



# The Survivorship of the Uncemented Iso-Elastic Monoblock Acetabular Component at a Mean of 6-Year Follow-up

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**Abstract** *Background:* Aseptic loosening, caused by wear and osteolysis, is the most frequent reason for hip replacement revision in the UK. To prevent aseptic loosening, an acetabular component with vitamin E added to irradiated highly cross-linked polyethylene (HXLPE) was developed to reduce oxidative degradation. *Questions/Purposes:* A prior study of the vitamin E-blended HXLPE acetabular component after 2 years of follow-up reported no adverse reactions or abnormal mechanical behavior. To further examine this hypothesis of reducing wear and osteolysis, we sought to evaluate outcomes after 6-year follow-up. *Methods:* A cohort of 95 of the 112 initial patients (84.2%) completed the 6 years of follow-up after receiving a vitamin E-blended HXLPE acetabular component. Evaluation was performed in terms of clinical (visual analog scale [VAS] score, VAS score with weight-bearing, VAS score for satisfaction, and Harris Hip Score) and radiological (inclination, polar gap, radiolucencies, migration, and 2-D linear femoral head penetration rate) assessment. *Results:* The mean VAS score for patient satisfaction was 8.75 and the mean Harris Hip Score was 91.8. There were two revisions because of deep infections and one because of a peri-prosthetic femoral fracture. Two acetabular components migrated initially; however, delayed acetabular stabilization occurred. Both

patients had good clinical scores at 72 months. The mean femoral head penetration rate was 0.036 mm/year. *Conclusions:* This prospective cohort study has shown no adverse reactions concerning the vitamin E additive, promising wear rates, no signs of osteolysis, a 100% survival rate for aseptic loosening, and an all-cause survivorship percentage of 97.4% at 6 years of follow-up.

**Keywords** vitamin E · polyethylene · iso-elastic · monoblock cup · femoral head penetration · total hip arthroplasty

## Introduction

There are good clinical results and long-term survival rates available with ultra-high-molecular-weight polyethylene (UHMWPE) monoblock acetabular components in total hip arthroplasty (THA) [11, 17]. Nonetheless, in the UK, aseptic loosening is still the most frequent reason for revision, most likely due to wear-induced osteolysis [12, 15]. In order to reduce the wear and osteolysis of the UHMWPE in THA, highly cross-linked polyethylene (HXLPE) was developed [13]. In HXLPE, the UHMWPE is exposed to radiation in order to increase the number of crosslinks, thereby improving the wear resistance. However, it has been demonstrated that irradiated polyethylene has a low stability to oxidation leading to embrittlement [20]. To efficiently reduce the oxidative degradation of irradiated HXLPE, the anti-oxidant vitamin E has been added [2]. Vitamin E-stabilized HXLPE has demonstrated superior oxidation stability, protecting it from embrittlement [1].

One acetabular component, the RM Pressfit Vitamys® (Mathys Ltd., Bettlach, Switzerland) is made of vitamin E-stabilized HXLPE in combination with its thin layer (136 µm) of single titanium particle coating, resulting in similar elastic modulus as cancellous bone (0.5–0.6 GPa) [6]. The combination ensures that this acetabular component is iso-elastic, which means that the elasticity of the

Level of Evidence: Level IV, Therapeutic Study

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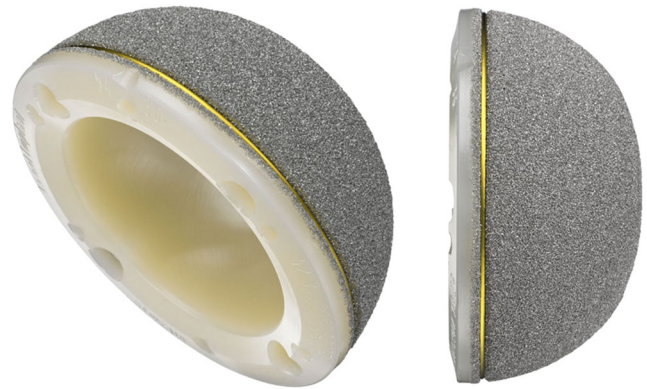
acetabular component in theory facilitates a more physiologic load transfer to the peri-prosthetic acetabular bone (in contrast to a metal backed acetabular component, which has a rigid modulus compared to cancellous bone). Therefore, vitamin E–stabilized HXLPE induces optimal conditions for bone on-growth by minimizing micromotions between the bone and the acetabular cup. Minimizing these micromotions prevents osteolysis [14]. Therefore, the combination of the vitamin E–blended HXLPE and the uncemented iso-elastic monoblock holds the promise of increased wear resistance and possible reduced risk of peri-prosthetic osteolysis. It is hoped that this cup design will lead to a reduced risk for aseptic failure and revision surgery.

