First Clinical 1-Year Outcomes of Partial Knee Arthroplasty with the Persona® Partial Knee

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Abstract

The Persona Partial Knee System (PPK) was introduced in February 2017. This implant is a medial fixed-bearing partial knee replacement. To evaluate the clinical and radiological results, a 10-year global multicenter study on partial knee arthroplasties performed with the PPK has been initiated. The goal of this paper was to report the clinical 1-year results of this ongoing study.

A total of 598 primary PPKs were implanted using the same standardized surgical technique between February 2017 and September 2018. Patients had a mean age of 64.9 years at time of surgery. Pre and post-operative (3 months and 1 year) functional scores and PROM scores were recorded in each center according to the same protocol. At 1-year follow-up, data for 185 knees were available.

Complications included: polyethylene exchange in two patients due to infection, one medial tibial plateau fracture with component retention, and a revision in one patient due to persistent pain. Kaplan-Meier (K-M) survival estimate at 1-year is 99.14% (95% confidence interval [CI], 97.08–99.75). A significant improvement was observed for all the patients between the preoperative and 1-year post-operative follow-up assessments with respectively an increase from 24.1 to 41.9 (range, 0-48) for the mean Oxford Knee Score (OKS); from 0.5 to 0.9 (range, 0-1) for the mean EQ-5D health score;and from 16.9 to 71.7 (range, 0-100) for the Forgotten Joint Score (FJS-12). 97.3% of the patients were either satisfied or very satisfied with results of the surgery.

The results of our study showed excellent clinical results at 1-year in fixed bearing partial knee arthroplasties performed with the medial Persona Partial Knee System, with no revisions due to aseptic loosening to date. This study will continue through a 10-year follow up.

Introduction

The Persona Partial Knee is a fixed bearing partial knee replacement system launched in 2017. The Persona Partial Knee is limited to the medial tibiofemoral compartment of the knee intended for patients with painful and/or disabling knee osteoarthritis. The PPK system consists of cobalt-chromium-molybdenum (Co-Cr-Mo) alloy femoral components, titanium alloy (Ti-6AI-4V) tibial baseplates, and Vivacit-E® highly crosslinked polyethylene tibial articular surfaces. It features optimized tibial coverage and femoral fit with morphometric implant design. The surgical procedure is performed with an intuitive spacer block technique.

The aim of this ongoing multicenter study was to analyze the 10-year follow-up clinical outcomes of the Persona Partial Knee. The study was initiated in 2017, with planned clinical follow-up visits at 3 months, 1 year, 2 years, 5 years, and 10 years post-surgery. The aim of this report is to document the first 1-year clinical results of the PPK.

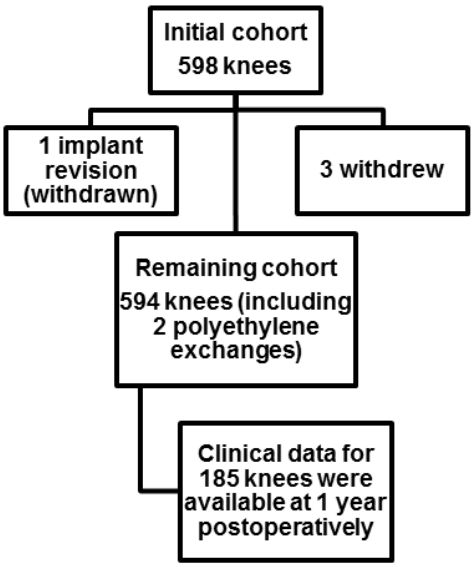
Methods

Patient Demographic

Between February 2017 and September 2018, 598 medial knees in 565 patients (33 bilaterals) were implanted with the Persona Partial Knee (Zimmer Biomet, Warsaw, IN, United States) at 26 institutions in the United States, Europe and Japan. The mean age at the time of surgery was 64.9 +/- 9.3 years (range, 37-88). 303 partial knee arthroplasties (50.7%) were in male patients and there were 319 arthroplasties (53.3%) on the left side. Mean BMI was 29.7 +/- 5.2 kg/m^2 (range, 19-48). The primary preoperative diagnosis was osteoarthritis in 567 knees (94.8%). Further preoperative diagnoses were avascular necrosis in 18 knees (3.0%); post-traumatic arthritis in 5 knees (0.8%); osteoarthritis, traumatic arthritis,

polyarthritis and/or severe chondrocalcinosis of the patellofemoral joint in 5 knees (0.8%); varus deformities in 2 knees (0.3%); and dysplasia-induced degeneration in 1 knee (0.2%).

