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**Modern femoral component design in total knee arthroplasty shows a lower patellar contact force during knee flexion compared to its predecessor**

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## Abstract

### *Background*

The relationship between the femoral component design in total knee arthroplasty (TKA) and the patellofemoral contact force, as well as the soft tissue balance, has not been well reported thus far.

### *Methods*

Twenty-eight mobile-bearing posterior-stabilised (PS) TKAs using the traditional model (PFC Sigma) and 27 mobile-bearing PS TKAs using the latest model (Attune) were included. Surgeries were performed using the measured resection technique assisted with the CT-based free-hand navigation system. After all the trial components were placed, patellar contact forces on the medial and lateral sides were measured using two uniaxial ultrathin force transducers with the knee at 0°, 10°, 30°, 60°, 90°, 120°, and 135° of flexion. The joint component gap and the varus ligament balance of the femorotibial joint were also measured. The non-paired Student t test was conducted to compare the values of the two groups.

### *Results*

The medial patellar contact force was significantly lower for Attune group than for PFC Sigma group at 120° of knee flexion ( $P = 0.0058$ ). The lateral patellar contact force was also significantly lower for Attune group than PFC Sigma group at 120° and 135° of knee flexion ( $P = 0.0068$  and  $P = 0.036$ ). The joint component gap, as well as the varus ligament balance, showed no statistically significant difference between the two groups.

### *Conclusions*

Reduced thickness and width of the anterior flange of the femoral component in the Attune may play a role in low patellar contact force.

**Keywords:** total knee arthroplasty; patellar contact force; soft tissue balance; femoral component design; Attune; PFC Sigma

## 1. Introduction

It has been reported that up to one in five patients continue to suffer from pain after Total knee arthroplasty (TKA) [1]. In some cases, the aetiology and pathogenesis of the pain have not been well understood, while patellofemoral maltracking, patellar tilt, and patellofemoral overstuffing have been reported as potential pain generators [2, 3]. Adequate treatment of the patellofemoral joint is one important aspect of TKA, and to address the problem, the number of TKA systems available on the orthopaedic market has substantially increased. From the patellofemoral point of view, the main goals of implant design are to aid in allowing neutral patellofemoral congruence throughout the knee's arc of motion as well as centralising the patella [4]. Because early designs in TKA focused only on the tibiofemoral articulation, higher rates of patellar instability were reported [5].

DePuy Synthes, a Johnson & Johnson Professional manufacturer of artificial knee implants, released the Press-Fit Condylar (PFC) Sigma in 1996 (DePuy Synthes, Warsaw, IN) based on the manufacturer's previous PFC system (Johnson & Johnson, Raynham, MA) which was introduced over 35 years ago, with a modified femoral component design for improved patellar tracking [6]. Design features of the PFC Sigma included modularity to increase intraoperative adaptability, an updated femoral coronal geometry, and a prolonged trochlear groove to improve patellar tracking beyond 90° of flexion. In recent years, several studies have investigated the functional outcome of the PFC Sigma knee systems [7-9], showing satisfactory midterm results. Unfortunately, however, anterior mechanism-related complications have been reported with an incidence of up to 21% by authors including the implant's designers [10, 11].

To improve patient satisfaction, functional outcomes, stability as well as operating room efficiency, the most recent design evolution, the Attune Primary Total Knee System (DePuy Synthes, Warsaw, IN) which is a modified version of the PFC Sigma, was released in 2013 by the same company. It has several design features which include extreme modularity (14 left and right femoral sizes, 10 tibial sizes), 1 mm tibial insert increments, a reduced intercondylar box-height ratio ( $<0.7$ ) thanks to distally extended trochlear groove, and a reduced femoral component profile, i.e., a thinner and narrower anterior trochlear flange of the femoral component than the PFC Sigma design, to offer greater functional benefits and a greater range of movement. It was

88 specially developed to more closely resemble the anatomical trochlear groove as  
89 patellofemoral maltracking, tilt, and overstuffing are important factors leading to  
90 pain and thus to unsatisfying results [12].

