

Implant Bespoke Report for:

DePuy

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

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

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NJR Recorded Usage

Implant Usage

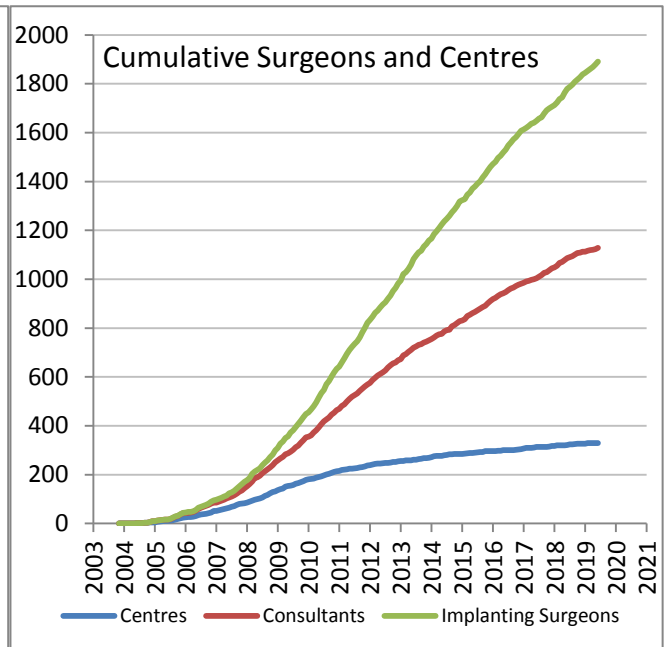
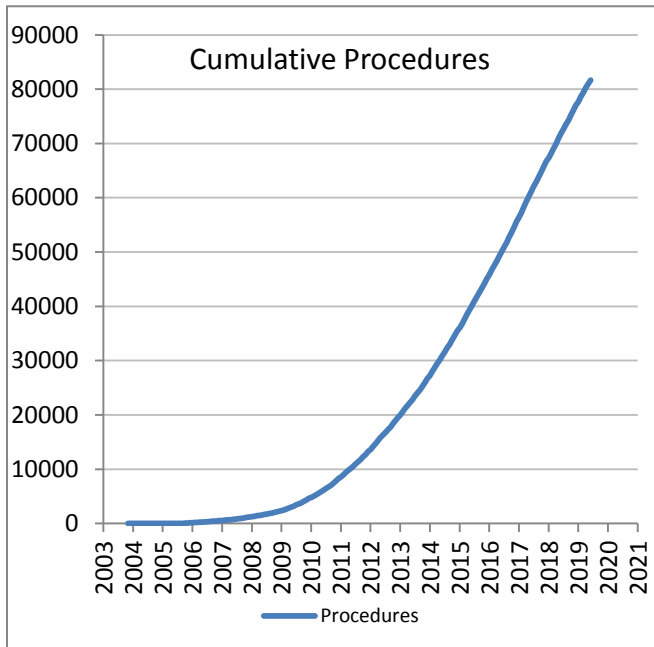
Date of first recorded usage in the NJR: **11 January 2004**

Date of last recorded usage in this dataset: **02 June 2019**

Maximum implantation time: 15.4 years

Mean implantation time: 4.1 years

Totals Recorded in NJR	Cumulative Total
Procedures	81,685
Patients	73,867
Centres	329
Consultants	1,128
Implanting Surgeons	1,891



Current Outcome	Year of implantation														Total	%
	Pre-2008	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019			
Death	248	260	496	616	714	642	653	553	395	296	158	48	1	5080	6.2%	
Revised	53	37	71	91	122	127	112	111	134	124	85	64	7	1138	1.4%	
Unrevised	949	830	1846	3052	4237	5576	6515	8150	9183	10177	10707	10292	3953	75467	92.4%	
Total	1250	1127	2413	3759	5073	6345	7280	8814	9712	10597	10950	10404	3961	81685	100%	

