

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 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 disassociation, 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). This registry data provides additional information regarding the risks of revision due to wear, liner disassociation, 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 September 2016, DePuy Synthes conducted a Kaplan-Meier analysis on the PINNACLE Acetabular Cup System for primary THA, encompassing 77,009 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 3.02% (95% CI: 2.70, 3.39; n=1,717) at 10 years and 3.35% (95% CI: 2.81, 3.99; n=107) at 12 years.¹ PINNACLE Cup System CoP (N=23,313) had a 10-year cumulative percent revision rate of 2.81% (95% CI: 2.20, 3.58; n=215). PINNACLE Cup System MoP (N=53,696) had a 10-year cumulative percent

[†] 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 $100 \times [1 - \text{Survivorship}]$.

revision rate of 3.07% (95% CI: 2.71, 3.48; n=1502). As reported to the NJR, the incidence of revision for wear, liner disassociation, osteolysis, and liner fracture are shown in the following table:

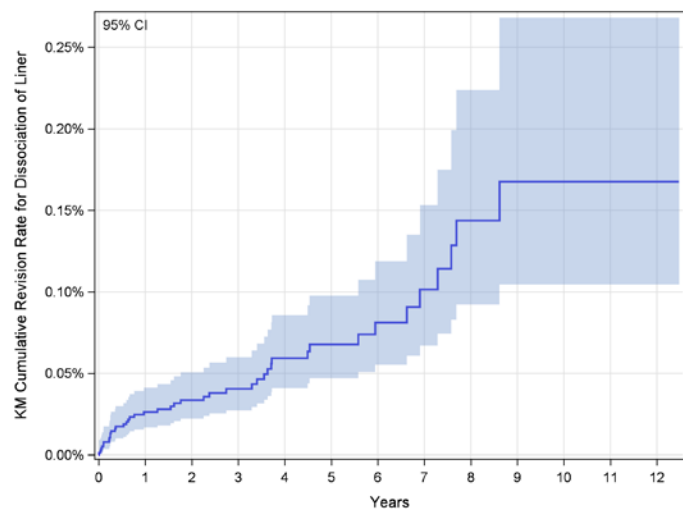
National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (September 2016)¹

PINNACLE Cup System Polyethylene Liners Implanted (N= 77,009)	
Reason for Revision	Crude Revision Rate
Wear	0.044%
Liner Disassociation	0.055%
Lysis	0.023%
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.

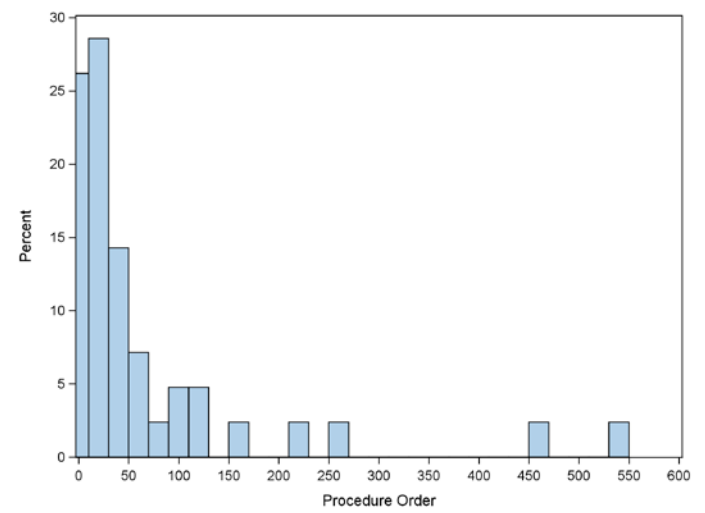
Specific to revision where liner disassociation was reported, the cumulative percent revision is provided in Figure 1 below.

Figure 1: Cumulative Revision Rate for Dissociation of Liner



Implant and patient factors were analyzed to determine associations. Factors included: liner style (neutral, neutral +4, lipped, +4 10 degree), liner material (GVF, MARATHON® Cross-Linked Polyethylene, ALTRX® Polyethylene), 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 was also more likely early in a surgeon’s experience with the PINNACLE System, with 70% 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 2016 AOANJRR (Table HT14) annual report, the PINNACLE Acetabular Cup System used in combination with CORAIL® (N=32,072) and SUMMIT® (N=4,043) Cementless Stems had 10-year cumulative percent revision rates of 5.0% and 2.5%, respectively. AOANJRR does not report cumulative percent revision rates 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 28mm 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 a decade of clinical use and more than 2.0 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 Sep 2016 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2016. *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, Adelaide: AOA, 2016. HT14 from 2016 AOA NJR. Retrieved from: <https://aoanjrr.sahmri.com/annual-reports-2016>

Extracted from Table HT14 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	7 Yrs	10 Yrs	15 Yrs
Corail	Pinnacle	854	32072	1.7 (1.6, 1.9)	2.6 (2.4, 2.8)	3.2 (2.9, 3.4)	3.8 (3.5, 4.1)	5.0 (4.4, 5.8)	
Summit	Pinnacle	77	4043	1.2 (0.9, 1.5)	1.7 (1.3, 2.2)	1.9 (1.5, 2.4)	2.5 (2.0, 3.2)	2.5 (2.0, 3.2)	

3. Sales Data, DePuy Orthopaedics, Inc., Warsaw, IN. 2000-2015 Pinnacle Unit Sales-Worldwide

Although 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 NJR do not vouch for the accuracy of the interpretation.

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