A Retrospective Study Comparing a Patient-specific Design Total Knee Arthroplasty With an Off-the-Shelf Design: Unexpected Catastrophic Failure Seen in the Early Patient-specific Design

Abstract

Background: Patient-specific design (PSD) total knee arthroplasty implants are marketed to restore neutral mechanical-axis alignment (MAA) and provide better anatomic fit compared with standard off-the-shelf (OTS) total knee arthroplasty designs. The purpose was to compare the Knee Society scores, radiographic outcomes, and complications of PSD and OTS implants.

Methods: Retrospective study analyzing PSD and OTS by a single surgeon. Implant design change in PSD occurred during the period of data collection leading to PSD-1 and PSD-2 subgroups. Radiographic data including MAA, femorotibial angle, coronal-tibial angle, tibial slope and patella-sulcus angle, and complications were analyzed. Minimum follow-up was 2 years or until revision, and patients completed Knee Society scores preoperatively and postoperatively at 3, 6, 12, 24 weeks, and final follow-up.

Results: There were 136 patients (154 knees), average age (62.76 ± 8.4 years), and follow-up (3.1 ± 1.5 years). The groups included PSD-1 (77 knees), PSD-2 (36 knees), and OTS (41 knees). The PSD-2 group had better Knee Society function scores compared with PSD-1 and OTS at all timepoints except final follow-up. PSD-2 had significantly shorter hospital stay ($P = 0.000012$) and less hemoglobin drop ($P = 0.032$) compared with PSD-1 and OTS. No differences were observed in MAA ($P = 0.349$) or final range of motion ($P = 0.629$) between the 3 groups. PSD-2 had more normal femorotibial angle, coronal-tibial angle, and tibial slope compared with PSD-1 and OTS. Failures requiring revision were 23% (18/77) PSD-1, 0% PSD-2, and 3% (1/35) OTS. Most common modes of failure were tibial subsidence (56%) and polyethylene locking mechanism failure (22%) in PSD-1.

Conclusion: Catastrophic failure was seen in the PSD-1 group with tibial subsidence and polyethylene locking mechanism failure. PSD-2 had better early Knee Society function scores, shorter hospital stay, lower hemoglobin drop, radiographic alignment, and no failures compared with PSD-1 and OTS.
Total knee arthroplasty (TKA) is a commonly done, successful surgical treatment to treat end-stage knee osteoarthritis. With modern surgical techniques and advances in implant technology, primary TKA can result in high 15- to 20-year implant survivorship with some studies reporting good survivorship greater than 20 years. However, it has been reported that up to one of five patients with TKAs are dissatisfied at 1 year. Recent research has been focused on improving component alignment, functional outcomes, and patient satisfaction after TKA, and patient-specific design (PSD) TKA was developed to provide patient-matched instrumentations and implants. Although previous investigations have been somewhat mixed in regard to component alignment, patient satisfaction, and pain scores, PSD TKA has been proven to improve accuracy of implantation, reduced surgical time, and facilitate the workflow in the operating room by using fewer surgical instruments.

The goal of our study is to retrospectively compare (1) patient-reported outcome scores, (2) radiographic outcomes, and (3) complication/revision rates between PSD TKA versus standard off-the-shelf (OTS) TKAs.

**Methods**

Institutional Review Board approval was obtained for a retrospective study from January 2011 until December 2014. The charts of all patients receiving a PSD- or OTS-designed TKA during the study period were reviewed, and they were included in the study if all inclusion criteria were met. The inclusion criteria were patients aged 40 to 85 years, with end-stage degenerative knee osteoarthritis, body mass index (BMI) ≤ 40 kg/m², and medically fit to undergo primary knee replacement. Exclusion criteria included patient’s age ≤ 40 or ≥ 85 years, BMI ≥ 40 kg/m², previous known allergy to nickel, active infection, and previous partial knee replacement. All patients were given the opportunity to choose between PSD or OTS after carefully explaining the two options, and patients were allowed to make the final decision regarding the implant used.

