

Implant Bespoke Report for:

DePuy

CORAIL Stem (All) / Pinnacle Cup

Comprising PRIMARY hips implanted up to:	02 June 2019
NJR Database extract:	01 August 2019
Produced on:	30 August 2019
Licenced for use until:	30 August 2021

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This report has been produced by the National Joint Registry of England, Wales and Northern Ireland (NJR). It summarises usage and outcomes associated with the CORAIL Stem (All) / Pinnacle Cup up to the specified dates. This analysis is based on data collected by the NJR and PROMs data collected by NHS Digital for the following combinations of products:

Femoral components	CORAIL Stem (All)
Acetabular Components	Pinnacle cups (excluding metal liners)
Comparator Group	All NJR Cementless Hips (excl. MoM)

Appendix A lists details of all CORAIL Stem (All) / Pinnacle Cup components included in this report.

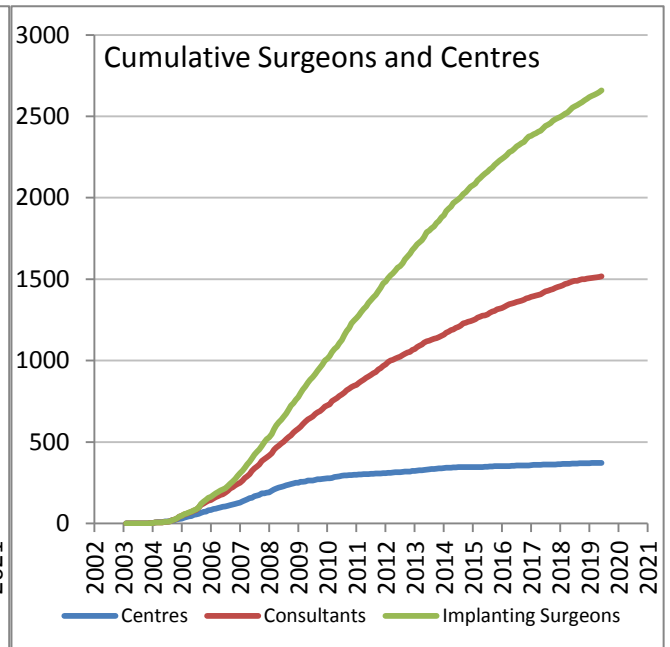
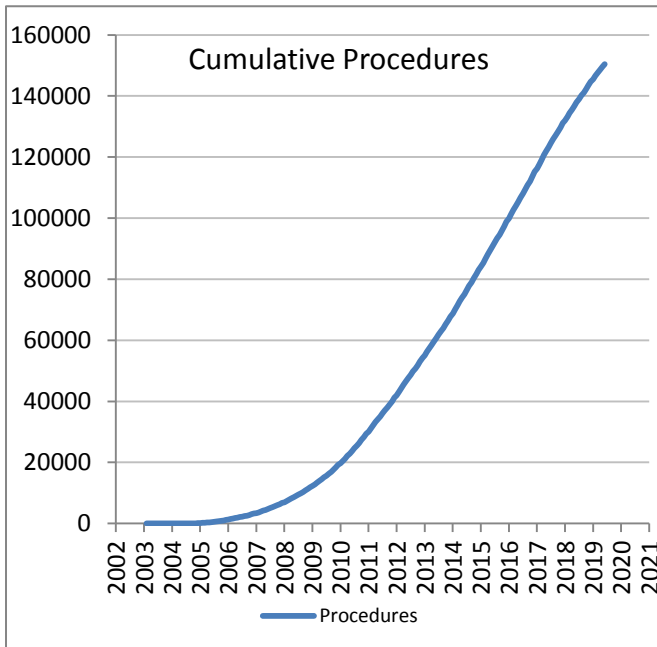
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NJR Recorded Usage

Implant Usage

Date of first recorded usage in the NJR: **03 June 2003**
 Date of last recorded usage in this dataset: **02 June 2019**
 Maximum implantation time: 15.5 years
 Mean implantation time: 5.0 years

