Wear and Lysis is the Problem in Modular TKA in the Young OA Patient at 10 Years

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Abstract

Background Most long-term followup studies of younger patients who underwent TKA include a relatively high percentage of rheumatoid patients, whose function and implant durability may differ from those with osteoarthritis (OA).

Questions/purposes The purpose of this study was to evaluate the minimum 10 year followup of TKA performed in more active patients with OA, using modular tibial components, to determine the durability of that construct. Specifically, we determined (1) survivorship; (2) revision rates; (3) functional scores; and (4) rates of radiographic failure at a minimum 10 year followup.

Methods We retrospectively reviewed 59 patients (67 knees) with OA who underwent primary total knee arthroplasty with posterior cruciate retaining (27%) or posterior cruciate substituting (73%) components which had modular tibial trays. Patients were evaluated clinically for need of revision and Knee Society, SF-36 and WOMAC scores as well as UCLA and Tegner activity scores. Radiographs were evaluated for loosening and osteolysis. The minimum followup of living patients was 10 years

(mean, 12.4 years; range, 10 to 18.4 years). Ten patients (11 knees) died; two patients (2 knees) were lost to followup.

Results Ten patients (11 knees; 16%) had revisions for aseptic loosening and/or osteolysis. Thirty-one patients (65%) were still performing moderate labor or sports activities. The average UCLA score was 5.5 (range, 2–9). No nonrevised knee demonstrated radiographic loosening.

Conclusion Most patients in this active patient population continued to have acceptable function although 16% underwent revision for wear and/or osteolysis. Isolated tibial insert exchange alone was performed in four of the 11 (36%) revised knees. These data should provide comparison for total knee arthroplasties performed in younger patients with newer designs and newer bearing materials.

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

Introduction

The utilization of total knee arthroplasty to treat endstage knee arthritis is currently experiencing its most substantial growth in patients under 55 years old. One study projected that between 2006 and 2030 there will be a 17-fold increase in the number of TKAs performed in this age group [16] and a demand for nearly a million knee arthroplasties for patients between 45 and 54 years old in 2030. Proper technique, component design, and materials for long-term durability in this age group are paramount due to the magnitude of the loads and the cycles of service these knees will be required to perform. Although there has been a dramatic rise in the numbers of TKAs performed in this

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This work was performed at the University of Iowa.

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population, there are very few long-term studies [4, 7, 12, 13] in this younger population, especially in patients with OA [5, 6]. The longest term studies of younger patients have reported survivorship up to 93.7% at 20 years [4], and survivorship of 96% and 85% at 10 and 15 years, respectively, for cohorts consisting entirely of patients with OA [6].

The majority of total knee prostheses placed today are fixed-bearing modular tray designs. Modularity in total knee arthroplasty allows increased intraoperative versatility and potential polyethylene exchange as a less destructive and potentially cost-effective option for revision. Drawbacks of modularity include backside wear which can contribute to osteolysis [3, 8, 9, 21]. It is in the younger, more active patient that differences in total knee prosthesis designs and materials may show the greatest differences in long-term durability.

The purpose of this study was to evaluate the minimum 10 year followup of TKA performed in more active patients with osteoarthritis, using modular tibial components, to determine (1) survivorship; (2) revision rates; (3) functional scores; and (4) rates of radiographic failure.

Patients and Methods

We retrospectively reviewed all 59 prospectively followed patients who underwent 67 cemented TKAs in patients 55 years of age and younger with OA using modular total knee prosthesis between January 1991 and November 1998. During that time, we performed no other TKAs using other implants in patients in this age range. The average age of the patients at the time of surgery was 48.5 years (range, 28.2–55.6 years). Study participants included 39 women (46 knees) and 20 men (21 knees). There were 30 right knees (45%) and 37 left knees (55%). Eight patients (14%) underwent bilateral TKAs. The average patient BMI was 33.6 (range, 18.8–53.0). Diagnosis was OA in 67 knees (100%), seven cases of which developed posttraumatically. Four knees had undergone previous meniscectomy, four had been treated with a high tibial osteotomy, and one had received a patellectomy. Ten patients (11 knees) had died and two patients (two knees) were lost to followup. The minimum followup among the 47 living patients was 9.9 years (mean, 12.4 years; range, 9.9 to 18.4 years). The study was carried out with IRB approval.

