

ANALYSIS OF TOTAL HIP REPLACEMENT USING THE CORAIL® PINNACLE® HIP SYSTEM IN THE NATIONAL JOINT REGISTRY FOR ENGLAND, WALES, NORTHERN IRELAND AND THE ISLE OF MAN

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Introduction

National joint registries provide valuable information on the revision rates and survivorship of orthopaedic implants. Typically they include large cohorts with data from all surgeons and from all centres, irrespective of surgeon experience level. The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) has been in operation since 2003 and in that time has collected data on over 890,000 primary total hip replacements (THR).¹

The purpose of this analysis is to examine the results of the CORAIL® PINNACLE® Hip System and compare to the cumulative revision rate (CRR) estimates variously available for the different classes of total hip replacement (THR). The NJR provide 64 different class rates across the possible permutations of articulation (Metal-on-Polyethylene, Ceramic-on-Polyethylene, Ceramic-on-Ceramic), fixation (Cemented, Uncemented, Hybrid), age (<55, 55-64, 25-74 and ≥75), and gender.² CRR estimates have been calculated for the equivalent categories from the CORAIL PINNACLE Hip System dataset. Analysis was conducted by a DePuy Synthes biostatistician on data made available from the NJR Supplier Feedback system, downloaded on 12th September 2017.³ The results are provided in Table 1. An annual time-point from the class data has been selected based on the latest available reliable annual estimate for the CORAIL PINNACLE Hip System (at least 40 hips surviving) for which a published rate exists.

The CRR estimates for uncemented CORAIL PINNACLE Hip System have been compared to the all fixation class rates by comparing the point estimates and 95% confidence intervals. As an additional comparison the final column provides the overall CRR estimates for the combinations of bearing and fixation before age or gender stratification, along with the equivalent published CRR estimate for CORAIL PINNACLE Hip System.^{4,5}

Summary

- In 62/64 combinations* CORAIL PINNACLE Hip System performs at least as well if not better than the class comparator. (*Articulation, Fixation, Age & Gender).
- In 6 comparisons the CORAIL PINNACLE Hip System performs statistically better than the class comparator.
- In 56/64 comparisons the CORAIL PINNACLE Hip System performs as well as the class comparator.
- The two exceptions are for the over 75 year old females with a cemented Metal-on-Poly and the under 55 year old males with a hybrid Ceramic-on-Ceramic.

Articulation	Fixation	Male				Female				Overall
		<55	55-64	65-74	>75	<55	55-64	65-74	>75	
Metal-on-Poly	Cemented	6.68 (5.16-8.63%)	5.12 (4.52-5.79%)	3.64 (3.35-3.94%)	2.77 (2.51-3.07%)	5.76 (4.67-7.10%)	4.13 (3.72-4.59%)	2.84 (2.66-3.03%)	2.00 (1.86-2.16%)	2.99 (2.89-3.09%)
	Uncemented	6.52 (5.19-8.16%)	5.33 (4.65-6.11%)	4.38 (3.88-4.94%)	3.65 (3.17-4.22%)	4.62 (3.68-5.80%)	4.56 (4.01-5.18%)	3.62 (3.26-4.02%)	3.64 (3.18-4.16%)	4.18 (3.97-4.39%)
	Hybrid	<i>7.65 (5.44-10.69%)</i>	4.69 (3.83-5.73%)	4.07 (3.53-4.69%)	3.50 (2.85-4.30%)	5.11 (3.70-7.05%)	3.50 (2.97-4.12%)	3.14 (2.80-3.53%)	2.33 (2.01-2.70%)	3.40 (3.20-3.62%)
	CORAIL PINNACLE	4.63 (2.00-10.57%)	4.00 (3.04-5.27%)	2.78 (2.21-3.51%)	2.78 (2.05-3.78%)	4.90 (3.19-7.48%)	2.48 (1.85-3.33%)	2.56 (2.04-3.21%)	3.02 (2.24-4.05%)	3.05 (2.71-3.43%)
Ceramic-on-Poly	Cemented	2.87 (1.99-4.13%)	2.20 (1.52-3.17%)	2.37 (1.71-3.26%)	1.41 (0.84-2.35%)	3.79 (2.68-5.35%)	2.47 (1.82-3.33%)	1.82 (1.39-2.36%)	1.36 (0.90-2.05%)	2.30 (2.03-2.61%)
	Uncemented	3.64 (2.90-4.56%)	3.56 (2.95-4.29%)	2.37 (1.90-2.95%)	2.18 (1.65-2.88%)	4.27 (3.24-5.62%)	3.92 (3.28-4.67%)	3.35 (2.85-3.95%)	2.03 (1.59-2.60%)	3.40 (3.14-3.68%)
	Hybrid	<i>2.63 (1.61-4.28%)</i>	<i>2.85 (1.81-4.47%)</i>	<i>2.92 (1.94-4.41%)</i>	<i>1.60 (1.06-2.44%)</i>	<i>3.66 (2.29-5.82%)</i>	2.59 (1.81-3.72%)	1.74 (1.35-2.23%)	1.21 (0.79-1.84%)	2.48 (2.11-2.91%)
	CORAIL PINNACLE	2.30 (1.49-3.54%)	4.32 (2.75-6.77%)	3.19 (1.38-7.28%)	2.00 (1.16-3.43%)	4.74 (2.52-8.80%)	1.96 (1.22-3.14%)	2.00 (1.37-2.91%)	1.62 (0.95-2.78%)	<i>2.78 (2.25-3.44%)</i>
Ceramic-on-Ceramic	Uncemented	5.05 (4.40-5.79%)	4.15 (3.63-4.74%)	3.57 (2.97-4.28%)	2.35 (1.81-3.06%)	4.95 (4.32-5.67%)	3.61 (3.18-4.09%)	2.66 (2.23-3.17%)	2.40 (1.91-3.01%)	3.99 (3.76-4.23%)
	Hybrid	3.33 (2.47-4.47%)	3.00 (2.31-3.90%)	2.85 (1.99-4.07%)	<i>1.93 (0.96-3.89%)</i>	3.04 (2.30-4.02%)	2.25 (1.78-2.85%)	2.82 (2.00-3.97%)	<i>1.18 (0.57-2.44%)</i>	2.78 (2.47-3.11%)
	CORAIL PINNACLE	5.67 (4.72-6.80%)	3.48 (2.84-4.26%)	3.45 (2.33-5.10%)	2.81 (1.90-4.13%)	4.91 (3.96-6.08%)	3.39 (2.79-4.10%)	2.37 (1.84-3.04%)	2.21 (1.49-3.28%)	3.90 (3.48-4.37%)

