative (46-299 days), 1-year postoperative (300-420 days), and greater than one year (421+ days) [18, 20], Table 1 displays the capture counts per time period. Because the PCS and PCS MCID models require both pre- and postoperative PCS, those models include 1791 surgeries (85%) (Table 1).

The PCS score and ROM degree changes were measured as the latest available postoperative recorded value subtracted by the latest preoperative value. The measurements were done by the surgeon or midlevel providers during follow up clinic visits as part of routine clinical care. The assessor was not blinded to the surgery. A positive score indicates more improvement compared to the reference category. The period captured by the PCS was included in the change model [15, 17] and the preoperative PCS and ROM were included as

applicable. We also documented any additional reoperations on the same knee within 90 days of the primary TKA.

All model variables were recorded preoperatively and obtained from our longitudinally maintained prospective institutional repository (Table 1). Our primary variables were implant type (PFC Sigma vs Attune; Depuy Synthes, Warsaw, IN). Adjusting factors included surgeon [21], year, bilateral, second unilateral, sex [21-23], race/ethnicity (non-Hispanic white or ethnic minority) [24, 25], age [21-23], tobacco use [26, 27], Charlson Comorbidity Index [21], PCS [21-23], PROMIS patient-reported mental function (MCS) [15, 17] and clinically measured body mass index (BMI) [23, 28].

2.3 Models

We created multivariate models for determining associations with TKA outcomes comparing use of PFC Sigma vs Attune implants. Our models included absolute postoperative PCS and a MCID PCS improvement of 5 points or greater [17-19], operative time, LOS, and facility discharge. Logistic regression was used for the PCS MCID, extended LOS, discharge disposition, and early reoperations models. We used linear regression for the length of surgery, LOS, absolute PCS change, and ROM change models. We used robust standard errors and clustered on individual patients to account for multiple primary TKAs. We also determined unadjusted differences for reoperation rate by implant type.

3. Results

3.1 Demographic

2116 TKA surgeries among 1984 patients were included in the study; 1603 (76%) utilized the Sigma implant, and 513 (24%) used Attune. This was a short term review including surgeries from April 2011 through July 2016. There were no unadjusted crude significant differences with respect to age ($P = 0.223$), sex ($P = 0.109$), alcohol use ($P = 0.894$), tobacco use ($P = 0.102$), Charlson morbidity score ($P = 0.082$); there was a statistical difference in preoperative BMI (32.80 (SD 7.93) for Sigma vs. 31.70 (SD 6.10) for Attune, $P = 0.006$) (Table 1). The unadjusted mean preoperative PCS scores were also statistically significant, but not clinically meaningful in their differences using standard measures [14-17], with Sigma 40.27 (SD 6.12) vs Attune 41.38 (6.52) ($P < 0.001$) (Table 1 and 2).

3.2 Length of surgery

The unadjusted mean length of surgery was 95.4 minutes (SD 21.2) for the Sigma cohort and 97.7 minutes (SD 17.8) for the Attune ($P = 0.029$). However, there was no significant difference after adjustment (Table 3). The greatest variation in operative time occurred among surgeons (range -5.37 to $+29.19$ minutes). Older patients and female sex were also associated with shorter operative time. (Appendix 1)

3.3 Length of stay

Among 2116 surgeries, 21% had LOS over 3 days (Table 1). Unadjusted mean length of stay was 3.15 days (95% CI 1.59 to 4.71) for Sigma, and 2.23 days (95% CI 1.11 to 3.35) for Attune, $P = < 0.001$ (Table 2). Attune implants were significantly associated with lower

absolute LOS (-0.37 days, 95% -0.61 – -0.13 , $P=0.002$) (Table 3). There was a temporal trend, with greater absolute LOS in 2015 and 2016 compared to previous years (2012). However, implant type was not associated with extended LOS (>3 days) (OR 0.80, 95% CI 0.45–1.42, $P=0.439$) (Table 3). Longer LOS was predicted by surgeon, age ≥ 75 years, preoperative Charlson > 0 , lower preoperative PCS, year of surgery, bilateral simultaneous TKAs, and morbid obesity (Appendix 2 and 3).

3.4 Discharge disposition

A total of 793 (40%) patients were discharged to a facility (Table 2). There was no difference in discharge to rehabilitation facility between Sigma vs. Attune (OR 0.65, 95% CI 0.39–1.09, $P=0.103$) (Table 3). Women, those with a Charlson Comorbidity Index ≥ 1 , and patients with morbid obesity all were associated with facility discharge. As expected, bilateral surgeries were strongly associated with facility discharge even with adjusting for other variables (OR 16.21, $P<0.001$). Older age and worse preoperative PCS scores all had higher dose-response associated values for facility discharge (Appendix 4).

