

Implant Bespoke Report for:

DePuy

Corail Stem (Collared Stem with Pinnacle Cup)

Comprising PRIMARY hips implanted up to:	07 March 2021
NJR Database extract:	06 May 2021
Produced on:	15 June 2021
Licensed for use until:	15 June 2023

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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 (Collared Stem with 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 (Collared Stem with Pinnacle Cup)
Acetabular Component	Pinnacle cups (excluding metal liners)
Comparator Group	All NJR Cemented Hips (excluding MoM)

Appendix A lists details of all Corail Stem components included in this report.

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NJR Recorded Usage

Implant Usage

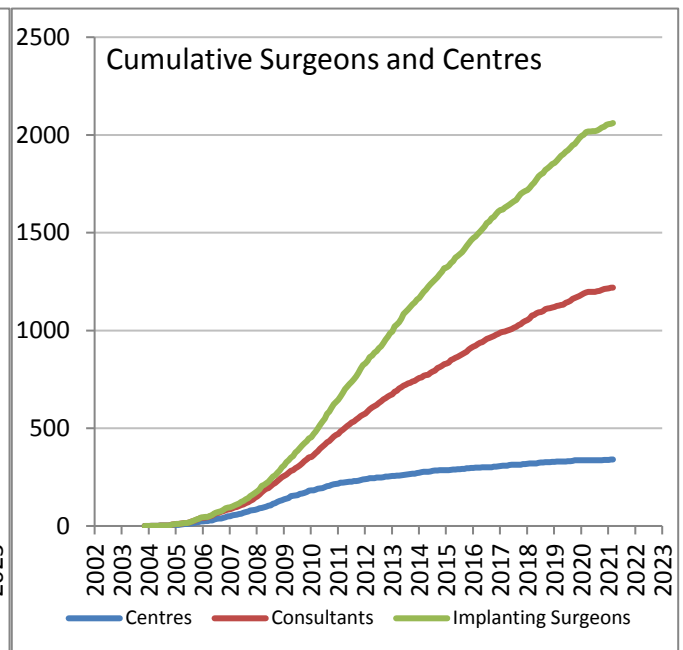
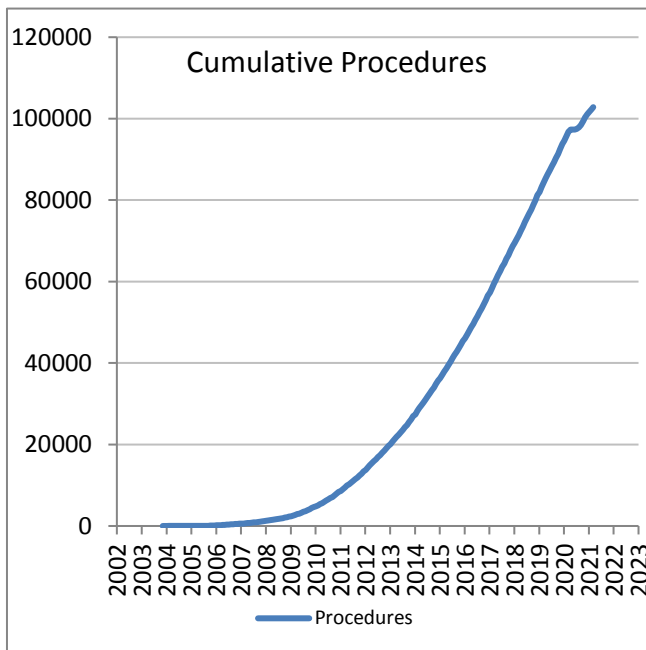
Date of first recorded usage in the NJR: **11 January 2004**

Date of last recorded usage in this dataset: **07 March 2021**

Maximum implantation time: **17.2 years**

Mean implantation time: **4.8 years**

Totals Recorded in NJR	Cumulative Total
Procedures	102,823
Patients	92,576
Centres	340
Consultants	1,219
Implanting Surgeons	2,061



