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Highly Cross-Linked Versus Conventional Polyethylene in Posterior-Stabilized Total Knee Arthroplasty at a Mean 5-Year Follow-up

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ABSTRACT

Concerns of highly cross-linked polyethylene (XLPE) in total knee arthroplasty (TKA) exist regarding fatigue resistance and oxidation, particularly in posterior-stabilized (PS) designs. A prospective cohort study of 114 consecutive PS TKAs utilized conventional polyethylene in 50 knees and second-generation annealed XLPE in 64 TKAs. Clinical (Short-Form 36, Knee Society Scores, and LEAS) and radiographic outcomes were evaluated at a mean of 5 years in 103 TKAs. Mean KSS scores were 12 points higher ($P = 0.01$) and SF-36 physical function subset 14 points higher ($P = 0.005$) in the XLPE group. There was no radiographic osteolysis or mechanical failure related to the tibial polyethylene in either group. At 5-year follow-up, no deleterious effects related to highly cross-linked posterior stabilized tibial polyethylene inserts were observed.

Osteolysis and polyethylene wear continue to persist as failure modes in total knee arthroplasty (TKA) [1–4]. Therefore, in an effort to improve the longevity and survivorship of TKA, particularly in younger and more active patients, highly cross-linked polyethylene (XLPE) was developed and is now available. Although 10-year results of XLPE in the hip demonstrate low wear and longevity and XLPE is now considered the gold standard in hip arthroplasty [5–9], the clinical performance of XLPE in total knee arthroplasty (TKA) remains largely unknown. Concerns exist regarding fatigue resistance and oxidation [10,11], particularly in posterior-stabilized (PS) designs due to the higher local stresses at the PS post, with a lone case report of XLPE post fracture reported in the literature [12].

Some early results of irradiated and re-melted XLPE in TKA report satisfactory results without any significant deleterious consequences in the short- to mid-term [13–16]. However, there are no mid-term clinical in vivo reports in the literature of annealed XLPE in total knee arthroplasty. The purpose of this study is to compare the clinical and radiographic outcomes of XLPE and conventional polyethylene in a PS TKA design at a minimum of 5-years. In particular, evaluation is performed to assess the occurrence of any mechanical complications related to the polyethylene such as early osteolysis, tibial insert bearing surface failure or post fracture.

Methods

A prospective cohort study of 114 consecutive TKAs in 83 patients was performed from May 2006 to March 2008, as a subset of a larger multi-center prospective study. Institutional review board approval was obtained prior to enrolling participants and data were collected prospectively. All TKAs utilized an identical posterior-substituting (PS) single-radius design (Triathlon; Stryker, Mahwah, NJ) and were performed by a single surgeon at a community hospital. Surgical approach was via a median para-patellar arthrotomy in all cases and ligament balance obtained based on the surgeon's manual and tactile judgment at the time of surgery. All of the TKAs were performed with cement fixation and the patella was resurfaced in every case.

Conventional polyethylene inserts were used in the first cohort of TKAs and second-generation highly cross-linked polyethylene inserts were implanted in the subsequent cohort of TKAs. The conventional polyethylene (N2Vac; Stryker, Mahwah, NJ) inserts are compression molded GU 1020 UHMWPE, packed in nitrogen and gamma-irradiated at 30 kGy. The highly cross-linked polyethylene (X3; Stryker, Mahwah, NJ) tibial inserts were manufactured GUR 1020 UHMWPE and cross-linking was performed with a cycled process of gamma-irradiation at 30 kGy followed by annealing at 130 °C for 8 hours, which was repeated 3 times sequentially [17].

All patients were clinically evaluated preoperatively, at 6 weeks, 3 months, 1 year, and annually thereafter out to 5 years with the clinical outcome measures Short-Form 36, Knee Society Score and Lower Extremity Activity Scale (LEAS). All patients were evaluated radiographically by an independent review at the same follow-up intervals with standard weight-bearing AP, lateral and patellofemoral radiographs.

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The radiographs were specifically analyzed for any radiolucency consistent with loosening or osteolysis.

Standard statistical Student's *t*-tests were utilized to compare the mean outcome variables between groups. Mean outcome scores at the different time periods between the two groups were compared. Statistically significant difference was considered at a *P*-value less than or equal to 0.05 between groups.

Results

Conventional polyethylene inserts were used in the first consecutive 50 knees and second-generation annealed XLPE was implanted in the subsequent 64 TKAs. Demographic data are shown in Table 1. There were 13 bilateral TKAs performed in 37 patients (25 female; 12 male) in the conventional polyethylene cohort and 17 bilateral TKAs performed in the group of 47 patients (29 female; 18 male) in the XLPE cohort. The mean age of the patients in the conventional polyethylene group is 67.3 years (range, 44–80 years) and 63.8 years (range, 45–80 years) in the highly cross-linked polyethylene group ($P = 0.03$). There was no difference between groups with respect to BMI ($P = 0.3$) with the conventional group having a mean value of 31.1 and the XLPE group a mean of 31.5. There was no difference in any mean preoperative outcome measures (Knee Society Score, SF-36, LEAS) between groups with numbers available.