The PSD group had TKAs done using patient-specific cutting guides for the femur and tibia together with custom-made femoral and tibial components. Preoperative CT scanning of the entire surgical lower extremity including the hip, knee, and ankle was done at least 6 weeks before surgery, according to a standard scanning protocol designed to calculate the mechanical axis of the leg and to determine sizing of the knee joint. Proprietary software was used by the manufacturer to create virtual 3D models of the tibia and femur, and the program was used to determine the optimal size and shape of the prosthetic tibial and femoral components. Patient-specific disposable cutting guides were made of polyamide and shipped to the operating room together with the custom implants in standard sterile packaging per manufacturer’s guidelines. During the study period, the manufacturer of the PSD implant changed the polyethylene locking mechanism and the shape of the polyethylene due to noted early failures thus creating a modified implant. The polyethylene has a lateral component and a medial component. All patients who had the early PSD implants were categorized in the PSD-1 group, and those with the modified implants were in the PSD-2 group. The use of the initial designed PSD implant was stopped after the early failures were noted. The PSD-1 implant was a cruciate-retaining total knee (iTotal G2 system; Conformis), and the PSD-2 implant was a cruciate-retaining total knee (iTotal G2 plus system).

In the OTS group, unilateral TKAs were done using posterior stabilized implants (Genesis II knee; Smith and Nephew). Standard weight-bearing radiographs including AP view of the lower extremities including the hip, knee, and ankle on the same image were used to determine the preoperative mechanical axis and also help determine the amount of valgus cut (3°, 5°, or 7°) to achieve a neutral mechanical axis postoperatively. In this control group, all cuts were done with intramedullary guides for the femur and extramedullary guides for the tibia using standard techniques. Preoperative templating was done to suggest sizes; however, final sizing was done using the standard jigs before the appropriate femoral and tibial components were implanted. All TKAs in the three groups were done during the study period by a single surgeon (T.A.C.) at a single institution, and all components were cemented. Three-peg all-polyethylene patella components were cemented using a free-hand cut, and conventional sizing methods were used in all knees.

Demographic data were collected including age, BMI, and laterality.

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Preoperative hemoglobin and hemoglobin before discharge were recorded. Blood loss during surgery and the need for blood transfusion during hospitalization were also recorded as well as length of hospital stay. A tourniquet was applied to the surgical extremity before incision and was taken down after application of final dressing. Tranexamic acid was given topically in the application of final dressing. Tra- somatic analysis test.

### Results

#### Demographics, Length of Stay, and Hemoglobin Drop

A total of 278 patients (PSD-1 = 94, PSD-2 = 48, OTS = 136) and 308 knees (PSD-1 = 106, PSD-2 = 55, OTS = 147) were identified for the study, and 136 patients (154 knees) were available at minimum 2-year follow-up. Follow-up was 50% at 2 years. The PSD-1 group had 71 patients (77 knees), the PSD-2 group had 30 patients (36 knees), and the OTS group had 39 patients (41 knees). The average age was 62.7 ± 8.4 years, and mean follow-up was 3.1 ± 1.5 years. The average age per group was 62.5 years (PSD-1), 62.8 years (PSD-2), and 63.0 years (OTS). There was no significant difference (P = 0.976) in age between the groups (Table 1). The average BMI for the three groups was 30.3 kg/m² (PSD-1), 28.9 kg/m² (PSD-2), and 34.4 kg/m² (OTS). The overall average BMI for all groups was 30.9 kg/m². The OTS group had a significantly (P < 0.01) higher BMI than the other groups (Table 1). The average length of stay for the PSD-2 group (2.1 days) was significantly less than the PSD-1 group (2.9 days, P < 0.01) and the OTS group (3.3 days, P < 0.01).

