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Fractures of a Single Design of Highly Cross-Linked Polyethylene Acetabular Liners: An Analysis of Voluntary Reports to the United States Food and Drug Administration

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ABSTRACT

Polyethylene liner fracture is a risk associated with the use of highly cross-linked UHMWPE. We performed a review of the voluntary reports of fractured liners to the US Food and Drug Administration to determine if any risk factors could be identified. There have been 74 reports of fractured Trilogy, Longevity liners to the US Food and Drug Administration since 1999. Most cases utilized small acetabular shells (≤54 mm) combined with large diameter heads (≥36 mm). Liners less than 7 mm thick at the weight bearing or 4.8 mm thick at the rim should be used with caution. At revision surgery, malpositioned shells should be revised and the use of a thin liner should be avoided.

Over the past decade, there has been an increase in the use of highly cross-linked ultra high molecular weight polyethylene (HXLPE) as a bearing surface for total hip arthroplasty. Cross-linking processes were developed to improve the resistance of conventional polyethylene to abrasion and wear. Wear reduction has been demonstrated in vitro [1–3] and in vivo [4–6]; however, this comes at the expense of compromised mechanical properties, including brittleness and decreased fracture toughness. Despite these effects, there have been few clinical reports of unexplained fractures of HXLPE liners [7–12].

The purpose of this study is to review the voluntary reports of fractured acetabular liners to the US Food and Drug Administration and discuss the findings with an analysis of a representative case from our institution as well as the currently available literature.

Analysis of voluntary reports to the Food and Drug Administration.

Methods and Materials

The United States Food and Drug Administration (FDA) maintains a database with reports of adverse events involving medical devices (MUADE – Manufacturer and User Facility Device Experience). The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. Searches on medical devices which may have malfunctioned or caused serious injury can be performed based on the following parameters: product problem (mode of failure), product class, brand name, manufacturer, event type, 510 K number, PMA number, and product code [13].

A search was carried out on April 26, 2013 with no time limit using following criteria: brand name "Longevity", and manufacturer "Zimmer". All 420 reports of adverse events listed in the search were reviewed for those that reported fractured, broken or cracked Longevity liners. Each record contains information (when available) on the following categories: the liner catalog number, device problem (fracture, break, etc), event date, need for re-operation, event description by the person submitting the report, and a manufacturer narrative, which is based on the material available (ie: narrative, radiographs, photographs and specimen). After careful review of 420 records of adverse events, 74 records that reported on the unequivocal fracture of a non-constrained, non-offset Longevity liner were analyzed. In all 74 cases, the patients required revision surgery.

Results

The catalog number, available for 70 of 74 records, and review of the narrative allowed identification of the product, material, geometry (standard, 10 or 20 degree elevation), liner size and femoral head size. Manufacturer's information was used to calculate the polyethylene thickness at 45 degrees from the pole and the polyethylene thickness at the rim for 72 of the 74 broken liners reported to the FDA. In addition, we recorded when present: associated traumatic events like fall or dislocation, inclination, version and time in situ.

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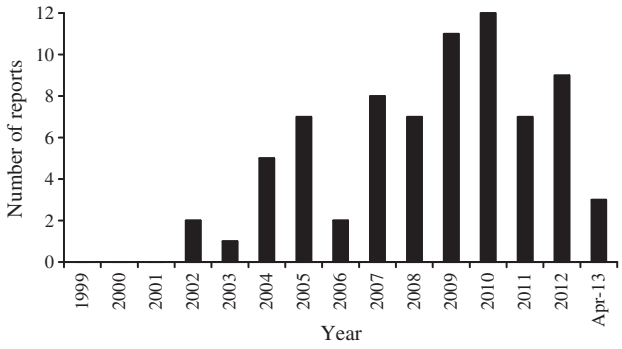

Fig. 1. Histogram demonstrating the increasing number of reports of fractured or broken Longevity HXLPE liners per year to the US FDA.

The number of reports of broken or fractured Longevity liners has increased since the introduction of Longevity to clinical practice in 1999 (Fig. 1). The average time in situ was 27 months (range: 1 to 96). The polyethylene thickness in the weight-bearing portion of the liner was ≤6 mm in 59 of 72 cases and ≤7 mm in 68 of 72 cases. Similarly, the polyethylene thickness at the rim, which is the area that fractured in the majority of the cases was ≤3.7 mm in 61 of 72 cases and ≤4.7 mm in 70 of 72 cases (Table 1). In an analysis of 44 reports in which polyethylene thickness in the weight-bearing area and at the rim, and time in situ of the implant were available, no correlation was detected between the material thickness and the time in situ ($r = -0.17$) (Fig. 2).

