



# Vitamin E-enriched polyethylene bearings are not inferior to Arcom bearings in primary total knee arthroplasty at medium-term follow-up

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## Abstract

**Introduction** The release of wear particles can be responsible for periprosthetic osteolysis, which can in turn, lead to aseptic loosening. Vitamin E-infused polyethylene (HXLPE Vit-E) has been shown, in vitro, to be more resistant to wear than conventional polyethylene (UHMWPE) by its crosslinking (HXLPE) and its higher resistance to oxidation. After reading a case report of a fracture of a vitamin E-enriched HXLPE bearing, the aim of this retrospective study was to evaluate fracture risk and clinical inferiority or not of vitamin-E HXLPE compared to conventional polyethylene in total knee arthroplasty (TKA).

**Materials and methods** Three hundred and forty-nine patients (403 TKAs) were contacted, to find out whether they had undergone revision surgery for any reason after a mean (SD) of 7 (1.5) years. Follow-up control radiographs were analyzed for periprosthetic radiolucent lines (RLL) and loosening. Two different Patient Reported Outcome Measurements Scores (PROMS), KOOS and FJS-12, were utilized to assess the daily functionality and identify potential problems.

**Results** No statistically significant difference in revision rate, occurrence of aseptic loosening or RLL nor outcome as measured with PROMS was observed.

**Conclusions** No bearing fractures or clinical inferiority was observed for vitamin E-enriched HXLPE at medium-term follow-up (7 years) compared to conventional Arcom polyethylene.

**Level of evidence** Level III, therapeutic study.

**Keywords** Polyethylene · Cross-linking · Vitamin E · Wear · Aseptic loosening

## Introduction

The increased usage of primary total knee arthroplasty (TKA) and especially its use in young and active patients made the debate about polyethylene wear and osteolysis actual again. Logically, the burden of revision TKA on the health care system will increase over time, except if the newly implanted materials withstand the activity profile of the new TKA patient, because of technological improvements [1]. Aseptic loosening is still the primary cause of revision TKA, but it is probably more because of failure of

primary fixation and debonding, than because of polyethylene (PE) wear and particle disease [2]. However, if the new types of polyethylene lead to new problems or early failure, it is better to pick up the emergency signals early.

Highly cross-linked polyethylene (HXLPE) has shown superior wear resistance compared to conventional ultra-high molecular weight polyethylene (UHMWPE) [3, 4]. But the radiation necessary for cross-linking forms free radicals, which makes the polyethylene prone to oxidation and could potentially weaken it over time [5, 6]. Two techniques have been developed in first-generation HXLPE to rectify this problem; annealing and remelting. However, the former technique does not eliminate free radicals optimally, and the latter, even though it is efficient against free radicals, reduces polyethylene fatigue strength [6, 7]. The use of vitamin E ( $\alpha$ -tocopherol), as an antioxidant, in second-generation HXLPE protects the polyethylene from oxidation by reacting with the free radicals while retaining the mechanical properties of the HXLPE [8].

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Today, there is still a lot of apprehension toward HXLPE on behalf of the surgeons because the first-generation polyethylene had lower fatigue strength [9–11]. Vitamin E-enriched HLXPE could be a solution to this problem, but a case report about early fracture of such type of polyethylene in a Vanguard knee alerted the medical community in 2013. A patient, with suboptimal alignment and soft tissue balancing, experienced an early failure, because of fracture of the vitamin E polyethylene [12–14].

Adding to that the current debate about the body's response to vitamin E-infused particles has not helped with the general adaptation of this product [12, 13].

The aim of this retrospective study was to review sequentially implanted patients with as primary outcome the revision rate of vitamin E polyethylene articular surfaces for aseptic loosening at a mid-term follow-up. Secondary outcome parameters were clinical outcome utilizing Patient Reported Outcome Measurements Scores (PROMS), radiological appearance of radiolucencies if present, as well as pain and swelling. This study group was compared to an Arcom polyethylene group.

