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Clinical Performance of the Optetrak Total Knee Prosthesis: A 11-year Follow-up Study

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Abstract

Background: The reported results of the Optetrak posterior stabilized total knee prosthesis, which is a modification of the Insall-Burstein knee prosthesis, are inconsistent. We determined whether the design changes of this posterior stabilized fixed-bearing knee prosthesis have achieved their intended objectives at minimum 10-year follow-up. Furthermore, we intended to delineate the specific features to which we attribute to the good outcomes of these Optetrak knee prosthesis.

Methods: These were 131 patients (mean age, 68.1 years). The mean follow-up was 10.4 years (range, 11-12 years). The patients were assessed clinically and radiographically with rating systems of the Knee Society. In addition, Western Ontario and McMaster Universities Osteoarthritis (WOMAC) questionnaire, UCLA (University of California at Los Angeles) activity score were determined preoperatively and at each follow-up.

Findings: The mean Knee Society knee score was 91 points (range, 70-100 points) at the final follow-up. The mean WOMAC score was 15 points (range, 4-56 points), and the mean UCLA activity score was 6.2 points (range, 4-8 points) at the final follow-up. No knee had an aseptic loosening of the components or osteolysis. The predicted implant survival at 10.4 years was 99% as the end point of any reoperation.

Conclusions: The findings of the present 10.4-year clinical study suggest that Optetrak posterior stabilized fixed-bearing cemented prosthesis obtained favorable clinical and radiographic results.

Keywords Clinical performance; Total knee Arthroplasty; Fixed-bearing; Mobile-bearing; Cemented; Posterior stabilized

Introduction

The ultimate goals of total knee arthroplasty (TKA) are pain relief, restoration of knee motion and clinical performance. Increasing efforts have been made over the past half century to improve the clinical results after TKA by refining their designs. More than 20 years ago, the Optetrak cemented posterior stabilized knee prosthesis (Exactech, Gainesville, Florida) was introduced. It is a modification of the Insall-Burstein posterior stabilized knee prosthesis (Zimmer, Warsaw, Indiana). The modification of the latter aimed to: reduce the localized stresses on the tibial polyethylene insert; to improve patellar tracking; to increase resistance to tibial subluxation; and to provide flexion greater than 120° while remaining stable in the frontal and sagittal planes.

The reported results of this posterior stabilized fixed-bearing total knee prostheses which were manufactured in February 2002 are inconsistent. Robinson [1] reported that predicted this fixed-bearing implant survival at 93 months was 97%. Furthermore, Robinson et al. [2] reported that survival rate of the fixed-bearing prosthesis was 98% at a mean 11.6 years follow-up. On the other hand, Thelu et al. [3] reported poor results of these fixed and mobile-bearing prostheses after a mean 25-month follow-up. They suggested the cumulated survival rate of this prosthesis at 36 months was 81% and 77% at 45 months. They believed that poor results of this prosthesis attributed to early tibial loosening and abnormal painful patellar contact on highly restricted trochlea.

We determined whether the design changes of Optetrak posterior stabilized fixed-bearing knee prosthesis have achieved their intended objectives at minimum 10-year follow-up. Furthermore, we intended to delineate the specific features to which we attribute to the good outcomes of these Optetrak knee prostheses.

Patients

We prospectively followed and retrospectively reviewed 111 patients (140 knees) who underwent primary TKAs from January

2006 to February 2007 using an Optetrak posterior stabilized fixed-bearing prosthesis. Nine patients (9 knees) were lost to follow-up. The remaining 102 consecutive patients (131 knees) formed our study cohort. The study group consisted of 90 women and 12 men with a mean age of 66.2 ± 7.5 years (range, 35-81 years) at the time of index surgery. The high prevalence of end-stage knee osteoarthritis in the female patients in this ethnic group might be attributed to the inherent varus deformity of the knee. The mean height of the patients was 156.7 ± 8.6 cm (range, 145-188 cm), the mean weight was 63.4 ± 8.9 kg (range, 48-84 kg), and the mean body mass index (BMD) was 27.1 ± 2.9 kg/m^2 (range, 20.2-41.1 kg/m^2). Seventy-two patients (71%) had BMD ranged between 20 and 29 kg/m^2, 28 (27%) had BMD ranged between 30 and 39 kg/m^2, and 2 (2%) had BMD over 40 kg/m^2. The preoperative diagnosis was osteoarthritis of knees in all patients (Table 1). The mean preoperative overall anatomical (femorotibial) knee alignment was 9° ± 6.1° varus (range, 8°-20°) on the basis of long-leg radiograph including femoral head and ankle.