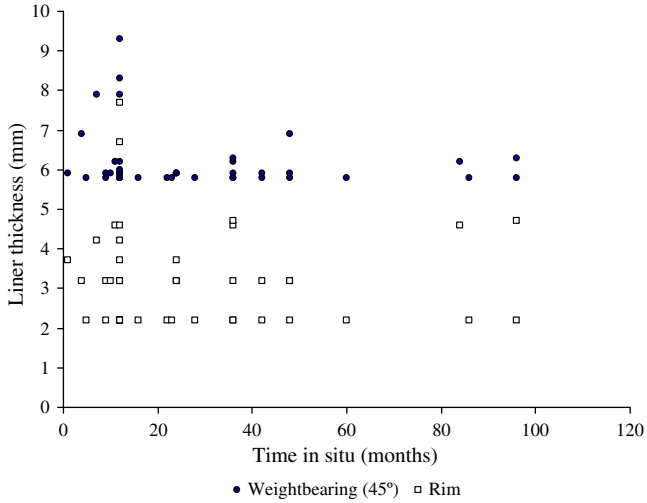

Fig. 2. Plot chart demonstrating the time in situ and polyethylene thickness in 44 broken Longevity liners reported to the FDA ($r = -0.17$).

Case Analysis

A 62-year-old female underwent a right total hip arthroplasty in 2008 at an outside institution utilizing a 52 mm Trilogy Trabecular Metal acetabular shell and 36 mm standard Longevity polyethylene liner (Zimmer, Warsaw, IN, USA), combined with a non-cemented, Kinectiv modular femoral stem (Zimmer, Warsaw, IN, USA) and a 36 mm cobalt chromium head. The patient's postoperative recovery was complicated by a single episode of dislocation that occurred 8 months postoperatively and required closed reduction.

Five years postoperatively (one month prior to consultation at our institution) the patient had a sudden onset of groin pain associated with clicking, occasional creaking, and squeaking coming from the right hip. Physical exam demonstrated a coxalgic gait, and the right hip had a painful and limited range of motion. Plain anteroposterior radiographs of the pelvis demonstrated eccentric position of the right prosthetic femoral head within the acetabular component. Also noted were several small fragments of metallic debris inferior to the acetabular component (Fig. 3). Deep joint infection was ruled out following a negative workup including a normal erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and fluoroscopic guided joint aspiration.

Differential diagnoses included: hip dislocation, severe polyethylene wear, and fracture/dislodgement of the liner [14]. Radiographs in AP, lateral and Judet views ruled out dislocation of the femoral head. The inclination of the acetabular component was 56 degrees. In addition, a CT scan of the hip demonstrated 20 degrees of acetabular anteversion and 17 degrees of femoral anteversion [15].

Table 1
Analysis or Reports of Fractured Longevity Liners to the Food and Drug Administration.

Variable		n	Unknown
Head size (mm)	28	4	2
	32	13	
	36	52	
	40	3	
Cup size (mm) [a]	48	7	2
	50-52-54	43	
	56	14	
	58	6	
	60	1	
	62	1	
WB PE thickness	≤6 mm	59	2
	>6 mm	13	
Rim PE thickness	≤4.6	68	2
	>4.6	4	
Geometry	Standard	37	3
	10	31	
	20	3	
Hx of fall		6	
Hx of dislocation		18	

[a] Longevity polyethylene liners are the same for 50, 52 and 54 mm shells. (WB, weight bearing. Geometry refers to whether there is an elevated rim on the liner. Standard refers to liners without an elevated rim, 10 refers to a 10° elevated rim, and 20 refers to a 20° elevated rim.)

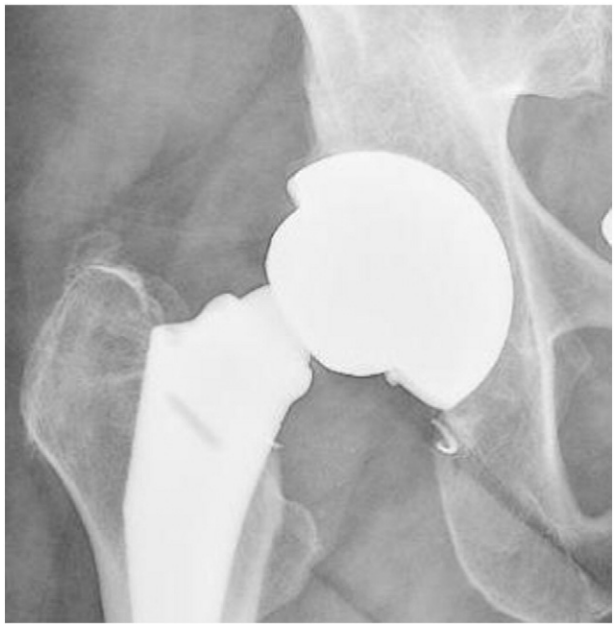

Fig. 3. Antero-posterior radiograph view of the right hip shows a well fixed, vertically oriented acetabular component. There is eccentric positioning of the femoral head and fragments of the locking ring are present in the inferior portion of the cup.