3.5 Reoperation rates

Reoperations within 90 days were 0.3% vs 1.0% for Sigma vs. Attune cohorts, respectively (5/1603 Sigma, 5/513 Attune, $P=0.158$) (Table 2). Reasons for reoperations included wound dehiscence (2 Sigma, 2 Attune), infection (2 Sigma, 2 Attune), hemoarthrosis (1 Attune), and patellar maltracking (1 Sigma). Counts were too low for multivariate analysis, with no revisions within this time period.

3.6 Knee range of motion

There was an unadjusted difference in ROM by implant type (Table 2). Sigma patients showed an unadjusted $+2.1$ degree increase in knee flexion (SD 15.7) compared to -0.1 degree decrease (16.9) in the Attune cohort ($P = 0.049$). Similar to PCS change, ROM change data were restricted to TKAs that had both preoperative and postoperative ROM recorded ($n=1158$, 55% of TKAs). For bilateral TKAs, we took the mean of the ROMs for both knees. However, there was no difference in ROM change by implant after adjustment (Attune $+2.30$ degrees, 95% CI -0.59 – 5.20 , $P=0.119$) (Table 3). Preoperative ROM, some surgeons, year, sex, and older age groups were associated with more improvement, while low preoperative mental function was associated with less improvement (Appendix 5).

3.7 Patient-reported outcomes

Approximately 59% of the Sigma cohort and 49% of the Attune cohort (Table 1) achieved an equal or greater improvement than the MCID for PCS improvement of at least 5 points [19] among patients with both preoperative and postoperative PCS. There was no adjusted MCID physical function improvement between the groups (OR 0.84; 95% CI 0.54 – 1.30, $P = 0.435$) (Table 3). There was no adjusted clinically meaningful difference in absolute PCS improvement in Sigma vs Attune implants (Attune $+0.12$, 95% CI -1.23 – 1.47 , $P = 0.864$) (Table 3). The adjusted absolute postoperative PCS scores improved at the 3-month, 1-year, and >1 -year collection periods in reference to 1-month PCS scores, which are the first recorded clinic values after surgery (Figure 1).

4. Discussion

Design modifications are introduced in total knee arthroplasty systems with the goal of improving physical function [29] and competing in the growing arthroplasty market [5, 6]. Most recently, Depuy launched the Attune total knee alongside their previously well-established PFC Sigma line [8]. Previous studies have published on improved anterior knee pain and crepitus in Sigma versus Attune knees [9, 10, 30], but have not focused on global patient-reported outcomes. Our study shows that the new Attune implant does not provide improved patient-reported physical function outcomes as measured by the physical component score of the PROMIS-10. There was little difference in length of surgery, extended length of stay (>3-days), postoperative discharge disposition, 90-day reoperation rates, and knee ROM between Sigma and Attune knees. The Attune cohort did have a decreased absolute length of stay but the role of the implant is unclear.

Length of surgery was not associated with implant selection. Instead, individual attending surgeons were associated with greater variations in operative duration (Appendix 1), as shown in Bao *et al* [20]. Women and older patients were associated with shorter length of surgery, possibly due to decreased muscle mass and increased ease of the procedure. While new instrumentation does have the potential to eliminate additional steps [31], we did not find a significant improvement in operative duration.

Interestingly, we found the Attune implant is associated with decreased absolute length of stay (Table 3), as shown in industry-funded research [32]. However, there was no difference by implant for an extended length of stay over 3 days (Table 3, Appendix 3), contrary to other reported data [33]. The increased sizing options to match patient anatomy may improve mechanical performance of the joint, provide ease of mobility, and result in earlier absolute discharge in the Attune patients. It is possible that despite controlling for year the absolute LOS difference could be due to a confounder not adjusted within our models. The Attune cohort may benefit from medical advances that are not related to the implant itself, such as enhanced recovery after surgery through the use of appropriate anesthesia and early physical therapy [34, 35].

Discharge disposition was similar between the cohorts, contrary to other published data suggesting lower odds of patient discharge to skilled nursing facility [32]. Increased comorbidities, older age, and morbid obesity predicted facility discharge, as previously published [36, 37]. While there is emphasis placed on discharge planning after total joint arthroplasty, discharge disposition will vary per physician practice pattern, patient insurance, and increased comorbidities, with likely little association with the implant.

The 90-day reoperation rates were not significantly different between the implants. Recent publication from DePuy Synthes estimate that Attune knee percent revision was 0.5% (Attune CR) and 0.4% (Attune PS) at one year, per their Australian Joint Registry Data [38, 39], which is different than our findings at 90 days. Our smaller sample size though makes the effects of our few reoperations more apparent. Further long-term data is required on the Attune implant complications and possible component failures.

