

Implant Bespoke Report for:

DePuy

Corail Stem (Collarless 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 (Collarless 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 (Collarless Stem with Pinnacle Cup)
Acetabular Component	Pinnacle cups (excluding metal liners)
Comparator Group	All NJR Cementless 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

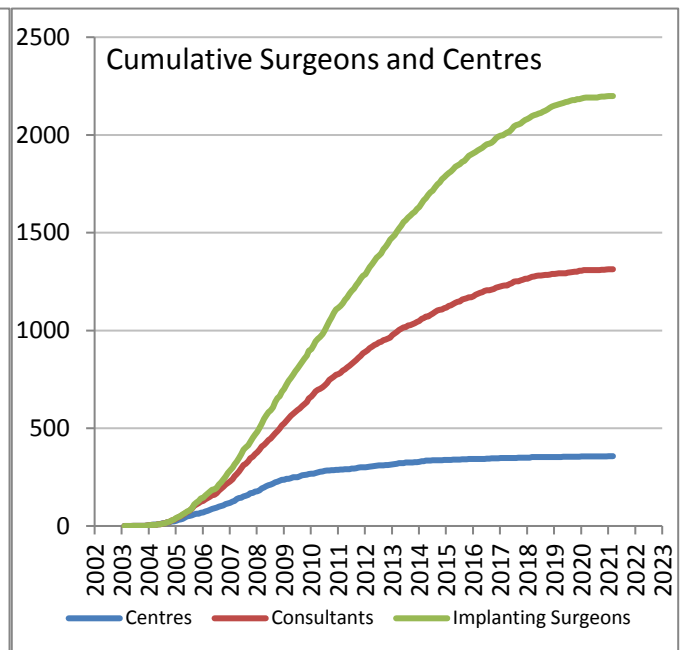
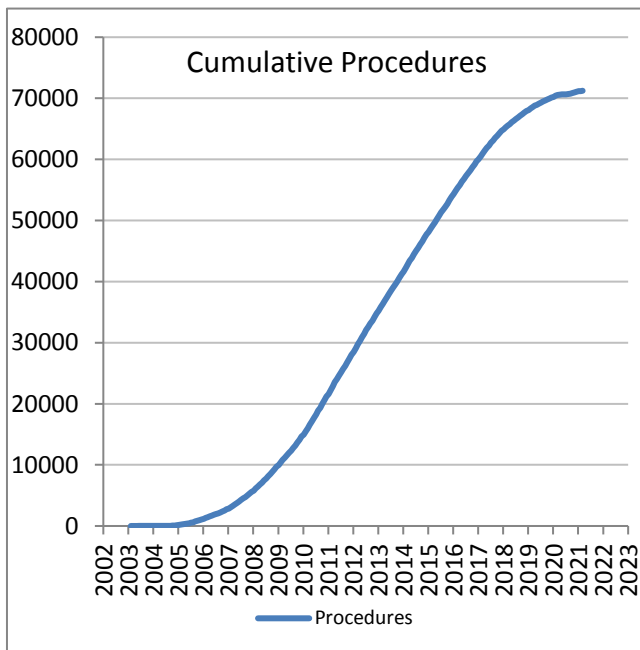
Date of first recorded usage in the NJR: **03 June 2003**

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

Maximum implantation time: 17.3 years

Mean implantation time: 7.4 years

Totals Recorded in NJR	Cumulative Total
Procedures	71,235
Patients	64,481
Centres	357
Consultants	1,313
Implanting Surgeons	2,199



Current Outcome	Year of implantation													Total	%
	Pre-2010	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021		
Death	3829	1211	1017	853	715	558	385	289	169	76	29	4	1	9136	12.8%
Revised	673	217	245	233	152	172	124	99	83	45	23	8	2	2076	2.9%
Unrevised	10426	5162	5601	5686	5508	5800	5669	5328	4645	3092	2117	906	83	60023	84.3%
Total	14928	6590	6863	6772	6375	6530	6178	5716	4897	3213	2169	918	86	71235	100%

