■ HIP

Low wear with vitamin E-infused highly cross-linked polyethylene

14 YEARS' FOLLOW-UP OF A RANDOMIZED RADIOSTEREOMETRIC ANALYSIS STUDY

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Aims

Highly cross-linked polyethylene (HXLPE) infused with vitamin E was introduced at the beginning of the 21st century. Vitamin E removes free radicals arising during gamma irradiation in order to cross-link the polyethylene. Removing free radicals was hypothesized to preserve mechanical properties and wear behaviour of the polyethylene in vivo. Excellent polyethylene wear behaviour of other HXLPEs has encouraged surgeons to use larger heads in total hip arthroplasty (THA) to address prosthesis dislocation. It is still unclear whether polyethylene wear remains low in the long term when using larger femoral heads. The aim of this study was to evaluate long-term polyethylene wear in uncemented THA with vitamin E-infused HXLPE liners with 32 or 36 mm ceramic femoral heads.

Methods

A total of 50 hips allocated to uncemented THA were included in this prospective randomized controlled trial from January 2009 to February 2010. They were randomized to either 32 or 36 mm Biolox Delta ceramic heads. The primary outcome was polyethylene wear measured with markerless radiostereometric analysis. The secondary outcome was patient-reported outcome measures measured by Harris Hip Score, Oxford Hip Score, and University of California, Los Angeles activity scale.

Results

At final follow-up (14 years), 32 hips were available for analysis (32 mm, n = 17; 36 mm, n = 15), and 18 hips had been lost to follow-up or were excluded: two hips due to infection, and one hip due to periprosthetic fracture. These three revised hips were excluded due to removal and/or change of prosthesis components. Mean polyethylene wear in the proximal direction was 0.10 mm (95% CI 0.05 to 0.16) and 0.01 mm (95% CI -0.06 to 0.07) for 32 and 36 mm femoral heads, respectively (p = 0.022). After the 'bedding-in' period wear was 0.04 mm (95% CI -0.02 to 0.11) and 0.02 mm (95% CI -0.06 to 0.10) for 32 and 36 mm, respectively (p = 0.628).

Conclusion

Polyethylene wear was extremely low for vitamin E-infused HXLPE with 36 mm ceramic femoral heads at 14 years of follow-up. There was no difference in wear between 32 and 36 mm heads after the 'bedding-in' period. The clinical outcome was excellent. Biolox Delta ceramic heads on vitamin E-infused HXLPE seem to be a safe option for 36 mm heads.

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Introduction

Since the beginning of the 2000s, we have seen the arrival of vitamin E-infused highly cross-linked polyethylene (VEPE).[1-3] The potential benefit of VEPE has been to further improve highly cross-linked polyethylene (HXLPE) wear properties in total hip arthroplasty (THA).[4-6] During the gamma irradiation process, free radicals are formed while cross-linking of the polyethylene occurs.[7] Vitamin E acts as a free radical scavenger and thereby reduces oxidative stress that may occur in the polyethylene. Removing free radicals will potentially improve the mechanical properties of the polyethylene.[8,9]

Larger head size increases the stability of a hip prosthesis and therefore reduces the risk of dislocation.[10] However, earlier experiences with conventional polyethylene and larger heads resulted in greater polyethylene wear, leading to higher revision rates.[11] Volumetric polyethylene wear has been shown to be less for HXLPE compared with conventional polyethylene.[12,13] Therefore, as the HXLPE showed improved wear resistance, surgeons have become more favourable towards using larger head sizes.

In terms of common femoral head bearing sizes, progressively fewer 28 mm heads have been used in Europe since the mid-2000s, with increasing use of 32 and 36 mm heads.[14,15] Others have studied polyethylene wear with large metal femoral heads (≥ 36 mm) in combinations with HXLPE/VEPE showing low wear rates, but only with mid-term follow-up (5 to 12.8 years).[16-18] Currently, there are no long-term results from randomized controlled trials (RCTs) published using uncemented THA with a ceramic-on-VEPE bearing combination and with a large femoral head size (36 mm).

