



## Original Research

## Short-term Functional Outcomes and Complications of Custom Patellofemoral Arthroplasty

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## ABSTRACT

**Background:** Patellofemoral arthroplasty (PFA) is a treatment option for isolated patellofemoral arthritis. Custom PFA is an innovative procedure utilizing patient-specific instrumentation. The purpose of this study is to evaluate short-term functional outcomes and complications of the custom PFA in treatment of isolated patellofemoral arthritis.

**Methods:** A retrospective study was conducted to analyze patients who received a PFA operation from a single surgeon. Inclusion criteria were surgical patients from 2012 to 2018 who underwent PFA using a custom prosthesis implant. Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) and Lower Extremity Functional Scale (LEFS) were collected before and after surgery.

**Results:** A total of 79 patients (94 knees) participated in the study; 55 (69.6%) were women. The median age was 57 at the time of index arthroplasty; 15 patients (30 knees) were bilateral. Follow-up rate was 94%. Median follow-up duration was 3.6 years (2–8.9). Overall prefunctional and postfunctional scores differed significantly for both KOOS, JR and LEFS. Postoperative scores increased for KOOS, JR by 27.5 points, and for LEFS, they increased 26.0 points;  $P < .001$  for both. Complications included 6 reoperations (6.7%) related to PFA: 4 conversions (4.4%) to total knee arthroplasty at a median of 2.5 (1.5–3) years after the index procedure, one vastus medialis oblique advancement (1.1%) secondary to patellar maltracking, and one manipulation under anesthesia (1.1%).

**Conclusions:** Custom PFA in patients with isolated patellofemoral arthritis showed good short-term functional outcomes and low revision rates with very few complications.

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## Introduction

Isolated patellofemoral arthritis is responsible for 9%–24% of all osteoarthritis cases of the knee [1–3]. When conservative treatment measures fail, various surgical options exist including arthroscopic procedures, patellofemoral realignment procedures, isolated patellofemoral arthroplasty (PFA), and total knee arthroplasty (TKA) [4,5]. Many studies have demonstrated the benefits of TKA in isolated patellofemoral arthritis, and TKA has been the main

treatment for many decades [6–9]. Although TKA is a well-established and accepted procedure for treatment of patellofemoral arthritis, it has its limitations and may not be the most optimal treatment for both younger, active patients and patients without tibiofemoral osteoarthritis.

By comparison, PFA maintains normal knee biomechanics as it preserves the unaffected tibiofemoral compartments protecting the integrity of the knee, which theoretically improves knee function and range of motion [10–13]. In a recent double-blinded randomized control study comparing 47 TKA vs 46 PFA, Odgaard et al. concluded patients treated with PFA had better knee function and satisfaction than TKA with similar short-term survival rates at 2 years [14]. Although PFA has shown promising results especially

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with the newer-generation prostheses, disadvantages associated with off-the-shelf prostheses involve soft-tissue impingement, overstuffing the patellofemoral joint, loss of anterior femoral bone stock, and patellar maltracking [15–17].

The trochlear component of PFA is consistently regarded as a major cause of early complications and failure [16,18,19]. Two major designs of the trochlear component are onlay and inlay [20]. In an onlay design, an anterior cut is made into the femur, with the onlay prosthesis replacing the anterior compartment of the knee. This design utilizes the same anterior cut of the femur as for TKA [20]. In comparison, the inlay design requires surgeons to create a bone bed by only removing cartilage. The exposed subchondral bone of the native trochlea is implanted with the inlay prosthesis which lies flush with the surrounding cartilage. In theory, the inlay trochlear design is more natural as there is no anterior femoral cut. However, early first-generation inlay PFAs were associated with high complication rates due to patellar maltracking [16–19]. With newer technology and the concept of patient-specific instrumentation, custom patellofemoral prostheses have been designed to recreate the patient's own knee anatomy to help improve the complication rate seen with earlier designs. Custom patient-specific inlay trochlear implants are designed to replicate a patient's unique trochlear anatomy theoretically improving patellofemoral tracking.

The purpose of this study was to evaluate short-term functional outcomes and complications of the custom PFA in the treatment of isolated patellofemoral arthritis. Our hypothesis was that custom PFA will show improved functional outcome scores with an acceptable complication rate and good short-term survival.

