Isolated Tibial Polyethylene Insert Exchange Outcomes After Total Knee Arthroplasty

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Abstract Total knee arthroplasty (TKA) using a modular design allows isolated tibial polyethylene insert exchange (ITPIE) as a treatment option for isolated polyethylene failure. We asked whether ITPIE in selected patients would provide high survivorship and identified factors predicting success or failure. We retrospectively reviewed 42 patients (42 knees) who underwent ITPIE for instability, stiffness, or aseptic effusions after TKA. All patients had well-aligned and well-fixed components documented by radiographs and intraoperative evaluation. We determined whether patients had been revised and evaluated unrevised patients using the Knee Society rating system. The minimum followup was 2 years (average, 5.6 years; range, 2–11 years). Twelve patients (29%) underwent subsequent revision of their ITPIE (58% survivorship at 11 years). Average time to revision was 3 years. Although mean Knee Society scores improved, nine of the 30 unrevised

patients (30%) had persistent pain at followup. Time from index TKA to ITPIE was associated with outcome; ITPIE less than 3 years from index TKA was 3.8 times more likely to undergo rerevision than ITPIE more than 3 years from index TKA. ITPIE for failed TKA is associated with unpredictable outcomes. ITPIE, even with well-defined and narrow indications, should be undertaken with caution. The longer the initial components performed successfully before ITPIE, the greater the likelihood of success after ITPIE.

Level of Evidence: Level II, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

TKA with a modular design was developed in the mid-1980s to give surgeons the flexibility to exchange the polyethylene without revising the tibial tray. Exchange of the polyethylene insert when the components are well-fixed and well-aligned reduces the complexity of the surgery, preserves bone stock, and may allow the patient an easier recovery [6].

Reported results have been mixed regarding the effectiveness of isolated tibial polyethylene insert exchange (ITPIE) for failed TKA resulting from instability, polyethylene wear, or stiffness. Engh et al. [5] reported six of 22 ITPIE for severe wear failed at an average of less than 5 years. Similarly, Babis et al. [1] described a cumulative survival rate of 63.5% at 5.5 years for patients who underwent ITPIE primarily for wear or instability. Failure rates for ITPIE have been reported from 6% to 27% [5, 6, 9].

ITPIE has been used for stiffness, instability, symptomatic effusion, pain, sepsis, and early polyethylene wear

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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with varying degrees of success [2–4]. Some authors [1, 2, 5] have proposed that despite the modular design, a complete revision is necessary for excellent long-term clinical results. However, Jensen et al. [8] reported short-term survival after ITPIE is similar to that of a total knee revision with exchange of all components.

To address this controversy, we asked whether (1) ITPIE when performed for instability, stiffness, or effusions believed to be the result of polyethylene wear would have high survival rates; (2) the reason for ITPIE would influence likelihood of revision; and (3) component design or time in situ of the original arthroplasty or other factors were correlated with the likelihood of success after ITPIE.

Patients and Methods

We used our outcomes database to identify 374 TKA revisions of 6152 TKAs performed at our institution by four senior arthroplasty surgeons, two of whom are authors of this article (CWC, KAE). Of the 374 TKA revisions, 67 were identified as ITPIE procedures performed between 1991 and 2005. We included all patients with well-aligned, well-fixed TKA components who underwent ITPIE secondary to instability, stiffness, or recurrent symptomatic aseptic effusion believed to be the result of polyethylene wear. We excluded 20 patients who had ITPIE for sepsis, patellar maltracking, patellofemoral pain, component malposition, or fracture. These exclusions left 47 patients (47 knees). The ITPIE was the first revision after index TKA for 46 of 47 patients; one patient had a previous revision TKA and then presented for an ITPIE. Eight patients had a revision of the polyethylene patellar component at the time of ITPIE. Of the 47 patients, seven had died. In five of the seven, we were able to determine the functional status of the knee at the time of death, but in two of the patients who died, the ultimate revision status was unable to be determined definitively. Three patients were lost to followup. We therefore had 42 patients for whom we had full followup data. There were 11 men and 31 women with a mean age at the time of ITPIE of 70.9 years (range, 46–85 years). The average body mass index was 28 kg/m² (range, 19–40 kg/m²). Diagnoses for index TKA were osteoarthritis (38 patients), rheumatoid arthritis (three patients), and osteonecrosis (one patient). The minimum followup after ITPIE was 2 years (average, 5.6 years; range, 2–11 years). Our prospective outcomes database and the review of data were approved by our Institutional Review Board.

Data collected on patients at the time of ITPIE included demographics, preoperative range of motion, and Knee Society (KS) rating system scores [7]. The reason for ITPIE and the type of implanted tibial polyethylene insert

(cruciate-retaining or posterior-stabilized) were also captured.