Our findings demonstrate that Attune implants do not appear to improve patient ROM changes relative to Sigma. Among adjusting factors, females and older patients had greater ROM improvement. Higher PCS scores were not associated with larger improvement in ROM, possibly because functional knee flexion ranges from 45 degrees to 105 degrees during various activities of daily living [43]. Year was a strong association, possibly demonstrating that patients with Attune implants did not have as much time to regain ROM since the implant is newer.

Patient-reported outcome measures (PROMs) help quantify a patient's perception about their physical, mental, and social health. There is growing support from clinicians, researchers, and payers for utilizing PROMs, specifically in Orthopaedics [40, 41]. Pay-for-performance metrics based on PROMs have been embraced by both the Centers for Medicare and Medicaid Services (CMS) and private insurance companies, and will likely continue to gain attention [42, 43], [44]. The goal of this paper was to focus on global patient-reported outcomes rather than knee specific outcomes to emphasize the value of overall improvement in a patient's life. A patient undergoing a total knee replacement has generalized goals for their outcomes, including participating in activities such as running or lifting objects, undergoing household chores, and conducting self-care. PROMIS-10 helps address these items by emphasizing the value of overall improvement in a patient's life.

We focused on physical function score between the two implants, as measured using the validated PROMIS-10 metric. Improved postoperative PCS scores were expected because knee arthroplasty is an effective surgical intervention to help alleviate pain and improve health-related quality of life in patients with degeneration of the knee joint [17, 18, 23, 45-47]. Prior studies aimed at defining MCID after TKA have demonstrated that 12% to 51% of patients do not experience this degree of improvement postoperatively in respect to pain and function [48, 49], similar to our data. A larger percentage of our patients might achieve MCID if the observation period was extended - physical function after TKAs can continue to improve up to two years postoperatively [50, 51], although that did not occur in our data (Figure 1). The mean preoperative PCS score in our cohorts was 40.8, almost one standard deviation from the healthy population norm of 50. If our patients had greater preoperative disability (lower PCS preoperative scores), we would expect higher clinically improvement in function (MCID gains) after TKA [17]. These results are relevant because it may imply surgeons are conducting procedures on patients with relative moderate disability.

This study has several limitations. First, although we had almost 99% inclusion rates for our operative times, LOS, and facility discharge outcomes, we did not have all the counts for postoperative PCS and BMI. These capture rates in an unfunded observational dataset are similar to the funded American Joint Replacement, Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement, and California Joint Replacement registries [18, 20, 52]. There are several potential causes for missing PCS in our registry. More recent surgeries (2015-2016) have lower follow-up rates because less time has passed. Patients with more comorbidities may also be more likely to have clinical visits and more opportunities to submit postoperative PCS, possibly skewing the results. Second, PROMIS provides a global health score which is not joint specific such as KOOS or WOMAC, possibly masking differences between the implants. Third, the cohort shows the results of

one academic institution and may not be generalizable. Fourth, most implant design changes address a specific clinical issue (ie. anterior knee pain, crepitus) or aim to improve longevity. The Attune was designed to address patella crepitus and clunk, which are not reported on our dataset. These events are rare and would need several years of multicenter data to tackle. Finally, our data collection does not extend though 10+ years to comment on longevity because the Attune was released in 2013. This is a short term review that focuses on patient reported outcomes based on knee implants. Strengths of this study include a large focus on variables rarely published or used as adjusters, such as physical function, mental function, and clinic-measured BMI, and we statistically adjusted for the time period in which postoperative PCS was captured.

5. Conclusions

Our findings reveal that the new Attune technology and implant design developments do not necessarily provide improved patient-reported outcomes compared to Sigma as measured through the PROMIS-10 physical component score. The decreased absolute length of stay has potential financial benefits, but additional studies are required before we can conclude if the implant effects LOS. With the constant struggles of adopting new technology and value-based care, we recommend that health systems consider potential effects on both outcomes and cost when evaluating new technology.

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Appendix

Appendix 1.

Associations of implant with length of surgery, in minutes (mean 96.5 minutes). A positive number is the additional minutes compared to the reference category.