Patient / Procedure Details

Patient Details

	Corail Stem (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM	All NJR hip replacement
Total Procedures	71,235	380,640	1,285,207
Total Patients	64,481	332,808	1,082,079
Demographics			
Mean age	64.6	65.1	68.6
< 50	8.5%	8.9%	5.9%
50 – 59	20.6%	19.7%	13.8%
60 – 69	37.5%	34.4%	28.9%
70 – 79	26.7%	28.1%	34.7%
≥ 80	6.8%	9.0%	16.6%
Median BMI	29	28	28
% BMI information available	64.2%	67.4%	62.7%
Underweight (BMI < 18.5)	0.5%	0.7%	0.9%
Normal (18.5 ≤ BMI < 25)	17.2%	19.1%	20.8%
Overweight (25 ≤ BMI < 30)	40.0%	38.9%	39.6%
Obese I (30 ≤ BMI < 35)	27.2%	26.9%	25.8%
Obese II (35 ≤ BMI < 40)	11.4%	10.7%	9.7%
Obese III (BMI ≥ 40)	3.6%	3.7%	3.3%
% Male	48.1%	44.0%	40.2%
ASA Grades			
P1 - Fit and healthy	18.4%	18.0%	15.6%
P2 - Mild disease not incapacitating	70.2%	69.1%	67.7%
P3 - Incapacitating systemic disease	11.1%	12.5%	16.2%
P4 / P5	0.3%	0.4%	0.6%
Indications			
Osteoarthritis	94.05%	93.06%	91.26%
Rheumatoid Arthritis	1.17%	1.20%	1.32%
Avascular Necrosis	2.44%	2.54%	2.53%
Fractured Neck of Femur	1.45%	1.90%	3.69%
CDH/DDH	1.73%	2.28%	1.58%
Other	1.29%	1.68%	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	192	239.81	<0.001
Dislocation / Subluxation	370	371.84	0.932
Adverse Soft Tissue Reaction	56	98.10	<0.001
Infection	276	300.95	0.12
Aseptic Loosening - Stem	525	439.34	<0.001
Aseptic Loosening - Socket	77	160.32	<0.001
Periprosthetic Fracture Stem	418	284.44	<0.001
Periprosthetic Fracture Socket	20	33.41	0.01
Malalignment Stem	64	72.99	0.273
Malalignment Socket	108	133.08	0.017
Wear Of Acetabular Component	70	113.50	<0.001
Lysis Stem	43	54.94	0.085
Lysis Socket	17	42.58	<0.001
Implant Fracture Stem	29	36.68	0.17
Implant Fracture Socket	87	54.49	<0.001
Implant Fracture Head	5	14.55	0.004
Dissociation of Liner	82	52.79	<0.001
Other / Not recorded	99	99.00	1
Total Revised	2076	2013.31	0.124

* Based on All Cementless Hips 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



