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Early outcomes of patient-specific posterior stabilized total knee arthroplasty implants

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ABSTRACT

Patient-specific implants have been linked to stiffness. The purpose of this study was to evaluate outcomes in patient-specific implants. We performed a retrospective review with a primary outcome of manipulation under anesthesia (MUA); secondary outcomes included Knee Society Scores (KSS), Knee Society Functional Scores (KSFS), range of motion (ROM), and Forgotten Joint Scores (FJS). Pre-operative measurements were similar in both groups. There was one MUA in the CPS and two in the OTS groups. There was no difference in postoperative scores. Our study suggests patient-specific implants have comparable rates of MUA and functional outcomes as conventional implants.

1. Introduction

The advent of the modern knee replacement began with the Total Condylar Prosthesis (Johnson & Johnson, New Brunswick, NJ; Howmedica, Rutherford, NJ), which was developed in 1974 at the Hospital for Special Surgery and was the first design to resurface all three compartments of the knee.[1] The long-term results of this implant were later reported with survivorship of 77% at 21 years post-operatively when revision for any reason was considered, and 85% when revision for mechanical failure was defined as the endpoint.[2,3] The original design was available in only one size, and was a cruciate-sacrificing design with stability provided by conformity between the articular surfaces.

Since the introduction of the Total Condylar Prosthesis, knee arthroplasty has undergone repeated and significant changes. These have included fixed and mobile-bearing designs as well as gender-specific sizing. Additionally, attempts have been made to improve alignment intraoperatively with navigation and kinetic sensors. With these improvements, modern off-the-shelf implants have been reported to have a survival rate up to 92% at 30 years.[4] While many changes have been made to the design and technique of knee arthroplasty, there has been relatively little improvement of patient reported outcomes seen in the literature.[5–16] In fact, up to 39% of patients report dissatisfaction[17–19] and as many as 10–15% of total knee arthroplasty patients have post-operative Knee Society Knee Scores that are less than excellent.[20] This rate of suboptimal functional scores alone should leave the knee arthroplasty community looking for an opportunity to improve outcomes. Furthermore, only two thirds of patients with perfect Knee Society Scores following TKA report feeling as if they have a normal knee, as defined by "The Forgotten Knee".[20] A disconnect between perfect outcome scores and patient satisfaction measured by "The Forgotten Knee" strengthens the rationale behind continuing implant development. To this end, patient-specific implants have been introduced in an attempt to fill this void.

Patient-specific implants rely on pre-operative imaging to create custom cutting blocks as well as customized implants with a goal of providing more normal knee kinematics and a better fit for the patient. Patil et al. used a cadaver model to show that patient-specific implants more closely recreated normal knee motion compared to conventional implants.[21] It has been proposed that by improving knee kinematics, these implants may be able to improve patient satisfaction and clinical outcomes. However, early reports with a cruciate retaining version have raised some concerns. In a series of 21 patients treated with cruciate retaining patient-specific implants compared to patients receiving a mix of cruciate retaining and posterior stabilized off-the-shelf implants, White et al. reported a drastic increase in their manipulation rate (28.6% vs 0%).[22] Since the report by White et al., a posterior stabilized version of the patient-specific implant has been released. To

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Table 1
Patient demographic data.

	OTS	CPS	p-value
n =	124	47	
BMI	30.3 ± 7.0	30.7 ± 5.7	= 0.69
Sex	42M:82F	18M:29F	= 0.59
Age	70.0 ± 8.5	66.9 ± 7.7	= 0.03

our knowledge, this is the only study currently available reporting outcomes of posterior stabilized patient-specific implants in total knee arthroplasty. The purpose of this study was to review our experience with a posterior stabilized, patient-specific implant compared to an off-the-shelf, posterior stabilized implant with regards to manipulation rates, as well as clinical outcomes and complications.

