Five-year migration and insert wear of uncemented tibial components with either conventional polyethylene or sequentially annealed highly crosslinked polyethylene inserts: a blinded randomized controlled trial using radiostereometric analysis

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Five-year migration and insert wear of uncemented tibial components with either conventional polyethylene or sequentially annealed highly crosslinked polyethylene inserts: a blinded randomized controlled trial using radiostereometric analysis

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Aims

The primary objective of this study was to compare the five-year tibial component migration and wear between highly crosslinked polyethylene (HXLPE) inserts and conventional polyethylene (PE) inserts of the uncemented Triathlon fixed insert cruciate-retaining total knee arthroplasty (TKA). Secondary objectives included clinical outcomes and patient-reported outcome measures (PROMs).

Methods

A double-blinded, randomized study was conducted including 96 TKAs. Tibial component migration and insert wear were measured with radiostereometric analysis (RSA) at three, six, 12, 24, and 60 months postoperatively. PROMS were collected preoperatively and at all follow-up timepoints.

Results

There was no clinically relevant difference in terms of tibial component migration, insert wear, and PROMs between the HXLPE and PE groups. The mean difference in tibial component migration (maximal total point migration (MTPM)) was 0.02 mm (95% confidence interval (CI) -0.07 to 0.11), which is below the value of 0.2 mm considered to be clinically relevant. Wear after five years for HXLPE was 0.16 mm (95% CI 0.05 to 0.27), and for PE was 0.23 mm (95% CI 0.12 to 0.35). The mean difference in wear rate was 0.01 mm/year (95% CI -0.02 to 0.05) in favour of the HXLPE group. Wear is mainly present on the medial side of the insert.

Conclusion

There is no clinically relevant difference in tibial component migration and insert wear for up to five years between the HXLPE conventional PE inserts. For the implant studied, the potential advantages of a HXLPE insert remain to be proven under clinical conditions at longer-term follow-up.

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Introduction

Wear of the tibial polyethylene (PE) inserts with subsequent wear particle-induced osteolysis about the implant is a common indication for revision of primary total knee arthroplasty (TKA).[1] More wear-resistant polyethylene could potentially reduce wear and thus implant loosening.[2] Crosslinking and thermal stabilization (second-generation HXLPE) are methods to improve the wear characteristics of PE and have been evaluated for acetabular components of total hip arthroplasty (THA) showing reduced wear.[3,4] Recently,

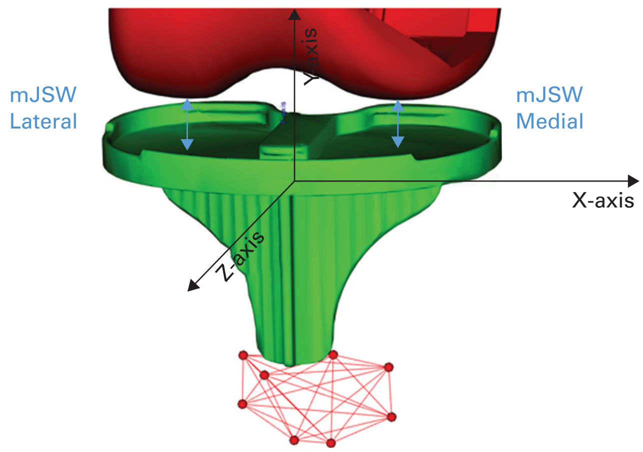

Fig. 1

Picture showing radiostereometric analysis measurement for medial and lateral minimal joint space width (mJSW) and the coordinate system for the migration measurements of a right tibial component.

Table I. Baseline characteristics.

Characteristic	Control, PE (n = 48)	Intervention, HXLPE (n = 48)
Sex, n		
Female	31	32
Male	17	16
Mean age, yrs (SD)	64 (10)	64 (10)
Mean BMI, kg/m² (SD)	29 (5)	30 (4)
Indication, n		
Osteoarthritis	47	47
Post-traumatic arthritis	1	1
Cigarette use, n		
Non-smoker	20	20
Current cigarette smoker	4	6
Ex-cigarette smoker	24	22
Preoperative hip-knee-ankle alignment, n		
Varus/neutral	36	33
Valgus	12	15
Insert thickness, n		
9 mm	25	27
11 mm	18	15
13 mm or more	5	6

HXLPE, highly crosslinked polyethylene; PE, polyethylene; SD, standard deviation.

second-generation HXLPE has been introduced in total knee arthroplasty (TKA). However, it is unknown whether second-generation HXLPE will reduce wear in TKA.

