PINNACLE® Acetabular Cup System

Clinical Summary
A Prospective, Randomized Study of Cross-Linked and Non-Cross-Linked Polyethylene for Total Hip Arthroplasty at 10-Year Follow-Up

230 hips randomized to receive either 5.0 Mrad cross-linked (MARATHON®) or non-cross-linked polyethylene liners with a DURALOC® 100 Series cup.

The wear rate for cross-linked liners was 0.04 ± 0.06 mm/yr, this is an 82% reduction in comparison to the reported wear rate for non-cross-linked liners at 0.22 ± 0.13 mm/yr. The osteolysis threshold is generally considered to be 0.10 mm/yr.

None of the hips with cross-linked liners had a lesion that was considered clinically important (at least 1.5cm²). In comparison 22% of the un-revised hips with non-cross-linked liners had clinically important lesions.

In the cross-linked group (116 MARATHON Liners) the 10 year survivorship rate for wear related complications with reoperation as an endpoint was 100%.

A total of 100 uncemented THRs were performed using the PINNACLE® acetabular cup with a MARATHON liner in 89 patients aged under 50 years (mean 42, range 19-50).

There were no cases of acetabular revision or osteolysis and 100% Kaplan–Meier survivorship at 10 years for the endpoints of revision for aseptic loosening of the acetabular component, radiographic evidence of loosening of the acetabular component, and revision of the acetabular component for acetabular mechanical failure.

100% of cups were well fixed, with no signs of radiological loosening at a minimum 10 years follow up.

The mean linear wear rates for cross-linked liners was 0.049 ± 0.04 mm/yr, this is a significant reduction in comparison to the wear rate recorded for the authors’ control group of non-cross-linked liners at 0.25 mm/yr (P <0.0001).

“This study demonstrates the durability of a third generation cementless modular acetabular component with moderately cross-linked polyethylene liners in terms of fixation, and reduction of wear and osteolysis in a younger population.”

Fixation and Wear With Contemporary Acetabular Components and Cross-Linked Polyethylene at 10-Years in Patients Aged 50 and Under

Over the last 15 years, the PINNACLE Acetabular Cup System has been provided to over 2,500,000 patients.\(^1\)

The CORAIL® Hip System celebrated 30 years in 2016, and in that time has been provided to over 2,000,000 patients.\(^2\)

In 2015 the CORAIL and CORAIL AMT Total Hip System and the PINNACLE Cementless Acetabular Cup were awarded an ODEP 10A* ratings by the Orthopaedic Data Evaluation Panel.\(^3\)

Australian Orthopaedic Association National Joint Replacement Registry Data for the CORAIL/PINNACLE Combination

According to the 2017 AOANJRR annual report, the CORAIL PInNACLE combination is the most implanted combination in cementless total hip replacement across Australia.\(^4\)

<table>
<thead>
<tr>
<th>Combination</th>
<th>Total</th>
<th>Year 1</th>
<th>Year 5</th>
<th>Year 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORAIL, PINNACLE</td>
<td>34,210</td>
<td>1.6% (1.5%-1.8%)</td>
<td>3.1% (2.9%-3.3%)</td>
<td>5.2% (4.6%-5.8%)</td>
</tr>
</tbody>
</table>

National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. Registry Data for the CORAIL/PINNACLE Combination

Based on the 2017 Annual Report, CORAIL PINNACLE was the most implanted combination in total hip replacement across England, Wales, Northern Ireland and the Isle of Man.\(^5,6\)

<table>
<thead>
<tr>
<th>Combination</th>
<th>Implantations</th>
<th>Year 3</th>
<th>Year 5</th>
<th>Year 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoC</td>
<td>37,846</td>
<td>1.79% (1.65%-1.93%)</td>
<td>2.40% (2.24%-2.58%)</td>
<td>3.90% (3.48%-3.47%)</td>
</tr>
<tr>
<td>CoP</td>
<td>21,533</td>
<td>1.21% (1.05%-1.39%)</td>
<td>1.74% (1.50%-2.00%)</td>
<td>2.78% (2.25%-3.44%)</td>
</tr>
<tr>
<td>MoP</td>
<td>48,744</td>
<td>1.37% (1.26%-1.48%)</td>
<td>1.70% (1.57%-1.84%)</td>
<td>3.05% (2.71%-3.43%)</td>
</tr>
</tbody>
</table>

* blue italics signify that fewer than 250 cases remained at risk at these time points
Fixation and Wear With a Contemporary Acetabular Component and Cross-Linked Polyethylene at Minimum 10-Year Follow-Up


The PINNACLE Sector cup (3 holes) was used in 149 hips and the PINNACLE Multi-hole cup was used in 1 hip. Supplementary fixation of two or three screws was used in all but one case in which no screws were used. MARATHON liners were used in all cases.

Average linear wear rate was 0.05 mm/yr and average volumetric wear rate was 16.23 mm³/yr. The linear steady state wear rate was 0.042 mm/yr.

No cases of acetabular osteolysis reported and only one case of femoral osteolysis was reported.

At 10 years follow up, survivorship with an end point of reoperation for any reason was 99.2 ± 2.9%.

No PINNACLE porous coated acetabular shells were revised at 10 Year follow up.

“Our results demonstrated that the cementless acetabular component utilized in this cohort had excellent durability at a minimum 10-year follow-up”

A Comparison of Second and Third-Generation Modular Cup Design, Is New Improved?


This study compared the clinical outcomes of a matched series of 42 DURALOC and 42 PINNACLE total hip replacements with a mean follow-up of 5.9 years.

The median Harris Hip Score was excellent for both groups, 97 (57-100) for DURALOC and 98 (53-100) for PINNACLE.

The mean wear rate for DURALOC was 0.04 ± 0.08 mm/yr and 0.03 ± 0.09 mm/yr for PINNACLE (P=0.81).

The mean volumetric wear based on the 2-dimensional head penetration was 160 ± 98 mm³ for DURALOC and 185 ±132 mm³ for PINNACLE (P=0.33).

The only difference in outcome between the two groups was the incidence of pelvic osteolysis seen on CT (P = 0.005, 2-tailed Fisher exact). No osteolysis was observed in the PINNACLE group. In the DURALOC group there were 9 osteolytic lesions identified in 8 hips.

The authors conclude that the most likely reason for the reduced incidence of retroacetabular osteolysis is due to differences in the locking mechanisms.
References

3. Orthopaedic Data Evaluation Panel. ODEP product ratings. Latest ODEP ratings can be found at www.odep.org.uk [Accessed 02/01/2017].

Table TY1: Cumulative Percent Revision of Primary Total Conventional Hip Replacement Combinations with 10 Year Data
(Primary Diagnosis OA)

<table>
<thead>
<tr>
<th>Femoral Stem</th>
<th>Acetabular Component</th>
<th>N Revised</th>
<th>N Total</th>
<th>Type of Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>DePuy</td>
<td>Pinnacl</td>
<td>82</td>
<td>155</td>
<td>THA</td>
</tr>
<tr>
<td>DePuy</td>
<td>Pinnacl</td>
<td>82</td>
<td>155</td>
<td>Acetabular</td>
</tr>
<tr>
<td>DePuy</td>
<td>Pinnacl</td>
<td>82</td>
<td>155</td>
<td>Other</td>
</tr>
</tbody>
</table>

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