The preliminary results after 2 years of follow-up showed no adverse reactions or abnormal mechanical behavior of the vitamin E–blended HXLPE acetabular component, therefore confirming its potential [9]. To further examine this hypothesis of reducing wear and osteolysis with a vitamin E–blended HXLPE acetabular component, medium-term clinical and radiological follow-up is necessary. This cohort study evaluates the 6-year follow-up of patients with an uncemented iso-elastic monoblock acetabular component with vitamin E–blended HXLPE in terms of clinical outcomes: visual analogue scale (VAS) for pain, VAS for pain with weight-bearing, VAS for satisfaction, Harris Hip Score (HHS), adverse reactions, complications, and revision rates. In terms of radiologic outcomes, inclination, polar gap, radiolucencies, and migration and 2-D linear femoral head penetration rate were evaluated.

## Methods

This prospective cohort study was carried out at a medium-size general hospital in the Netherlands. Institutional review board approval was obtained. Full informed consent in writing was acquired from all participating patients. A total of 112 patients (117 prosthetic implants) were included between September 2009 and May 2011. Description of patients inclusion and exclusion criteria, documentation of baseline characteristics, surgical procedures, and implants can be seen in the prospective cohort study of the 2 years of follow-up of the vitamin E–blended HXLPE acetabular component [9] (Fig. 1). This 6-year follow-up cohort consisted of 112 patients: 74 were female (66.1%) and 38 were male (33.9%). Mean age was 63.8 years old (range, 40 to 86 years), and mean body mass index was 26.15 (range, 19–35). The indication for THA was primary osteoarthritis in 104 cases (92.8%), an acute femoral neck fracture in one case (0.9%), congenital hip dysplasia in four cases (3.5%), secondary osteoarthritis due to Perthes disease in one case, slipped capital femoral epiphysis in another case, and post-traumatic avascular necrosis in another (2.7%) (Table 1).

After 72 months, 17 patients (17 hips) were lost to follow-up (15.2%). The poor general health of eight patients made it impractical for them to come for follow-up evaluation. Three of the patients were of advanced age, making travel impractical. Others suffered from dementia, recent myocardial infarction, deafness, polyarthritis, or metastatic



**Fig. 1.** The uncemented monoblock acetabular cup with vitamin E–blended highly cross-linked polyethylene.

disease. One patient was lost to follow-up in earlier appointments but was able to attend after 72 months. This patient was clinically and radiologically evaluated, but the measurements could not be compared to the 3-, 12-, and 24-month follow-up visits. One patient did not want to come because of complications with a previous vascular surgical procedure at our hospital. Four patients had died (3.6%), one patient due to urosepsis after the 24 months of follow up, and three others within 24 months (one from acute respiratory distress syndrome due to pneumonia and cardiac decompensation at day 10 after surgery and the second from metastatic lung cancer; the third patient’s cause of death is unknown). Three patients were excluded because of revision surgery (these patients will be described in the Results section). A total of 95 patients (100 hips, 84.8%) completed almost the 72 months of follow-up (mean 71.4 months, range 57.8–82.4 months).

Post-operative clinical and radiological follow-up was scheduled for each patient at 3, 12, 24, and 72 months after surgery. At the 72-month follow-up visit, the HHS was used to evaluate clinical outcomes [10]. Furthermore, the VAS was filled in by the patient for rest pain, load pain, and patient satisfaction and was documented by one of the investigators (T.E.S.). The VAS for satisfaction has been validated in prior work [3]. Complications and adverse reactions were also noted. These follow-up assessments were performed by one of the primary investigators (T.E.S.) and consisted of a patient history and a physical examination.

