

■ HIP

Vitamin E-diffused liners show less head penetration than cross-linked polyethylene liners in total hip arthroplasty: a ten-year multi-arm randomized trial

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Aims

The primary outcome was investigating differences in wear, as measured by femoral head penetration, between cross-linked vitamin E-diffused polyethylene (vE-PE) and cross-linked polyethylene (XLPE) acetabular component liners and between 32 and 36 mm head sizes at the ten-year follow-up. Secondary outcomes included acetabular component migration and patient-reported outcome measures (PROMs) such as the EuroQol five-dimension questionnaire, 36-Item Short-Form Health Survey, Harris Hip Score, and University of California, Los Angeles Activity Scale (UCLA).

Methods

A single-blinded, multi-arm, 2 × 2 factorial randomized controlled trial was undertaken. Patients were recruited between May 2009 and April 2011. Radiostereometric analyses (RSAs) were performed from baseline to ten years. Of the 220 eligible patients, 116 underwent randomization, and 82 remained at the ten-year follow-up. Eligible patients were randomized into one of four interventions: vE-PE acetabular liner with either 32 or 36 mm femoral head, and XLPE acetabular liner with either 32 or 36 mm femoral head. Parameters were otherwise identical except for acetabular liner material and femoral head size.

Results

A total of 116 patients participated, of whom 77 were male. The median ages of the vE-PE 32 mm and 36 mm groups were 65 (interquartile range (IQR) 57 to 67) and 63 years (IQR 58 to 66), respectively, and of the XLPE 32 mm and 36 mm groups were 64 (IQR 58 to 66) and 61 years (IQR 54 to 66), respectively. Mean total head penetration was significantly lower into vE-PE acetabular liner groups than into XLPE acetabular liner groups (-0.219 mm (95% confidence interval -0.348 to -0.090); $p = 0.001$). There were no differences in wear according to head size, acetabular component migration, or PROMs, except for UCLA. There were no cases of aseptic loosening or failures requiring revision at long-term follow-up.

Conclusion

Significantly lower wear was observed in vE-PE acetabular liners than in XLPE acetabular liners. No difference in wear was observed between different head size or PROMs except for the UCLA at ten years.

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Introduction

Increases in primary total hip arthroplasties (THAs) over the last decade have required researchers to develop new and more effective methods of reducing wear.^{1,2} The most commonly

used acetabular bearing surface is made of cross-linked polyethylene (XLPE). The aim of using XLPE was to reduce the wear and the risk of osteolysis which was seen with previous ultra-high molecular weight polyethylene (UHMWPE)

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components.³ Polyethylene (PE) is exposed to radiation to induce cross-linking between the chains of the polyethylene polymers. Radiation creates free radicals prone to oxidative degradation in PE, which are usually removed by the process of annealing or remelting.⁴ However, annealing or remelting usually reduces resistance to wear, and a compromise between resistance to fatigue crack propagation, wear resistance, and oxidative stability is necessary.⁴

An alternative solution is to use PE that contains an antioxidant, such as vitamin E (α -tocopherol), to chemically remove free radicals. A cross-linked PE vitamin E (vE-PE) bearing surface should reduce free radicals while maintaining wear resistance.⁵ Moreover, this material has shown minimal wear rates in experimental settings, and enhanced resistance to fatigue crack propagation and oxidation.^{6,7} Short-term follow-up studies have either favoured vE-PE or shown similar head penetration to XLPE. However, it is unclear whether these results will be maintained into the longer term.⁸⁻¹²

Evidence on the effect of different head sizes on vE-PE wear remains sparse.^{2,13,14} The nature of randomized controlled trials (RCTs) makes it difficult to measure long-term outcomes. Revision rate and PE wear are associated variables. While PE wear can be estimated using a radiostereometric analysis (RSA), absolute risk of revision cannot be measured with certainty due to the long-term success of THA, high drop out rates with long-term studies and low overall revision rates.^{15,16}

The primary aim of this multi-arm RCT was to investigate acetabular liner component wear related to its material and head size as measured by head penetration. Specifically, the objectives were to examine head penetration between vE-PE and XLPE liners in an uncemented acetabular component, and between 32 mm and 36 mm femoral heads, with ten-year follow-up. We have previously reported the results at five years of follow-up.¹⁷ The secondary aim was to compare acetabular component migration between the different liners and head sizes. Furthermore, we compared patient-reported outcome measures (PROMs) between the different head sizes. We hypothesized that vE-PE liners would show significantly less wear than XLPE liners after ten years.