Variable	Additional Min	95% CI Low	95% CI High	P-Value
Implant (ref = Sigma)				
Attune	-2.87	-6.70	0.96	0.143
Surgeon (ref = Surgeon 0)				
1	10.68	8.15	13.20	<0.001
2	20.30	14.53	26.07	<0.001
3	24.32	18.19	30.44	<0.001
4	1.70	-3.22	6.63	0.498
5	21.58	19.46	23.69	<0.001
6	-2.23	-4.55	0.10	0.060
7	29.17	24.86	33.49	<0.001
8	11.86	7.86	15.85	<0.001

Variable	Additional Min	95% CI Low	95% CI High	P-Value
9	-5.37	-8.02	-2.71	<0.001
Bilateral (ref = No)				
Yes	7.90	5.55	10.25	<0.001
Second TKA (ref = No)				
Yes	-2.60	-5.61	0.42	0.092
Year (ref=2011)				
2012	-0.81	-3.69	2.07	0.582
2013	-1.41	-4.45	1.63	0.362
2014	1.20	-1.90	4.30	0.448
2015	7.79	2.68	12.90	0.003
2016	2.28	-3.36	7.92	0.428
Sex (ref=Male)				
Female	-6.09	-7.67	-4.50	<0.001
Age Group (ref = <55)				
55-59	-2.88	-5.80	0.04	0.053
60-64	-2.32	-5.17	0.53	0.111
65-69	-2.48	-5.43	0.46	0.099
69-74	-6.18	-8.86	-3.50	<0.001
75-79	-6.28	-9.27	-3.29	<0.001
80+	-8.24	-11.41	-5.06	<0.001
Tobacco (ref = Never)				
Quit	-0.61	-2.19	0.98	0.454
Yes	-3.37	-6.51	-0.23	0.036
Charlson (ref=0)				
1	-0.01	-1.96	1.94	0.989
2+	-0.43	-2.37	1.51	0.663
BMI Group (ref= <25)				
25-29	-0.59	-3.24	2.05	0.659
30-34	-0.35	-3.08	2.39	0.804
35-39	2.02	-0.93	4.98	0.180
40+	6.65	2.84	10.45	0.001
PCS Group (ref= > 50)				
40-49	-1.33	-3.93	1.28	0.318
30-39	-1.47	-4.23	1.30	0.299
20-29	-0.33	-5.75	5.09	0.906

Uses robust standard errors and clusters on the patient due to multiple primary TKAs.

Appendix 2.

Associations of Implant with Length of Stay. Coefficient is difference in length of stay compared to the reference value, in days. A negative day is a shorter duration. All surgeries included, N=2,116 surgeries among 1,984 patients.

Variable	Days	95% CI Low	95% CI High	P-Value
Implant (ref = Sigma)				
Attune	-0.37	-0.61	-0.13	0.002
Surgeon (ref = Surgeon 0)				
1	0.37	0.13	0.61	0.003
2	-0.03	-0.38	0.32	0.873
3	-0.75	-1.17	-0.33	<0.001
4	0.17	-0.08	0.42	0.188
5	0.07	-0.13	0.26	0.501
6	0.10	-0.10	0.29	0.324
7	-0.07	-0.30	0.16	0.536
8	-0.33	-0.58	-0.08	0.010
9	0.03	-0.25	0.32	0.812
Bilateral (ref = No)				
Yes	0.70	0.50	0.89	<0.001
Second TKA (ref = No)				
Yes	-0.02	-0.22	0.18	0.853
Year (ref=2011)				
2012	-0.42	-0.66	-0.18	0.001
2013	-0.38	-0.62	-0.14	0.002
2014	-0.18	-0.45	0.10	0.207
2015	-0.64	-0.94	-0.33	<0.001
2016	-0.70	-1.05	-0.36	<0.001
Sex (ref=Male)				
Female	0.08	-0.05	0.21	0.210
Age Group (ref = <55)				
55-59	-0.03	-0.23	0.18	0.788
60-64	0.07	-0.14	0.29	0.516
65-69	0.18	-0.03	0.38	0.097
69-74	0.28	0.002	0.56	0.049
75-79	0.45	0.21	0.68	<0.001
80+	0.70	0.36	1.04	<0.001
Tobacco (ref = Never)				
Quit	0.04	-0.08	0.16	0.494
Yes	0.06	-0.18	0.31	0.607
Charlson (ref=0)				

Variable	Days	95% CI Low	95% CI High	P-Value
1	0.22	0.07	0.38	0.005
2+	0.33	0.17	0.49	<0.001
BMI Group (ref= <25)				
25-29	-0.03	-0.20	0.14	0.761
30-34	0.10	-0.13	0.32	0.399
35-39	0.15	-0.07	0.38	0.181
40+	0.38	0.12	0.64	0.004
PCS Group (ref= > 50)				
40-49	0.12	-0.02	0.27	0.100
30-39	0.40	0.22	0.58	<0.001
20-29	0.92	0.25	1.60	0.008

Appendix 3.

Associations of Implant with Extended LOS (>3 days, 21%), OR>1 indicates higher odds of longer LOS.