The objective of this study was to evaluate long-term polyethylene wear in THA with 32 or 36 mm ceramic heads articulating with a VEPE liner. We hypothesized that there was no difference in polyethylene wear between patients receiving 32 and 36 mm femoral heads.

Previously, two- and six-year results of this study have been published in 2015 and 2019, respectively,[19,20] and there was no difference in polyethylene wear between the groups with 32 and 36 mm ceramic femoral heads. In this study, we present the long-term results at 14 years of follow-up.

Methods

This study is a prospective RCT with nearly 14 years of follow-up. VEPE liners (E-poly; Zimmer Biomet, USA) in uncemented Exceed ABT (Zimmer Biomet) shells with 32 or 36 mm Biolox Delta ceramic heads (manufactured by Ceramtec for DePuy, Germany) were used. All patients received an uncemented Corail stem (DePuy). The E-poly liner was infused with vitamin E after the gamma irradiation process (irradiation dose 100 kGy at room temperature) and then sterilized by 30 kGy.[6]

Overall, 50 hips (49 patients aged 50 to 65 years, 35 females) were operated on from January 2009 until February 2010 at Lovisenberg Diaconal Hospital, a large-volume hospital. Block randomization was performed by ten-case increments. After reaming of the acetabulum, the scrub nurse selected one of ten envelopes randomizing the patient to either a 32 or 36 mm femoral head. The inclusion criterion was primary osteoarthritis without structural abnormality. To detect a polyethylene wear difference of 0.1 mm (SD 0.1) and to achieve a power of 80% with $\alpha = 0.05$, we calculated that 17 patients had to be included in each group. To compensate for possible drop-outs, we included 50 patients. We evaluated clinical outcome with Harris Hip Score (HHS),[21] Oxford Hip Score (OHS),[22] and University of California, Los Angeles activity scale (UCLA).[23] For further details regarding the study methods, please see our previously published earlier article.[19] The primary outcome was polyethylene wear measured with markerless radiostereometric analysis (RSA). The secondary outcome was patient-reported outcome measures (PROMs) measured by the HHS, OHS, and UCLA activity scale.

At final follow-up, 32 patients (32 hips) were available for RSA (Figure 1). Overall, 17 patients had 32 mm heads, and 15 patients had 36 mm heads. Patients were followed with HHS and OHS, in addition to the UCLA activity scale to evaluate clinical outcome.[24,25] Mean age at follow-up was 74 years (66 to 79) (Table I).

Radiostereometric analysis. Markerless RSA was conducted postoperatively, three months, one year, two years, six years, and at 14 years of follow-up. A combination of one mobile and one fixed X-ray source was used with a uniplanar calibration cage until six years of follow-up (RSA Biomedical, Sweden).[19,20] At 14 years of follow-up, we used two fixed X-ray sources using the same RSA cage (cage number 43). PST and SMR performed the RSA. Precision has previously been calculated for wear to be 0.17 mm in the proximal direction, and was based on double examinations postoperatively and at the two-year follow-up.[19,20]

Radiology. We obtained anteroposterior (AP) radiographs and lateral views of the femur postoperatively and at three months, two years, six years, and 14 years. To measure osteolysis and radiolucency around the implants at 14 years of follow-up, two authors (PST, EL) used Mdesk v.4.1.5 (UmRSA Biomedical, Sweden) to review the radiographs. A third author (SMR) was consulted when necessary to reach a consensus.

We recorded radiolucent lines (RLLs) around the cup by measuring the percentage of the cup perimeter which had RLLs, and noted which of the three DeLee-Charnley zones these were located in and the extent of interface involvement, ranging from 0% (A), < 50% (B), 50% to 99% (C), or 100% (D).[26,27] Additionally, osteolysis was measured digitally and, if present, the total number of mm^2 involved was recorded and the DeLee-Charnley zone affected was noted.

RLLs around the stem were recorded in Gruen zones (zones 1 to 7 on AP view, zones 8 to 14 on lateral view).[28,29] The percentage of the total stem perimeter that was affected was noted, along with the corresponding Gruen zone for both the AP and lateral views. Whether osteolysis around the stem was present was also noted.

