Polyethylene Quality Affects Revision Knee Liner Exchange Survivorship

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Abstract

Background Options to treat patients with wear or osteolysis include full revision, partial (tibial or femoral) revision, and isolated polyethylene exchange. It is unclear whether one choice is superior to the other. Polyethylene quality reportedly influences the survivorship of primary TKA, but similar reports are not described for revision TKA.

Questions/purposes We compared the failure rate for the three procedures and the influence of polyethylene quality on failure.

Patients and Methods We retrospectively evaluated 123 patients with 135 TKAs in which wear or osteolysis was thought to have contributed to the need for surgery. Twenty-five percent had an isolated polyethylene

exchange, 39% a single-component revision, and 36% a full revision. We determined survivorship of the revisions. The mean follow-up for the 123 patients was 6.2 years. Fifteen patients (16 knees, or 12%) were lost before 5-year evaluations leaving 108 patients (119 knees, or 88%) for comparison of rerevision rates.

Results Five-year survivorship was similar for all three procedures: $82\% \pm 14\%$ for polyethylene exchange, $89\% \pm 8\%$ for partial revision, and $88\% \pm 10\%$ for a full revision. Polyethylene sterilization had the strongest influence on rerevision. Survivorship was $73\% \pm 16\%$ for knees revised with gamma-in-air polyethylene compared to $92\% \pm 6\%$ for nongamma or gamma-in-barrier sterilization methods.

Conclusions The survival rates of isolated polyethylene exchange for wear or osteolysis are similar to those of a single-component or full revision when the components are well aligned and well fixed. Polyethylene sterilization influenced revision TKA survivorship in this study and should be reported in future studies.

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

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Each author certifies that his or her institutional review board approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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Introduction

Revisions for polyethylene wear or osteolysis are a subset of all revisions and are reported to account for 8% to 24% of TKA revisions [3, 11, 14]. Although wear and osteolysis may not be the leading causes of revision, they are leading causes of late revision [17]. As such and considering the increased use of TKA in younger patients, the frequency of revisions for wear and osteolysis is likely to increase.

Traditionally wear, osteolysis, and loosening as modes of failure resulted in a tibial, femoral, or full-knee revision because early TKA components were nonmodular. The advent of modular TKA implants in the 1980s allowed surgeons to perform an isolated polyethylene exchange. An isolated polyethylene exchange is a less expensive, surgically easier procedure that has reduced patient morbidity. In 1994, the senior author (GAE) first described treating patients with osteolysis having a modular implant [9]. Well-fixed, well-aligned components were maintained whenever possible in the face of wear and osteolysis. Since then, several authors have questioned the benefits of isolated polyethylene exchange [2, 8, 13, 15, 20, 21]. Series with 27 to 68 patients followed for 3.3 to 5.6 years have documented a 6% to 29% failure rate for isolated polyethylene exchange [2, 8, 13, 15, 20, 21]. To complicate the debate about performing an isolated polyethylene exchange, authors have often included diagnoses such as stiffness, instability, and synovitis [2, 15, 21], which may have different rerevision rates compared to revisions for osteolysis or wear.

Polyethylene quality is an important variable that has not been mentioned in revision TKA studies. Although polyethylene quality influences the revision rates of primary unicompartmental knee arthroplasty [6] and TKA [5, 7, 10, 12], the effect of polyethylene quality on knee revision results has not been defined. It is possible poor-quality gamma-in-air polyethylene used at revision could have accounted for the high revision rates reported for isolated polyethylene exchanges.

We therefore (1) compared the rerevision rates and survivorship of isolated polyethylene exchange, partial-revision, and full-revision procedures and (2) determined whether polyethylene quality influences the rerevision rates and survivorship of revisions for wear or osteolysis.

Patients and Methods

From our institutional database, we identified 163 patients who had 177 knee revisions performed between 1986 and 2002 in which osteolysis or wear was thought to have contributed to the need for surgery. A review of radiographs and operative notes on all cases resulted in elimination of 40 patients (42 revised TKAs) in which osteolysis or wear was not a factor contributing to revision. These exclusions left 123 patients with 135 revisions. These 135 revisions were 22% of all 616 revisions performed during the same dates by four surgeons. The indications for revision included (1) loosening secondary to wear or osteolysis, (2) impending loosening with wear or osteolysis, (3) impending wear-through, (4) wear-related late instability, (5) progressive osteolytic bone loss, and

(5) debris-related synovitis. Whenever possible well-fixed, correctly aligned components were maintained and an isolated polyethylene exchange was performed. Well-fixed tibial trays were revised if the locking mechanism was damaged or there was evidence of severe backside wear. Component revisions were performed for loose or malaligned components. Of these 123 patients, 25% had an isolated polyethylene exchange, 39% a single-component revision, and 36% a full revision. We determined survivorship of the revisions in this group. The mean followup was 6.2 years. Fifteen patients (16 knees, or 12%) were lost before 5-year evaluations (mean followup, 0.8 years; range, 0–3.2 years), leaving 108 patients (119 knees, or 88%) for comparison of rerevision rates. The data for this subset of patients are summarized (Table 1). Of the 119 knees, 93 (78%) had their primary procedure performed at our clinic.