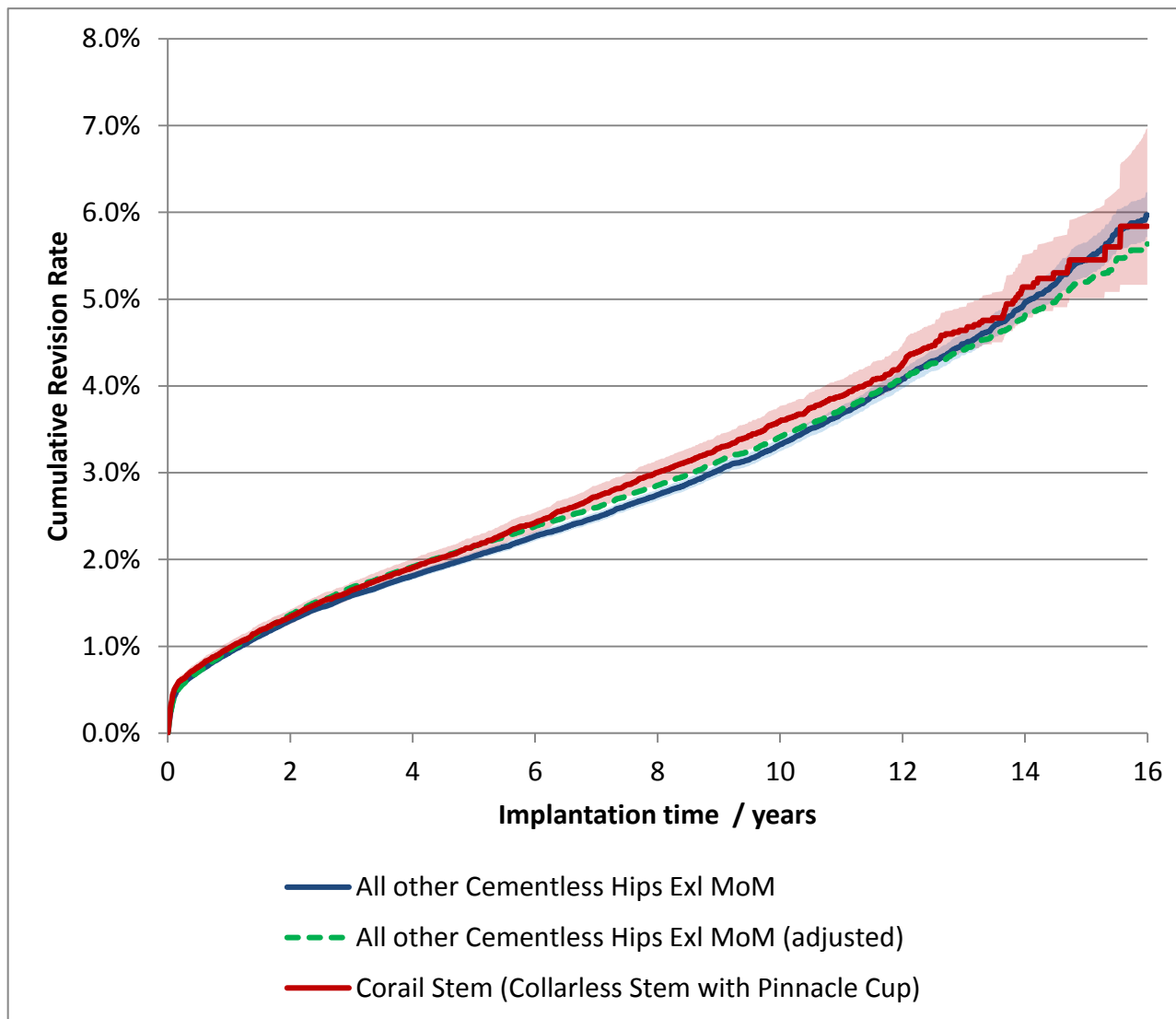
Components Revised	Number of procedures	Corail Stem (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM
Femoral only	845	41%	30%
Acetabular only	411	20%	26%
Both femoral and acetabular	581	28%	31%
Neither femoral nor acetabular revision recorded *	239	12%	13%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