## Material and methods

A retrospective study of patients treated with custom PFA by a single adult reconstruction fellowship-trained orthopedic surgeon was conducted. Chart review in the senior author's practice identified patients who had isolated patellofemoral arthritis determined by history, physical examination, and radiographs. Study inclusion criteria were patients who had undergone a PFA from 2012 to 2018. Established indications for PFA [14,21] included degenerative changes limited to the patellofemoral joint and failure of prior conservative treatments. All patients had a minimum of 2 years in follow-up. The study excluded those patients diagnosed with patellofemoral arthritis who were not treated with the custom patellofemoral implant. The study protocol was approved by the local institutional review board.

### Implant design and surgical technique

The custom patellofemoral prosthesis KineMatch (Kinamed, Camarillo, CA) is a resurfacing custom inlay prosthesis, and it was exclusively used in this study. A computed tomography (CT) scan of the patient's knee is obtained and uploaded into a software program that creates a three-dimensional model of the patient's native trochlea. This construct is then converted to a custom cobalt-chromium implant specific to the patient's anatomy.

The surgical technique was first described in the literature by Sisto and Sarin in 2007 [13]. A standard midline incision is utilized to expose the patellofemoral joint, and the patella is everted. The custom, 3-D-printed drill guide is then placed onto the trochlea, and the surgeon outlines the drill guide to determine the margin of cartilage to be removed. Using a ring curette, the cartilage inside the outline is removed until the subchondral bone is exposed. The drill guide is then placed on the subchondral bone with a secure fit predetermined by the CT scan. The drill guide is held in place with 2

headless pins, and 3 holes are drilled. The patella is then measured and cut according to surgeon preference. The trochlear prosthesis is then placed in conjunction with an all-polyethylene patellar button with a 25-mm radius of curvature. The knee is then trialed with particular attention to patellofemoral tracking. The components are then cemented in a standard fashion.

### Data collection and storage

Data collected from patient charts included demographic information: age, gender, weight, height, and body mass index, along with comorbidities, prior knee surgeries, pain duration, and any failures of conservative measures. Surgical information included dates of surgery, preoperative and postoperative functional scores, along with tourniquet time and complications.

Complications were categorized into 2 groups: major complication and minor complication. A major complication was defined as any adverse event for which additional surgical treatment was required. Major complications included stiffness requiring manipulation under anesthesia, patellar realignment, and conversion to TKA. A minor complication was defined as any adverse event for which additional nonsurgical treatment was required. Minor complications included wound infection, neuralgia, and tendonitis. Reoperation unrelated to surgery were defined as any knee arthroscopy procedure performed after the index procedure secondary to a new injury.

Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools [22,23]. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources.

### Clinical and functional evaluation

Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) [24,25] and Lower Extremity Functional Scale (LEFS) [26] were collected both preoperatively and postoperatively in the outpatient setting. For patients who could not come to the clinic, a telephone interview was conducted after informed consent was obtained. The KOOS, JR contains 7 items coded 0 to 4, none to extreme, respectively. The raw score is then converted to an interval score, which ranges from 0 to 100, where 0 represents total knee disability and 100 represents perfect knee health. The LEFS consists of 20 questions subdivided into 4 groups coded 0 to 4, extreme difficulty/unable to perform to no difficulty, respectively. The maximum score of 80 indicates no functional limitations, and the minimum score of 0 indicates extreme limitations.

### Statistical analysis plan

A power analysis was conducted in IBM SPSS SamplePower using *t*-test for paired samples to determine the required sample size. One goal of the study was to test the null hypothesis that the mean difference (or change) within pairs is 0.00 on the LEFS. The criterion for significance ( $\alpha$ ) was set at 0.05 using a two-tailed test. With the proposed sample size of 23 pairs of cases, the study will have 91% power to yield a statistically significant result, including a standard error of 2.52 with a 95% confidence interval of 3.56 to 13.84. This computation assumed the population from

which the sample will be drawn had a mean difference of 9.0 with a standard deviation of 12.1 on the LEFS. These results were drawn from the study by Alcock et al. [27]. This effect was selected as the smallest effect that would be important to detect at 2 weeks after surgery, in the sense that any smaller effect would not be of clinical or substantive significance.

