

Brief communication

Early failure of a modern moderately cross-linked polyethylene acetabular liner

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ABSTRACT

Modern polyethylene components for total hip arthroplasty have shown excellent long-term wear properties. However, among 204 primary total hip arthroplasty procedures performed by one surgeon using the Exactech Connexion GXL Liner, we identified 5 cases of severe polyethylene wear and osteolysis which occurred within 5 years of the index surgery. Among the 5 cases, all patients had a size 36 head with an acetabular component from size 52 to 56 mm. All patients had a UCLA activity scale score of at least 6 at the time that the osteolysis was detected. The average wear rate was 0.265 mm \pm 0.207 mm per year. This review of 5 cases of catastrophic early polyethylene wear demonstrates a concerning trend with the use of the Exactech Connexion GXL liner. Further investigation is warranted to evaluate material characteristics which may have caused this accelerated wear and to prevent recurrences of this complication in the future.

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Introduction

Osteolysis related to polyethylene debris is a well-documented cause of late revision total hip arthroplasty (THA) [1]. However, modern highly cross-linked polyethylene has shown favorable wear properties in THA and is associated with longer survival compared to conventional polyethylene [2].

Despite these benefits, there have been reports of early failure of highly cross-linked polyethylene acetabular liner components due to catastrophic fracture of the liner as well as initiation of cracks in the liner in the early postoperative period [3,4]. Furthermore, Tower et al. [5] showed that highly cross-linked polyethylene was more susceptible than conventional polyethylene to fatigue damage, particularly with an increased cup abduction angle.

Because of the concern for polyethylene fracture, some implant companies chose to use “moderate” cross-linking of polyethylene acetabular components to balance the benefits of highly cross-linked polyethylene for wear rates with the drawback of component fracture. The Exactech Connexion GXL liner (Exactech, Inc.,

Gainesville, FL) is a vacuum-packaged, moderately cross-linked non-vitamin E liner which was manufactured using 2 irradiation doses of 25 mGy for a total irradiation dose of 50 mGy.

The senior author performed 204 primary total hip arthroplasty procedures over a 2-year period using the Exactech Connexion GXL liner. Among this cohort, we identified 5 cases of severe polyethylene wear and osteolysis which occurred within 5 years of the index surgery. The purpose of this investigation was to perform a comprehensive review of these 5 cases in order to understand the early failure mechanism.

Material and methods

Medical records including operative reports, office notes, and postoperative imaging were retrospectively reviewed. All 5 cases were initially performed through a direct anterior approach. The implants used, in addition to the Exactech Connexion GXL liner, were a Novation Crown Cup (Exactech), Novation Element or Alton cementless femoral stem (Exactech), and Biolog Delta femoral head (Exactech). Cup sizes ranged from 52 mm to 56 mm and all cases utilized a 36-mm femoral head. Lot numbers for the liner used in each of the 5 cases were different. Radiographs were examined for linear wear using Roman V 1.70 software (Institute of Orthopaedics, Oswestry, UK), which has been used in prior studies to evaluate polyethylene wear in total hip arthroplasty [6]. Before

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revision surgery, all patients were evaluated for infection using history, physical examination, and laboratory studies (sedimentation rate and C-reactive protein). Laboratory values for all 5 patients were within normal limits.

All 5 cases had undergone revision by the time of this publication. For each of these cases, the retrieved polyethylene implant was evaluated and photographed. The activity level of each patient at the time of discovery of early osteolysis was evaluated using the UCLA Activity Score [7,8].

Results

All 5 patients presented with hip pain after a number of years of excellent function free of pain. All radiographs demonstrated linear wear with acetabular and/or femoral osteolysis (Fig. 1). MRI showed significant synovitis with associated osteolysis in every case. All patients were men with a high activity level, and an average UCLA activity score of 7.4 (Table 1). Socket abduction angle was between 38° and 44° in all cases. Average linear wear measured was 0.265 ± 0.207 mm/y and on average a total of 1.18 mm during the follow-up period.

Each of the identified patients underwent revision of head and liner, synovectomy, debridement of the osteolytic lesions and grafting with crushed cancellous bone. Each socket and stem were clinically and radiographically well-fixed. Retrieved liners had grossly visible and palpable wear but no discoloration suggestive of oxidation (Fig. 2). Liners were revised to the Novation XLE vitamin E polyethylene (Exactech) of the same size.

Discussion

The 5 cases included in this investigation show unusual early excessive polyethylene wear from a modern moderately cross-linked acetabular liner. The exact cause of this early wear is

Table 1
Cases.

Number	Age	Follow-up time (y)	BMI	Cup size	Cup abduction (degrees)	UCLA score	Linear wear (mm/y)
1	60	4.8	29.8	52	39	7	0.203
2	74	3.9	28.5	54	40	9	0.632
3	31	5.0	27.4	52	40	6	0.175
4	59	5.3	47.5	56	44	7	0.176
5	63	5.0	35.4	52	38	8	0.137

unknown. We believe there may have been a variation in the processing of at least a batch of GXL polyethylene liners that created a predisposition for early wear, as all cups were implanted in an appropriate abduction angle and the patients did not have specific risk factors for early failure other than high activity level. To our knowledge, this is the first report to document the early failure of this specific polyethylene liner, which is still currently being sold. This finding has been reported to the company.

