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Polyethylene Liner Dissociation Is a Complication of the DePuy Pinnacle Cup: A Report of 23 Cases

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Abstract

Background Polyethylene liner dissociation is a rare but catastrophic event in total hip arthroplasty (THA), and certain implant designs are known to be at greater risk. Although the DePuy Pinnacle (Warsaw, IN, USA) modular acetabular construct has an excellent record of fixation and wear, an unexpectedly high number of liner dissociations has been noted.

Questions/purposes The purposes of this study were (1) to characterize the clinical parameters observed in a large group of patients who have experienced liner dissociations with the DePuy Pinnacle acetabular component; (2) to describe the radiographic findings in this group of patients; and (3) to calculate a minimum frequency of this complication.

Methods Since 2001, 23 patients with previously well-functioning THAs presented with sudden atraumatic polyethylene liner dissociation at four separate institutions. These THAs were performed between 2001 and 2013. Eight different arthroplasty specialists had performed the index hip arthroplasties using the DePuy Pinnacle acetabular component with a polyethylene liner. Polyethylene failures were evaluated for liner type and radiographic cup position. For three of the surgeons who contributed cases, institutional registries allowed the calculation of the number of components of this type that they used during the period in question, which provided a conservative estimate of the frequency of this type of failure.

Results All 23 liner failures occurred atraumatically in previously asymptomatic THAs at a mean of 48 months (range, 3–138 months). Patients characteristically reported a new and sudden onset of discomfort with audible,

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
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reproducible squeaking. Surgical inspection of dissociated liners demonstrated displacement of polyethylene with shearing of the peripheral locking tabs. Radiographic evaluation demonstrated that 14 cups were well positioned and nine cups were malpositioned outside the so-called safe zone. Conservative estimates of the frequency of this complication from the three surgeons' practices whose institutional registries allowed calculation of the lowest possible frequency were 0.32% (six of 1888), 0.77% (three of 391), and 0.82% (three of 367).

Conclusions With this report of 23 additional liner dissociations, we suggest that surgeons should be aware of the problem and take extra precautions when using this implant to ensure locking mechanism integrity at the time of surgery. We caution that the frequency of liner dissociation may be higher than previously reported.

Level of Evidence Level IV, therapeutic study.

Introduction

Although the modular DePuy Pinnacle acetabular component (Warsaw, IN, USA) is commonly used, this implant has been associated with catastrophic polyethylene liner disassociations. The frequency with which this complication occurs is unknown, but to our knowledge, there are 16 reported liner failures in four publications [3, 5, 9, 10], and a 2008 public database described a collection of 41 Pinnacle liner disassociations [8, 10]. In 2013, the National Joint Registry of England and Wales reported a 0.04% polyethylene liner disassociation rate with a 0.01% liner fracture rate in 35,522 hips with a 97% survivorship of metal-on-polyethylene hips and a 98% survivorship of ceramic-on-polyethylene hips. The Australian and American Joint Replacement Registries have reported similar survivorship (Table 1). Although the potential for a catastrophic acetabular locking mechanism and liner disassociation failure exists in all modular acetabular designs, the literature suggests that only the current Pinnacle design and the historic Harris Galante (Zimmer, Warsaw, IN, USA) 1 and 2 cups are at greater risk for this unusual complication [2, 16, 19].

Table 1. Published reports of Pinnacle polyethylene liner failures

Year	Number of cases	Source
2008	41	FDA public database describes a collection of liner dissociations; MAUDE database [8, 10]
2009	1	First published case of liner dissociation by Mesko [10]; *J Arthroplasty*
2012	4	Gray et al. [3]; *J Bone Joint Surg*
2012	1	Mayer et al. [9]; *Orthopedics*
2013	10	Jameson et al. [5]; National Joint Registry for England and Wales reports a 0.04% dissociation rate in 35,522 hips; *J Bone Joint Surg Br*

In four recent cases of spontaneous disassociation, Gray et al. [3] attributed failure of the Pinnacle to component malposition and exaggerated impingement of the polyethylene in offset, face-changing liners. Two other papers, however, also noted a total of two similar liner disassociations in the absence of these proposed risk factors [9, 10]. The authors could not identify mechanisms of causality but noted that retrieval findings showed a compromised locking mechanism. It has also been suggested that prominent screw heads could contribute to the locking mechanism failure, but many of these cases did not have screw fixation.