With regard to statistical analyses, participant characteristics along with pre- and post-test scores were summarized as frequencies and percentages, means and standard deviations, or medians with minimum and maximum values. To evaluate the primary hypothesis for LEFS and the KOOS, JR scores, matched pairs tests were conducted. To determine which statistical test to use, data were first evaluated for the normality assumption using the Kolmogorov-Smirnov test. Because results showed nonconformance, a nonparametric exact Wilcoxon signed ranks test was used for evaluating the paired data. In addition, exact testing was used to account for small sample sizes. Functional score differences by gender were also evaluated using the exact Mann-Whitney U test. To determine rates of complications, data were summarized with frequencies and percentages. All analyses were conducted in IBM SPSS Statistics version 26 using the two-tailed test with the level of significance set at  $\alpha = 0.05$ .

## Results

### Participant characteristics

Between September 2012 and July 2018, 79 patients underwent PFA, 15 of which were bilateral, for a total of 94 PFAs. Four patients were lost to follow-up, and 1 patient was removed from the primary surgeon's practice for illicit drug use for a 94% follow-up rate. Two patients underwent conversion to TKA within 2 years of the index procedure and were not included in the functional outcome statistical analysis. Seventy-two patients and 87 PFAs were included in the final analysis. Table 1 summarizes participant characteristics.

### Preoperative functional scores

The overall median preoperative KOOS, JR score was 57.1 (24.9, 76.3) with 47.0 (8.0, 63.0) for the LEFS. In the KOOS, JR subgroup analysis, scores of men were significantly higher than those of women: The median for men was 61.6 (44.9, 76.3), while the median for women was 52.5 (28.0, 61.0),  $P < .001$ . Similar results were observed for the LEFS: The median score was 52.5 (28.0, 61.0) for men and 44.0 (8.0, 63.0) for women,  $P = .015$ .

### Postoperative functional scores

Median follow-up duration between preoperative and postoperative scores was 3.6 years (2-8.9). The overall median postoperative KOOS, JR score was 84.6 (44.9, 100.0), with 73.0 (28.0, 80.0) for the LEFS. For the KOOS, JR, scores of men and women were

similar: The median for men was 84.6 (59.4, 100.0), and for women, it was 84.6 (44.9, 100.0),  $P < .297$ . Similar results were observed for the LEFS: The median score was 72.5 (28.0, 79.0) for men and 73.0 (32.0, 80.0) for women,  $P = .869$ .

### Comparison of prefunctional and postfunctional scores

Overall prefunctional and postfunctional scores differed significantly for both KOOS, JR and LEFS represented in Figure 1. Post scores increased for KOOS, JR by 27.5 points, and for LEF, they increased by 26.0 points;  $P < .001$  for both. This difference was greater for women in both scores. KOOS, JR scores for men increased by 23 points, and for women, they increased by 32.1 points, while for the LEFS, scores increases were 20 points for men and 29 points for women. While post scores are similar for both genders, the observed differences are best accounted for by the lower preoperative scores for women.

### Complications

Complications are summarized by major (Table 2) and minor (Table 3) complications. There were 6 total reoperations related to patellofemoral replacement: 4 conversions to TKA at a median of 2.5 (1.5-3) years after the index procedure (women accounted for 3 of the 4), 1 vastus medialis oblique advancement secondary to patellar maltracking, and 1 additional patient required manipulation under anesthesia. Ten patients underwent knee arthroscopy for new injuries unrelated to patellofemoral replacement. Other minor complications included neuralgia, tendinitis, and a wrist fracture due to a fall, all of which were incurred by women and resolved with conservative treatment.

