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## Primary Arthroplasty

## Multicenter Study of Highly Cross-linked vs Conventional Polyethylene in Total Knee Arthroplasty

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## ABSTRACT

**Background:** Despite substantial interest and use of highly cross-linked polyethylene (HXLPE) in total knee arthroplasty (TKA), outcomes remain largely unknown. The purpose of this study is to compare HXLPE and conventional polyethylene at 4- to 5-year follow-up.**Methods:** A prospective multicenter study of 307 posterior-stabilized TKAs (168 conventional and 139 HXLPE) was performed. Short-Form-6D, Short-Form 36, Knee Society Score, Lower Extremity Activity Score, health-related quality of life outcomes, and radiographs were collected preoperatively and at routine postoperative intervals.**Results:** Two hundred twenty-four patients obtained a minimum 4- to 5-year follow-up for analysis. There were no osteolysis or polyethylene failures in either group. Although both conventional and HXLPE poly groups showed significant improvements in all measures from preoperative baselines ( $P < .05$ ), the XLPE group had slightly greater mean Knee Society Score function ( $P = .04$ ), Lower Extremity Activity Score ( $P = .03$ ), and Short-Form 36 Physical Composite Score ( $P = .03$ ) scores and a greater improvement in Short-Form 6D health-related quality of life of 0.16 points ( $d = 1.02$ , 95% CI: 0.01–1.11) at latest follow-up.**Conclusion:** The study findings support comparative safety and outcomes of HXLPE related to mechanical failure or osteolysis in the midterm. However, longer-term follow-up is warranted to assess whether wear and mechanical properties of HXLPE are maintained in vivo.

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Osteolysis and polyethylene wear continue to persist as failure modes in total knee arthroplasty (TKA) [1–4]. To improve the longevity and survivorship of TKA, particularly in younger and more active patients, highly cross-linked polyethylene (HXLPE) was developed and is now available. Although 10-year results of HXLPE in the hip demonstrate low wear and longevity and is now considered the gold standard in hip arthroplasty [5–9], the clinical performance of HXLPE in 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 HXLPE post fracture reported in the literature [12].

Some early results of irradiated and remelted HXLPE in TKA report satisfactory results without any significant deleterious consequences in the short term to midterm [13–16]. An initial single-surgeon series of conventional and annealed HXLPE has recently been reported [17]. The purpose of this study is to compare the clinical and radiographic outcomes of HXLPE and conventional polyethylene in a PS TKA design at 5-year follow-up in a multicenter and multisurgeon study.

## Methods

Three-hundred and seven primary PS TKAs were performed by 7 board-certified arthroplasty surgeons at 6 institutions between May 2006 and March 2008 as part of a prospective, longitudinal, multicenter study. Institutional review board approval was obtained for the study. Subjects were enrolled if they met the selection criteria and agreed to sign an institutional review board–approved informed consent. Inclusion was defined as any

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patient with late-stage osteoarthritis who could be treated with a cemented TKA and had intact collateral ligaments. Patients were excluded for body mass index >40, neuromuscular, metabolic, immunologic disorders, or inability to complete outcome measures or radiographic assessments. All TKAs used an identical PS single-radius design (Fig. 1; Triathlon; Stryker, Mahwah, NJ). Ligament balance was obtained based on the surgeon's manual and tactile judgment at the time of surgery. All the TKAs were performed with cement fixation.

Conventional polyethylene inserts were used in the first cohort of 168 TKAs, and second-generation HXLPE inserts were implanted in the subsequent cohort of 139 TKAs. The conventional polyethylene (N2Vac; Stryker) tibial inserts are compression molded GU 1020 UHMWPE, packed in nitrogen, and gamma irradiated at nominal 3MRad. The HXLPE (X3; Stryker) inserts were manufactured GUR 1020 UHMWPE, and cross-linking was performed with a sequential process of irradiation at nominal 3MRad followed by annealing at 130°C for 8 hours, which was repeated 3 times [18].

All patients were clinically evaluated preoperatively, at 6 weeks, 3 months, 1 year, and annually thereafter out to 5 years with the health-related quality of life (HRQoL) measure, Short-Form 6D (SF-6D); the Short-Form 36 (SF-36) health survey; first-generation Knee Society Score (KSS); and the Lower Extremity Activity Scale (LEAS). The SF-6D quantifies patient perceptions of their health quality related to physical functioning, role limitations, social functioning, pain, mental health, and vitality, resulting in a single index ranging from 0 to 1 or full health. Effect sizes (Cohen's *d*) [19] were calculated to identify the clinical importance of changes in SF-6D HRQoL [20–22] with effect sizes (*d*) of 0.2 to 0.3 interpreted as small, 0.5 as medium, and >0.8 as large [19]. The Mental Composite Score and Physical Composite Score (PCS) of the SF-36 are reported. The KSS function and pain/motion subscores are presented.