Totals Recorded in NJR	Cumulative Total
Procedures	150,465
Patients	134,036
Centres	373
Consultants	1,517
Implanting Surgeons	2,660



Current Outcome	Year of implantation														Total	%
	Pre-2008	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019			
Death	1569	1049	1321	1475	1382	1215	1098	861	582	418	200	61	1	11232	7.5%	
Revised	305	202	255	288	343	332	248	263	236	210	145	98	14	2939	2.0%	
Unrevised	5086	4067	5861	8588	10197	11560	12294	14211	15055	15657	15430	13366	4922	136294	90.6%	
Total	6960	5318	7437	10351	11922	13107	13640	15335	15873	16285	15775	13525	4937	150465	100%	

Patient / Procedure Details

Patient Details

	CORAIL Stem (All) / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All NJR hip replacement
Total Procedures	150,465	402,309	1,075,142
Total Patients	134,036	350,193	919,850
Demographics			
Mean age	65.8	65.2	69.3
< 50	7.4%	8.7%	5.1%
50 – 59	18.8%	19.4%	12.4%
60 – 69	35.4%	34.9%	28.9%
70 – 79	29.2%	28.1%	36.2%
≥ 80	9.3%	8.8%	17.5%
Median BMI	28	28	28
% BMI information available	68.4%	65.5%	62.6%
Underweight (BMI < 18.5)	0.6%	0.7%	0.9%
Normal (18.5 ≤ BMI < 25)	18.2%	18.8%	20.8%
Overweight (25 ≤ BMI < 30)	39.4%	39.2%	39.5%
Obese I (30 ≤ BMI < 35)	26.9%	26.9%	25.8%
Obese II (35 ≤ BMI < 40)	11.1%	10.8%	9.7%
Obese III (BMI ≥ 40)	3.7%	3.7%	3.3%
% Male	43.7%	44.3%	38.7%
ASA Grades			
P1 - Fit and healthy	16.7%	18.2%	14.4%
P2 - Mild disease not incapacitating	70.8%	69.2%	68.5%
P3 - Incapacitating systemic disease	12.2%	12.2%	16.5%
P4 / P5	0.3%	0.4%	0.6%
Indications			
Osteoarthritis	94.15%	93.26%	91.42%
Rheumatoid Arthritis	1.08%	1.20%	1.35%
Avascular Necrosis	2.10%	2.50%	2.49%
Fractured Neck of Femur	1.92%	1.77%	3.53%
CDH/DDH	1.49%	2.14%	1.51%
Other	1.13%	1.63%	2.11%

Total of indications may exceed total number of implants, since more than one indication can be listed per case.

Revision and Survivorship

Reasons for Revision

Reasons for revision of primary procedures in which the implant was used.

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Unexplained Pain	287	367.97	<0.001
Dislocation / Subluxation	586	651.47	0.002
Adverse Soft Tissue Reaction	90	120.17	<0.001
Infection	452	510.65	0.001
Aseptic Loosening - Stem	701	638.53	0.003
Aseptic Loosening - Socket	131	237.08	<0.001
Periprosthetic Fracture Stem	407	479.87	<0.001
Periprosthetic Fracture Socket	29	63.48	<0.001
Malalignment Stem	114	126.93	0.169
Malalignment Socket	178	212.01	0.005
Wear Of Acetabular Component	101	156.34	<0.001
Lysis Stem	55	67.94	0.072
Lysis Socket	25	46.52	<0.001
Implant Fracture Stem	37	53.22	0.007
Implant Fracture Socket	128	84.46	<0.001
Implant Fracture Head	8	19.67	0.002
Dissociation of Liner	110	82.53	<0.001
Other / reason not recorded	148	165.64	0.094
Total Revised	2939	3235.89	<0.001

* Based on All NJR Cementless Hips (excl. MoM) adjusted for agegroup, gender, and indications