The PFC Knee System (DePuy, Warsaw, IN) was used in all cases, with the PFC Sigma design utilized in the cases performed in 1996, 1997 and 1998. The modular metal-backed tibial tray was titanium, and the femoral component was a cobalt-chrome alloy. In 18 (27%) of the knees, a cruciate retaining design was used while in 49 knees (73%), a posterior cruciate substituting prosthesis was

utilized. Early in the study period, the surgeon selected CR implants in patients with better motion and less deformity, while later on he performed PS knees even in this subset of patients. All components were cemented. The thickness of the polyethylene insert was labeled as 8 mm (minimum thickness, 6 mm) in 3 knees (4%), 10 mm (minimal thickness, 8 mm) in 40 knees (60%), 12.5 mm (minimal thickness, 10 mm) in 15 knees (22%), 15 mm (minimal thickness 13.0 mm) in 8 knees (12%), and 17.5 mm (minimal thickness, 15 mm) in 1 knee (2%). The first 46 (69%) inserts in the series utilized polyethylene that had been sterilized with gamma irradiation in air. The subsequent 21 (31%) inserts, implanted in 1997 and 1998, were sterilized with gamma irradiation in an inert environment utilizing gamma vacuum foil technology.

All surgery was performed by the senior author (JJC). A standard medial parapatellar approach was made to expose the joint in all cases. The tibia was first cut perpendicular to the longitudinal axis of the tibia, and the distal femoral cut was then made 5° to 7° of valgus. The flexion gap was prepared using a measured resection technique for the cruciate retaining cases and gap balancing for the cruciate substituting cases. Patella resurfacing was used in all cases, with the exception of one knee that had a previous patellectomy. Cases were performed in a high air exchange room and prophylactic antibiotics were administered.

Patients began walking with crutches or a walker the day after surgery and advanced to a cane as tolerated, with physical therapy twice a day and continuous passive motion machines. Routine followup included clinic visits at 6 weeks, 3 months, and 1 year post operatively, with AP, lateral and Merchant radiographs obtained at the time of the 3 month followup. Examination includes both clinical questionnaires as well as physical exam for stability and range of motion. From 1 year postoperatively, patients are encouraged to follow up at 2–3 year intervals at which time examination and radiographs are repeated. If they are having problems or symptoms, they are followed more regularly.

Clinical evaluation included preoperative Knee Society scores [14] and, at final followup, the need for reoperation, the Knee Society score, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [1], SF-36 general health questionnaire, and activity level via the UCLA [26] and Tegner [25] scales. All patients were encouraged to return for routine clinical and radiographic followup. Sixteen patients were unable or unwilling to return for full clinical evaluation and in 10 of these patients, local radiographic evaluation was arranged and obtained. Clinical followup was obtained from 44 of 47 living patients (94%).

Radiographs including standing AP, lateral, and Merchant views were obtained. Minimum 10-year radiographic

followup was obtained for 41 of 47 living patients (47 of 54 knees, 87% of knees in living patients). Of the remaining seven knees in living patients, four had 9-year followup radiographs, and the remaining three knees had 3-year, 1-year, and 0.5-year radiographs, respectively. Mean radiographic followup was 11.2 years (range, 0.6–15.6 years and median, 11.3 years). Radiographic evaluation included analysis for limb alignment and radiolucencies per the Knee Society protocol [10], osteolysis, and signs of gross polyethylene wear. Osteolysis was defined as a lesion greater than 5 mm² that was not present on immediate postoperative films [20]. All radiographic findings were agreed upon through consensus by two authors (JJC and ANO). The knees were divided into three groups: those in neutral to varus alignment ($n = 3$), those aligned at 0° to 5° valgus ($n = 14$), and those aligned at greater than 5° valgus ($n = 37$).

Among the deceased patients, contact was made with a surviving relative. In all cases, the survival of the prosthesis at the time of death was confirmed. In addition, it was confirmed there were no pending reoperations at the time of death. Thus, the status of the index components was known for all patients either at the time of death or at final followup with the exception of the two lost to followup.

Kaplan-Meier survivorship analysis [15] with 95% confidence intervals was performed with the endpoints of: (1) reoperation for any reason; and (2) revision of the tibial and/or femoral component for aseptic loosening and/or osteolysis. In addition, Fisher's exact test was used to determine differences in revision rates when compared to the variables of age, sex, BMI, postoperative knee alignment, and year of index operation.

