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Case report

Pinnacle polyethylene liner dissociation: a report of 3 cases

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ABSTRACT

We describe 3 cases of DePuy Pinnacle polyethylene dissociations, their presentations, and treatment. A 34-year-old female with arthritis secondary to dysplasia, a 51-year-old male with avascular necrosis of the femoral head, and a 57-year-old female with osteoarthritis were treated with total hip arthroplasty. Acute nontraumatic polyethylene liner dissociations occurred at 31, 42, and 2 months postoperatively. They were treated with component retention and modular femoral head and liner revision. The 51-year-old male subsequently developed a prosthetic joint infection requiring explant of his components. Although dissociation of polyethylene liners from the DePuy Pinnacle acetabular components is an uncommon complication, this problem may increase in prevalence with longer term follow-up, and vigilance is recommended.

Introduction

Modular acetabular components allow for intraoperative flexibility and are commonly used in primary total hip arthroplasty (THA). The DePuy Pinnacle acetabular component (Warsaw, IN) is a commonly used implant that has been associated with polyethylene liner dissociation [1-6].

A report of a 2008 Food and Drug Administration (FDA) database revealed 41 cases of DePuy Pinnacle liner dissociations [1], and since 2009, a total of 6 publications reported on an additional 52 cases of this complication [1-6]. The frequency of this complication is not clear, and based on the National Joint Registry (NJR) of England and Wales in 2013, the frequency was estimated at 0.04% [7]. More recent 2017 reports estimate the frequency to be between 0.17% and 0.82%, and it has been cautioned that the frequency of liner dissociation may be higher than that previously reported [5,7].

The DePuy Pinnacle design incorporated a liner taper-lock mechanism to accommodate metal, ceramic, and polyethylene liners and has demonstrated, in laboratory settings, push-out and lever-out strength that is weaker than the previous generation Duraloc acetabular component [8,9]. The decreased pull-out and lever-out strength of this design change is likely largely responsible for the polyethylene liner dissociations reported here and in other reports.

Case histories

This case series describes our experience with 3 cases of THA performed through the direct anterior approach (DAA) using the DePuy Pinnacle modular acetabular component with postoperative polyethylene dissociations, their presentations, and treatment. One of the patients has expired of unrelated causes, and the other 2 provided written consent for inclusion in this report. We reviewed the design of the Pinnacle acetabular component and locking mechanism as a potential cause for this failure mechanism.

Case 1

A 34-year-old female was diagnosed with right hip arthritis secondary to hip dysplasia and underwent a right THA in March, 2015. This was performed through a DAA on a modified fracture table. Her demographic data, components, and postoperative radiographic acetabular positions are listed in Table 1. At the time of surgery after the acetabular component was placed and the positioning was verified with fluoroscopic imaging, retractors were

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Table 1
Patient demographics, components, and acetabular component position.

Age	Sex	Preoperative diagnosis	BMI (kg/m^2)	THA date	Time to liner disassociation (mo)	Acetabular component/ liner	Femoral component/ head	Abduction angle	Anteversion angle
34	Female	Arthritis, Dysplasia	28	March 2015	31	DePuy Pinnacle 50 mm, neutral AltrX HXLPE (5.7 mm thickness)	DePuy Corail, ceramic 32 + 1 mm	42°	28°
57	Female	Osteoarthritis	33	October 2015	2	DePuy Pinnacle 52 mm, neutral AltrX HXLPE (6.5 mm thickness)	DePuy Corail, ceramic 32 + 5 mm	40°	22°
51	Male	AVN	26	October 2013	42	DePuy Pinnacle 54 mm neutral AltrX HXLPE (7.4 mm thickness)	DePuy Corail, ceramic 32 + 1 mm	37°	24°

AVN, avascular necrosis; BMI, body mass index.

used for a complete view of the periphery of the component. The component was slightly more anteverted than usual in this case to make sure that no anterior cup overhang would cause psoas tendon irritation. Overhanging osteophytes were not required to be removed, and soft tissue that could be interposed between the component and liner was debrided. The liner was placed under direct visualization and positioned with the locking tabs to match their appropriate position in the cup. This was impacted into place, and then a tonsil hemostat was used to attempt to pry the liner free of the acetabular component to ensure it was locked into place; the liner was impacted one more time. After the femoral component was placed, the hip was taken through stability testing with external rotation of the leg to 90 degrees and gradual extension of the leg to a minimum of 45 degrees. No posterior impingement was identified with this maneuver. Her postoperative course was unremarkable, and her preoperative and postoperative imaging (Fig. 1a and b) revealed no evidence of complication with well-fixed components and good restoration of leg length and offset without loosening or migration.