## Patients and methods

### Patients

In this monocentric retrospective study, all patients that had undergone total knee arthroplasty by the knee team of the Saint-Luc University hospital (Brussels, Belgium) between 2008 and 2012 were included. Two study groups were created depending whether a Vanguard (Zimmer Biomet Inc., Warsaw, IN, USA) posterior-stabilized (PS) type of implant was used with a conventional PE (Arcom) or with a HXLPE vitamin E-enriched PE (E-Poly). All patients had primary osteoarthritis at the time of surgery. All prostheses were cemented. Patients suffering from cancer, rheumatoid arthritis, osteoporosis or renal failure at the time of surgery were not included in the study because of the potential impact on bone quality, and therefore, implant fixation. This leads to a total study group of 427 eligible patients (507 TKAs). All included patients were first contacted by phone to obtain their initial oral consent to continue with a phone discussion and their status at actual evaluation. This date of contact was considered the last actual follow-up and status could be: active unrevised, revised, deceased (contact with family), lost to follow-up (no contact possible over phone or mail) and finally withdrawn (patient gave his actual status, but did not participate in further data collection). Patients were informed that a postal package would follow with a to be signed informed consent requiring signature, and several questionnaires informing about their actual clinical outcome. Patients with bad scores or inquiries were asked to come

back for a clinical and radiological check-up. The study protocol and the consent form were approved by the institution's ethical committee (number of reference: B-403201629778).

Patients needed to confirm whether their TKA had been revised, if they still had pain or not (no, occasional or pain needing a painkiller) and if they experienced swelling or not (patient perception).

### Patient Reported Outcome Measurements Scores

Two PROMs, the Forgotten Joint Score (FJS-12) and the Knee injury and Osteoarthritis Outcome Score (KOOS) were sent to evaluate functional and clinical results.

The FJS-12 assesses subtle differences about the ability of a prosthesis to be forgotten about in everyday activities [15, 16]. English, French and Dutch versions were used depending of the native language of the patient [17–19]. The answers lead to a score between 0 and 100 with a minimum of 8 answers (8/12) necessary for the score to be valid [20].

The KOOS is divided into five parts assessing pain, symptoms, activities of daily living (ADL), functionality in sport and recreation (Sport / Rec) and quality of life (QOL). Each of the subparts give a score of 0–100, the score of each subpart was compared individually. The English, French and Dutch versions were used depending of the native language of the patient [21, 22].

### Radiographic analysis

Postoperative radiographs were all reviewed for periprosthetic radiolucent lines (RLLs). Radiology was guided by fluoroscopy directly after surgery, at 6 weeks, 3 months, 1 year, 2 years and 5 years post-operation [23]. The RLLs were described according to two methods.

The first method used the modified radiographic evaluation system of radiolucent lines described by Bach et al., which consists in adding up the RLL widths found on a component. The result can be classified as absent or narrow if the sum < 4 mm or wide if the sum > 4 mm [24].

The second method distinguishes the physiological RLLs from the pathological RLLs as described by Smith et al. and Goodfellow et al. [25–27]. The physiological RLLs are stable over time, < 2 mm and limited by sclerotic bone. The pathological edges are > 2 mm, grow over time and are not limited by sclerotic bone. Different RLLs are described according to the Ewald model [28].

### Study population characteristics

Of the 427 patients (507 TKAs) included in the study, only 349 (403 knees) could be contacted, meaning 104 prostheses were lost to follow-up. For 37 patients (43 TKAs), death could be documented on file or by a contact with their

family. All died of causes unrelated to their prosthesis within a mean ( $\pm$  SD) period of 4 (2) years post-surgery. None of those patients had been revised before their death. Forty-one patients (9.5%) (61 TKAs) were lost to follow-up because they were unreachable over phone or mail. The mean (SD) time to follow-up for this study group was 7 years (1.5). The Arcom group consisted of 153 TKAs with 40 (26%) men and 113 (74%) women with a mean (SD) age at the time of surgery of 69 (11) years. The mean (SD) BMI was 30 (6.5). The E-Poly group consisted of 250 knees, 73 (29%) men and 177 (71%) women with a mean (SD) age at time of surgery of 68 (10) years. The mean (SD) BMI for this group was 29.5 (6.5). Statistical analysis showed that both groups were similar. Demographic characteristics and their  $p$  values are resumed in Table 1.