Patient / Procedure Details

Patient Details

	CORAIL Collared Stem / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All NJR hip replacement
Total Procedures	81,685	402,309	1,075,142
Total Patients	73,867	350,193	919,850
Demographics			
Mean age	66.7	65.2	69.3
< 50	6.6%	8.7%	5.1%
50 – 59	17.3%	19.4%	12.4%
60 – 69	33.7%	34.9%	28.9%
70 – 79	31.2%	28.1%	36.2%
≥ 80	11.3%	8.8%	17.5%
Median BMI	28	28	28
% BMI information available	72.3%	65.5%	62.6%
Underweight (BMI < 18.5)	0.7%	0.7%	0.9%
Normal (18.5 ≤ BMI < 25)	19.0%	18.8%	20.8%
Overweight (25 ≤ BMI < 30)	39.0%	39.2%	39.5%
Obese I (30 ≤ BMI < 35)	26.7%	26.9%	25.8%
Obese II (35 ≤ BMI < 40)	11.0%	10.8%	9.7%
Obese III (BMI ≥ 40)	3.7%	3.7%	3.3%
% Male	40.3%	44.3%	38.7%
ASA Grades			
P1 - Fit and healthy	15.3%	18.2%	14.4%
P2 - Mild disease not incapacitating	71.3%	69.2%	68.5%
P3 - Incapacitating systemic disease	13.1%	12.2%	16.5%
P4 / P5	0.4%	0.4%	0.6%
Indications			
Osteoarthritis	94.20%	93.26%	91.42%
Rheumatoid Arthritis	1.01%	1.20%	1.35%
Avascular Necrosis	1.86%	2.50%	2.49%
Fractured Neck of Femur	2.34%	1.77%	3.53%
CDH/DDH	1.30%	2.14%	1.51%
Other	1.00%	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	102	140.06	<0.001
Dislocation / Subluxation	258	314.44	<0.001
Adverse Soft Tissue Reaction	33	46.60	0.034
Infection	208	246.73	0.006
Aseptic Loosening - Stem	258	259.52	0.947
Aseptic Loosening - Socket	57	94.59	<0.001
Periprosthetic Fracture Stem	76	245.34	<0.001
Periprosthetic Fracture Socket	10	33.80	<0.001
Malalignment Stem	54	59.87	0.437
Malalignment Socket	84	91.84	0.399
Wear Of Acetabular Component	44	59.34	0.033
Lysis Stem	17	22.71	0.268
Lysis Socket	9	13.83	0.208
Implant Fracture Stem	12	22.70	0.012
Implant Fracture Socket	47	34.50	0.027
Implant Fracture Head	4	6.89	0.323
Dissociation of Liner	39	37.59	0.79
Other / reason not recorded	58	75.36	0.028
Total Revised	1138	1475.78	<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 $p < 0.001$