91  
92 Anterior knee pain after TKA has been reported in as many as 45% of patients [13, 14],  
93 and was reported to be related to high patellofemoral contact force [15, 16]. It must  
94 be recognised that the PFC Sigma knee implant has been historically related to a  
95 higher incidence of extensor mechanism complications if compared to different  
96 systems [10], and the design modifications to the femoral compartment in the Attune  
97 system might have affected the postoperative patellar contact force. Reducing the  
98 thickness and width of the anterior flange of the femoral component in the Attune  
99 may reduce the overall extensor mechanism and retinacular tension, which can lower  
100 the contact force between the trochlea and the patella. Previous studies have been  
101 published on improved anterior knee pain in the Attune compared with the PFC  
102 Sigma [2, 3, 17], however, to date, the results of these efforts to decrease the patellar  
103 contact force with implant design changes have not been well reported.

104  
105 In this study, to this end, patellar contact force was measured in knees with the PFC  
106 Sigma and the Attune. Because previous cadaver and clinical studies showed that the  
107 patellar contact forces on the medial and lateral sides were different [18, 19], the  
108 patellar contact force was measured at both the medial and lateral sides. The  
109 intraoperative soft tissue balance assessed by the tensor, including the component  
110 gap and the varus ligament balance, was also examined as the importance of  
111 intraoperative soft tissue balance on the patellofemoral joint has been reported as  
112 well. The study hypothesised that modifications of the femoral component design of  
113 the Attune system would lead to a decreased patellar contact force compared with  
114 the PFC Sigma system, without any difference in the intraoperative soft tissue  
115 balance between the two systems.

## 2. Materials and methods

This study was approved by the institutional review board of the authors' affiliated institutions, and informed consent was obtained from all the patients. The inclusion criteria were substantial pain and loss of function due to varus-type osteoarthritis of the knee. To make a fair assessment and minimise the influence of clinical variables, exclusion criteria included valgus deformity of the knee, severe bony defects requiring bone graft or augmentation, revision TKA, and active knee joint infection. In addition to the knee condition, patients who agreed to participate were included in the study.

Twenty-eight consecutive TKA cases (28 patients; 25 women, three men) between April 2013 and December 2013 met the above criteria for mobile-bearing PS TKA using the PFC Sigma, and they were compared with 27 consecutive TKA cases (27 patients; 24 women, three men) between May 2016 and February 2017 which met the above criteria for mobile-bearing PS TKA using the Attune. All TKAs were performed using the computed tomography (CT)-based free-hand navigation system (Vector Vision, DePuy-BrainLAB, Heimstetten, Germany) by two senior authors (T.M. and K.T.), both with an experience of >10 years with TKA. The two study groups were not matched preoperatively, however, there were no statistical differences in patient demographics between the two groups. Patient demographics, pre-and postoperative range of motion of the knee, and hip-knee-ankle angle (HKA) of each group are shown in Table 1.

### *Operative procedure and intraoperative measurement*

All surgeries in both groups were performed using the measured resection technique. Firstly, two minimally invasive reference arrays were implanted on screws in the distal femur and proximal tibia. After inflating the air tourniquet to a pressure of 250 mm Hg, the knees were exposed with the medial parapatellar approach. For kinematic referencing, the detection of the kinematic centre of the hip was performed with controlled movement. For registration, the centre of the distal femur, medial/lateral epicondyle, anterior cortex point, Whiteside's line, tracing medial/lateral condyle and anterior femoral cortex, medial/lateral malleolar, centre of the proximal tibia, medial/lateral tibial contour point, tibial anteroposterior direction, and tracing tibial plateau were recorded. When the monitor screen showed the leg as defined and the planned implant size and orientation after the registration and verification of the tibia

