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Research Article

Does High Flexion Explain Aseptic Failure in a High Flexion Posterior Stabilized Direct Compression Molded Polyethylene Modular Total Knee?

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Abstract

Background: The Logic PS knee combined with the Fit tibial tray is a modular high flexion implant which became available in 2010. Early clinical results and knee range of motion reported with this prosthesis have been excellent, but some late aseptic failures have raised concerns. We are presenting our experience with this prosthesis to understand the incidence and possible explanations for aseptic failures.

Methods: A cohort of 260 primary total knees performed by the senior author with 2-to-8.7-year follow-up data were evaluated. Data pertaining to patient demographics, surgical technique, implant constraint and implant survival were collected prospectively in an IRB approved registry. Patients who could not return in person prospectively were contacted retrospectively by phone or email. Each aseptic failure was identified and assessed. Retrieved implants were examined.

Results: Average follow-up was 58 (24-104) months. Eighty-nine percent reported good or excellent Oxford knee scores and 9 of 10 satisfaction at latest follow-up. Implant survival with aseptic revision of either tibial or femoral component as an end point was 98%. Five implants (1.9%) underwent aseptic revision. One at 7 months for tibial malposition and instability and 4 at a mean 70.5 months for polyethylene wear, osteolysis, or femoral loosening.

Conclusions: A high percentage of patients in our study reported good or excellent clinical results at a mean 58 months. Four failures at 70.5 months, however, exhibited either severe damage to the posterior aspect of the tibial post, backside wear of the modular tibial junction, articular surface wear, and/or femoral loosening. These kinds of failures rarely seen in the previous PS design suggest an increase in the magnitude of the anteriorly directed force felt by the tibial post, insert, insert-baseplate junction and femoral cam in this newer high flexion design. The observations in this study cannot prove such an explanation, but hopefully will stimulate further study. There were no cases of Fit tray tibial loosening or polyethylene damage consistent with oxidation. Patient follow-up and x-ray are recommended at or before 70 months in patients receiving this implant.

Keywords: Osteolysis; PS Logic; Aseptic Loosening; Polyethylene

Introduction

The Logic Posterior Stabilized total knee is a cemented modular implant that evolved from the Insall Burstein Posterior Stabilized (Zimmer Biomet, Warsaw, IN; Johnson and Johnson, New Brunswick, NJ) and Optetrak PS (Exactech, Inc. Gainesville, FL) knee lineage [1]. The femoral component was introduced in 2008 as a high flexion descendent of these designs. The Fit modular tray was introduced in 2010. Together they included a modified cam and post, posterior tibial insert chamfer, bone preserving cylindrical femoral box, direct compression molded polyethylene insert, and an additional posterior femoral radius of curvature [2-4]. These design changes successfully accommodated 145 degrees of knee flexion fulfilling the requirements of a high flexion knee.

The Fit tibial component included a cobalt chrome tray, trapezoidal stem with medial and lateral fins and the same improved locking mechanism successfully used in the prior Optetrak modular knee. Early results of the Logic PS knee were reported to be very successful [3,5,6]. Recently, however, concerns have been raised regarding cases of aseptic loosening and osteolysis [7,8]. The causes of such concerns may be multifactorial and require close clinical, radiographic, and retrieval analyses to understand. To determine the incidence

and possible explanations for such concerns, we have reviewed our institutional experience with this implant and examined retrieved inserts.

We hypothesized that the Logic PS/Fit tray total knee is a clinically successful design with a low rate of aseptic failure.

Materials and Methods

The senior author performed 427 primary cemented Logic PS or PSC (posterior stabilized constrained) Fit tray total knees from 3/5/2012 to 2/18/2019. All surgeries were performed with a tensor with either traditional jigs or GPS Pro computer navigation (Exactech, Gainesville, FL). From 1/1/2016 to 5/2/2019, 147 (40.7%) of the knees were performed using GPS computer navigation. All inserts were processed by direct compression molding. The manufacturer has provided the time between packaging and implantation for each case.

