The Journal of Arthroplasty 29 (2014) 66–70

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Fixation, Survival and Osteolysis with a Modern Posterior-Stabilized Total Knee Arthroplasty

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ARTICLE INFO

Article history:
Received 28 March 2013
Accepted 1 May 2013

Keywords:
knee arthroplasty
posterior-stabilized
tibial fixation
survival
osteolysis

ABSTRACT

Early failure of the NexGen prosthesis with a 3° fluted, 4 hole tibial component has been reported. We evaluated fixation, survival and osteolysis with the NexGen LPS prosthesis with a 7° fluted, solid tibial component at a mean of 10 years. Knees were evaluated using Knee Society and LEAS scores, survival analysis, and univariable modeling. No knee had tibial loosening or debonding. With the endpoint mechanical failure (132 knees), the 12 year survival was 88.8% (CI 61.5–97.1).With failure defined as any reoperation (132 knees), the 12 year survival was 88.1% (CI 62.3–96.7). Osteolysis occurred in 16 knees, associated with male gender and LEAS score >10. Loosening was not seen with this tibial component.

Posterior-stabilized total knee arthroplasty components, implanted with cement, remain a popular option for patients of all ages with end-stage arthritis of the knee. Following the success of so-called first- generation non-modular and second-generation modular posterior-stabilized prostheses [1–4], a third-generation modular, posterior-stabilized prosthesis (NexGen Legacy PS, Zimmer, Warsaw IN) with improved patellofemoral kinematics was introduced in 1998. Studies reporting the early and mid-term results of this prosthesis have been encouraging, with lower rates of lateral retinacular release, anterior knee pain and patella complications [5–9]. Survival of the posterior cruciate ligament retaining version of this prosthesis with a cemented 4-pegged modular tibial component was reported as 97% at 10 years, with only one tibial component loosening [10]. However, there have also been reports of early femoral component loosening, tibial post fracture, and tibial component loosening with the posterior-stabilized version of this prosthesis designed for higher degrees of flexion or for implantation through so-called mini incisions [11–14]. Most recently, there was a report of a high rate of early failure with this prosthesis, 4.3% revised at a mean follow-up of 38 months, using a cemented 4-hole, 3° fluted tibial component [15]. The cause of aseptic loosening was isolated debonding of the tibial component from the cement.

The purpose of this study was to determine the rates of reoperation, mechanical failure, and osteolysis with the third generation modular posterior stabilized prosthesis in which a 7° solid, fluted tibial component only was implanted. We asked two questions: [16] What are the rates of tibial component loosening, and survival (defined as any reoperation and mechanical failure) of the NexGen LPS prosthesis with a 7° solid, fluted tibial component? [15] What is the incidence and factors associated with radiographic osteolysis at a mean follow-up of 10 years?

Methods

Between May 1998 and July 2004, one surgeon performed 293 consecutive primary NexGen Legacy posterior-stabilized (Zimmer, Warsaw, IN) total knee arthroplasties in 220 patients. This was the only prosthesis performed during this time span, except for 16 knees in which a constrained condylar prosthesis was required for severe medial collateral ligament insufficiency. A minimum follow-up time of 8 years was selected because that was the first amount of time that osteolysis was first noted on radiographs. Fifty-six patients (71 knees) had died prior to a minimum follow-up of 8 years (mean follow-up 3 years, range, less than 1–7 years). None of these patients had any problem or reoperation. Forty-five patients (55 knees) could not be located and were considered lost to follow-up. At the time of last follow-up of mean 4.4 years (range, less than one to seven years), there were no problems or reoperation. For 28 patients (35 knees) we were able to contact them by telephone to determine the status of the knee, but could not get them to return for examination and radiographs. Although these 28 patients have not had a reoperation, they were also excluded from analysis.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2013.05.002.

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0883-5403/2901-0015$36.00/0 – see front matter © 2014 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.arth.2013.05.002

There were 132 knees in 94 patients who had complete clinical and radiographic follow up at a mean of 10 years (range, 8 to 14 years). There were 105 knees in 72 female patients and 27 knees in 22 male patients. The mean patient age was 68 years (range, 52–87 years). The mean patient weight was 85 kg (range, 47–112 kg) and the mean BMI was 30.8 kg/m^2 (range, 16.6–44.9 kg/m^2). The preoperative diagnosis was osteoarthritis in 112 knees, rheumatoid arthritis in 11 knees, osteonecrosis in three knees, and other (psoriatic, post-traumatic and Charcot-like arthritis) in six knees.

All knees were performed by one surgeon through a midline skin incision and a modified Insall medial parapatellar approach, with routine resurfacing of the patella [17]. An intramedullary alignment jig, positioned parallel to Whitesides' line [16], was used for the distal femoral resection, and an extramedullary alignment jig was used for the proximal tibial resection. All knees were balanced using a spacer bar technique and all components were implanted with separate batches of Simplex-P cement (StrykerHowmedicaOsteonics, Rutherford NJ), with a large bore syringe used for the 7° fluted, solid, titanium alloy tibial component (Fig. 1 A–B). The polyethylene liner was fabricated from the resin GUR 1050, compression molded, sterilized by gamma irradiation (2.5–4 CGy) in nitrogen and inserted into a dovetail locking mechanism (Zimmer, Warsaw IN). The polyethylene liner thickness was nominally 10 mm in 77 knees (58 patients), 12 mm in 42 knees (35 patients), 14 mm in 11 knees (10 patients), 17 mm in one knee, and 20 mm in one knee. Postoperatively, all patients ambulated full weight-bearing with a walker or crutches on the first or second postoperative day, had formal physical therapy, and a continuous passive motion machine while in the hospital. After discharge, patient received home or outpatient supervised physical therapy until the appropriate goals of ambulation and motion were obtained.