and femur in both the coronal and sagittal planes, the surgeon fixed the classical cutting block to the desired orientation, which was guided by the system. The anterior and posterior cruciate ligaments were sacrificed before the bony resections. A distal femoral osteotomy was performed perpendicular to the femoral mechanical axis according to the planned resection height and angle on the navigation system. After the procedure, a proximal tibial osteotomy was performed in the same way, ensuring that each cut was made perpendicular to the mechanical axis in the coronal plane, with 3° of posterior inclination along the sagittal plane and 10 mm below the highest point of the articular cartilage on the lateral tibial plateau. After removal of osteophytes and appropriate release of medial soft tissue were performed, the extension gap was checked using a standard rectangular block and residual lateral laxity was permitted [20]. After confirmation of the neutral alignment of the knee with the spacer block and alignment rod, the size of the femoral component and amount of the posterior femoral osteotomy were planned. The femoral rotation angle was targeted to the surgical trans-epicondylar axis, and the bony resections were performed after virtual planning on the screen. If osteophytes were present on the posterior aspect of the femur, they were removed. Following each bony resection, a knee balancer (Ligament Sensor Tensor, DePuy Synthes, Warsaw, IN) which distracted the medial and lateral gaps with a spring tensioning force of 150 Nm was fixed to the tibia and the femoral trial prosthesis was placed [19]. The PF joint was repaired by temporarily suturing the portion of the medial parapatellar arthrotomy. The soft tissue balance of the femorotibial joint, including the joint component gap (the distance between the seesaw plate and cut tibial surface) and the varus ligament balance, was subsequently measured with the knee at 0°, 10°, 30°, 60°, 90°, 120°, and 135° of flexion guided by the navigation system. During each recording, the thigh and crus were aligned in the sagittal plane to eliminate the external load on the knee. At the time of patellar resurfacing, the bone resection thickness of the patella was adjusted to that of the patellar component being placed. To obtain better tracking, the patellar component was placed medially and the remaining lateral edge was trimmed and resected. After all bony resections, the patellar contact force was measured medially and laterally using two uniaxial ultrathin (100 µm) force transducers (FlexiForce; Nitta Corporation, Osaka, Japan). Two FlexiForce devices were placed side by side between a trial component of the patella and a metal plate fixed to the patellar osteotomy surface, as previously reported [19] (Figure 1). In assessing the patellar contact force, the medial parapatellar arthrotomy was repaired by suturing with more than five stitches. The real-time assessment of the patellar

contact force was performed at 0°, 10°, 30°, 60°, 90°, 120°, and 135° of knee flexion, guided by the navigation system. After all the prostheses were implanted, no lateral retinacular release was needed in all the cases based on the assessment of patellar tracking.

#### *Statistical analyses*

All measurements were expressed as the mean  $\pm$  standard error of the mean. The non-paired Student *t*-test was utilised to compare the medial and lateral patellar contact force, the component gap, and the varus ligament balance of PFC Sigma group and those of Attune group at each flexion angle. To determine the intra-observer and inter-observer reliability of the measurements of the patellar contact force, two investigators (T.M. and K.T.) assessed the first 10 patients twice and calculated intra-class correlation coefficients (ICCs). The ICCs for intra-observer reliability were  $>0.82$  (range, 0.82–1.00) and those for inter-observer reliability were  $>0.84$  (range, 0.84–0.96) for all measurements. A *p* value of  $<0.05$  was considered statistically significant. Data analyses were performed using BellCurve for Excel (Social Survey Research Information Co., Ltd., Tokyo, Japan). In a pilot study, a power analysis indicated that 27 patients in each group would be required using G\*Power 3.121 when power was set at 0.8 and alpha was set as 0.05.



### 3. Results

The medial patellar contact force was significantly lower for Attune group (mean, 0.6 kgf) than for PFC Sigma group (mean, 1.5 kgf) at 120° of knee flexion ( $p = 0.0058$ ; Table 2 and Figure 2). The lateral patellar contact force was also significantly lower at 120° and 135° of knee flexion for Attune group (mean, 3.3 kgf at 120° of knee flexion and 5.8 kgf at 135° of knee flexion) than for PFC Sigma group (mean, 7.2 kgf at 120° of knee flexion and 9.4 kgf at 135° of knee flexion) ( $p = 0.0068$  (120°) and  $p = 0.036$  (135°); Table 2 and Figure 3). At the other flexion angles, the medial and lateral patellar contact force showed no significant differences between the two groups.

There was no statistically significant difference between PFC Sigma group and Attune group in the joint component gap as well as the varus ligament balance (Table 3).

#### 4. Discussion

The goal of this study was to examine the patellar contact force in traditional and modern femoral component design by comparing the PFC Sigma with the Attune. Patellar contact force was significantly lower especially on the lateral side in Attune group compared with PFC Sigma group.