Methods

Trial design. This study was a patient-blinded, multi-arm, 2×2 factorial RCT. The study was initially designed for 100 patients, with recruitment between May 2009 and April 2011 at two regional hospitals in Denmark (Odense University Hospital and Middelfart Hospital). This RCT is reported according to the Consolidated Standards of Reporting Trials guidelines for multi-arm RCTs.¹⁸

Patients. The patients included were aged between 40 and 70 years, had primary osteoarthritis of the hip, and were able to follow the proposed rehabilitation programme. Patients were excluded if they had dysplasia (centre-edge angle $< 20^\circ$), severe anteversion of the femoral neck, previous radiotherapy, were unable to participate in the rehabilitation programme, had malignancy, femoral cerclage during surgery, or required screw augmentation to secure fixation of the acetabular shell. Patients requiring an acetabular shell with a diameter < 54 mm were also excluded, due to the need for adequate space to accommodate

the 36 mm femoral head size. By implementing these exclusion criteria, we aimed to create a more focused and controlled study population, allowing for a more reliable evaluation of the factors under investigation.

Intervention. This was a 2×2 study and the patients were blinded to which liner and head size they received. A patient was assigned to one of four intervention groups: 1) XLPE acetabular liner (ArComXL; Zimmer Biomet, USA) with 32 mm head (XLPE, 32 mm); 2) XLPE with a 36 mm head (XLPE, 36 mm); 3) vE-PE acetabular liner (E1; Zimmer Biomet) with a 32 mm head (vE-PE, 32 mm); or 4) vE-PE with a 36 mm head (vE-PE, 36 mm).

Patients undergoing THA received plasma-sprayed, porous-coated uncemented acetabular components (Exceed ABT; Zimmer Biomet) and uncemented, porous-coated femoral components (Bi-Metric; Zimmer Biomet) with cobalt-chrome (Co-Cr) femoral heads (Zimmer Biomet). The posterior approach was used in all patients in the lateral position. The proximal femur and periacetabular bone was marked with ten tantalum beads (diameter = 0.8 mm). The patients received antibiotics and tranexamic acid during surgery. Rehabilitation started on the day of the operation, with pain management and discharge completed according to standard procedures.

Outcomes and PROMs. We defined the primary endpoint, wear, as the total proximal head penetration into the liner as measured by RSA after ten years.¹⁷ The secondary endpoints were acetabular component migration and PROMs: the EuroQol five-dimension questionnaire (EQ-5D), which assesses general health and is used with the Danish time trade-off value set,^{19,20} 36-Item Short-Form Health Survey (SF-36), which sums to a mental and physical health summary,²¹ Harris Hip Score (HHS), which ranges from 0 to 100 with higher scores corresponding to better outcomes, and assesses pain, function, deformity, and movement,^{22,23} and University of California, Los Angeles (UCLA) activity scale, which measures physical activity and uses a Likert-esque scale from 0 to 10.²⁴ These PROMs were administered postoperatively and at each follow-up.

Radiostereometric analysis. RSA was performed in accordance with the RSA guidelines at baseline (within seven days after surgery) and at three, 12, 24, 60, 84, and 120 months.¹⁶ X-rays were produced with two synchronized, ceiling-mounted, and mobile roentgen tubes angled at approximately 35° to each other; the exposure was set to 130 kV and 20 mA. The two X-rays were performed simultaneously while the patient was in supine position with the hip situated over a uniplanar calibration cage (Cage 43; RSA Biomedical, Sweden). All patient radiographs were analyzed with model-based RSA (MBRSA; version 4.2, RSACore, Netherlands) using contour detection software.

The RSA precision was calculated from double examinations and was comparable to those previously reported in our previous follow-up study.¹⁷ Examinations with a mean rigid body fitting error > 0.350 mm and a condition number > 135 were rejected according to the RSA guidelines.¹⁶

Adverse events. An investigation using the Danish Regional Patient Registry was performed on each patient at their ten-year follow-up to identify any reported parameters or indications for revision hip arthroplasty.