### Statistical analysis

No pre-study power analysis was performed since no data were available on the frequency of polyethylene fracture, and therefore, two retrospective groups of adequate size were compared. To ensure the homogeneity of both groups, a Student  $t$  test was used to compare age and BMI. The frequency of the sexes was compared with a Pearson Chi-square test. The statistical study used to compare the frequency of revision and onset of RLL between the two groups was a Pearson Chi-square test. If the frequency of occurrence of a phenomenon was fewer than 5, a Fisher test was favored. As a nonparametric variable, the comparison of the medians provided by the PROMS was compared by a Mann–Whitney test. The program used for the statistical study was IBM SPSS Statistics 20 (SPSS Inc) and the level of significance  $p < 0.05$  for all tests.

## Results

### Revision rate

Ten reoperations (6.5%) were reported in the Arcom group and 11 (4.4%) in the E-poly group, of which only 1 in each group was a revision surgery because of aseptic loosening. Statistical analysis showed no significant difference between the two groups regarding the number of loosening ( $p = 1$ ) or the total number of complications requiring revision ( $p = 0.35$ ). Table 2 shows the diagnosis that led to reoperation. Most cases were second surgeries without removal of components, most often because of falls and trauma. Polyethylene exchange was done both for early postoperative and late haematogenous infections.

### Radiographic analysis

Radiological analysis according to the modified radiographic evaluation system of Bach et al. [25–27] revealed a narrow

**Table 2** Etiology of reoperation

Etiology	Arcom		E-poly	
	<i>n</i>	<i>T</i> (m)	<i>n</i>	<i>T</i> (m)
Aseptic loosening	1	5	1	26
Infection	3	11, 12, 52	4	1, 1, 50, 63
Traumatic	6		5	
Patella fracture	2	1, 18	1	45
Supracondylar fracture	0		1	1
Instability	1	9	0	
Permanent patellar dislocation	1	13	0	
Extensor and MCL disruption	0		1	1
Patellar tendon rupture	0		1	3
Clunk syndrome	1	21	1	16
Iliotibial band syndrome	1	17	1	23
Total	10		11	

*n* Incidence of cases, *t* Time between surgery and revision (months)

**Table 1** Study groups' demographic characteristics

Characteristic	Arcom Mean (SD)	E-poly Mean (SD)	<i>p</i>
Age at surgery	69 (11)	68 (10)	0.25
BMI	30 (6.5)	29.5 (6.5)	0.16
	<i>n</i>	<i>n</i>	
Gender			0.51
Male	40	73	
Female	113	177	

RLL in the tibial implant in 38 cases in the Arcom group and in 44 cases in the E-Poly group. Statistical analysis showed no statistically significant difference between the two groups ( $p=0.82$ ). Only three patients in the Arcom group and two in the E-Poly group showed wide RLLs without a significant difference ( $p=0.68$ ). No RLLs were observed in the femoral and patellar components.

Analysis according to the method of Smith et al. [25–27] showed for the tibial compartment, 40 knees with a physiological RLL in the Arcom group, compared to 46 in the E-Poly group. Statistical analysis showed no significant difference between the two groups ( $p=0.83$ ). Only one pathological RLL was found in the Arcom group. No RLL was observed in the femoral or patellar compartments.

### Patient Reported Outcome Measurements Score analysis and subjective outcome

Statistical analysis of the FJS-12 and KOOS did not show any significant difference between the two groups. The medians obtained and  $p$  values are reported in the attached Table 3. Seventeen out of 153 (11%) Arcom bearings had remaining pain needing so now and then a painkiller compared to 25 out of 250 (10%) of the vitamin E bearings. All were reviewed clinically and radiographically and no aseptic loosening or bearing failure could be observed. Fourteen out of 153 (9%) of the Arcom group had swelling and 27/250 (11%) of the E-Poly group without significant difference.