Table 1. Comparison of CRR estimates for CORAIL PINNACLE Hip System to class rates stratified by articulation, fixation, gender and age (2017 NJR) (Blue cells are 7 years data, green cells are 10 year data). Estimates in blue italics indicate that fewer than 250 cases remain at risk at the time shown. Data extracted from Table 3.7 (2017 NJR)² and NJR Supplier Feedback System.³

Further Analysis

The standard CORAIL Femoral Stem is available both with and without a collar. Analysis of the CORAIL STD Collared and CORAIL STD Collarless Stems has been conducted⁶ and includes an unadjusted Kaplan-Meier survival analysis with an end point of revision of any component for any cause, as well as an adjusted hazard ratio. Based on the findings of this analysis, the CORAIL PINNACLE Hip System cohort has been limited to CORAIL STD Collared Stem only, and this combination has been compared to the cumulative revision rate (CRR) estimates variously available for the different classes of total hip replacement (THR).

As per the data on all CORAIL Hip design variants, the analysis was conducted by a DePuy Synthes biostatistician on data made available from the NJR Supplier Feedback system, downloaded on 12th September 2017.³ The results for the CORAIL STD Collared Stem are provided in Table 2. All other methodology remains consistent.

Summary

- Across all 64 comparisons CORAIL PINNACLE Hip System with CORAIL STD Collared Stems performs at least as well if not better than the class comparator.
- In 15 comparisons the CORAIL PINNACLE Hip System with CORAIL STD Collared Stems performs statistically better than the class comparator.
- In 49/64 comparisons the CORAIL PINNACLE Hip System with CORAIL STD Collared Stems performs as well as the class comparator.