Current Outcome	Year of implantation													Total	%
	Pre-2010	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021		
Death	1295	853	1020	1028	1066	955	777	714	505	332	186	32	0	8763	8.5%
Revised	167	103	126	146	129	130	156	152	130	108	67	27	3	1444	1.4%
Unrevised	3341	2811	3940	5186	6101	7745	8869	10347	11503	12118	12305	7069	1281	92616	90.1%
Total	4803	3767	5086	6360	7296	8830	9802	11213	12138	12558	12558	7128	1284	102823	100%

Patient / Procedure Details

Patient Details

	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM	All NJR hip replacement
Total Procedures	102,823	400,204	1,285,207
Total Patients	92,576	355,202	1,082,079
Demographics			
Mean age	66.5	73.6	68.6
< 50	6.7%	1.4%	5.9%
50 – 59	17.9%	5.4%	13.8%
60 – 69	33.8%	21.9%	28.9%
70 – 79	30.7%	44.4%	34.7%
≥ 80	10.9%	26.9%	16.6%
Median BMI	28	28	28
% BMI information available	74.3%	59.2%	62.7%
Underweight (BMI < 18.5)	0.7%	1.1%	0.9%
Normal (18.5 ≤ BMI < 25)	18.7%	22.6%	20.8%
Overweight (25 ≤ BMI < 30)	38.9%	40.1%	39.6%
Obese I (30 ≤ BMI < 35)	27.1%	24.8%	25.8%
Obese II (35 ≤ BMI < 40)	11.1%	8.6%	9.7%
Obese III (BMI ≥ 40)	3.6%	2.7%	3.3%
% Male	42.3%	33.5%	40.2%
ASA Grades			
P1 - Fit and healthy	15.0%	10.7%	15.6%
P2 - Mild disease not incapacitating	71.5%	67.7%	67.7%
P3 - Incapacitating systemic disease	13.2%	20.8%	16.2%
P4 / P5	0.4%	0.8%	0.6%
Indications			
Osteoarthritis	94.20%	90.87%	91.26%
Rheumatoid Arthritis	0.95%	1.36%	1.32%
Avascular Necrosis	1.95%	2.25%	2.53%
Fractured Neck of Femur	2.40%	4.79%	3.69%
CDH/DDH	1.31%	0.60%	1.58%
Other	0.96%	2.13%	2.12%

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 - excluding Metal on Metal

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

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Unexplained Pain	106	115.42	0.376
Dislocation / Subluxation	328	378.17	0.006
Adverse Soft Tissue Reaction	35	36.01	0.929
Infection	279	389.10	<0.001
Aseptic Loosening - Stem	333	269.63	<0.001
Aseptic Loosening - Socket	71	201.12	<0.001
Periprosthetic Fracture Stem	107	239.86	<0.001
Periprosthetic Fracture Socket	13	16.25	0.507
Malalignment Stem	63	58.47	0.523
Malalignment Socket	102	82.49	0.025
Wear Of Acetabular Component	51	52.96	0.83
Lysis Stem	25	28.18	0.626
Lysis Socket	13	34.19	<0.001
Implant Fracture Stem	13	22.17	0.042
Implant Fracture Socket	54	32.76	<0.001
Implant Fracture Head	4	5.50	0.647
Dissociation of Liner	54	35.52	0.001
Other / Not recorded	68	65.29	0.689
Total Revised	1444	1698.76	<0.001

* Based on All Cemented Stems Exl MoM (excluding metal on metal), adjusted for agegroup, gender, indications, and implantation year