Thirty-one months after the operation, she was in the shower and heard a "pop" without a preceding traumatic event that was associated with acute pain and audible squeaking. She presented to the emergency department, and radiographs showed asymmetric position of the femoral head within the acetabular component (Fig. 1c). She was taken to the operative room the following day and treated with revision of the polyethylene liner and femoral head with retention of the acetabular and femoral components. At the time of revision surgery, there was dissociation of the liner with rotational displacement noted upon capsulotomy (Fig. 2a) with direct contact of the ceramic head to the liner metal shell. After the capsulotomy, the femoral head was removed by impacting the head with a bone tamp as gentle traction was applied to the foot through the fracture table. The femoral head and liner was then removed which revealed loss of 4 of the locking tabs at the polyethylene rim of the polyethylene liner (Fig. 2b). The acetabular component was then inspected visually with the assistance of a small dental type mirror; no damage was noted to the component or locking mechanism on the cup. We identified no evidence to suggest impingement with abnormal wear patterns on the periphery of the liner, retained metal acetabular component, or neck of the femoral component. A new neutral polyethylene liner was placed, and a femoral head of the same size and neck length was placed. She is now 6 months from her revision surgery without any further complications.

Case 2

A 57-year-old female was diagnosed with right hip osteoarthritis and underwent a right THA in August 2015. This was performed through a DAA on a modified fracture table. Her demographic data, components, and postoperative radiographic acetabular positions are listed in Table 1. The surgical details were the same as those described previously. Her postoperative course was unremarkable, and her preoperative and postoperative imaging revealed no evidence of complication with well-fixed

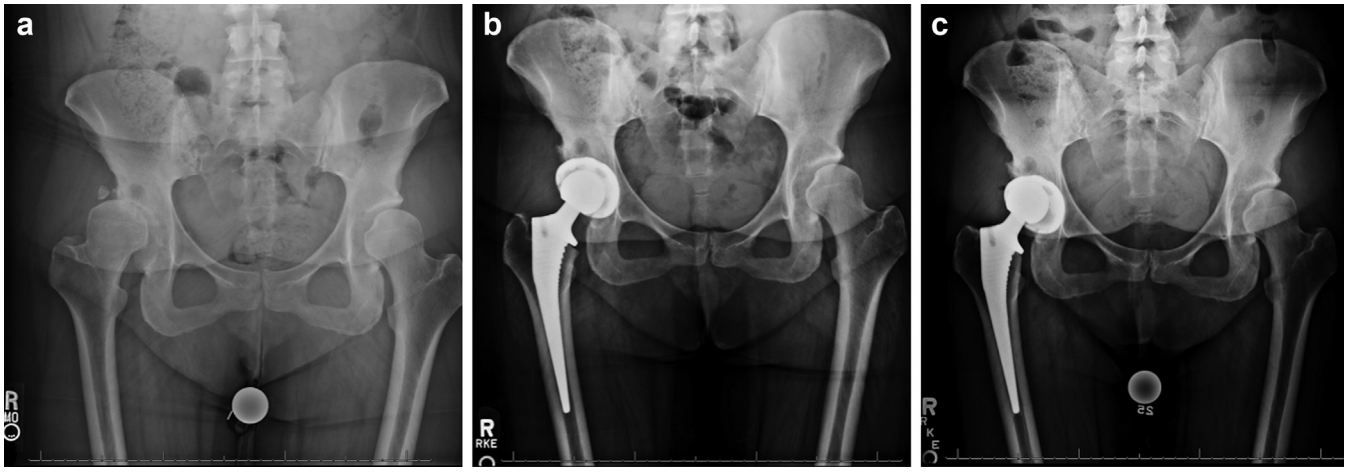

Figure 1. (a) Preoperative and (b) postoperative anteroposterior (AP) pelvis radiographs and (c) AP pelvis radiograph showing liner disassociation with asymmetrical position of the femoral head within the acetabular component for case 1.