Articulation	Fixation	Male				Female			
		<55	55-64	65-74	>75	<55	55-64	65-74	>75
Metal-on-Poly	Cemented	3.33 (2.51-4.41%)	5.12 (4.52-5.79%)	2.35 (2.17-2.55%)	2.08 (1.91-2.27%)	2.57 (2.02-3.27%)	4.13 (3.72-4.59%)	2.84 (2.66-3.03%)	1.46 (1.36-1.56%)
	Uncemented	3.38 (2.69-4.25%)	5.33 (4.65-6.11%)	2.78 (2.51-3.08%)	2.95 (2.62-3.32%)	2.99 (2.43-3.68%)	4.56 (4.01-5.18%)	3.62 (3.26-4.02%)	2.58 (2.35-2.84%)
	Hybrid	3.45 (2.42-4.89%)	4.69 (3.83-5.73%)	2.45 (2.15-2.79%)	2.40 (2.07-2.78%)	2.51 (1.81-3.48%)	3.50 (2.97-4.12%)	3.14 (2.80-3.53%)	1.78 (1.59-1.99%)
	CORAIL PINNACLE	3.17 (1.01-9.71%)	2.01 (1.06-3.80%)	1.38 (0.94-2.03%)	1.53 (1.11-2.11%)	4.26 (2.14-8.38%)	1.45 (0.90-2.33%)	1.21 (0.86-1.70%)	1.28 (0.87-1.89%)
Ceramic-on-Poly	Cemented	2.01 (1.39-2.90%)	1.12 (0.82-1.53%)	1.24 (0.90-1.70%)	1.41 (0.84-2.35%)	1.88 (1.35-2.62%)	1.67 (1.28-2.16%)	1.55 (1.23-1.95%)	1.36 (0.90-2.05%)
	Uncemented	3.27 (2.63-4.07%)	2.16 (1.82-2.57%)	1.48 (1.24-1.78%)	2.18 (1.65-2.88%)	2.35 (1.89-2.93%)	2.59 (2.23-3.02%)	2.44 (2.11-2.83%)	2.03 (1.59-2.60%)
	Hybrid	1.88 (1.26-2.79%)	1.63 (1.19-2.23%)	1.68 (1.26-2.23%)	1.60 (1.06-2.44%)	1.52 (1.03-2.25%)	1.71 (1.27-2.31%)	1.74 (1.35-2.23%)	1.21 (0.79-1.84%)
	CORAIL PINNACLE	1.66 (0.89-3.11%)	1.21 (0.55-2.67%)	0.49 (0.16-1.47%)	2.62 (1.09-6.19%)	3.17 (1.98-5.06%)	0.82 (0.47-1.43%)	1.35 (0.76-2.40%)	1.89 (0.67-5.25%)
Ceramic-on-Ceramic	Uncemented	3.79 (3.42-4.21%)	3.07 (2.78-3.39%)	2.64 (2.34-2.98%)	2.14 (1.66-2.77%)	3.26 (2.94-3.62%)	3.61 (3.18-4.09%)	2.10 (1.85-2.39%)	2.40 (1.91-3.01%)
	Hybrid	2.59 (1.95-3.44%)	2.30 (1.79-2.95%)	2.03 (1.49-2.76%)	1.93 (0.96-3.89%)	3.04 (2.30-4.02%)	2.25 (1.78-2.85%)	1.87 (1.38-2.53%)	1.18 (0.57-2.44%)
	CORAIL PINNACLE	3.27 (2.29-4.67%)	2.65 (1.71-4.11%)	2.04 (1.24-3.37%)	3.20 (1.54-6.62%)	3.18 (2.32-4.34%)	2.73 (1.72-4.33%)	1.85 (1.26-2.72%)	0.80 (0.26-2.46%)

Table 2 Comparison of CRR estimates for CORAIL PINNACLE Hip System with CORAIL STD Collared (KA) stems to class rates stratified by articulation, fixation, gender and age (2017 NJR) (Yellow cells are 5 years data, blue cells are 7 years data, green cells are 10 year data). Estimates in blue italics indicate that fewer than 250 cases remain at risk at the time shown. Data extracted from Table 3.7 (2017 NJR)² and NJR Supplier Feedback System.³

Key Messages

As an overall system, the CORAIL PINNACLE Hip System performs very well when compared to the class comparators as provided by the NJR². In 62 of the 64 possible combinations of age, gender, articulation and fixation, the CORAIL PINNACLE Hip System demonstrates cumulative revision rates at least equivalent to the class comparator, and in 6 combinations CORAIL PINNACLE Hip System statistically better than the class comparator.

When the same analysis is performed on the CORAIL STD Collared Stem, which has been shown to demonstrate a significantly decreased risk of revision when compared to the CORAIL STD Collarless Stem, it is shown that across all 64 comparisons CORAIL PINNACLE Hip System with CORAIL STD Collared Stems performs at least as well if not better than the class comparator, and performs statistically better in 15 combinations.

References

1. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 14th Annual Report, 2017. Table 3.3. Available from: www.njrreports.org.uk
2. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 14th Annual Report, 2017. Table 3.7. Available from: www.njrreports.org.uk
3. NJR-NJR data from 1st April 2003 -12th September 2017 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2017. Note: NJR-NJR PMS data do not include Hospital Episode Statistics (HES) data linkage. Revisions may therefore be underreported.
4. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 14th Annual Report, 2017. Table 3.6. Available from: www.njrreports.org.uk
5. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 14th Annual Report, 2017. Table 3.9. Available from: www.njrreports.org.uk
6. Data on file: Mantel J, Leopold J. 2017. ANALYSIS OF COLLARED AND COLLARLESS TOTAL HIP REPLACEMENT USING THE CORAIL® FEMORAL UNCEMENTED COMPONENT IN THE NATIONAL JOINT REGISTRY FOR ENGLAND, WALES, NORTHERN IRELAND AND THE ISLE OF MAN. Internal White Paper.

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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