The PFC Sigma was one of the most used prostheses in primary TKA, and it boasts a “J curve” femoral design (three different tangential radius curves in sagittal profile), single radius curve in coronal profiles, and refined edges of the femoral box and trochlear groove. Although very good survival rates after long-term follow up were reported, the PFC Sigma has been associated with relatively high rates of patellofemoral crepitus and anterior knee pain, which was thought to have contributed to patients’ dissatisfaction after TKA [3, 12]. The theoretical advantages of the Attune suggested by the provider are increased conformity between the femoral component and the polyethylene insert with a gradually reducing femoral radius, an innovative s-curve design of the posteriorly stabilised cam for gradual femoral rollback and stability, an extensive range of sizes for a diverse population, an improved polyethylene insert locking mechanism and incorporation of an antioxidant polyethylene insert. Besides, the provider focused on the optimisation of the patellofemoral tracking, thus the Attune knee system was designed to provide a higher degree of anatomical conformity regarding the trochlear groove and patella [2, 3, 21]. A recent study has demonstrated a 3° flatter trochlear groove in the Attune compared with the PFC Sigma [12, 22]. These modifications have improved the radii of curvature in the coronal plane and replicated an anatomic trochlear groove in early and mid-flexion to ensure the stability of the patella within the groove during the range of motion [12]. A higher degree of anatomic concordance could be the reason for the low patellar contact force in Attune group in the current study.

Patellofemoral kinematics including patellofemoral maltracking, tilt, and overstuffing are important issues after TKA and anterior knee pain after TKA was reported to be related to high patellofemoral contact force [15, 16, 23]. Also, abnormal patellar tracking after TKA can lead to crepitation, an overload to the polyethylene implants, and abnormal implant wear [24, 25]. This highlights the importance of femoral component design in determining patella kinematics, and factors such as trochlear groove geometry have been shown to play a major role in it [22, 26]. MacIntyre et al.

examined patients with anterior knee pain and healthy individuals and found a higher lateral tilt in the symptomatic group [27]. We found lower patellar contact force especially on the lateral side in Attune group compared with PFC Sigma group, which can increase the advantage of the Attune. Also, Martin et al. reported that a significant decrease in the incidence of patellar crepitus was observed in patients implanted with the Attune vs the PFC Sigma PS-TKA, and mentioned that it was likely related to specific implant design changes in the patellofemoral articulation, including a reduced intercondylar box ratio as well as reduced thickness and width of the anterior flange of the femoral component [2]. Although a relationship between the incidence of patellar crepitus and patellar contact force is unclear, it may partially support our current results.

Appropriate soft tissue balance is well known as an important factor for the success of TKA. In this study, the intraoperative soft tissue balance of the femorotibial joint throughout the range of motion, including the joint component gap and the varus ligament balance, was similar to the pattern previously reported by Matsumoto et al. [19], i.e., the component gap increased toward flexion and then decreased toward deep flexion, and the varus balance was maintained. They also reported that a reduced lateral patellar contact force was related to the lateral laxity at flexion and high postoperative flexion angle in mobile-bearing PS TKA [19]. As the tightness at the lateral side of the femorotibial joint closely relates to the tightness in the patellofemoral joint, lateral laxity at the femorotibial joint might be important for reducing lateral patellar contact force. In the current study, no statistically significant difference between PFC Sigma group and Attune group in the soft tissue balances was found, thus it was not supposed to be the reason for the difference in the patellar contact force between the two groups.

Some studies are comparing the clinical outcomes after TKA with the use of the PFC Sigma and the Attune. Carey et al. compared the outcomes after TKAs with the PFC sigma and those with the Attune knee systems in 21 patients who each have a prosthesis in opposite knees, and there was a significant difference in pre- to 6-month postoperative outcomes in two groups concerning improvement in range of motion, WOMAC, Oxford Knee and SF-12 Scores [12]. Song et al. compared 300 TKAs using Attune and 300 TKAs using the PFC Sigma and described that the Knee Society Knee Score and range of motion of the Attune group were better than those of the PFC Sigma group around two years postoperatively [28]. Indelli et al. reported that a

statistically significant decrease in postoperative anterior knee pain and deeper postoperative knee flexion were shown in a consecutive group of 100 patients undergoing TKA using the Attune matched by age, gender, body mass index to 100 patients having the PFC Sigma [17]. The influence of patellar contact force on the clinical outcomes should be investigated in future studies, as no study has directly assessed the relationships between them thus far.