† multiple reasons may be listed for one revision procedure

Significantly better, $p < 0.001$

Significantly better, $p < 0.05$

Significantly worse $p < 0.05$

Significantly worse $p < 0.001$



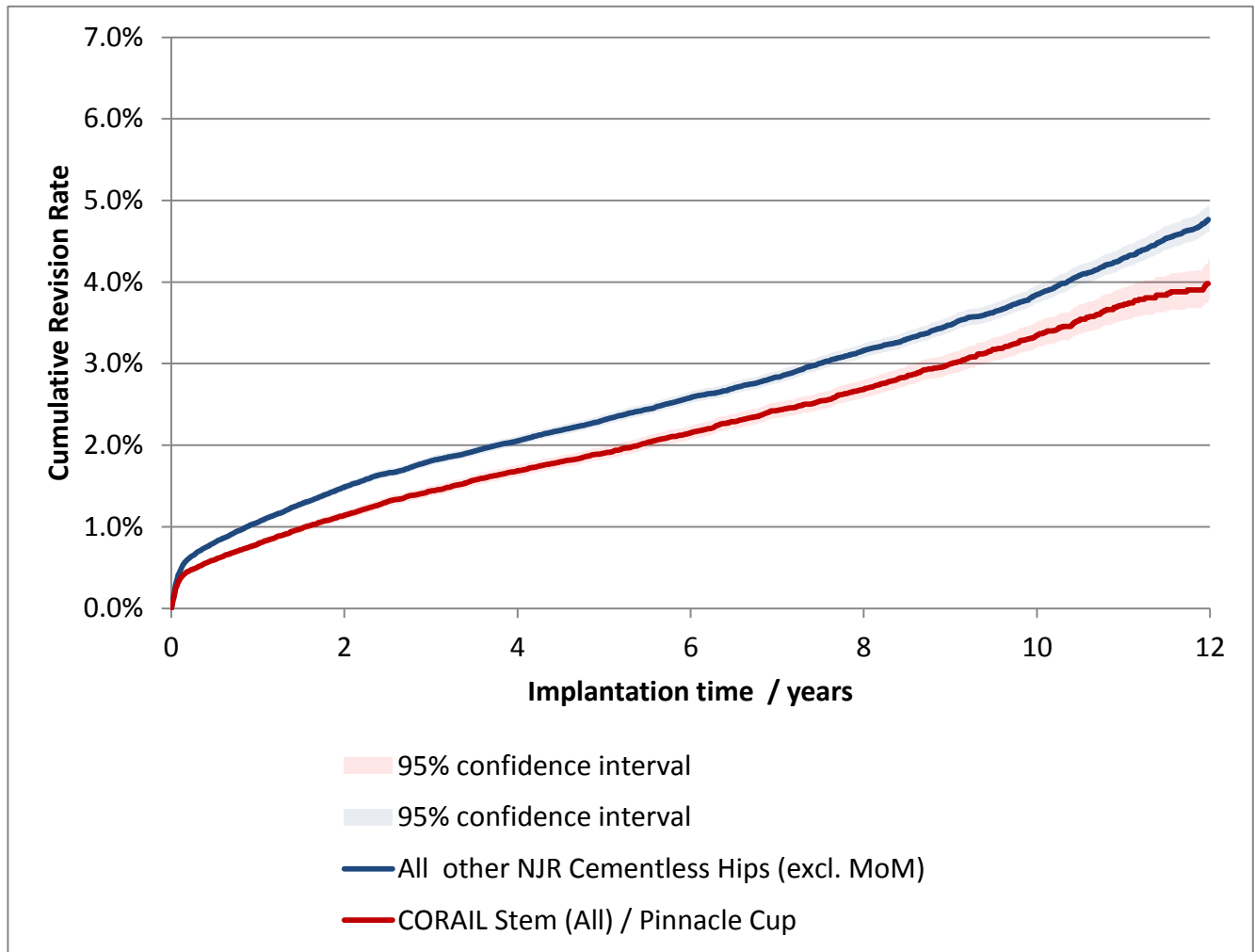
Components Revised	Number of procedures	CORAIL Stem (All) / Pinnacle Cup	All other NJR Cementless Hips (excl. MoM)
Femoral only	1025	35%	30%
Acetabular only	662	23%	27%
Both femoral and acetabular	845	29%	32%
Neither femoral nor acetabular revision recorded *	407	14%	11%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision.



