



Case report

Superior rim fracture of a vitamin E-infused highly cross-linked polyethylene (HXLPE) liner leading to total hip arthroplasty revision

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ABSTRACT

This case report looks at the failure of a vitamin E-infused highly cross-linked polyethylene acetabular liner that fractured at the superior rim of the locking mechanism. This calls to question whether there is a problem with the vitamin E-infused product or a flaw in the design of the liner or possibly a combination of the 2. Although there has been discussion of a possible minimum rim polyethylene thickness, there has not been a minimum thickness established. In addition, in the case of offset liners, indentations which are a part of a locking mechanism can cause the minimum rim dimension to be much less than the specified nominal thickness. This case serves as an interesting observation and contributes to the discussion of rim liner polyethylene thickness and minimum rim thickness.

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Introduction

A major historic factor that limits the durability of a total hip arthroplasty is excessive polyethylene wear resulting in periprosthetic osteolysis. Radiation of the polyethylene to a highly cross-linked polyethylene (HXLPE) results in better wear properties than nonirradiated polyethylene [1]. This process leaves residual oxygen-free radicals that left unaddressed will lead to polyethylene oxidation and rapid failure. Currently, there are 3 Food and Drug Administration–approved pathways to address the elimination of these free radicals, and after each of these processes, the products are packaged in an oxygen-free environment. First, subsequent heat treating the irradiated product above its melting point is a proven method to quench all residual free radicals [2]. Unfortunately, this process also results in decreased tensile strength of the material with a possible elevated risk of fracture [3]. Second, sequential annealing below the material melting point decreases the residual free radicals [4]. This maintains the desired polyethylene strength; however, studies show that it is not as effective as remelting in eliminating all residual free radicals. Thus, the concern remains that eventually

oxidation and material failure can still occur. Third, a free radical scavenger is added to the polyethylene during processing. Vitamin E or a derivative stabilizes free radicals more effectively than annealing and eliminates the need for melting of the product [5]. In vitro, there are numerous studies which show that vitamin E-infused HXLPE increases strength and wear resistance in comparison to the polyethylene without additive [6]. However, it is unclear what influence these additives impose in vivo on the strength of the material because no studies have proven efficacy in vivo [7]. In one randomized study, Lindalen et al. [8] demonstrated a low wear of vitamin E-infused HXLPE in 32-mm and 36-mm heads at 2-year follow-up; however, the amount of wear with noninfused HXLPE was not compared.

While the following is not the first reported case of fracture of the vitamin E-infused HXLPE acetabular liner [9], it is important to note that there have been many reported cases of melt processed liners that have also fractured at the superior rim which have been suspected to be due to minimum rim thickness of polyethylene liners. This case report reiterates that polyethylene liners can experience fracture without excessive wear and that there is a need to improve on the current standard.

Case history

The authors of the following case report have had the patient consent to having her data being submitted for publication. A 66-year-old

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Figure 1. Anteroposterior (AP) radiograph of the pelvis made 6 weeks postoperatively showing acceptable position of the components.

woman with a body mass index of 26.67 kg/m² underwent an elective left total hip arthroplasty via a minimally invasive posterolateral approach for the treatment of severe osteoarthritis. She received a 52-mm RingLoc Press-Fit Cup (Biomet, Warsaw, IN) with a 36-mm E-Poly RingLoc acetabular liner (size 23) (Biomet, Warsaw, IN) +3-mm offset MAX-ROM. An 11-mm × 120-mm generation 4 polished cemented femoral stem was lateralized offset with a +3-mm cobalt-chrome head and a type 1 taper was placed (Biomet, Warsaw, IN). Additionally, a 14-mm centralizer was placed. At 6 weeks postoperatively, an anteroposterior pelvis (Fig. 1), which showed the abduction angle to be approximately 45–50°, and a cross-table lateral of the left hip (Fig. 2), which showed the acetabular component to be in 45° of anteversion, were taken.