Variable	Odds Ratio	95% CI Low	95% CI High	P-Value
Implant (ref = Sigma)				
Attune	0.80	0.45	1.42	0.439
Surgeon (ref = Surgeon 0)				
1	2.34	1.57	3.50	<0.001
2	3.32	1.32	8.37	0.011
3	--	--	--	--
4	1.83	0.75	4.49	0.184
5	1.82	1.20	2.76	0.005
6	2.54	1.73	3.74	<0.001
7	1.06	0.55	2.03	0.868
8	1.08	0.47	2.50	0.854
9	1.50	0.85	2.66	0.164
Bilateral (ref = No)				
Yes	2.64	1.90	3.66	<0.001
Second TKA (ref = No)				
Yes	1.11	0.68	1.81	0.674
Year (ref=2011)				
2012	0.57	0.38	0.84	0.004
2013	0.58	0.39	0.88	0.009
2014	0.81	0.52	1.24	0.330
2015	0.39	0.21	0.71	0.002
2016	0.33	0.13	0.79	0.013

Variable	Odds Ratio	95% CI Low	95% CI High	P-Value
Sex (ref=Male)				
Female	1.19	0.93	1.52	0.158
Age Group (ref = <55)				
55-59	0.99	0.64	1.54	0.956
60-64	1.05	0.69	1.59	0.832
65-69	1.23	0.82	1.85	0.310
69-74	1.43	0.92	2.24	0.111
75-79	2.09	1.31	3.34	0.002
80+	2.57	1.54	4.27	<0.001
Tobacco (ref = Never)				
Quit	1.17	0.91	1.49	0.219
Yes	1.40	0.84	2.32	0.197
Charlson (ref=0)				
1	1.42	1.07	1.88	0.016
2+	1.63	1.21	2.20	0.001
BMI Group (ref= <25)				
25-29	0.75	0.47	1.18	0.213
30-34	1.03	0.64	1.66	0.895
35-39	1.13	0.68	1.86	0.637
40+	1.35	0.81	2.25	0.244
PCS Group (ref= > 50)				
40-49	1.36	0.72	2.58	0.339
30-39	2.72	1.42	5.20	0.003
20-29	3.48	1.53	7.92	0.003

-- Surgeon did have enough variation (all short LOS) and could not be calculated. Their patients remain in the model.

Uses robust standard errors and clusters on the patient due to multiple primary TKAs

Appendix 4.

Associations of implant with facility discharge (n=793, 38%). OR > 1 indicate higher odds of facility discharge

Variable	Odds Ratio	95% CI Low	95% CI High	P-Value
Implant (ref = Sigma)				
Attune	0.65	0.39	1.09	0.103
Surgeon (ref = Surgeon 0)				
1	1.57	1.04	2.36	0.030
2	1.02	0.40	2.60	0.973
3	0.28	0.04	1.89	0.192
4	2.84	1.41	5.73	0.004
5	0.87	0.58	1.31	0.504

Variable	Odds Ratio	95% CI Low	95% CI High	P-Value
6	1.05	0.73	1.51	0.807
7	1.15	0.68	1.96	0.595
8	0.64	0.30	1.38	0.254
9	1.22	0.72	2.05	0.461
Bilateral (ref = No)				
Yes	16.21	11.25	23.35	<0.001
Second TKA (ref = No)				
Yes	1.38	0.89	2.13	0.151
Year (ref=2011)				
2012	1.07	0.72	1.61	0.732
2013	1.33	0.88	2.00	0.182
2014	1.21	0.77	1.89	0.407
2015	1.06	0.59	1.91	0.843
2016	1.22	0.57	2.64	0.607
Sex (ref=Male)				
Female	2.01	1.56	2.59	<0.001
Age Group (ref = <55)				
55-59	1.48	0.88	2.48	0.136
60-64	3.19	1.95	5.22	<0.001
65-69	5.25	3.20	8.60	<0.001
69-74	8.56	5.13	14.27	<0.001
75-79	17.64	10.09	30.84	<0.001
80+	22.61	12.43	41.14	<0.001
Tobacco (ref = Never)				
Quit	0.96	0.74	1.23	0.719
Yes	1.19	0.70	2.02	0.515
Charlson (ref=0)				
1	1.37	1.02	1.84	0.036
2+	1.47	1.09	1.98	0.011
BMI Group (ref= <25)				
25-29	0.80	0.53	1.20	0.280
30-34	1.00	0.65	1.55	0.983
35-39	0.87	0.55	1.40	0.577
40+	2.67	1.63	4.36	<0.001
PCS Group (ref= > 50)				
40-49	1.44	0.90	2.30	0.129
30-39	2.60	1.57	4.30	<0.001
20-29	5.65	2.60	12.25	<0.001

Uses robust standard errors and clusters on the patient due to multiple primary TKAs.

Does not include 2 in-hospital deaths for reasons not related to the TKA.

Appendix 5.

