



## Original Research

# Acetabular Liner Dissociation: A Comparative Study of Two Contemporary Uncemented Acetabular Components

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## ABSTRACT

**Background:** There are a number of reports of polyethylene liner dissociation of third-generation modular acetabular components. This study compares our experience with 2 contemporary systems to determine whether this is an implant- or class-specific problem.

**Methods:** This is a single-center retrospective study of 961 primary total hip arthroplasties using 2 third-generation modular cementless acetabular shells: Pinnacle (535) and R3 (426) with a polyethylene liner. Details of all revisions were obtained from local databases and the New Zealand Joint Registry. Kaplan-Meier survival curves were calculated for all-cause revision, acetabular reoperation (including liner exchange), and liner dissociation.

**Results:** There were 17 revisions in group 1 (Pinnacle; DePuy Synthes): 17 for recurrent dislocation, 6 for liner dissociations (1.12%), 3 for femoral loosening, and one for deep infection. In group 2 (R3; Smith and Nephew), there were 4 revision procedures: one for infection, 2 for dislocation, and one femoral revision for periprosthetic fracture. There were significantly higher proportions revised in group 1 for all-cause revision, acetabular reoperation, and dissociation ( $P = .024$  to  $0.038$ ). The 7-year survival for all-cause revision was 96.1% for Pinnacle and 99.0% for R3 ( $P = .022$ ), and that in the acetabular reoperation group was 96.9% for Pinnacle and 99.3% for R3 ( $P = .035$ ).

**Conclusions:** There was a higher revision rate for the Pinnacle acetabular component than for the R3 at 7 years. This was mainly due to polyethylene liner dissociation that can occur early or late. It appears to be a problem specific to the Pinnacle cup design rather than a feature of similar third-generation acetabular components.

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## Introduction

Uncemented acetabular components are widely used in modern total hip arthroplasty (THA) [1–3]. Most are modular, which has a number of advantages including the ability to use supplementary screw fixation, and allow ceramic and polyethylene bearings, different head sizes, and the use of lipped and face-changing liners. A problem with modularity is polyethylene liner dissociation, which was a complication of older uncemented acetabular components [4,5]. Improvements in locking mechanisms had almost eliminated this problem. However, the problem has reemerged with the

development of third-generation acetabular components [6–11]. These cups have been designed to accept multiple liner options and use a taper lock mechanism with no locking ring. The polyethylene liner is recessed within the shell to reduce the risk of rim fractures.

In recent years, there has been a shift away from cemented cups toward modular uncemented acetabular components in our unit. The most frequently used are the Pinnacle cup (DePuy Synthes, Warsaw, IN) and the R3 cup (Smith and Nephew, Memphis, TN), which were introduced around the same time and have a similar design. We have previously reported a series of liner dissociations with the Pinnacle cup from our unit and concluded that although some cases could be attributable to technical issues such as incomplete seating, impingement, and malalignment, the increasing numbers reported, including late dissociations, and the lack of reports with other systems suggested a problem with the locking mechanism [11]. The rate of liner dissociation is reported to

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be very low [6,7,12], but it may be underreported particularly in registry studies [6]. It is not clear whether this is an implant-specific issue or a feature of other third-generation designs.

The purpose of this study was to compare our experience with 2 similar contemporary third-generation modular acetabular components used over the same time period from the same center. The primary outcome was revision for liner dissociation. Secondary outcomes were all-cause revision and acetabular reoperation. The null hypothesis was that there is no difference between the 2 systems.

## Material and methods

This is a retrospective comparative study comparing all primary THAs performed at either our public or private hospital using the Pinnacle Cup (group 1) and the R3 cup (group 2) between August 2007 and August 2019, with minimum 1-year follow-up. All patients undergoing primary THA using these cups and any subsequent revision were identified from our local audit database cross-referenced to the New Zealand Joint Registry (NZJR) [1]. Only patients with a polyethylene liner were included. All indications for surgery including acute fracture were included. All procedures were performed by or under the direct supervision of 10 consultant surgeons experienced in hip arthroplasty. Approach and implant choice were at the surgeon's discretion. All 10 surgeons used the Pinnacle cup, with 6 also using the R3 cup.