The most common designs revised were Anatomic Modular Knee® (AMK) (69 knees; DePuy Orthopaedics, Inc, Warsaw, IN), Synatomic™ (20 knees; DePuy), and Porous-Coated Anatomic™ (PCA) (14 knees; Howmedica, Rutherford, NJ). These three designs were 87% of the cases. Femoral condylar penetration was measured for the medial and lateral compartments using a previously defined technique [16]. The mean medial penetration was 2.99 mm (range, 0–11 mm) and mean lateral penetration 1.05 mm (range, 0–8 mm); 57% of these had more than 2 mm of medial penetration while 20% had more than 2 mm of lateral penetration. Polyethylene sterilization data were

Table 1. Summary of the patients with known outcome

Variable	Value
Number of patients/knees	108/119
Followup (years)*	6.9 (0.3–17)
Age (years)*	68 (31–88)
Weight (pounds)*	187 (108–320)
Male gender	55%
Knee score (preoperative)*	43 (6–92)
Function score (preoperative)*	62 (10–100)
Medial wear (mm)*	2.99 (0–11)
Lateral wear (mm)*	1.05 (0–8)
Revision polyethylene (number of knees)	
Nongamma	68 (57%)
Gamma in air	35 (29%)
Gamma inert	15 (13%)
Osteolysis visible on radiograph (number of knees)	86 (72%)
Tibial lesions (number)	97
Tibial size (cm ²)*	4.1
Femoral lesions (number)	81
Femoral size (cm ²)*	3.7

* Values are expressed as mean, with range in parentheses.

recorded for all revisions and categorized as gamma in air, gamma in inert environment, or nongamma. One case had an unknown sterilization. We used serial radiographs when available, the most recent radiograph, and intraoperative evaluation to determine whether an implant was well aligned and well fixed. Osteolysis was measured by a single reviewer (CAE) on the prerevision and most recent followup films. Osteolysis was defined as a geographic area of bone lacking a normal trabecular pattern. Two-dimensional areas were determined by measuring the maximum lesion dimension and the dimension measured perpendicular to that measurement. Eighty-six knees had measurable osteolysis on the prerevision radiograph. For these 119 knees with known outcome, the index revision procedure was a polyethylene exchange in 31 (26%), a single-component revision in 49 (41%), and a full revision in 39 (33%). The mean followup in this subset of patients was 6.9 years (range, 0.3–17 years).

Our clinical practice is to evaluate surgical patients at 1, 2, 5, and 10 years after surgery. Patients without followup are contacted. All data for this study were obtained retrospectively from medical records and radiographs. The review was approved by our institutional review board.

We performed a power analysis to determine the number of knees needed for each of the three revision groups. To reach a power of 80%, we needed 100 to 150 knees in each of the three revision groups to show a difference of 10% to 20% in the rerevision rates with a medium effect size ($w = 0.3$). The full population of 123 patients described

above was used for survivorship comparisons, but a subset of 108 patients who were not lost before 5 years was reported for comparison of rerevision rates using a Pearson's chi square test. Kaplan-Meier survivorship analysis was performed with rerevision as the end point for the entire group. We compared survival by operation type and type of polyethylene using a log rank test. We used SPSS[®] 8.0 (SPSS Inc, Chicago, IL) for the analyses.

Results

Our goals were to (1) compare the rerevision rates and survivorship of isolated polyethylene exchange, partial-revision, and full-revision procedures; and (2) determine whether polyethylene quality influences the rerevision rates and survivorship of revisions for wear or osteolysis. However, for completeness, we describe rerevisions before addressing these specific questions. Seventeen of the 119 knees (14%) were rerevised at a mean followup of 4.6 years (range, 0.8–11 years) (Table 2). Ten rerevisions were for wear or osteolysis at a mean followup of 5.2 years (range, 3.1–10.7 years). All rerevisions for wear or osteolysis had gamma-in-air polyethylene placed at the index revision. There were no rerevisions for wear or osteolysis in patients with nongamma or gamma-in-inert polyethylene. Three knees were rerevised for loosening at 1.4, 3.5, and 6.5 years. There were two knees rerevised for infection at 0.8 and 4.3 years. One knee was rerevised for

