

Implant Summary Report for:

Heraeus Medical

Hips using Palacos Cement

Comprising PRIMARY hips implanted up to:	13 January 2024
NJR Database extract:	12 February 2024
Produced on:	23 February 2024
Licensed for use until:	23 February 2025

Contents

Recorded Usage in NJR	2
Patient and Procedure Details	3
Revision and Survivorship	4
Patient Reported Outcome Measures	12
APPENDIX A – Component List	17

This report has been produced by the National Joint Registry (NJR). It summarises usage and outcomes associated with the Hips using Palacos Cement 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:

Cemented Components	Hips using Palacos Cement
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Appendix A lists details of all Palacos Cement products included in this report.

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NJR Recorded Usage

Implant Usage

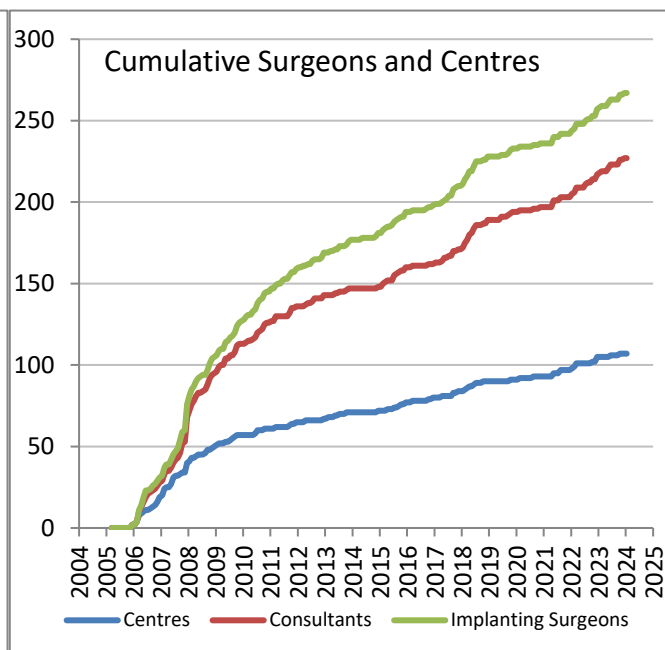
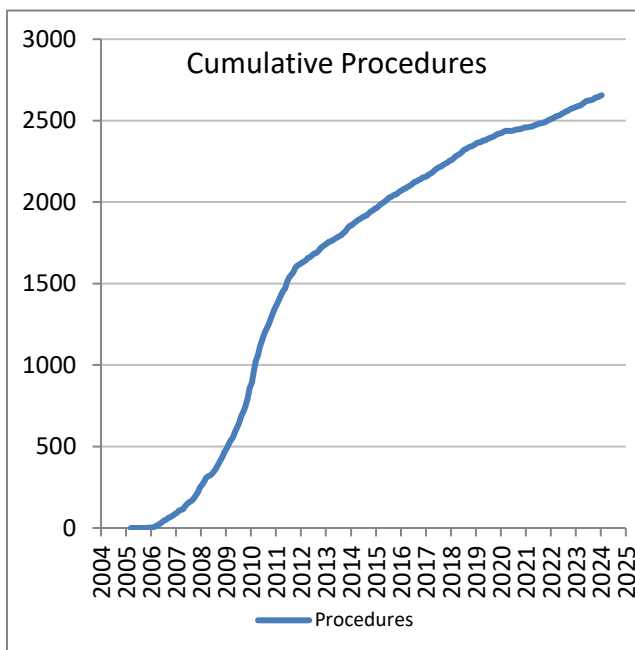
Date of first recorded usage in the NJR: **15 November 2005**

Date of last recorded usage in this dataset: **09 January 2024**

Maximum implantation time: 18.2 years

Mean implantation time: 8.8 years

Totals Recorded in NJR	Cumulative Total
Procedures	2,656
Patients	2,517
Centres	107
Consultants	227
Implanting Surgeons	267



Current Outcome	Year of implantation													Total	%
	Pre-2013	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024		
Death	865	43	28	32	17	19	10	4	5	3	0	0	0	1026	38.6%
Revised	59	4	4	4	3	4	4	1	3	1	0	1	0	88	3.3%
Unrevised	818	66	74	74	66	78	85	60	29	46	76	66	4	1542	58.1%
Total	1742	113	106	110	86	101	99	65	37	50	76	67	4	2656	100%