Cox Proportional Hazards model for revision risk ratio of CORAIL Stem (All) / Pinnacle Cup / All other NJR Cementless Hips (excl. MoM), with endpoint as any revision.

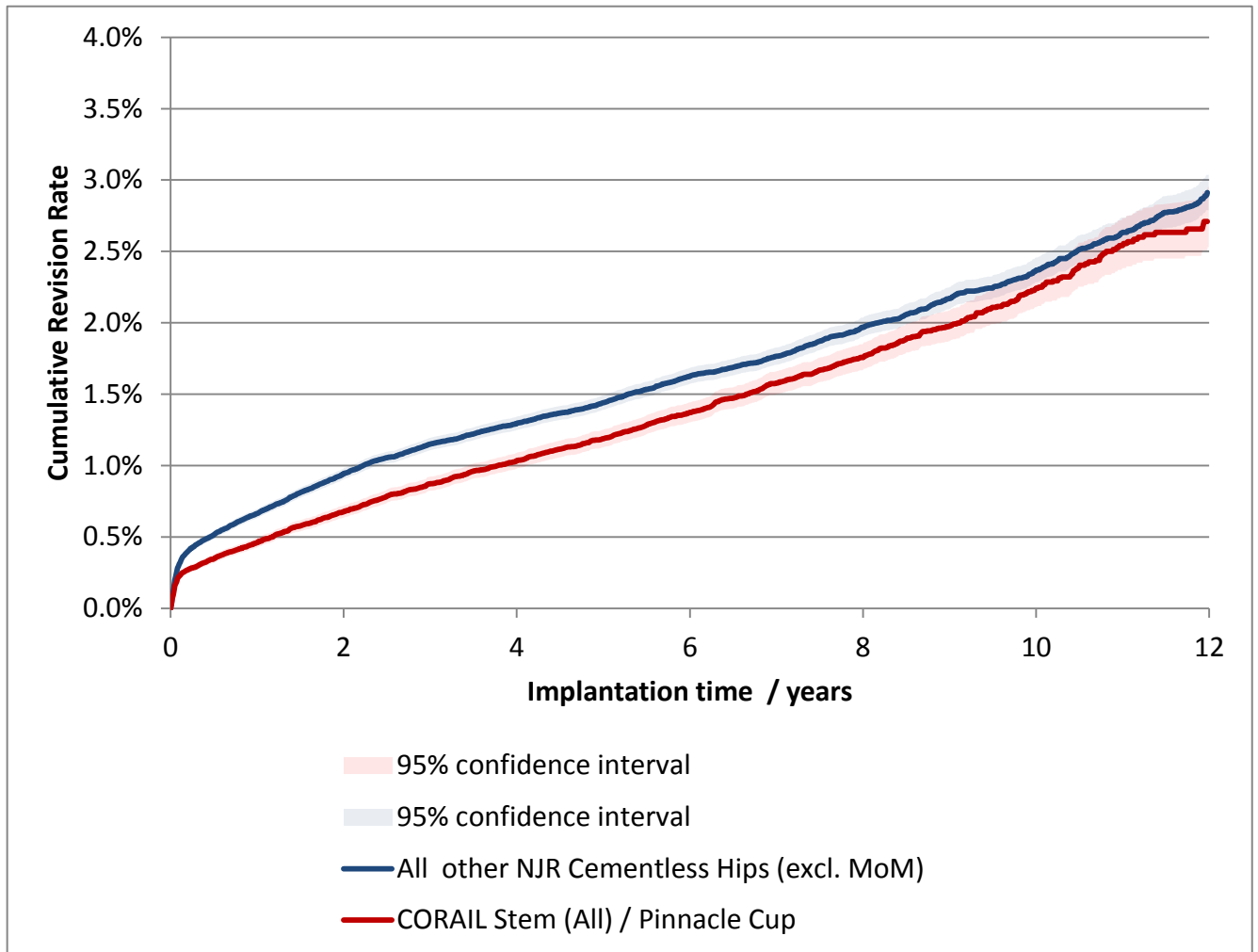
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.83 (0.80 - 0.87)	<0.001
All bearings. Adjusted for age, gender, year cohort and indications.	0.86 ‡ (0.82 - 0.90)	<0.001 ‡