Surgery and the postoperative course ensued uneventfully until 25 months postoperatively when she presented to the emergency department because of a fall at home where she suffered an anterosuperior dislocation of her left total hip arthroplasty. There was no record of any problems with the patient's total hip before dislocation (Fig. 3). An attempt of closed reduction under conscious sedation was performed in the emergency department and was unsuccessful. The patient was then taken to the operating room where general anesthetic was induced but a stable reduction could not be achieved. The patient was awoken, the dilemma was discussed with her, and consent for an open reduction and possible revision of the implants was granted. At the time of revision, it was discovered that the acetabular component was still in 45° of anteversion which was unchanged from the 6-week postoperative primary total hip arthroplasty (THA) and that the polyethylene liner had fractured superiorly into 2 main fragments (Fig. 4) and then removed. There was no visual evidence of excessive polyethylene wear; however, the polyethylene bearing was not sent for analysis. For the revision procedure, a 56-mm Trident hemispherical shell with 3 dome screws and a 36 X3 neutral polyethylene liner (Stryker, Mahwah, NJ). The cemented stem was found to be loose and revised with a Modular Restoration 21-mm × 195-mm bowed stem with a 23 + 10 cone body and a 36 + 5 cobalt-chrome head (Stryker, Mahwah, NJ) (Fig. 5). Intraoperative cultures were taken and found to be negative. The patient had an uneventful postoperative course and continues to do well at 1-year postsurgery.

Discussion

HXLPE is proven to decrease long-term wear and has become the standard for polyethylene used in total hip arthroplasty. While HXLPE

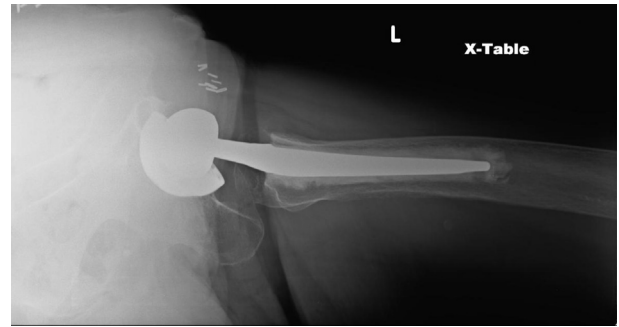


Figure 2. Cross-table lateral radiograph of the left hip 6 weeks postoperatively showing 45° of anteversion of the acetabular component.

did decrease wear, the irradiation necessary for production leaves residual free radicals which when left unaddressed can link with ambient oxygen and lead to predictable polyethylene failure. As noted previously, there are 3 Food and Drug Administration–approved means to decrease and eliminate residual free radicals. One of these is the addition of vitamin E or its derivative, an oxygen scavenger, to the HXLPE following irradiation and processing below the melting temperature of the polyethylene. It is believed that the hydrophobicity of the carbon chain in the vitamin E molecule allows it to diffuse into the polyethylene. After diffusion, the vitamin E molecule uses a hydrogen atom from its –OH group to transfer the free radical off the polyethylene chain. It is thought that if oxygen molecules are introduced to the polyethylene, they will react with the vitamin E molecule and not the polyethylene molecule. This subsequently prevents oxidative degradation of the polyethylene or a decrease in the tensile strength of the material [10]. While in vitro it has been shown that there is increased tensile strength and decreased wear, no study to date has shown vitamin E polyethylene to be superior to noninfused polyethylene in vivo.

While this is the second reported case of fracture of a vitamin E-infused HXLPE acetabular liner, there have been reports on polyethylene liners without vitamin E infusion that have shown rim failure or cracking at the superior aspect of the liner. This calls to question whether there may be a problem with the vitamin

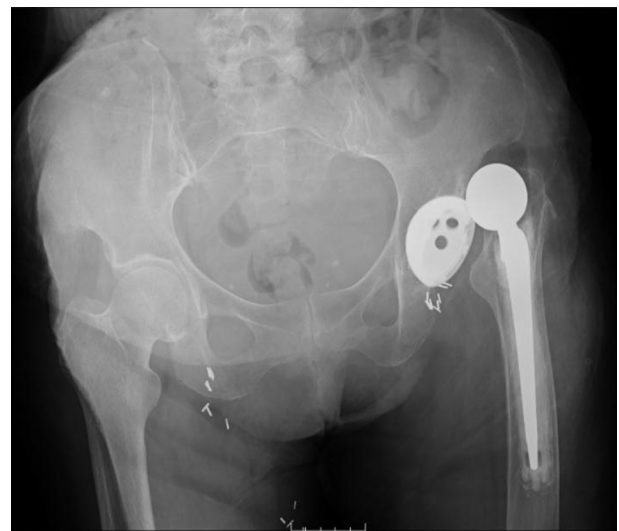


Figure 3. AP radiograph of the pelvis made 25 months postoperatively showing anterior and superior dislocation of the femoral head and was later discovered to be due to polyethylene fracture.