All patients were informed, consented, and entered prospectively into an IRB approved institutional total joint database. Inclusion criteria were patient age > 18 years and surgical procedure with use of Logic PS or PSC Fit tray total knee. Exclusion criteria were patients with < 2 years follow-up data. Patients were prospectively instructed to return for follow-up at 6 weeks, 3 months, 1 year, 5 years, and 10 years. X-rays were obtained at follow-up. Patients who did not return in-person for this study were contacted by phone or email acquiring implant survival data, knee ratings, Oxford scores, patient satisfaction scores, and adverse event reports. 260 of the cases had ≥ 2-year follow-up data (24 to 104 months) and comprised our study cohort. Pooled two-sample t-tests were used to compare parametric populations. Significance was defined as $p < 0.05$. Statistical analysis was performed in JMP Pro 16 (Cary, NC).

Three different cements were used serially: Cemex fast set with Gentamycin (Exactech) from 3/5/12 to 5/13/14 (275 knees), Simplex with and without Tobramycin (Stryker, Kalamazoo, MI) from 5/20/14 to 9/22/15 (34 knees), and Simplex HV with and without Gentamycin (Stryker) from 9/22/15 to 3/2/2020 (118 knees). Each cement was mixed according to the manufacturer's instructions using their designated mixing equipment and not used until the beginning of dough phase as determined by the glove stick test. Cemex cement monomer and polymer were self-contained in a sealed mixing cylinder. Vacuum was used briefly with both Simplex cements at the beginning of mixing to reduce polymer fumes in the operating room.

Bone surfaces were washed with pulsatile lavage before cementing. Sclerotic bone surfaces were drilled. Tourniquet was used in all cases unless contraindicated due to vascular pathology. As soon as dough phase was reached cement was applied to the posterior condyles of the femoral implant and then pressed into the tibial peg hole with finger pressure and unto the tibial plateau. No cement was applied to the tibial component or other areas of the femoral component.

The modular tibial tray and final inserts were preassembled on the back table by the attending surgeon during cement mixing to be certain that inserts were fully engaged. The tibial component with its final plastic insert were inserted manually onto the cement and into the cement filled tibial peg hole as a monoblock component and pressed into place. The tibial impactor and mallet were used to additionally seat the implant. Extruded cement was removed with Freer elevators. Dough phase cement from the same mixing was placed on the two distal condylar femoral surfaces and the distal anterior femur. After placement and impaction of the femoral component the knee was fully extended, the patella cemented and pressure applied anteriorly for 30 seconds to additionally fully extend and pressurize the tibial and femoral cement mantles as described by Walker., *et al.* [9] The entire cementation process was timed in a series of knees and took 4 to 5 minutes after the beginning of dough phase. The knee was then flexed briefly to remove additionally extruded cement and re-extended with the heel on a bump for polymerization, wound irrigation, and deep tissue closure.

All inserts, removed in aseptic revisions were saved, photographed, and studied (Figures 1-3,5). One of the inserts removed for osteolysis which showed little obvious surface damage was digitally scanned and compare with an identical unused insert (Figure 4). This insert was stored in a freezer and later sent to the Harris Orthopaedic laboratory at Mass General Hospital for oxidation measurements.

Results

Our study cohort consisted of 260 knees (61%) with an average follow-up of 58 months (24-104 months). Median follow-up was also 58 months. 63% were female. Average BMI was 32.1. Average age at surgery was 64 years. There were 79 bilateral procedures, 33 were simultaneous and 46 were staged. Diagnoses were primary osteoarthritis (84%), secondary OA (6%), inflammatory arthritis (4%), and other (6%). Mean function scores improved from 47 to 76 ($p < 0.0001$). Mean Oxford scores improved from 17 to 40 ($p < 0.0001$). At last follow up, 89% of our cohort reported good or excellent results, based on a descriptive categorization of scores [10,11]. Furthermore, the OKS change score, another recent and clinically meaningful interpretation [12] was greater than 16 demonstrating a "much better" outcome on a population level. Patient satisfaction scores averaged 9.0 (range 1-10).