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision



Cox Proportional Hazards model for revision risk ratio of CORAIL Stem (All) / Pinnacle Cup / all other All other NJR Cementless Hips (excl. MoM), with endpoint as Femoral revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.85 ‡ (0.81 - 0.90)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.87 ‡ (0.82 - 0.92)	<0.001 ‡

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Period /years	Endpoint: Any component revised				Endpoint: Femoral Revision			
	At Risk	CORAIL Stem (All) / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR	At Risk	CORAIL Stem (All) / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR
0	150,465	-	-	-	150,465	-	-	-
1	135,669	0.8% (0.7% - 0.8%)	1.0% (0.9% - 1.0%)	0.8% (0.8% - 0.8%)	135,669	0.5% (0.4% - 0.5%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)
2	119,593	1.1% (1.1% - 1.2%)	1.4% (1.3% - 1.4%)	1.1% (1.1% - 1.1%)	119,593	0.7% (0.6% - 0.7%)	0.8% (0.8% - 0.9%)	0.7% (0.7% - 0.7%)
3	101,785	1.4% (1.4% - 1.5%)	1.7% (1.6% - 1.7%)	1.4% (1.4% - 1.4%)	101,785	0.9% (0.8% - 0.9%)	1.0% (1.0% - 1.1%)	0.9% (0.9% - 0.9%)
4	84,946	1.7% (1.6% - 1.8%)	1.9% (1.9% - 2.0%)	1.6% (1.6% - 1.6%)	84,946	1.0% (1.0% - 1.1%)	1.2% (1.2% - 1.2%)	1.0% (1.0% - 1.1%)
5	68,834	1.9% (1.8% - 2.0%)	2.2% (2.1% - 2.2%)	1.9% (1.8% - 1.9%)	68,834	1.2% (1.1% - 1.3%)	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)
6	54,311	2.2% (2.1% - 2.2%)	2.4% (2.4% - 2.5%)	2.1% (2.1% - 2.1%)	54,311	1.4% (1.3% - 1.4%)	1.5% (1.5% - 1.6%)	1.4% (1.4% - 1.4%)
7	41,519	2.4% (2.3% - 2.5%)	2.7% (2.6% - 2.7%)	2.4% (2.3% - 2.4%)	41,519	1.6% (1.5% - 1.7%)	1.7% (1.6% - 1.7%)	1.5% (1.5% - 1.6%)
8	29,640	2.7% (2.6% - 2.8%)	3.0% (2.9% - 3.1%)	2.7% (2.6% - 2.7%)	29,640	1.8% (1.7% - 1.8%)	1.9% (1.8% - 1.9%)	1.8% (1.7% - 1.8%)
9	19,350	3.0% (2.9% - 3.1%)	3.3% (3.2% - 3.4%)	3.0% (2.9% - 3.0%)	19,350	2.0% (1.9% - 2.1%)	2.1% (2.0% - 2.2%)	2.0% (1.9% - 2.0%)
10	11,853	3.3% (3.2% - 3.5%)	3.7% (3.6% - 3.8%)	3.3% (3.3% - 3.4%)	11,853	2.2% (2.1% - 2.4%)	2.3% (2.2% - 2.4%)	2.2% (2.2% - 2.3%)
11	6,905	3.7% (3.5% - 3.9%)	4.1% (4.0% - 4.2%)	3.8% (3.7% - 3.8%)	6,905	2.5% (2.4% - 2.7%)	2.6% (2.5% - 2.7%)	2.5% (2.5% - 2.6%)
12	3,537	4.0% (3.8% - 4.3%)	4.5% (4.4% - 4.7%)	4.2% (4.2% - 4.3%)	3,537	2.7% (2.5% - 3.0%)	2.8% (2.7% - 3.0%)	2.9% (2.8% - 2.9%)
13	1,528	4.4% (4.1% - 4.8%)	5.0% (4.9% - 5.2%)	4.7% (4.6% - 4.8%)	1,528	3.0% (2.7% - 3.3%)	3.2% (3.0% - 3.3%)	3.2% (3.1% - 3.2%)
14		(-)	5.7% (5.4% - 5.9%)	5.2% (5.1% - 5.3%)		(-)	3.5% (3.3% - 3.6%)	3.5% (3.4% - 3.6%)
15		(-)	6.2% (5.9% - 6.6%)	5.8% (5.6% - 6.0%)		(-)	3.8% (3.5% - 4.0%)	3.9% (3.7% - 4.0%)