Radiostereometric analysis (RSA) is a highly accurate technique to measure 3D migration and wear of prosthesis components relative to bone.[5] Several studies have shown that short-term prosthesis migration, as measured using RSA predicts long-term failure by aseptic loosening.[6] The minimum joint space width (mJSW) between the metal joint surfaces can be measured directly in 3D from RSA data. If the mJSW decreases, the polyethylene insert thickness has reduced as a result of wear.

The aim of our study was to evaluate whether HXLPE inserts in TKA reduce early- and mid-term (five-year) wear and tibial component migration as measured with RSA, compared to inserts of conventional PE in patients treated with TKA for end-stage osteoarthritis (OA).

Methods

A total of 96 TKAs were enrolled in a double-blinded randomized controlled trial at the Lange Land Hospital (Zoetermeer, the Netherlands) between 2011 and 2014. The study was performed in compliance with the Declaration of Helsinki,[7] was approved by the institutional ethics committee (No: 10-068), and all patients gave informed consent. The study protocol has been registered a priori (NCT02525588). All patients scheduled for TKA with primary OA during the study period were eligible. Patients who were scheduled for primary TKA and provided informed written informed consent were eligible; patients with a BMI > 40 kg/m² were excluded. More details on inclusion and exclusion criteria can be found in the protocol (NCT02525588).

The Triathlon uncemented TKAs (Stryker Orthopaedics, USA) were implanted by four surgeons with more than 25 procedures experience with this prosthesis (VR, RdR, PL, HK). This prosthesis has a single radius design; both femur and tibia components have enhanced porous substrates (peri-apatite (PA)) for initial bony ingrowth. Condylar-stabilized (CS) inserts were used in all patients. The CS insert substitutes the posterior cruciate function without the use of a post by having a deeper dish. Surgery was performed under regional (83%) or general anaesthesia (17%). A medial parapatellar arthrotomy with bone-referencing and resection-balancing techniques were used. During surgery, six to eight tantalum markers (1 mm diameter) were inserted in the proximal tibia to define a reference frame for migration measurements. In all cases a tourniquet was used and the posterior cruciate ligament (PCL) was retained. Mean skin-to-skin operating time was comparable, about 60 minutes for both groups.

The interventional group received a CS HXLPE (X3) insert, a gas plasma sterilized second-generation ultra-high-molecular-weight polyethylene (UHMWPE) sequentially irradiated and annealed polyethylene, with in vitro superior properties for wear resistance,[8,9] mechanical strength,[10] and oxidation resistance.[11]

The control group received a CS N2Vac insert made of conventional UHMWPE sterilized with γ radiation in vacuum and packaged in nitrogen gas, with a known track record in TKA.[12]

A computer-generated random sequence list of ten blocks was used for randomization for either type of insert. Allocation to type of insert was determined by opening an opaque envelope by the scrub nurse during surgery. The actual allocation (HXPLE or conventional PE) remained concealed to the surgeon because both insert types look identical. The primary outcome measures of the study were wear and tibial component migration as determined by RSA.

Secondary outcomes, consisting of Knee Society Score (KSS),[13] the Lower Extremity Activity Scale (LEAS),[14] EuroQoL five-dimension questionnaire (EQ-5D),[15] and 36-Item Short-Form Health Survey questionnaire (SF-36),[16] were recorded preoperatively and at all follow-up timepoints.

