5- to 9-year Survivorship of Single-radius, Posterior-stabilized TKA

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Abstract We studied 1030 consecutive cemented primary TKAs performed by the primary author (OMM) using a single-radius, posterior-stabilized total knee prosthesis with 5 years' minimum followup to determine whether an accelerated early failure rate was associated with this design. At 5 to 9.5 postoperative years, 32 knees had been revised at an average of 2.4 postoperative years (range, 0.1–8.2 years) because of infection (11), periprosthetic fracture (10), aseptic loosening (eight), stiffness (two), and late hemarthrosis (one). Four had only the tibial insert revised. One-half of all failures occurred within 1.5 years. The cases of aseptic loosening involved the femoral component in one patient, tibial component in five, and both components in two. With only seven patients (0.7%) having unknown outcomes, the overall failure rate was 4.9 per 1000 person-years for the study period. The Kaplan–Meier survivorship using any part of the prosthesis removed or revised for any reason as the end point was 95.8% (95% confidence interval, 93.7%–95.5%), and with aseptic loosening as the end point, it was 98.6% (95% confidence interval, 96.5%–99.4%). The midterm survivorship rates were comparable to those of other posterior-stabilized total condylar designs and are not suggestive of excessive risk of early failure.

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

Introduction

Knee arthroplasty prostheses with a single-radius femoral component design were introduced in 1996 in an attempt to more accurately reproduce the kinematics of the natural knee [8]. This design has been associated with improved extensor mechanism function and increased functional stability in posterior-stabilized designs [5, 15, 22, 23]. Several features of this device, however, have been implicated as potential causes of early failure. First, the single mediolateral femoral component radius could predispose the polyethylene insert to edge loading and accelerated wear if liftoff occurs during load-bearing gait [12]. Also, the possibility of implant-cement mantle separation from macrostructured cobalt-chrome implants has been observed in at least one bench study [16]. Finally, this device features an open box cam-post design, which potentially could result in unintended wear problems and soft tissue entrapment [20]. In the only published report of midterm outcomes for this device, favorable clinical outcomes were reported at 5 years [11]. However, the series was small ($n = 103$) and thus does not adequately test the propensity for accelerated rates of early failure. Survivorship rates of 95.6% to 97% have been reported for modern cemented, posterior-stabilized total condylar designs at 5 to 8 postoperative years [1, 3, 7, 17].

Given the concerns described, a review was done to ascertain whether an accelerated failure rate was present in a large population of consecutive, posterior-stabilized, single-radius design TKAs with at least 5 years followup.

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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 was obtained.

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The primary objective of this review was to calculate the survivorship of this prosthesis to 9.5 years followup. Additionally, we sought to document the reasons any revisions were needed in the series and to assess the condition of retrieved components with respect to evidence of polyethylene wear, cement debonding, and post-cam impingement. Finally, conditions requiring reoperation without requiring component revision were analyzed.

Materials and Methods

The study population consisted of 830 patients who underwent 1030 consecutive primary TKA procedures performed by one surgeon (OMM) between November 6, 1996, and April 6, 2001, using the same single-radius, posterior-stabilized total knee prosthesis (Scorpio[®] posterior-stabilized total knee system; Stryker Orthopaedics, Mahwah, NJ) with a fully cemented application. Approximately 2/3 of the patients were female, with a mean age of 69 years (Table 1). Of the 1030 procedures, 978 (95%) were performed for osteoarthritis, 42 (4%) for rheumatoid arthritis, and 10 (0.9%) for other diagnoses. Three hundred seventy of the 1030 TKAs in this series (36%) were performed as part of a bilateral procedure under the same anesthetic.

All TKA procedures were performed using the same surgical technique. The subvastus approach [13] was used in all cases. Flexion-extension axis localization [14] was used to determine the rotational and anteroposterior position of the femoral component. The Scorpio[®] PS tibial polyethylene insert was used in 212 patients (all before March 1998), and the Scorpio[®] Flex posterior-stabilized insert was used in 818. The Scorpio[®] Flex incorporated condylar surface modifications with a relaxed posterior slope for decreased rotational conformity at the potential risk of decreased stability. Insert subtype groups did not differ in any of the assessed demographic characteristics (Table 1). Patellas were resurfaced with polyethylene

components in all cases. All components were fully cemented over all surfaces of bone. The postoperative and rehabilitative care was the same for all patients. Patients in the cohort were followed postoperatively under the normal practice of postsurgical care, which included routine office followup at 5 postoperative years and every 2 to 3 years or as needed thereafter.