The radiological assessment was performed by one of the authors (J.A.R.M.) according to a standardized scoring form. The inclination of the acetabular component was noted. Although the cup is designed to allow screw fixation (Fig. 1), no screws were used in this series. The presence of radiolucencies and osteolysis around the acetabular component was scored, and if present, the affected zone was noted. Furthermore, the Brooker classification was used for scoring the presence of heterotopic ossifications.

The femoral head penetration measurements were performed on a Picture Archiving and Communication System (PACS) workstation with a high-resolution monitor using View Pro-X software version 4.0.8.9 (Rogan-Delft,

**Table 1** Demographics of 112 patients (117 hips)

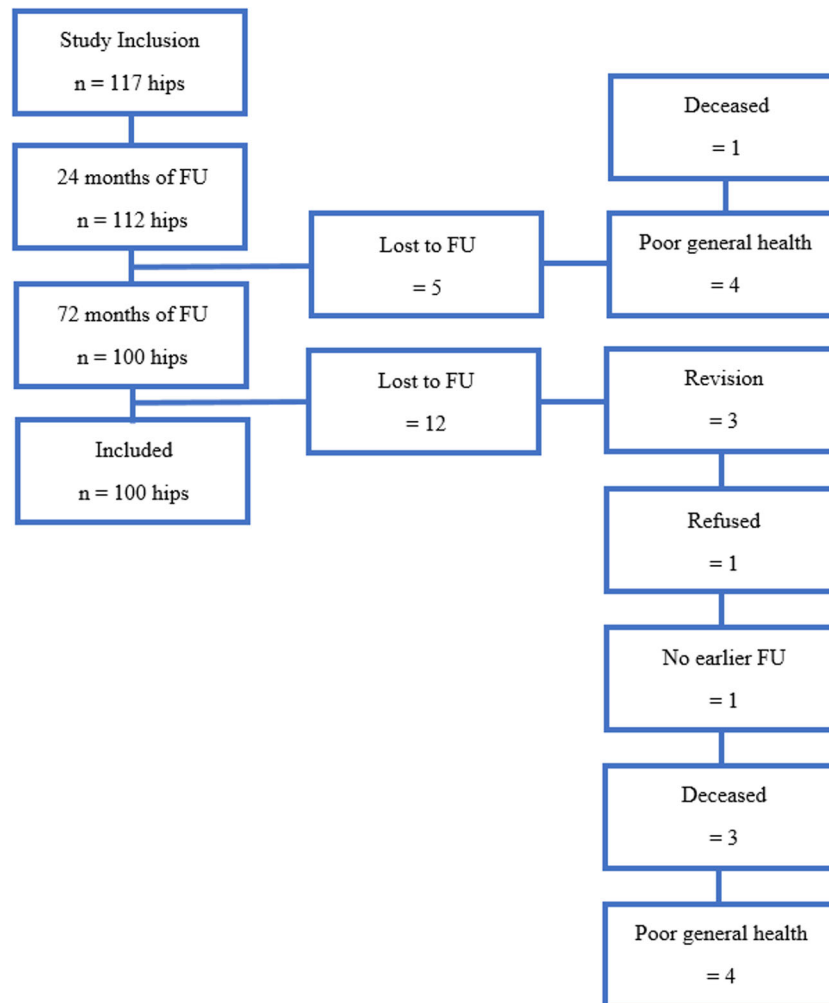
|                          | Mean (range) | N (%)       |
|--------------------------|--------------|-------------|
| Age                      | 63.8 (40–86) |             |
| Body mass index          | 26.2 (19–35) |             |
| Gender                   |              |             |
| Male                     |              | 38 (33.9%)  |
| Female                   |              | 74 (66.1%)  |
| Diagnosis                |              |             |
| Primary osteoarthritis   |              | 104 (92.8%) |
| Acute fracture           |              | 1 (0.9%)    |
| Congenital hip dysplasia |              | 4 (3.5%)    |
| Secondary osteoarthritis |              | 3 (2.7%)    |