2. Materials and methods

After obtaining Institutional Review Board (IRB) approval, we conducted a retrospective review of all primary total knee arthroplasties (TKAs) performed at our institution by the senior author from March 2015 through December 2015. We identified a total of 47 patient-specific, posterior stabilized TKAs and 124 off-the-shelf, posterior stabilized TKAs. Patient demographics including age, sex, and body mass index (BMI) were recorded. Knee Society Scores (KSS), Knee Society Functional Scores (KSFS), and range of motion (ROM) were recorded at the pre-operative and 3 month post-operative visit. Patients were then contacted greater than one year post-operatively and asked to complete the validated Forgotten Joint Score (FJS) survey by telephone.[23] Patients were divided into one of two groups: Custom-PS (CPS) or off-the-shelf PS (OTS). Patient-specific surgeries were performed with the ConforMIS iTotal PS system (ConforMIS, Bedford, MA) and off-the-shelf surgeries were performed with the Zimmer Persona PS system (Zimmer, Warsaw, IN). A minimum of 3 month follow-up was required for all patients to be included in the manipulation analysis. Patients were indicated for manipulation under anesthesia (MUA) if their ROM was less than 90° by the 6 week follow-up visit. The primary outcome measure was the need for MUA within 3 months of surgery. Secondary outcomes included 3 month post-operative KSS, KSFS and ROM, as well as FJS collected at a minimum of one year post operatively and complications or revision for any reason. Statistical analysis was performed utilizing the Student's *t*-test for differences in mean's. Values are presented as the mean ± standard deviation and exact p values are presented except when < 0.001.

3. Results

One-hundred and seventy-one patients were identified for inclusion in the study with 47 in the CPS group and 124 in the OTS group. All patients completed the minimum 3 month follow-up and were included in the subsequent analysis. Patient demographics were similar between the CPS and the OTS groups in terms of BMI (30.7 ± 5.7 v. 30.3 ± 7.0; p = 0.69) and sex (18 male and 29 female v. 42 male and 82 female; p = 0.59) (Table 1). There was however a significant difference in age, with the OTS group approximately 3 years older on average (66.9 ± 7.7 v. 70.0 ± 8.5; p = 0.03). Both groups demonstrated similar pre-operative KSS, KSFS, and ROM (52.7 ± 10.8 v. 55.1 ± 12.5; p = 0.23, 56.3 ± 16.3 v. 51.8 ± 16.0; p = 0.11 and 109.4 ± 9.6 v. 109.3 ± 9.1; p = 0.94, respectively) (Fig. 1).

There was one manipulation performed within the first three months post-operatively in the CPS group (1/47; 2.12%) and two in the OTS group (1/47, 2.12% v. 2/124, 1.6%; p = 0.82). Early manipulation was performed an average of 6.6 weeks (range 6–7 weeks) following surgery. One additional manipulation was performed in the OTS group 1.8 years post-operatively. There was no significant difference between the CPS and the OTS groups in terms of 3 month post-operative KSS (91.1 ± 9.6 v. 91.7 ± 10.2; p = 0.73), KSFS (81.4 ± 15.3 v. 77.6 ± 19.4; p = 0.19) or ROM (118.8 ± 11.0 v. 119.3 ± 6.1; p = 0.76) (Fig. 2). The average improvement, defined as post-operative score minus pre-operative score, demonstrated similar improvements in the CPS and OTS groups for KSS (38.3 ± 14.4 v. 36.6 ± 15.7; p = 0.49), KSFS (25.1 ± 18.4 v. 25.8 ± 21.6; p = 0.82) and ROM (9.4 ± 13.9 v. 10.0 ± 10.0; p = 0.77) (Fig. 3).

Of the one-hundred and seventy-one patients included in the initial cohort, seventy-four completed the FJS telephone survey. There were 16 CPS and 58 OTS patients. As with the original cohort, these patients were similar in BMI (31.6 ± 5.3 v. 30.9 ± 6.4; p = 0.65) and sex (7 male and 9 female v. 21 male and 37 female; p = 0.37), however, there was a significant difference in patient age with the OTS group 7 years older on average (64.4 ± 7.3 v. 71.3 ± 8.2; p = 0.003) (Table 2). The FJS surveys were completed an average of 1.9 years post-operatively (range 1.4–2.6 years) and the length of follow-up was similar between