Our study had some limitations. Firstly, the patellar contact force and the kinematics were measured under anaesthesia in this study. Future studies should be conducted to compare these values of the implanted knee between under anaesthesia and during daily living activities. Secondly, in assessing the patellar contact force, the medial capsule was repaired as tightly as possible by suturing with more than five stitches, however, skin and capsule closure methods may influence the patellar contact force. Thirdly, the relationship between the patellar contact force and femorotibial joint kinematics which affect patellofemoral tracking was not evaluated. Appropriate lateral laxity was reported to be important for appropriate patellar tracking [19], and the intraoperative soft tissue balance of the femorotibial joint kept varus balance and acquired the appropriate lateral laxity throughout the knee range of motion in the present study though. Fourthly, the two study groups were not matched preoperatively although there were no statistical differences in patient demographics between them. Fifthly, only mobile-bearing TKAs were evaluated and compared in this study. The results could be different in fixed-bearing TKAs, as the patellar contact force was reported to be lower with mobile-bearing insert than with fixed-bearing insert on both medial and lateral side [29]. Sixthly, this study is only an intraoperative evaluation and we have not measured clinical outcomes such as Knee Society Knee Score or Oxford Score. Lastly, we have not measured subjective outcomes including anterior knee pain and patient satisfaction in this series.

## 5. Conclusions

The present study indicated that the patellar contact force was significantly lower, especially on the lateral side in patients using the Attune than in patients using the PFC Sigma at knee flexion, whereas no significant difference in the intraoperative soft tissue balance between the two groups was found. Reduced thickness and width of the anterior flange of the femoral component in the Attune may play a significant role in low patellar contact force, which can help patients to achieve a higher degree of postoperative satisfaction through better patellar kinematics.

340 **Conflict of interest**

341 The authors have declared no conflict of interest.

342

343 **Ethical approval**

344 The study was approved by the Review Board at our institution.

345

346 **Funding**

347 None declared.

348

349

## **Legends to Figures**

### **Figure 1**

The patellar contact force was measured medially and laterally using two uniaxial ultrathin (100  $\mu\text{m}$ ) force transducers (FlexiForce; Nitta Corporation, Osaka, Japan). Two FlexiForce devices were placed side by side between a trial component of the patella and a metal plate fixed to the patellar osteotomy surface.

### **Figure 2**

Medial patellar contact force showed increased value with flexion both in Attune group and PFC Sigma group. PFC Sigma group showed significantly higher values compared with Attune group at 120 degrees of flexion ( $p < 0.05$ ).

### **Figure 3**

Lateral patellar contact force showed increased value with flexion both in Attune group and PFC Sigma group. PFC Sigma group showed significantly higher values compared with Attune group at 120 and 135 degrees of flexion ( $p < 0.05$ ).

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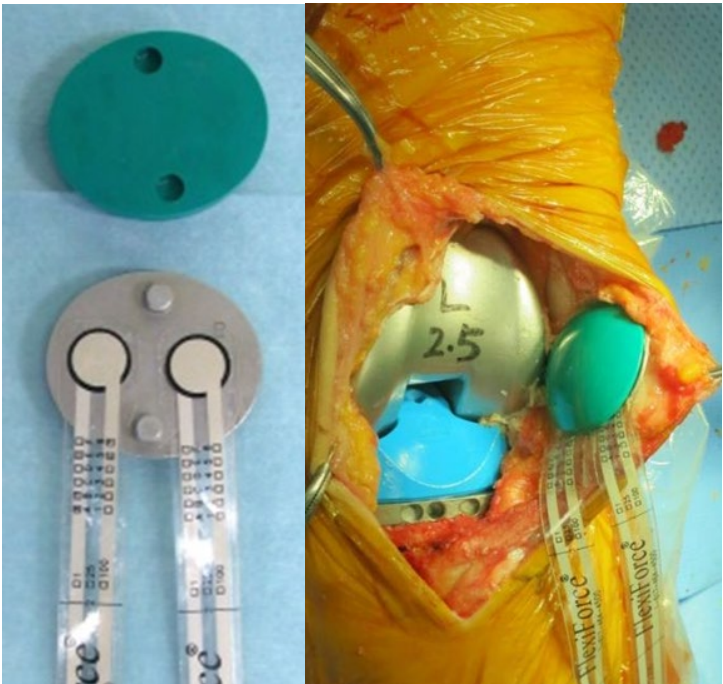
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1 **Figure 1**