Implant survival at a mean 58 months with aseptic revision of tibial or femoral components as an end point was 98%. Three were revised for osteolysis and polyethylene wear, one for malposition of a tibial component, and one for aseptic femoral loosening. The knee with a malpositioned tibia was revision at 7 months because of pain and mid flexion instability. The components were not loose. This early retrieved insert had no visible wear. The tibial component was reimplanted in proper alignment with a stemmed component and a posterior stabilized constrained (PSC) insert. Four other knees underwent aseptic revisions at 41, 74, 80, and 87 months. These cases will each be described in detail in figures 1-5. All the aseptic revision cases were originally performed with tourniquet. None of the aseptic revision cases had PSC inserts. Data pertaining to each case are listed.

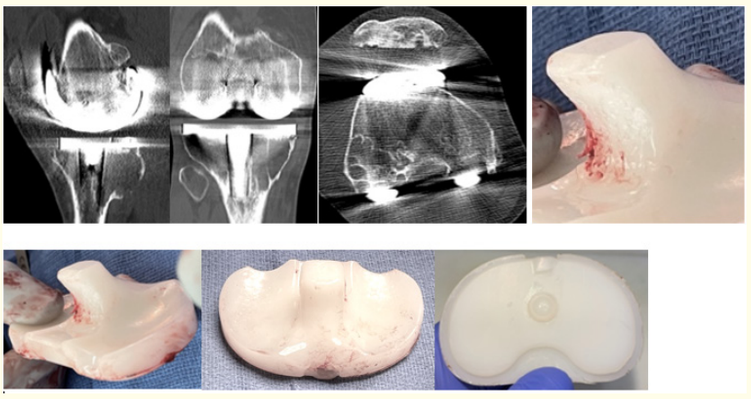

Figure 1: Case Example 1: Aseptic Revision. The first case was in a male competitive slalom water skier and surfer who had had multiple ACL reconstructions and revisions prior to his total knee. He underwent a right total knee replacement with patellar resurfacing, using Cemex fast set cement. At index surgery he was 51 years old, 5'1" and 188 lbs. He continued his vigorous sporting activities following his total knee surgery. Revision was required at 87 months because of the sudden onset of posterior medial knee pain. Infection workup was negative. An x-ray and CT scan revealed a large posterior lytic tibial lesion and a femoral lytic area. An avulsion fracture had occurred in the region of the semimembranosus tendon attachment. At revision, both lateral femoral and medial tibial osteolysis was found. Neither the femoral nor tibial components were loose although the femoral component was easily removed. Osteolysis was undermining both implants. The insert showed severe wear on the back of the tibial post and complete obliteration of the 0.5mm deep labeling on the anterior aspect of the insert backside. The time from insert packaging to index surgery was 21 months.

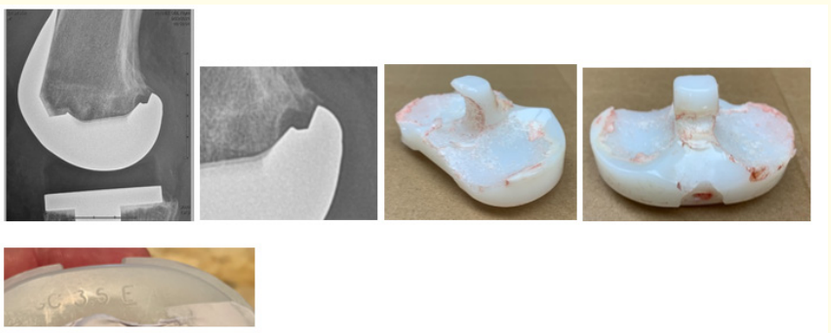

Figure 2: Case Example 2: Aseptic Revision. The second case was a right total knee without patellar resurfacing, performed in a 263 lb. 59-year-old ligamentously lax male with Simplex HV cement. He explained that as an automobile mechanic he was called "the monkey" because he could get into unique positions. Revision was performed because of progressive swelling, pain, and instability. Infection workup was negative. Revision at 41 months consisted of a complete synovectomy and insert exchange with a thicker PSC insert. The patella was resurfaced. The insert revealed severe abrasive wear in both compartments. Wear was most pronounced posterior medially and anterior laterally plus circumferentially around the post consistent with gross rotational instability. There was partial disappearance of backside labeling. At revision, the femoral component was solidly fixed and retained but there were osteolytic areas anterior to both posterior femoral flanges. X-rays revealed absence of posterior femoral condyle cement. Synovial histology revealed large fragments of polyethylene debris. The time from packaging to index surgery was 84 months.