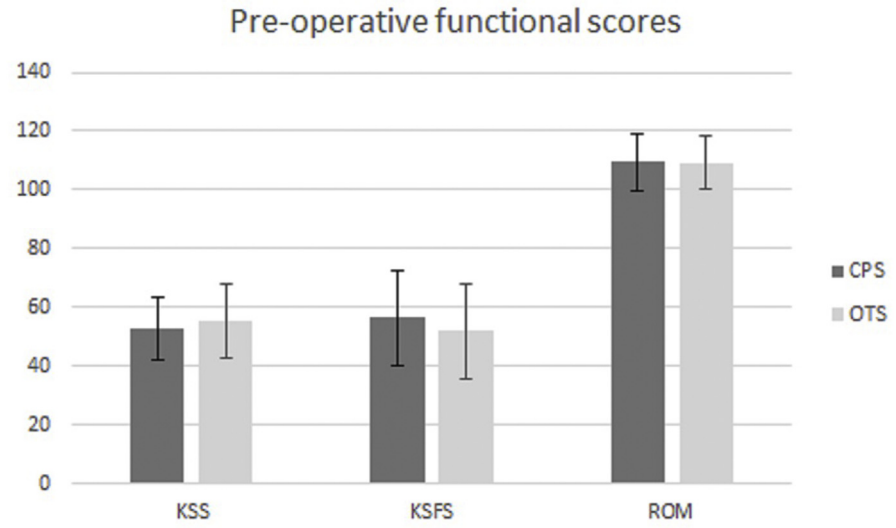

Fig. 1. There was no significant difference in the pre-operative functional outcome scores between the patient-specific (CPS) and the off-the-shelf (OTS) groups. KSS-Knee Society Score; KSFS- Knee Society Functional Score; ROM-range of motion.

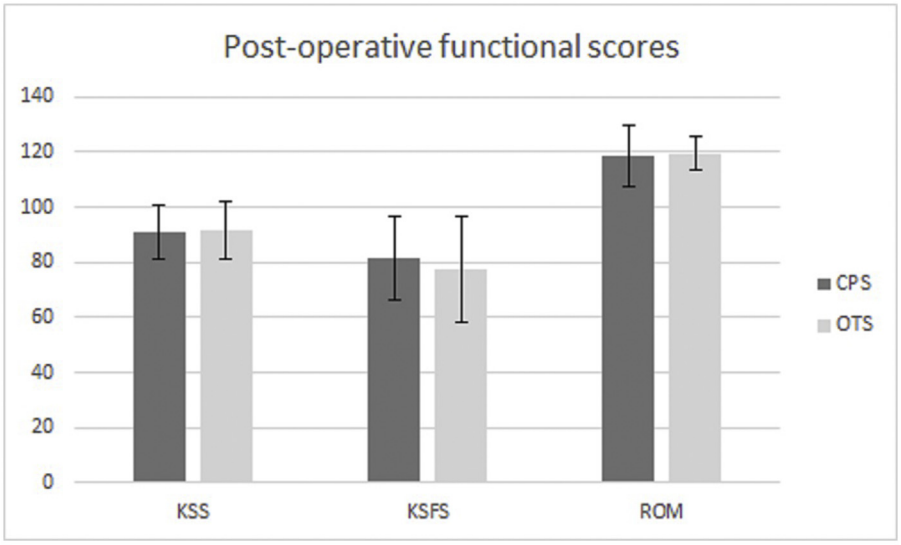

Fig. 2. Post-operative functional scores were obtained three months post-operatively and compared between the two groups. There was no significant difference in post-operative functional scores.