Veenendaal, Netherlands). All measurements were performed by a single observer (J.A.R.M.) using a computer-assisted method for measuring femoral head penetration of all-polyethylene acetabular components (modified dual-circle technique) previously described by Geerdink et al. [7]. The anteroposterior pelvic radiographs were calibrated using the size of the prosthetic femoral head as a reference. The distance between the center of the femoral head and the

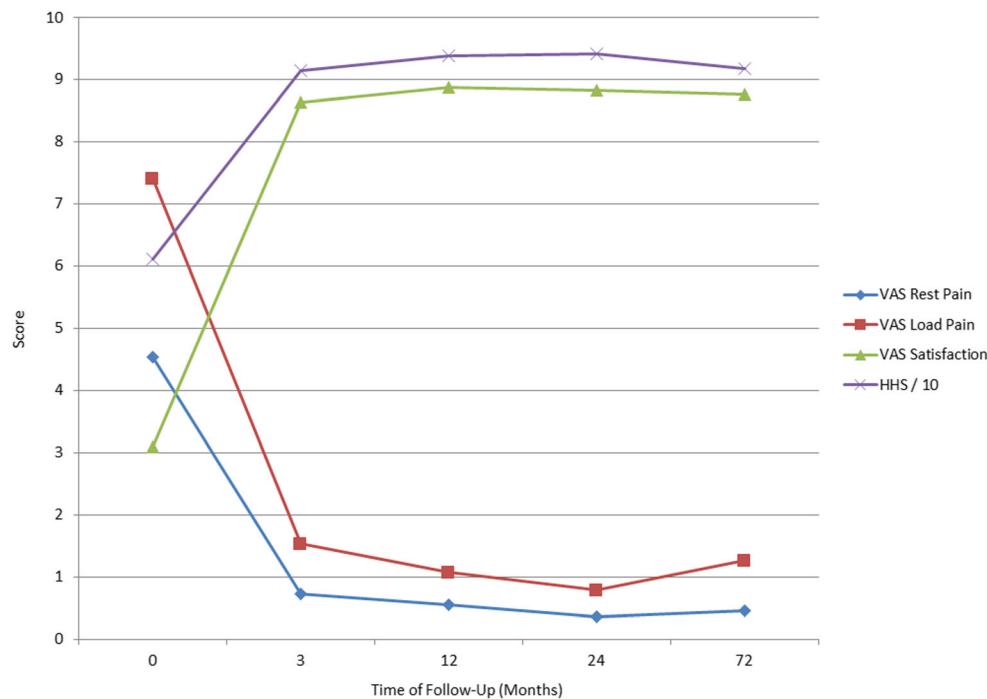
center of the acetabular component was measured. The femoral head penetration rate was calculated by subtracting the distance measured at follow-up at around 72 months from the distance measured at baseline, at 12 months, and at 24 months of follow-up and subsequently divided by the given follow-up interval (Fig. 2).

**Statistical Analysis**

Statistical analysis was performed using SPSS Statistics, version 23.0 (IBM Corp., Armonk, NY, USA). The distribution of the data was checked using the Shapiro-Wilk test. The femoral head penetration measurements were non-normally distributed, indicating the need for a non-parametric test. The Wilcoxon signed-rank test was used to test for significant differences in femoral head penetration between the different follow-up intervals. Multiple linear regression was used to assess whether age, body mass index, femoral head diameter, and acetabular component inclination correlated with the femoral head penetration rate. The significance level ( $\alpha$ ) was set at 0.05.



**Fig. 2.** Summary of follow-up (FU).



**Fig. 3.** The mean visual analog scale (VAS) scores for pain while resting, pain during weight-bearing, and patient satisfaction and the Harris Hip Score at the first day post-operatively, and at months 3, 12, 24, and 72.

