

Clinical Results of PINNACLE® Acetabular Cup System Polyethylene Bearings in National Joint Replacement Registries

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Since its U.S. introduction in 2000 and subsequent international release in 2003, the PINNACLE® Acetabular Cup System has become one of the most widely used and clinically successful modular acetabular systems.^{1,2} Since its first implantation, the PINNACLE Cup System has been provided for more than 2.5 million patients worldwide.³

Due to its widespread utilization in over 50 countries, many comprehensive and clinically significant data sources exist to evaluate the clinical performance of the PINNACLE Cup. Specific to this paper, data sources from two well-established national joint registries are referenced to report on the incidence of observed reasons for revisions with polyethylene bearings in the PINNACLE Acetabular Cup System.

Implant selection, patient characteristics, and surgical technique during primary THA may have a direct impact on the procedure's outcome. Some of the more common reasons for acetabular component revision include dislocation, infection and cup loosening. Less commonly reported events include mismatched components, liner dissociation, liner fracture, and peri-prosthetic socket fracture.

The capabilities of the patented PINNACLE Cup design currently allow for the application of three bearing configurations in a single modular acetabular system, including Metal-on-Polyethylene (MoP), Ceramic-on-Polyethylene (CoP), and Ceramic-on-Ceramic (CoC).

To deliver this level of flexibility, the PINNACLE Cup incorporates a circumferential taper locking feature that is designed to maximize backside conformity while supporting the locking surface area. The clinical performance of the PINNACLE Acetabular Cup System across all bearing combinations has been reported in

many forums. National joint registries provide valuable information on the revision rates/survivorship estimates of newer and older implants alike. Typically they include large cohorts with contributions from all surgeons, irrespective of experience level, as well as variations in standard of care and hospital processes. This paper specifically includes data sources from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) and the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). These registry data provide additional information regarding the risks of revision due to wear, liner dissociation, liner fracture, and femoral and/or acetabular osteolysis specific to articulations with polyethylene bearings.

National Joint Registry for England, Wales, Northern Ireland and the Isle of Man Data for PINNACLE Cup System Polyethylene Bearings

Based on data supplied for post-marketing surveillance by the National Joint Registry Centre on 10 October 2017, DePuy Synthes conducted a Kaplan-Meier analysis on the PINNACLE Acetabular Cup System for primary THA, encompassing 95,290 hips. This analysis examined the cumulative percent revision rates[†] of MoP and CoP bearing articulations in combination with all DePuy Synthes cemented and cementless stems.

For DePuy Synthes PINNACLE Cups with polyethylene liners, the cumulative percent revision rate is 2.94% (95% CI: 2.68, 3.22; n=3,421) at 10 years and 3.80% (95% CI: 2.98, 4.85, n=112) at 13 years.¹ PINNACLE Cup System CoP (N=32,055) had a 12-year cumulative percent revision rate of 2.84% (95% CI: 2.31, 3.51; n=100). PINNACLE Cup System MoP (N=63,235) had a 13-year cumulative percent revision rate of 4.04% (3.01, 5.40, n=85). See Table 1 for details.

[†] All references to survivorship estimates discussed were calculated according to the Kaplan-Meier method with revision of any component for any reason, unless otherwise noted. Cumulative percent revision rate is defined as 100 x [1-Survivorship].

Table 1: Clinical Results of PINNACLE Polyethylene Bearings in National Joint Replacement Registries with Revision for Any Reason as the Endpoint, (95% CI), n with Later Follow-up¹

Articulation	N Total	12 Years	13 Years
CoP	32,055	2.84% (2.31, 3.51) n=100	Data available 2019
MoP	63,255	3.48% (3.06, 3.95) n=514	4.04% (3.01, 5.40) n=85

As reported to the NJR, the incidence of revision for wear, liner dissociation, osteolysis, and liner fracture are shown in the following table:

National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (October 2017)¹

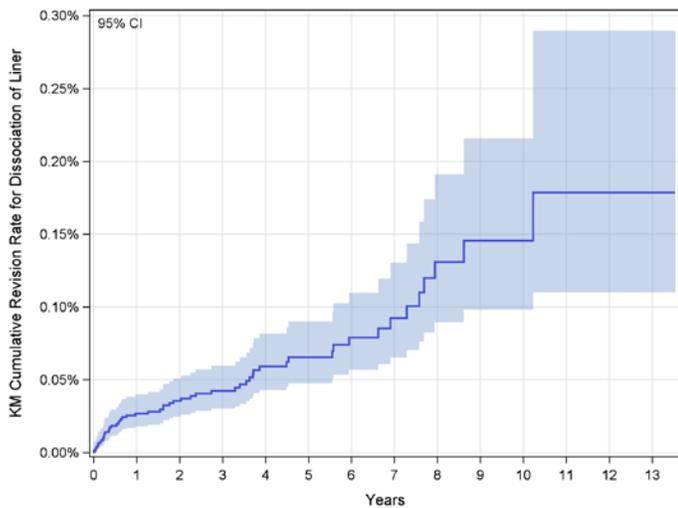
PINNACLE Cup System Polyethylene Liners Implanted (N= 95,290)

Reason for Revision	Crude Revision Rate
Wear	0.049%
Liner Dissociation	0.057%
Lysis	0.026%
Liner Fracture	0.009%

The NJR allows multiple reasons for revision. For this analysis the following hierarchy was used: 1) Liner Fracture, 2) Liner Dissociation, 3) Wear, 4) Lysis.