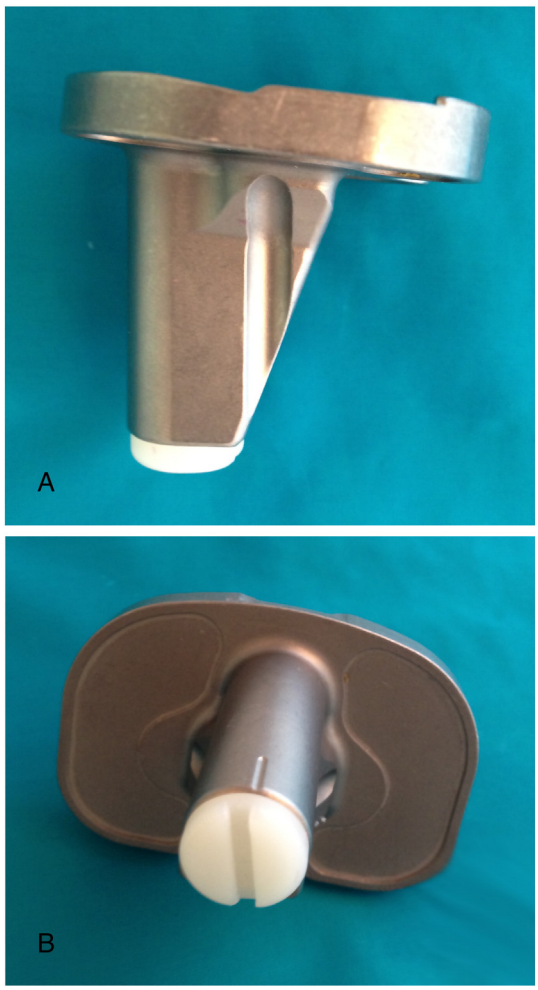

Fig. 1. (A) Side view of 7° solid fluted tibial component. (B) View of the underside of the tibial component.

The patients were evaluated clinically by one experienced clinical research nurse (ES) using the rating systems of the Hospital for Special Surgery and the Knee Society [18,19]. We specifically examined each knee at most recent follow-up for the presence of a palpable knee effusion. In addition, patients were assessed at the most recent follow-up visit using the Lower Extremity Activity Scale (LEAS). This is a self-administered questionnaire is a linear 12-item scale, scored from 1 (lowest activity) to 18 (highest activity), which reflects an individual's typical daily activity [20,21]. For the patients who had only telephone follow-up, they were questioned about problems with the knee and if there had been any reoperation.

The knees were evaluated radiographically with standing anteroposterior radiographs, supine lateral radiographs, and tangential radiographs of the patella. The radiographic scoring system of the Knee Society was used to determine the overall alignment of the knee, the presence of radiolucent lines in zones adjacent to the cement mantle, and migration of the components using hard copies of radiographs [22]. The alignment of the components in the sagittal plane was not measured. Serial radiographs were reviewed for changes in the bone that were consistent with osteolysis (defined as well-circumscribed, circular or oval lytic lesions) and for progression of radiolucent lines [23]. Computerized axial tomography and fluoroscopic positioning was not done, but oblique views of the knee were performed if there was suspicion of femoral osteolysis.

Kaplan-Meier survivorship analysis at 10 and 12 years was calculated using the entire cohort of 293 knees (220 patients). For one survival curve, considering only those patients examined and with radiographs as "complete", the end point was any mechanical failure of the knee, defined as aseptic loosening, instability, or polyethylene wear (with osteolysis). For the second survival curve, the end point was reoperation for any reason (infection, supracondylar fracture, or unexplained pain). Univariable generalized linear models were used to estimate the odds associated between risk of osteolysis and categorical variables (gender, diagnosis, polyethylene thickness, presence of a knee effusion) and continuous variables (patient age, body mass index, LEAS score). All statistical analyses were conducted using SAS version 9.2 or higher (SAS Institute Inc, Cary, NC). All statistical tests were two-sided with a significance level of 0.05.

Results

There was no knee (entire cohort of 293 knees) that had tibial component loosening or tibial component debonding. Of the cohort of 132 knees seen for examination and radiographs, there were three knees (two patients) with mechanical failure: bilateral femoral component loosening (one femoral revision at 9 years) in one patient with neuropathic-like arthropathy and one knee revised (polyethylene liner exchange only) for painful synovitis and osteolysis. In this knee revised at 12 years for synovitis and osteolysis, there was wear of the posterior half of the medial polyethylene and slight wear of the medial side of the base of the tibial post. Of the entire cohort of 293 knees, there were three other knees that had any reoperation: one knee with late infection treated by debridement and liner exchange; one knee with a supracondlyar fracture treated with an intramedullary rod; and one knee with both (non-loose) components revised by another surgeon for unexplained pain (not relieved by revision, but later relieved by ipsilateral total hip arthroplasty). The operative report and preoperative radiographs did not demonstrate loosening. With the endpoint as mechanical failure, the 10 year survival was 96.2% (95% confidence intervals, 84.1 to 99.2%) and