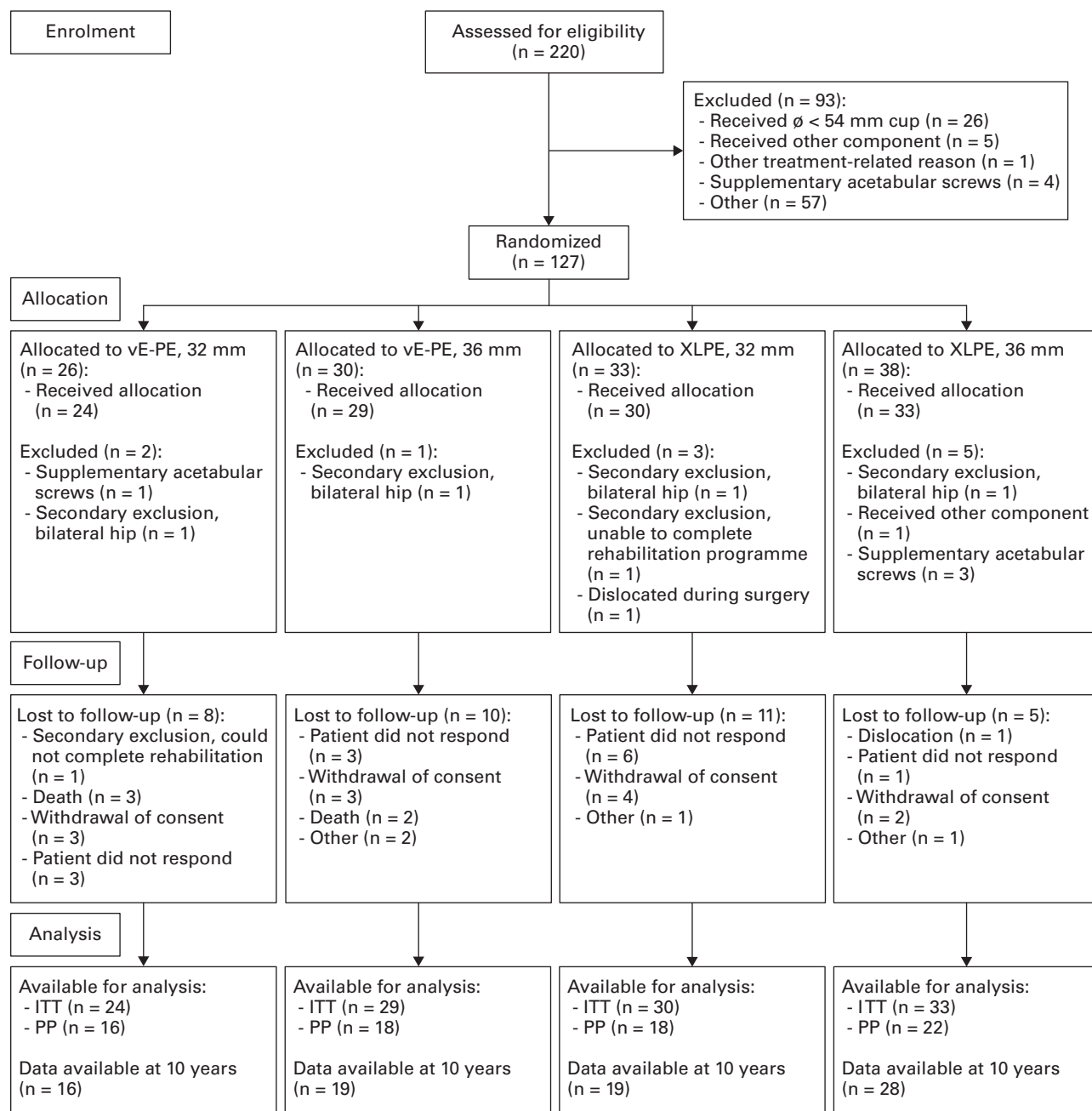


Fig. 1

Flowchart in accordance with Consolidated Standards of Reporting Trials guidelines.¹⁸ The flow diagram shows the number of total hip arthroplasty patients who initially agreed to participate and were assessed for eligibility, then randomized and allocated to one of the four interventions: a vitamin E-diffused polyethylene liner (vE-PE) with a 32 mm head or 36 mm head, or a cross-linked polyethylene liner (XLPE) with a 32 mm head or 36 mm head. Note that the group 'Other' were excluded as a result of no screening data being available for these patients. ITT, intention-to-treat; PP, per protocol. $\varnothing$ = diameter.