Associations for ROM change (degrees), obtained from subtracting latest preoperative ROM from latest postoperative ROM. Includes 1158 surgeries (55%) because it requires both scores. A positive change indicates a larger improvement in ROM compared to the reference category.

Variable	ROM Change	95% CI Low	95% CI High	P-Value
Preoperative ROM (continuous)	-0.75	-0.81	-0.69	<0.001
Implant (ref = Sigma)				
Attune	2.30	-0.59	5.20	0.119
Surgeon (ref = Surgeon 0)				
1	-3.79	-6.42	-1.15	0.005
2	0.92	-3.78	5.61	0.702
3	1.10	-10.06	12.25	0.847
4	2.20	-3.07	7.47	0.413
5	2.39	-0.06	4.85	0.056
6	0.005	-2.08	2.09	0.997
7	0.46	-2.36	3.27	0.750
8	6.01	2.79	9.22	<0.001
9	-1.46	-5.04	2.13	0.425
Bilateral (ref = No)				
Yes	2.42	-0.18	5.01	0.068
Second TKA (ref = No)				
Yes	0.26	-2.16	2.69	0.830
Year (ref=2011)				
2012	-0.42	-3.60	2.77	0.797
2013	-2.72	-6.01	0.57	0.105
2014	-4.15	-7.56	-0.73	0.017
2015	-7.10	-11.08	-3.13	<0.001
2016	-12.20	-17.04	-7.37	<0.001
Sex (ref=Male)				
Female	1.84	0.42	3.26	0.011
Age Group (ref = <55)				
55-59	2.34	-0.61	5.30	0.120
60-64	3.88	1.25	6.51	0.004
65-69	3.93	1.32	6.54	0.003
69-74	4.02	1.27	6.77	0.004
75-79	3.97	1.00	6.93	0.009
80+	4.02	0.98	7.06	0.010
Tobacco (ref = Never)				
Quit	0.52	-0.92	1.95	0.482

Variable	ROM Change	95% CI Low	95% CI High	P-Value
Yes	2.20	-0.52	4.91	0.113
Charlson (ref=0)				
1	-0.24	-1.92	1.44	0.781
2+	-0.84	-2.57	0.89	0.340
BMI Group (ref= <25)				
25-29	-0.06	-2.43	2.31	0.961
30-34	-1.80	-4.36	0.77	0.170
35-39	-0.33	-3.01	2.34	0.807
40+	-1.57	-4.60	1.45	0.307
PCS Group (ref= > 50)				
40-49	0.40	-2.13	2.94	0.755
30-39	0.52	-2.22	3.26	0.709
20-29	3.73	-0.48	7.94	0.082

Uses robust standard errors and clusters on the patient to account for multiple primary TKAs

Appendix 6.

Associations for clinically significant physical function improvement (>5 pts PCS post-op compared to pre-op). Includes 1791 surgeries (85%) because it requires both scores. An OR>1 indicates higher odds of clinically significant improvement compared to the reference category.

Variable	OR	95% CI Low	95% CI High	P-Value
Implant (ref = Sigma)				
Attune	0.84	0.54	1.30	0.435
Surgeon (ref = Surgeon 0)				
1	0.70	0.49	1.02	0.061
2	0.90	0.41	1.98	0.797
3	1.52	0.44	5.31	0.509
4	0.42	0.21	0.85	0.016
5	0.66	0.48	0.92	0.014
6	0.73	0.52	1.01	0.058
7	0.37	0.20	0.69	0.001
8	1.09	0.63	1.90	0.756
9	0.64	0.41	1.01	0.053
Bilateral (ref = No)				
Yes	1.45	0.99	2.15	0.059
Second TKA (ref = No)				
Yes	0.79	0.53	1.19	0.258
Year (ref=2011)				
2012	1.73	1.17	2.55	0.006
2013	1.47	0.99	2.18	0.059

Variable	OR	95% CI Low	95% CI High	P-Value
2014	1.47	0.96	2.28	0.082
2015	1.72	0.99	2.99	0.055
2016	1.37	0.66	2.83	0.399
Sex (ref=Male)				
Female	1.20	0.97	1.49	0.097
Age Group (ref = <55)				
55-59	1.22	0.83	1.79	0.319
60-64	1.23	0.85	1.78	0.267
65-69	1.38	0.96	1.99	0.085
69-74	1.51	1.01	2.26	0.046
75-79	1.62	1.30	2.56	0.036
80+	1.20	0.74	1.97	0.458
Tobacco (ref = Never)				
Quit	0.85	0.68	1.05	0.136
Yes	0.82	0.54	1.27	0.380
Charlson (ref=0)				
1	0.71	0.55	0.92	0.010
2+	0.73	0.56	0.95	0.019
BMI Group (ref= <25)				
25-29	1.26	0.86	1.83	0.233
30-34	1.11	0.75	1.64	0.613
35-39	0.78	0.51	1.18	0.237
40+	0.72	0.46	1.12	0.143
PCS Group (ref= > 50)				
40-49	4.83	3.21	7.25	<0.001
30-39	9.54	6.09	14.95	<0.001
20-29	35.27	16.09	77.32	<0.002
Post-Op PCS Collection Period (ref = 1-45 Days)				
46-299	2.64	1.76	3.97	<0.001
300-420	4.14	2.73	6.29	<0.001
421+ Days	3.51	2.23	5.53	<0.001

Uses robust standard errors and clusters on the patient to account for multiple primary TKAs

Appendix 7.