† 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



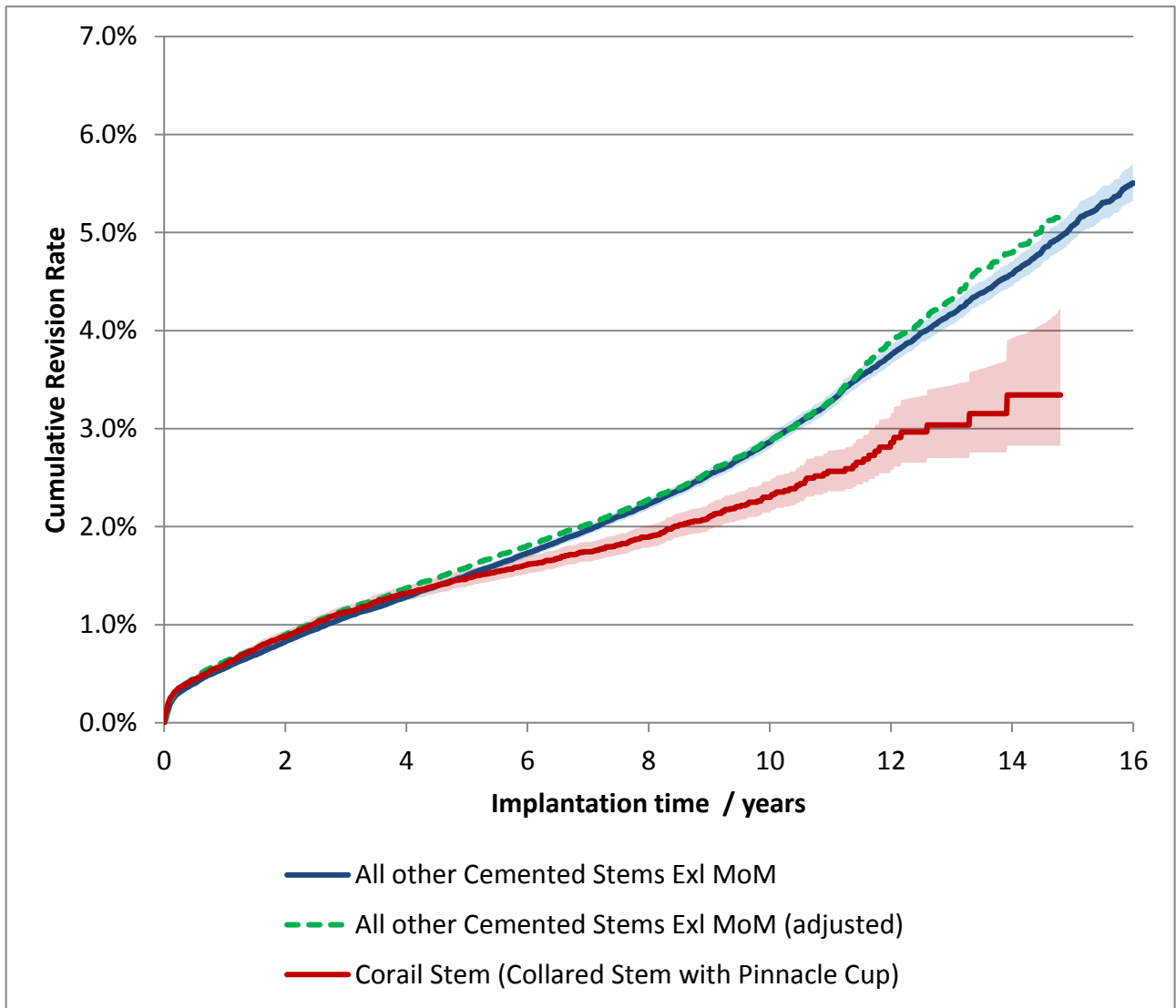
Components Revised	Number of procedures	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM
Femoral only	419	29%	17%
Acetabular only	354	25%	25%
Both femoral and acetabular	406	28%	50%
Neither femoral nor acetabular revision recorded *	265	18%	7%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Corail Stem (Collared Stem with Pinnacle Cup) / All other Cemented Stems Exl MoM, with endpoint as any revision.