## Discussion

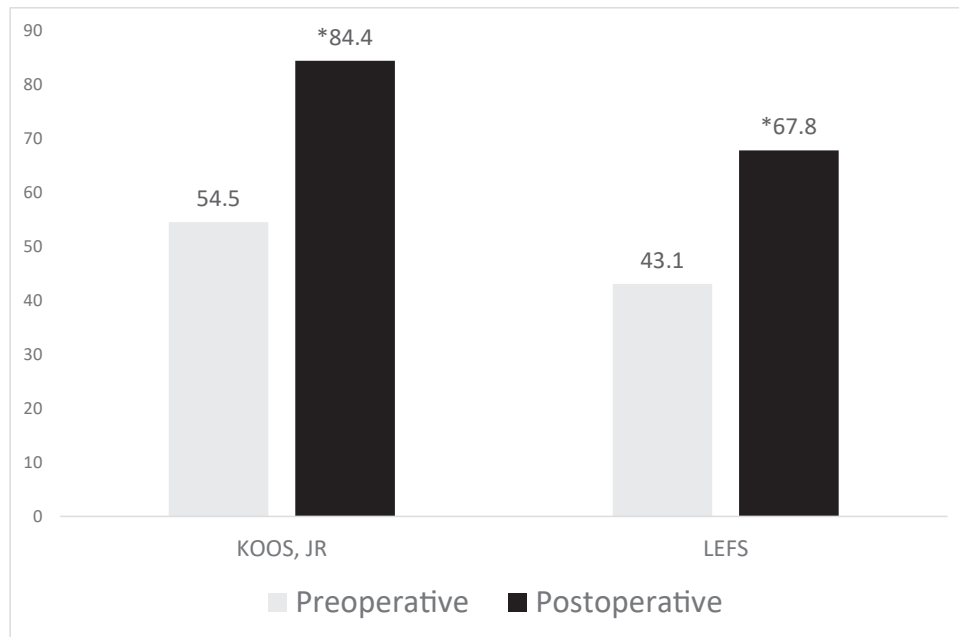
Isolated patellofemoral arthritis is a prevalent and disabling disease affecting 1 out of every 10 individuals [1,3]. Many surgical treatment options exist with no uniform consensus [4,5]. Although modern PFA designs have improved, custom PFA theoretically improves patellofemoral tracking by utilizing patient-specific instrumentation replicating the patient's native trochlear anatomy, in turn allowing young patients to maintain their prior level of activity. To our knowledge, this report is the largest series investigating outcomes of the custom PFA.

In our study, patients undergoing custom PFA for isolated patellofemoral arthritis had a significant improvement in KOOS, JR and LEFS scores. These improvements were equal for both male and female patients. These results demonstrate that significant improvements in pain and function are achievable in the short term. Four patients underwent conversion to TKA, 1 patient underwent manipulation under anesthesia, and 1 patient underwent patellar stability procedure 6 weeks after the index procedure. Revision rate was 6.7%, which is below the reported revision rate for all off-the-shelf PFA [28]. One interesting finding in our study was that 10 patients (11.2%) underwent knee arthroscopy after the index procedure due to a new injury. With the custom PFA, there are no activity restrictions allowing patients to return to a high level of activity including sports, running, and hiking, making it an attractive option for active patients.

Our study produced significant improvement in patient-reported outcome scores consistent with the current literature. Sisto and Sarin in 2006 studied a custom PFA prosthesis and reported excellent short-term outcomes in 25 patients with average follow-up duration of 6 years. No revisions were required in their young population (average age: 45 years) [15]. Butler and Shannon performed a study on the custom PFA, reporting outcomes on 22

**Table 1**  
Participant characteristics.

Number of patients (n)	74 (89 knees)
Men	19 (22 knees)
Women	55 (67 knees)
Median age years (min, max)	57 (32, 84)
Bilateral	15 (30 knees)
Body mass index	30.8 ± 5.9
Prior surgery on operative knee	30 (33.7%)
Median duration of knee pain in months (min, max)	24 (3, 360)



**Figure 1.** Functional outcome scores. Overall prefunctional and postfunctional scores differed significantly for both KOOS, JR and LEFS. Postfunctional scores increased for KOOS, JR by 27.5 points, and for LEFS, they increased by 26.0; \* $P < .001$  for both.

PFA with an average follow-up duration of 60 months [29]. They reported significantly lower postoperative patient-reported Western Ontario and McMaster Universities Osteoarthritis Index scores than preoperative scores.