Knees were selected for ITPIE if the surgeon believed the components were properly aligned and well-fixed based on examination and radiographs. Adequate alignment was defined as 5° to 7° of tibiofemoral valgus as measured on standard office radiographs, neutral flexion of the femoral component ($\pm 3^\circ$), and posterior tibial slope of 2° to 10°. Fixation was considered satisfactory if there was no evidence of component migration, subsidence, change of alignment, and absence of progressive radiolucencies on radiographs. Adequate rotational alignment was determined based on clinical examination of the limb with attention paid to the rotational position of the femoral epicondyles, patella, tibial tubercle, and malleoli. The ITPIE was performed for 23 patients with instability, four with stiffness, and 15 with recurrent symptomatic aseptic effusion believed to be the result of polyethylene wear at a median of 3.1 years (range, 8 months to 17.2 years) after the index TKA (Table 1). A cruciate-retaining design was used for the index arthroplasty in 26 knees (63%) and a posterior-stabilized design was used for 15 knees (37%). In one knee, the cruciate status was not able to be determined from the records available. ITPIE was performed for all three diagnoses (instability, stiffness, and effusion) in patients with both cruciate-retaining and posterior-stabilized component designs (Table 2).

All ITPIEs were performed using a medial parapatellar approach and there were no unique aspects of the surgery that could have influenced the outcome. Preoperative computed tomographic scanning was not used for this group of patients. Component fixation was rechecked intraoperatively using manual tools to apply tensile forces and varus-valgus loads to the components. Intraoperative assessment of rotation was based on gross inspection of component position relative to the tibial tubercle and the femoral epicondyles.

Postoperative followup visits were scheduled for patients at 1 month, 3 months, and 12 months postoperatively. Beyond 12 months, followup regimens were variable and reflected individual surgeon preferences, differences in patient compliance, and patient-specific recommendations. Patients were evaluated at all postoperative visits by the operating surgeon, which included clinical examination (pain, range of motion, revision status), radiographs, and patient questionnaires. KS scores were generated based on these visits. Pain at the various followup intervals was determined from an item on the KS questionnaire filled out by the patients, who were asked to rate their pain as nonexistent, mild, moderate, or severe. The most recent followup of each patient was used for the present study. Nine patients unable to follow up in person (nonambulatory or nonlocal) were contacted by telephone

Table 1. ITPIE failure by diagnosis*

Indication for ITPIE	Number of ITPIEs	Revised (%)	Unrevised with persistent pain (%) ⁺	Failure (%)	p Value for failure
Instability	23	7 (30%)	6 (26%)	13 (57%)	0.217
Stiffness	4	1 (25%)	2 (50%)	3 (75%)	
Effusion	15	4 (27%)	1 (7%)	5 (33%)	
Total	42	12 (29%)	9 (21%)	21 (50%)	

* Data regarding polyethylene insert were available for 35 of 42 ITPIEs; ITPIE = isolated tibial polyethylene insert exchange.

⁺ Persistent pain of moderate to severe intensity.

Table 2. ITPIE revision rates by component design (cruciate-retaining versus posterior-stabilized) and diagnosis

Indication for ITPIE	Cruciate-retaining			Posterior-stabilized		
	Number of ITPIEs	Revised (%)	p Value	Number of ITPIEs	Revised (%)	p Value
Instability	12	4 (50%)	0.786	10	3 (75%)	0.653
Stiffness	1	0 (0%)		3	1 (25%)	
Effusion	13	4 (50%)		2	0 (0%)	
Total	26	8 (31%)		15	4 (27%)	

ITPIE = Isolated tibial polyethylene insert exchange.

by one of us (SEW) to determine their revision status (whether they had additional surgery after the ITPIE). The function portion of the KS was administered over the telephone as well. Families of patients who died were contacted to find out if the patient had a revision of the ITPIE before death. All telephone assessments were made by the first author of this paper.

The ITPIE was defined as a failure if the patients underwent a revision of the ITPIE for any reason (repeat ITPIE or other components revised) or if they had persistent pain of moderate to severe intensity recorded on their pain questionnaire. Implant success was defined as the ITPIE remaining in situ without pain of moderate or severe intensity. The Kaplan-Meier method was used to compute survivorship of the ITPIE with revision for any reason as the end point. Chi square tests were used to compare ITPIE failure rates among the various indications for ITPIE (instability, stiffness, and effusion) and between component design types (cruciate-retaining or posterior-stabilized). An odds ratio was calculated to assess the risk of having a revision of the ITPIE in patients categorized by the time from index TKA to ITPIE (< 3 years or ≥ 3 years). All statistical analyses were conducted using SPSS (Version 13.0 for Windows; SPSS Inc, Chicago, IL).