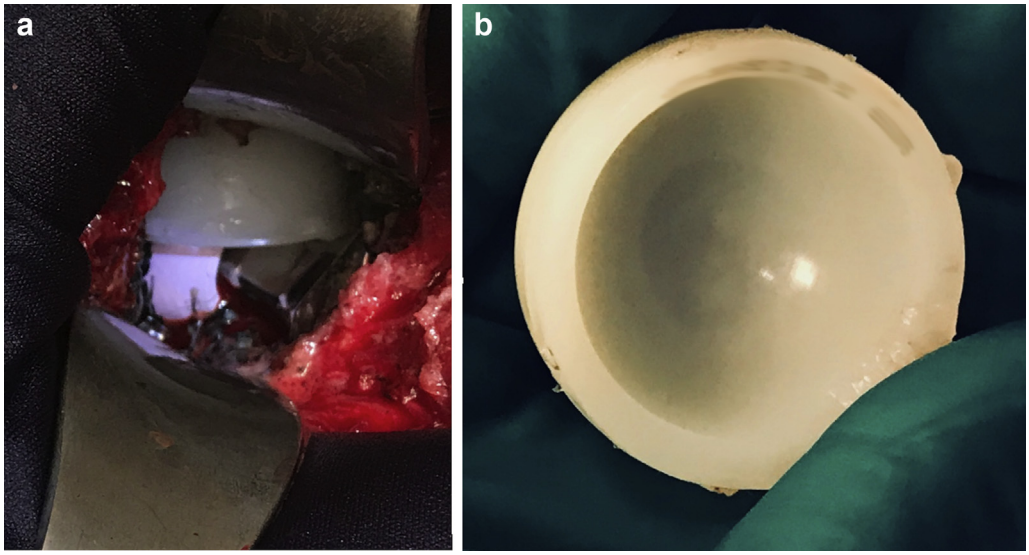

Figure 2. (a) Intraoperative photograph after capsulotomy showing disassociation of the polyethylene liner with rotational displacement, and (b) intraoperative photograph of the retrieved polyethylene liner with loss of 4 of the locking tabs at the rim in case 1.

components and good restoration of leg length and offset without loosening or migration (Fig. 3a and b).

Two months after operation, she was in her garden and bending over when she felt a "pop" which caused her to drop to her knees. Afterward, she reported minimal pain but a persistent audible squeaking sound with every step. She called our office and was instructed to present for radiographs which showed asymmetric position of the femoral head within the acetabular component (Fig. 3c). She was taken to the operating room the following day and treated with revision of the polyethylene liner and femoral head with retention of the acetabular and femoral components. The revision surgical details were the same as those described previously, and she is now 27 months from the revision THA and reports no complications.

Case 3

A 51-year-old male with a history of alcoholism was diagnosed with left hip avascular necrosis and collapse of the femoral head. He underwent left THA in October 2013 after sobriety for 3 months before surgery. This was performed through a DAA on a modified fracture table. His demographic data, components, and radiographic acetabular positions are listed in Table 1. The surgical details were the same as those described previously. His postoperative course was unremarkable, and his preoperative and postoperative imaging revealed no evidence of complication with well-fixed components and good restoration of leg length and offset without loosening or migration (Fig. 4a and b).

Forty-two months after the operation, he called to state that he was having pain in the anterior hip and hearing a squeaking noise for the last 2 days; he denied trauma, but he stated that he had been binge drinking again and had fallen down several times recently. He was advised to proceed to our emergency department, and imaging showed asymmetric position of the femoral head within the acetabular component (Fig. 4c). He was taken to the operating room the following day and treated with revision of the polyethylene liner and femoral head with retention of the acetabular and femoral components. The revision surgical details were the same as those described previously. Unfortunately, after this revision surgery, he relapsed into alcoholism, smoking, and poor compliance overall,

Figure 3. (a) Preoperative and (b) postoperative AP pelvis radiographs and (c) AP pelvis radiograph showing liner disassociation with asymmetrical position of the femoral head within the acetabular component for case 2.