In the event of any reoperation or revision surgery, comprehensive evaluation of the condition of all components was routinely performed and documented in the medical record. The articular surfaces of the patellas and tibias were examined for severity of wear and any nonintended surface damage. All metal components were grasped with mechanical attachable handles and manipulated to verify they were well fixed. The interfaces between the components and host bone were routinely probed along the margins of all 10 femoral zones and along the margins of the notch. The tibial interfaces were probed medially, anteriorly, and laterally. The integrity of the locking mechanism was tested by prying against the tibial tray on the medial and lateral sides of the knee.

Before the review, the study was approved by the Institutional Review Board. We obtained informed consent for retrospective research. Institutional Review Board-approved waiver of consent and authorization was obtained for patients who had died. We retrospectively collected demographic information, followup status, and data related to any reoperations, revisions, and joint-related complications from medical records and electronic clinic databases. Determination of decedent status and dates of death were obtained for all patients from the US Social Security Death Index. Patients who were seen at their last followup but were not yet within 6 months of the due date for followup were presumed to be in followup. Diligent effort was made to contact each living patient who either was due for followup within 6 months or late for followup to ascertain their current status, particularly with respect to any possible history of knee complications not reflected in the records of our clinic.

Table 1. Patient characteristics by gender

Patient characteristics	All patients (n = 830)	Male (n = 277)	Female (n = 553)
Age (years)*	68.8 (23–93)	67.5 (24–93)	69.5 (28–92)
Height (inches)*	66.5 (54–78)	70.2 (58–83)	64.5 (54–74)
Weight (pounds)*	195 (88–365)	210.9 (130–365)	185.6 (88–350)
Body mass index (kg/m ²)*	30.93 (16.9–58.9)	30.14 (18.3–58.9)	31.29 (16.9–55.3)
Race			
White	740 (89.5%)	333 (91.7%)	586 (88.3%)
Black	84 (10.1%)	29 (8.0%)	75 (11.3%)
Other	3 (0.4%)	1 (0.3%)	3 (0.4%)

* Values are expressed as means, with ranges in parentheses.

None reported having treatment of complications or revision surgery performed elsewhere. Seven patients (0.7%) who were believed to be living could not be located by telephone, mail, or knowledgeable proxy and were presumed lost to followup. One hundred forty-one patients (17%) representing 165 cases (16%) had died during the followup period. Death dates were available for all. Four patients who had died were known to have had revision surgery before their death. At the time of this report, the average current age of patients who are living is 74.9 years, and 34% of the surviving members of the cohort (235 of 689) are currently older than 80 years. The observation period for this study ended April 6, 2006.

The minimum postoperative followup for all patients was 5 years. The mean ($\pm$ standard deviation) postoperative time of the study end date was 7.0 ± 1.28 years (range, 5.0–9.4 years). The median postoperative time was 6.9 years. Mean postoperative time for implants with the standard Scorpio[®] PS inserts was 8.9 ± 0.32 years (range, 8.0–9.4 years) and with Scorpio[®] Flex inserts $6.6 \pm .97$ years (range, 5.0–8.4 years).

Kaplan–Meier product limit estimates [9] with 95% confidence limits were computed using the following events as failure end points [4, 18]: (1) any part of the prosthesis no longer in situ; (2) femoral component and/or tibial baseplate no longer in situ; (3) revision of the femoral or tibial component for aseptic loosening; and (4) death of the patient. Standard errors for confidence limits were computed using Greenwood's formula. Survival estimates were reported as corresponding to 5 and 9.5 years postoperative time. The 5-year survival estimate refers to the latest computed Kaplan–Meier estimate before 5 years, and the 9.5-year estimate refers to the final estimate for the study. Regarding the primary survivorship end

point (revision of any part of the component for any reason), 173 knees remained in the analysis when the latest revision occurred at 8.2 postoperative years. For all survival analyses, patients without failure were censored on the date of the competing end point, death, or study end date, whichever occurred first. Patients lost to followup were censored at the date of last contact. Worst-case survival estimates and 95% confidence intervals were calculated under assumptions that all patients lost to followup had reached the end point on the day after the date of last contact.

Person-time failure rates were calculated and Mantel–Haenszel methods were used to test for differences in failure rate between insert subtype groups. The log-rank test was used to test for differences in survival curves by insert subtype. SAS[®] Version 9.1 (SAS Institute, Cary, NC) software was used for statistical analyses. Alpha was set at 0.05 for statistical tests.