Figure 3: Case Example 3: Aseptic Revision. The third case was a 200 lb., 56-year-old female nurse who underwent a right total knee replacement with patellar resurfacing and Simplex T cement. Revision was required at 79 months because of increasing pain and swelling. Work up for infection was negative. X-rays demonstrated a widening medial tibial lytic lesion at the cement bone interface and a large medial femoral condyle lytic area. At revision neither femoral nor tibial components were loose. However, both lytic areas were undermining components jeopardizing fixation. As a result, both femoral and tibial components were revised. Examination of the tibial insert revealed a small area of pitting anterior medially and a measurable 1.6mm thinning of the medial side of the insert. The medial articular surface was burnished. Backside anterior labeling was still present. The back of the post was smooth but burnished. To better understand the loss of thickness, the implant was scanned and compared with an original insert of the same size revealing loss of material on both the top and backsides of the insert medially (Figure 4). The time from packaging to insertion was 5 months. Oxidation measurements were not elevated.

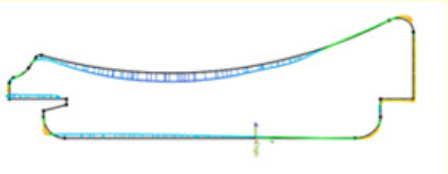

Figure 4: Digital scan of the medial compartment of the tibial insert in case example 3 demonstrating loss of material from the top (blue) and bottom (green) of the insert.

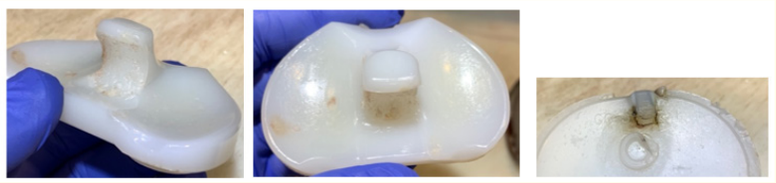

Figure 5: Aseptic Revision. The fourth case was a right total knee replacement with patellar resurfacing using Simplex cement in a 181 pound, 44-year-old woman. Revision was necessary at 74 months because of progressive knee pain and swelling. The patient was noted to have exceptionally high flexion prior to her revision. At surgery the femoral component was loose and easily removed from an intact cement mantle. There was severe wear of the posterior aspect of the post but little damage to the articular surfaces. There was no osteolysis. The time from packaging to surgery was 56 months.

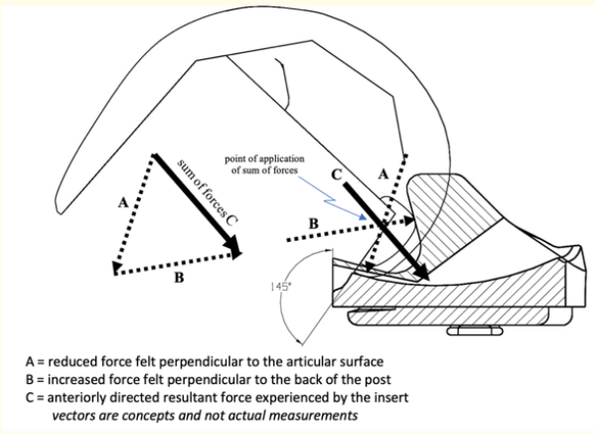

Figure 6: Forces felt by the tibial insert in a high flexion posterior stabilized knee to be compared to those in the IBPS knee described by Insall., *et al*. in 1982 [13].

Discussion

The Logic PS/Fit tray total knee is a high flexion posterior stabilized implant designed to accommodate 145 degrees of flexion. The clinical results in our series were excellent with a high rate of implant survival and patient satisfaction at a mean 58 months. The incidence of aseptic revision in our series was 1.9% (5/260) at a mean 58 months. One early aseptic revision was required due to technical error and should not be considered as a failure related to the implant.