In addition, we recorded whether the pedestal sign was present or not,[30] and graded the presence of heterotopic bone using the Brooker classification (graded 0 to 4).[31,32]

The study was approved by the Regional Ethics Committee South-Eastern Norway Regional Health Authority and was conducted in compliance with the Declaration of Helsinki.[33] All patients provided written informed consent prior to study participation. The study has been registered at ClinicalTrials.gov (identifier NCT00804388).

Statistical analysis. Data analyses were done using SPSS Statistics v. 29.0 (IBM, USA). Polyethylene wear measured with RSA was presented in mm (mean with 95% CI), in the proximal direction (y-axis) and in total 3D. Difference in wear was tested using the non-parametric independent samples Mann-Whitney U test. The statistical significance level was defined as a p-value < 0.05. Patient characteristics were presented in years (mean (SD)) for follow-up time and age at final follow-up. To present PROM data, means (SD) were calculated. PROMs data were explored with histograms and did not follow

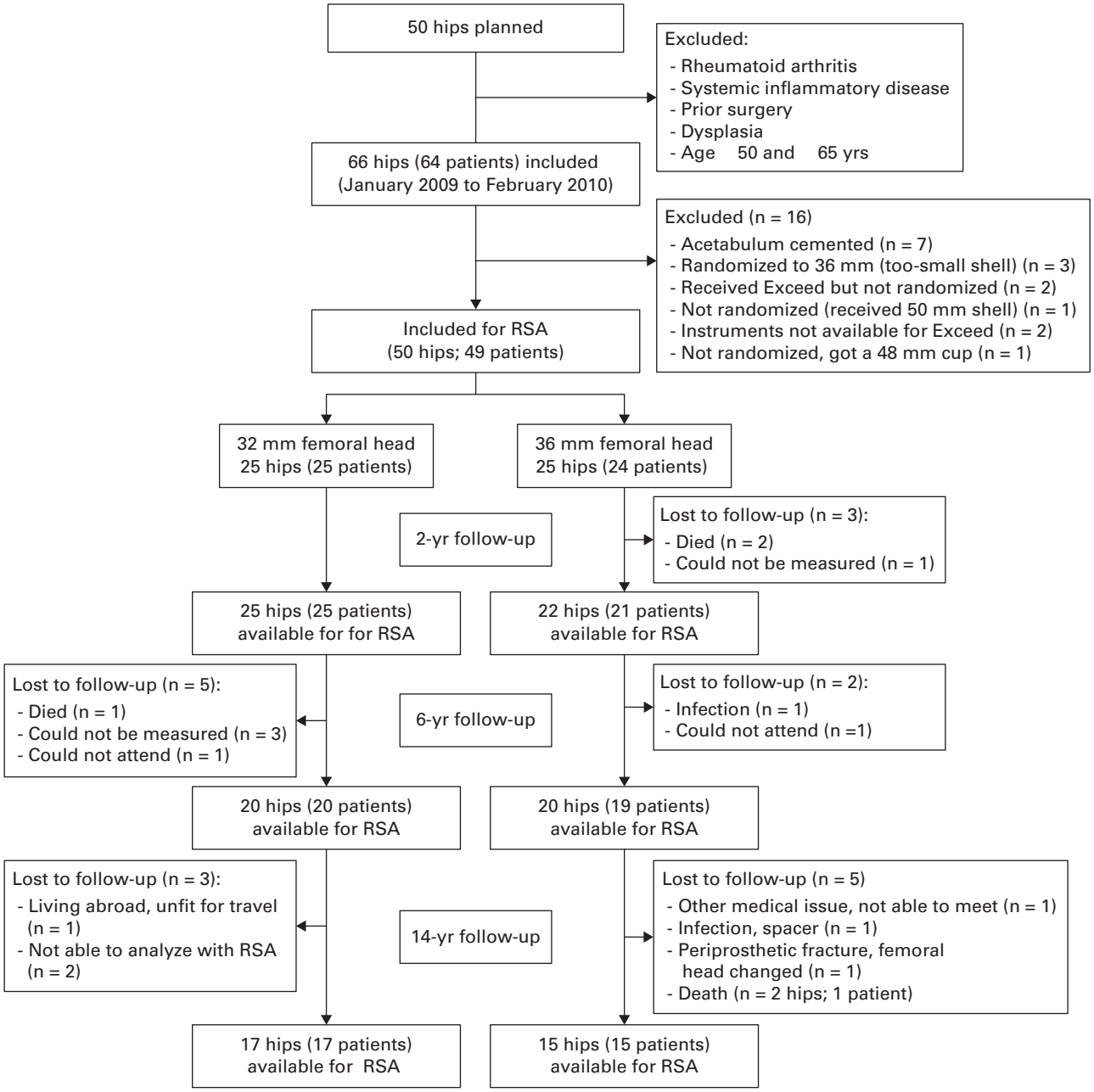

Fig. 1

Flowchart in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. In total, 50 hips (32 mm heads n = 25, 36 mm heads n = 25) were included from January 2009 until February 2010. Finally, 17 hips with 32 mm heads and 15 hips with 36 mm heads were available for radiostereometric analysis (RSA) at the 14-year follow-up.

a normal distribution. The Mann-Whitney U test was therefore used to test group differences.

Results