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



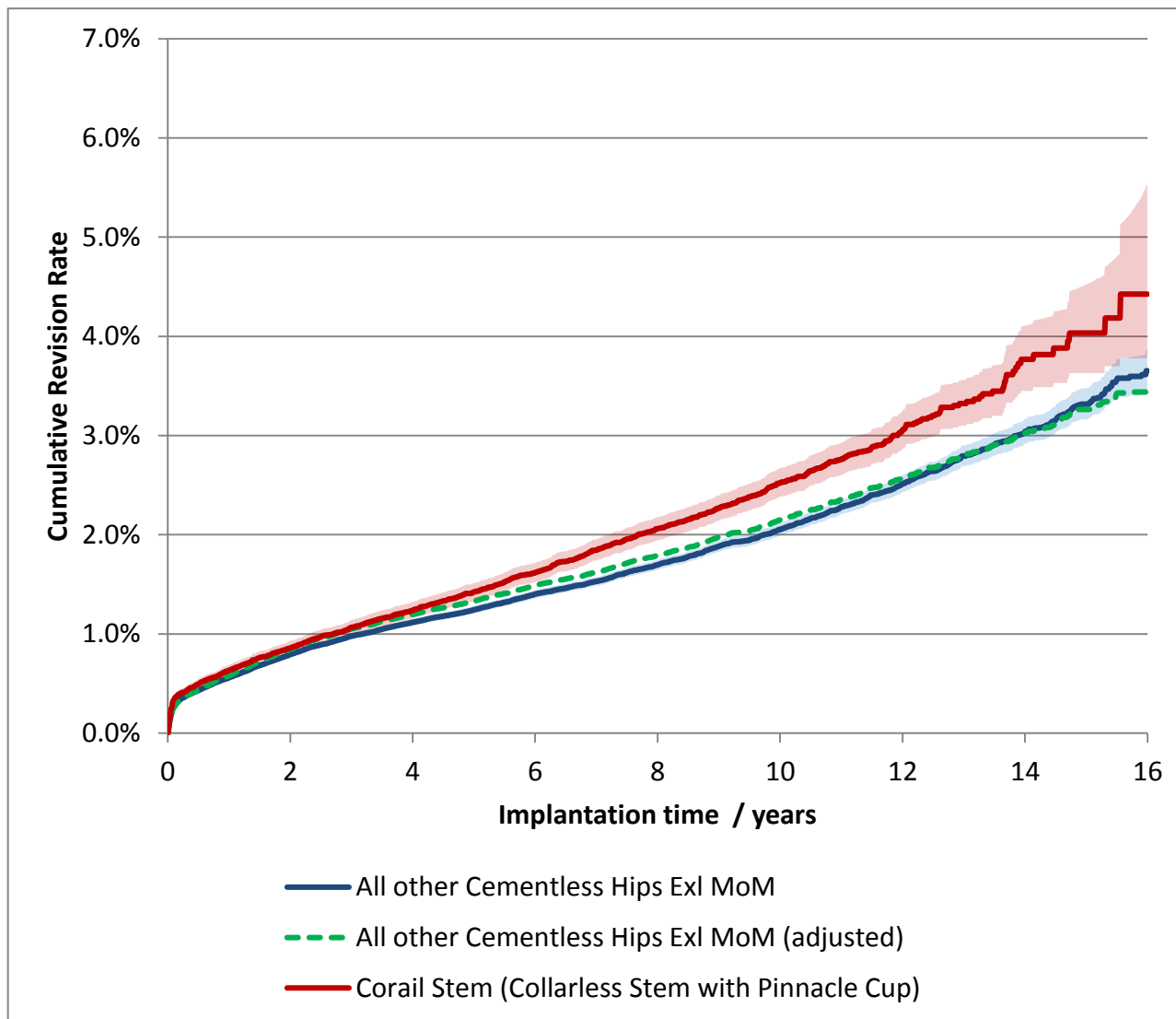
Cox Proportional Hazards model for revision risk ratio of Corail Stem (Collarless Stem with Pinnacle Cup) / All other Cementless Hips Exl MoM, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	1.06 (1.01 - 1.11)	0.012
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.04 (0.99 - 1.09)	0.118

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision. Excluding Metal-on-Metal