Sample size. This parallel 2×2 factorial design trial was designed to investigate whether vE-PE liners showed lower wear than XLPE liners. The risk of type 1 error was set to 5% with the power of 80%. Wear was expected to decrease from 0.05 mm/year with XLPE to 0.0005 mm/year with vE-PE, and the minimal clinically relevant difference was set at 0.05 mm/year. Based on these parameters, we required 15 hips for each

group. A total of 25 patients were included per arm, to account for dropouts and secondary exclusions.¹⁷

Randomization. Lots were randomly computer-generated, and placed in sealed envelopes in two blocks: one with 100 lots of 25 per group, and another with 28 lots of seven per group. This was necessary due to over-recruitment at the participating hospitals. The study was blinded to patients, and the

Table I. Baseline demographics and clinical characteristics of patients who underwent total hip arthroplasty and answered patient-reported outcome measures in two regional hospitals from 2009 to 2011.

Characteristic	vE-PE, 32 mm	vE-PE, 36 mm	XLPE, 32 mm	XLPE, 36 mm
Total, n	24	29	30	33
Male sex, n (%)	19 (79)	20 (69)	19 (63)	19 (58)
Median age, yrs (IQR)	65 (57 to 67)	63 (56 to 66)	64 (58 to 66)	61 (54 to 66)
Mean BMI, kg/m ² (range)	28 (22 to 40)	29 (22 to 36)	28 (20 to 41)	27 (21 to 38)
ASA grade, n (%)				
I	8 (31)	10 (33)	8 (27)	13 (41)
II	14 (54)	14 (47)	15 (50)	8 (25)
III	1 (4)	1 (3)	1 (3)	1 (3)
Data not available	3 (12)	5 (17)	6 (20)	11 (31)
Median blood loss, ml (IQR)	450 (225 to 550)	300 (200 to 600)	350 (300 to 400)	350 (225 to 400)
Median duration of anaesthesia, mins (IQR)	90 (75 to 105)	80 (66 to 95)	75 (65 to 84)	83 (71 to 99)
Median days hospitalized (IQR)	3 (3 to 3)	3 (2 to 3)	3 (2 to 4)	3 (3 to 5)
Mean Harris Hip Score (range)	47 (29 to 80)	49 (18 to 81)	50 (13 to 74)	44 (21 to 74)
Median UCLA activity scale (IQR)	6 (4 to 7)	6 (4 to 8)	6 (5 to 7)	5 (4 to 7)
Median EQ-5D index (IQR)	0.72 (0.66 to 0.72)	0.66 (0.59 to 0.72)	0.72 (0.57 to 0.72)	0.72 (0.59 to 0.72)
Median EQ-5D VAS (IQR)	65 (46 to 83)	60 (40 to 70)	70 (50 to 79)	75 (60 to 90)
Mean SF-36 PCS (range)	40 (29 to 52)	37 (24 to 54)	37 (21 to 48)	39 (20 to 56)
Mean SF-36 MCS (range)	55 (37 to 65)	52 (29 to 66)	51 (29 to 64)	55 (35 to 67)

Permission to reproduce this table was granted by author K. Kjærgaard.¹⁷

ASA, American Society of Anesthesiologists; EQ-5D, EuroQoL five dimension three-level questionnaire; IQR, interquartile range; MCS, mental component summary; PCS, physical component summary; SF-36, 36-Item Short-Form Health Survey; UCLA, University of California, Los Angeles; VAS, visual analogue scale; vE-PE, vitamin E-diffused crosslinked polyethylene liners; XLPE, cross-linked polyethylene liners.

envelopes were opened immediately before the acetabular liners were inserted.

Registration and ethics. Oral and written informed consent was obtained from all patients, who could withdraw their consent at any time. This trial was approved by the Regional Committees on Health Research Ethics for Southern Denmark (S-20080151) and the Danish Data Protection Agency (14/35949 and 18/31287), and complied with the Declaration of Helsinki.²⁵ This trial was registered at ClinicalTrials.gov (NCT02196792).

Statistical analysis. The patients were divided into intention-to-treat (ITT) and per-protocol (PP) groups. PP was defined as patients in the ITT group who were present at all RSA follow-ups. The mean and standard deviation (SD) or median and interquartile ranges (IQRs) were used as descriptive statistics. The statistical analysis followed an analysis protocol previously reported on ClinicalTrials.gov (NCT02196792). Mixed-effects analyses were performed using the restricted maximum likelihood method.²⁶ We classified acetabular component liner material, head size, and time as fixed effects and patients as random effects. In addition, we included interactions between material and head size with time. A *p*-value < 0.05 was considered statistically significant. PROM analyses were adjusted to account for baseline values. We tested the mixed-effect estimates for significance using a Wald test. Independent statisticians managed all statistics using Stata v. 17 (StataCorp, USA).