Radiostereometric analysis. After a mean 13.7 years of follow-up, the mean proximal polyethylene wear (y-axis) was 0.10 mm (95% CI 0.05 to 0.16) and 0.01 mm (95% CI -0.06 to 0.07) for 32 and 36 mm heads, respectively (p = 0.022) (Table II and Figure 2). When removing the 'bedding-in' period (one year) wear was 0.04 mm (95% CI -0.02 to 0.11) and 0.02 mm (95% CI -0.06 to 0.10), for 32 and 36 mm, respectively (p = 0.628). The total 3D mean polyethylene wear was 0.22 mm (CI 0.15 to 0.29) and 0.21 mm (95% CI 0.14 to 0.28), respectively in the 32 and 36 mm groups (Table II and Figure 3). Without the 'bedding-in' period the mean total 3D wear was 0.05 mm (95% CI -0.03 to 0.12) and 0.07 mm (95% CI -0.01 to 0.14; p

Table I. Patient demographics and patient-reported outcome measures at final follow-up.

Variable	Total	32 mm head	36 mm head	p-value
Patients, n	32	17	15	N/A
Mean follow-up, yrs (SD)	13.7 (0.25)	13.7 (0.26)	13.7(0.25)	N/A
Mean age at final follow-up, yrs (SD)	74 (3.5)	75 (2.7)	74 (4.2)	N/A
Sex, n				
Female	23	14	9	
Male	9	3	6	
Mean Harris Hip Score (SD)	93.3 (9.5)	92.1 (11.1)	94.8 (7.4)	0.478
Mean Oxford Hip Score (SD)	16.6 (7.9)	17.9 (9.0)	15.2 (6.6)	0.132
Mean UCLA activity scale (SD)	6.6 (1.8)	6.2 (1.7)	7.0 (2.0)	0.142

N/A, not applicable; UCLA, University of California, Los Angeles.

Table II. Polyethylene wear from baseline/postoperatively to 14-year follow-up.

Variable	32 mm head	36 mm head	Mean difference	p-value
Total, n	17	15		
Baseline to 14-year follow-up				
Mean proximal wear (y-axis), mm (95% CI)	0.10 (0.05 to 0.16)	0.01 (-0.06 to 0.07)	0.09	0.022
Mean total 3D wear, mm (95% CI)	0.22 (0.15 to 0.29)	0.21 (0.14 to 0.28)	0.01	0.682
One-year to 14-year follow-up*				
Mean proximal wear (y-axis), mm (95% CI)	0.04 (-0.02 to 0.11)	0.02 (-0.06 to 0.10)	0.02	0.628
Mean total 3D wear, mm (95% CI)	0.05 (-0.03 to 0.12)	0.07 (-0.01 to 0.14)	0.02	0.502

*Excluding the 'bedding-in' period.

= 0.502). There was no significant difference between the two groups regarding wear in the proximal or total 3D direction, when removing the 'bedding-in' period.