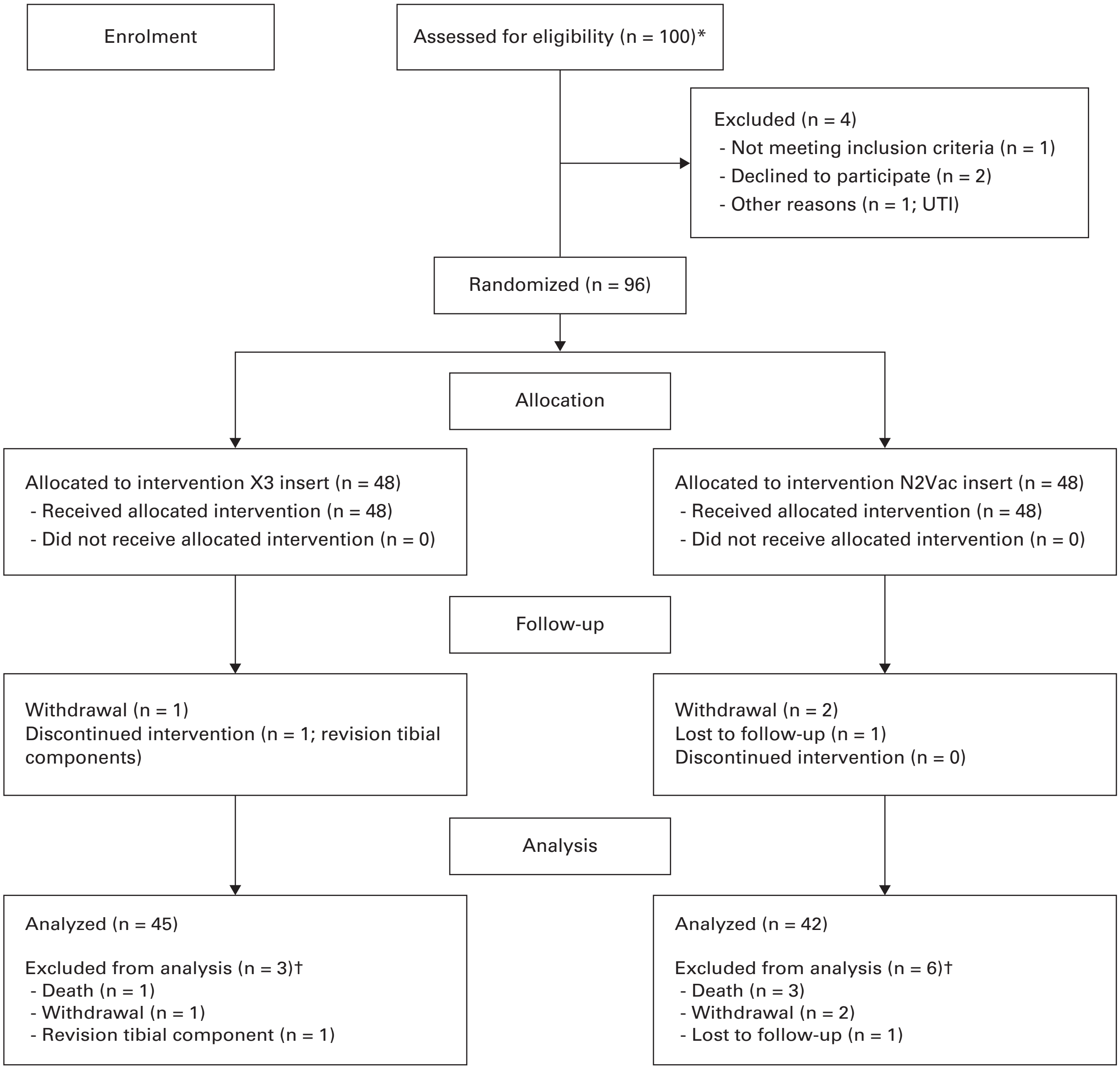

Fig. 2

CONSORT flowchart. *During the study period, 293 primary total knee arthroplasties were performed in our institution of which 100 patients were asked to participate and 96 were included. †Patients were analyzed until the moment of death, loss to follow-up, or withdrawal. UTI, urinary tract infection.

Patients, caregivers, and outcome assessors were blinded to type of insert. All RSA examinations were performed both standing and supine, except for the direct postoperative exam which was only performed supine.