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

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	1.19 (1.12 - 1.26)	<0.001
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.14 (1.08 - 1.21)	<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 (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM	All THR	At Risk	Corail Stem (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM	All THR
0	71,235	-	-	-	71,235	-	-	-
1	69,324	1.0% (0.9% - 1.1%)	0.9% (0.9% - 1.0%)	0.8% (0.8% - 0.8%)	69,324	0.6% (0.6% - 0.7%)	0.6% (0.5% - 0.6%)	0.5% (0.5% - 0.5%)
2	66,560	1.3% (1.3% - 1.4%)	1.3% (1.3% - 1.3%)	1.1% (1.1% - 1.1%)	66,560	0.9% (0.8% - 0.9%)	0.8% (0.8% - 0.8%)	0.7% (0.7% - 0.7%)
3	62,626	1.6% (1.6% - 1.7%)	1.6% (1.5% - 1.6%)	1.3% (1.3% - 1.4%)	62,626	1.1% (1.0% - 1.1%)	1.0% (0.9% - 1.0%)	0.9% (0.8% - 0.9%)
4	57,270	1.9% (1.8% - 2.0%)	1.8% (1.8% - 1.9%)	1.6% (1.5% - 1.6%)	57,270	1.2% (1.2% - 1.3%)	1.1% (1.1% - 1.2%)	1.0% (1.0% - 1.0%)
5	51,012	2.2% (2.1% - 2.3%)	2.0% (2.0% - 2.1%)	1.8% (1.8% - 1.8%)	51,012	1.4% (1.3% - 1.5%)	1.2% (1.2% - 1.3%)	1.2% (1.1% - 1.2%)
6	44,306	2.4% (2.3% - 2.5%)	2.3% (2.2% - 2.3%)	2.0% (2.0% - 2.0%)	44,306	1.6% (1.5% - 1.7%)	1.4% (1.4% - 1.4%)	1.3% (1.3% - 1.3%)
7	37,540	2.7% (2.6% - 2.9%)	2.5% (2.4% - 2.5%)	2.3% (2.2% - 2.3%)	37,540	1.8% (1.7% - 2.0%)	1.5% (1.5% - 1.6%)	1.5% (1.4% - 1.5%)
8	30,999	3.0% (2.9% - 3.1%)	2.7% (2.7% - 2.8%)	2.5% (2.5% - 2.6%)	30,999	2.1% (1.9% - 2.2%)	1.7% (1.6% - 1.7%)	1.7% (1.6% - 1.7%)
9	24,529	3.3% (3.1% - 3.4%)	3.0% (3.0% - 3.1%)	2.8% (2.8% - 2.9%)	24,529	2.3% (2.1% - 2.4%)	1.9% (1.8% - 1.9%)	1.9% (1.8% - 1.9%)
10	18,194	3.6% (3.4% - 3.8%)	3.3% (3.2% - 3.4%)	3.1% (3.1% - 3.2%)	18,194	2.5% (2.4% - 2.7%)	2.1% (2.0% - 2.1%)	2.1% (2.0% - 2.1%)
11	12,194	3.9% (3.7% - 4.1%)	3.7% (3.6% - 3.8%)	3.5% (3.4% - 3.5%)	12,194	2.8% (2.6% - 2.9%)	2.3% (2.2% - 2.4%)	2.3% (2.3% - 2.4%)
12	7,934	4.3% (4.0% - 4.5%)	4.1% (4.0% - 4.2%)	3.9% (3.9% - 4.0%)	7,934	3.1% (2.9% - 3.2%)	2.5% (2.4% - 2.6%)	2.6% (2.6% - 2.7%)
13	4,516	4.6% (4.4% - 4.9%)	4.5% (4.4% - 4.6%)	4.3% (4.3% - 4.4%)	4,516	3.3% (3.1% - 3.6%)	2.8% (2.7% - 2.9%)	2.9% (2.8% - 3.0%)
14	2,200	5.1% (4.8% - 5.5%)	5.0% (4.8% - 5.1%)	4.7% (4.7% - 4.8%)	2,200	3.8% (3.5% - 4.1%)	3.0% (2.9% - 3.2%)	3.2% (3.1% - 3.2%)
15	923	5.5% (5.0% - 6.0%)	5.4% (5.2% - 5.7%)	5.2% (5.1% - 5.3%)	923	4.0% (3.6% - 4.5%)	3.3% (3.2% - 3.5%)	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