Table 1: Demographic Data on the 102 patients (131 knees).

Parameter	Value
Gender (M: F ratio)	12 : 90
Age* (yr)	66.2 ± 7.5 (35-81)
Height* (cm)	156.7 ± 8.6 (145-188)
Weight* (kg)	63.4 ± 8.9 (48-84)
Body mass index* (kg/m^2)	27.1 ± 2.9 (20.2-41.1)
Diagnosis (no. of patients [no. of knees])	
Osteoarthritis	102 (131)
Duration of follow-up÷ (yr)	10.3 (10-11)

* The values are given as the mean and the standard deviation, with the range in parentheses

÷ The value is given as the mean, with the range in parentheses

All TKAs were performed by the senior author. The procedure was carried out through a midline skin incision of 10 to 12 cm in length using a medial parapatellar arthrotomy. Extramedullary instrumentation was used for the tibial component and intramedullary for the femoral side. The femoral valgus angle for the intramedullary guide was determined preoperatively on standardized long-leg weight-bearing radiographs. It was between 5° to 7°. The anterior and posterior cruciate ligaments were resected in all knees. Ligamentous balance was restored and 10 mm of tibial bone was resected from least affected side to achieve a surface which was perpendicular to the shaft of the tibia in the coronal plane with a posterior slope of 3° in the sagittal plane. Resection of the distal femur (9 mm) and the posterior femoral condyles (9 mm) was attempted to remove a thickness of bone which was equal to that of the femoral component to be implanted. During femoral and tibial resection the tibia was prepared first in all knees. Anterior cortical reference was used for the anterior-posterior cut of the distal femur. Femoral component rotation was determined using three reference axes: (1) the transepicondylar axis, (2) the mid-trochlear line (Whiteside line), and (3) 3° of external rotation relative to the posterior aspect of the condyles. The tibial component rotation was determined using the medial 1/3 of the tibial tuberosity and attachment site of posterior cruciate ligament. Ligamentous balance was estabilixhed first in knee extension and then in knee flexion with use of a tensor. Metal backed tibial components were used in all knees.

The Optetrak prosthesis includes a cemented femoral implant in cobalt-chromium alloy that is anatomic and asymmetrical. The trochlear groove is deep and oblique and outward (7°) to facilitate patellar tracking. The surface coating between the tibial surface and the bone with a microbead porosity. The keel is small, short, round, and with wings. The tibial post was moved anteriorly to reduce the impingement between cam and post. The patella is a symmetrical and spherical dome with a slightly concave slope matching the shape of the prosthetic trochlear with a choice of 4 patellar implant sizes. All femoral, tibial and patellar implants were cemented (Figure 1)

Figure 1: Optetrak fixed-and mobile-bearing posterior stabilized prostheses; Anterior view of the fixed-bearing prosthesis; A femoral component in cobalt chromium alloy that is anatomic and asymmetrical; The tibial tray with fixed bearing polyethylene is made of titanium alloy; The trochlear groove is deep and oblique upward and outward (7°); The femoral condyles presented a symmetrical curve radius; Tibial keel is small, short, round and with wings.

The knee was placed in a continuous passive motion after the splint was removed (on the second day after the operation). All patients began walking with crutches or a walker and started active and passive range of knee motion exercise on the second day after the operation. Patients used the crutches or walker, with full weight bearing, for 6 weeks and a cane when necessary thereafter.