## Results

The mean VAS score for pain while resting went from 4.53 (range, 0–9) at baseline to a mean of 0.36 (range, 0–6) at 24 months' follow-up to a mean of 0.45 (range, 0–6) at 72 months' follow-up. The mean VAS score for pain during weight-bearing showed a comparable course from a mean of 7.41 (range, 3–10) pre-operatively to 0.79 (range, 0–6) at 24 months' follow up and 1.26 (range, 0–8) at 72 months' follow-up. The mean VAS scores for patient satisfaction was 3.09 (range, 0–6) pre-operatively and went to 8.82 (range, 3–10) at 24 months' follow-up and 8.75 (range, 4–10) at 72 months' follow-up. The mean HHS was 61.1 (range, 21–90) at baseline and increased to 94.2 (range, 60–100) at 24 months and decreased to 91.8 (range, 55–100) at 72 months (Fig. 3). Four patients scored 70 or lower after 72 months. One patient with an HHS of 55 had fibromyalgia and a contralateral THA that was revised because of persistent instability. One patient with an HHS of 68 had persisting complaints of pseudoradicular pain due to lumbar degeneration. One patient with an HHS of 70 suffered from polyarthritis of both feet. One patient had an HHS of 70,

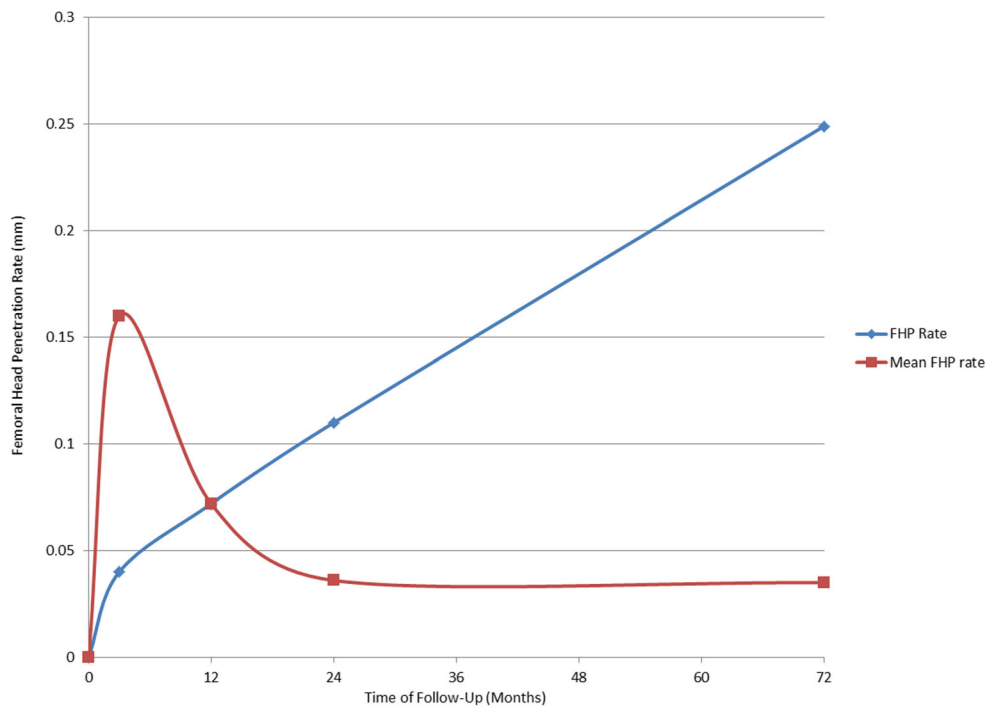
mainly because of pain persisting after a hemi-arthroplasty of the contra-lateral hip after a proximal femur fracture.

No adverse reactions associated with the clinical application of vitamin E-blended HXLPE iso-elastic monoblock acetabular component were observed during this study. Two new complications occurred during the period after the 24-month follow-up and the 72-month follow-up: one patient suffered a peri-prosthetic femoral fracture and had stem revision surgery in another hospital, and one patient had a deep infection and was treated with a two-stage revision surgery with additional intravenous antibiotic treatment. Complications before the 24-month follow-up consisted of one case of post-operative internal bleeding, treated successfully with the coiling of a branch of the medial circumflex femoral artery. One case of an iatrogenic fracture of the greater trochanter was treated with cerclage wiring. One case of iatrogenic femoral perforation and one case of iatrogenic perforation of the acetabulum were documented. Both patients were treated conservatively with a partial weight-bearing regimen. Furthermore, there was one case of peri-prosthetic femoral fracture (Vancouver A) due to a fall that was treated with femoral stem