All patients were evaluated radiographically at the same follow-up intervals with standard anteroposterior, lateral and patellofemoral (sunrise view) radiographs. Radiographs were reviewed by an independent practicing orthopedic surgeon and specifically analyzed for radiolucency consistent with loosening or osteolysis, in addition to gap, subsidence, and position of components.

Descriptive statistics and Student's *t* test for unpaired and paired observations (SAS version 9.3, Cary, NC) were used to compare patient demographics in the 2 study groups, outcome scores between groups at follow-up, and within-group changes relative to preoperative baseline scores. Statistical significance was defined as  $P \leq .05$ .

## Results

An initial single-surgeon subset of 114 TKAs from this multicenter trial has been reported and published previously [17]. Conventional polyethylene inserts were used in the first 168 knees, and second-generation HXLPE inserts were implanted in the subsequent 139 TKAs. The mean age of patients in the conventional polyethylene group was 65.5 (range, 40–80) years and 64.1 (range, 44–79) years in the HXLPE group ( $P = .15$ ). There was no difference between groups with respect to the body mass index ( $P = .57$ ) with both groups having a mean value of 31.0. There were no differences by group in preoperative SF-6D HRQoL, SF-36 PCS and Mental Composite Score, and KSSs ( $P > .05$ ). The HXLPE group had a 1-point higher mean LEAS score preoperatively ( $P = .02$ ).

Thirteen patients died, and 70 patients were lost to follow up before the 5-year follow-up. Five TKAs underwent a liner exchange for wound-related or deep joint infection, one tibial component in the conventional poly TKA group was revised 15 months after the index procedure for aseptic loosening unrelated to the polyethylene, one conventional polyethylene was revised for treatment

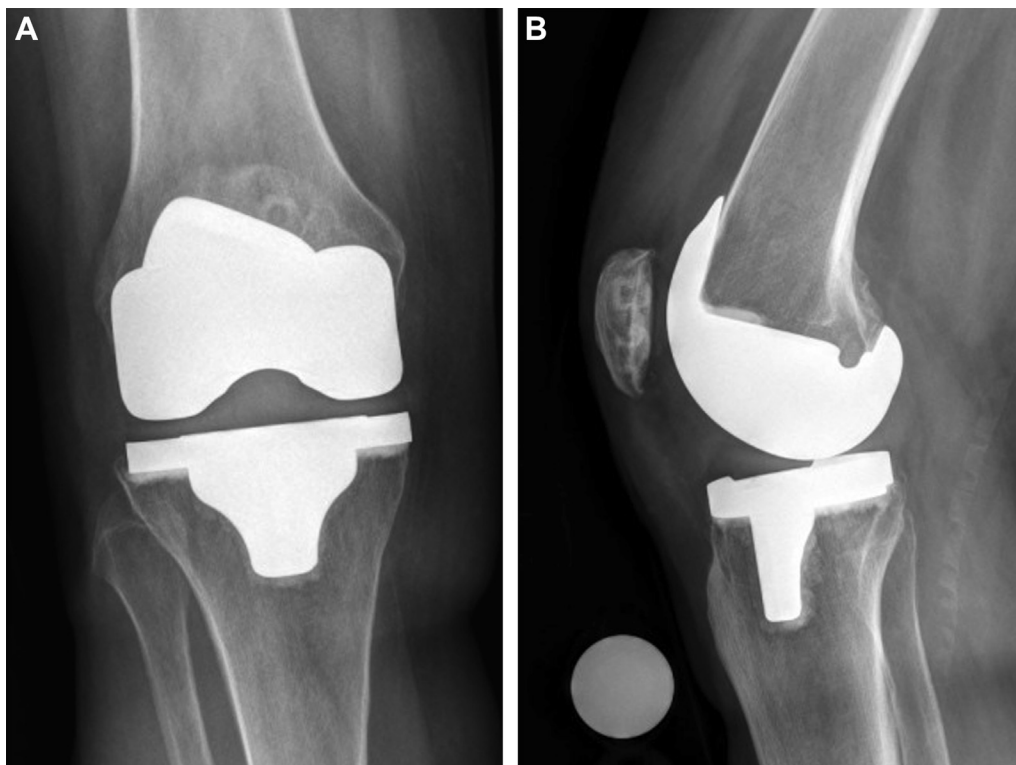


Fig. 1. (A) Anteroposterior and (B) lateral radiographs of the posterior-stabilized total knee arthroplasty (Triathlon; Stryker, Mahwah, NJ).

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