Patient / Procedure Details

Patient Details

	Hips using Palacos Cement	All other cement brands in NJR	All NJR hip replacement
Total Procedures	2,656	970,121	1,600,803
Total Patients	2,517	836,937	1,328,627
Demographics			
Mean age	73.8	71.2	68.8
< 50	1.5%	4.0%	6.1%
50 – 59	6.0%	10.3%	14.5%
60 – 69	21.9%	25.4%	29.1%
70 – 79	45.4%	39.6%	34.6%
≥ 80	25.2%	20.7%	15.7%
Median BMI	27	28	28
% BMI information available	56.4%	65.6%	65.7%
Underweight (BMI < 18.5)	1.3%	1.0%	0.9%
Normal (18.5 ≤ BMI < 25)	24.7%	22.2%	20.9%
Overweight (25 ≤ BMI < 30)	42.0%	39.4%	39.2%
Obese I (30 ≤ BMI < 35)	21.5%	25.0%	25.7%
Obese II (35 ≤ BMI < 40)	7.7%	9.3%	9.9%
Obese III (BMI ≥ 40)	2.8%	3.1%	3.3%
% Male	33.7%	36.8%	40.2%
ASA Grades			
P1 - Fit and healthy	12.7%	11.9%	14.2%
P2 - Mild disease not incapacitating	67.8%	66.6%	67.6%
P3 - Incapacitating systemic disease	18.8%	20.5%	17.4%
P4 / P5	0.7%	0.9%	0.7%
Indications			
Osteoarthritis	93.52%	89.05%	90.65%
Rheumatoid Arthritis	0.94%	1.39%	1.29%
Avascular Necrosis	3.01%	2.61%	2.61%
Fractured Neck of Femur	3.35%	4.96%	3.72%
CDH/DDH	2.90%	1.18%	1.60%
Other	1.47%	3.34%	2.74%

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 - all bearing types

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

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Unexplained Pain	7	7.19	1
Dislocation / Subluxation	27	16.88	0.02
Adverse Soft Tissue Reaction	5	5.64	1
Infection	11	12.39	0.886
Aseptic Loosening - Stem	14	8.34	0.056
Aseptic Loosening - Socket	9	15.34	0.123
Periprosthetic Fracture Stem	16	14.41	0.598
Periprosthetic Fracture Socket	0	1.34	0.648
Malalignment Stem	8	1.63	<0.001
Malalignment Socket	1	3.36	0.275
Wear Of Acetabular Component	5	3.91	0.452
Lysis Stem	5	2.59	0.12
Lysis Socket	4	3.75	0.793
Implant Fracture Stem	1	1.65	1
Implant Fracture Socket	0	0.33	1
Implant Fracture Head	0	0.34	1
Dissociation of Liner	0	0.71	1
Other / reason not recorded	5	3.19	0.259
Total Revised	88	77.86	0.256

[†] multiple reasons may be listed for one revision procedure ^{*} Based on All NJR Hips with Cement, adjusted for agegroup, gender, indications, and implantation year

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	Hips using Palacos Cement	All other cement brands in NJR
Femoral only	19	22%	21%
Acetabular only	24	27%	19%
Both femoral and acetabular	43	49%	51%
Neither femoral nor acetabular revision recorded [*]	2	2%	9%

^{*} includes isolated head and/or liner exchange

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	4	4.28	1
Dislocation / Subluxation	27	16.64	0.018
Adverse Soft Tissue Reaction	2	1.04	0.278
Infection	11	12.03	0.885
Aseptic Loosening - Stem	11	7.19	0.184
Aseptic Loosening - Socket	9	14.40	0.185
Periprosthetic Fracture Stem	15	13.09	0.578
Periprosthetic Fracture Socket	0	1.25	0.641
Malalignment Stem	8	1.41	<0.001
Malalignment Socket	1	2.92	0.382
Wear Of Acetabular Component	5	3.83	0.442
Lysis Stem	4	2.02	0.146
Lysis Socket	4	3.21	0.569
Implant Fracture Stem	0	1.53	0.415
Implant Fracture Socket	0	0.30	1
Implant Fracture Head	0	0.27	1
Dissociation of Liner	0	0.66	1
Other / reason not recorded	3	2.14	0.478
Total Revised	77	66.91	0.22