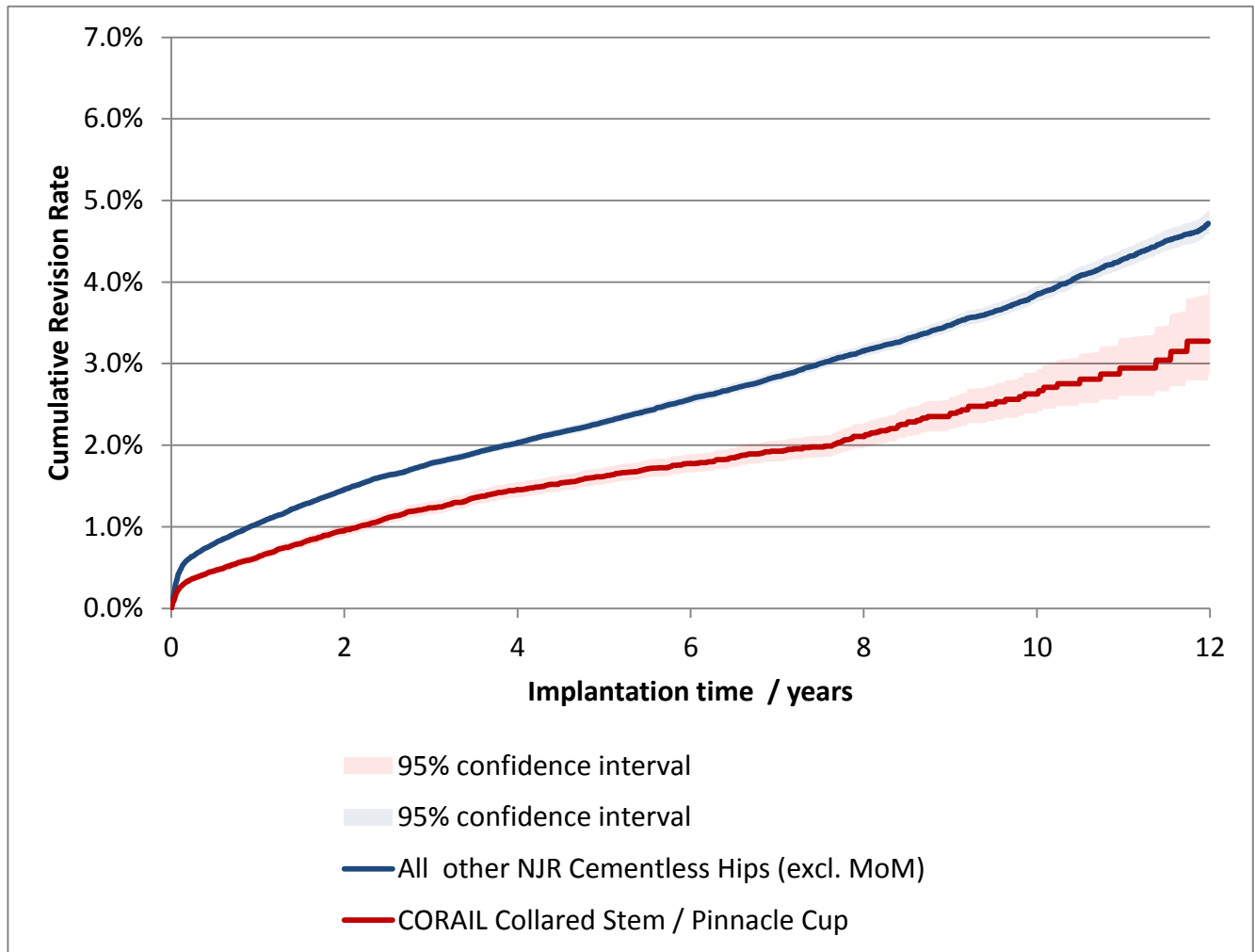
Components Revised	Number of procedures	CORAIL Collared Stem / Pinnacle Cup	All other NJR Cementless Hips (excl. MoM)
Femoral only	326	29%	32%
Acetabular only	292	26%	25%
Both femoral and acetabular	327	29%	31%
Neither femoral nor acetabular revision recorded *	193	17%	12%

* 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 Collared Stem / Pinnacle Cup / All other NJR Cementless Hips (excl. MoM), with endpoint as any revision.