Patient demographics and operative variables are shown in Table 1. There were 535 hips in the Pinnacle group and 426 in the R3 group. There was a higher proportion of females in the Pinnacle group. The Pinnacle group was significantly more likely to have been performed via a lateral approach using an uncemented stem, a neutral liner, and a 28-mm metal head than the R3 group. The R3 group had significantly longer mean follow-up. The NZJR and our

audit database were used to identify any revision procedure on these patients. Chart and radiographic reviews were used to determine the causes of revision including specifically those due to liner dissociation.

## Design and surgical technique

The Pinnacle shell is made from titanium and has no hole, cluster (3-hole), and multihole options. It has a short taper locking system that allows it to take ceramic and metal inserts. Marathon polyethylene liners were used in all cases in this study. These are gamma-irradiated with 5 Mrad in gas and are fully annealed.

The R3 shell is also made of titanium and has a hydroxyapatite coat. There are no-hole and 3-hole options. The highly cross-linked polyethylene (XLPE) is gamma-irradiated in gas with 10 Mrad and fully annealed. There are 20-degree lipped or neutral options. Our preference is to use a no-hole shell with a central hole cover unless supplementary screw fixation is felt necessary. Initially, we found it difficult to seat the liner within the shell because of blood interfering with the highly conforming geometry. This was less of a problem with the cups with holes for screw fixation. We now routinely keep our R3 polyethylene liners in the freezer at  $-18^{\circ}\text{C}$ . The small degree of shrinkage of the liner allows egress of any blood or fluid and allows secure locking.

## Statistical analysis

A paired t-test was used to compare continuous variable and Fisher's exact test for categorical variables. Kaplan-Meier survival curves with 95% confidence intervals were drawn for all-cause revision, acetabular reoperation (including liner exchange), and liner dissociation. An a priori power study calculation assumed there were no further cases of liner dissociation compared with the 6 cases we have reported previously. We estimated that we needed 400 THAs using the R3 cup to show a statistically significant difference between the groups (Fisher's exact test,  $P < .05$ ).

## Results

### Group 1 (Pinnacle)

There were a total of 17 revisions. There were 6 liner dissociations (1.12%). All had previously been identified and detailed in our case series [11]. The mean time to presentation with dissociation was 37 months (range: 4.5 months to 10.8 years), with 4 of 6 presenting within 13 months of the initial procedure. The remaining 2 cases were at almost 5 years and 10.8 years, respectively. Five were male, and 5 underwent a lateral approach. Screws had not been used in any of the shells. A 32-mm head was used in one case and 28-mm heads in the remaining 5 patients. A neutral liner was used in all cases. The primary operations had been performed by or under the supervision of 4 different surgeons over a 10-year period. At revision, the liners were all grossly loose and typically the 3 superior antirotation tabs had sheared off. All shells were well positioned and well fixed, and none were revised. One femoral stem was impinging posteriorly because of excessive femoral anteversion and was revised. A new liner was inserted in 5 cases, and a liner was cemented into the shell in one case because of concerns about the locking mechanism. There have been no cases of repeat dissociation or failure (Table 2).

Seven revisions were for recurrent dislocation (6) or subjective instability (1). All shells were well fixed at the time of revision. One patient with deep infection underwent debridement with liner and head exchange. There were 3 revisions for loosening of uncemented stems.