Radiology. RLLs around the cup were noted in three out of 32 patients. In these, the interface around the cup was affected 4% (DeLee-Charnley zone I), 5% (DeLee-Charnley zone I), and 21% (DeLee-Charnley zone I and III). Osteolysis around the cup was noted in two patients with a measured area of 16 mm^2 and 94 mm^2 both in DeLee-Charnley zone I.

There were RLLs in relation to the stem in ten out of 32 patients in the AP view (eight out of 32 patients in lateral view, all eight also present in AP view). Of the patients with RLLs, four had involvement > 10% of the total stem interface (21% in Gruen zone 1 and 7, 27% in Gruen zone 1 and 7, 28% in Gruen zone 1 and 7, and 35% in Gruen zones 1, 2, 6, and 7 recorded on AP view). There were no signs of osteolysis around the stem in any of the patients in the study, and no stems had signs of loosening. The pedestal sign was present in 21 out of 32 patients. Heterotopic bone ossification was recorded in four patients (Brooker grades 1, 1, 3, and 3).

Clinical outcome. The mean HHS was 93 (SD 9.5), OHS was 17 (SD 7.9), and the UCLA activity scale was 6.6 (SD 1.8) (Table I). There was no statistically significant difference between 32 and 36 mm heads in any of the clinical outcome scores.

Discussion

We found extremely low polyethylene wear at 14 years with vitamin E-infused highly cross-linked polyethylene in combination with ceramic femoral heads (Figures 2 and 3). No significant difference was observed between 32 and 36 mm heads when excluding the 'bedding-in' period. Radiologically, there was no clinically relevant osteolysis around the cup or stem. We observed only minimal signs of radiolucency around prosthesis components in a limited number of the 32 patients included in the study at 14 years' follow-up. Clinical outcome scores were generally good to excellent among the entire patient cohort.

We defined the 'bedding-in' period as one year postoperatively. Our earlier analysis has, however, indicated that the majority of the bedding-in period seems to occur during the first three months postoperatively.[19,20] Not excluding the 'bedding-in' period, 36 mm heads showed lower polyethylene wear in the proximal direction at the final follow-up than the 32 mm heads. One could speculate that the larger diameter heads distribute the stress over a larger area causing a lower degree of creep for the 36 mm femoral heads. A study from 2022 evaluating large ceramic heads (≥ 40 mm) in combination with VEPE liners showed initial femoral head penetration during a one-year 'bedding-in' period, but thereafter, femoral head penetration did not increase significantly.[34]

The wear in this study was extremely low. We found in our study that there was mean proximal polyethylene wear of 0.04 mm and 0.02 mm for 32 and 36 mm, respectively (excluding the 'bedding-in' period) at the final 14-year follow-up. In line with these findings, several other studies with mid-term results show low polyethylene wear with VEPE liner combinations.[35–40] A recent prospective study with a ten-year follow-up from 2024 has shown significantly lower polyethylene wear when using VEPE liners compared with highly cross-linked liners.[41] Moreover, RCTs including cemented VEPE cups have shown lower polyethylene wear compared with moderately cross-linked polyethylene.[42–44]

Spece et al[45] concluded, in a systematic review from 2023 with 41 studies with a maximum of seven years of follow-up, that VEPE exhibited lower or equivalent wear rates compared with polyethylene without vitamin E (both HXLPE and conventional ultra-high molecular weight polyethylene).