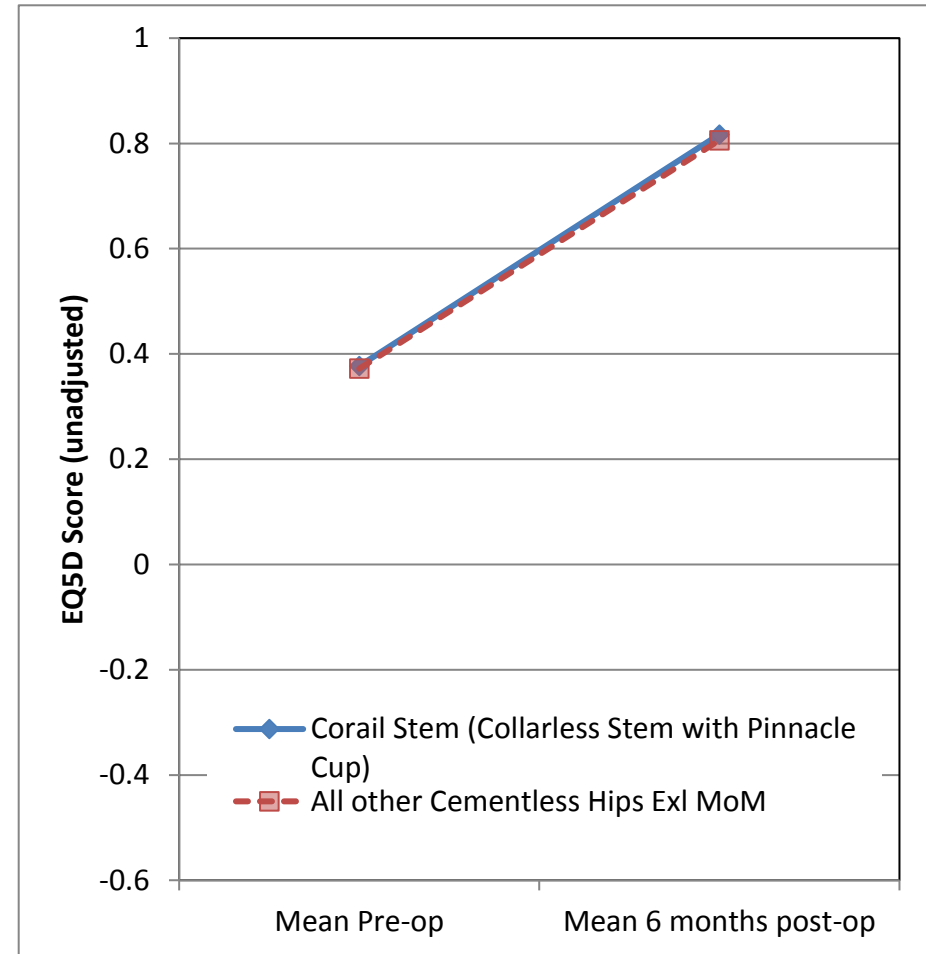
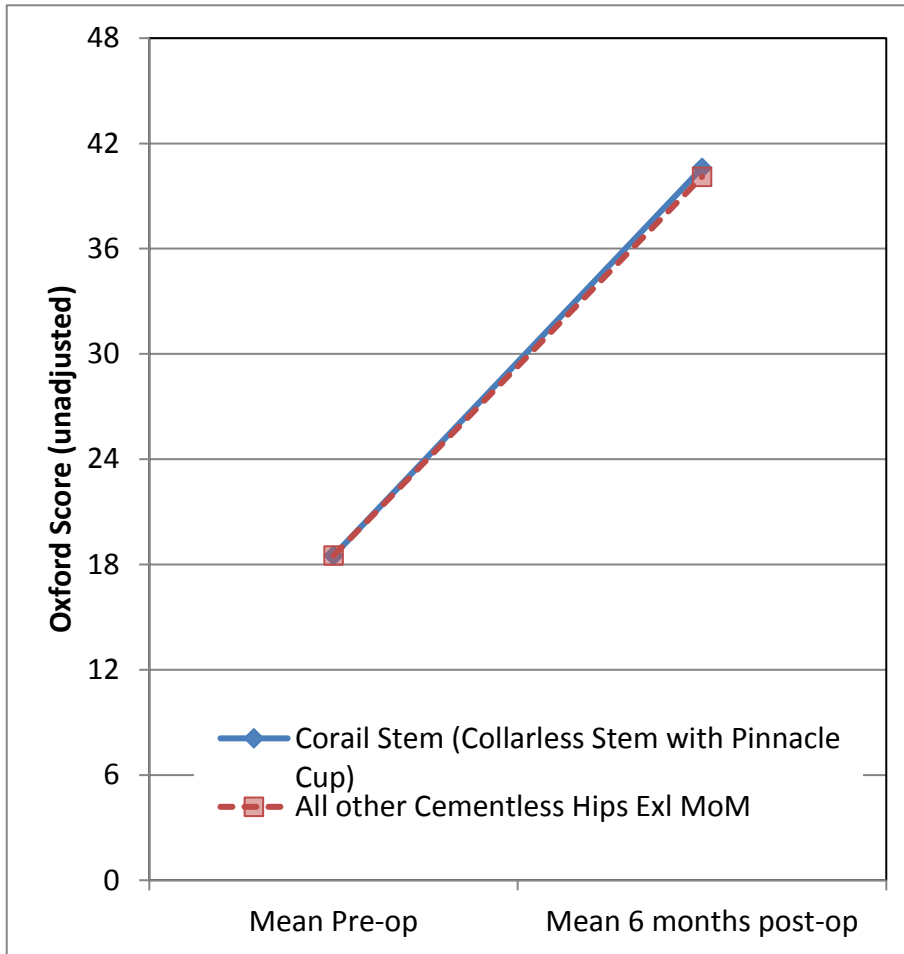
Bespoke Report for:

Corail Stem (Collarless Stem with Pinnacle Cup)