We therefore sought to (1) characterize the clinical parameters observed in a large group of patients who have experienced liner dissociations with the DePuy Pinnacle acetabular component; (2) describe the radiographic findings in this group of patients; and (3) to calculate a minimum frequency of this complication.

Materials and Methods

Between 2007 and 2014, eight surgeons treated a total of 25 liner dissociations; one surgeon with two dissociations chose not to participate, leaving 23 locking-mechanism failures available for this retrospective study. These THAs were performed between 2001 and 2014 at four hospitals (Providence Saint John's Hospital, Santa Monica, CA, USA; Lahey Clinic Foundation, Burlington, MA, USA; Michigan Orthopaedic Center, Lansing, MI, USA; and Penn Presbyterian Medical Center, Philadelphia, PA, USA). For three of the surgeons at three of those centers who contributed cases, institutional registries allowed the calculation of the number of components of this type that they used during the period in question, which provided for a conservative estimate of the proportion of patients experiencing this failure (because some patients who were lost to followup may have had the complication, the actual risk could be higher than estimated here).

There were 15 Pinnacle liners with neutral designs and one lipped design, at three hospitals, and the remaining seven liners were +4-mm offset with 10° face-changing geometry at the fourth hospital. Retrieved implants underwent gross visual inspection by the operative surgeons at the time of revision for patterns of wear, impingement, and fracture.

Radiographs were reviewed by the operative surgeon. All cups had adequate radiographs for analyses. Radiographic cup stability was determined by the method of

Table 2. Patient demographics and radiographic liner configurations at the time of presentation

Patient number	Age at index procedure (years)	Gender	Time in situ (months)	Liner type	Abduction angle (degrees)	Anteversion angle (degrees)	Head/liner size (mm)	New components
1	74	F	18	Neutral	46	22	32	36-mm metal liner
2	63	M	59	Neutral	45	20	28	Polyethylene liner
3	74	M	102	Neutral	44	17	28	Polyethylene liner
4	79	M	22	Neutral	43	13	32	Polyethylene liner
5	65	F	128	Neutral	45	21	28	Polyethylene liner
6	79	M	138	Neutral	55	15	28	Polyethylene liner
7	54	M	40	Neutral	40	25	28	Polyethylene liner
8	76	M	3	Neutral	48	21	36	36-mm metal liner
9	72	F	119	Neutral	44	22	28	Polyethylene liner
10	59	F	70	Neutral	30	25	28	Polyethylene liner
11	76	M	23	Neutral	45	20	32	36-mm metal liner
12	69	M	51	Neutral	45	20	28	36-mm metal liner
13	60	M	121	Neutral	45	20	28	shell/36-mm polyethylene liner
14	61	M	19	Neutral	42	25	36	Shell/polyethylene liner
15	33	M	27	Lipped	50	35	36	Shell/(+4) neutral liner
16	68	M	80	(+4) neutral	40	41	28	Shell/polyethylene liner
17	58	F	10	(+4) 10° face-changing	54	24	32	Shell/(+4) 10° face-changing
18	71	F	3	(+4) 10° face-changing	51	22	36	Shell/(+4) 10° face-changing
19	52	F	34	(+4) 10° face-changing	60	23	36	Shell/(+4) 10° face-changing
20	32	F	3	(+4) 10° face-changing	55	0	32	Shell/(+4) 10° face-changing
21	52	F	20	(+4) 10° face-changing	44	20	32	(+4) 10° face-changing
22	84	M	8	(+4) 10° face-changing	46	−5	36	(+4) 10° face-changing
23	74	F	12	(+4) 10° face-changing	54	24	32	(+4) 10° face-changing

F = female; M = male.

Tompkins et al. [17] and radiographic stem fixation was assessed by the method of Engh et al. [1]. Radiographic cup position was calculated by the method of Lewinnek et al. [6] (Table 2).

Results

Clinical Parameters

All 23 patients had well-functioning THAs before dissociation. No patients reported trauma or injury before the onset of symptoms. Patients characteristically reported a new and sudden onset of discomfort with audible, reproducible squeaking. The mean time in situ was 48 months (range, 3–138 months). Radiographs consistently demonstrated internal subluxation of the head superiorly within the cup (Fig. 1). Intraoperative findings consistently documented well-fixed acetabular and femoral implants. However, the polyethylene liner often was found to have displaced by rotating away from its original position (Fig. 2), leaving the femoral head prosthesis in direct contact with the inner metal shell of the acetabular cup (Fig. 3).