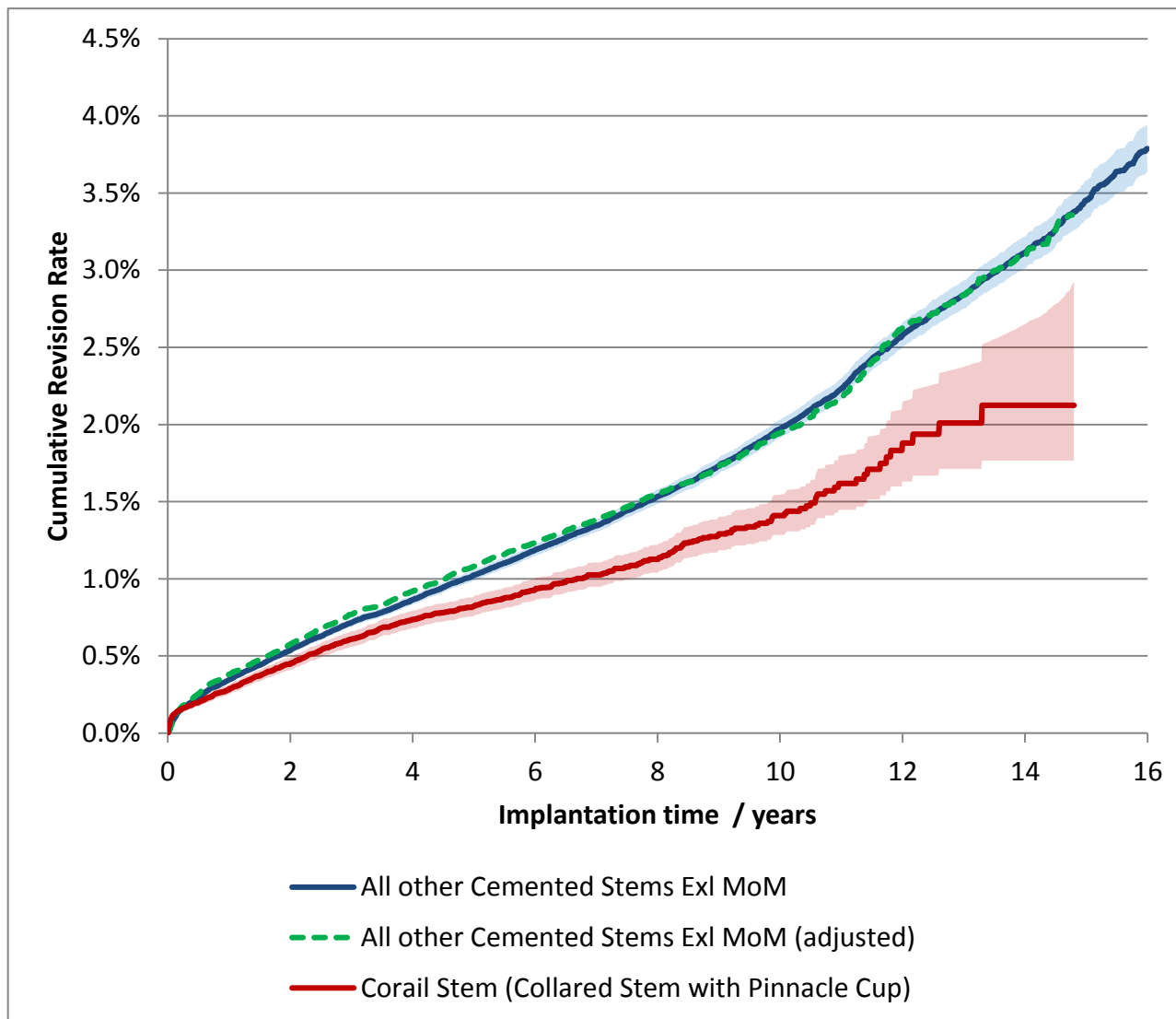
Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	0.84 ‡ (0.79 - 0.89)	<0.001 ‡
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.81 ‡ (0.77 - 0.86)	<0.001 ‡

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Corail Stem (Collared Stem with Pinnacle Cup) / All other Cemented Stems Exl MoM, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	0.72 (0.67 - 0.77)	<0.001
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.71 (0.66 - 0.77)	<0.001