## Discussion

The main finding of this retrospective study was that no inferiority of the vitamin E polyethylene could be objectivized at a mean of 7-year follow-up with a minimal follow-up of 5 years. No higher incidence of revision, aseptic loosening, fractured bearings, radiolucencies or periprosthetic osteolysis was observed. For the secondary outcomes, no difference was observed in PROM scores or pain and swelling.

This study has several limitations. First, it is a retrospective study with a telephone contact status check-up at latest

follow-up. This means that patients who might be developing polyethylene wear, but were not feeling the early symptoms would not be captured as failures in this study. An important study group was compared here, it would have been difficult to have them all come back for in-person evaluation for study purposes. Most patients told us over the phone they would refuse anyway since they were doing well. Furthermore, this was not an RSA study that would have been capable of detecting early failure [29]. An attempt was made to evaluate the patients to the best of our possibilities with PROM Scores and questions about pain and swelling. Patients with bad scores (lower than published mean scores) or inquiries were asked to come back for a clinical and radiological check-up. No implant loosening was observed in these patients. Second, for the revised patients not the same polyethylene algorithm was applied. The early and late haematogenous infections received a polyethylene exchange, and therefore, the late ones were retrieved from the study follow-up since the polyethylene cannot be considered at same follow-up as their metallic components. The periprosthetic fractures all resulted from a fall and were never spontaneous. Despite the falls, the polyethylenes were not exchanged and in theory could prove later to be damaged. This appeared not to be an issue at the revision surgery neither during this study follow-up. Third, for none of the exchanged polyethylenes, the retrieved bearings were sent for analysis to the company (Zimmer Biomet, Warsaw, US) for analysis of oxidation or early non-macroscopic damage.

Barrack reported a case of early fracture of a tibial bearing in a patient 30 months after arthroplasty [14]. Since it was a Vanguard (Zimmer Biomet, Warsaw, IN, US) type of total knee replacement with a vitamin E-enriched HXLPE, this case attracted our attention since our group was already using this type of bearing for several years before. Two reasons for this early failure have been put forward by the author in their case report. The first cause was the polyethylene thickness of the tibial liner, which was only 10 mm accounting for 6 mm of vitamin E-enriched HXLPE. But according to the retrieval analysis, only 5.1 mm was measured at the lowest point. Bartel et al. have shown that the thinner the tibial implant is, the more stress it undergoes [30]. The second cause was that the patient could have had a collateral ligament imbalance combined with a posterior cruciate ligament insufficiency. The revision was done with a polyethylene exchange with 16 mm thickness and anteroposterior constraint leading to a neutral postoperative alignment. In contrast to this case report of Barrack, this type of complication was not found in this larger series of operated patients. Of course, there is the weakness of a retrospective study with a loss to follow-up of 9.5%. However, all the remaining patients were contacted in person confirming they had not been revised. Furthermore, the good PROM Scores did not reveal coming problems in the near future.

**Table 3** Median outcome scores of PROM

	Arcom	E-poly	$p$
FJS-12	73	78	0.08
KOOS			
Pain	83	86	0.28
Symptoms	82	86	0.71
ADL	78	84	0.10
Sport/Rec	45	48	0.79
QOL	88	81	0.90

In the vitamin E-enriched study group, 57% of patients had received a 10-mm thickness polyethylene without fractures of the bearing at a mean of 7 years. All of the included bearings were also exclusively posterior-stabilized and potentially more at risk for fractures of the post [31, 32].

Aseptic loosening is still the main cause of TKA revision, in theory it could be caused by wear particles that lead to periprosthetic osteolysis and progressive loosening [33, 34]. The objective of HXLPE stabilized by vitamin E is three-fold. Increase resistance to oxidation and wear while retaining the mechanical properties of UHMWPE [8, 35, 36]. Conventional UHMWPE has high mechanical strength, but is subject to wear. The irradiation necessary for its sterilization makes it prone to oxidation and is the cause of a gradual loss of its qualities over time. Cross-linking of polyethylene makes it possible to improve wear resistance, but residual free radicals make it particularly prone to oxidation. Post-radiation thermal treatments used in first-generation HXLPE to eliminate the free radicals are either insufficient or responsible for a significant loss of mechanical properties [5]. The addition of vitamin E as an antioxidant allows the HXLPE to benefit from crosslinking without losing the mechanical properties caused by thermal treatments [37]. Ponzio et al. found in a retrieval analysis of antioxidant-HXLPE lower rates of pitting and scratching [38].