Results

Recruitment. A total of 220 patients were considered eligible for this study, of whom 93 were excluded for the following reasons (Figure 1): four required supplementary acetabular screws, 26 received an acetabular component < 54 mm, five received other manufacturers' components, one experienced surgical

complications, and 57 were excluded due to other reasons. Overall, 11 of the 127 patients who underwent randomization did not receive their allocated intervention. They were excluded for the following reasons: five underwent screening failure, one received other components, four required acetabular screws, and one had a dislocation during surgery and received other components.

In total, 116 patients underwent both the intended intervention and randomization. At the ten-year timepoint, 34 were lost to follow-up, and 82 remained enrolled. Their baseline data are presented in Table I.

Head penetration. We found significantly lower mean total head penetration into vE-PE than into XLPE (-0.219 mm (95% confidence interval (CI) -0.348 to -0.090); *p* = 0.001) at ten-year follow-up (Figure 2, Table II).

However, penetration did not differ significantly between 32 mm and 36 mm head sizes: -0.065 mm (95% CI -0.195 to 0.066; *p* = 0.332; Figure 2 and Table II). The PP analysis showed similar results (Supplementary Table i).

Acetabular component migration. Acetabular component migration did not differ significantly between vE-PE and XLPE groups. The difference was -0.209 mm (95% CI -0.441 to 0.023; *p* = 0.078) (Table II). The head size of 32 mm and 36 mm femoral heads did not influence component migration. The difference was -0.075 mm (95% CI -0.307 to 0.156; *p* = 0.523) (Table II). However, acetabular component migration up to the final follow-up differed significantly from baseline measurements within each liner and head size group. However, migration appeared to stabilize after 12 months (Supplementary Figure a).

PROMs. PROMs did not differ significantly between 32 and 36 mm head size groups, except for the UCLA activity scale, which was 1.2 points higher in the 36 mm group than in the