Revision and Survivorship

Cumulative Revision Rate

Excluding Metal on Metal Bearings

Period /years	Endpoint: Any component revised				Endpoint: Femoral revision			
	At Risk	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM	All THR	At Risk	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM	All THR
0	102,823	-	-	-	102,823	-	-	-
1	95,425	0.6% (0.5% - 0.6%)	0.6% (0.5% - 0.6%)	0.8% (0.8% - 0.8%)	95,425	0.3% (0.3% - 0.3%)	0.3% (0.3% - 0.4%)	0.5% (0.5% - 0.5%)
2	81,826	0.9% (0.8% - 0.9%)	0.8% (0.8% - 0.9%)	1.1% (1.1% - 1.1%)	81,826	0.4% (0.4% - 0.5%)	0.5% (0.5% - 0.6%)	0.7% (0.7% - 0.7%)
3	68,159	1.1% (1.1% - 1.2%)	1.1% (1.0% - 1.1%)	1.3% (1.3% - 1.4%)	68,159	0.6% (0.6% - 0.7%)	0.7% (0.7% - 0.7%)	0.9% (0.8% - 0.9%)
4	55,603	1.3% (1.2% - 1.4%)	1.3% (1.2% - 1.3%)	1.6% (1.5% - 1.6%)	55,603	0.7% (0.7% - 0.8%)	0.9% (0.8% - 0.9%)	1.0% (1.0% - 1.0%)
5	43,732	1.5% (1.4% - 1.6%)	1.5% (1.5% - 1.5%)	1.8% (1.8% - 1.8%)	43,732	0.8% (0.8% - 0.9%)	1.0% (1.0% - 1.1%)	1.2% (1.1% - 1.2%)
6	33,706	1.6% (1.5% - 1.7%)	1.7% (1.7% - 1.8%)	2.0% (2.0% - 2.0%)	33,706	0.9% (0.9% - 1.0%)	1.2% (1.2% - 1.2%)	1.3% (1.3% - 1.3%)
7	24,920	1.7% (1.6% - 1.8%)	2.0% (1.9% - 2.0%)	2.3% (2.2% - 2.3%)	24,920	1.0% (0.9% - 1.1%)	1.3% (1.3% - 1.4%)	1.5% (1.4% - 1.5%)
8	17,767	1.9% (1.8% - 2.0%)	2.2% (2.2% - 2.3%)	2.5% (2.5% - 2.6%)	17,767	1.1% (1.0% - 1.2%)	1.5% (1.5% - 1.6%)	1.7% (1.6% - 1.7%)
9	11,906	2.1% (2.0% - 2.2%)	2.5% (2.5% - 2.6%)	2.8% (2.8% - 2.9%)	11,906	1.3% (1.2% - 1.4%)	1.7% (1.7% - 1.8%)	1.9% (1.8% - 1.9%)
10	7,259	2.3% (2.1% - 2.5%)	2.9% (2.8% - 2.9%)	3.1% (3.1% - 3.2%)	7,259	1.4% (1.3% - 1.5%)	2.0% (1.9% - 2.0%)	2.1% (2.0% - 2.1%)
11	3,965	2.6% (2.4% - 2.8%)	3.3% (3.2% - 3.4%)	3.5% (3.4% - 3.5%)	3,965	1.6% (1.4% - 1.8%)	2.2% (2.2% - 2.3%)	2.3% (2.3% - 2.4%)
12	2,016	2.9% (2.6% - 3.2%)	3.8% (3.7% - 3.8%)	3.9% (3.9% - 4.0%)	2,016	1.9% (1.6% - 2.1%)	2.6% (2.5% - 2.7%)	2.6% (2.6% - 2.7%)
13	1,050	3.0% (2.7% - 3.4%)	4.2% (4.1% - 4.3%)	4.3% (4.3% - 4.4%)	1,050	2.0% (1.7% - 2.4%)	2.8% (2.8% - 2.9%)	2.9% (2.8% - 3.0%)
14	474	3.3% (2.8% - 3.9%)	4.6% (4.5% - 4.7%)	4.7% (4.7% - 4.8%)	474	2.1% (1.8% - 2.7%)	3.1% (3.0% - 3.2%)	3.2% (3.1% - 3.2%)
15		(-)	5.1% (4.9% - 5.2%)	5.2% (5.1% - 5.3%)		(-)	3.5% (3.3% - 3.6%)	3.5% (3.4% - 3.6%)