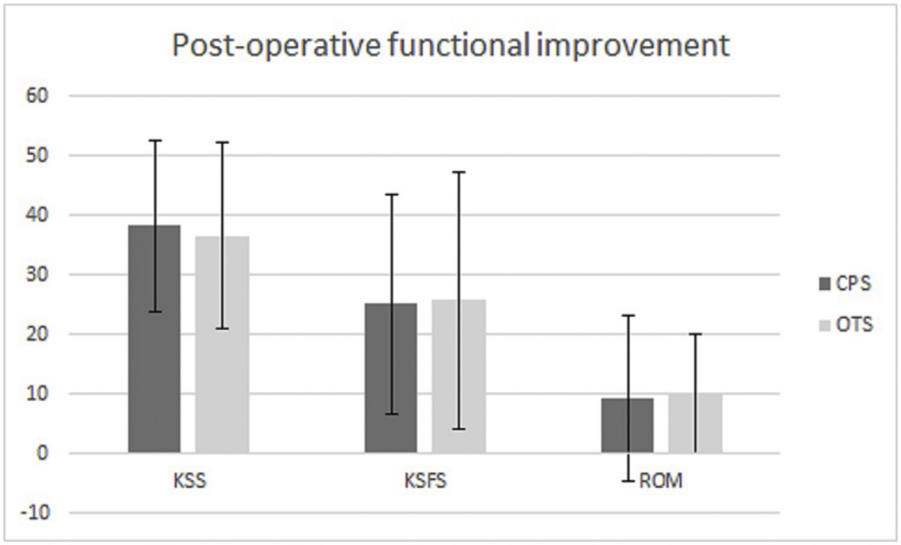

Fig. 3. The functional improvement was defined as the post-operative score minus the pre-operative score. Both groups demonstrated a substantial increase in their functional scores, however, there was no difference in the amount of post-operative functional improvement between the two groups.

Table 2
Forgotten Joint Score survey patient demographics.

	OTS	CPS	p-value
n =	58	16	
BMI	30.9 ± 6.4	31.6 ± 5.3	= 0.65
Sex	21M:37F	7M:9F	= 0.37
Age	71.3 ± 8.2	64.4 ± 7.3	= 0.003
Length of follow-up	1.93 ± 0.3	1.85 ± 0.3	= 0.37

the CPS and OTS groups (1.85 ± 0.3 v. 1.93 ± 0.3; p = 0.37). There was no difference in the Forgotten Joint Scores between the two groups (56.0 ± 26.9 v. 62.1 ± 25.7; p = 0.42) (Fig. 4).

Among the OTS group, there was one arthroscopic debridement for patellar crepitation performed 15 months post-operatively and one patient who sustained a patellar fracture after a fall which required surgical fixation. Four patients in the CPS group required subsequent arthroscopic debridement due to symptomatic patellar crepitation. All procedures were performed greater than 6 months post-operatively (range 7–17 months). One additional patient in the CPS group required multiple subsequent procedures following the initial MUA 7 weeks post-operatively; a synovial debridement and polyethylene exchange 6 months post-operatively, then a revision TKA 20 months post-operatively, followed finally by a MUA 3 months following revision surgery.

4. Discussion

Total knee arthroplasty has a long history and has generally been regarded as a very successful surgery for the treatment of end-stage degenerative knee arthritis. Despite the relatively favorable outcomes seen over time, a significant proportion of patients are unsatisfied with their results.[17–20] Total knee replacement has undergone significant modifications since the Total Condylar Prosthesis was introduced over 40 years ago, with the aim of improving patient outcomes and satisfaction. While some of these improvements and design modifications have clearly led to the increased longevity of implants, others have had a less dramatic effect. The most recent advance in the design of knee