Results

Twelve of 42 patients (29%) went on to further revision after ITPIE. The mean time to revision was 3 years (range, 2 weeks to 8.7 years). At 11 years, survivorship of the ITPIE with revision as the end point was 58% (95%

confidence interval, 42%–72%) (Fig. 1). Of those revised, three patients underwent a repeat ITPIE, eight patients had multiple components exchanged, and one patient had a resection arthroplasty as a result of infection. Thirty of the 42 patients (71%) were unrevised at final followup or death. Of these 30, the mean range of motion before the ITPIE was 103° (range, 55°–125°) and after the ITPIE at last followup was 113° (range, 88°–125°). Mean KS function scores increased from 52.7 preoperatively to 65.4 at followup and mean KS knee scores increased from 58.6 to 85.4. Despite improvements in KS scores and range of motion, moderate to severe pain at final followup was reported by nine of 30 (30%) of the unrevised patients (or 21% of the entire cohort [nine of 42]). The overall failure rate (revision of ITPIE or moderate to severe pain in unrevised patients) was 50%.

Failure rates were not statistically different for patients having ITPIE for instability, stiffness, or effusion (Table 1). Of the 12 patients who had revisions, seven originally underwent IPTIE for instability, one for stiffness, and four for recurrent symptomatic aseptic effusions believed to be the result of polyethylene wear.

Component design did not predict ITPIE revision. Revision of the ITPIE occurred in 31% of cruciate-retaining designs and 27% of posterior stabilized designs (Table 2). Differences in revision rates were not observed among the three diagnostic indications (instability, wear, stiffness) that led to the ITPIE in either the cruciate-retaining or posterior-stabilized cohorts. We identified no differences ($p = 0.202$) in failure rates among the cruciate-retaining knees that had lipped and nonlipped inserts placed at the time of ITPIE; four of the eight (50%)

Fig. 1 At a followup of 11 years, survivorship of the isolated tibial polyethylene insert exchange (ITPIE) with revision as the end point was 58%.

of the lipped inserts and eight of 33 (24%) of the nonlipped inserts were revised. Patients who underwent ITPIE less than 3 years from their index TKA were 3.8 times more likely ($p = 0.059$) to later have a revision than patients who underwent ITPIE more than 3 years from their index TKA (Fig. 2). Twenty-three patients underwent ITPIE more than 3 years from their index TKA. This group had an 83% success rate with only four patients in this group having a revision of the ITPIE. One had all components exchanged at 5.6 years after the ITPIE. Two underwent a second ITPIE at 4.7 years and 8.7 years after the initial ITPIE. One additional patient had femoral and tibial components exchanged 1.7 years after ITPIE.

Discussion

Modular design of TKA allows the surgeon to exchange the polyethylene without revising well-fixed components. Although an excellent concept, previous reports have failed to demonstrate predictable positive long-term results. We measured survival of ITPIE in patients who underwent the procedure for instability, stiffness, or effusions believed to be the result of polyethylene wear. We also assessed whether the reason for ITPIE influenced the likelihood of revision and if component design or time in situ of the original arthroplasty were associated with the likelihood of success after ITPIE.

We note several limitations of the study. First, our study consisted of a small, heterogeneous patient population. The results of this study might therefore not directly apply to a larger heterogeneous population. Second, the operative

Fig. 2 This graph depicts the relationship of time in situ of original TKA (before isolated tibial polyethylene insert exchange [ITPIE]) to rate of reoperation after ITPIE. Revisions occurred more often in patients who underwent ITPIE less than 3 years from their index TKA.

reports that were reviewed did not always provide detail as to surgical findings such as ligamentous integrity and foci of osteolysis, and the clinical records did not always detail the magnitude and direction of instability patterns. Other surgeons might define ligamentous stability differently because this is a subjective evaluation. Third, the sterilization method of the polyethylene substantially affects clinical outcome, especially during the era of gamma sterilization in air. Unfortunately, we were unable to determine the sterilization technique for the polyethylene in all of the included patients. With new sterilization techniques, results in the future with this procedure may improve. Lastly, the cases were gathered over a 14-year interval, which included multiple surgeons with multiple implants. Prosthetic designs have evolved over this era as has our understanding of the potential pitfalls of ITPIE. These design changes and the expertise of the various surgeons may have affected the outcomes positively or negatively. Despite these limitations, the high failure rate seen across diagnostic groups leaves a clear message that this procedure should be undertaken with caution.