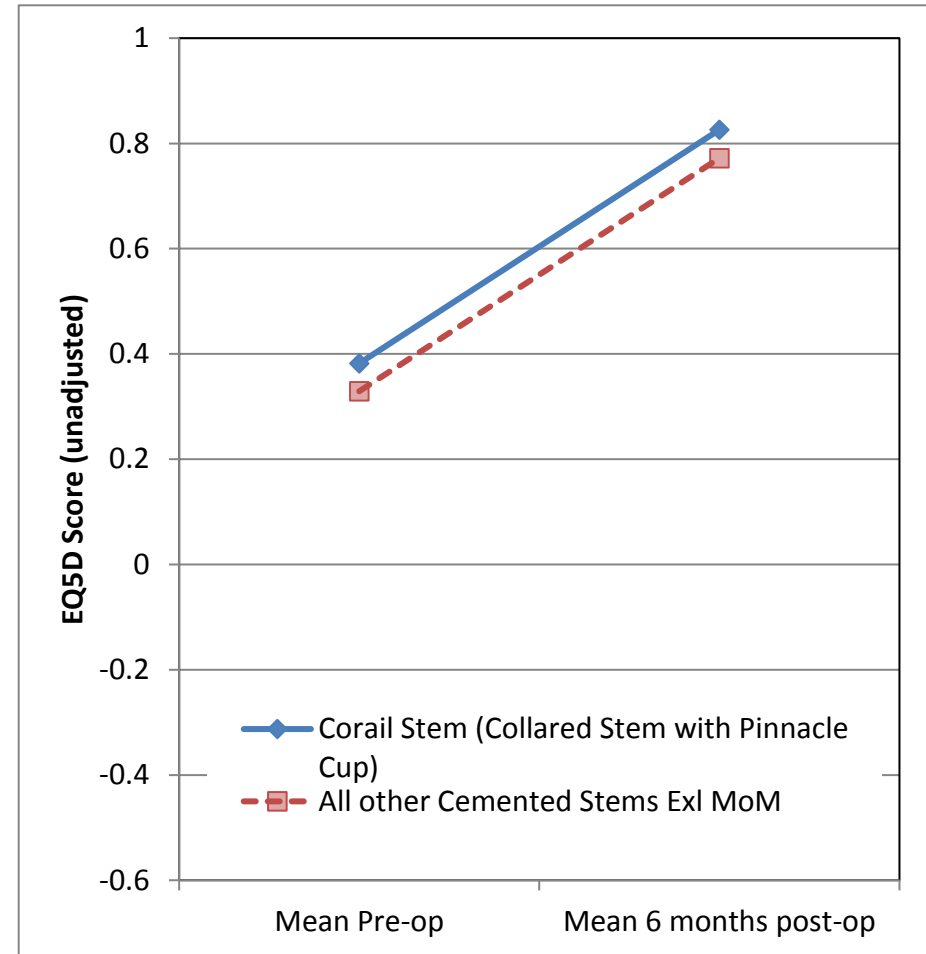
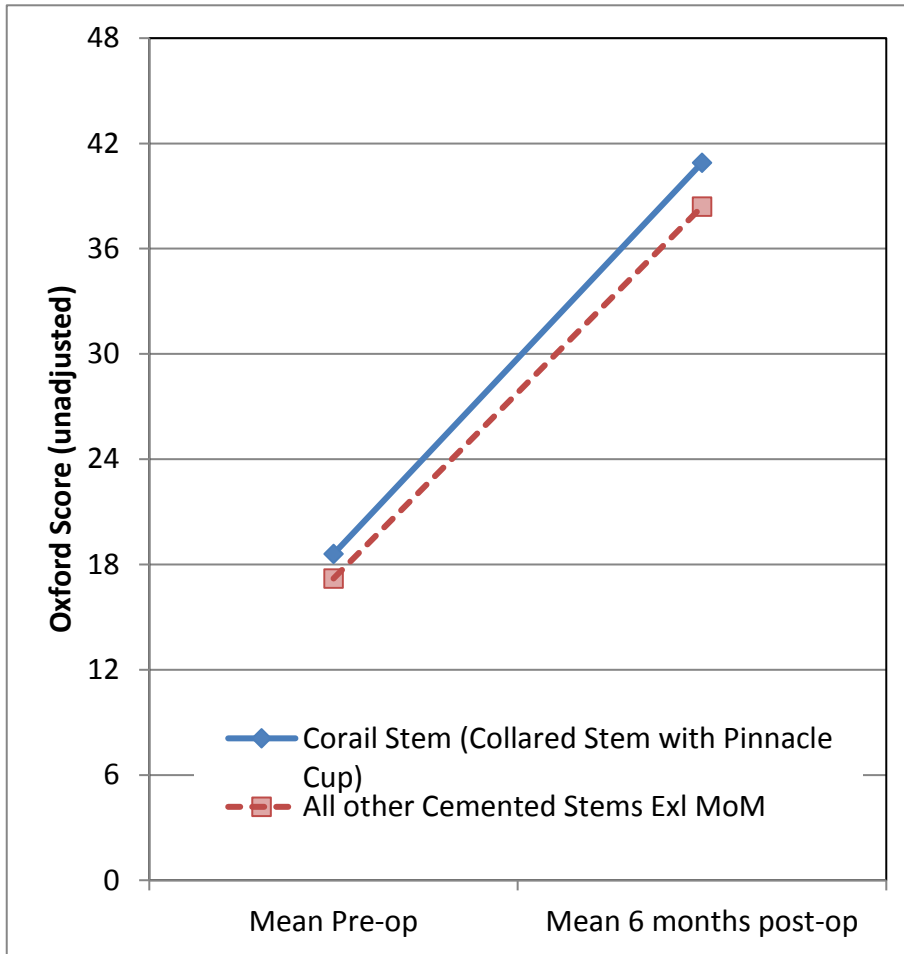
Cumulative revision rate with 95% confidence intervals