**Table 1**  
Comparison of baseline demographics and operative variables for Group 1 (Pinnacle) and Group 2 (R3).

Patient demographics and operative details	Group 1 Pinnacle	Group 2 R3	P value
Number	535	426	
Male	249 (47%)	229 (54%)	.03
Female	286 (53%)	197 (46%)	
Age	66.3 (41–95)	63.1 (33–81)	<.001
Deaths	34 (6.4%)	23 (5.4%)	.58
Femoral component			
Exeter (Stryker)	258 (48%)	275 (64%)	<.001
CORAIL (DePuy Synthes)	274 (51%)	5 (1%)	
Polar stem (Smith and Nephew)		110 (26%)	
Spectron (Smith and Nephew)		19 (5%)	
Synergy (Smith and Nephew)		16 (4%)	
Others	3 (1%)	1	
Head material			
Ceramic	311 (58%)	289 (68%)	.002
Metal	224 (42%)	114 (27%)	<.001
Oxinium		23 (5%)	<.001
Head size			
28 mm	234 (44%)	99 (23%)	<.001
32 mm	293 (55%)	323 (76%)	<.001
36 mm	8 (1%)	4 (1%)	.14
Approach			
Posterior	337 (63%)	397 (93%)	<.001
Lateral	198 (37%)	29 (7%)	<.001
Cup			
No hole	303 (57%)	314 (74%)	<.001
Three-hole	224 (42%)	111 (26%)	<.001
Multihole	6 (1%)	1 (0.2%)	
Mean follow-up/years (SD) range	4.1 (3.1) (1–11.9 years)	5.0 (2.3) (1–10.3 years)	$P < .001$

SD, standard deviation.

**Table 2**  
Details of patients who had an acetabular liner dissociation.

Age	Sex	Indication for primary THA	Time to presentation with dissociation (months)	Acetabular details (shell, liner)	Femoral component, head	Approach	Cup abduction angle	Cup anteversion angle	Revision procedure
69	M	OA	12.3	Pinnacle 56/28 mm Neutral No screws	CORAIL (KHO) 28 mm metal	Lateral	38	10	Change of liner
87	M	# NOF	13.1	Pinnacle 56/32 mm 10 degree lip No screws	CORAIL (KHO) 32 mm ceramic	Posterior	35	24	Change of liner
58	M	OA	4.43	Pinnacle 54/28 mm Neutral No screws	CORAIL (KLA) 28 mm ceramic	Lateral	40	4	Change of liner
64	M	OA	58.3	Pinnacle 56/28 mm Neutral No screws	CORAIL (KHO) 28 mm ceramic	Lateral	41	2	Cemented liner in the existing cup Stem revised for impingement
70	M	OA	130	Pinnacle 58/28 mm Neutral No screws	CORAIL (KHO) 28 mm ceramic	Lateral	37	10	Change of the liner
61	F	# NOF	5	Pinnacle 50/28mm Neutral No screws	Exeter V40 28 mm ceramic	Lateral	42	11	Change of the liner

OA, osteoarthritis; #NOF, fractured neck of the femur; KHO, high offset; KLA, lateralized.

### Group 2 (R3)

There were 4 revision procedures in total. There were no cases of liner dissociation. There were 3 revisions of the liner and head: one for early deep infection and 2 for dislocation at 11 and 18 months, respectively. There was one femoral revision for periprosthetic fracture at 15 months.

There was a significantly higher proportion revised in group 1 for liner dissociation, all-cause revision, and acetabular reoperation (any reason) ( $P = .024$  to  $0.038$ , Fisher's exact test) (Table 3).

The revision rate for dislocation (excluding dissociation) was higher in group 1 (1.3%) than in group 2 (0.5%) but did not reach statistical significance (Fisher's exact test,  $P = .3$ ). With a low number of dissociations and dislocations observed and a large number of surgeons, there were no statistically significant differences between surgeons in dissociation or dislocation rates. (Table 4).