Figure 1 Study population



Operative Information

The average duration of surgery was 56.2 ± 14.2 minutes (range, 21-120). The Gender Solutions® Patello-Femoral Joint system (Zimmer Biomet, Warsaw, IN) was implanted with the Persona Partial Knee in 9 knees.

The average length of hospital stay (LOS) was 4.2 ± 7.1 days (range, 0-67), but this varied considerably between regions due to standard of care differences. (United States: 0.5 ± 0.9 days, Europe: 4.4 ± 2.6, Japan: 41.1 ± 12.7). Outpatient (including same day or 23-hour discharge) surgeries were performed in 124 patients (21.1%). 64.1% of surgeries in the U.S. were conducted as outpatient procedures, whereas Europe had 1.5% and Japan 0%.

Data Collection

Follow-up procedures include patient-reported outcomes, patient satisfaction, radiographic assessments and adverse event reporting.

The study requires that all sites collect the patient-reported Oxford Knee Score[1], EQ-5D[2] and the Self-Administered Patient Satisfaction Scale for Primary Hip and Knee Arthroplasty[3]. In addition, some sites collected study-optional data such as the Forgotten Joint Score [4].

Statistical analysis

K-M survivorship analysis with corresponding 95% confidence interval (CI) was performed. Comparisons between the pre-operative and post-operative values for the different scores were performed using Student-t test for linked samples considering a p-value <0.05 as significant. The statistical analysis was performed with SAS Enterprise Guide version 12 (SAS Institute Inc, Cary, NC, United States).

Results

Clinical and radiographic outcomes

Patient satisfaction assessed by the Self-Administered Patient Satisfaction Scale for Primary Hip and Knee Arthroplasty showed 97.3% of patients to be either satisfied or very satisfied with the results of surgery at a 1-year follow-up. Similarly, 96.2% of patients were satisfied or very satisfied with the results of surgery regarding pain relief. The derived Patient Satisfaction Score was 92.5 at 1-year follow-up.

Figure 2 Overall satisfaction with the surgery

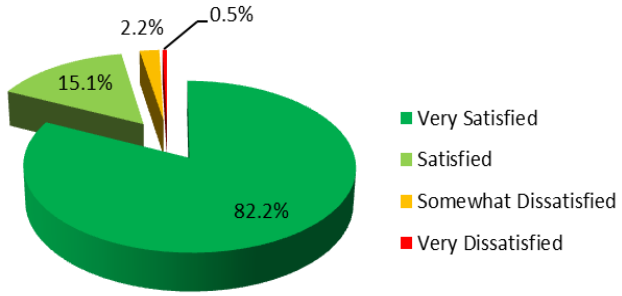
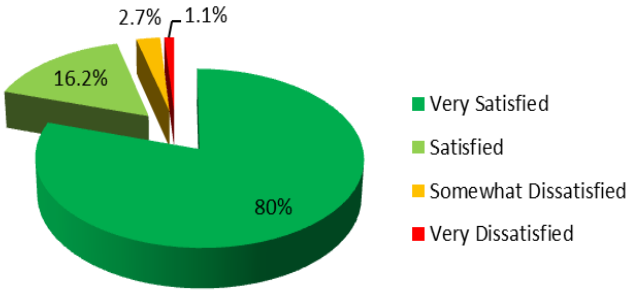
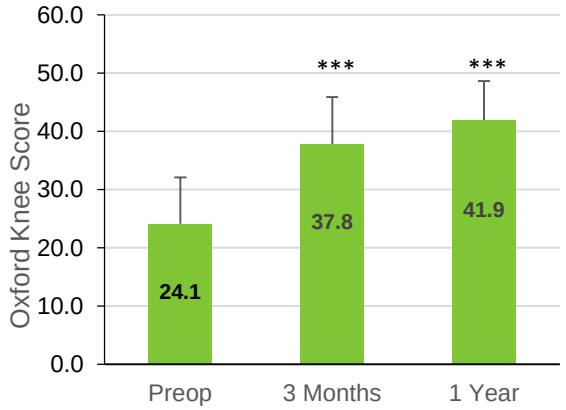