Associations with implant for absolute change in PCS score. Includes 1791 (85%) of possible TKAs due to requiring both pre- and post-operative scores. A positive value indicates a greater improvement compared to the reference.

Variable	Additional PCS Improvement Score	95% CI Low	95% CI High	P-Value
Implant (ref = Sigma)				
Attune	0.12	-1.23	1.47	0.864
Surgeon (ref = Surgeon 0)				
1	-0.17	-1.39	1.05	0.787
2	1.38	-0.90	3.66	0.236
3	0.90	-3.04	4.84	0.655
4	-1.62	-3.63	0.40	0.116
5	-0.83	-1.88	0.22	0.121
6	-0.53	-1.54	0.49	0.312
7	-1.58	-3.40	0.25	0.091
8	0.39	-1.20	1.98	0.628
9	-1.01	-2.42	0.40	0.160
Bilateral (ref = No)				
Yes	1.32	0.05	2.58	0.042
Second TKA (ref = No)				
Yes	-0.98	-2.20	0.24	0.116
Year (ref=2011)				
2012	1.89	0.61	3.17	0.004
2013	0.89	-0.43	2.21	0.185
2014	0.62	-0.76	2.01	0.378
2015	1.01	-0.74	2.76	0.257
2016	0.86	-1.38	3.11	0.452
Sex (ref=Male)				
Female	0.93	0.26	1.60	0.006
Age Group (ref = <55)				
55-59	0.36	-0.92	1.64	0.583
60-64	0.03	-1.20	1.27	0.958
65-69	0.14	-1.07	1.34	0.826
69-74	0.36	-0.94	1.66	0.583
75-79	1.00	-0.51	2.52	0.195
80+	-0.06	-1.61	1.50	0.943
Tobacco (ref = Never)				
Quit	-0.67	-1.35	0.01	0.055
Yes	-0.97	-2.45	0.52	0.201

Variable	Additional PCS Improvement Score	95% CI Low	95% CI High	P-Value
Charlson (ref=0)				
1	-0.88	-1.70	-0.06	0.036
2+	-1.31	-2.13	-0.49	0.002
BMI Group (ref= <25)				
25-29	0.47	-0.67	1.61	0.422
30-34	-0.02	-1.21	1.18	0.981
35-39	-0.59	-1.91	0.72	0.374
40+	-0.79	-2.14	0.56	0.250
PCS Group (ref= > 50)				
40-49	5.32	4.05	6.59	<0.001
30-39	8.75	7.40	10.11	<0.001
20-29	12.84	10.64	15.03	<0.001
Post-Op PCS Collection Period (ref = Post 1-45 Days)				
46-299	3.32	2.24	4.40	<0.001
300-420	5.42	4.29	6.55	<0.001
421+ Days	4.91	3.61	6.22	<0.001

Uses robust standard errors and clusters on the patient due to multiple primary TKAs.

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Figure 1.
Mean physical component score (PCS) from preoperative to postoperative time periods.
Capture counts per implant identified within time periods

Table 1.

Unadjusted Comparisons of Sigma and Attune implants (N=2,116)

Variable	Sigma (n=1,603; 76%)		Attune (n=513, 24%)		P-Value
	n	%	n	%	
Surgeon (ref = Surgeon)	356	22	198	39	<0.001
2	347	22	0	0	
3	7	<1	38	7	
4	0	0	12	2	
5	5	<1	57	11	
6	259	16	67	13	
7	388	24	25	5	
8	93	6	15	3	
9	3	<1	101	20	
10	145	9	0	0	
Bilateral (ref = No)	1201	75	439	86	<0.001
Yes	402	25	74	14	
Second TKA? (ref=No)	1511	94	471	92	0.048
Yes	92	6	42	8	
Year (ref =2011)	269	17	0	0	<0.001
2012	439	27	0	0	
2013	497	31	0	0	
2014	303	19	87	17	
2015	89	6	261	51	
2016	6	<1	165	32	
Sex (ref=Male)	673	42	236	46	0.109
Female	930	58	277	54	
Race/Ethnicity (ref = Non-Hispanic White)	1572	98	50	98	0.571
Yes	31	2	12	2	
Mean Age (SD)	65.50 (9.88)		66.11 (9.72)		0.223
Age Group (ref= <55)	228	14	55	11	0.451
55-59	234	15	79	15	
60-64	294	18	92	18	
65-69	320	20	118	23	
70-74	244	15	78	15	
75-80	164	10	50	10	
80+	119	7	41	8	
Tobacco Use (ref=Never)	736	47	249	49	0.102
Quit	715	45	239	47	
Passive	7	<1	1	<1	
Yes	118	7	23	4	