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

Patient Reported Outcomes

Comprising PROMs data up to and including: 31/12/2019

PROMs Analysis



Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/12/2019

Oxford Hip Score (0 - 48)	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM	All THR in NJR
Paired Records	33,972	108,038	342,959
PreOp score	18.6 (18.5 - 18.7)	17.2 (17.2 - 17.3)	17.9 (17.9 - 18.0)
6 month score	40.9 (40.8 - 41.0)	38.4 (38.3 - 38.4)	39.5 (39.5 - 39.5)
6 month score (adjusted)	40.3 (40.3 - 40.4)	39.0 (39.0 - 39.0)	39.5 (39.5 - 39.5)
Health gain	22.3 (22.2 - 22.4)	21.1 (21.1 - 21.2)	21.6 (21.5 - 21.6)
Health gain (adjusted)	22.4 (22.3 - 22.5)	21.1 (21.0 - 21.1)	21.6 (21.5 - 21.6)
p value (adjusted health gain)	< 0.001		
Score Improved	97.8%	97.1%	97.3%

EQ-5D Index (-0.59 - 1.00)	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM	All THR in NJR
Paired Records	31,382	98,635	315,677
PreOp score	0.382 (0.379 - 0.386)	0.329 (0.327 - 0.331)	0.353 (0.352 - 0.354)
6 month score	0.826 (0.824 - 0.829)	0.772 (0.771 - 0.774)	0.794 (0.794 - 0.795)
6 month score (adjusted)	0.813 (0.811 - 0.816)	0.784 (0.782 - 0.785)	0.794 (0.794 - 0.795)
Health gain	0.444 (0.440 - 0.448)	0.443 (0.441 - 0.446)	0.441 (0.440 - 0.442)
Health gain (adjusted)	0.460 (0.458 - 0.462)	0.431 (0.429 - 0.432)	0.441 (0.441 - 0.442)
p value (adjusted health gain)	< 0.001		
Score Improved	91.0%	89.1%	89.7%

EQ-VAS (0 - 100)	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM	All THR in NJR
Paired Records	30,212	94,001	303,007
PreOp score	66.2 (66.0 - 66.5)	64.2 (64.0 - 64.3)	64.8 (64.7 - 64.9)
6 month score	79.0 (78.8 - 79.2)	75.4 (75.3 - 75.5)	77.0 (76.9 - 77.1)
6 month score (adjusted)	77.9 (77.7 - 78.0)	76.4 (76.3 - 76.5)	77.0 (76.9 - 77.0)
Health gain	12.8 (12.5 - 13.0)	11.2 (11.1 - 11.4)	12.2 (12.1 - 12.3)
Health gain (adjusted)	13.1 (12.9 - 13.2)	11.6 (11.5 - 11.7)	12.2 (12.1 - 12.3)
p value (adjusted health gain)	< 0.001		
Score Improved	67.8%	64.1%	66.4%

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

Figures in parentheses represent the 95% confidence interval for the mean

Bespoke Report for:

Corail Stem (Collared Stem with Pinnacle Cup)

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM
Much better	31182	93370
A little better	2359	10646
About the same	608	2951
A little worse	315	1626
Much worse	264	1053

Answer to 6-months general health question:

"Overall, how are your problems now, compared to before your operation?"