The 4 aseptic revisions (1.5%) occurred at a mean 70.5 months and were due to combinations of polyethylene wear, osteolysis, and femoral loosening. Three of the cases developed osteolysis (1.2%). Two of these required major revision of both tibial and femoral components with metaphyseal cones due to bone loss. The third osteolysis case required synovectomy and liner exchange with a PSC insert. The original femoral and tibial base plate components were left in place. One aseptic revision was due to femoral loosening at 74 months. There were no cases of tibial aseptic loosening and there was no pattern of failure related to cement type.

The Insall Burstein Posterior Stabilized (IBPS) knee was originally designed to accommodate 120 degrees of flexion [9]. There were concerns at the time that the posterior stabilized cam mechanism might result in increased tibial loosening compared to the Total Condylar knee [1]. Insall., *et al*, explained that the resultant force experienced by the IBPS monoblock tibial component as it accommodated 120 degrees of flexion was directed downward in line with the tibial stem [13]. This along with the reported low incidence of aseptic loosening with the PS design at 2-4 years alleviated concerns. Both the IBPS knee and the subsequent Optetrak Posterior Stabilized knee went on to successful long-term results [5,14].

However, since that time several things have changed that might explain our 4 aseptic failures. First, tibial components became modular introducing a new implant interface. In the Optetrak lineage, a more secure three-part locking mechanism including a peripheral rim, a central mushroom, and a posterior metal overhang were combined with tighter tolerances to reduce the possibility of clinically significant backside wear. Tolerances were tightened to minimize insert motion. This made placement of the insert more challenging but was felt to reduce insert movement and subsequent backside wear. The senior author elected to engage the insert before cementing to assure that there were no seating errors. The Optetrak PS knee at 11 years showed no radiographic signs of osteolysis [14]. Jayabalan., *et al.* performing a retrieval analysis of 71 modular PS knee inserts of several designs found that 100% of earlier retrieved IB-II inserts showed evidence of backside wear while only 17% of the newer Optetrak PS inserts showed any evidence of backside wear [15]. They concluded that locking mechanisms greatly affected the occurrence of backside wear. They demonstrated the improvement of insert engagement in the Optetrak modular knee. Although modern locking mechanisms have improved, they cannot completely eliminate movement between the insert and baseplate.

Second, implants are now designed to accommodate even more than 120 degrees of flexion. Ruel., *et al.* reported that 41% of the Logic PS knee cases achieved >130 degrees of flexion compared to 19% in the earlier Optetrak PS design [16].

Third, patients who achieve such high flexion, are also more likely to use it. Our competitive slalom water skier and surfer (Case 1), for example, would not consider discontinuing his athletic pas-

sions despite being advised otherwise. Furthermore, high flexion does not necessarily have to involve exceptional activities. Han., *et al.* reported that squatting, kneeling, or sitting cross-legged could be achieved in 85% of a cohort of aseptic loosened high flexion implant cases compared to 49% of a well-fixed, high flexion knee cohort [17]. Our case of femoral loosening (Case 4) was observed to have exceptionally high knee flexion prior to her revision but was not involved in extreme activities.

As a result, in high flexion activities in posterior stabilized high flexion knees, there can be a reduction in the downward force perpendicular to the articular surface of the insert and an increase in the force perpendicular to the posterior face of the post. A finding in 3 of our retrieved inserts was severe damage to the posterior aspect of the tibial post. During that situation, the resultant force felt by the insert would be directed more anterior than that described for the IBPS knee. (Figure 6). Some have had concerns that this might overwhelm previously successful implant fixation, polyethylene components, and tibial locking mechanisms. Paterson., *et al.* examined whether high flexion designs resulted in more articular surface, backside, and post damage and whether flexion angles achieved correlated with more insert damage [18]. They found greater backside wear and post damage in a high flexion design but did not find greater articular surface damage. Daines., *et al.* in their study did not find high flexion designs were associated with higher insert damage. The Logic PS knee retrieval times in their study, however, were short [19]. Only one of their retrieved inserts exceeded 25 months and that implant was revised for loosening. Schnaser., *et al.* reported, from the same institution, also noted that there was no difference in polyethylene surface damage between high flexion and posterior stabilized designs [20]. But again, follow-up times in their report for the Logic PS implant were only 3 to 29 months. Our study benefits from an average follow-up of 58 months and we noted that cases of aseptic failure occurred at a mean 70.5 months.