Two of the authors assessed the patients *via* both physical examination and knee-scoring preoperatively, at three months, at one year after surgery, and 2 or 3 years thereafter with the use of the Knee Society system [4] and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire [5] as well as the UCLA (University of California at Los Angeles) activity scale [6]. The mean duration of follow-up

was 10.4 years (range, 10 to 11 years). At the time of each follow-up, radiographic data were analyzed and recorded by a different author, who was not part of the operative team. To ascertain instability of the knee, we asked patients whether they had given way sensation. We also carefully examined the stability of the knee in full extension, midrange (60°) flexion, and full flexion to ascertain any instability of the tibial bearing. Patellar pain specifically was questioned.

The active arc of motion of knee with the patient in the supine position was measured two times with use of a standard (60 cm) goniometer preoperatively and each follow-up by two observers. The chance-corrected kappa coefficient [7,8] for interobserver agreement ranged from 0.81 to 0.91. All clinical data were compiled and collected by a separate research associate.

Standing anteroposterior hip-to-ankle radiographs, supine anteroposterior and lateral radiographs, and skyline patellar radiographs of knee were made preoperatively and at each follow-up. The radiographs were evaluated by one observer, who was not a member of the operating team, to determine the anatomic axis of the limb, alignment of the components, posterior tibial slope, posterior femoral condylar offset, level of joint line, presence and location of radiolucent lines at the bone-cement or cement-implant interface, and patellar tilt or dislocation with use of the Knee Society system [4]. All radiographs were made under fluoroscopic guidance to control ration of the knee.

The changes in knee scores, WOMAC scores, and UCLA activity scores were evaluated using two-tailed Student's t-test. Chi-squared tests were used to analyze radiological data and rates of complication. All statistical analyses were performed with the SPSS, version 14.0 (SPSS Inc., Chicago, Illinois) with a significance level of $p<0.05$.

Results

Preoperative Knee Society knee score, WOMAC scores, and UCLA activity score improved significantly at the final follow-up (Table 2). The mean preoperative Knee Society knee score (standard deviation) was 26 (9) points (range, 16-35 points), and the mean postoperative Knee society knee score was 90 (11.9) points (range, 70-100 points). The mean preoperative total WOMAC score (standard deviation) was 58 (17) points (range, 36-94 points), and the mean postoperative total WOMAC score (standard deviation) was 16 (8) points (range, 5-46 points). The mean preoperative UCLA activity score was 2.2 points (range, 1-4 points), and the mean postoperative UCLA activity score was 6.5 points (range, 4-10 points). The mean preoperative range of knee motion was 125° ± 9° (range, 95°-140°) and the mean postoperative range of knee motion was 123° ± 9° (range, 75°-140°). At the final follow-up, 83 patients (81%) had no pain, 12 (12%) had mild pain, 7 (7%) had moderate pain. No patient had severe pain. No patient complained of patellar pain.

Table 2: Clinical Results for 102 patients (131 knees).

Parameters	Preoperative	Final Follow-up
Knee Society knee score÷ (points)		
Total knee score	26 ± 9 (16 to 35) [21 to 41]	90 ± 11.9 (70 to 100) [81 to 98]
Function score	52 ± 11 (35 to 65) [46 to 63]	79 ± 15 (30 to 100) [62 to 98]
Pain (no. of patients)		
None	-	82 (80%)
Mild	-	15 (15%)
Moderate	-	5 (5%)
Severe	102 (100%)	-
WOMAC score÷ (points)	58 ± 17 (36 to 94) [59 to 71]	16 ± 8 (5 to 46) [13 to 18]
Range of motion÷ (deg)	125 ± 9 (95 to 140)	123 ± 9 (75 to 140)
UCLA activity score÷ (points)	2.2 (1-4)	6.5 (4-10)

÷ The values are given as the mean, with the range in parentheses and the 95% CI in brackets