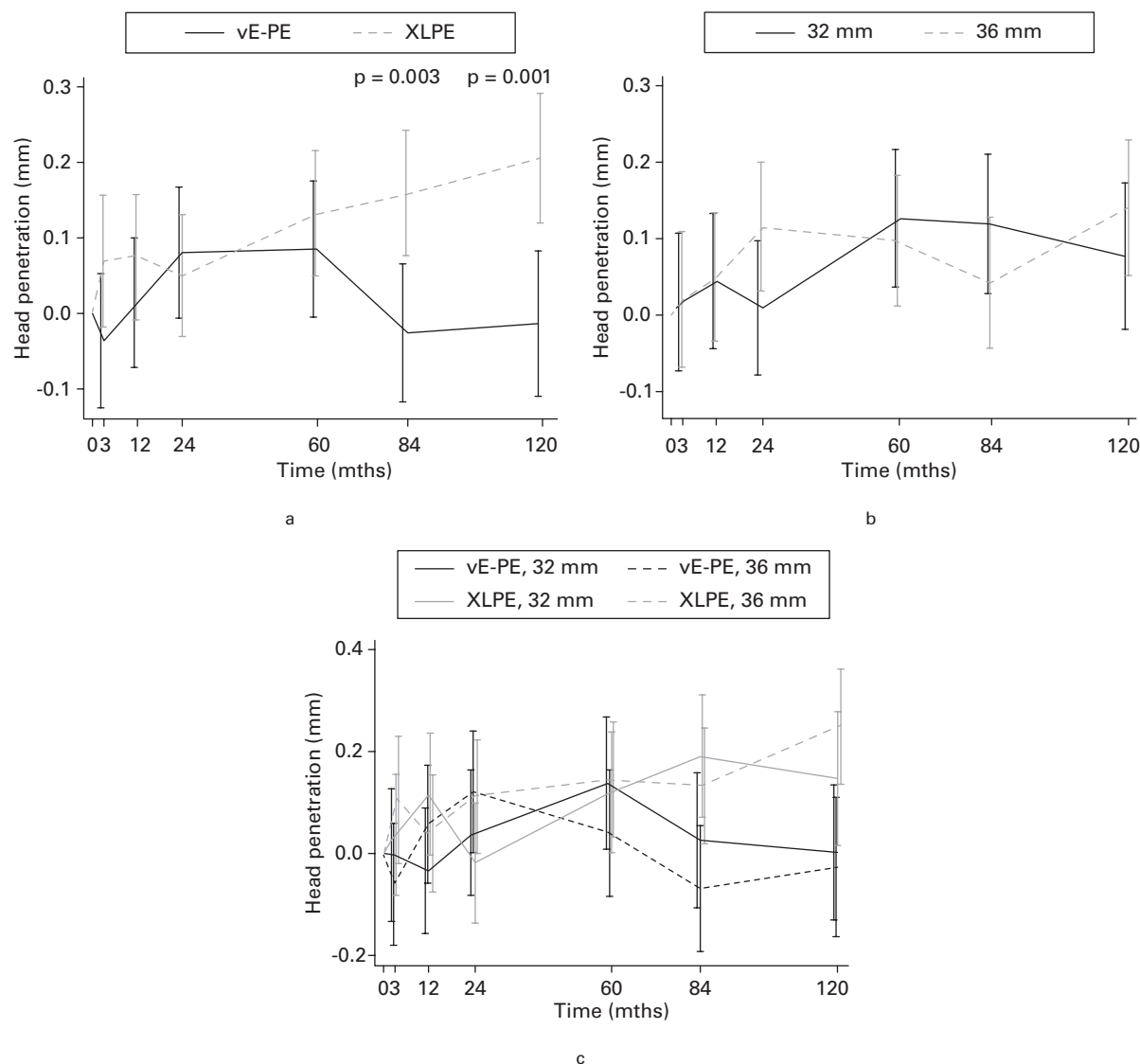


Fig. 2

Liner wear outcomes shown as mean femoral head penetration with 95% confidence intervals for the intention-to-treat population. Patients received a total hip arthroplasty with either vitamin E-diffused cross-linked polyethylene (vE-PE) liner or cross-linked PE (XLPE) liner and 36 mm head size or 32 mm head size. a) Wear between vE-PE and XLPE; $p = 0.003$ refers to seven-year data, while $p = 0.001$ refers to ten-year data. b) Wear between 32 mm and 36 mm heads. c) Wear for individual intervention groups.

32 mm group (-1.2 (95% CI -2.1 to -0.2); $p = 0.017$) (Table II). Nevertheless, individual within-head size group PROM improvements were all significantly better than baseline at the ten-year follow-up, except for the UCLA activity scale in the 32 mm head size group.

Adverse events. One patient in the 36 mm XLPE group underwent revision two days after surgery due to dislocation and was excluded from the trial.

Discussion

To our knowledge, this study has the longest follow-up period (ten years) comparing the wear outcomes of vE-PE and XLPE acetabular component liners. We found that total head penetration was significantly lower for vE-PE liners compared to

XLPE liners at the ten-year follow-up ($p = 0.001$). Our results support our hypothesis that vE-PE liners would show significantly lower wear than XLPE liners. These findings show that vitamin E prevents the reduced wear resistance seen in XLPE liners due to processes such as annealing or remelting.⁴ Furthermore, we did not observe a significant influence of head size on wear. This finding aligns with previous studies that demonstrated that total head penetration and wear rates are independent from femoral head size.^{27–29}

No patients experienced aseptic loosening, and only one underwent revision due to dislocation two days after surgery. Given that the THA lifespan is usually 20 years,^{2,14} the sample size was small, and the wear rate was low, other revisions would have been unlikely. Moreover, wear in this study was below the

Table II. Intention-to-treat outcomes of patients who underwent total hip arthroplasty illustrated as within-group changes from baseline to ten years, and between-group difference at ten years, according to the predetermined analysis plan.

