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 of cross-linked liners was 0.04 ± 0.06 mm/yr, which is an 82% reduction in comparison to the reported wear rate of 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 lesions considered clinically important.

The cross-linked group (116 MARATHON liners) showed a 100% survivorship rate for wear related complications at 10 years, with reoperation as an endpoint.

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

A total of 100 uncemented THR 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.

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

The mean linear wear rates of cross-linked liners was 0.05 ± 0.04 mm/yr, which 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.”
Since its launch in 2000, the PINNACLE Acetabular Cup System has been provided to over 3,400,000 patients.\(^1\)

The CORAIL® Hip System celebrated 30 years in 2016, and in that time has been provided to over 2,500,000 patients.\(^2\)

In 2019 the PINNACLE Cementless Acetabular Cup was awarded an ODEP 13A* by the Orthopaedic Data Evaluation Panel.\(^3\)

In 2018 the CORAIL and CORAIL AMT Total Hip System were awarded an ODEP 13A* by the Orthopaedic Data Evaluation Panel.\(^3\)

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

According to the 2019 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>Implantations</th>
<th>Year 5</th>
<th>Year 10</th>
<th>Year 15</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORAIL, PINNACLE</td>
<td>47,247</td>
<td>3.3% (3.1-3.5)</td>
<td>5.3% (5.0-5.7)</td>
<td>6.8% (6.0-7.8)</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 2019 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>
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<th>Year 10</th>
<th>Year 13</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoC</td>
<td>41,769</td>
<td>2.44% (2.29-2.60)</td>
<td>3.94% (3.68-4.23)</td>
<td>4.87% (4.31-5.49)</td>
</tr>
<tr>
<td>CoP</td>
<td>34,002</td>
<td>1.58% (1.42-1.77)</td>
<td>2.88% (2.39-3.48)</td>
<td>3.13% (2.55-3.83)</td>
</tr>
<tr>
<td>MoP</td>
<td>60,875</td>
<td>1.59% (1.49-1.71)</td>
<td>2.97% (2.72-3.23)</td>
<td>4.07% (3.56-4.64)</td>
</tr>
</tbody>
</table>

\textit{Blue italics signify that fewer than 250 cases remained at risk at these time points. The numbers in brackets represent the 95\% confidence interval around the cumulative revision rate estimate.}
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 whilst the 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”

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 of 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 observed 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 concluded that the most likely reason for the reduced incidence of retroacetabular osteolysis was due to differences in the locking mechanisms.
References


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DePuy Synthes


DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46582
USA
Tel: +1 (800) 366 8143
Fax: +1 (800) 669 2530

DePuy International Ltd
St Anthony’s Road
Leeds LS11 8DT
England
Tel: +44 (0)113 270 0461

DePuy (Ireland)
Loughbeg
Ringaskiddy
Co. Cork
Ireland
Tel: +353 21 4914 000
Fax: +353 21 4914 199

jnjmedicaldevices.com
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