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 1.5 million patients3 and has a strong track record of helping to reduce pain and restore mobility for patients.

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. Observed events, which are infrequently reported include mismatched components, liner disassociation, liner fracture, and peri-prosthetic socket fracture.

The capabilities of the patented PINNACLE Cup design 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 and Northern Ireland (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 and Northern Ireland Data for PINNACLE® Cup System Polyethylene Bearings

Based on data supplied for post-marketing surveillance by the National Joint Registry Centre on 10 September 2014, DePuy Synthes Joint Reconstruction conducted a Kaplan-Meier analysis on the PINNACLE Acetabular Cup System for primary THA, encompassing 49,092 hips. This analysis examined the cumulative percent revision rates† of MoP and CoP bearing articulations in combination with all DePuy Synthes Joint Reconstruction cemented and cementless stems (PINNACLE Cup System MoM cumulative percent revision is referenced in DePuy Synthes Joint Reconstruction catalog DSUS/JRC/1014/0530).

For DePuy Synthes Joint Reconstruction PINNACLE Cups with polyethylene liners, the cumulative percent revision rate is 3.39% (95% CI: 2.33, 4.93; n=115) at 10 years.1 PINNACLE Cup System CoP (N=11,777) had a 9-year cumulative percent revision rate of 1.72% (95% CI: 1.37, 2.15; n=103). PINNACLE Cup System MoP (N=37,315)

† 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].
had a 10-year cumulative percent revision rate of 3.74% (95% CI: 2.45, 5.70; n=90). The incidence of revision for wear, liner disassociation, osteolysis, and liner fracture are shown in the following table:

**National Joint Registry for England, Wales and Northern Ireland (September 2014)**

<table>
<thead>
<tr>
<th>Reason for Revision</th>
<th>Crude Revision Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wear</td>
<td>0.04%</td>
</tr>
<tr>
<td>Liner Disassociation</td>
<td>0.04%</td>
</tr>
<tr>
<td>Lysis</td>
<td>0.02%</td>
</tr>
<tr>
<td>Liner Fracture</td>
<td>0.01%</td>
</tr>
</tbody>
</table>

According to the 2014 AOANJRR annual report, cumulative percent revision rates vary by femoral head size for the class of non-modified polyethylene bearings (Figure HT22 shown below). According to NJR data specific to femoral head size was also stratified and analyzed. The cumulative percent revision rates in the table below do not show a statistically significant difference for large heads (>32mm) within the PINNACLE Cup System when a polyethylene liner was used (HR=1.07, p=0.590, adjusted for age and gender). This is inconsistent with the class of modified polyethylene in the 2014 AOANJRR which showed an increased risk of revision for larger heads after 1 month of implantation (Figure HT25 shown below).

**National Joint Registry for England, Wales and Northern Ireland (September 2014)**

<table>
<thead>
<tr>
<th>Head Size</th>
<th>5 Years</th>
<th>7 Years</th>
<th>10 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;36mm</td>
<td>1.64%</td>
<td>2.10%</td>
<td>3.44%</td>
</tr>
<tr>
<td>(N=41,843)</td>
<td>(1.49, 1.81)</td>
<td>(1.88, 2.35)</td>
<td>(2.30, 5.12)</td>
</tr>
<tr>
<td>≥36mm</td>
<td>2.27%</td>
<td>2.27%</td>
<td>Data available</td>
</tr>
<tr>
<td>(N=7,249)</td>
<td>(1.71, 3.02)</td>
<td>(1.71, 3.02)</td>
<td>2017</td>
</tr>
</tbody>
</table>

*Majority of all PINNACLE Cup ≥36mm liners are MARATHON® Liner and would be in the AOANJRR class of modified polyethylene.

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

According to the 2014 AOANJRR (Table HT13) annual report, the PINNACLE Acetabular Cup System used in combination with CORAIL® (N=22,250) and SUMMIT® (N=3,244) Cementless Stems had 10-year cumulative percent revision rates of 4.8% and 2.2%, 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

**Conclusion**

*DePuy Synthes Joint Reconstruction’s PINNACLE Acetabular Cup System remains one of the most widely used and clinically successful modular acetabular systems. With over a decade of clinical application and more than 1.5 million cups¹ 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 2014 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2014. Note: NJR-NJR Supplier Feedback data do not include Hospital Episode Statistics (HES) data linkage. Revisions may therefore be underreported.


Figure HT22: Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Type of Polyethylene (Primary Diagnosis OA)

![Graph showing cumulative percent revision over years since primary procedure for Non-Cross-Linked and Cross-Linked polyethylenes.](image)

HR - adjusted for age and gender

**Non Cross-Linked vs Cross-Linked**
- 0 - 1Mth: HR=0.84 (0.72, 0.99); p=0.04
- 1Yr - 4Mth: HR=0.95 (0.81, 1.10); p=0.36
- 6Mth - 1.5Yr: HR=1.35 (1.34, 1.38); p<0.001
- 1.5Yr - 5Yr: HR=1.68 (1.31, 2.14); p=0.001
- 5Yr - 6Yr: HR=2.05 (1.50, 2.80); p<0.001
- 6Yr - 8Yr: HR=1.49 (1.02, 2.12); p=0.037
- 8Yr - 9Yr: HR=3.11 (1.74, 5.64); p=0.001
- 9Yr - 10Yr: HR=3.00 (2.25, 4.06); p<0.001

Figure HT25: Cumulative Percent Revision of Primary Total Conventional Hip Replacement using Cross-linked Polyethylene by Head Size (Primary Diagnosis OA)

![Graph showing cumulative percent revision over years since primary procedure for Cross-Linked polyethylene with different head sizes.](image)

HR - adjusted for age and gender

**Cross-Linked <22mm vs Cross-Linked >22mm**
- 0 - 1Mth: HR=0.75 (0.63, 0.90); p=0.004
- 1Mth - 6Mth: HR=0.82 (0.74, 0.91); p<0.001

**Cross-Linked <22mm vs Cross-Linked >22mm**
- Entire Period: HR=0.80 (0.70, 0.92); p=0.008

**Cross-Linked <22mm vs Cross-Linked >22mm**
- 0 - 1Mth: HR=0.70 (0.58, 0.85); p=0.068
- 1Mth - 2Yr: HR=1.71 (1.05, 2.76); p=0.030

Table HT13: Cumulative Percent Revision of Primary Total Conventional Hip Replacement with Cementless Fixation

<table>
<thead>
<tr>
<th>Femoral Component</th>
<th>Acetabular Component</th>
<th>N Revised</th>
<th>N Total</th>
<th>1 Yr</th>
<th>2 Yrs</th>
<th>3 Yrs</th>
<th>5 Yrs</th>
<th>7 Yrs</th>
<th>10 Yrs</th>
<th>13 Yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corail</td>
<td>Pinnacle</td>
<td>513</td>
<td>2250</td>
<td>1.6 (1.4, 1.7)</td>
<td>2.4 (2.2, 2.7)</td>
<td>3.1 (2.8, 3.4)</td>
<td>3.6 (3.2, 4.1)</td>
<td>4.8 (3.9, 5.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summit</td>
<td>Pinnacle</td>
<td>50</td>
<td>3244</td>
<td>1.0 (0.7, 1.4)</td>
<td>1.4 (1.1, 2.0)</td>
<td>1.6 (1.2, 2.2)</td>
<td>2.2 (1.6, 3.1)</td>
<td>2.2 (1.6, 3.1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>