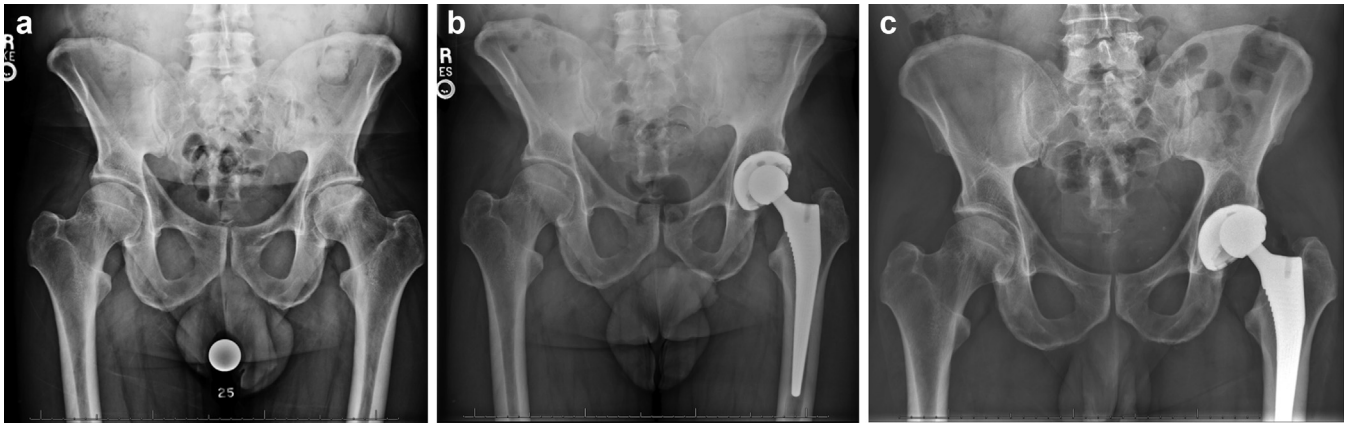

Figure 4. (a) Preoperative and (b) postoperative AP pelvis radiographs and (c) AP pelvis radiograph showing liner disassociation with asymmetrical position of the femoral head within the acetabular component for case 3.

and 5 weeks after the revision surgery, he presented with signs and symptoms of a nonhealing wound and drainage. He was treated with a stage 1 explant of components, debridement, and antibiotic spacer placement. Owing to social and compliance issues, he is currently awaiting a second-stage reimplantation as he is having severe difficulty maintaining his sobriety despite 2 attempts at rehabilitation admissions.

Discussion

All modular acetabular designs have the possibility of having a catastrophic acetabular locking mechanism failure with liner dissociation. This was seen with early acetabular designs such as the first and second generation of the Zimmer, Harris-Galante (Warsaw, IN) acetabular components which were at risk for polyethylene dissociation due to the fragile locking tines and liner-cup mismatch [10-13].

DePuy launched its third-generation modular uncemented acetabular component, the Pinnacle, around 2000, with the primary difference in design from the second-generation Duraloc cup relating to the shell-liner locking mechanism [8]. The Duraloc incorporated a wire locking ring that engaged near the cup rim to prevent dissociation, whereas the Pinnacle cup incorporated a 10 degree taper-locking mechanism near the equator of the shell and liner derotation tabs for rotational stability [8]. This design change allowed the Pinnacle to be able to accept polyethylene, metal, or ceramic bearing liners [5]. The polyethylene liner only incorporated derotation tabs in every other position. In addition, a neutral liner sits slightly elevated to the acetabular shell. If impingements were to occur, it is likely that this would happen at the neck-liner interface (Fig. 5).

At this time, there was a shift from ultra–high-molecular-weight polyethylene (UHMWPE) to highly cross-linked polyethylene (HXLPE), with DePuy reporting that the majority of their sales were for the Marathon HXLPE liner [1]. The more recent HXLPE developed by DePuy is the AltrX, with slight differences in radiation dose. The shift to majority HXLPE resulted in improved wear, but the HXPLE liner underwent an intermediate dose of radiation (7.5 MRad AltrX, 5 MRad Marathon) permitting moderate cross-linking, which is known to decrease fatigue strength to fracture. In addition, these liners are remelted to reduce free radicals, which may have an effect on the ultimate tensile strength and potentially increase the risk of fracture of the derotation tabs [4]. In laboratory testing of push-out force, the Pinnacle was similar for HXPLE and UHMWPE liners (180 lbf) and worse than the Duraloc HXPLE (500 lbf) and UHMWPE (610 lbf). Lever-out strength for the