Figure 3 Overall satisfaction with pain relief



A significant improvement of the Oxford Knee Score was observed from 24.1±8.0 (range, 1.0 – 45.0; n=589) preoperatively to 41.9±6.7 at 1-year follow-up (range, 15.0 – 48.0; n=185, P=<0.0001), (Fig.4).

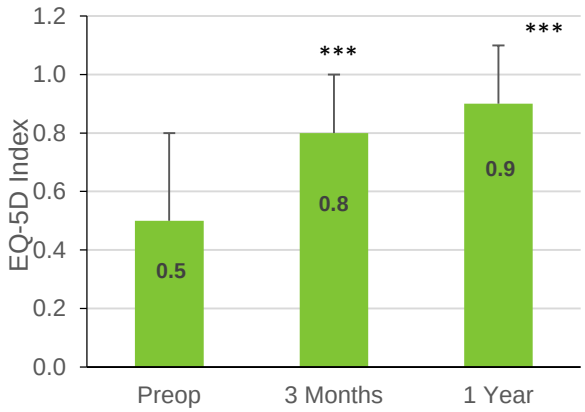
Figure 4 Oxford Knee Score



***: p < 0.0001 compared to preop values

The EQ-5D Index improved significantly from 0.5±0.3 (range, -0.3 – 1.0; n=592) preoperatively to 0.9±0.2 at 1-year follow-up (range, -0.2 – 1.0; n= 184, P=<0.0001), (Fig.5).

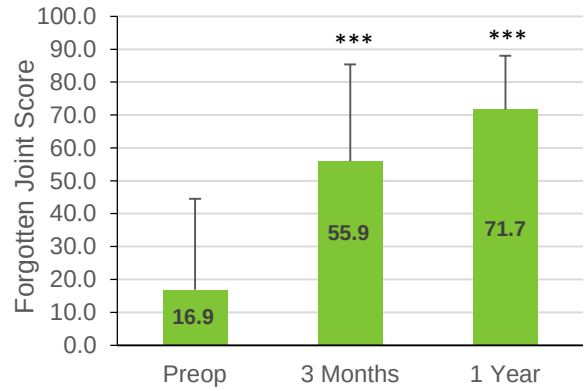
Figure 5 EQ-5D Index



***: p < 0.0001 compared to preop values

Forgotten Joint Scores improved from 16.9±16.3 (range, 0–94; n=380) preoperatively to 71.7± 27.6 at 1 year follow-up (range, 0 – 100; n= 122, P=<0.0001), (Fig. 6).

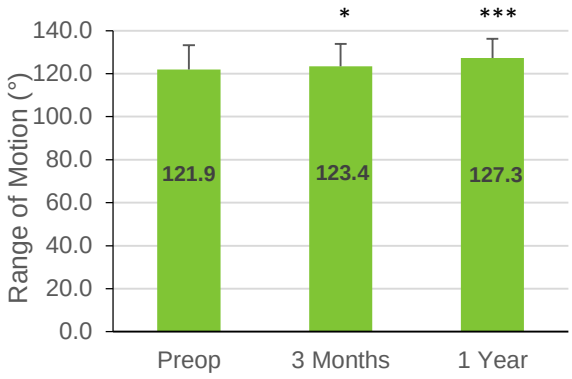
Figure 6 Forgotten Joint Score



***: p < 0.0001 compared to preop values

The mean total range of knee flexion (ROM) increased from 121.9°±11.3 (range, 80–150; n=593) preoperatively to 127.3°±8.9 at 1-year follow-up (range, 100 – 150; n= 184, P=<0.0001), (Fig. 7).