2

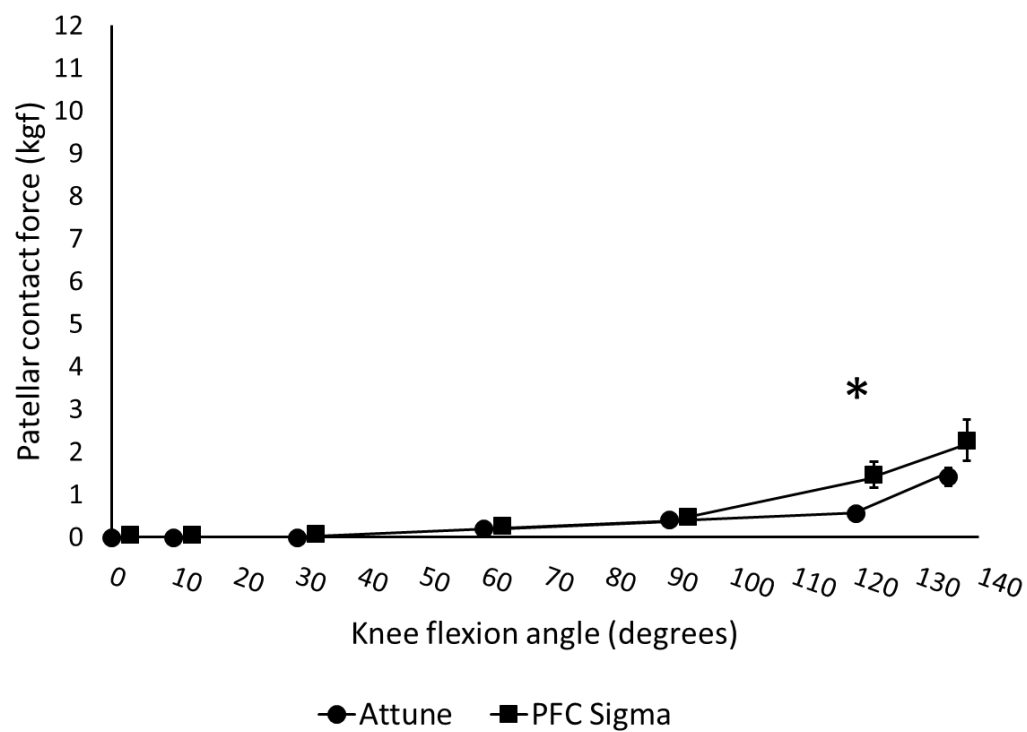
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1    **Figure 2**

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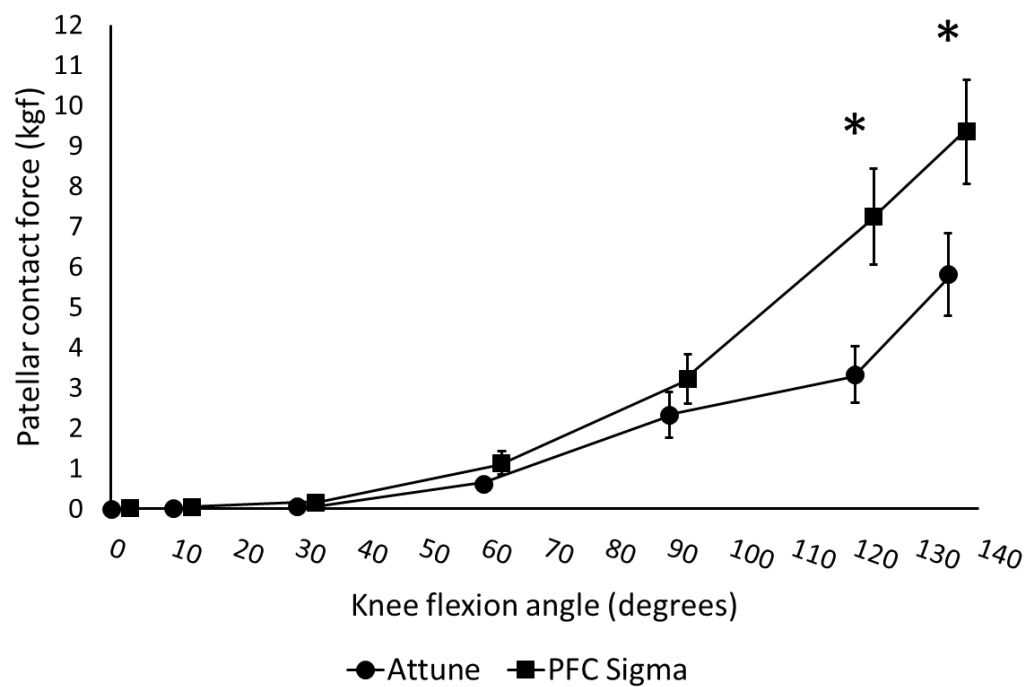