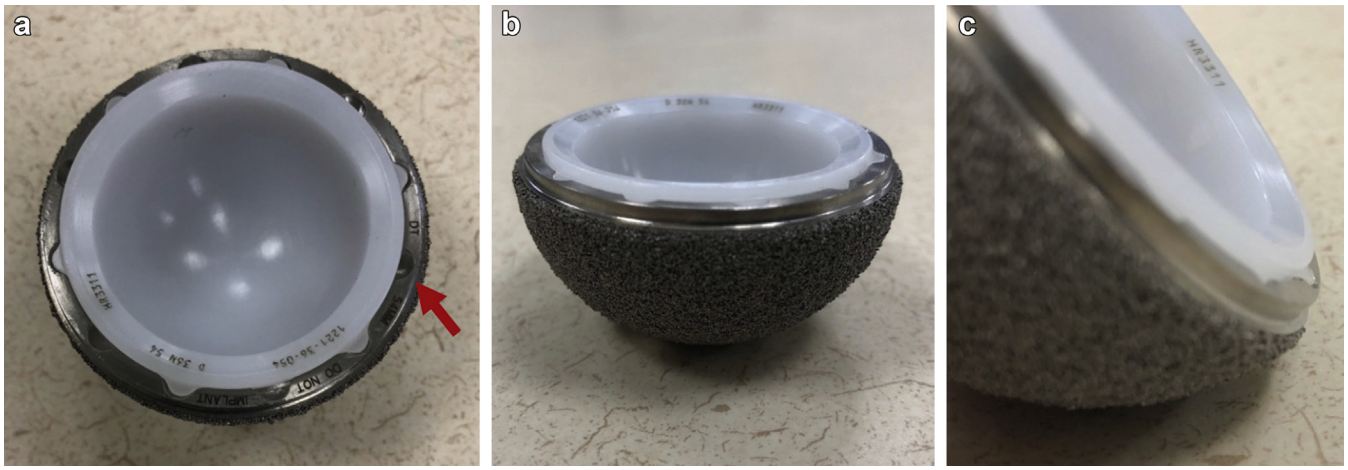

Figure 5. The DePuy Pinnacle acetabular component with neutral polyethylene liner is shown here, (a) direct view highlighting the absence of antirotation tabs in every other position (red arrow), (b) side view demonstrating the elevation of the polyethylene edge over the acetabular shell, and (c) oblique view showing the antirotation steps sitting flush while the polyethylene edge is elevated.

Pinnacle was similar for HXPLE and UHMWPE (200 in-lbf) and worse than that for the Duraloc HXPLE (580 in-lbf) and UHMWPE (700 in-lbf) [9]. This series of changes may be responsible for the clinical manifestation of liner dissociations that are now being reported.

In 2009, the first published case of DePuy Pinnacle liner dissociation was described by Mesko [1], who also reviewed the 2008 report of the Central Adverse Event Reporting to the FDA Manufacturer and User Facility Device Experience database which revealed 41 additional cases of Pinnacle polydissociations. Since this initial case report, other authors have reported on their experiences with Pinnacle polyethylene liner dissociation; however, the frequency of this complication varies.

The frequency of Pinnacle liner dissociations in 2013 was estimated at 0.04% based on the NJR of England and Wales [7]. However in 2017, Napier et al. [2] reported 8 polyethylene dissociations from a single-surgeon experience within the UK health-care system of 4751 cases and estimated a frequency of 0.17%. They suggest that the increased frequency seen in their series, 3.4 times higher than the NJR, may be due to underreporting of reason for revision as a weakness of registry data. A 2017 multicenter report of 23 Pinnacle liner dissociations calculated conservative estimates of the frequency to be 0.32%, 0.77%, and 0.82% based on 3 surgeons' practices with institutional registries [5]. Based on the senior author's (J.G.) experience with this implant in 440 primary THAs, this remains an uncommon complication; however, with longer follow-up, we may see this increase.

Two of the 3 patients we present had radiographic abduction angles and anteversion angles that were considered to be within the Lewinnek safe zone [14]. Our measurement of acetabular component anteversion was based on the methodology proposed by Liaw et al. [15]. The abduction angle in case 1 was within the safe zone but presented with a slightly increased anteversion angle just outside of the “safe zone”. This angle better matched her anatomy with her underlying hip dysplasia. Increased anteversion has been described as appropriate positioning in the dysplastic patient population [15,16].