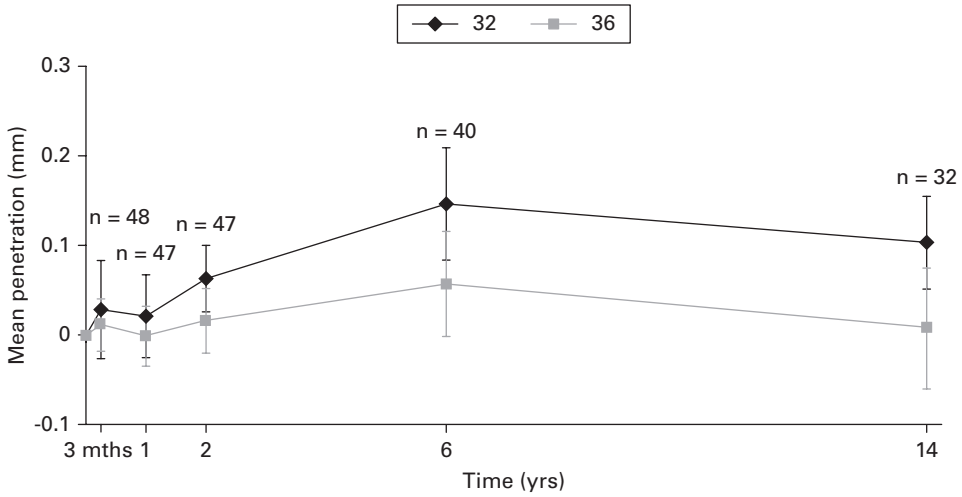

Fig. 2

Line chart of the mean proximal femoral head penetration (with 95% CI) of the 32 mm (black) and 36 mm (grey) femoral head groups. At the two-year follow-up, 47 hips were available for radiostereometric analysis (n = 25 with 32 mm, n = 22 with 36 mm), at the six-year follow-up, 40 hips were available for analysis (n = 20 with 32 mm, n = 20 with 36 mm), and at the 14-year follow-up, 32 hips were available for analysis (n = 17 with 32 mm, n = 15 with 36 mm). At the three-month follow-up, there were 48 hips and at the one-year follow-up, 47 hips available for analysis.

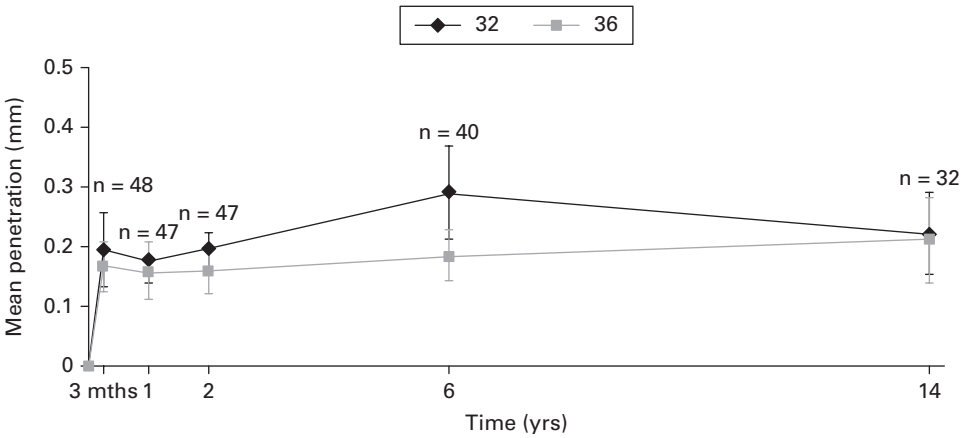

Fig. 3

Line chart of the mean total 3D femoral head penetration (with 95% CI) of the 32 mm (black) and 36 mm (grey) femoral head groups. At the two-year follow-up, 47 hips were available for radiostereometric analysis (n = 25 with 32 mm, n = 22 with 36 mm), at the six-year follow-up, 40 hips were available for analysis (n = 20 with 32 mm, n = 20 with 36 mm), and at the 14-year follow-up, 32 hips were available for analysis (n = 17 with 32 mm, n = 15 with 36 mm). At the three-month follow-up, there were 48 hips and at the one-year follow-up, 47 hips available for analysis.