Hemoglobin delta between preoperative and postoperative hemoglobin (usually on the day of discharge) in the PSD-2 group (0.61 g/dL) was significantly less (P < 0.05) than the OTS group (1.20 g/dL) but not significantly different from the PSD-1 group (0.87 g/dL) (Table 1). Intra-

### Table 1

| Demographic, Length of Stay, and Hgb Drop Data | PSD-1 | PSD-2 | OTS | P Value | Comments |
|-----------------------------------------------|-------|-------|-----|---------|----------|
| Age (yr)                                       | 62.65 ± 8.3 | 62.78 ± 6.7 | 63.03 ± 10.1 | 0.976 | PSD-1 versus OTS (P < 0.01) |
| BMI (kg/m²)                                    | 30.34 ± 4.5 | 28.85 ± 5.2 | 34.44 ± 7.1 | <0.001<sup>a</sup> | PSD-2 versus OTS (P < 0.01) |
| Length of stay (d)                             | 2.88 ± 1.1 | 2.08 ± 0.6 | 3.3 ± 1.2 | <0.001<sup>a</sup> | PSD-1 versus PSD-2 (P < 0.01) |
| Hgb drop (g/dL)                                | 0.87 ± 0.9 | 0.61 ± 0.3 | 1.20 ± 1.3 | 0.031<sup>a</sup> | PDS-2 versus OTS (P < 0.05) |

BMI = body mass index, Hgb = hemoglobin, PSD = patient-specific design
cells were transfused. At discharge, the hemoglobin measured 10 g/dL.

**Knee Society Scores**

There was a continuous improvement in the Knee Society knee score at all postoperative time points until final follow-up in all groups. At 3 weeks, the PSD-1 group had clinically significant ($P < 0.05$) higher scores compared with the OTS group, and at 6 weeks, the PSD-2 group had clinically significant ($P < 0.01$) higher scores compared with the OTS group. However, after 6 weeks, there was no difference between any of the groups with regard to the Knee Society knee score. All groups had excellent scores at final follow-up (Table 2).

Radiographic Outcomes and Final Range of Motion

There was no statistically significant difference between the groups in preoperative ($P = 0.728$) and postoperative ($P = 0.349$) mechanical alignment, as well as final range of motion (0.629). The PSD-2 group showed no statistically notable differences in femorotibial angle, coronal-tibial angle, or tibial slope when compared with normal femorotibial angle ($5^\circ$), normal coronal-tibial angle ($0^\circ$), and normal tibial slope ($5^\circ$). The PSD-1 and OTS groups showed femorotibial angle, coronal-tibial angle, and tibial slope that were statistically different from normal (Table 4). All three groups showed no statistically notable difference in patella sulcus angle when compared with normal of $0^\circ$.

**Complications**

There was a 23% (18/77) failure rate in the PSD-1 group requiring revision. The most common modes of failure were tibial subsidence (Figure 1) which accounted for 66% and polyethylene locking mechanism failure (Figure 2) which accounted for 22%. The remaining 12% were treated by outside surgeons, and the reasons for failure were unknown. There were no complications in the PSD-2 group. One patient in the OTS group had patella component loosening that required a revision surgery.

**Discussion**

The main findings of this study include the unexpected high early failure rate in the early PSD implant that was attributed to failure of the polyethylene locking mechanism and tibial component subsidence. After the manufacturer changed the design with creation of the modified implant, no failures were seen. The modified PSD-2 implants had better early (up to 6 weeks) Knee Society outcome scores compared with standard OTS implants. Both implant types had excellent postoperative mechanical alignment and ranges of motion. The PSD-2 group showed statistically significantly more normal radiographic alignment compared with the other 2 groups; however, the clinical significance is unknown.

There are several advantages of PSD total knee systems including less surgical instrumentation sets requiring smaller sterile area in operating room, less hospital inventory spaces, and shorter surgical set-up time. Multiple trays are not required, and the presurgical setup is simplified with PSD TKAs when compared with OTS knees that require multiple trays which can result in greater delays in preoperative set up time.
postoperative clean up, and turnover time, in addition to the intraoperative search and find time. Furthermore, several studies have shown reduction in procedural time due to proper sizing of the components (completed preoperatively by the manufacturer using 3D imaging modalities), improved tibial and femoral implant fit, and improved rotational alignment with less mechanical-axis outliers. The reduction in turnover/surgical time and the lack of the need for autoclaving multiple surgical instrument sets can potentially decrease episodes-of-care costs. With PSD implants, hospitals and surgical center do not have to keep a large inventory of different sized implants, as every implant is made specifically for one patient and shipped directly to the surgical center. Although a CT scan is needed preoperatively for PSD implants, this is mostly covered by insurance companies with a small copay from the patient depending on their insurance plan.