Results

Kaplan-Meier survivorship with the endpoint of reoperation for any reason (Fig. 1) and the endpoint of revision of the tibial and/or femoral component for aseptic loosening and/or osteolysis (Fig. 2) resulted in survivorship of $78.5\% \pm 16\%$ at 10 years, $69\% \pm 16\%$ at 15 years, and $69\% \pm 16\%$ at 18 years, and $93\% \pm 6\%$ at 10 years, $81\% \pm 15\%$ at 15 years, and $81\% \pm 15\%$ at 18 years, respectively.

Overall, 15 patients had 20 reoperations. Five knees underwent nine reoperations for non-wear-related reasons (two for hematogenous infection, two for trauma related instability, and one for a patella fracture). For complications related to wear and osteolysis, 10 patients (11 knees) had reoperations for a revision rate of 16.4% (Table 1) at an average 8.3 years (range, 5.4–14.5). Average age at time of index operation for the 10 revised patients (11 knees) was 49.1 years. Six of the revised were PS knees and five

Fig. 1 The graph shows the Kaplan-Meier survivorship curve with accompanying 95% confidence intervals for the endpoint of reoperation for any reason.

were CR knees. We observed no differences for the need for revision when compared to the variables of age at time of index surgery ($p = 0.76$), BMI ($p = 0.67$), nor gender ($p = 1.00$). There was a difference between the year of the index operation and the need for revision with the largest percent of revisions falling in the 1994–1996 group ($p < 0.001$). From 1991–1993, one out of 10 knees required revision. From 1994–1996, 10 out of 28 knees required revision. None of the 29 knees from 1997 and 1998 required revision (Fig. 3).

Followup Knee Society scores averaged 91.2 (range, 57 to 100) for the clinical and 79.5 (range, 35 to 100) for the functional. This compares to the preoperative clinical and functional scores of 52.2 (range, 18 to 70) and 51.1 (range, 18 to 89), respectively. At last followup average scaled WOMAC scores (lower score demonstrating better result) were 11.8 for pain, 31.1 for stiffness, and 24.9 for function. Current activity level of each patient was assessed using both the UCLA and Tegner activity level ratings. The average UCLA activity level score was 5.6 (range, 2 to 9) while the average Tegner score was 3.4 (range, 1–6). These averages correlated with patients regularly participating in moderate activities. The average preoperative range of motion in the knees was 106° (range, 70–130) and at latest followup it was 114° (range, 80–130). The average range of motion for the posterior substituting knees was 115°; the average for the cruciate retaining knees was 109°.

Fig. 2 The graph shows the Kaplan-Meier survivorship curve with accompanying 95% confidence intervals for the endpoint of revision of tibial and/or femoral component for osteolysis/aseptic loosening.

Fig. 3 The graph shows reoperations for wear and/or aseptic loosening by year of index surgery.

Radiographic evaluation of the non-revised knees resulted in none demonstrating circumferential radiolucencies. Eleven knees showed incomplete radiolucent lines all measuring 1 mm or less, except for one femoral radiolucency which was 2 mm. Early changes consistent with osteolysis were evident in four non-revised knees, all of which were 1 cm² or less. Two unrevised patients had

Table 1. Revisions for aseptic loosening and/or osteolysis

Case (Pt) [Side]	Year of index operation	Age (yrs)	Gender	Time to revision (yrs)	Components revised	Reason for revision
1 (1) [L]	1996	54	F	5.4	Liner and femoral component	Osteolysis
2 (1) [R]	1996	54	F	5.6	Liner	Osteolysis and polyethylene wear
3 (2)*	1995	53	M	6.4	Liner, femoral and tibial components	Aseptic loosening and osteolysis
4 (3)**	1994	47	F	6.7	Liner and femoral component	Osteolysis and polyethylene wear
5 (4)	1995	49	F	6.9	Liner	Osteolysis and polyethylene wear
6 (5)	1996	48	F	7.2	Liner, femoral and tibial components	Osteolysis and polyethylene wear
7 (6)	1994	49	M	7.3	Liner	Osteolysis and polyethylene wear
8 (7)	1994	50	F	7.7	Liner	Osteolysis and polyethylene wear
9 (8)*	1993	35	M	9.3	Liner, femoral and tibial components	Aseptic loosening and osteolysis
10 (9)	1996	55	F	11.3	Liner, femoral and tibial components	Aseptic loosening and osteolysis
11 (10)	1995	49	F	14.5	Liner, femoral and tibial components	Osteolysis and polyethylene wear

* Revision performed at an outside institution; ** Patient required an additional revision 4.2 years later.

asymmetric thinning of the polyethylene. We observed no difference between the three groups based on preoperative knee alignment (neutral to varus, 0° to 5° valgus, and greater than 5° valgus) and the need for wear-related revision ($p = 0.47$).