**Table 2** Revision summary

|      | Age | M/F | Implantation | Indication | Revision       | Indication               |
|------|-----|-----|--------------|------------|----------------|--------------------------|
| Case |     |     |              |            |                |                          |
| 1    | 61  | F   | 18-01-2010   | Prim.      | 24-09-2012     | Deep infection           |
| 2    | 60  | F   | 06-08-2010   | Prim.      | 07-01-2011     | Deep infection           |
| 3    | 73  | F   | 21-04-2010   | Prim.      | Other hospital | Peri-prosthetic fracture |

*Prim* primary osteoarthritis



**Fig. 4.** Total and mean femoral head penetration (FHP) rate from the first day post-operatively to months 3, 12, 24, and 72. FHP in mm, mean FHP rate in mm/year.

revision and cerclage wiring of the greater trochanter. Three patients had a superficial wound infection treated with oral antibiotics. Two patients had a deep infection and were treated with surgical debridement and irrigation. One patient suffered from a deep infection and needed a two-stage revision surgery with intravenous antibiotic treatment. This patient was free of infection at 72 months of follow-up [9] (Table 2). Of the initial 112 included patients, 2.7% suffered from a deep infection. This is relatively high compared to our local benchmark of 1.1% of deep infections from 2010 to 2016. The all-cause 6-year survival to revision rate is 97.4%. The 72-month survival rate for aseptic loosening of this iso-elastic monoblock acetabular component with vitamin E-blended HXLPE is 100%.

There were no changes in inclination angle between months 24 and 72. After 72 months, the polar gap (1 mm) that could still be seen on the post-operative radiographs of one patient after 24 months was still present and unchanged.

**Table 3** Total femoral head penetration rates

| Follow-up interval (months) | Total femoral head penetration (mm) | Range           | Standard deviation |
|-----------------------------|-------------------------------------|-----------------|--------------------|
| 0–12                        | 0.072                               | 0.020 to 0.164  | 0.033              |
| 0–24                        | 0.109                               | 0.038 to 0.209  | 0.036              |
| 0–72                        | 0.249                               | 0.196 to 0.329  | 0.030              |
| 12–24                       | 0.036                               | –0.027 to 0.093 | 0.025              |
| 12–72                       | 0.180                               | 0.07 to 0.300   | 0.048              |
| 24–72                       | 0.141                               | 0.04 to 0.250   | 0.050              |

Radiolucencies behind the acetabular component were present in six cases after 24 months. One of those had a two-stage revision because of a deep infection. The other was the patient with the iatrogenic acetabular perforation. This patient had a radiolucency in DeLee and Charnley zone 1 at 24 months that resolved at 72 months. In two cases, the radiolucency in DeLee and Charnley zone 2 remained stable. The remaining 2 cases showed resolution of the radiolucencies after 72 months. And lastly, one case did show a radiolucency in DeLee and Charnley zone 2 after 72 months, which was not apparent on previous radiographs. This patient had an HHS of 100 and a VAS satisfaction score of 10.

No screws were used to fixate the acetabular cup, and after 72 months two cases of migration of the acetabular component were observed. The second case was excluded in the previous study. This patient was, at that time, not capable of coming to the hospital because of poor health. However, after 72 months, he was able to attend the appointment. The AP pelvic radiograph showed a decrease in inclination from 52 to 42°. The patient did not have any pain and scored 96 points on the HHS. The other case was already described [9]. The inclination angle of this acetabular component decreased from 40 to 12° within a period of 2 months post-operatively and was stable for the remainder of follow-up. This patient had a slight pain in the hip, scored 9.5 points for satisfaction, and had an HHS of 94 points after 72 months.