Cumulative revision rate with 95% confidence intervals

Rate is only reported for times where more than 40 remain at risk

Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 29/03/2018

Oxford Hip Score (0 - 48)	CORAIL Stem (All) / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR in NJR
Paired Records	48,838	116,146	285,430
PreOp score	18.6 (18.5 - 18.7)	18.5 (18.5 - 18.6)	18.0 (17.9 - 18.0)
6 month score	40.6 (40.5 - 40.6)	40.0 (40.0 - 40.1)	39.3 (39.3 - 39.4)
6 month score (adjusted)	40.0 (39.9 - 40.0)	39.6 (39.5 - 39.6)	39.4 (39.3 - 39.4)
Health gain	22.0 (21.9 - 22.0)	21.5 (21.4 - 21.5)	21.4 (21.3 - 21.4)
Health gain (adjusted)	22.0 (21.9 - 22.0)	21.5 (21.5 - 21.6)	21.3 (21.3 - 21.4)
p value (adjusted health gain)	< 0.001		
Score Improved	97.6%	97.2%	97.2%

EQ-5D Index (-0.59 - 1.00)	CORAIL Stem (All) / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR in NJR
Paired Records	45,108	107,480	262,456
PreOp score	0.380 (0.377 - 0.383)	0.374 (0.372 - 0.376)	0.353 (0.352 - 0.355)
6 month score	0.819 (0.816 - 0.821)	0.805 (0.804 - 0.807)	0.791 (0.790 - 0.792)
6 month score (adjusted)	0.806 (0.804 - 0.808)	0.796 (0.795 - 0.798)	0.792 (0.791 - 0.793)
Health gain	0.439 (0.436 - 0.442)	0.431 (0.429 - 0.433)	0.438 (0.436 - 0.439)
Health gain (adjusted)	0.451 (0.449 - 0.453)	0.442 (0.440 - 0.443)	0.437 (0.436 - 0.438)
p value (adjusted health gain)	< 0.001		
Score Improved	90.6%	89.6%	89.5%

EQ-VAS (0 - 100)	CORAIL Stem (All) / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR in NJR
Paired Records	43,240	103,443	251,616
PreOp score	66.2 (66.0 - 66.4)	65.5 (65.4 - 65.7)	65.0 (64.9 - 65.0)
6 month score	78.4 (78.3 - 78.6)	77.8 (77.7 - 77.9)	76.7 (76.7 - 76.8)
6 month score (adjusted)	77.4 (77.2 - 77.5)	77.1 (77.0 - 77.2)	76.8 (76.7 - 76.9)
Health gain	12.2 (12.0 - 12.4)	12.3 (12.2 - 12.4)	11.8 (11.7 - 11.9)
Health gain (adjusted)	12.3 (12.2 - 12.5)	12.0 (11.9 - 12.1)	11.8 (11.7 - 11.8)
p value (adjusted health gain)	< 0.001		
Score Improved	67.0%	66.9%	65.6%

Adjusted scores correspond to the NHS Digital version 3 casemix-adjustment model. This includes patient variables from PROMs, HES, and IMD data.