Table 2. Rerevision reason, index procedure type, and polyethylene sterilization

Knee	Reason for rerevision	Years	Sterilization method	Revision type	Gender	Age (years)	Time to index revision (years)
1	Infection	0.81	GVF	Full	Male	72	10
2	Loose tibia	1.39	GVF	Poly	Male	56	5.5
3	Osteolysis/wear	3.1	AIR	Poly	Male	69	5.25
4	Wear	3.2	AIR	Poly	Male	76	5.5
5	Femoral loosening	3.52	GVF	Full	Male	73	4.9
6	Pain	3.82	GP	Full	Female	68	14.2
7	Osteolysis/fracture	3.88	AIR	Poly	Male	55	4.9
8	Infection	4.29	GP	Partial	Female	75	7
9	Osteolysis	4.46	AIR	Partial	Male	62	4.5
10	Wear	4.47	AIR	Poly	Male	47	3
11	Osteolysis/failed patella	4.69	AIR	Partial	Male	47	4.3
12	Wear/instability	4.9	AIR	Partial	Male	65	3.25
13	Wear/instability	5.97	AIR	Poly	Female	68	3.5
14	Loose tibia	6.51	GP	Partial	Male	61	4.7
15	Wear	7.1	AIR	Partial	Male	44	4.1
16	Osteolysis/wear	10.72	AIR	Poly	Male	58	4.5
17	Unknown	?	GVF	Full	Female	74	10

GVF = gamma in inert; AIR = gamma in air; GP = gas plasma; poly = polyethylene exchange; partial = tibia only.

Table 3. Rerevisions and polyethylene type

Treatment option	Failures/rerevisions for each treatment option	Polyethylene type	Failures/rerevisions for each polyethylene type
Polyethylene exchange	7/31 (23%) (1 success has unknown polyethylene)	Gamma in air	6/14 (43%)
		Gamma inert	1/5 (20%)
		Nongamma	0/11 (0%)
Single-component revision	6/49 (12%)	Gamma in air	4/11 (36%)
		Gamma inert	0/2 (0%)
		Nongamma	2/36 (6%)
Full revision	4/39 (10%)	Gamma in air	0/10 (0%)
		Gamma inert	3/8 (38%)
		Nongamma	1/21 (5%)

pain at 3.8 years and one was rerevised at an outside institution for an unknown reason. Patients who underwent rerevisions tended to be younger (63 versus 68 years; $p = 0.07$), heavier (201 versus 183 pounds; $p = 0.08$), and male (76% versus 51%; $p = 0.06$). Patients who were rerevised had a shorter ($p = 0.005$) time from primary surgery to the index revision (70 versus 100 months). The osteolysis and condylar penetration noted at the time of the index revision were not factors contributing to rerevision.

Our primary purpose was to compare the rerevision rate and survivorship for the three procedures performed for wear or osteolysis (Table 3). There was no difference ($p = 0.27$) in the rerevision rates in the subset of 119 knees: 23% (seven of 31) of isolated polyethylene exchanges, 12% (six of 49) of single-component revisions, and 10% (four of 39) of full revisions failed, requiring a rerevision. Survivorship analysis was performed for the full cohort of 135 knees as another technique to compare the durability of the three procedures and evaluate the influence of polyethylene quality. Survivorship free of rerevision for the entire cohort was $87\% \pm 6\%$ at 5 years. The 5-year survivorship rates for the three types of procedures with rerevision as the end point were not different (log rank test, $p = 0.34$): $82\% \pm 14\%$ for polyethylene exchange, $89\% \pm 8\%$ for partial revision, and $88\% \pm 10\%$ for full revision.

Our secondary purpose was to evaluate the influence of polyethylene quality on the rate of rerevision and survivorship. In the subset of 119 knees, the 83 knees that did not have a gamma-in-air polyethylene had fewer ($p = 0.004$) rerevisions (seven, 8%) than the 35 gamma-in-air knees (10, 28%). The mean length of followup for the gamma-in-air and the nongamma knees was similar (74 versus 78 months; $p = 0.65$). Survivorship at 5 years for the entire cohort with rerevision as the end point was lower ($p = 0.002$) for knees revised with gamma-in-air polyethylene ($73\% \pm 16\%$) than for knees revised with nongamma or gamma-in-barrier polyethylene ($92\% \pm 6\%$) (Fig. 1).