Wear. Model-based RSA (MBRSA) was used to determine the mJSW in the standing RSA images between the femoral condyles and the upper plane of the tibial component on the medial and lateral side (Figure 1). Positive wear values indicate loss of PE thickness (i.e. wear), while negative wear values results indicate that the location of the mJSW of the femoral condyle(s) had moved to a position where the insert was thicker than the contact position of the mJSW in the baseline position, or possible contact loss.[17] Change in mJSW with regard to the baseline at 1.5 months was determined on standing RSA radiographs undertaken at 24 and 60 months. To study the possible effect of creep, change in mJSW was also calculated with regard to a 12-month baseline.[18]

Migration. A baseline supine RSA examination was obtained before patient discharge (within one week postoperatively). Follow-up supine RSA examinations were made at 1.5, three, six, 12, 24, and 60 months postoperatively.

For the RSA acquisitions, the patient was positioned above (supine RSA) or in front of (standing RSA) the calibration box (Medis CarbonBox nr. 027; Medis Specials, Netherlands).

Table II. Migration for the 89 double examinations of the tibial component.

Tibial component (n = 89)	Translation, mm			Rotation, °			MTPM, mm*
	x-axis	y-axis	z-axis	x-axis	y-axis	z-axis	
Mean	-0.01	0.00	0.01	0.02	-0.04	0.01	0.30
SD	0.05	0.04	0.12	0.21	0.33	0.06	0.16
Upper limit 95% CI	0.09	0.07	0.24	0.43	0.61	0.13	
Minimum migration value (mm/°)	-0.12	-0.08	-0.26	-0.60	-1.32	-0.25	0.09
Maximum migration value (mm/°)	0.23	0.10	0.31	0.56	0.91	0.14	0.94

*As MTPM is not normally distributed, the 95% CI row was not populated for this variable.
CI, confidence interval; MTPM, maximal total point motion; SD, standard deviation.

Table III. Wear precision measurements from the 82 available standing double examinations.

Variable	Medial wear	Lateral wear
Mean	-0.01	-0.03
SD	0.22	0.26
Upper limit 95% CI	0.43	0.47
Minimum	-0.63	-1.23
Maximum	0.79	0.78

CI, confidence interval; SD, standard deviation.

Radiographs were made with a fixed and mobile roentgen tube. Computer-aided design (CAD) implant models allowed for implant migration analysis with model-based RSA software (RSAcore, the Netherlands)[19] following the guidelines on RSA (see Figure 1).[20,21]

Migration is summarized as maximal total point motion (MTPM) defined as the largest 3D migration of any point on the prosthesis surface.[19] Translations (mm) and rotations (°) of the prosthesis components were calculated using a coordinate system (Figure 1) with its origin in the geometrical centre of the prosthesis in the baseline evaluation and of which, for a right-sided implant, the transverse axis is medial translation (Tx), longitudinal axis is proximal translation (Ty), and sagittal axis is anterior translation (Tz). Rotations (Rx, Ry, Rz) are defined about these axes following the right-hand screw rule. Migration of left-sided prostheses were recalculated in order to describe the migration in anatomical terms for a right-sided prosthesis.

Precision. To determine the clinical precision of the RSA set-up, double supine examinations at 12 months, for migration, and double standing examinations at 60 months, for wear, were acquired as recommended.[20]

Statistical analysis. Previous RSA wear studies show that the expected wear rate of conventional UHMWPE is 0.13 mm a year (standard deviation (SD) 0.08).[21,22] A clinically relevant difference to detect changes in wear would be a SD of 0.1 mm a year. Sample sizes of 27 patients in each group would achieve 95% power to detect a difference of -0.1 mm wear between the null hypothesis (that both group means are 0) and the alternative hypothesis (that the mean of group 2 is 0.1) with estimated group SDs of 0.1 and with a significance level (α) of 0.05 using a two-sided independent-samples *t*-test. However, because of limited data on in vivo insert wear measurements with RSA, and to compensate for possible loss of follow-up, 50 knees per study group were included. A linear mixed-effects model was used to analyze migration data and comparison between groups.[23] MTPM was log-transformed during statistical modelling to obtain a normal distribution, calculated as log(MTPM + 1). All statistical analyses were performed in the R-software environment (R Foundation for Statistical Computing, Austria).