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 (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM	All THR in NJR
Paired Records	23,766	110,692	342,959
PreOp score	18.5 (18.4 - 18.7)	18.5 (18.4 - 18.5)	17.9 (17.9 - 18.0)
6 month score	40.6 (40.5 - 40.7)	40.1 (40.1 - 40.2)	39.5 (39.5 - 39.5)
6 month score (adjusted)	39.9 (39.8 - 40.0)	39.7 (39.6 - 39.7)	39.5 (39.5 - 39.5)
Health gain	22.0 (21.9 - 22.1)	21.6 (21.6 - 21.7)	21.6 (21.5 - 21.6)
Health gain (adjusted)	21.9 (21.8 - 22.0)	21.7 (21.7 - 21.8)	21.6 (21.5 - 21.6)
p value (adjusted health gain)	< 0.001		
Score Improved	97.5%	97.2%	97.3%

EQ-5D Index (-0.59 - 1.00)	Corail Stem (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM	All THR in NJR
Paired Records	21,986	102,533	315,677
PreOp score	0.377 (0.373 - 0.381)	0.372 (0.370 - 0.374)	0.353 (0.352 - 0.354)
6 month score	0.817 (0.814 - 0.820)	0.806 (0.805 - 0.808)	0.794 (0.794 - 0.795)
6 month score (adjusted)	0.803 (0.801 - 0.806)	0.799 (0.797 - 0.800)	0.794 (0.794 - 0.795)
Health gain	0.440 (0.436 - 0.445)	0.434 (0.432 - 0.436)	0.441 (0.440 - 0.442)
Health gain (adjusted)	0.450 (0.447 - 0.453)	0.445 (0.444 - 0.447)	0.441 (0.441 - 0.442)
p value (adjusted health gain)	< 0.001		
Score Improved	90.5%	89.7%	89.7%

EQ-VAS (0 - 100)	Corail Stem (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM	All THR in NJR
Paired Records	21,064	98,951	303,007
PreOp score	65.8 (65.5 - 66.1)	65.2 (65.1 - 65.3)	64.8 (64.7 - 64.9)
6 month score	78.4 (78.1 - 78.6)	78.0 (77.9 - 78.1)	77.0 (76.9 - 77.1)
6 month score (adjusted)	77.2 (77.0 - 77.5)	77.3 (77.2 - 77.4)	77.0 (76.9 - 77.0)
Health gain	12.6 (12.3 - 12.9)	12.8 (12.6 - 12.9)	12.2 (12.1 - 12.3)
Health gain (adjusted)	12.5 (12.2 - 12.7)	12.5 (12.4 - 12.6)	12.2 (12.1 - 12.3)
p value (adjusted health gain)	0.47		
Score Improved	67.8%	67.6%	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 (Collarless Stem with Pinnacle Cup)

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Corail Stem (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM
Much better	21793	99020
A little better	1783	9045
About the same	391	2281
A little worse	228	1407
Much worse	198	1133

Answer to 6-months general health question:

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

Satisfaction

Response	Corail Stem (Collarless Stem with Pinnacle Cup)	All other Cementless Hips Exl MoM
Excellent	11471	50865
Very Good	8170	37613
Good	3368	16622
Fair	1017	5739
Poor	339	1942

Answer to 6-months general health question:

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

Disclaimer

Disclaimer

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
3L92507	Corail Collarless Stem K8S 125mm	3289
3L92509	Corail Collarless Stem K9S 130mm	4382
3L92510	Corail Collarless Stem K10S 140mm	8654
3L92511	Corail Collarless Stem K11S 145mm	12842
3L92512	Corail Collarless Stem K12S 150mm	11104
3L92513	Corail Collarless Stem K13S 155mm	5214
3L92514	Corail Collarless Stem K14S 160mm	2641
3L92515	Corail Collarless Stem K15S 165mm	1157
3L92516	Corail Collarless Stem K16S 170mm	443
3L92518	Corail Collarless Stem K18S 180mm	169
3L92520	Corail Collarless Stem K20S 190mm	8
L20309	Corail High Offset Collarless Stem KHO9 130mm	1252
L20310	Corail High Offset Collarless Stem KHO10 140mm	2545
L20311	Corail High Offset Collarless Stem KHO11 145mm	4674
L20312	Corail High Offset Collarless Stem KHO12 150mm	5312
L20313	Corail High Offset Collarless Stem KHO13 155mm	3534
L20314	Corail High Offset Collarless Stem KHO14 160mm	2258
L20315	Corail High Offset Collarless Stem KHO15 165mm	1178
L20316	Corail High Offset Collarless Stem KHO16 170mm	539
L20318	Corail High Offset Collarless Stem Size 18	38
L20320	Corail High Offset Collarless Stem Size 20	2

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