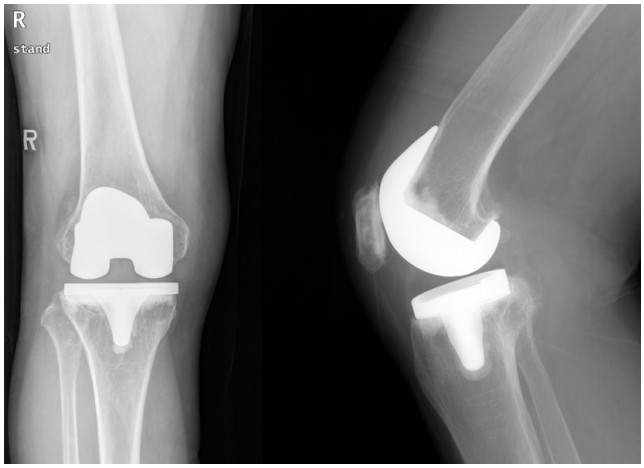

Figure 2: Radiographic evaluation of the knees of a 61-year-old woman with an end stage of osteoarthritis following total knee Arthroplasty; Anteroposterior radiograph of right knee 11 years after surgery, demonstrating that the Optetrak fixed-bearing prosthesis is fixed in a satisfactory position; There is no evidence of radiolucent line or osteolysis; Lateral radiograph of right knee 11 years after surgery, demonstrating that the Optetrak fixed-bearing prosthesis is embedded in a satisfactory position; There is no evidence of radiolucent line or osteolysis.

The alignment of the knee improved substantially. The mean preoperative knee alignment was 9.3° ± 5° (range, 5°-20°) varus, which was improved to the mean 5.5° (4°-8°) valgus. No patient in this series had valgus deformity preoperatively. The positions

of the femoral and tibial components were satisfactory in all knees. Preoperative joint line and posterior femoral condylar offset were well restored after the operation. The prevalence of radiolucent line (<1 mm) was 14% (18 knees) around the femoral component and 6% (8 knees) around the tibial component. No knee had a radiolucent line wider than 1 mm. No knee had an aseptic loosening of the component or osteolysis (Figure 2) (Table 3). The predicted implant survival at 10.4 years was 99% as the end point of any reoperation.

Table 3: Radiographic Results for 102 patients at the Final Follow-up Evaluation (10.4 years).

Parameters	
Tibiofemoral angle* (deg)	
Preoperative	9.3 (6-20) varus
Final follow-up	5.5 (4-8) valgus
Femoral component position* (deg)	
Anteroposterior	97 (96-99)
Sagittal	3 (2-4)
Tibial component position* (deg)	
Anteroposterior	88 (87-90)
Sagittal	87 (85-88)
Joint line (mm)*	
Preoperative	15.8 (14-17)
Final follow-up	15.7 (13-17)
Posterior femoral condylar offset*	
Preoperative	26.1 (24-27)
Postoperative	25.9 (24-27)
Radiolucent line ≤ 1 mm (%) Femoral side	
Anterior femoral condyle	12 knees (9%)
Posterior femoral condyle	7 knees (5%)
Tibial side Medial tibial plateau	9 knees (7%)
Radiolucent line > 1 mm (%)	
Femoral side	0 knee (0%)
Tibial side	0 knee (0%)
Osteolysis	0 knee (0%)
* The values are given as the mean, with the range in parentheses	

Two knees (1%) had early deep infection. These two knees were treated with open debridement, tibial polyethylene liner change and intravenous antibiotics for 6 weeks. There was no further recurrence of infection.

Discussion

The Optetrak cemented posterior stabilized prosthesis was a modification of the Insall-Burstein posterior stabilized prosthesis to improve patellar tracking, to provide flexion greater than 120° and to increase resistance to tibial subluxation. There is little evidence in the literature with regard to whether this prosthesis, which is a modification of the Insall-Burstein knee prosthesis, improves the clinical and radiographic results of TKA further. In addition, the available studies of the Optetrak TKA have short-term follow-up periods and use different tibial keel models. Therefore, the clinical benefits after long-term follow-up are not clear. We made four assessments with respect to the clinical results, radiographic results, revision rate and complication rate. In the current study, clinical function, and survivorship of the knee components were excellent. Furthermore, complication rate was very low.