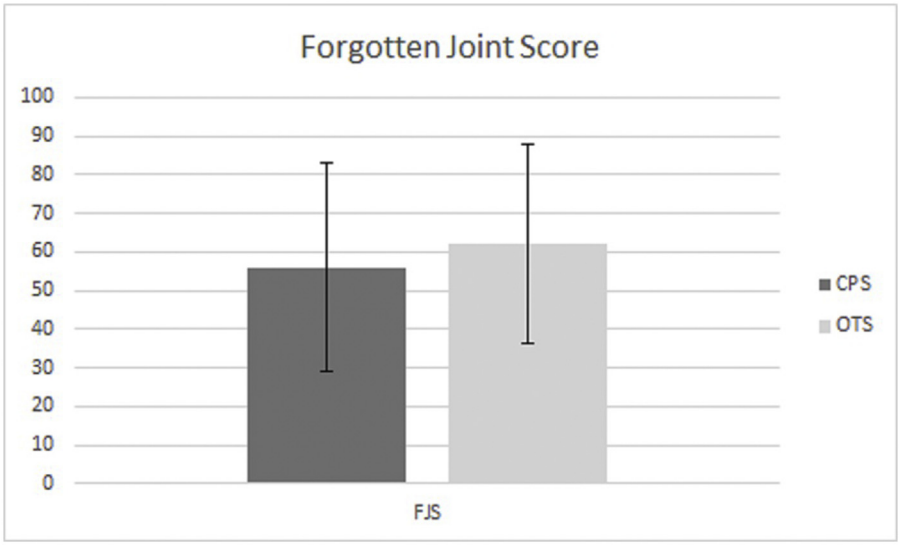

Fig. 4. The Forgotten Joint Score (FJS) survey was completed by phone an average of 1.9 years post-operatively. There was no significant difference in the FJS between the two groups.

replacements has come in the form of patient-specific implants. These implants are based off of pre-operative imaging of a patient's knee and were designed to more closely recreate the anatomy and kinematics of a native knee with the goal of producing a more natural feel.[21] There has been relatively little published about these implants since their introduction and, to our knowledge, no reports which have included the ConforMIS iTotal PS system.

White et al. previously reported an extreme increase in the manipulation rate in patient-specific, cruciate retaining knee replacements. Our data, however, did not show any significant increase in manipulations when using a patient-specific, posterior stabilized implant. While their findings are concerning, it does not appear to be associated with the PS design. Our data appears to suggest that patient-specific PS implants perform as well as existing off-the-shelf implants in the early post-operative period with no significant increase in manipulation rates. Additionally, we did not find any difference in the Forgotten Joint Scores that were collected at greater than one year post-operatively. We did, however, find an increase in the rate of symptomatic patellar crepitation requiring surgical debridement among patients with patient-specific implants compared to those with off-the-shelf implants. This is a previously unreported complication associated with the patient-specific PS system and resulted in 8.5% of patients requiring an additional surgery for debridement of symptomatic crepitation. This represented a relative risk of 10.5 compared to the off-the-shelf group.

Our study does contain limitations which should be addressed. First, its retrospective nature has inherent potential for selection bias with potentially more motivated patients requesting the CPS TKA. Further, as the primary surgeon also noticed an increase in the manipulation rate of his custom CR implants, a decrease in stiffness may represent a learning curve in the implantation of the CPS knee arthroplasty. However, the CPS group does include his first CPS implantation, so we believe the lack of difference found in manipulation rates is likely a true finding. Another limitation that should be discussed is that due to the relatively high Knee Society Scores in the off-the-shelf group, it would be difficult to demonstrate a significant increase in the functional scores of the CPS group. Additionally, less than half of the patients included in the original cohort completed the FJS survey once contacted. The relatively low response rate, 43%, could be considered a potential source of bias. With the low response and relatively good functional scores in both groups, the study is underpowered to detect a small, but potentially significant difference in FJS scores. Further, three months is a short time period for follow-up to assess outcomes after knee arthroplasty. However, we felt that this was sufficient length of follow-up to address the primary outcome of manipulation rates as the majority of manipulations are typically performed within the first 6–12 weeks following surgery. However, since the main aim of this study was to compare manipulation rates, we believe the results are still valuable. Future studies should take into account the inclusion of additional outcome measures and longer term follow-up.

Total knee arthroplasty has a long and successful track record, but there is still room for improvement. As patients undergoing TKA continue to get younger, their expectations continue to push the limits of what current implants can provide. Implant design has changed significantly since the Total Condylar Prosthesis revolutionized knee replacement and will continue to transform until patient satisfaction improves. Patient-specific implants are the latest modification available in the ever changing field of knee arthroplasty, and while concerns regarding stiffness in the cruciate retaining design have been raised, it does not appear to affect the posterior stabilized system. This study does report a novel complication of patellar crepitation necessitating repeat operation at a rate of 8.5% with the patient-specific posterior stabilized implant. Further investigation will be needed to determine if patient-specific implants are truly an improvement over the existing off-the-shelf implants or if they simply represent the newest change without any significant progress in functional or patient reported outcomes.

Conflicts of interest

One or more of the authors reports personal fees from ConforMIS and Zimmer-Biomet outside the submitted work. No funding was provided for the completion of the present work.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jor.2018.11.003.

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