Figure 4. Photograph of fractured polyethylene component at the superior rim into 2 fragments with no visible thinning of the liner.

E-infused product or a flaw in the initial design of the liner or a combination of the 2. Should this size of acetabular liner be used with a locking mechanism? Owing to locking mechanism indentations, there is an even further decrease in minimal thickness at the superior rim of acetabular liners. Material failure was reported by Berry et al. where they looked at 10 cases of polyethylene liner failure in THA with 3 different manufacturers. They found that all 10 liners that fractured had thin polyethylene at the rim with a minimum thickness of <5 mm. They believed that having a thin polyethylene rim was a contributing factor that could increase the risk for catastrophic failure in polyethylene liners. In a case report by Waewsawangwong et al. [11], they reported that the minimum thickness of HXLPE at the rim in addition to mechanical properties of HXLPE, a more vertical cup and the use of a large femoral head all played a role in fracture of the superior rim of the liner in their case. However, they end their report by stating that they believe that there should be a minimum rim liner thickness and that they would recommend at least 6 mm to minimize failure. In a study by Tower et al. [12], they suggested that the minimum thickness at the equatorial region was the critical dimension with respect to liner failure. In their report, all 4 liners that cracked at the superior rim had a minimum rim thickness of <4 mm. Additionally, they state that in offset liners, the minimum rim dimension can be much less than the specified nominal thickness especially with indentations that are part of the locking mechanism. It is important to note that in the report by Bates and Mauerhan [9], there was also failure of the superior aspect of the vitamin E-infused polyethylene liner and that there was a minimum thickness of 4.8 mm in their case. In the current study, the minimum polyethylene thickness for the offset liner dome was 5.8 mm, at 45° was 4.8 mm, and at the rim locking mechanism was 3 mm. While there was no visual evidence of excess wear, the bearing was not sent for analysis and we can not determine what the wear was at the site of fracture. From Yamaguchi et al. [13], the mean wear vector in the coronal plane is

8.1° laterally and this in combination with the decreased thickness at the rim could have contributed to the fracture.

While the 2 most recent cases are not sufficient in the amount of information to support that there should be a minimal thickness of the superior rim of E-poly liners, it does establish a probable cause of polyethylene fracture in this case. While polyethylene thickness is a potential cause, there were other confounding factors in this case which limits our ability to establish a definitive cause of fracture. First, there was the traumatic event which ultimately led to dislocation and the discovery of the fractured polyethylene liner. Second, the patient was at added risk of polyethylene failure because it was a 36-mm liner with a 52-mm cup. Third, the acetabular component had approximately 45° of anteversion after primary THA which is greater than optimal and could contribute to failure.

This case serves as a reminder that predictably successful implant longevity comes from appropriate indications for the procedure, a well-positioned implant, compliance by the patient in the perioperative time frame to allow sufficient healing and rehabilitation, and proven materials and product designs. Until sufficient reports of this material's failure are described in other patients with no other confounding factors, we consider this case an interesting observation.

Summary

This case serves as an interesting observation and contributes to the discussion of rim liner polyethylene thickness and minimum rim thickness. In this case, there was a failure of a vitamin E-infused HXLPE acetabular liner that fractured at the superior rim of the locking mechanism. This calls to question whether there is a problem with the vitamin E-infused product or a flaw in the design of the liner or possibly a combination of the 2. While there has been discussion of a possible minimum rim polyethylene thickness, there has not been a minimum thickness established. While offset liners have indentations as a part of a locking mechanism, this can cause the minimum rim dimension to be much less than the specified nominal thickness. While many claim that polyethylene thickness at liner locking mechanisms is not compromised, this case demonstrates a fracture of the superior rim of the locking mechanism in a HXLPE liner.



Figure 5. AP radiograph of the pelvis made 6 weeks postoperatively following revision of hip components.

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