The total mean two-dimensional linear femoral penetration after 72 months was 0.249 mm (range, 0.196–0.329; SD,



**Table 4** Mean femoral head penetration rates

| Follow-up interval (months) | Mean femoral head penetration (mm/yearly) | Range           | Standard deviation |
|-----------------------------|---|-----------------|--------------------|
| 0–12                        | 0.072                                     | 0.020 to 0.164  | 0.033              |
| 12–24                       | 0.036                                     | –0.027 to 0.093 | 0.025              |
| 24–72                       | 0.035                                     | 0.010 to 0.060  | 0.013              |
| 12–72                       | 0.036                                     | 0.010 to 0.060  | 0.010              |

0.030). The mean two-dimensional linear femoral head penetration rate was 0.042 mm/year (range, 0.033–0.055; SD, 0.005). The total femoral head penetration from month 12 to month 72, thus excluding the bedding-in time, was 0.180 mm (range, 0.070–0.300; SD, 0.048) (Fig. 4). The mean femoral head penetration rate per year over this period, thus again excluding the bedding-in time, was 0.036 mm/year (range, 0.010–0.060; SD, 0.010) (Tables 3 and 4).

The Wilcoxon signed-rank test showed a statistically significant difference between the femoral head penetration rate in the first 12 months (0.072 mm/year; range, 0.020–0.164; SD, 0.033) and in the last 60 months (0.036 mm/year) ( $p = 0.000$ ). The first 12 months were also statistically significantly different from the period between the 12th and the 24th month (0.036 mm/year; range, –0.027–0.093; SD, 0.025), as previously reported [9].

This latter period was not statistically significantly different from the mean yearly femoral head penetration rate over the last 48 months (0.035 mm/year; range, 0.010–0.060; SD 0.013) ( $p = 0.897$ ) (Table 5). Backward multiple linear regression showed no correlation between the femoral head penetration rate and age, body mass index, femoral head diameter, or acetabular component inclination ( $p > 0.05$ ) (Table 6).

## Discussion

This prospective cohort study of patients with an uncemented iso-elastic monoblock acetabular component with vitamin E-blended HXLPE after 6 years of follow-up shows no adverse reactions concerning the vitamin E additive, no signs of osteolysis, a 100% survival rate for aseptic loosening, and a mean two-dimensional linear femoral penetration rate of 0.036 mm/year. These medium-term results confirm the hypothesis that vitamin E-blended HXLPE is a promising, durable bearing.

This study is limited by the methodologic limitations mentioned in the 24-month follow-up study of Halma

**Table 5** Wilcoxon signed-rank test of yearly mean femoral head penetration rate between different follow-up intervals

| Follow-up interval | Follow-up interval | <i>p</i> value |
|--------------------|--------------------|----------------|
| 0–12               | 12–24              | 0.000*         |
| 0–12               | 12–72              | 0.000*         |
| 12–24              | 24–72              | 0.897          |

\* $p < 0.05$  = statistically significant**Table 6** Multilinear regression analyses of femoral head penetration rate with patient characteristics

|                                  | <i>p</i> value |
|----------------------------------|----------------|
| Age                              | 0.604          |
| Body mass index                  | 0.992          |
| Acetabular component inclination | 0.927          |
| Femoral head diameter            | 0.606          |

$p < 0.05$  = statistically significant

et al. [9]. These consisted of not using advanced imaging techniques to assess the acetabular bone quality, using an unvalidated wear rate measurement method, and using standing and supine pelvic radiographs for evaluation [9]. Another important limitation is that a different investigator performed the radiographic measurements at 72 months' follow-up. Even though this investigator was instructed by the investigator of the 24 months' follow-up, it could have led to differences in the radiographic measurements. Even so, 6 years is a medium term of follow-up and does not guarantee long-term success. At the same time, the femoral head penetration rate measurement has an excellent inter-observer reliability of 0.87 [7].

The results of this study support the conclusions of Nebergall et al. that a vitamin E-diffused HXLPE bearing has improved wear resistance over an HXLPE bearing [16]. The femoral head penetration rate is also within the mean wear rate recognized by Callary et al., namely 0.00 to 0.06 mm/year [4]. It is also less than the mean femoral head penetration rate of 0.042 mm/year from the systematic review of Kurtz et al. [13]. This supports the concept that vitamin E-blended HXLPE has an improved performance compared to the conventional UHMWPE, with a mean femoral head penetration rate of 0.137 mm/year [13]. Second, other studies with HXLPE report results ranging from 0.023 to 0.063 mm/year, which implies good results of this vitamin E-blended HXLPE of 0.036 mm/year, when it has reached the steady-state penetration rate after 1 year. This period was recommended by a recent systematic review as the period allowed for bedding-in and creep [4]. That it has reached the steady-state penetration rate at 1 year in this study is supported by comparing the yearly wear rate of the last 4 years with the mean wear rates of the first and the second years. The first year is statistically significantly different from the mean yearly wear rate of the last 5 years ( $p = 0.000$ ), while the second year is not statistically significantly different from the last 4 years ( $p = 0.8976$ ) [9] (Table 5).