Seven patients (10 TKAs) died or were lost to follow-up and one underwent revision for infection at 3 months postoperatively. One hundred three TKAs obtained 5-year clinical follow-up. The mean follow-up of the conventional group was 5.5 years (range, 4.8–7.4 years) and he mean follow-up for the XLPE group was 5.2 years (range, 4.3–5.8 years). The mean preoperative, 6-week, 3-month, 1-year, 2-year and 5-year outcome measures of Knee Society Score, SF-36 and LEAS are shown graphically in Figs. 1, 2 and 3, respectively. The mean Knee Society Scores were similar in both groups preoperatively ($P = 0.97$), however, the mean KSS function scores at 5-years follow-up were 12 points higher in the highly cross-linked polyethylene group compared to the conventional group ($P = 0.01$) (Fig. 1). While the mean physical function subset SF-36 scores were higher in the conventional polyethylene group preoperatively ($P = 0.12$), the difference was not statistically significant. However, the mean physical function SF-36 scores at 5-year follow-up were 14 points higher ($P = 0.007$) in the highly cross-linked polyethylene group, compared to the conventional polyethylene group (Fig. 2). The mean preoperative LEAS scores were lower in the conventional polyethylene group ($P = 0.057$); however there was no difference in LEAS scores between groups at the 5-year follow-up interval ($P = 0.97$) (Fig. 3). There was no statistical difference in the other outcome measures at any follow-up intervals with the numbers available (Figs. 1–3). There were no revisions for any reason in either group with the exception of lone revision for infection at 3 months in the conventional polyethylene group. There was no radiographic osteolysis or mechanical failures related to the tibial polyethylene in either group.

Discussion

The incidence and utilization of total knee arthroplasty continue to increase, particularly in younger and more active patients. While some contend that wear-related failures are not a predominant failure mechanisms in TKA, osteolysis and polyethylene wear continue to persist as causes for revision in total knee arthroplasty (TKA) [1–4]. As younger and more active patients place greater demand on the TKA polyethylene, there are data to support the notion that greater wear and wear-related failures may occur in younger patients [18,19]. In a retrospective review of 6275 total knee arthroplasties, McCalden et al [19] reported a significantly higher (4×) rate of failure from wear and osteolysis in younger patients under the age of 55, compared to those 55 years old or greater. In a recent population-based study of 120,538 TKAs in the California Patient Discharge Database from 2005 to 2009, Meehan and colleagues [18] reported that the risk of aseptic mechanical failure in patients less than 50 years of age was 4.7 times greater than those 65 or over, lending further support for the deleterious effects of the increased activity level and demands of younger patients on the TKA biomaterials.

In an effort to improve the longevity and survivorship of TKA, particularly in younger and more active patients, highly cross-linked polyethylene (XLPE) was developed. Long-term results of XLPE in total hip arthroplasty out to ten years have demonstrated that low wear significantly improved over conventional polyethylene and excellent survivorship [5–9]. Subsequently, XLPE is now considered the gold standard in hip arthroplasty. However the clinical performance of XLPE in total knee arthroplasty (TKA) lacks the longer-term follow-up that exists with XLPE in hip arthroplasty. Furthermore, concerns exist regarding fatigue resistance and oxidation due to the biomechanical environment and forces that exist in TKA, particularly in posterior-stabilized (PS) designs due to the higher local stresses at the PS post-cam mechanism [10,11]. There is a lone case report of XLPE post fracture reported in the literature; however, the mechanical environment of the XLPE was extreme due to hyper-extension of both the femoral and tibial components and resulted in anterior damage of the XLPE post [12].

Some early results of irradiated and re-melted XLPE in TKA report satisfactory and encouraging results without any significant deleterious consequences in the short-term [13–16]. In the first series to report in vivo clinical results of XLPE in the knee, Hodrick et al [16] reported 100 cruciate-retaining TKAs with XLPE at a minimum of 69 months of follow-up compared to a similar series of 100 TKAs with conventional polyethylene and failed to observe any wear-related failures or osteolysis in either group. In another series of cruciate-retaining TKA, Minoda et al [15] reported two-year clinical results of irradiated and remelted XLPE compared to conventional polyethylene and reported no failures related to polyethylene or osteolysis in either group.

While these initial reports in cruciate-retaining TKA were encouraging, only recently have in-vivo reports of XLPE in posterior-stabilized TKA designs emerged [13,14]. Long et al [14] documented the results of 120 consecutive PS TKAs with an irradiated, remelted XLPE at a minimum of two years (mean 52 months) of clinical and radiographic follow-up and reported no wear-related complications, osteolysis or post-fractures. In a recent report from Korea of 308 bilateral posterior-substituting TKAs in 20 men and 288 women, Kim and Park [13] implanted one knee with irradiated, re-melted XLPE and the contralateral TKA with conventional polyethylene and followed patients to a minimum of 5 years. The authors reported no failures of the PS post, no failures of the locking mechanism and no osteolysis in either the conventional polyethylene or the XLPE TKA groups [13]. While this study had a preponderance of female patients due to the disproportionate incidence of osteoarthritis in Asian females, the results at mid-term remain encouraging. However, there are no reports in the literature of annealed XLPE in total knee arthroplasty.

Our reports presented here support those previously discussed mid-term results of XLPE in the knee [13–16]. At a mean of five-year clinical follow-up in a consecutive series of PS TKA comparing conventional and XLPE inserts, we failed to identify any polyethylene-related mechanical or wear-related failures in either group. As compared to the only other 5-year follow-up in XLPE in a PS design reported by Kim and Park [13] whose patients were overwhelmingly female, our data are more

Table 1
Demographic Characteristics for Cohorts.

	Conventional Group	XLPE Group
Knees	50	64
Patients	37	47
Female/Male patients	25/12	29/18
Mean age (years)	67.3	63.8
Mean BMI	31.1	31.5
Mean follow-up (years)	5.5	5.2
Reoperations	1	0