* Based on All NJR Hips with Cement (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



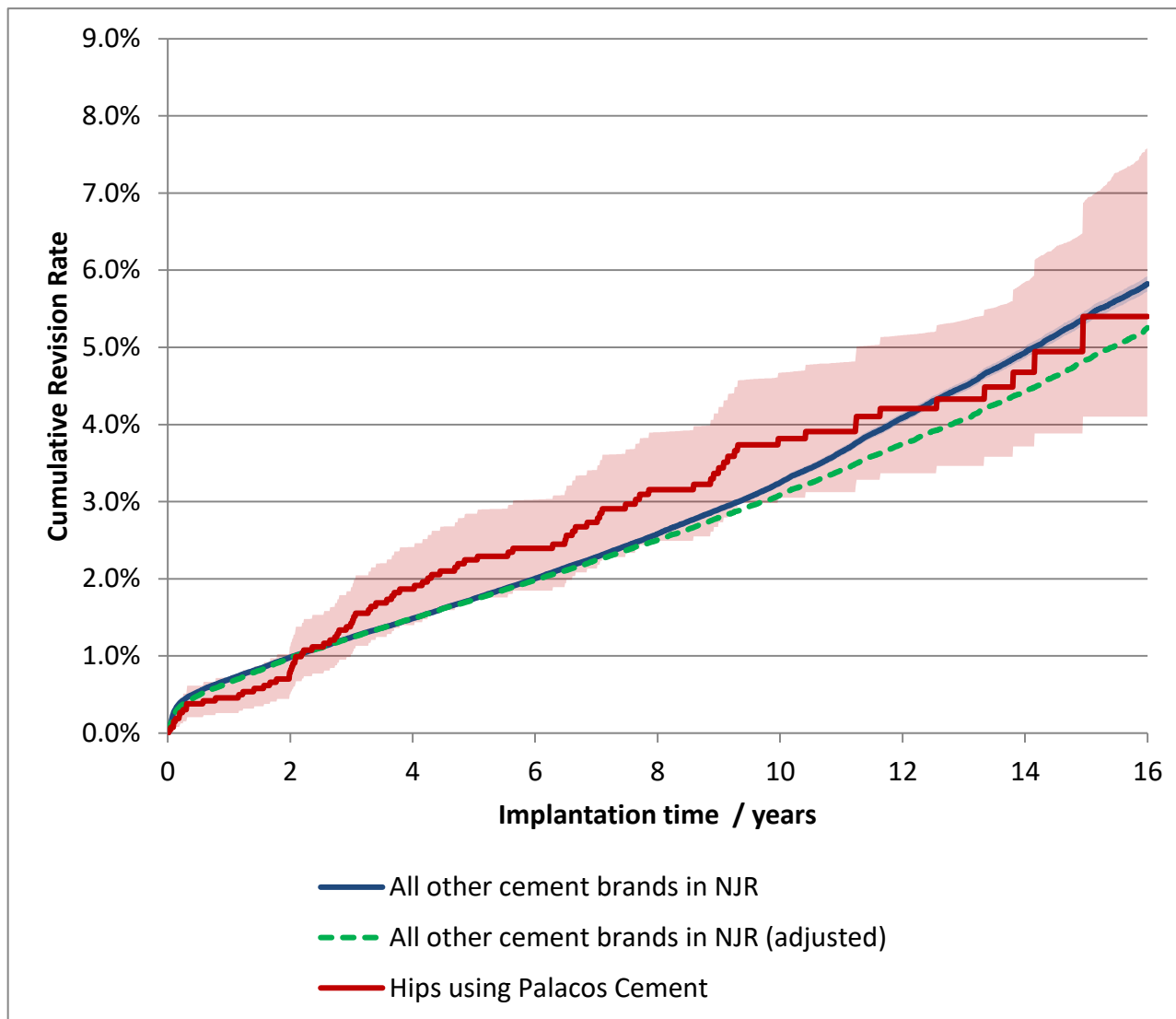
Components Revised	Number of procedures	Hips using Palacos Cement	All other cement brands in NJR
Femoral only	17	22%	23%
Acetabular only	24	31%	23%
Both femoral and acetabular	34	44%	43%
Neither femoral nor acetabular revision recorded *	2	3%	11%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