Results

During the study period, 293 patients had primary TKAs, of whom 100 were eligible and 96 were included (Figure 2). All 96 remaining cases underwent unilateral TKA procedures, with 48 cases in each study arm. In accordance with the randomization, baseline patient characteristics that could be possible confounders (such as sex, smoking, and BMI) were comparable between the groups. The two groups were similar in terms of insert thickness (Table I).

Double examinations. The results of the double examinations for migration (n = 89, supine) and wear (n = 83, standing) are presented in Table II and Table III, indicating high precision.

Migration. The tibial component migration (MTPM) is shown in Figure 3; all migration results are presented in the Supplementary Material. All RSA measurements for MTPM, rotation, and translation showed a similar migration for both study groups, except Rx, meaning posterior tilt was noted in the first six months in the HXLPE group (Figure 4). After six months, migration in both HXLPE and PE groups stabilized. On average, at five years postoperatively, the increase in posterior slope (Rx) was 0.43° (95% CI 0.23 to 0.64) for the HXLPE and 0.09° (95% CI -0.12 to 0.30) for the PE (p = 0.006, linear mixed-effects model) (Figure 4).

At five years' follow-up, the mean difference in migration (MTPM) was 0.02 mm (95% CI -0.07 to 0.11).

Wear. From the 87 knees with a minimum of five years of follow-up, insert wear for 84 knees could be calculated by comparing the mJSW at 60 months with the mJSW at 1.5 months (Figures 5 and 6). Two knees were excluded for the following reasons: for one patient it was unclear whether the RSA radiograph at 1.5 months was made with the patient standing or not; for the second patient, the 1.5-month RSA radiograph was not made with the patient standing and could therefore not be compared with the standing 60-month radiograph. Wear results are summarized in Table IV. Medial wear (creep included) after five years for HXLPE was 0.16 mm (95% CI 0.05 to 0.27), and for PE 0.23 mm (95% CI 0.12 to 0.35). The mean difference in medial wear rate was 0.01 mm/year (95% CI -0.02 to 0.05) in favour of the HXLPE group. A wear rate of 0.05 mm/year (95% CI 0.02 to 0.07) was measured on the medial side for the PE group only (Figure 5).

Clinical results. During the five-year follow-up period, one tibial component with HXLPE insert has been revised after one year for malrotation of the tibial component. The femoral

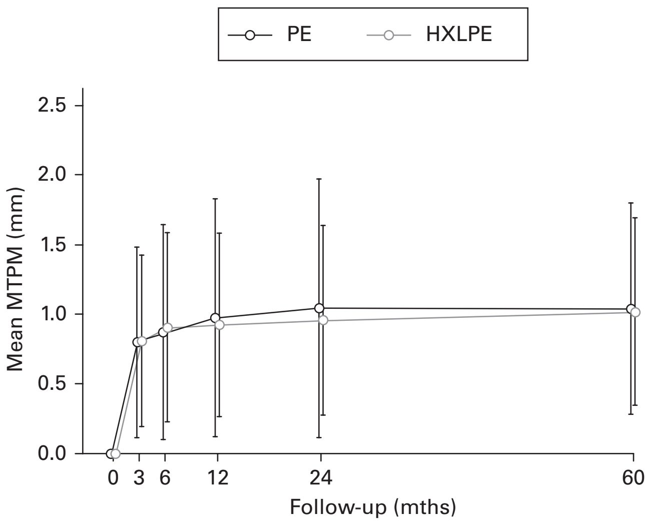

Fig. 3

Graph showing maximal total point motion (MTPM) migration during five-year follow-up for the highly crosslinked polyethylene (HXLPE) insert group and the polyethylene (PE) insert group. There was no difference in MTPM migration between the HXLPE insert group and the PE insert group. Error bars represent the standard deviation.