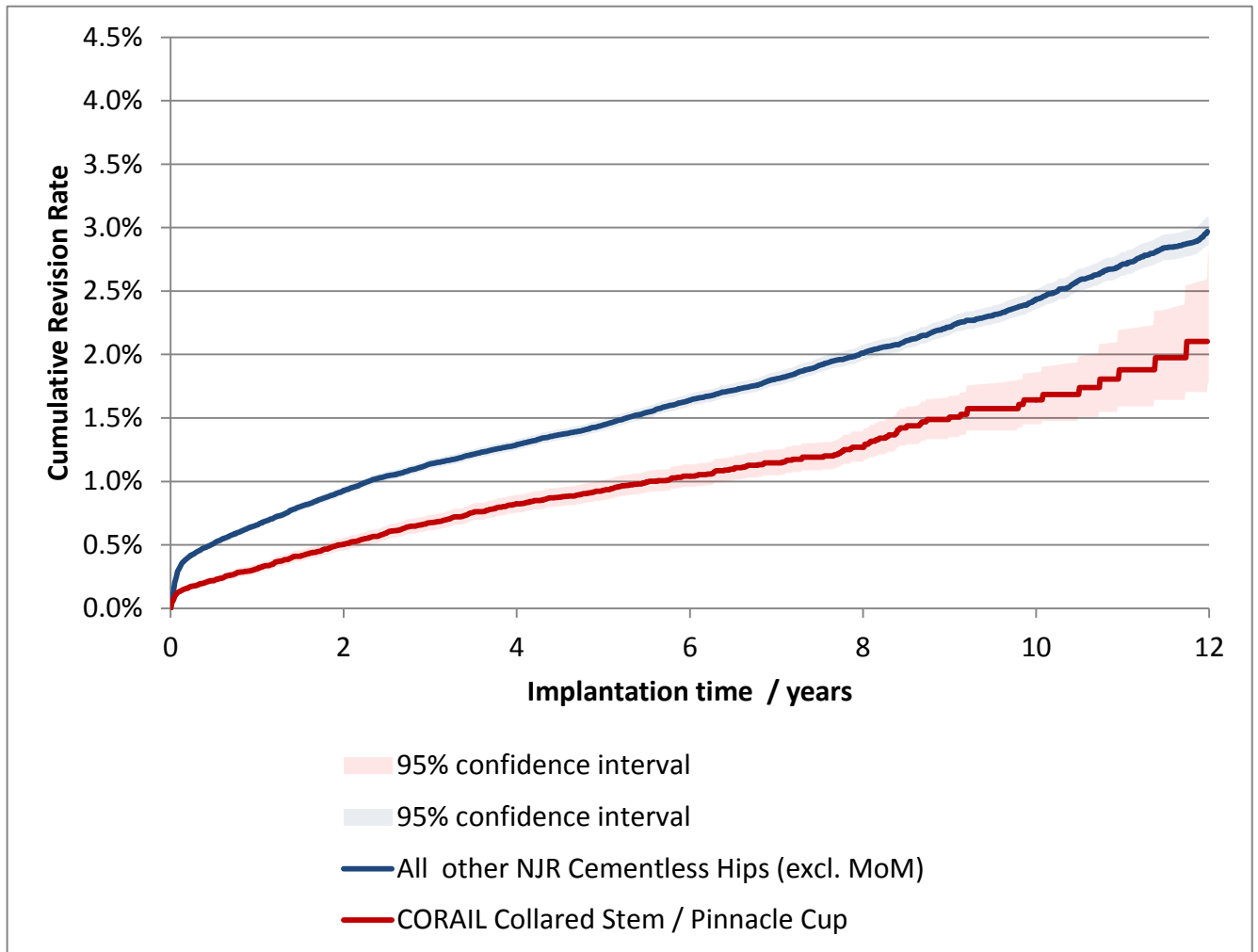
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.68 (0.64 - 0.73)	<0.001
All bearings. Adjusted for age, gender, year cohort and indications.	0.72 ‡ (0.68 - 0.77)	<0.001 ‡

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision



Cox Proportional Hazards model for revision risk ratio of CORAIL Collared Stem / 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.	0.62 ‡ (0.57 - 0.67)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.65 ‡ (0.60 - 0.71)	<0.001 ‡