Clinical success of PFAs has been proven with many studies over a variety of implant types [10,11,15,21,30–38]. This success has been amplified over the past 10 years with new improvement in the design. In a recent systematic review published in 2017, Vanderlist and Chawla reported that PFA studies published before 2010 had higher annual revision rates than the studies published after 2010 [28]. Implant design remains one of the most critical aspects of obtaining a successful outcome with isolated PFA [19,39]. The anatomy of the trochlear groove is highly variable, presenting challenges for off-the-shelf patellofemoral prostheses [15,40]. Custom inlay PFA does not require femoral bone resection, presenting an advantage over previous implants [13,15]. Only the overlying articular cartilage needs to be removed as the implant was designed from the patient's bone. This resurfacing allows for proper fit of the implant, restoring the patient's anatomy without sacrificing bone stock and avoiding the risk of overstuffing the patellofemoral joint. Further advantages of the design include approximation of normal knee kinematics and patellofemoral tracking as more specific alignment and depth of the trochlear groove is achieved [13,15].

The cost of the custom implant is a fair concern when compared to an off-the-shelf PFA. There are no studies in the literature reviewing the cost analysis of a custom PFA. However, Fredborg et al. [41] demonstrated that off-the-shelf PFA provided better and cheaper outcomes at 1 year when compared to TKA.

**Table 2**  
Major complications.

Conversion to TKA (%)	4 (4.5%)
Median time to conversion in years (min, max)	2.5 (1.5, 3)
Manipulation under anesthesia	1 (1.1%)
VMO advancement secondary to patellar maltracking	1 (1.1%)
Total complications (%)	6 (6.7%)

VMO, vastus medialis oblique.

While the implant cost is similar to the cost of an off-the-shelf prosthesis, the custom PFA is more expensive in a two-fold manner. First, a preoperative CT scan of the knee must be obtained. There is a technical fee for the CT scan but no professional fee as the scan is not interpreted. The implant is then created and manufactured specifically for the patient using the CT scan. It takes approximately 8 weeks to manufacture the custom PFA. Although the upfront cost of a custom PFA is greater than the cost of an off-the-shelf PFA, custom instrumentation may decrease adverse events. In a recent systematic review investigating custom implants for knee arthroplasty, the authors concluded that the initial high cost of custom implants may be offset with savings over time due to the likelihood of fewer adverse events [42]. Off-the-shelf implants have standardized instrumentation for femoral alignment and resection, whereas custom PFA requires no standardized instrumentation or attention to the femoral alignment allowing the surgeon to both efficiently and accurately insert the implant.

There are several limitations to this study. Our study did not have a control group for comparison, resulting in the inability to report on differences in outcomes between both custom PFA and off-the-shelf PFA, as well as differences between inlay and onlay trochlear designs. Furthermore, this was a retrospective review that included a small sample, the majority of which were women, predisposing our results to gender bias. Finally, because follow-up time was variable and incomplete for some participants, additional complications unknown to us may have occurred. For example, some patients may have undergone conversion to TKA by another surgeon.

**Table 3**  
Minor complications.

Patellar tendinitis	2 (2.2%)
Quadriceps tendinitis	2 (2.2%)
Geniculate neuralgia	2 (2.2%)
Wrist fracture 6 weeks after surgery s/p fall	1 (1.1%)
Total complications <sup>a</sup> (%)	6 (6.7%)

<sup>a</sup> All minor complications resolved with conservative treatment.



## Conclusions

The custom PFA showed good short-term functional outcomes and low revision rates in patients with isolated patellofemoral arthritis with very few complications. We believe patients with severe isolated patellofemoral arthritis who have failed nonoperative management may benefit from custom PFA. Further level-1 randomized controlled trials are needed to determine the true functional outcomes of custom PFA when compared to off-the-shelf implants.

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## Conflicts of interest

The authors declare there are no conflicts of interest.

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## CRediT authorship contribution statement

**Joshua T. Rogers:** Writing – review & editing, Writing – original draft, Methodology, Data curation. **Jack A. Nolte:** Writing – review & editing, Investigation, Data curation. **Brayden Strine:** Writing – review & editing, Data curation. **Rosey Zackula:** Validation, Methodology, Formal analysis. **Jake Bianco:** Writing – review & editing, Writing – original draft. **Tarun Bhargava:** Writing – review & editing, Supervision, Project administration, Methodology.

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