**Table 3**  
Comparison of revision and survival rates between group 1 and group 2.

Revision and survivorship details	Group 1 (Pinnacle) N = 535	Group 2 (R3) N = 426	P value
All-cause revision	17 (3.2%)	4 (0.9%)	<b>.024</b>
Rate/100 ocys (95% CIs)	0.78 (0.46-1.25)	0.19 (0.05-0.48)	
KM survival at 7 years % (95% CIs)	96.1 (94.1-98.2)	99.0 (98.1-100)	<b>.022</b>
All acetabular reoperations	14 (2.6%)	3 (0.7%)	<b>.027</b>
Rate /100 ocys (95% CIs)	0.64 (0.35-1.10)	0.14 (0.03-0.41)	
KM survival at 7 years % (95% CIs)	96.9 (95.2-98.7)	99.3 (98.5-100%)	<b>.035</b>
Acetabular dissociation	6 (1.12%)	0 (0%)	<b>.038</b>
Rate /100 ocys (95% CIs)	0.28 (0.10-0.60)	0 (0.00-0.17)	
KM survival at 7 years % (95% CIs)	98.7 (97.4-100)	100 (100-100)	

Ocys, observed component years; KM, Kaplan-Meier; 95% CIs, 95% confidence intervals.

Bold denotes statistical significance  $P < .05$ .

Kaplan-Meier survival curves were calculated to 7 years (Figs. 1-3). There was a statistically significant decreased survival in group 1 for all end points. The Kaplan-Meier all-cause survivorship for the Pinnacle cup was 96.1% at 7 years compared with 99.0% for the R3 cup. The survival for any acetabular reoperation at 7 years was 96.9% (Pinnacle) and 99.3% (R3). The hazard ratio was 3.6 for all-cause revision ( $P = .022$ ) and 3.9 for any acetabular reoperation ( $P = .035$ ).

### Discussion

We have shown a higher revision rate for the Pinnacle acetabular component than for the R3 cup at short-term follow-up to 7 years. This is primarily due to polyethylene liner dissociation that occurred in 6 of 535 cases (1.1%). There were no cases of liner dissociation in the R3 group, suggesting that the problem is specific to the Pinnacle cup rather than a feature of the third-generation acetabular design. Both cups had excellent survivorship for revision for other reasons.

The Pinnacle cup was launched in 2003 and the R3 shell in 2008. Both are widely used and have excellent registry results [2,3]. In the National Joint Registry for England, Wales, Northern Ireland, and the Isle of Man (NJR), the Pinnacle cup with a ceramic-on-polyethylene bearing has a survivorship of 97.19% at 10 years and a cumulative revision rate of 5.2% at 10 years in combination with the CORAIL stem (DePuy Synthes, Warsaw, IN) [3]. In the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), it has a cumulative revision rate of 6.8% at 10 years in combination with the CORAIL stem. In other reports, it has a survivorship for all-cause revision of 95.2% to 99.2%, acetabular revision of 97.0% to 100% at 10 years [12,13], and a cumulative revision rate of 2.5% at 10 years [14]. Our survival figures of 96.1% all-cause survival and 96.9% for acetabular reoperation are in line with these studies.

In the NJR, the R3 cup has a cumulative all-cause revision rate of 2.0% at 7 years and 2.6% at 10 years. The rate for acetabular revision is 0.9% at 7 years and 1% at 10 years. This excluded metal-on-metal bearings but did include ceramic-on-ceramic bearings [3]. The AOANJRR reports a cumulative all-cause revision rate for the R3 cup of 3.3% for ceramic on XLPE and 4.4% for metal on XLPE at 10 years [2]. Others have reported similar results, but ceramic liners were used in a large proportion of hips [15,16]. Our figures of 99.0% for

**Table 4**

Number of procedures contributed by each surgeon with numbers of revisions for dissociation and dislocation observed for Pinnacle and R3 acetabular systems.

Surgeon	Pinnacle			R3		
	Number	Dissociation	Dislocation	Number	Dissociation	Dislocation
1	77	1	0	81	0	0
2	17	1	0	111	0	1
3	25	0	0	0	0	0
4	22	0	1	0	0	0
5	42	0	0	200	0	1
6	137	3	2	3	0	0
7	151	0	3	1	0	0
8	39	0	0	0	0	0
9	19	0	0	30	0	0
10	6	1	0	0	0	0
	535	6	6	426	0	2

all-cause revision and 99.3% for acetabular reoperation at 7 years compare favorably with these.