Results

The overall survivorship rate for the series was 95.8% (Table 2; Fig. 1) with 32 knees of 31 patients (23 female, eight male; 32 cases) having undergone removal of any part of the original component for any reason (Tables 3, 4). The average time from TKA to revision was 2.4 ± 1.73 years (range, 0.1–8.2 years) with $\frac{1}{2}$ of all failures occurring within 1.5 years. Seven of the 32 revised knees have had one to three additional revision surgeries for subsequent problems. The average patient age at the first revision procedure was 69.8 ± 10.68 years (range, 44–86 years). The mean age of patients undergoing revision at the time of the index procedure was 67.4 ± 10.80 years

Table 2. Kaplan–Meier survival estimates using alternative end points (n = 1030)

End point	Postoperative time (years)	Survival estimate (95% confidence limits)
Any part of original component not in situ		
All reasons	5	97.2% (96.0%–98.1%)
	9.5	95.8% (93.7%–97.5%)
All reasons, infection excluded*	5	98.2% (97.1%–98.9%)
	9.5	96.4% (94.3%–97.8%)
Femoral component and/or tibial baseplate not in situ		
All reasons	5	97.6% (96.4%–98.4%)
	9.5	97.0% (95.4%–98.0%)
All reasons, infection excluded*	5	98.5% (97.5%–99.1%)
	9.5	97.3% (95.2%–98.5%)
Aseptic loosening only	5	99.4% (98.6%–99.7%)
	9.5	98.6% (96.5%–99.4%)

* Infected cases censored.

Fig. 1 The Kaplan–Meier survival curve with 95% confidence intervals for 1030 consecutive cemented Scorpio[®] posterior-stabilized total knee implantations is shown. The end point for the analysis is any part of the original component no longer in situ for any reason.

(range, 43–84 years). Major differences were not detected between revised and unrevised knees by gender, race, or age at implantation; height, weight, or body mass index of the patient; or operative side or day of the week the index procedure was done. Assuming all seven patients lost to followup underwent revision on the day after the date of last contact, the worst-case survival estimate for all causes of prosthesis failure at 9.5 postoperative years was 95.2% (95% confidence interval, 93.0%–96.7%). Using death of the patient as the end point, the Kaplan–Meier estimate for survival of the patient at 9.5 postoperative years was 80.0% (95% confidence interval, 76.7%–83.0%).

Reasons for the initial failure (initial revision procedure to the joint) included perioperative infection (two), late hematogenous infection (nine), periprosthetic fracture (10), aseptic loosening (eight), stiffness (two), and hemarthrosis (one). In four of the 32 patients, the initial revision involved exchange of the polyethylene insert only (one for hemarthrosis, one for stiffness, and two for infection with an incision and drainage procedure). The patient with hemarthrosis underwent subsequent femoral component revision to convert to a closed-box design. Two of the 10 failures resulting from periprosthetic fracture were bilateral patellectomies in one patient after the same traumatic fall. The others involved fractures of the distal femur in seven

and the proximal tibia in one. In 26 failures, the initial revision procedure involved the tibial and/or femoral component.

Aseptic loosening occurred at an average 4.10 ± 2.38 postoperative years (range, 0.8–8.2 years) and involved the femoral component in one knee, tibial component in five, and both components in two. No primary components were removed for aseptic loosening during any subsequent revision procedure. No patient in this series was given a recommendation for revision for radiographically evident component loosening who did not undergo revision surgery during the study period. There has been no case of patellar revision for a reason other than infection or patellar fracture. During the study period, the Scorpio[®] Flex implant had a lower rate of revision for all reasons than Scorpio[®] PS implants; however, the difference was not detected in noninfected cases (Table 3). Review of the infected cases did not reveal any pattern to suggest a relationship to implant type or times in which the cases were done. Nine of the 11 infections occurred more than 1 year after the index procedure and were believed to represent secondary

Table 4. Survival analysis life table with number of failures at annual intervals

Interval (years)	Number at start	All causes*		Noninfection causes [†]	
		Number failed	Number withdrawn	Number failed	Number withdrawn
0–1	1030	13	13	11	15
1–2	1004	5	20	1	24
2–3	979	2	21	1	22
3–4	956	5	34	3	36
4–5	917	3	21	2	22
5–6	893	0	281	0	281
6–7	612	2	221	2	221
7–8	389	1	175	0	176
8–9	213	1	155	1	155
9–10	57	0	57	0	57

* Any part of component not in situ for any reason; [†]any part of prosthesis not in situ for any reason excluding infection (infected revisions treated as withdrawn).