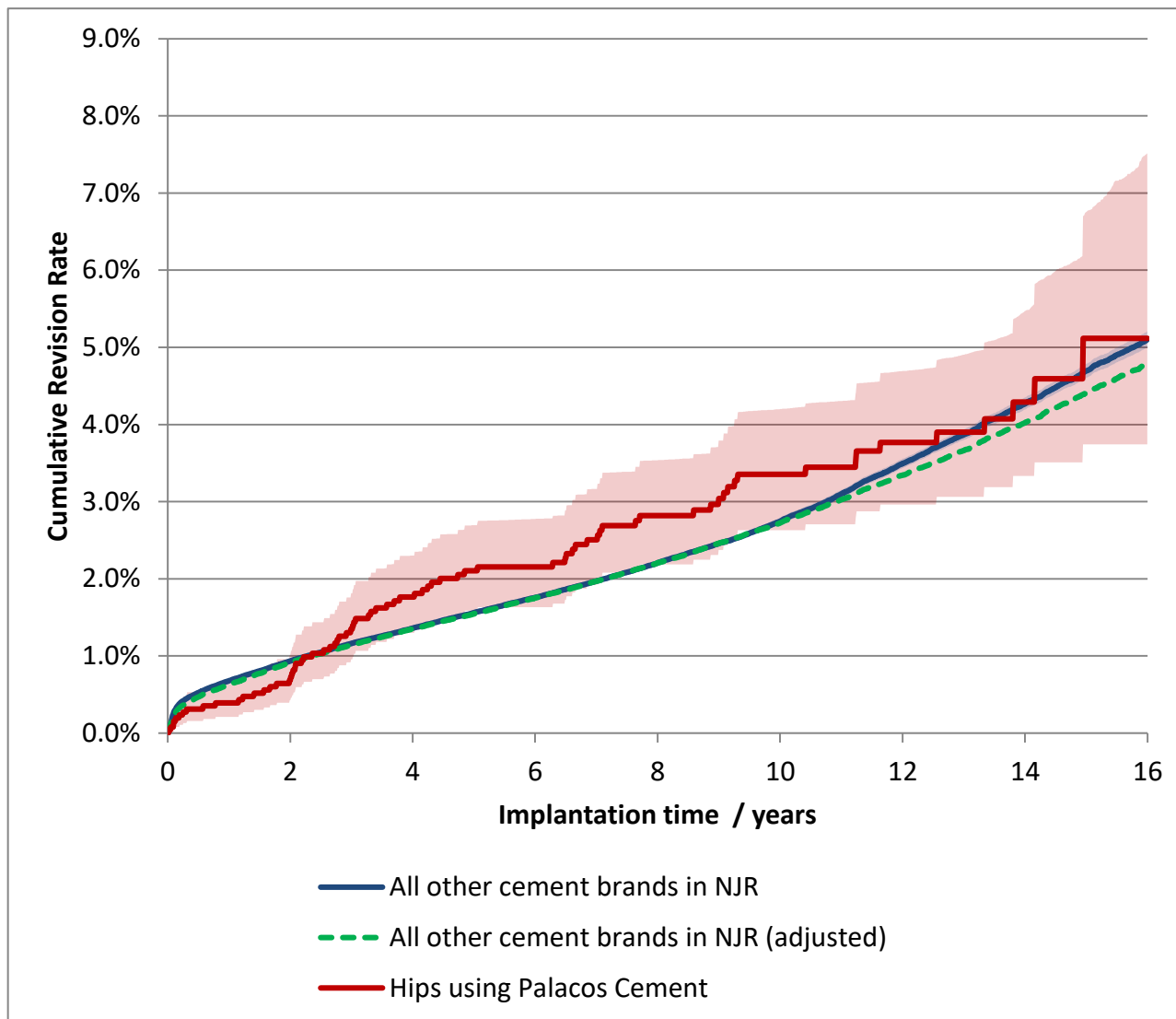
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	1.05 (0.86 - 1.30)	0.620
All bearings. Adjusted for age, gender, year cohort and indications.	1.13 (0.92 - 1.40)	0.249