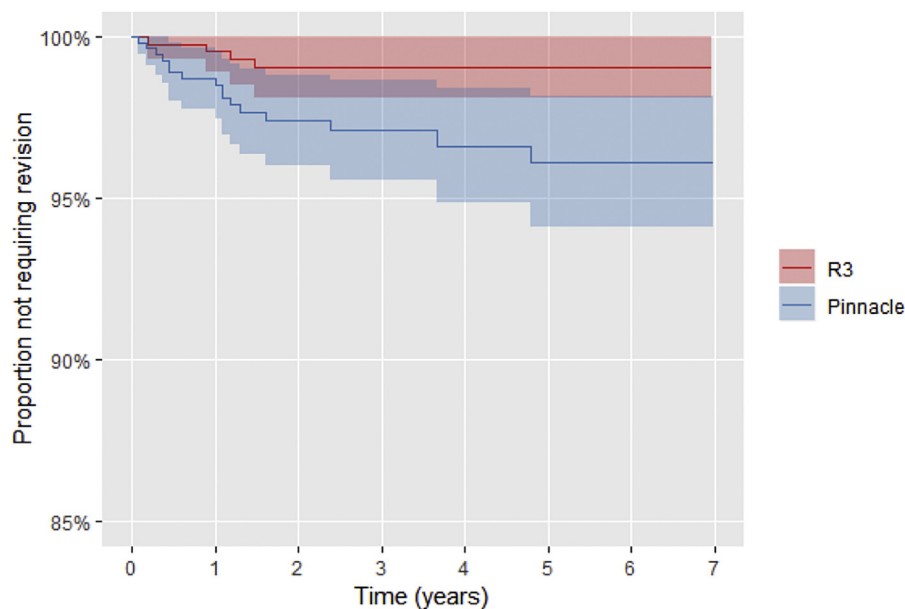
There have been multiple case reports and series of dissociations with the Pinnacle cup [6–11,17]. These can be early (within 2 years) or late (2 to 10 years) [10,11]. The rate of liner dissociation with the Pinnacle system is reported to be very low at between 0.17% and 0.8%, but it may be under-reported particularly in registry studies [6,7]. Jameson et al reported only 10 cases of liner dissociations in 13,923 (0.07%) hip arthroplasties from the NJR [18].

We are aware of only one case report with the R3 cup that occurred after a fall in a 56-year-old man 5 years after a complex primary hip replacement [19]. However, a further case report of liner dissociation leading to catastrophic failure of an oxinium head appears to be an R3 shell [20]. There are only 4 revisions reported for liner dissociations in the NJR out of 27,936 cups (0.014%) [3]. However, this includes ceramic and metal liners. The AOANJRR reports 3 revisions for acetabular liner breakage with the R3 from 35,963 hips (0.008%) but does not have a specific field for liner dissociation [2].

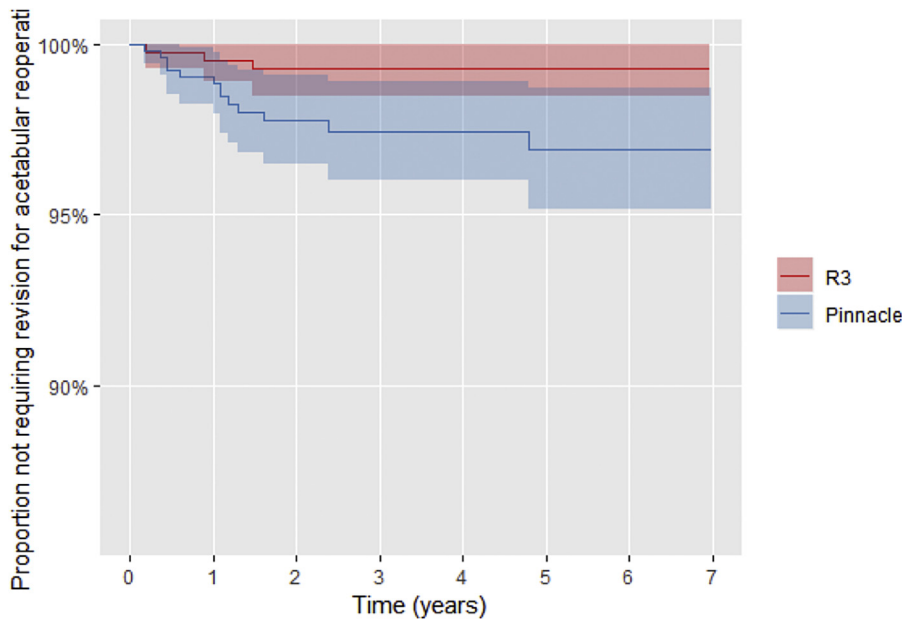
Most surgeons and company representatives we have spoken to have suggested that incorrect seating of the polyethylene liner is the reason for the dissociations seen. Although the antirotation tabs sit flush within the shell, the liner is approximately 1 mm proud.