The femoral head thus articulated with the inner metal shell to create the clunking and squeaking sensation

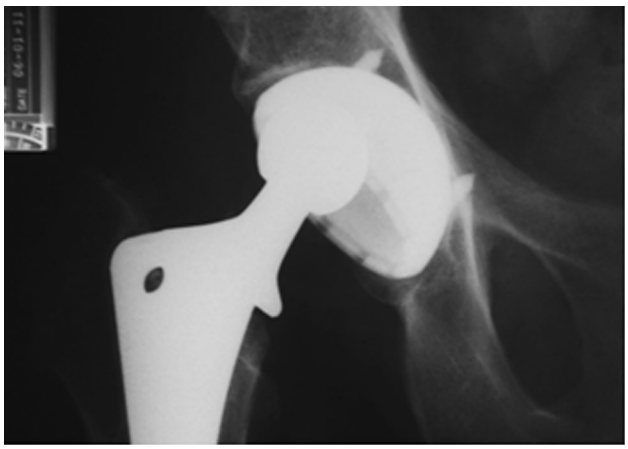

Fig. 1 Diagnostic radiographs revealed migration of the femoral head within the cup.

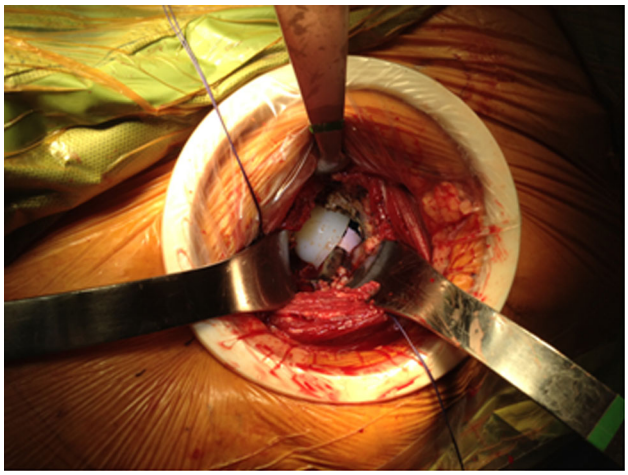

Fig. 2 Intraoperative findings showed the liner had displaced resulting in direct contact with the femoral head with the inner metal shell.

described on presentation by patients. Gross surgical inspection of the liner itself typically demonstrated fracture of the three antirotation locking tabs at the periphery of the polyethylene rim. Soft tissues were found to be without obvious inflammation in all but one hip. This hip demonstrated extensive tissue metallosis after a 3-month delay in revision resulting from medical comorbidities.

Radiographic Findings

All cups and stems were well fixed radiographically according to the methods of Tompkins et al. [8] and Engh et al. [1]. According to the recommendations of Lewinnek et al. [6], 14 cups were well positioned and nine cups were malpositioned outside the so-called safe zone. Well-positioned cups were defined as cups that had both abductions and anteversions within the safe zone. The mean abduction

Fig. 3 Ex situ model showing direct contact of femoral head prosthesis with the inner metal shell as a result of liner subluxation.

of all 23 cups was 47° (range, 30°–60°) and the mean anteversion was 20° (range, −5° to 35°). The mean abduction of the well-positioned cups was 43° (range, 30°–48°) and the mean anteversion was 21° (range, 13°–25°). Of the nine cups that were well malpositioned, six were overabducted, two were overanteverted, and two were underanteverted. There no malpositioned cups that were underabducted. The mean abduction of the malpositioned cups was 55° (range, 51°–60°). The mean anteversion for the malposition cups that were overanteverted was 38° (range, −35° to 41°). The mean anteversion for the malposition cups that were underanteverted was −2.5° (range, 0° to −5°).

Conservative Estimate of the Frequency of Dissociation

Conservative estimates of the proportion of patients experiencing this complication from the three surgeons' practices whose institutional registries allowed calculation of the lowest-possible proportions of patients experiencing liner dissociation were 0.32% (six of 1888), 0.77% (three of 391), and 0.82% (three of 367).