Discussion

In terms of total hip arthroplasty in the young, it has been stated that “The challenge comes when patients between 45 and 50 years of age are to be considered for the operation, because then every advance in technical detail must be used if there is to be a reasonable chance of 20 and more years of trouble-free activity” [2]. This statement is equally

pertinent to total knee arthroplasty. Most mid- and long-term studies on knee arthroplasty in younger patients have a relatively large percentage of rheumatoid patients who were somewhat inactive (Table 2) [4, 7, 12, 13]. There is comparatively little information on cohorts of younger patients with only OA [5, 6, 17, 19, 22–24] although this young OA group has the largest growth projections in the future [16]. The purpose of this study was to evaluate the minimum 10-year followup of TKA performed in more active patients with osteoarthritis, using modular tibial components, to determine (1) survivorship; (2) revision rates; (3) functional scores; and (4) rates of radiographic failure.

We note several limitations. First, we had a limited number of cases available for inclusion. However, we

Table 2. Previous studies of TKA in younger patients

Report	Diagnosis	Design	Years of operations	Mean followup time	N	Average age at index operation	Survivorship
Duffy et al., J Arthroplasty, 2007 [6]	100% OA	All CR, modular	1987–1994	12 years	52	53	96% at 10 years; 85% at 15 years; Endpoint = revision for any reason
Lonner et al., CORR, 2000 [17]	100% OA	Variable, 84% cemented	1982–1994	7.9 years	32	35	90.6% at 8 years; Endpoint = revision for aseptic failure
Diduch et al., JBJS Am, 1997 [5]	100% OA	107 PS, 15 APT	1977–1992	9.3 years	108	51	87% at 18 years; Endpoint = any reoperation
Ranawat et al., J Arthroplasty, 2005 [22]	100% OA	100% APT and PS; PFC modular(23) and Sigma(31)	1992–2000	5 years	54	57	N/A; 1.8 % failure rate (1 post-traumatic failure)
Tai et al., JBJS Br, 2006 [24]	100% OA	All cementless; all CR	1992–2000	7.9 years	118	50.7	97.5% at 10 years; Endpoint = revision of femoral or tibial comp.
Mont et al., J Arthroplasty, 2002 [19]	100% OA	All CR, modular	1991–1995	7.2 years	35	43	N/A; 3% failure rate; Failure = any reoperation
Hofmann et al., CORR, 2002 [13]	57% OA, 25% RA, 18% other	All cementless; 57% CR, 43% PS	1986–1998	9.3 years	75	42	N/A; 0% aseptic failure; 12 liner exchanges
Duffy et al., CORR, 1998 [7]	63% RA, 24% OA, 13% other	All cemented; 58% APT, 42% MBM	1977–1983	12.6 years	74	43	95% at 15 years; Endpoint = revision or moderate to severe pain
Gill et al., J Arthroplasty, 1997 [12]	54% OA, 43% RA, 3% AS	All CR	1977–1989	9.9 years	68	50.7	96% at 18 years, worst case; 60% Endpoint = any revision
Crowder et al., J Arthroplasty, 2005 [4]	100% RA	51% APT, 49% MBM	1977–1983	18 years	47	43	93.7% at 20 years; Endpoint = any revision
Stern et al., CORR, 1990 [23]	100% OA	All cemented PS	1979–1987	6.2 years	68	51	N/A; 5.9% failed; Failure = reoperation for any reason
Odland et al. [current study]	100% OA	All cemented; 73% PS, 27% CR	1991–1998	12.4 years	67	48.5	16.4% wear-related failure

OA = osteoarthritis; RA = rheumatoid arthritis; AS = ankylosing spondylitis; CR = cruciate retaining; PS = posterior stabilizing; APT = all-polyethylene tibia; MBM = metal-backed monoblock.

included all patients with a single implant system, prospectively collected data, long-term clinical followup, a high percentage of radiographic followup, and a low number of patients lost to followup. In addition, all surgeries were performed by a single surgeon. Second, there is the potential for interobserver variability of radiographic measurements. Radiographic findings were agreed upon by consensus of two of us. Third, there were changes in design and polyethylene processing during the study. As stated previously, the first 46 (69%) tibial inserts were polyethylene sterilized with gamma irradiation in air while the subsequent 21 (31%) inserts implanted in 1997 and 1998 were sterilized with gamma irradiation in an inert environment utilizing gamma vacuum foil technology.