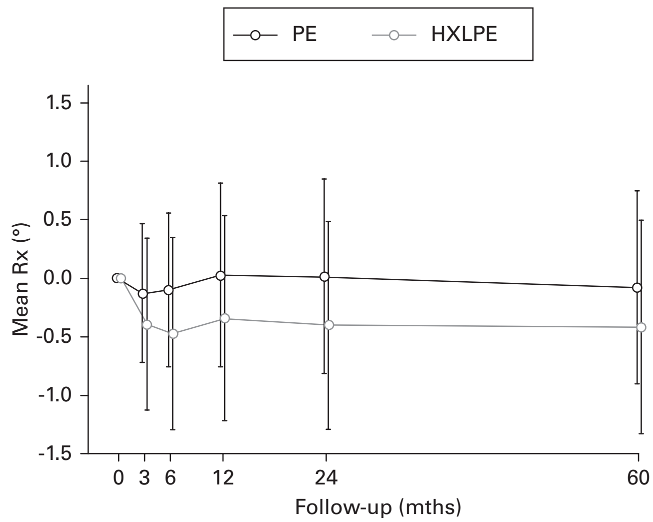

Fig. 4

Graph showing the rotation around the x-axis (slope) during five-year follow-up for the highly crosslinked polyethylene (HXLPE) insert group and the polyethylene (PE) insert group. The rotation around the x-axis (slope) was higher in the HXLPE insert group compared with the PE insert group. Error bars represent the standard deviation.

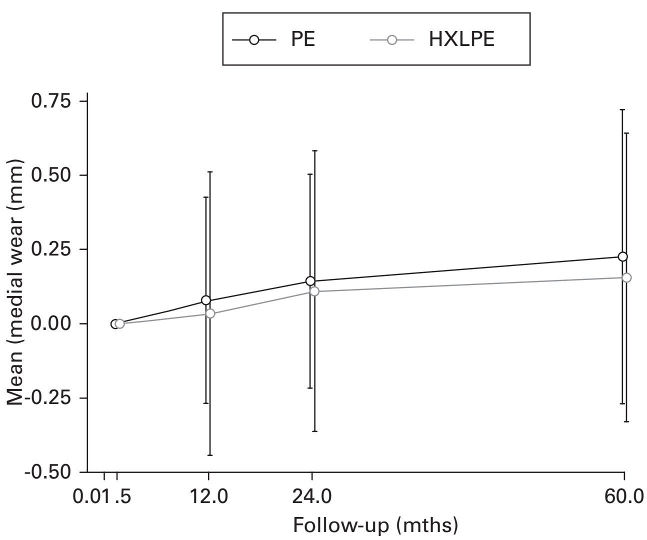

Fig. 5

Graph showing medial wear during five-year follow-up for the highly crosslinked polyethylene (HXLPE) insert group and the polyethylene (PE) insert group. There was no significant difference in wear between the HXLPE insert group and the PE insert group. Error bars represent the standard deviation.

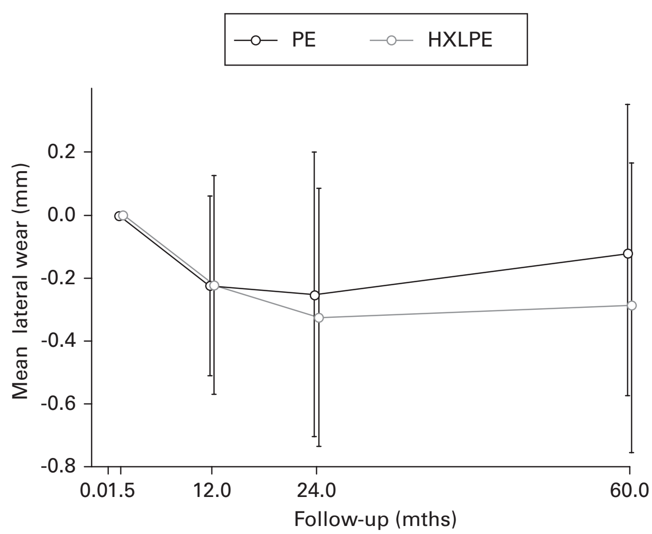

Fig. 6

Graph showing lateral wear during five-year follow-up for the highly crosslinked polyethylene (HXLPE) insert group and the polyethylene (PE) insert group. There was no significant difference in wear between the HXLPE insert group and the PE insert group. Error bars represent the standard deviation.

component of this patient was not revised. Prior to the revision, the tibial component was stable and had migrated 0.58 mm (MTPM) at one year postoperatively. No other revisions have been performed during the study period. There were no periprosthetic joint infections in either group.