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1    **Figure 3**

2



3

**Table 1**

Comparison of patient demographics, pre- and postoperative range of motion of the knee and hip-knee-ankle angle (HKA) between our study groups

SEM: standard error of the mean

	<b>Attune (n=27)</b>	<b>PFC Sigma (n=28)</b>	<b>p value</b>
<b>Gender (M/F) (n)</b>	3/24	3/25	0.962
<b>Age (years), mean (range)</b>	77.1 (65-85)	79.1 (66-88)	0.224
<b>Extension (°), mean (SEM)</b>			
<b>Preoperative</b>	-5.9 (1.3)	-6.3 (1.1)	0.847
<b>Postoperative</b>	-0.9 (0.4)	-0.9 (0.4)	0.956
<b>Flexion (°) , mean (SEM)</b>			
<b>Preoperative</b>	123.5 (2.2)	125.7 (2.7)	0.538
<b>Postoperative</b>	121.5 (1.8)	123.4 (1.8)	0.452
<b>HKA angle (°) , mean (SEM)</b>			
<b>Preoperative</b>	7.4 (1.1)	6.9 (1.3)	0.747
<b>Postoperative</b>	1.1 (0.4)	1.1 (0.4)	0.956

**Table 2**

Medial and lateral patellar contact force

\*:  $P < 0.05$

SEM: standard error of the mean

	Attune (n=27)	PFC sigma (n=28)	p value
<b>Medial patellar contact force (kgf), mean (SEM)</b>			
Knee flexion angle			
0°	0.0 (0.0)	0.0 (0.0)	0.331
10°	0.0 (0.0)	0.1 (0.1)	0.331
30°	0.0 (0.0)	0.1 (0.1)	0.15
60°	0.2 (0.0)	0.3 (0.1)	0.54
90°	0.4 (0.1)	0.5 (0.1)	0.666
120°	0.6 (0.1)	1.5 (0.3)	0.0058*
135°	1.4 (0.2)	2.3 (0.5)	0.114
<b>Lateral patellar contact force (kgf), mean (SEM)</b>			
Knee flexion angle			
0°	0.0 (0.0)	0.0 (0.0)	0.331
10°	0.0 (0.0)	0.0 (0.0)	0.694
30°	0.1 (0.0)	0.1 (0.0)	0.099
60°	0.6 (0.1)	1.1 (0.3)	0.098
90°	2.3 (0.6)	3.2 (0.6)	0.299
120°	3.3 (0.7)	7.2 (1.2)	0.0068*
135°	5.8 (1.0)	9.4 (1.3)	0.036*

**Table 3**

Intraoperative tibiofemoral soft tissue balance showed no significant difference between the two groups

SEM: standard error of the mean

	Attune (n=27)	PFC sigma (n=28)	p value
<b>Joint component gap (mm) , mean (SEM)</b>			
Knee flexion angle			
0°	9.7 (0.2)	9.5 (0.4)	0.758
10°	11.7 (0.4)	11.4 (0.5)	0.631
30°	13.5 (0.5)	13.2 (0.4)	0.677
60°	14.0 (0.6)	13.8 (0.5)	0.848
90°	14.3 (0.5)	14.3 (0.3)	0.918
120°	14.1 (0.5)	14.1 (0.3)	0.903
135°	13.6 (0.5)	13.4 (0.4)	0.855
<b>Varus ligament balance (°) , mean (SEM)</b>			
Knee flexion angle			
0°	1.1 (0.4)	1.0 (0.4)	0.885
10°	1.6 (0.4)	1.4 (0.4)	0.784
30°	1.8 (0.5)	1.6 (0.4)	0.706
60°	1.8 (0.5)	1.6 (0.6)	0.853
90°	1.9 (0.5)	1.7 (0.5)	0.796
120°	2.4 (0.4)	2.1 (0.6)	0.662
135°	2.8 (0.4)	2.6 (0.7)	0.813