Table 3. Prevalence and rate of TKA failure* by revision reason[†]

Cause of Failure [†]	All Cases (n = 1030)		Scorpio [®] PS (n = 212)		Scorpio [®] flex (n = 818)		p Value
	Number	Rate per 1000 person-years [‡]	Number	Rate per 1000 person-years	Number	Rate per 1000 person-years	
All causes	32 (3.1%)	4.9	13 (6.1%)	8.1	19 (2.3%)	3.9	0.034
Infection only	11 (1.1%)	1.6	6 (2.8%)	3.7	5 (0.6%)	1.0	0.020
Noninfection only	21 (2.0%)	3.2	7 (3.3%)	4.4	14 (1.7%)	2.9	0.345
Aseptic loosening only	8 (0.8%)	1.2	3 (1.4%)	1.8	5 (0.6%)	1.0	0.388

* Failure is any part of prosthesis not in situ; [†]reason for initial revision procedure to the joint; [‡]total observed implant time = 6618 years.

infections. Survival curves for noninfected failures were not different between insert subtypes ($p = 0.3640$ for removal of any component, $p = 0.5113$ for removal of femoral and/or tibial component; log-rank test).

Inspection of components at the time of the revision procedures did not reveal findings to suggest that polyethylene wear, cement debonding, or post impingement was a primary cause of failure in any case. The tibial insert was revised during each of the 32 initial revision procedures, including the patellectomy procedures; all were well fixed in their tibial trays. Burnishing was present on all polyethylene inserts, with small amounts of pitting visible on the medial and/or lateral compartments of 27 of the 32. In each specimen, the patterns of burnishing were uniform, with no peripheral area of increased deformation suggestive of edge loading. Regarding cement bonding, small areas of periprosthetic bone resorption were observed around the femoral components of 19 of the 24 cases that were revised for reasons other than aseptic loosening. These areas were limited to 2 to 6 mm in width and depth and did not in any case extend more than 4 mm under the edge. Similar areas were noted around the medial edges of 12 tibial components, with none extending more than 4 mm under the edge of the tray. Of the eight cases of aseptic loosening, the tibial component was loose in seven and had tipped further into varus. The medial plateau of the tibias was covered with dense fibrous tissue, and in four of these, the medial cement mantle was fractured, with the majority of the cement still fixed to the undersurface of the tibial tray. In the three cases of femoral component loosening, fibrous tissue membranes were present under the entire component. Bony resorption 5 to 7 mm deep was present under the anterior flange and posterior condyles. The bone of the distal condyles was well preserved, with no pockets of lysis seen in the notch area. Most of the cement mantle remained well fixed to the components. Regarding post wear, 23 inserts had anterior post markings from contact with the distal trochlear edge of the femoral components. There were small areas of coarse abrasion present on the sides and top edges of the posts of 29 of the 32 revised inserts.

Several other joint-related complications were noted in this series that did not result in revision. There were 16 cases of late (> 6 postoperative months) hemarthrosis, seven of which required surgical treatment (six arthroscopies, one arthrotomy). Two patients underwent arthroscopy as a result of refractory synovitis of undetermined etiology and two as a result of patellar clunk. Forty-three knees experienced transient synovitis responsive to nonoperative treatment. Forty-nine knees underwent closed manipulation for stiffness. Ten underwent surgical repair of fracture of the knee region (distal femoral to proximal tibial shaft) that did not require revision of the prosthesis.

All of these occurred at times distant from the index procedure and were believed to be unrelated to the arthroplasty. There was no case of patellar subluxation or any dislocation of the knee. Major differences were not found between insert subtype groups for frequency or time to onset of the complications described.

Discussion

We studied 1030 consecutive primary TKAs using a cemented, single-radius, posterior-stabilized total knee prosthesis with 5 years' minimum followup to determine whether an accelerated early failure rate was associated with this design.