Regarding the secondary outcomes, both groups improved in Knee Society Score, the LEAS, EQ-5D, and SF-36, and there were no clinically relevant differences between the groups (Supplementary Material).

Discussion

The results of this RSA study show that there is no clinically relevant difference between HXLPE and conventional PE inserts with regard to migration and insert wear of the uncemented

Table IV. Results of the wear and wear rate over the five-year follow-up. To study the effect of creep, the wear rate between one- and five-year follow-up is also presented. All values are presented as means and 95% confidence intervals.

Variable	HXLPE	PE	Difference (HXLPE–PE)
Medial wear, 5 yrs (mm)	0.16 (0.05 to 0.27)	0.23 (0.12 to 0.35)	-0.08 (-0.25 to 0.10)
Medial wear rate, 0 to 5 yrs (mm/yr)	0.03 (-0.03 to 0.09)	0.05 (0.02 to 0.07)	-0.01 (-0.05 to 0.02)
Medial wear rate, 1 to 5 yrs (mm/yr)	0.03 (-0.04 to 0.09)	0.04 (0.01 to 0.07)	-0.01 (-0.05 to 0.03)
Lateral wear, 5 yrs (mm)	-0.28 (-0.39 to -0.18)	-0.12 (-0.23 to -0.01)	-0.16 (-0.33 to 0.00)
Lateral wear rate, 0 to 5 yrs (mm/yr)	-0.05 (-0.10 to 0.01)	-0.01 (-0.03 to 0.01)	-0.04 (-0.07 to 0.00)
Lateral wear rate, 1 to 5 yrs (mm/yr)	-0.01 (-0.08 to 0.06)	0.03 (0.00 to 0.06)	-0.04 (-0.08 to 0.00)

HXLPE, highly crosslinked polyethylene; PE, polyethylene.

(CS) tibial components for up to five years postoperatively. This suggests that the conventional PE inserts are non-inferior to HXLPE insert in terms of migration and wear. The mean difference in migration (MTPM) was 0.02 mm (95% CI -0.07 to 0.11), which is not significant, and below the value of 0.2 mm which is considered to be clinically relevant.[19] The mean difference in insert wear rate was 0.01 mm/year (95% CI -0.02 to 0.05), which is also not significant, although for the PE group a wear rate of 0.05 mm/year (95% CI 0.02 to 0.07) was measured on the medial side. It is suggested that a knee insert with a wear rate below 0.03 mm/year to 0.04 mm/year would be unlikely to require revision for wear-related reasons in the long term.[24]

Our results are in accordance with a non-randomized study, in which no mechanical failure or radiological osteolysis was observed with either conventional or HXLPE inserts with a cemented Triathlon PS knee at four- to five-year follow-up.[25] This implant is the same implant as was used in our study, except it was cemented and posterior-stabilized, while the implant in our study was uncemented and cruciate-retaining.

Contrary to our findings, a registry study showed that revision for any reason was only lower in the HXLPE group for patients who were both younger than 60 years of age with a BMI of more than 35 kg/m^2.[26] While it is unclear if (residual) confounding factors may have caused this finding for the registry study, it could very well be that certain high-risk patient groups may benefit from HXLPE inserts. Further randomized controlled trials dedicated to these high-risk patient groups are necessary.

We should consider the following limitations. First, our study evaluated only one type of uncemented single radius total knee (Triathlon), with a condylar-stabilizing insert, so the observed results apply only to that implant and surgical technique, and are not necessarily generalizable to other designs.