Specific to revision where liner dissociation was reported, the cumulative percent revision is provided in Figure 1 below.

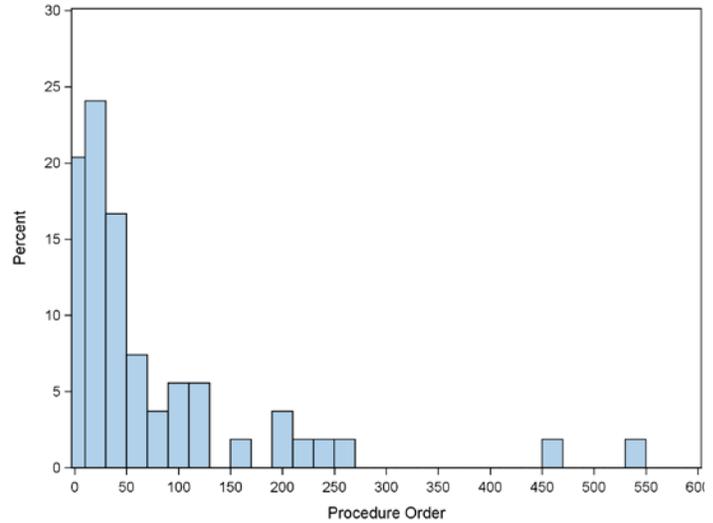
Figure 1: Cumulative Revision Rate for Dissociation of Liner



Implant and patient factors were analyzed to determine association with dissociation. Factors included: liner style (neutral, neutral +4, lipped, +4 10 degree), liner material (GVF, MARATHON[®] Cross-Linked Polyethylene, ALTRX[®] Polyethylene Liner), liner thickness, head size, head material (metal, ceramic), shell diameter, BMI, surgeon system usage. Results indicated a lower rate of revision associated with

the lipped liner, and a higher early post-operative rate associated with obese patients. Revision due to dissociation was also more likely early in a surgeon’s experience with the PINNACLE System, with 63% of revisions occurring within the first 50 cases (Figure 2).

Figure 2: Liner Dissociations by Procedure Order



Australian Orthopaedic Association National Joint Replacement Registry Data for all PINNACLE Cup System Bearing Combinations

According to the 2017 AOANJRR (Table HT12) annual report, the PINNACLE Acetabular Cup System used in combination with CORAIL[®] (N=37,501) and SUMMIT[®] (N=4,377) Cementless Stems had 10-year cumulative percent revision of 5.3% and 3.1%, respectively. AOANJRR does not report cumulative percent revision or revision reasons for any specific stem, cup and bearing combination other than Metal-on-Metal (e.g. SUMMIT Stem, PINNACLE Cup, Metal-on-Polyethylene bearing).² Therefore, please note that these results do include bearings other than Metal-on-Polyethylene (e.g. Ceramic-on-Ceramic, Ceramic-on-Polyethylene, and 28 mm Metal-on-Metal).

Conclusion

DePuy Synthes’ PINNACLE Acetabular Cup System remains one of the most widely used and clinically successful modular acetabular systems. With over 15 years of clinical use and more than 2.5 million cups³ provided for patients, the reported cumulative percent revision rates with this implant system and its polyethylene options are well documented. As the utilization of Ceramic-on-Polyethylene and Metal-on-Polyethylene articulations continues to grow, these data points suggest that the PINNACLE Acetabular Cup System is one of the most widely studied and clinically robust acetabular systems available for patients.

References:

1. NJR-NJR data from 1st Apr 2003-10th OCT 2017 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2017. *Note: NJR-NJR Supplier Feedback data do not include Hospital Episode Statistics (HES) data linkage. Revisions may therefore be underreported.*
2. Australian Orthopaedic Association National Joint Replacement Registry Annual Report. (2017). Figure HT12, Pages 88-89. Full summary of all data is available from: <https://aoanjrr.sahmri.com/annual-reports-2017>

Extracted from Table HT12 Cumulative Percent Revision of Primary Total Conventional Hip Replacement with Cementless Fixation

Femoral Component	Acetabular Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	16 Yrs
Corail	Pinnacle	1082	37501	1.8 (1.6, 1.9)	2.7 (2.5, 2.8)	3.3 (3.1, 3.5)	5.3 (4.8, 5.9)		
Summit	Pinnacle	97	4377	1.2 (0.9, 1.6)	1.9 (1.5, 2.3)	2.1 (1.7, 2.6)	3.1 (2.4, 4.0)		

3. Sales Data, DePuy Orthopaedics, Inc., Warsaw, IN. 2000-2017 Pinnacle Unit Sales-Worldwide

The data used for this analysis was obtained from the NJR Supplier Feedback System. All analyses of NJR data were undertaken by DePuy Synthes. The Healthcare Quality Improvement Partnership ("HQIP") and the National Joint Registry ("NJR") take no responsibility for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation.

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