Discussion

Finite element analyses suggest a correlation among locking mechanism design, pullout strength, and the risk of liner disassociation. This laboratory finding was historically supported by examining clinical failures of first-

generation locking mechanisms in the early Harris Galante 1 (Zimmer) cup [16, 19]. The relatively fragile locking tines and liner-cup mismatch of the Harris Galante cup led to an unusually high number of failures not seen in other designs. Similarly, the DePuy Pinnacle has also demonstrated in the laboratory a pullout strength that is weaker than its prior designs [11, 14, 18]. The clinical correlation of this is now apparent. We report 23 cases of liner dissociation with this acetabular component, and in the practices of three of the surgeons in this series whose institutional registries permitted a conservative estimate of the frequency of this complication, it was between 0.32% and 0.82% (six of 1888 to three of 367).

This study has several important limitations. First, the conservative estimate of the frequency we report is the lowest-possible proportion of patients experiencing this complication, because some patients who were lost to followup may have had the complication treated elsewhere. The actual likelihood of this complication may thus be higher than estimated. Second, surgeon-specific error is possible but seems unlikely with seven different surgeons reporting the problem. Two of the surgeons have since stopped using the device. Surgeons who continue to use the device should be careful to correctly seat the liner, clear soft tissue debris, and check initial liner stability. Alternatively, the liners may have failed for technical reasons. Initial liner malseating or soft tissue interposition at the liner-cup interface may have compromised liner stability. Prominent screw heads have also been implicated as a contributing factor to liner disassociation. However, these are risks for all modular designs, and the high proportion of patients experiencing the complication appears to remain unique to the DePuy Pinnacle acetabular cup.

In the early 2000 s, a series of changes to accommodate a choice of bearing modularity were made to the inner geometry of the new DePuy Pinnacle design [13]. The locking ring and rotation tabs were replaced with a taper-lock mechanism that could accept polyethylene, metal, or ceramic. The outer geometry of the liner changed from an onset design to an inset design with six peripheral locking tabs. Importantly, the nature of the polyethylene also changed. The conventional polyethylene was replaced with a highly crosslinked material irradiated to 50 kGy that improved wear but lowered mechanical strength [4, 15]. This combination of changes to cup geometry, peripheral liner shape, and material strength may be responsible for the relative weakening of the locking mechanism and the correlative increase in reported liner failures. Although a taper-lock mechanism may be sufficient for hard bearings, it may become insufficient for the mechanically softer highly crosslinked polyethylene because it rounds out over time (Fig. 4).

Impingement is likely to be a major factor in mechanical failure. Understandably, Pinnacle liner disassociations are

Fig. 4 A taper-lock mechanism may cause the peripheral tabs of a polyethylene liner, unlike the alternate hard bearings, to round over time.

previously reported in cases of cup malposition [3], and indeed malposition may have been a risk factor in nine of these failures. However, component impingement may take place even in well-positioned cups. Although 14 cups in this series were positioned within the so-called safe zone, one prior report found impingement in 60% of well-functioning cups [7], many of which were also well positioned. Thus, the ability to tolerate the mechanical strains of impingement should be built into current designs.

Although all polyethylene liners are subject to impingement, most other designs do not disassociate as frequently. As noted, we report a very conservative estimate of the frequency of liner failure that ranges from 0.32% to 0.82%. The British registry reported a rate of 0.1% for modular DePuy Pinnacle cups [5].

No liner may be able to resist mechanical failure in situations of excessive impingement; however, well-designed cups and locking mechanisms should be able to resist liner disassociation. The manufacturer should consider a design change. The DePuy Duraloc cups improved the strength of the locking mechanism seen in mechanical testing by increasing the polyethylene thickness, adding interior antirotation tabs, and including a Dynamic Locking Ring. Except in one case of locking ring fatigue fracture, no other cases of liner disassociation were identified [12]. If surgical technique is a risk factor for failure, then the design is too technique-sensitive. The cup design should allow for easy insertion without risk of dissociation failure. The manufacturer recommends acetabular revision in cases in which metal-on-metal burnishing is observed, and we believe revision should also be considered when there is acetabular component malposition. Although the benefits of modularity are clear, the locking mechanism and material properties of the liner need to be sufficiently robust to withstand the cyclical strain of impingement. In this study,

we report 23 failures of DePuy Pinnacle polyethylene liner dissociations at four separate institutions. We suggest that surgeons should be aware of the problem. We suggest that the frequency of liner dissociation with this implant may be much higher than previously believed. We suggest that all polyethylene Pinnacle liners be tested for locking mechanism integrity at the time of implantation and that visual inspection of the entire rim of the acetabular component should be performed. If screw fixation is used for acetabular shell fixation, the screw heads should be seated below the interface with the plastic shell.

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