The failures in the present study were most commonly related to osteolysis with or without aseptic loosening (11 knees, 16.4%) (Table 1). Survivorship at 10 years was lower in our series than in other reports (Table 2). Two series having comparable average followup reported a revision rate for polyethylene wear and osteolysis of 11.5% in 52 knees [6], and 0% revision rate for wear, osteolysis and loosening in 108 knees [5]. The first cohort [6] is the most comparable to the present series in terms of minimum 10 year followup and the use of a similar PFC device; however, all were posterior cruciate retaining and most were performed before 1994. The second cohort had a large percentage of monolithic metal backed or all polyethylene tibial components with a substantially lower revision rate of 0%, although not all cases were followed for 10 years, with a range of followup from 3 to 18 years [5].

The relatively high 16.4% revision rate for wear related failures was not associated with age, BMI, or gender at the time of index surgery; however, this was in general a young, active population by knee arthroplasty standards. Alignment and preservation or substitution of the posterior cruciate ligament did not correlate with failure, but most knees were anatomically aligned. The one variable that did correlate with failure was the year of the index procedure. All failures related to polyethylene wear, osteolysis and loosening occurred in cases performed between 1993 and 1996 with all but one in the 3 year period between 1994 and 1996, years in which the polyethylene used was still sterilized in air, as opposed to in an inert environment. Several studies have demonstrated a higher failure rate related to polyethylene wear and osteolysis for this device during the time interval of the failures in this study [11]. There were no failures in the cases with polyethylene that was sterilized in an inert environment although these were the cases at the end of the study (1997, 1998) with less followup. Even when adjusting comparison to failures within the first ten years of followup, for the three groups implanted from 1991 to 1993, from 1994 to 1996, and from

1997 to 1998, we found a difference with the largest percent of knees requiring revision in the 1994–1996 group. In addition, there were no failures in cases performed before 1993, likely due to the relatively low number of knees implanted during this time period relative to the other two periods (Fig. 3).

Functional scores were encouraging with activity levels correlating to patients participating in moderate activity. These functional results should serve as a benchmark for other cohorts of total knee arthroplasty in young patients as longer followup becomes available.

Radiographic analysis resulted in two cases each of osteolysis and asymmetric wear in knees that were not revised. These findings warrant close followup, especially in light of other series of modular total knee arthroplasties showing increased failures after 10 years of followup [18].

Although 36% (four of the 11) of the revisions performed for wear-related reasons were isolated tibial insert exchanges in this series, the authors would like to emphasize that these were in isolated cases where the components were well-fixed and the knees were well-aligned. All of these cases were identified early on (all inserts exchanged within 7.7 years of index procedure) and allowed for the use of modularity to replace the tibial inserts. The caveat is this is not a common occurrence. In fact, in a recent multicenter study of tibial insert exchanges for cases of wear and osteolysis presented at the Knee Society involving the senior author, seven surgeons at four institutions performed 25 insert exchanges over an approximate 10.5 year period (less than 1% of all the total knee arthroplasty revisions during that time) [Callaghan et al., 2010, submitted for publication].

The authors hoped to answer whether knee arthroplasties with modular tibial trays resulted in survivorship comparable to those performed without modularity in the younger patient population at long-term followup, but testing the hypothesis is difficult because there are no comparable series with similar lengths of followup in young patients with OA, and because many of the components in this series were performed during a time interval where there is now concern regarding the polyethylene processing utilized [11]. However, these and other knee arthroplasty studies of younger patients with OA should provide a benchmark for cases of similar cohorts with newer designs and materials to evaluate any improvement in survivorship with these more recent technologies. It is in this patient population where there is the most room for improvement in implant durability. Larger series in this age group, including multicenter studies, should be studied when new techniques and designs are implemented.

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