This does not mean that polyethylene damage to the post in earlier PS designs did not occur. Gilbert., *et al.* described considerable damage in multiple designs in a retrieval study and stated that *"Damage to the posterior surface of the post is expected since repeated articulation with the femoral cam during flexion provides the mechanical constraint to femoral anterior translation that is the prime basis of the PS design"* [3].

The interfaces experiencing load in an implanted posterior stabilized highly flexed modular knee include the femoral fixation interfaces; the cam and post; the femoral-tibial articular surfaces; the insert-baseplate surfaces; and the tibial fixation interfaces. Any of these interfaces can fail. In our cohort, we saw femoral loosening, posterior post damage, insert articular surface wear, and insert backside wear. Our case of femoral loosening (Case 4) occurred at the cement implant interface with an intact cement mantle. There was no osteolysis. However, if such debonding at the implant cement interface is only mildly symptomatic movement of the inner surface of the femoral component would be expected to eventually result in small particulate debris, osteolysis, gross loosening and metal burnishing as reported by Malahias., *et al*. [7]. Small particulate polyethylene debris from backside surfaces of the insert can also result in osteolysis. Our three cases of osteolysis (Case 1-3) are examples of these modes of failure.

Although the incidence was low any case of polyethylene wear resulting in osteolysis is concerning. Design changes that increased the femoral-tibial conformity to 0.96 first in the Optetrak knee and then continued in the Optetrak Logic knee has had an excellent record for resisting polyethylene wear [14]. In addition, the use of direct compression molded polyethylene has had an excellent track record with respect to polyethylene wear. Ritter reporting on 4,583 Anatomic Graduated Component total knees with a monoblock tibia using DCM polyethylene found no cases of osteolysis at 8 years [21]. Long., *et al.* found a 92.3 percent implant survival of the monoblock DCM polyethylene IBPS knee at 30 years in young active patients [22]. Here, however we are reporting on a modular component. Lombardi., *et al.* recognizing the advantage of articular surface wear with DCM polyethylene questioned whether the use of DCM polyethylene showed less backside wear in modular tibial components [23]. Looking at retrieved inserts, they found that backside wear still occurred, but the amount was less than that seen with non-compression molded polyethylene [15,24].

It is reasonable to question whether there has been a change in the DCM polyethylene itself. The manufacture of the Logic PS knee insists that there have been no changes in the production of their DCM polyethylene between the Optetrak PS knee and the Logic PS knee. However, Exactech has reported that the vacuum packaging if their inserts did not contain a secondary barrier layer containing ethylene vinyl alcohol that further protects against oxygen. But we did not see delamination in any of our retrieved inserts and the oxidation measurement of one insert was unremarkable. The time between insert packaging and implantation in our cases also did not support oxidation as an explanation.

Conclusions

A high percentage of patients in our study of Logic PS high flexion knee cases with the Fit tibial tray reported good or excellent clinical results at a mean 58 months. There were 4 cases (1.54%) that required aseptic revision at a mean 70.5 months. Taken indi-

vidually these 4 cases failed in different ways, however each may be explained by a change in the direction and magnitude of the resultant force felt by the tibia and femoral cam in high flexion activities. Our study cannot prove such an explanation; however, it does raise questions that will require further study. Cement type did not correlate with aseptic failure and there were no cases of delamination suggestive of polyethylene oxidation. There were also no cases of Fit tray loosening, although osteolysis beneath the tray would likely eventually jeopardies fixation. Follow-up examination and x-rays in patients with this high flexion PS knee are recommended at or before 70 months. Monoblock tibias would eliminate backside wear and enhanced femoral fixation might reduce the risk of femoral component loosening.

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Declarations of Competing Interest

GBR and BAL: No commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article. RPR: Consultant for Exactech, Inc. Gainesville, FL; Expert witness for Stryker, Osartis, Exactech; Exactech is the sponsor for the UM joint registry.

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