‡ Hazard ratio varies with time

Cumulative Revision Rate

Period /years	Endpoint: Any component revised				Endpoint: Femoral Revision			
	At Risk	CORAIL Collared Stem / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR	At Risk	CORAIL Collared Stem / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR
0	81,685	-	-	-	81,685	-	-	-
1	70,711	0.6% (0.6% - 0.7%)	1.0% (0.9% - 1.0%)	0.8% (0.8% - 0.8%)	70,711	0.3% (0.3% - 0.4%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)
2	59,337	1.0% (0.9% - 1.0%)	1.4% (1.3% - 1.4%)	1.1% (1.1% - 1.1%)	59,337	0.5% (0.5% - 0.6%)	0.8% (0.8% - 0.9%)	0.7% (0.7% - 0.7%)
3	47,692	1.2% (1.2% - 1.3%)	1.7% (1.6% - 1.7%)	1.4% (1.4% - 1.4%)	47,692	0.7% (0.6% - 0.7%)	1.0% (1.0% - 1.1%)	0.9% (0.9% - 0.9%)
4	37,432	1.5% (1.4% - 1.5%)	1.9% (1.9% - 2.0%)	1.6% (1.6% - 1.6%)	37,432	0.8% (0.8% - 0.9%)	1.2% (1.2% - 1.2%)	1.0% (1.0% - 1.1%)
5	28,076	1.6% (1.5% - 1.7%)	2.2% (2.1% - 2.2%)	1.9% (1.8% - 1.9%)	28,076	0.9% (0.9% - 1.0%)	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)
6	20,258	1.8% (1.7% - 1.9%)	2.4% (2.4% - 2.5%)	2.1% (2.1% - 2.1%)	20,258	1.0% (1.0% - 1.1%)	1.5% (1.5% - 1.6%)	1.4% (1.4% - 1.4%)
7	14,039	1.9% (1.8% - 2.1%)	2.7% (2.6% - 2.7%)	2.4% (2.3% - 2.4%)	14,039	1.1% (1.0% - 1.3%)	1.7% (1.6% - 1.7%)	1.5% (1.5% - 1.6%)
8	8,794	2.1% (2.0% - 2.3%)	3.0% (2.9% - 3.1%)	2.7% (2.6% - 2.7%)	8,794	1.3% (1.2% - 1.4%)	1.9% (1.8% - 1.9%)	1.8% (1.7% - 1.8%)
9	4,918	2.4% (2.2% - 2.6%)	3.3% (3.2% - 3.4%)	3.0% (2.9% - 3.0%)	4,918	1.5% (1.3% - 1.7%)	2.1% (2.0% - 2.2%)	2.0% (1.9% - 2.0%)
10	2,511	2.6% (2.4% - 2.9%)	3.7% (3.6% - 3.8%)	3.3% (3.3% - 3.4%)	2,511	1.6% (1.4% - 1.9%)	2.3% (2.2% - 2.4%)	2.2% (2.2% - 2.3%)
11	1,281	2.9% (2.6% - 3.3%)	4.1% (4.0% - 4.2%)	3.8% (3.7% - 3.8%)	1,281	1.9% (1.6% - 2.2%)	2.6% (2.5% - 2.7%)	2.5% (2.5% - 2.6%)
12	615	3.4% (2.9% - 4.0%)	4.5% (4.4% - 4.7%)	4.2% (4.2% - 4.3%)	615	2.3% (1.8% - 2.8%)	2.8% (2.7% - 3.0%)	2.9% (2.8% - 2.9%)
13	232	4.0% (3.2% - 5.2%)	5.0% (4.9% - 5.2%)	4.7% (4.6% - 4.8%)	232	2.7% (2.0% - 3.7%)	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 Collared Stem / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR in NJR
Paired Records	26,505	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 - 40.7)	40.0 (40.0 - 40.1)	39.3 (39.3 - 39.4)
6 month score (adjusted)	40.1 (40.0 - 40.2)	39.6 (39.5 - 39.6)	39.4 (39.3 - 39.4)
Health gain	22.0 (21.9 - 22.1)	21.5 (21.4 - 21.5)	21.4 (21.3 - 21.4)
Health gain (adjusted)	22.1 (22.0 - 22.2)	21.5 (21.5 - 21.6)	21.3 (21.3 - 21.4)
p value (adjusted health gain)	< 0.001		
Score Improved	97.7%	97.2%	97.2%

EQ-5D Index (-0.59 - 1.00)	CORAIL Collared Stem / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR in NJR
Paired Records	24,443	107,480	262,456
PreOp score	0.381 (0.377 - 0.385)	0.374 (0.372 - 0.376)	0.353 (0.352 - 0.355)
6 month score	0.821 (0.818 - 0.824)	0.805 (0.804 - 0.807)	0.791 (0.790 - 0.792)
6 month score (adjusted)	0.810 (0.807 - 0.812)	0.796 (0.795 - 0.798)	0.792 (0.791 - 0.793)
Health gain	0.440 (0.436 - 0.444)	0.431 (0.429 - 0.433)	0.438 (0.436 - 0.439)
Health gain (adjusted)	0.455 (0.452 - 0.457)	0.442 (0.440 - 0.443)	0.437 (0.436 - 0.438)
p value (adjusted health gain)	< 0.001		
Score Improved	90.7%	89.6%	89.5%

EQ-VAS (0 - 100)	CORAIL Collared Stem / Pinnacle Cup	All NJR Cementless Hips (excl. MoM)	All THR in NJR
Paired Records	23,449	103,443	251,616
PreOp score	66.4 (66.2 - 66.7)	65.5 (65.4 - 65.7)	65.0 (64.9 - 65.0)
6 month score	78.6 (78.4 - 78.8)	77.8 (77.7 - 77.9)	76.7 (76.7 - 76.8)
6 month score (adjusted)	77.6 (77.4 - 77.8)	77.1 (77.0 - 77.2)	76.8 (76.7 - 76.9)
Health gain	12.2 (11.9 - 12.4)	12.3 (12.2 - 12.4)	11.8 (11.7 - 11.9)
Health gain (adjusted)	12.6 (12.4 - 12.8)	12.0 (11.9 - 12.1)	11.8 (11.7 - 11.8)
p value (adjusted health gain)	< 0.001		
Score Improved	66.7%	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 Collared Stem / 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
3L92508	Corail Collared Stem K18A 180mm	119
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