This makes it harder to assess seating circumferentially by the use of a dissector. In our experience, if the R3 shell is incorrectly seated, it does not lock and can be easily flipped out by gentle testing at the notch in the rim. Freezing the liner made it easier to seat if a no-hole R3 shell was used. It was suggested by colleagues in another center and, although this is not included in the surgical technique or reported in the literature, we now do it routinely. However, the absence of reported dissociations with the R3 system suggests that this is not critical. If the liner is incompletely seated in the Pinnacle, the locking mechanism may be strong enough to avoid immediate dissociation but may fail early. However, this is unlikely to explain the late cases that we saw at 5 and 10 years.

The locking mechanism in the Pinnacle cup has a relatively short taper and includes a ridge or barb on the liner that locks into a single groove close to the rim of the shell. There are 6 antirotation tabs that sit flush with the shell and resist rotation but have no effect on pull-out strength. The polyethylene sits approximately 1 mm proud of the surface of the metal shell. In contrast, the R3 cup has a longer taper and double-locking groove at some distance from the rim. There are 12 derotation tabs that fit into reciprocal peripheral recesses as in the Pinnacle cup. The liner and tabs sit flush with the face of the metal shell. In addition, there is a small cut out in the shell that allows for gentle testing of the liner after



**Figure 1.** Kaplan-Meier curve showing survival over up to 7 years of follow-up (all-cause revision, censored at the time of death). Percentage survival at final follow-up: R3 = 99.0% (95% CI: 98.1% to 100.0%); Pinnacle = 96.1% (95% CI: 94.1% to 98.2%). Hazard ratio (HR) (Pinnacle) = 3.6 (95% CI: 1.2 to 10.8;  $P = .022$ ). CI, confidence interval.



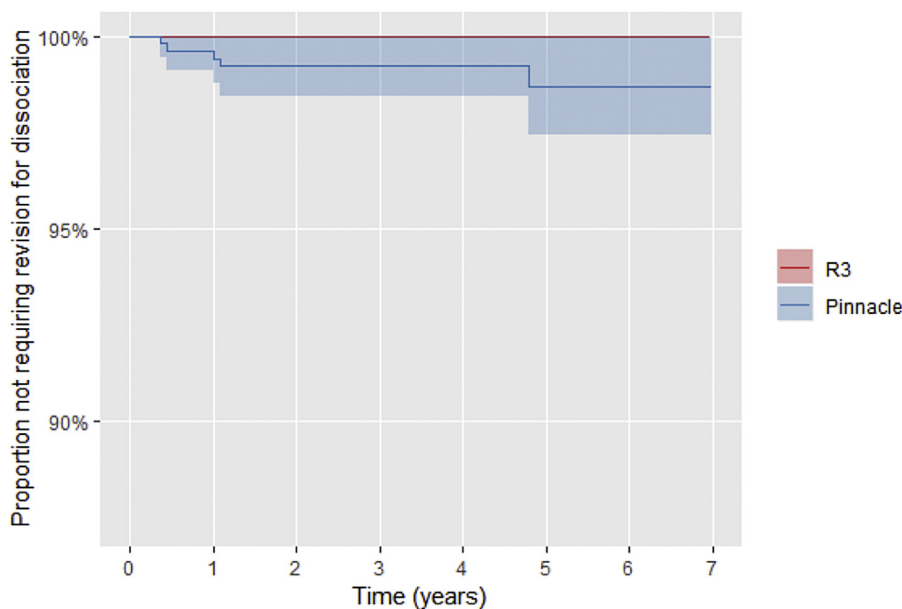
**Figure 2.** Kaplan-Meier curve showing survival over up to 7 years of follow-up (revision for acetabular reoperation, censored at the time of death or the first revision). Percentage survival at final follow-up: R3 = 99.3% (95% CI: 98.5% to 100.0%); Pinnacle = 96.9% (95% CI: 95.2% to 98.7%). HR (Pinnacle) = 3.9 (95% CI: 1.1 to 13.6;  $P = .0353$ ). CI, confidence interval; HR, hazard ratio.