Impingement has been suggested to be a cause of previous reports of dissociation of Pinnacle liners in offset, face-changing liners, or in cases of cup malposition [2,3]. Even with well-designed implants and appropriately positioned implants, it is possible for impingement to occur due to greater-than-average range of motion or pelvic tilt variations [17-20]. It is possible that even with well-positioned components in these cases, impingement may have been a factor leading to dissociation. All 3 of our cases described were patients at increased risk for having impingement or dislocation. The patient in case 1 had a cup position appropriate for her underlying hip dysplasia; this also introduced some risk for impingement. In case 2, the patient had previous lumbar spinal fusion, and in case 3, the patient was a former alcoholic who relapsed and had multiple falls before the liner dissociation. However, at the time of revision surgery, no visual signs of impingement were noted on the polyethylene liners, acetabular components, or necks of the femoral stems. In addition, all the liners in this series were neutral, non-offset, nonlipped, and non–face-changing liners.

All modular liners can be subject to this same possibility of impingement and dissociation. However, outside of the previously mentioned Zimmer Harris-Galante cup and the DePuy Pinnacle cup, surgeon-initiated case reports of liner dissociations are extremely sparse. Unpublished data from the NJR since 2003 reported 60 polyethylene liner dissociations in 196,599 THAs (0.046%), with manufacturer frequency of 21 Depuy Pinnacle, 10 Stryker Trident, 6 Furlong JRI CSF, 6 Zimmer Trilogy, and 17 classified as ‘Other’ [2].

All 3 of our cases were treated with retention of the acetabular component and placement of a new polyethylene liner as all 3 cases were treated within days of the patient feeling the liner pop out of place. At the time of revision surgery, all acetabular components were closely inspected for damage to the acetabular component, and none of the locking mechanisms had severe metal burnishing. In addition, a new liner was trialed and could not be levered out with an instrument demonstrating an intact locking mechanism of the cup. Previous reports of dissociation and delayed presentation with damage to the acetabular component or even metallosis required revision of the cup [2,5]. We agree with the previous authors that if any metal burnishing or cup malposition is present, cup revision should be performed. However, if the surgeon is going to retain the acetabular component, it is important to consider the risk of subsequent dissociation. Napier et al. [2] reported that 2 of 4 patients in their series who were treated with acetabular retention suffered a second episode of liner dissociation. Singleton [6] reported that 6 patients treated with acetabular retention had no further episodes of subsequent dissociation at 9 months to 2 years of follow-up.

This report of 3 cases has a number of limitations. First, this is a single-surgeon experience using the DAA and may introduce selection bias. With this approach, there is the possibility of decreased circumferential visualization during liner insertion and impaction. This could possibly lead to soft-tissue entrapment during impaction; however, in all cases, the senior author used the same technique of placing the liner under direct visualization and impacting into place and then using a tonsil hemostat to attempt to pry the liner free of the acetabular component to ensure locking and again impacting one final time. In addition, with the DAA approach, the senior author only checks for posterior impingement with external rotation and extension, so some anterior or lateral impingement could be missed. However, we also make sure that there is no anterior overhang of the acetabular component above the anterior rim of the acetabulum, which should limit any component-to-component impingement anteriorly. As there is an increase in the DAA for THA in the United States, this could lead to a rise in this complication; however, this complication would be expected to be seen increasing with other modular acetabular components as well. It is possible that in the future, other authors will report this complication with other acetabular component designs, but currently there is a paucity of evidence of this in the published literature. We also would like to note the excellent long-term performance of the Pinnacle acetabular cup with polyethylene liners with reports from the Australian and NJR for England and Wales showing 10-year survivorship rates of over 94%.

All cases were reported to the US Department of Health and Human Services MedWatch and the FDA Safety Information and Adverse Event Reporting Program. This can be accessed by other health-care professionals for voluntary reporting at www.fda.gov/safety/medwatch FDA Form 3500. We also reported the cases to our local distributor with a request to notify the manufacturer.

Summary

Dissociation of the polyethylene liner from DePuy Pinnacle acetabular components remains an uncommon complication, and this prosthesis has an excellent track record in registry studies. However, due to this potentially avoidable complication, the senior surgeon has shifted to using a different acetabular component for primary THA. Surgeons need to be vigilant during surgery to ensure complete engagement of the locking mechanism without soft-tissue interposition of modular acetabular component liners and to minimize impingement. As other authors have suggested who also are reporting this complication [5], we believe that our report

can help to raise awareness of this potentially under-reported failure mechanism and create a productive discussion between surgeons and the implant manufacturer moving forward.