Second, despite the fact this was a large RSA study, it was still too small to stratify for different age, sex, smoking habits, and BMI groups,[27] to substantiate whether the differences found in larger registry studies were due to differences in insert wear and tibial component migration.

Our study has the following strengths: first, we used highly accurate methods (RSA) to measure migration and wear in a large number of knees (n = 96). Double examinations for both migration and wear show sufficient precision in the obtained results. Second, weightbearing (WB) positions were acquired for the wear assessments in TKA, which have shown to be superior in comparison to wear measurements for non-weightbearing positions.[17] Third, surgeons, patients, and researchers were blinded to the intervention until after five years of follow-up. The two types of PE look identical, and on (RSA) radiographs these insert types are similar.

In the first two postoperative years, the majority of the tibial components translated between -0.5 and 0.5 mm and rotated between -1.0° and 1.0°. The out-of-plane migrations (z-axis translation/x- and y-axes rotations) showed slightly larger varying migration results over time.

In general, the largest amount of migration of the tibial components was within the first three postoperative months after which the migration stabilized. The mean tibial component MTPM increased rapidly after surgery until three months, and levelled out between three and six months. This is in line with recommendations to use the six-month MTPM values as a threshold predictive of future implant loosening.[6]

Between the PE and the HXPLE insert, there were no clinically relevant different MTPM migration patterns observed in the five-year follow-up period. Due to individual knee migrations, the variation (SDs) for the different insert types are slightly different with more patients in the HXLPE insert group who have a larger, but not necessarily continuous, posterior tilting of the tibial component. It might be that the stiffer HXLPE, in comparison to the more flexible/softer PE,[28] directs more stress to the tibial baseplate, leading to a larger posterior tilting in the tibia tray in the first six months.

The Triathlon uncemented PA-coated tibial baseplate with the more flexible PE CS insert also shows a slightly lower Rx (mm) and Rx (°) in initial fixation in comparison to the more rigid HXLPE CS insert,[28] but after six months no further differences were observed.

The predominant translation direction of the tibial component was subsidence (negative y translation). The predominant rotation was x rotation, increasing slope. In a RSA study on cemented TKA with concave inserts, Saari et al[29] found predominantly varus-valgus tilting of the tibial component. This different direction of migration is probably due to differences in implant, insert design, fixation type, implant position, or patient selection. Every type of prosthesis has its own migration pattern;[6] these patterns could also differ with different fixation (cemented/uncemented) insert materials, shape, (PS, CS, CR), and probably insert thickness and stability.

Based on the results for insert wear at 12, 24, and 60 months postoperatively, there was no clinically relevant difference. Most wear was observed at the medial side of the insert. This observation is in line with an earlier study that also showed that most wear occurs on the medial side.[30]

The lateral wear for both insert groups is negative. This ‘negative’ wear is most likely explained by movement of the lateral femoral condyle (during follow-up) to a position that is not the deepest (most minimal) position on the insert. We also calculated a slightly lower wear rate using the 12-month examination as a baseline for wear measurements instead of the 1.5-month examination. This difference might be caused by a possible combination of wear and creep measured during the first postoperative year.[18]

In conclusion, the results of our study show that there is no clinically relevant difference in terms of tibial component migration and wear for up to five years' follow-up between the HXLPE and conventional PE inserts. For the implant used in the study, the theoretical advantages of HXLPE remained theoretical. A longer follow-up is needed to show any clinically relevant difference between the two types of PE.

Take home message

- The theoretical lower wear rate of highly crosslinked polyethylene remains theoretical for the knee prosthesis.

Supplementary material

In depth migration, wear, and clinical outcome data from this study.

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The trial was performed in compliance with the Declaration of Helsinki and Good Clinical Practice guidelines. A favourable opinion of the study protocol (NL32489.098.10. METC No: 10-068) by Medisch Ethische Toetsingscommissie (METC) Zuidwest Holland, the Netherlands, was received on April 28, 2011 and was registered in Clinical Trials (ClinicalTrials. gov ID NCT02525588). Informed consent was obtained from all patients. Reporting of the trial was in accordance with the CONSORT statement.

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