Previously reported wear rates using other bearings have been lower than the rates reported in our study. Some considerations can be offered as to why this polyethylene does not provide the lowest reported wear rate. First of all, studies evaluating long-term wear rates tend to show a diminishing wear rate with an increasing time period after 5 years of follow-up [13]. Considering that this medium-term study has a mean follow-up time that just passes the

5-year mark, the wear rate at long-term follow-up might be even lower than those of other long-term studies. Second, the method to measure the femoral head penetration rate in this study tends to increase the measured wear rate compared to measurements done by a software program that analyzes digitized radiographs, such as Martell's Hip Analysis Suite [13]. Third, there might be a role of plastic deformation in the femoral head penetration rate, and it could be different from the volumetric wear [8].

It has been established in a systematic review that HXLPE has an 87% lower incidence of osteolysis after 5 years compared to conventional UHMWPE bearings [13]. Although osteolysis and increased risk of revision surgery due to loosening is rare below a linear wear rate of 0.1 mm/year [5], this study cohort demonstrated no osteolysis or revision for aseptic loosening after 6 years of follow-up, suggesting that the vitamin E-blended HXLPE may prove promising for long-term survival. These promising results may also be related to a more physiologic load transfer by this acetabular component that has iso-elastic properties, which are quite similar to peri-prosthetic acetabular bone [6]. Another promising result suggesting the potential for successful peri-prosthetic bone ingrowth and fixation ingrowth is the good clinical outcome of the two patients in whom migration of the acetabular component occurred. Early migration is a known predictor for aseptic loosening. One patient showed migration of the acetabular component within 3 months of iatrogenic acetabular perforation during the surgical procedure. Nonetheless, this patient showed no osteolysis after 6 years and scored very good clinical results, with VAS satisfaction of 9.5 and HHS score of 94. The second patient was not included in the 6 years of follow-up; his health did not allow him to attend the 3-, 12-, and 24-month follow-up visits. Nevertheless, he was capable of attending after 72 months. Pelvic radiographs showed that his acetabular component migrated from an inclination of 52 to 42°. Despite this migration, the patient still had an HHS score of 94. Both cases of migration can be attributed to insufficient initial primary stability and secondary ingrowth, as both had very good clinical results after 72 months. It is likely that delayed acetabular component stabilization occurred, the latter being a well-recognized phenomenon [18]. A 2017 study by Wyatt et al. also showed a low degree of migration with Einzel-Bild-Röntgen-Analyse and similar all-cause survivorship [19].

In conclusion, the findings of this mid-term study suggest promising clinical and radiological outcomes with the iso-elastic vitamin E-blended HXLPE acetabular component. A randomized controlled trial comparing this acetabular component to an HXLPE without vitamin E should be conducted. Further follow-up is needed to determine if these wear rates lead to less osteolysis and aseptic loosening in the long-term. For now, this prospective cohort study has shown no adverse reactions concerning the vitamin E additive, promising wear rates, no signs of osteolysis, a 100% survival rate for aseptic loosening, and an all-cause survivorship percentage of 97.4% at 6 years of follow-up.

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### Compliance with Ethical Standards

**Conflict of Interest:** T.E. Snijders, MD, J.J. Halma, MD, J.R.A. Massier, S.M. van Gaalen, MD, PhD, and A. de Gast, MD, PhD, declare that they have no conflict of interest.

**Human/Animal Rights:** All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

**Informed Consent:** Informed consent was obtained from all patients for being included in this study.

**Required Author Forms** Disclosure forms provided by the authors are available with the online version of this article.

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