Satisfaction

Response	Corail Stem (Collared Stem with Pinnacle Cup)	All other Cemented Stems Exl MoM
Excellent	16864	40733
Very Good	11380	39079
Good	4622	20840
Fair	1416	6963
Poor	424	1856

Answer to 6-months general health question:

"How would you describe the results of your operation?"

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Disclaimer

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
3L92498	Corail Collared Stem K8A 115mm	3374
3L92499	Corail Collared Stem K9A 130mm	6147
3L92500	Corail Collared Stem K10A 140mm	12926
3L92501	Corail Collared Stem K11A 145mm	19438
3L92502	Corail Collared Stem K12A 150mm	15794
3L92503	Corail Collared Stem K13A 155mm	7962
3L92504	Corail Collared Stem K14A 160mm	4066
3L92505	Corail Collared Stem K15A 165mm	1756
3L92506	Corail Collared Stem K16A 170mm	701
3L92508	Corail Collared Stem K18A 180mm	137
3L92521	Corail Collared Stem K20A 190mm	10
3L93709	Corail Collared Lateralised Coxa Vara Stem KLA9 130mm	2469
3L93710	Corail Collared Lateralised Coxa Vara Stem KLA10 140mm	4019
3L93711	Corail Collared Lateralised Coxa Vara Stem KLA11 145mm	6284
3L93712	Corail Collared Lateralised Coxa Vara Stem KLA12 150mm	5347
3L93713	Corail Collared Lateralised Coxa Vara Stem KLA13 155mm	2679
3L93714	Corail Collared Lateralised Coxa Vara Stem KLA14 160mm	1491
3L93715	Corail Collared Lateralised Coxa Vara Stem KLA15 165mm	644
3L93716	Corail Collared Lateralised Coxa Vara Stem KLA16 170mm	265
3L93718	Corail Collared Lateralised Coxa Vara Stem Size 18	21
3L93720	Corail Collared Lateralised Coxa Vara Stem Size 20	1
L971109	Corail 135 High Offset KHO (Collar) Size 9	291
L971110	Corail 135 High Offset KHO (Collar) Size 10	673
L971111	Corail 135 High Offset KHO (Collar) Size 11	1571
L971112	Corail 135 High Offset KHO (Collar) Size 12	1754
L971113	Corail 135 High Offset KHO (Collar) Size 13	1139
L971114	Corail 135 High Offset KHO (Collar) Size 14	788
L971115	Corail 135 High Offset KHO (Collar) Size 15	404
L971116	Corail 135 High Offset KHO (Collar) Size 16	216
L971118	Corail 135 High Offset KHO (Collar) Size 18	33
L971120	Corail 135 High Offset KHO (Collar) Size 20	12
L971208	Corail 125 Standard Neck SN (Collar) Size 8	65
L971209	Corail 125 Standard Neck SN (Collar) Size 9	74
L971210	Corail 125 Standard Neck SN (Collar) Size 10	74
L971211	Corail 125 Standard Neck SN (Collar) Size 11	9
L971212	Corail 125 Standard Neck SN (Collar) Size 12	7
L971213	Corail 125 Standard Neck SN (Collar) Size 13	1
L971308	Corail 135 Short Neck SN (Collar) Size 8	55
L971309	Corail 135 Short Neck SN (Collar) Size 9	35
L971310	Corail 135 Short Neck SN (Collar) Size 10	72
L971311	Corail 135 Short Neck SN (Collar) Size 11	9
L971312	Corail 135 Short Neck SN (Collar) Size 12	7
L971313	Corail 135 Short Neck SN (Collar) Size 13	3

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