PSD TKA minimizes bone cuts, eliminates the use of intramedullary rods to determine alignment, and provides complete metal coverage of cut bony surfaces which can decrease blood loss due to avoidance of notable intramedullary and cancellous surface bone bleeding. This study showed a statistically significantly lower perioperative blood loss in the PSD-2 group when compared with the OTS group, with one patient in the OTS group requiring blood transfusion (due to pulmonary embolism and midcalf hematoma) compared with none in the PSD groups. However, clinical significance of this difference in blood loss among the groups is unknown. Also, the patients with PSD-2 had decreased length of stay compared with the OTS group, with one patient in the OTS group. Also, patient-specific design implants have a smaller footprint on cementless surfaces, which can decrease the risk of cement leak and increase cement engagement.

### Table 3

**Knee Society Function Score**

| Timeline | PSD-1 | PSD-2 | OTS | P Value | Comments |
|----------|-------|-------|-----|---------|----------|
| Preop    | 56.1 ± 7.5 | 53.2 ± 5.2 | 48.9 ± 7.1 | 0.135 | PSD-1 versus PSD-2 (P < 0.01) |
| 3 wk     | 57.4 ± 22.4 | 72.3 ± 9.8 | 61.2 ± 14.7 | <0.001 | PSD-2 versus OTS (P < 0.05) |
| 6 wk     | 72.2 ± 15.7 | 82.2 ± 8.0 | 73.3 ± 11.2 | 0.001 | PSD-1 versus PSD-2 (P < 0.01) |
| 12 wk    | 82.1 ± 12.5 | 89.2 ± 5.4 | 85.0 ± 5.6 | 0.002 | PSD-2 versus OTS (P < 0.01) |
| 6 mo     | 83.9 ± 17.5 | 93.4 ± 10.6 | 91.9 ± 3.5 | 0.001 | PSD-1 versus PSD-2 (P < 0.01) |
| Final    | 91.4 ± 18.6 | 96.1 ± 11.5 | 95.1 ± 5.3 | 0.293 | PSD-1 versus OTS (P < 0.05) |

PSD = patient-specific design
Excellent = 80 to 100, good = 70 to 79, fair = 60 to 69, and poor = ≤ 60.

### Table 4

**Radiographic Outcomes Including Preoperative Mechanical Axis (MA), Postoperative Mechanical Axis, Femorotibial (Fem-Tib) Angle, Coronal-Tibial (Cor-Tib) Angle, Tibial Slope, and Patella Sulcus (PS) Angle**

|       | PSD-1 | PSD-2 | OTS | P Value |
|-------|-------|-------|-----|---------|
| Preop MA | -3.97° ± 3.5° | -3.89° ± 3.46° | -3.32° ± 5.2° | 0.728 |
| Postop MA | -1.34° ± 4.6° | -0.35° ± 1.8° | -1.43° ± 2.8° | 0.349 |
| Fem-tib angle | 4.09° ± 2.7° (P = 0.004) | 4.10° ± 3.0° (P = 0.075) | 2.29 ± 3.8° (P < 0.001) | 0.001 |
| Cor-tib angle | 1.08° ± 1.9° (P < 0.001) | -0.11° ± 1.0° (P = 0.524) | -1.46° ± 1.5° (P < 0.001) | 0.001 |
| Tibial slope | 6.40° ± 2.9° (P < 0.001) | 5.53° ± 3.9° (P = 0.420) | 4.00° ± 2.5° (P = 0.028) | 0.001 |
| PS angle | 0.22° ± 1.4° (P = 0.143) | 0.83° ± 2.8° (P = 0.083) | -0.77° ± 2.9° (P = 0.153) | 0.001 |
| Final ROM | 124.2° ± 6.0° | 123.8° ± 7.4° | 122.7° ± 8.2° | 0.629 |