We found in our study that there was no significant difference in polyethylene wear between 32 and 36 mm femoral head sizes (excluding the 'bedding-in' period). This is supported by other studies. Tsikandylakis et al[18] found at the five-year follow-up that large metal femoral heads (36 mm to 44 mm) in combination with VEPE liners did not increase liner wear compared with 32 mm femoral heads. Another study from 2023 evaluating THA with 36 mm metal heads with HXLPE liners showed low polyethylene wear up to mean follow-up of 12.8 years.[17] The authors concluded that using HXLPE liners with 36 mm metal heads in 52 mm or 50 mm shells (liner thickness 5.5 mm in all but one) was a safe option. Additionally, results from a RCT with a ten-year follow-up published in 2023 showed that there was less polyethylene wear in the VEPE group with 32 mm or 36 mm heads compared with the HXLPE group. They found no difference when they studied 32 mm or 36 mm heads separately.[16]

RLLs were scarce and had not increased from six years to the final follow-up either on the cup or stem side. Although there were pedestal signs at the tip of the stem present in 21 patients,[30,46] none of the stems were clinically loose. This corroborates earlier findings of low biological activity and less osteolysis with HXLPE wear particles.[13]

This study was not designed, and did not have sufficient power, to evaluate differences in clinical outcome scores

between the study groups. However, it was noted that at 14 years of follow-up, 28 of the 32 patients still recorded good or excellent clinical outcome based on HHS (> 80). Considering normal ageing as a possible cause for a reduction of the HHS after 14 years, a mean for the entire cohort of 93 can be considered a clinical success.

From six to 14 years, eight hips were lost to follow-up (n = 3 from 32 mm group, n = 5 from 36 mm group). Reasons for loss to follow-up included living abroad, other medical issue, periprosthetic infection (operated with spacer), periprosthetic fracture (change of prosthesis components), death (one patient, two hips), and two hips for which RSA images could not be analyzed due to technical issues (Figure 1). There were changes of prosthesis components during revision for both the periprosthetic infection and periprosthetic fracture and, therefore, both these hips were excluded. The initial power calculation, described in the first article from 2015, defined 17 hips in each group as sufficient to measure polyethylene wear difference of 0.1 mm between the two groups.[19] However, at the 14-year follow-up, there were a total of 17 and 15 hips, respectively, in the 32 and 36 mm head size groups available for RSA. Regardless, the polyethylene wear measured is extremely low for both head sizes.

Another issue to consider is the precision measurements from the original 2015 article,[19] which was calculated to be 0.17 mm in the proximal direction. This precision is slightly poorer than shown in a comparative study by Röhrl et al,[47] which had a precision of 0.15 mm in the proximal direction with metallic or zirconium ($Zr0_2$) heads. An explanation could be the difference in head material. The contours of a ceramic head, as used in the current study, are not as concise as with a metallic head. One could speculate that the extremely low polyethylene wear in both groups is limited by precision and, therefore, measuring a lower level of wear in the 36 mm group is uncertain. Regardless, we did not find more wear in the 36 mm group, which gives credence to using this head size in primary THA with VEPE liners.

Furthermore, it is important to mention that although the same RSA cage was used for the 14-year follow-up, the manufacturer with two fixed X-ray sources from General Electronic (USA) was different from the previous follow-up, when we used a combination of a mobile X-ray source from Siemens (Germany) and a fixed X-ray source from Siemens. This could potentially also alter the RSA precision.

Another limitation is that approximately 70% of hips (23/32) included in this study were from females, and therefore we cannot rule out any selection bias related to sex.

A strength is that, to our knowledge, this is the RCT with the longest follow-up comparing 32 and 36 mm heads with VEPE liners, using RSA. It is important to underline that the measured wear is below the level of the precision of RSA, however RSA is the best we have at the moment to measure in vivo wear in THA. Perhaps new methods in the future will be able to measure wear of polyethylene liners with even greater precision, but it is doubtful whether this will contribute anything clinically.

In conclusion, there was extremely low polyethylene wear at the 14-year follow-up using this type of VEPE in combination with 32 and 36 mm ceramic heads. Clinical outcome scores were excellent, and we found only limited signs of radiolucency around the prosthesis components. At the 14-year follow-up, this articulation seems to be a safe option also for 36 mm heads.

Take home message

- At 14-year follow-up, there was extremely low polyethylene wear using vitamin E-infused HXLPE (VEPE) in combination with both 32 and 36 mm ceramic heads.
- The articulation used in this study with ceramic heads on VEPE seems to be a safe option to use in total hip arthroplasty.

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Data sharing:
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