Outcome	vE-PE (95% CI)	XLPE (95% CI)	vE-PE vs XLPE (95% CI)	p-value
Comparison between vE-PE and XLPE				
Total head penetration (mm)	-0.012 (-0.114 to 0.089)	0.207 (0.087 to 0.326)	-0.219 (-0.348 to -0.090)	0.001
Head penetration rate, mm/yr				
0 to 3 mths	0.141 (-0.236 to 0.517)	-0.277 (-0.643 to 0.090)	0.417 (-0.108 to 0.943)	0.120
3 mths to 1 yr	-0.066 (-0.194 to 0.062)	-0.008 (-0.134 to 0.117)	-0.058 (-0.237 to 0.121)	0.527
1 to 2 yrs	-0.067 (-0.161 to 0.027)	0.025 (-0.065 to 0.115)	-0.091 (-0.222 to 0.039)	0.527
2 to 5 yrs	-0.002 (-0.034 to 0.031)	-0.027 (-0.057 to 0.002)	0.026 (-0.018 to 0.070)	0.250
5 to 7 yrs	0.056 (0.005 to 0.107)	-0.013 (-0.058 to 0.031)	0.069 (0.001 to 0.137)	0.046
7 to 10 yrs	-0.004 (-0.040 to 0.031)	-0.016 (-0.047 to 0.016)	0.011 (-0.036 to 0.059)	0.644
Secondary outcomes				
Cup migration, mm	0.155 (-0.020 to 0.329)	0.363 (0.159 to 0.568)	-0.209 (-0.441 to 0.023)	0.078
Comparison between 32 and 36 mm				
	32 mm (95% CI)	36 mm (95% CI)	32 mm vs 36 mm (95% CI)	p-value
Total head penetration, mm	0.076 (-0.025 to 0.176)	0.140 (0.018 to 0.263)	-0.065 (-0.195 to 0.066)	0.332
Head penetration rate, mm/yr				
0 to 3 mths	-0.067 (-0.446 to 0.312)	-0.078 (-0.450 to 0.294)	0.011 (-0.520 to 0.542)	0.968
3 mths to 1 yr	-0.035 (-0.165 to 0.095)	-0.039 (-0.165 to 0.087)	0.004 (-0.177 to 0.186)	0.962
1 to 2 yrs	0.034 (-0.062 to 0.130)	-0.065 (-0.156 to 0.025)	0.050 (-0.016 to 0.116)	0.962
2 to 5 yrs	-0.039 (-0.071 to -0.007)	0.006 (-0.025 to 0.037)	-0.045 (-0.089 to -0.000)	0.048
5 to 7 yrs	0.004 (-0.046 to 0.054)	0.027 (-0.019 to 0.074)	-0.024 (-0.092 to 0.045)	0.498
7 to 10 yrs	0.014 (-0.021 to 0.049)	-0.033 (-0.065 to -0.000)	0.047 (-0.001 to 0.095)	0.053
Secondary outcomes				
Cup migration	0.235 (0.061 to 0.408)	0.310 (0.104 to 0.516)	-0.075 (-0.307 to 0.156)	0.523
Harris Hip Score	31 (24 to 37)	36 (29 to 44)	-6 (-14 to 2)	0.139
UCLA activity scale	0.6 (-0.1 to 1.4)	1.8 (0.9 to 2.7)	-1.2 (-2.1 to -0.2)	0.017
EQ-5D index	0.17 (0.10 to 0.23)	0.16 (0.09 to 0.22)	0.01 (-0.06 to 0.08)	0.806
EQ-5D VAS	12 (4 to 19)	10 (2 to 18)	2 (-7 to 10)	0.715
SF-36 PCS	10 (7 to 12)	10 (6 to 14)	-1 (-4 to 3)	0.777
SF-36 MCS	1 (-2 to 4)	3 (-1 to 6)	-1 (-5 to 2)	0.439

CI, confidence interval; EQ-5D, EuroQol five-dimension questionnaire; IQR, interquartile range; MCS, mental component summary; PCS, physical component summary; SF-36, 36-Item Short-Form Health Survey; UCLA, University of California, Los Angeles; VAS, visual analogue scale; vE-PE, vitamin E-diffused highly cross-linked ultra-high-molecular weight polyethylene liner; XLPE, medium cross-linked polyethylene liner.

reported osteolysis threshold of 0.1 mm/year,¹⁵ except for the zero- to three-month results. This exception could be attributed to the early creep phase that is present during the first months after surgery.³⁰

Numerous studies have examined the effects of vitamin E on PE wear. Six of the most recent studies, with the same RSA technique as this study, compared wear vE-PE and XLPE acetabular component liners, but came to different conclusions.^{8–12,17} Two reported no difference in wear at five and seven years, while four reported lower wear in vE-PE liners at two to five years. These reports show that there is no established consensus regarding whether vE-PE liners show better wear resistance than XLPE liners. These reported differences could be explained by sources of systematic error such as biological variability, ‘noise’ within the software, the in-hospital location, and the correct placement of patients before performing RSA.