Bespoke Report for:

CORAIL Stem (All) / Pinnacle Cup

Responses are not case mix adjusted

Patient Reported Outcomes



Chi-squared p-value for difference: <0.001

Chi-squared p-value for difference: <0.001

Answer to 6-months general health question: Overall, how are your problems now, compared to before your operation?

Answer to 6-months general health question: How would you describe the results of your operation?

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
3L92498	Corail Collared Stem K8A 115mm	3,009
3L92499	Corail Collared Stem K9A 130mm	5,329
3L92500	Corail Collared Stem K10A 140mm	11,044
3L92501	Corail Collared Stem K11A 145mm	16,383
3L92502	Corail Collared Stem K12A 150mm	13,316
3L92503	Corail Collared Stem K13A 155mm	6,713
3L92504	Corail Collared Stem K14A 160mm	3,446
3L92505	Corail Collared Stem K15A 165mm	1,527
3L92506	Corail Collared Stem K16A 170mm	599
3L92507	Corail Collarless Stem K8S 125mm	3,177
3L92508	Corail Collared Stem K18A 180mm	119
3L92509	Corail Collarless Stem K9S 130mm	4,240
3L92510	Corail Collarless Stem K10S 140mm	8,397
3L92511	Corail Collarless Stem K11S 145mm	12,434
3L92512	Corail Collarless Stem K12S 150mm	10,752
3L92513	Corail Collarless Stem K13S 155mm	5,025
3L92514	Corail Collarless Stem K14S 160mm	2,556
3L92515	Corail Collarless Stem K15S 165mm	1,119
3L92516	Corail Collarless Stem K16S 170mm	423
3L92518	Corail Collarless Stem K18S 180mm	166
3L92520	Corail Collarless Stem K20S 190mm	8
3L92521	Corail Collared Stem K20A 190mm	8
3L93709	Corail Collared Lateralised Coxa Vara Stem KLA9 130mm	2,271
3L93710	Corail Collared Lateralised Coxa Vara Stem KLA10 140mm	3,570
3L93711	Corail Collared Lateralised Coxa Vara Stem KLA11 145mm	5,495
3L93712	Corail Collared Lateralised Coxa Vara Stem KLA12 150mm	4,574
3L93713	Corail Collared Lateralised Coxa Vara Stem KLA13 155mm	2,262
3L93714	Corail Collared Lateralised Coxa Vara Stem KLA14 160mm	1,245
3L93715	Corail Collared Lateralised Coxa Vara Stem KLA15 165mm	524
3L93716	Corail Collared Lateralised Coxa Vara Stem KLA16 170mm	233
3L93718	Corail Collared Lateralised Coxa Vara Stem Size 18	17
3L93720	Corail Collared Lateralised Coxa Vara Stem Size 20	1
L20309	Corail High Offset Collarless Stem KHO9 130mm	1,212
L20310	Corail High Offset Collarless Stem KHO10 140mm	2,468
L20311	Corail High Offset Collarless Stem KHO11 145mm	4,501
L20312	Corail High Offset Collarless Stem KHO12 150mm	5,100
L20313	Corail High Offset Collarless Stem KHO13 155mm	3,367
L20314	Corail High Offset Collarless Stem KHO14 160mm	2,146
L20315	Corail High Offset Collarless Stem KHO15 165mm	1,137
L20316	Corail High Offset Collarless Stem KHO16 170mm	517
L20318	Corail High Offset Collarless Stem Size 18	34
L20320	Corail High Offset Collarless Stem Size 20	1