PSD = patient-specific design, ROM = range of motion
Negative values for MA, Fem-Tib, and Cor-Tib indicate varus alignment, while positive values indicate valgus alignment. Negative values for PS angle indicate medial patella tilt, and positive values indicate lateral patella tilt. ROM data.
start times were not dictated by implant choice; they were set by surgical posting and were random. We do not believe the surgical start times had a notable effect on hospital length of stay among the groups. We also report improved short-term functional outcome scores up to 6 weeks. Although the benefits were plateaued after 6 weeks, we believe that this is critical and valuable for the patients during early postoperative recovery phase after TKA. Such benefits may allow the patient to actively participate in a recovery program and allow quicker return to his/her work or desired activities.

The early PSD implant polyethylene had a high posterior lip, and the patient-specific guides only allowed up to a maximum 5° of posterior tibial slope which was the limit set by the FDA. It was theorized that...
Figure 2

Top three images are immediate postoperative AP, lateral, and sunrise views of the right knee of a 62-year-old woman status-post total knee arthroplasty with PSD-1 implant; middle three images are 6-month postoperative AP, lateral, and sunrise views of the right knee of the same patient with lateral polyethylene dislocation; Bottom three images are coronal, sagittal, and axial CT scan images of right knee showing dislocation of lateral polyethylene insert (encircled) lodged in the suprapatellar recess.
during deep flexion, there was posterior impingement due to limited posterior tibial slope and high posterior lip, and, over time, there was a compensatory posterior subsidence of the tibial baseplate on the tibia. This led to instability and ultimately failure of the polyethylene locking mechanism. The design changes to the early PSD implant included improved locking mechanism of the polyethylene to the tibial baseplate, a reduced posterior lip on the polyethylene, and allowance of more posterior tibial slope. The resultant modified PSD did not show any early failures in this study.

High viscosity cement (Cobalt; DJO surgical) was used for all cases. Kopinski et al21 showed evidence of cement debonding from tibial component after total knee using the high viscosity cement (Cobalt). Given that this cement was used for all patients in this study and subsidence was only noted in the PSD-1 group, it is theorized that the cement did not play a role in these failures. There was a statistically notable difference in the BMI between the PSD and OTS groups with the OTS group having a higher BMI. There have been multiple studies that have evaluated the effects of BMI on clinical outcomes after TKA and have shown that Knee Society score, Western Ontario and McMaster Universities Osteoarthritis Index, Hospital for Special Surgery Index, Hospital for Special Surgery score, Western Ontario and McMaster Universities Osteoarthritis Society score, and Visual Analog Scale are not important when patients have a BMI of 40 kg/m².22,23 Although there were differences in average BMI between the PSD and OTS groups, all patients had to have a BMI ≥ 40 kg/m² to be included in this study. There are several limitations of this study. First, this study was not randomized or blinded, and it was retrospective. Second, the study compared posterior stabilized TKA (OTS group) with cruciate retaining TKA (PSD groups) with different manufacturers. However, there have been multiple studies that have reported similar outcomes between cruciate-retaining and posterior-stabilized TKAs.24 Third, there is only short-to medium-term follow-up. The strengths of this study include radiographic and clinical evaluation of 136 consecutive patients with sufficient short- to medium-term follow-up by a single surgeon, and this is the first study of its kind to report high catastrophic failure of iTotal G2 system by Conformis, which has been replaced with the modified design (iTotal G2 plus system).

Conclusion

This study reports an unexpected high incidence of tibial baseplate subsidence, polyethylene locking mechanism, and ultimately failure requiring revision with the early PSD implant which was eliminated with the modified design. The modified designed implant had better early outcome scores only up to 6 weeks, shorter hospital stay, and lower blood loss compared with standard off-the-shelf design TKAs.

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