Several limitations of this study should be noted. First, because the case series was retrospectively derived from the practice of one surgeon who only used one implant, a control group was not available for direct comparison. We therefore relied on ecologic comparisons to published reports to judge the relative adequacy of the survival of this implant. Second, although the large sample size and small loss to followup are considerable strengths of the study, the single-surgeon cohort was homogeneous with regard to surgical technique, perioperative and postoperative care routine, and geography, and thus may or may not approximate the survival experience of other cohorts or of population-based groups of patients who had TKA. Finally, although surgical revision is the most objective and most commonly cited end point for the study of joint replacement failure times, it is criticized for having low sensitivity for detecting the occurrence of clinically significant failure [4]. Rigorous assessment of radiographic outcomes might have provided a more precise failure end point with regard to our study questions; however, an independently conducted radiographic followup review of all patients was not feasible given the size of the cohort. We attempted to compensate for this limitation by applying diligent effort to accurate ascertainment of each patient's survivorship outcome and by reporting results conservatively using all revisions for all causes as the primary end point and including the worst-case survival estimate.

The overall survival rate of 95.8% was consistent with rates of other modern cemented, posterior-stabilized total condylar designs [1–3, 6, 7, 17]. Given that the worst-case survival estimate was 95.2% among this large population with a very low number of unknown patient outcomes (0.7%), it is unlikely that the features specific to the Scorpio[®] design cause a reduction of in vivo survival in the first 5 to 8 years of implantation. Infection was the leading cause of revision in this series, with 1.1% affected, which is consistent with rates of 1.3% and 1.0% reported in two large series [6, 10]. In our study, 80% of the infections

occurred more than 2 years after the index procedure. The rate of infection was higher in the more conforming Scorpio[®] PS insert type; however, we are unable to identify or speculate about a causal relationship to account for this observation. Controlling for infection, the survivorship and revision rates appeared comparable between insert types. The high risk of late infection of TKA implants remains a major concern. One half of all failures we observed occurred within the first 18 months of implantation (Table 4; Fig. 1), which is consistent with documented patterns of hazard for failure of total knee prostheses [19]. Nevertheless, failure was a rare outcome of these implants. The average recipient of a TKA in this study faced a substantially greater risk of dying than of surviving to observe a prosthesis failure [18].

Regarding edge loading, we saw no evidence of delamination or fracturing of the polyethylene articular surfaces in any of the revised components. The uniformity of burnishing patterns we observed suggested the loads placed on the tibial articular surfaces were evenly distributed in each compartment. These observations are consistent with reported findings of a microscopic analysis of 20 single-radius, posterior-stabilized total knee prostheses [20]. Four of the cases of aseptic loosening from the current series were included in that analysis.

There were eight failures caused by aseptic loosening, representing 0.78% of the total population of 1030 knees; however, we did not observe evidence to implicate implant cement mantle separation as a primary failure mechanism in any of these. Of the five tibias that loosened, four were noted originally to have been placed in 3° to 6° mechanical varus, which probably contributed to their subsequent failure [10]. At revision, all of the loosening were noted to have occurred at the bone–cement interface, with only small areas of cement separation from either cobalt-chrome component.

With the open-box design, coarse abrasions were present along the side walls of the tibial posts in most cases; however, very little osteolysis was seen around the components. The damaged areas were also relatively small, suggesting the particles generated from this unintended abrasive wear probably were not the primary cause of failure in these cases.

Some concerns remain related to the open-box design of this device regarding the high incidence (16 cases [1.6%]) of late hemarthrosis we observed. Seven of these patients eventually underwent reoperation to evacuate the hematoma and cauterize bleeding tissue. In five of these patients, there was obvious bleeding coming from hypertrophic soft tissue, which had grown into the notch where it was subject to mechanical trauma from the post-cam mechanism. In two cases, there were abrasions of the periosteal covering of the osteotomized notch area resulting in slight but persistent bleeding. Although the rate of hemarthrosis seen

here is lower than the 3% reported by Sorrells et al. [21] in a series of nonposterior-stabilized rotating-platform knees, we believe the open-box design may increase the risk of this complication. This intraarticular bleeding resulted in only one revision in the series at large, however, and thus did not contribute appreciably to the risk of failure.

We could not identify evidence to suggest polyethylene wear or separation of cement from either the femoral or tibial prosthesis led to accelerated rates of early failure with this posterior-stabilized TKA device in this series of more than 1000 TKAs with 5 years' minimum followup. Although the complications related to the open-box design did not substantively increase the implant failure rate at midterm, they remain an important concern. This open-box design does present several advantages, including reduced risk of intercondylar fracture during femoral component seating and reduced requirement for femoral bone resection (which may be particularly noteworthy in very small patients). We believe design modifications aimed at reducing the risk of soft tissue trauma in the notch should be explored in future designs.

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