Only one aseptic loosening was observed in each group during this study. The other revisions were for other causes and cannot be considered a failure of the prosthesis. According to Schroer et al., 35.3% of revisions occur during the first 2 years after surgery and 60.2% within 5 years [39]. According to this study, aseptic loosening is not very frequent within both these study groups with a minimal minimum follow-up of 5 years and a mean follow-up of 7 years. Takemura et al. found the same in their study comparing vitamin-E-infused HXLPE with conventional PE at 2 years postoperatively [40].

Peri-prosthetic RLLs are radiolucent zones located between the bone–cement or implant–cement interface [41]. Physiological RLLs appear most often directly after surgery or in the following year and develop during the first 6–12 months. Then, they consolidate, disappear or become pathological; no correlation with an increased rate of revision has been noted for these RLL [27, 42]. Early RLLs are due to osteolysis linked to bone necrosis caused by the heat of the cement, debonding of the cement–implant interface, micro-movements of the bone–cement interface with separation from the implant, allergy to the cement or the presence of polyethylene debris. Pathological RLLs defined as measuring more than 2 mm, are progressive, and have no sclerotic lines. They may appear *de novo* or develop from physiological RLLs within 2 years post-operation. They are linked to a higher rate of revision, especially because of loosening or infection [42].

Wear particles are known to cause an inflammatory reaction by macrophage activation, triggering an inflammatory cascade. The resulting periprosthetic bone resorption is largely responsible for aseptic loosening [43]. Wear particles are the result of different types of knee-specific wear and damage modes. Just as for the hip, abrasion and adhesion wear are found in TKA. However, because of TKA's particular kinetics, which combines anterior–posterior translation, flexion–extension and rotation, bearings mainly undergo delamination wear [44]. Wannomae et al. compared HXLPE vitamin-E delamination resistance with conventional UHMWPE in vitro. Unlike conventional PE, HXLPE showed no signs of delamination even after accelerated aging [45]. Other studies also showed a significant reduction in abrasion and adhesion wear of HXLPE compared to UHMWPE [46, 47]. It was also noted that wear particle oxidation stimulates an inflammatory reaction, hence the HXLPE Vit-E is less affected by this phenomenon [48–50].

There have been concerns about the possible toxicity of vitamin E on surrounding tissues. Although  $\alpha$ -tocopherol is a naturally present element in the human body, some believe that the alterations it undergoes during implant manufacturing and its elution into surrounding tissue after implantation could have local and systemic harmful effects [13]. Wolf et al. studied the effects of these substances and showed that there was no impact on cell proliferation, fibroblast mitochondrial activity or membrane integrity, and no evidence of cytotoxicity or genotoxicity [51]. Bichara et al. studied the effect of wear particles from vitamin E polyethylene on a murine model. They noticed that the wear particles from UHMWPE Vit-E caused less inflammation and osteolysis than standard UHMWPE [52].

## Conclusion

Following the report of the early fracture of a vitamin E-enriched implant, the clinical performance of this type of polyethylene was compared to conventional polyethylene. No articular surface fractures were observed in either group. Frequency of revision for aseptic loosening, radiological analysis and PROM Scores showed no difference between the two groups at medium-term follow-up (minimum 5 years). The benefit with vitamin E-enriched polyethylene being mainly on the implant's lifespan, a prospective comparative study beyond 20–25 years is necessary to show its theoretical superiority.

## Compliance with ethical standards

**Conflict of interest** No funding was received for this study. Samy Ftaita and Aurélie Vanden Berghe declare no conflict of interest. Emmanuel Thienpont declares to be at speaker's bureau for Convatec, KCI, Lima,



Medacta, OrthoSensor and ZimmerBiomet. He receives royalties from ZimmerBiomet.

**Ethical approval** Each author certifies that his institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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