Figure 7 Range of Knee Flexion

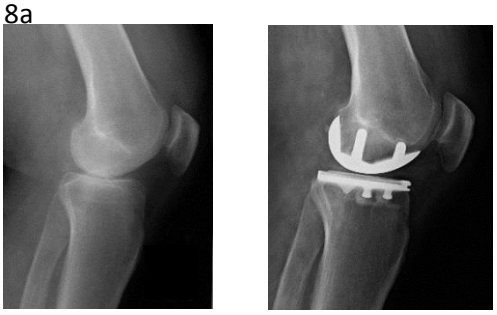


*: p < 0.05 compared to preop values, ***: p < 0.0001 compared to preop values

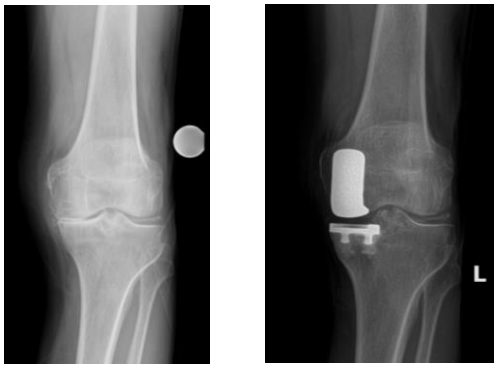
The 1-year radiographic results of 185 PPKs showed 3 cases of non-progressive radiolucency around the femoral component. Incomplete tibial radiolucencies were observed in 2 patients at 1 year. In summary, the radiographic analysis at latest follow-up showed no progressive lucencies, indicating no cases suggestive of implant loosening.

Figure 8a Medio-lateral Radiographs of a PPK: preop (left) and 1-year postop (right) and **8b:** Antero-posterior radiograph of a PPK: preop (left) and 1-year postop (right)

8a



8b



Survival and Complications

At the time of this review in October 2018, 4 knees of the 598 enrolled knees were withdrawn from the study: 2 knees were withdrawn due to lost to follow-up visit, 1 knee due to patient requested discontinuation and 1 knee due to implant revision. There were 3 revisions reported but none of the revisions were assessed to be device-related. Out of the 3 revisions, 1 case resulted in implant revision due to progressive/persistent pain. This revision was reported by the patient's family and performed by a surgeon not participating in the study. Therefore, it is unknown which components were revised and the patient was withdrawn from the study. In the other 2 revision cases, both cases were treated with open debridement and polyethylene exchange, and the patients remained in the study. In addition, 1 patient had a medial tibial plateau fracture approximately 2 weeks after surgery and a non-operative treatment was initiated, but due to a secondary displacement 2 months later, an open reduction/internal fixation of the proximal tibia with retention of the components was performed. The 1-year K-M overall survival estimate for any reason was 99.14% (95% CI, 97.08–99.75).

Discussion

We report preliminary 1-year results of PKA performed with the fixed bearing Persona Partial Knee System from a mid and long-term multi-center study.

At 1-year follow-up, K-M survival estimate of the device is 99.14% with revision for any reason as the endpoint. No implant was revised for aseptic loosening; there were 2 polyethylene exchanges due to infection and one implant was revised due to progressive pain. The survival/revision performance of the PPK has only been documented in one national registry report: the 2018 report of the National Joint Registry of England, Wales and Northern Ireland (NJR)[5]. It reports a 1-year revision rate, with revision of any component as endpoint, of 0.0% (95% CI, 0.0–8.0) for the PPK compared to 1.1% for all other partial knees registered in the NJR.

In our study, the mean EQ-5D Index was 0.9 $\pm$ 0.2, indicating very good health state of the patients 1 year after surgery (maximum index is 1)[2]. The mean Oxford knee score in the patients who have reached the 1-year follow-up visit was significantly higher compared to the preoperative visit and was 41.9 $\pm$6.7 points, therefore falling in the excellent result category (41-48 points)[6].

The study showed that, 97.3% of patients were either satisfied or very satisfied with the results of surgery at 1-year follow-up. In addition, 96.2% of patients were satisfied or very satisfied with the results of surgery concerning pain relief.

In conclusion, the study documented excellent outcomes at 1-year for arthroplasties performed with the fixed bearing Persona Partial Knee System. This study will continue through a 10-year follow up.

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