We observed a 29% revision rate in our cohort of patients undergoing ITPIE. Although we wanted to see if reoperation rates were different depending on the diagnostic indication for ITPIE, we ultimately found the revision rate in our series was similar for knees that had ITPIE for instability, stiffness, and effusion believed to be the result of polyethylene wear (30%, 25%, and 27%, respectively). The discouraging results we observed were similar to most other authors who have reported on ITPIE [1, 2, 4–6, 8] (Table 3).

We found 30% of ITPIEs performed for instability went on to further revision. Our findings are in agreement with another published study [1] of 27 knees that underwent ITPIE for instability. In that study, failure was defined as

revision or severe pain. At a mean of 5.8 years, 55.6% (15 of 27) had survived. Our results were similar, with 57% of the ITPIE performed for instability ultimately judged to be failures. In another small series of patients [4] who had ITPIE for knee instability, four of 14 patients had persistent instability at a mean of 56 months postoperatively.

The second indication we investigated was stiffness. We only had four patients in our series who underwent ITPIE for stiffness. Nevertheless, one of these patients went on to further revision surgery, and two of the others had persistent pain. In all, three of the four patients in this group did poorly with ITPIE in our hands. Our findings are similar to those reported in another small series of seven knees that underwent ITPIE for stiffness [2]. Two knees in that study were revised at 2.5 years after ITPIE. Of the five remaining patients, four reported severe pain and one patient had moderate or occasional pain.

The third indication we investigated was effusion believed to be the result of polyethylene wear. Our finding that 27% of knees that had ITPIE for effusion went on to further surgery is similar to a prior report [5] of 48 knees with ITPIEs for wear. In that study, 17% (eight of 48) of the overall cohort failed at an average of 4.5 years after the exchange. However, a subgroup of 22 patients in that study had ITPIE for severe polyethylene wear, and six patients (27%) within that subgroup failed at less than 5 years. Despite the poor results observed for ITPIEs we performed for wear and the previously referenced study [5], at least one report [6] has described better results. In that study, 68 knees from four centers were followed for an average of 3.6 years after ITPIE for wear and osteolysis. Those authors reported 84% of the patients retained their components and lacked progression of osteolysis after the ITPIE. Although more encouraging than our results, the failure rate of 16% reported by those authors is still worrisome, and their followup (3.6 years) was shorter than ours (5.6 years).

We found time in situ of the index arthroplasty predicted success of the ITPIE; TKAs that had been in situ for 3 years or longer had a 3.8-fold lower revision rate than TKAs that had been in situ less than 3 years at the time of ITPIE. In total, 83% of TKAs in our series with a service life of over 3 years at the time of ITPIE were free of further revision at final followup. In one study with the highest success rate after ITPIE [8], a group of patients with ITPIE was compared for reoperation and severe knee pain at a mean of 3.3 years with a group of patients with full TKA revision. Survivorship in the two groups was similar. The patients in that series were operated on at an average of 9 years after the index TKA and, as such, we believe the generally favorable survival these authors report is in agreement with our findings that knees with longevity before ITPIE are likely to do well after ITPIE. This appears intuitive, because knees that have functioned well over a long period of time are unlikely to have substantial abnormalities of alignment, rotation, or soft tissue balance.

In summary, we studied a heterogeneous group of patients undergoing ITPIE for instability, stiffness, and effusions believed to be the result of wear. We observed a high rate of failure across all three diagnoses with 29% (12 of 42) undergoing reoperation. We also identified moderate to severe pain at final followup in 30% (nine of 30) of the unrevised patients. Including the patients with moderate to severe pain as failures increased the overall clinical failure rate to 50% (21 of 42 patients). The patients who fared best in our series were those who had the longest successful in situ service of the original arthroplasty. We believe ITPIE is a procedure that should be undertaken with caution. For patients who are less than 3 years from their index TKA, ITPIE is associated with an unpredictable outcome. For patients who have a well-functioning TKA and begin to experience symptoms related to instability or effusions believed to be the result of wear, more than 3 years from their index procedure, ITPIE is a reasonable treatment option.

Table 3. Reported ITPIE outcomes

Authors	Diagnosis	Number of patients	Followup time (average)	Failure rate
Babis et al. [1]	Instability	27	5.8 years	44% revised or painful
Babis et al. [1]	Multiple	56	4.6 years	25% revised
Babis et al. [2]	Stiffness	7	4.2 years	86% revised or painful
Brooks et al. [4]	Instability	14	56 months	29% unstable
Engh et al. [5]	Wear	48	7.4 years	17% revised
Engh et al. [5]	Severe wear	22	less than 5 yrs	27% revised
Griffin et al. [6]	Wear/lysis	68	3.6 years	16% revised or lysis
Jensen et al. [8]	Multiple	27	40 months	15% revised
Current study	Multiple	42	5.6 years	29% revised and 21% painful

ITPIE = Isolated tibial polyethylene insert exchange.

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