There are conflicting results for Optetrak TKA in the literature. One study has suggested that poor results of Optetrak prosthesis after a mean 25-monts follow-up. By contrast, other studies found excellent results at 5 and 11 year follow-up [1,2]. Thelu et al. [3] reported that their Knee Society knee score at 25-months follow-up was 83.7 points (range, 13-100 points) and Knee society knee function score was 82.6 points (range, 30-100 points). On the contrary, Robinson [1] reported that the average Knee Society knee score was 92 points (range, 59-100 points) at 5 years follow-up. In our study, the mean Knee Society knee score was 91 points (range, 70 to 100 points) at 10.4 years follow-up. Thelu et al. [3] observed 20 cases (19%) of pain related to an anomaly in the patellar tracking. They felt that deep trochlear with its prominent edges of Optetrak femoral component was attributable to high incidence of patellofemoral pain. We and Robinson [1,2] did not have patellofemoral problems. We feel in the current study that well balanced patellofemoral alignment would not produce anomaly in patellar tracking, causing patellar pain.

Thelu et al. [3] reported high incidence of radiolucent line around the tibial component (38%). They insisted that the fixation mode (keel geometry) and the high level of stress (high congruency) played a role in the occurrence of highs incidence of radiolucent line. They found that 25 tibial components (22%) had aseptic loosening. By contrast, Robinson [1,2] did not observe any aseptic loosening of the tibial components at 5 and 11 years follow-up, respectively. We also found no aseptic loosening of the tibial components at 10.4 years follow-up.

Thelu et al. [3] performed 13 revisions for either resistant patellofemoral pain (4 knees) or early aseptic loosening of the tibial components (9 knees). They further observed that, at the end of their analyses, 10 more patients remained with pain and presented worrisome radiological and clinical signs indicating of the tibial component loosening or patellofemoral impingement. Therefore, with the endpoint of tibial component loosening, the cumulative Kaplan-Meier survival rate was 89 ± 4% at 25 months, 81 ± 9.1% at 36 months, and only 77 ± 12% at the follow-up at 45 months. Robinson [1] reported that the only revision was the patellectomy due to avascular necrosis and fragmentation at 5 years follow-up. Therefore, using aseptic

revision of any component as an end point, 99% implants were predicted to survive at 93 months. In another study, Robinson [2] reported that survival rate with revision for aseptic loosening as an end point was 100% at 11 years follow-up. In the current study, survival rate of the implant was 99% at 10.4 years. We believe the good results of these TKAs are attributable to: the small stature and light weight of patients; preponderance of female patients; good cementing technique with pulsed lavage and cement; pressurization; correct flexion and extension gaps; and well-balanced ligaments.

In vivo kinematic studies [9-16] have shown that in fixed-bearing posterior-substituting total knee designs, eccentric angular loading on the post is common if axial rotation occurs; this can place increased stress at the locking mechanism of modular fixed-bearing designs. This increased stress in turn results in increased backside wear in fixed-bearing designs and an increased risk of osteolysis, especially in patients in whom matte-finished tibial trays have been implanted. The absence of osteolysis in the current study may be related to several factors: a high percentage (88%) of the patients were female and had a relatively low body weight (mean, 62 kg), the polyethylene inserts used were sterilized with gamma irradiation in a vacuum, the inserts had a short shelf-life, and follow-up was not sufficiently long to reveal osteolysis.

Thelu et al. [3] reported postoperative complications included thromboembolic disease (4 phlebitis and 1 pulmonary embolism) and 4 early revisions (one for hematoma and 3 deep infections. Robinson [1] observed that 2 knees had mild crepitation, one patellar avascular necrosis with fragmentation, and one infection. In our study, we had 2 early deep infections, which were treated with open debridement, tibial polyethylene liner change, and intravenous antibiotics for 6 weeks. There was no further recurrence of infection.

The limitation of this study was the small sample size and lack of inter observer comparisons, and this could produce bias in interpreting the radiological results. Other limitations included the low body weight of the patients, the good pre-operative range of knee motion and the relatively young age of this ethnic group of patients which might limit general applicability to other group of patients. On the other hand, although this study had low body weight, daily activities including farming, squatting and lifting were vigorous.

The findings of the present 10.4 year clinical study suggest that Optetrak posterior stabilized fixed-bearing prosthesis obtained favorable clinical and radiographic results.

Informed Consent

All patients gave informed consent to the study

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