impaction. It has a push-out strength of 1112 N and resists 40 Nm of torque [21]. The manufacturer claims that it can be reinserted without damaging the locking mechanism.

Other reasons suggested for dissociation may include malposition of the shell, use of face changing liners, impingement, polyethylene fatigue, and rim fracture with thin polyethylene and larger heads [6,7,10,11,22-24]. There were no cases of cup malposition in those patients who dissociated. A higher proportion of 28-mm heads were used in the Pinnacle group, and 28-mm heads were used in 5 of the 6 cases observed. A smaller head size may increase the risk of femoral neck impingement on the polyethylene in the Pinnacle system, whereas the polyethylene is fully recessed in the

R3 system. The XLPE in the R3 shell has more cross-linking so would be expected to be weaker and therefore should be more prone to rim failure than the Marathon (DePuy Synthes, Warsaw, IN) polyethylene. We are not aware of any change in the biomechanical properties of the R3 polyethylene liners from storing them at  $-18^{\circ}\text{C}$ .

This study reports the experience of well-trained surgeons who are familiar with many uncemented cups. Many used both components in this study. We have not previously identified liner dissociation as a problem in our unit [25]. Therefore, from our results and a review of the literature and registry data, we believe that we are witnessing a problem with the locking mechanism,



**Figure 3.** Kaplan-Meier curve showing survival over up to 7 years of follow-up (revision for dissociation, censored at the time of death or the first revision). Percentage survival at final follow-up: R3 = 100.0% (95% CI: 100.0% to 100.0%); Pinnacle = 98.7% (95% CI: 97.4% to 100.0%). CI, confidence interval.

albeit rare, that appears to be specific to the Pinnacle cup rather than the similar third-generation cups.

A limitation of this study is that the groups are not comparable in a number of ways including the approach, gender proportion, femoral component used, and head size. We routinely freeze the liners for the R3 cup to aid insertion but did not do so for the Pinnacle system. We do not have full clinical and radiological follow-up on all cases and did not collect patient-reported outcome scores. However, the end point of dissociation is so dramatic that we believe that revision is an appropriate end point to use for this study. There were more cases in the Pinnacle group with a shorter mean follow-up. Most occurred within the first 13 months, so it is likely that with minimum 1-year follow-up, we have identified early failures. However, as some occurred later than 5 years, the rate may rise with longer follow-up. Owing to the small size of our country and a relatively geographically isolated area, we are confident that the combination of our arthroplasty and audit database, cross-referenced to the NZJR, has identified the correct reason for all the revisions.

### Conclusions

We saw a higher revision rate for the Pinnacle acetabular component than for the R3 cup at 7 years. This is mainly due to polyethylene liner dissociation that can occur early or late. It appears to be a problem specific to the Pinnacle cup design rather than a feature of the similar third-generation acetabular components. The incidence is low, and it will require large national joint registries to collect data on liner dissociation to further address the question.

### Conflict of interest

Dunedin Hospital receives an educational grant from DePuy Synthes to support an Arthroplasty Fellow.

For full disclosure statements refer to <https://doi.org/10.1016/j.artd.2020.04.016>.

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