Moderately cross-linked polyethylene acetabular liners have shown favorable wear rates compared to conventional polyethylene, both in clinical trials and in biomechanical models [6,9]. The purported benefits of moderate cross-linking include decreased wear compared to conventional polyethylene, along with increased fracture toughness compared to highly cross-linked polyethylene [5,9]. However, the radiographic wear rates in this study were markedly higher than prior studies reporting on either highly cross-linked or conventional polyethylene. The mean linear wear rate among these 5 cases was 0.265 mm/y. In comparison, McCalden et al. [10] reported a wear rate in the first 5 years after THA of 0.003 mm/y for highly cross-linked polyethylene and 0.051 mm/y for conventional polyethylene. The wear rates among these 5 cases were several-fold higher than among previously reported polyethylene components.

Although this investigation raised our concern about the Exactech Connexion GXL liner, further study in this area is warranted. A larger clinical series of this implant may further demonstrate the benefits and drawbacks of this moderately cross-linked polyethylene liner. Analysis of the retrieved polyethylene components would be beneficial to understand material characteristics which may adversely affect the longevity of the liner, and this is currently underway for these cases. It is unclear at this point whether this problem affected all liners in this series or only specific batches due to potential variation in manufacturing techniques.

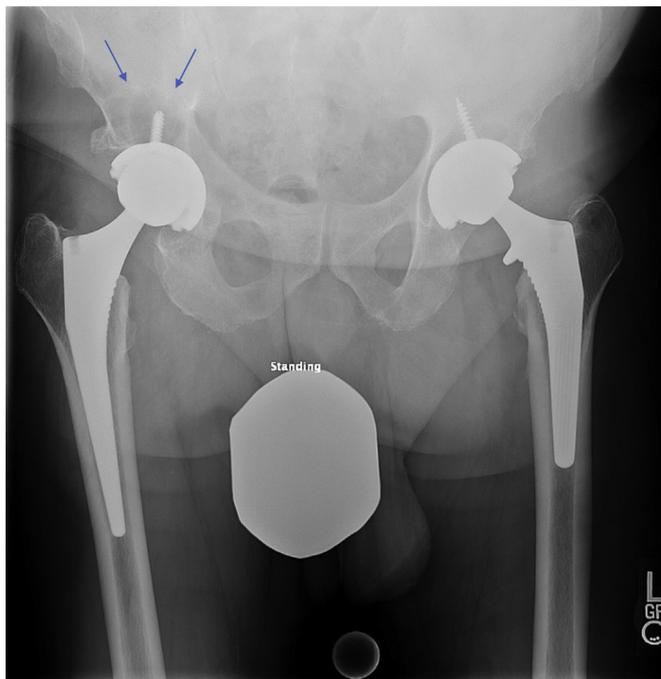


Figure 1. Example of osteolysis. Anteroposterior (AP) pelvis radiograph demonstrates bilateral total hip arthroplasty. The left hip appears well fixed. The right hip contains the Exactech Connexion GXL liner. There is extensive osteolysis of the supra-acetabular region with asymmetric polyethylene wear, as indicated by the arrows.

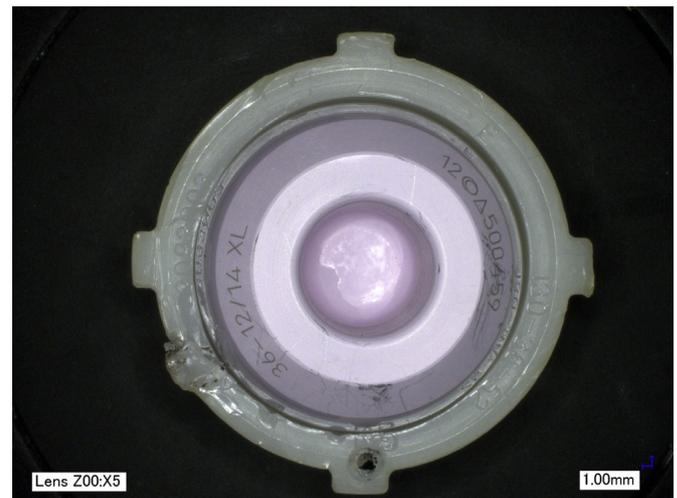


Figure 2. Retrieved polyethylene component. The retrieved polyethylene and ceramic head show that the head no longer fits concentrically within the polyethylene due to severe asymmetric wear.

Conclusion

This review of 5 cases of catastrophic early polyethylene wear demonstrates a concerning trend with the use of the Exactech Connexion GXL liner. Further investigation is warranted to evaluate material characteristics which may have caused this wear and to prevent recurrences of this complication in the future.

Conflict of interest

Amar S. Ranawat, MD, reports royalties from DePuy, A Johnson & Johnson Company Stryker; Speakers bureau/paid presentations for DePuy, A Johnson & Johnson Company Mako, Convatec, Stryker; Paid consultant for Arthrex, Ceramtec, DePuy, A Johnson & Johnson Company; Stock for Conformis, Strathspey Crown; Research support from DePuy, A Johnson & Johnson Company, Stryker; Medical/Orthopaedic publications editorial/governing board for *Journal of Arthroplasty*, *CORR*, *JBJS*; Board member/committee appointments for a society, American Association of Hip and Knee Surgeons (AAHKS), AAOS, Eastern Orthopaedic Association (EOA), The Hip Society, The Knee Society.

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All other authors declare no potential conflicts of interest.

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