Variable	Sigma (n=1,603; 76%)		Attune (n=513, 24%)		P-Value
	n	%	n	%	
Charlson (ref=0)	939	59	273	53	0.082
1	334	21	115	22	
2+	330	21	125	24	
Mean BMI (SD)	32.80 (7.93)		31.70 (6.10)		0.006
BMI Group (ref= <25)	164	14	61	13	0.009
25-29	360	30	151	32	
30-34	263	22	132	28	
35-39	220	18	83	17	
40+	200	17	51	11	
Next Knee Surgery within 30 days of primary TKA? (ref = No)	1598	100	509	99	0.156
Yes	5	<1	4	1	
Next Knee Surgery within 90 days of primary TKA? (ref = No)	1596	100	508	99	0.158
Yes	7	<1	5	1	
Laterality among Unilaterals (ref = Left)	559	47	208	48	0.826
Right	628	53	228	52	

Table 2:

Unadjusted variables comparing Sigma and Attune implants

Variable	Sigma	Attune	P-Value
Length of surgery (SD)	95.4 (21.2)	97.7 (17.8)	0.029
Length of stay (SD)	3.15 (1.56)	2.23 (1.12)	<0.001
Discharged to facility (%)	663 (41%)	130 (25%)	<0.001
Number of reoperation (%)	5 (0.3%)	5 (1.0%)	0.158
PCS Score (SD)	40.27 (6.12)	41.38 (6.52)	0.001
Mean PCS change (SD)	6.80 (7.63)	4.85 (7.32)	<0.001
PCS change >5pts (%)	792 (59%)	217 (49)	<0.001
Preoperative Mean ROM (Degrees) (SD)	107.5° (13.8) (n=862)	109.1° (13.8) (n=386)	0.066
Postoperative ROM (Degrees) (SD)	110.4° (12.6) (n=1145)	109.7° (12.5) (n=415)	0.303
ROM Change (Degrees) (SD)	+2.1° (15.7) (n=822)	−0.1° (16.9) (n=336)	0.031

* For percent change, based on Sigma (n=1,603; 76%) and Attune (n=513, 24%)

Table 3:

Adjusted variables comparing Sigma and Attune implants

Variable		95% CI Low	95% CI High	P-Value
Length of surgery	Minutes: -2.87	-6.7	0.96	0.143 [*]
Length of stay (LOS)	Days: -0.37	-0.61	-0.13	0.002 [¥]
Extended LOS	OR: 0.8	0.45	1.42	0.439 [§]
Facility discharge	OR: 0.65	0.39	1.09	0.103 [^]
MCID PCS improvement	OR:0.84	0.54	1.3	0.435 [❖]
Absolute PCS improvement	Score: +0.12	-1.23	1.47	0.864 [□]
Range of motion	Degrees: 2.3	-0.59	5.2	0.119 [†]

All values are Attune relative to reference Sigma.

^{*} Associations of implant with length of surgery, in minutes (mean 96.5 minutes). A positive number is the additional minutes compared to the reference category.

[¥] Associations of implant with length of stay. Coefficient is difference in length of stay compared to the reference value, in days. A negative day is a shorter duration. All surgeries included, N=2,116 surgeries among 1,984

[§] Associations of implant with extended LOS (>3 days, 21%), OR>1 indicates higher odds of longer LOS.

[^] Associations of implant with facility discharge (n=793, 38%). OR > 1 indicate higher odds of facility discharge.

[❖] Associations for clinically significant physical function improvement (>5 pts PCS post-op compared to pre-op). Includes 1791 surgeries (85%) because it requires both scores. An OR>1 indicates higher odds of clinically significant improvement compared to the reference category.

[□] Associations with implant for absolute change in PCS score. Includes 1791 (85%) of possible TKAs due to requiring both pre- and post-operative scores. A positive value indicates a greater improvement compared to the reference.

[†] Associations of implant for ROM change (degrees), obtained from subtracting latest preoperative ROM from latest postoperative ROM. Includes 1158 surgeries (55%) because it requires both scores. A positive change indicates a larger improvement in ROM compared to the reference category.