Studies have shown that acetabular component sizes ≥ 58 mm and inclination angles $\geq 45^\circ$ are correlated with PE wear.^{31,32} No similar studies to ours have investigated inclination angle or the influence of these parameters, and only two reported the acetabular component size used.^{10,17} One study investigated highly XLPE with vitamin E and UHMWPE components, and found no significant difference in PE wear with increasing acetabular component inclination angle.³³ Therefore, PE wear relative to

acetabular component inclination angle might explain differences in results over the same period.

This study confirmed our previous report’s conclusion, at five-year review, that a longer follow-up was needed to evaluate actual differences in wear.¹⁷ A significant difference in wear between vE-PE and XLPE liners was found at seven and ten years (Figure 2a). There was a slight decrease in wear from the fifth year in the vE-PE liner group at both seven and ten years. This decrease in wear represents the ITT results and potentially reflects the loss of follow-up subjects at ten years, of whom 75% were in the vE-PE group. Another possible explanation is the challenge of measuring penetration of the acetabular liner material that displays wear close to zero. However, the wear in the PP population (Supplementary Figure b) shows a more flat, horizontal, linear trend with less deviation. This pattern supports the assumption that dropouts explain the negative wear rate in vE-PE between seven and ten years.

Migration analysis showed no significant difference in wear between acetabular liner materials and head sizes. These findings confirm previous data showing that implants which are stable for two years do not progress to clinical loosening.³⁴

All groups showed PROM improvement from baseline with no significant differences between head sizes, except for the UCLA activity scale. While a minimal clinically important

difference in the UCLA activity scale has not yet been established for THA, a one-level increase is expected to provide a meaningful clinical difference.³⁵ None of the other PROMs were significant, and we do not think the UCLA activity scale has any clinical significance, as the study was not designed to adjust for multiple comparisons, and because the UCLA activity scale was not the primary outcome of this trial.³⁵

The only differences in the intervention groups were head size and acetabular liner material; all other parameters were identical between the groups. We believe that our patients were representative of most THA patients, considering that 80% of patients undergoing THA is for primary osteoarthritis.² The primary outcome was assessed using a standardized protocol.¹⁶ We performed ITT and PP analyses to strengthen our results by reducing potential biases due to differential dropouts. Both analyses were statistically significant and favoured vE-PE over XLPE. Moreover, the sample size calculation was consistent with similar RCTs.^{9,10}

While we included a randomization process and used the gold-standard RSA,³⁶ the most sensitive and accurate measurement technique, this study still had limitations. The acetabular liners did not contain implanted tantalum beads. Therefore, only the model-based RSA method was used, which might have compromised our outcome accuracy. However, studies have shown that the marker method is clinically inconsequential and that model-based method's precision is sufficient.³⁷ This study's single-blinded, randomized nature permitted the surgeons to contribute a conscious or unconscious observer bias while performing the surgery with either acetabular liner type. In addition, it is important to note that all surgeries in this study were performed by three highly experienced orthopaedic surgeons (OO, CH, SO). Further, this study's insufficient and decentralized trial organization impacted patient recruitment and randomization. While this trial was designed for 100 patients, 127 were randomized, and additional randomization envelopes had to be generated. These measures were implemented upon the realization by the involved parties that an excess number of patients had provided consent to participate. This unintentional increase demonstrated a lack of administrative coordination between its different hospital sites. Finally, 34 patients were lost to follow-up after ten years, which is expected in any long-term follow-up study. We expected the loss to follow-up to occur at random, as no group of patients suffered from any clinical complications or side effects associated with a requirement for revision surgery.

In summary, this ten-year RCT found a significant difference in wear between vE-PE and XLPE acetabular liner components that favoured vE-PE, but no significant differences in wear between 32 mm and 36 mm head sizes. All PROMs did not differ significantly between head sizes, except for the UCLA activity scale, and all PROMs reported improvements from the baseline. While we found that vE-PE liners provided superior performance with reduced head penetration compared to XLPE liners, longer follow-up is still needed to determine any significant clinical differences that may still arise.



Take home message

- Head penetration is superior in vitamin E-diffused crosslinked polyethylene (vE-PE) compared to crosslinked polyethylene liners.
- Safe use of vE-PE liner at ten-year follow-up potentially reduces the need for revision surgery in the long term.

Supplementary material



Graphs and estimates from the per-protocol analysis.

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