Fig. 1 Five-year survivorship with rerevision as the end point was lower ($p = 0.002$) for knees revised with gamma-in-air polyethylene ($73\% \pm 16\%$) than for knees revised with nongamma or gamma-inert polyethylene ($92\% \pm 6\%$). Gray lines show confidence intervals.

Discussion

Published results of revision TKA include 7- to 10-year survivorship of 79% to 91% [1, 14, 18, 19]. However, patients and surgeons often want to know the durability of revisions for a specific diagnosis. Wear and osteolysis are common reasons for knee revision [4]. Although they are not the most common reasons, they are leading causes of late revision [17]. Patients who have wear or osteolysis and are candidates for surgery can have procedures ranging from a full revision to an isolated polyethylene liner exchange. Because the results of isolated polyethylene exchange have a 6% to 29% reported failure rate at 3 to 6 years, some authors have advocated a more extensive component revision even when the femoral and tibial components are well fixed and well aligned [2, 9, 13, 15, 20, 21]. This is despite the fact that additional bone loss, uncertain new fixation, longer surgical time, and increased patient morbidity are important concerns when revising

tibial and femoral implants [9, 13]. Our first purpose was to compare rerevision rates and survivorship for isolated polyethylene exchange, partial revision, and full revision for wear or osteolysis. Our second purpose was to report the influence of polyethylene quality on the rerevision rates and survivorship in revision surgery for wear or osteolysis.

The primary limitation of this study is an insufficient number of cases. Our power analysis indicated we would need 300 to 450 revisions for wear or osteolysis with 100 to 150 in each of the three groups. A study of this size has not been conducted and would likely have to be a multicenter analysis. Since our rerevision rate was higher (although not statistically higher) for isolated polyethylene exchange, there is a possibility that a difference exists among the three types of revisions, but we could not prove it because of insufficient case volume. However, even if the rerevision rate for isolated polyethylene exchange is slightly higher than that of partial or full revision, the procedure has merit for some patients and surgeons because of a comparatively reduced morbidity, the bone-sparing nature, and the ease of that procedure.

Our primary goal was to compare rerevision rates and survivorships for isolated polyethylene exchange and partial and full revisions performed for wear or osteolysis. We found no difference. The incidences of rerevision were 23%, 12%, and 10%, respectively, for polyethylene exchange, partial revision, and full revision. The 5-year survivorship rates were 82%, 89%, and 88%, respectively, for polyethylene exchange, partial revision, and full revision. Although we have previously referenced the 6% to 29% failure rates of isolated polyethylene exchanges [2, 8, 13, 15, 20, 21], we note none of the studies actually compared isolated exchange to the option of a partial or complete revision. Furthermore, these studies sometimes included diagnoses such as stiffness and early-onset instability, making meaningful comparisons to reoperation for wear and osteolysis difficult. Although neither our survivorship analysis nor revision rates favored one procedure over the other, there was a trend toward higher rerevisions in patients who had an isolated polyethylene exchange. We point out the rates were strongly influenced by the use of gamma-in-air polyethylene in 14 (six failed) of the 31 isolated polyethylene exchanges.

This leads to our second goal to evaluate the influence of polyethylene quality on revision rates and survivorship in our patients. Polyethylene quality influences the revision rates of primary TKA [5–7, 10, 12]. It is possible and even likely gamma-in-air-sterilized polyethylene, especially if inadvertently shelf-aged, could have contributed to the poor results reported in the literature for isolated polyethylene exchange. Extrapolating our revision rates (from Table 2) in cases that did not use gamma-in-air polyethylene, the rerevision rate is 6% (one of 16), 5% (two of 38),

and 14% (four of 29) for isolated polyethylene exchange, partial revision, and full revision, respectively ($p = 0.04$). Our 6% failure rate for isolated polyethylene exchange when good-quality polyethylene was used matches one of the better reports from the literature. Further support that polyethylene quality influenced our rerevision rate is evidenced by the 73% survivorship for gamma-in-air polyethylene, which was lower than the 92% for other polyethylene types. The only rerevisions for wear or osteolysis (10 of 17; Table 2) were in patients who had a gamma-in-air polyethylene used at the index revision.

In conclusion, isolated polyethylene exchange when components are well aligned, well fixed, and without backside wear can be successfully used to treat patients undergoing revision for wear or osteolysis as long as the replacement polyethylene quality is good. This is justified by the absence of a statistical difference in either the incidence of rerevision or the survivorship of the three surgical options. Gamma-in-air polyethylene used for revision surgery did not perform as well as nongamma-in-air-sterilized polyethylene. Although gamma-in-air polyethylene is no longer used, our findings create a cause to question the conclusions of previous authors who failed to report the polyethylene type used at revision. Revision outcome studies should include a description of the polyethylene used.

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