References

[1] Mesko JW. Acute liner disassociation of a Pinnacle acetabular component. J Arthroplasty 2009;24(5):815.

[2] Napier RJ, Diamond O, O'Neill CKJ, O'Brien S, Beverland DE. The incidence of dissociated liners in 4,751 consecutive total hip arthroplasties using Pinnacle polyethylene acetabular liners. Hip Int 2017;27:537.

[3] Gray CF, Moore RE, Lee GC. Spontaneous dissociation of offset, face-changing polyethylene liners from the acetabular shell: a report of four cases. J Bone Joint Surg Am 2012;94(9):841.

[4] Mayer SW, Wellman SS, Bolognesi MP, Attarian DE. Late liner disassociation of a Pinnacle system acetabular component. Orthopedics 2012;35(4):e561.

[5] Yun A, Koli EN, Moreland J, et al. Polyethylene liner dissociation is a complication of the DePuy pinnacle cup: a report of 23 cases. Clin Orthop Relat Res 2016;474(2):441.

[6] Singleton N. Polyethylene liner dissociation with the DePuy pinnacle cup: a report of 6 cases. Ortho Res Online J 2018;3(5).

[7] Jameson SS, Baker PN, Mason J, et al. Independent predictors of failure up to 7.5 years after 35 386 single-brand cementless total hip replacements: a retrospective cohort study using National Joint Registry data. Bone Joint J 2013;95-B(6):747.

[8] Powers CC, Ho H, Beykirch SE, et al. A comparison of a second- and a third-generation modular cup design: is new improved? J Arthroplasty 2010;25(4):514.

[9] Postak PD, Ratzel AR, Greenwald AS. Highly cross-linked polyethylene modular acetabular designs: performance characteristics. 2003. Available from: http://orl-inc.com.

[10] Gonzalez della Valle A, Ruzo PS, Li S, Pellicci P, Sculco TP, Salvati EA. Dislodgment of polyethylene liners in first and second-generation Harris-Galante acetabular components. A report of eighteen cases. J Bone Joint Surg Am 2001;83-A(4):553.

[11] Saito S, Ryu J, Seki M, Ishii T, Saigo K, Mori S. Analysis and results of dissociation of the polyethylene liner in the Harris-Galante I acetabular component. J Arthroplasty 2008;23(4):522.

[12] Werle J, Goodman S, Schurman D, Lannin J. Polyethylene liner dissociation in Harris-Galante acetabular components: a report of 7 cases. J Arthroplasty 2002;17(1):78.

[13] Peters CL, Sullivan CL. Locking mechanism failure in the Harris-Galante porous acetabular component associated with recurrent hip dislocation. J Arthroplasty 2002;17(4):507.

[14] Lewinnek GE, Lewis JL, Tarr R, Compere CL, Zimmerman JR. Dislocations after total hip-replacement arthroplasties. J Bone Joint Surg Am 1978;60(2):217.

[15] Liaw CK, Yang RS, Hou SM, Wu TY, Fuh CS. Measurement of the acetabular cup anteversion on simulated radiographs. J Arthroplasty 2009;24(3):468.

[16] Zhang J, Wang L, Mao Y, Li H, Ding H, Zhu Z. The use of combined anteversion in total hip arthroplasty for patients with developmental dysplasia of the hip. J Arthroplasty 2014;29(3):621.

[17] Zhang J, Wei J, Mao Y, Li H, Xie Y, Zhu Z. Range of hip joint motion in developmental dysplasia of the hip patients following total hip arthroplasty with the surgical technique using the concept of combined anteversion: a study of Crowe I and II patients. J Arthroplasty 2015;30(12):2248.

[18] Malik A, Dorr LD, Long WT. Impingement as a mechanism of dissociation of a metasul metal-on-metal liner. J Arthroplasty 2009;24(2):323.e313.

[19] Barrack RL. Dislocation after total hip arthroplasty: implant design and orientation. J Am Acad Orthop Surg 2003;11(2):89.

[20] Siebenrock KA, Kalbermatten DF, Ganz R. Effect of pelvic tilt on acetabular retroversion: a study of pelves from cadavers. Clin Orthop Relat Res 2003;407:241.