Revision and Survivorship

Cumulative Revision Rate

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



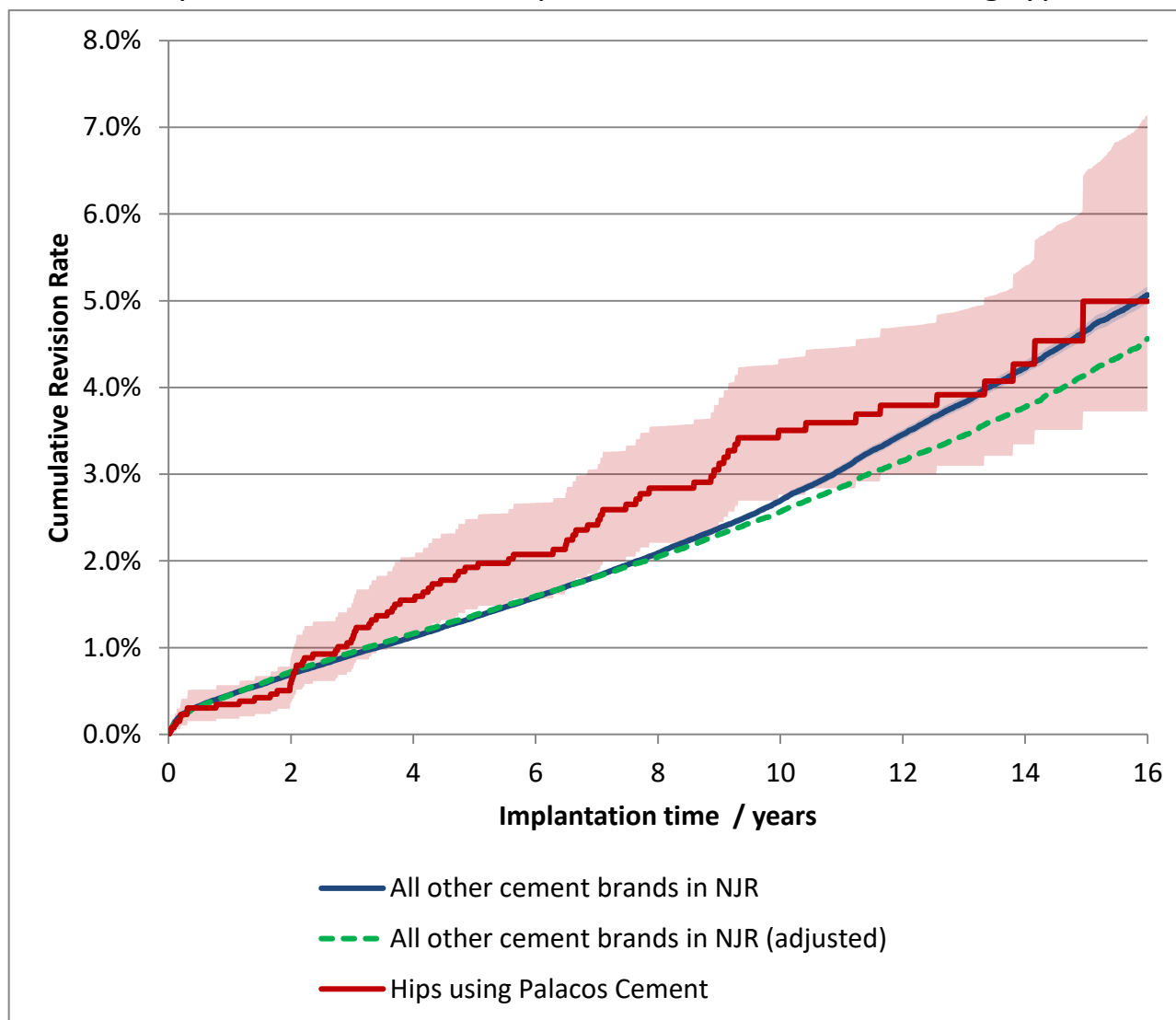
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	1.11 (0.89 - 1.39)	0.344
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.15 (0.92 - 1.44)	0.216

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Cemented Component Revision. All Bearing types



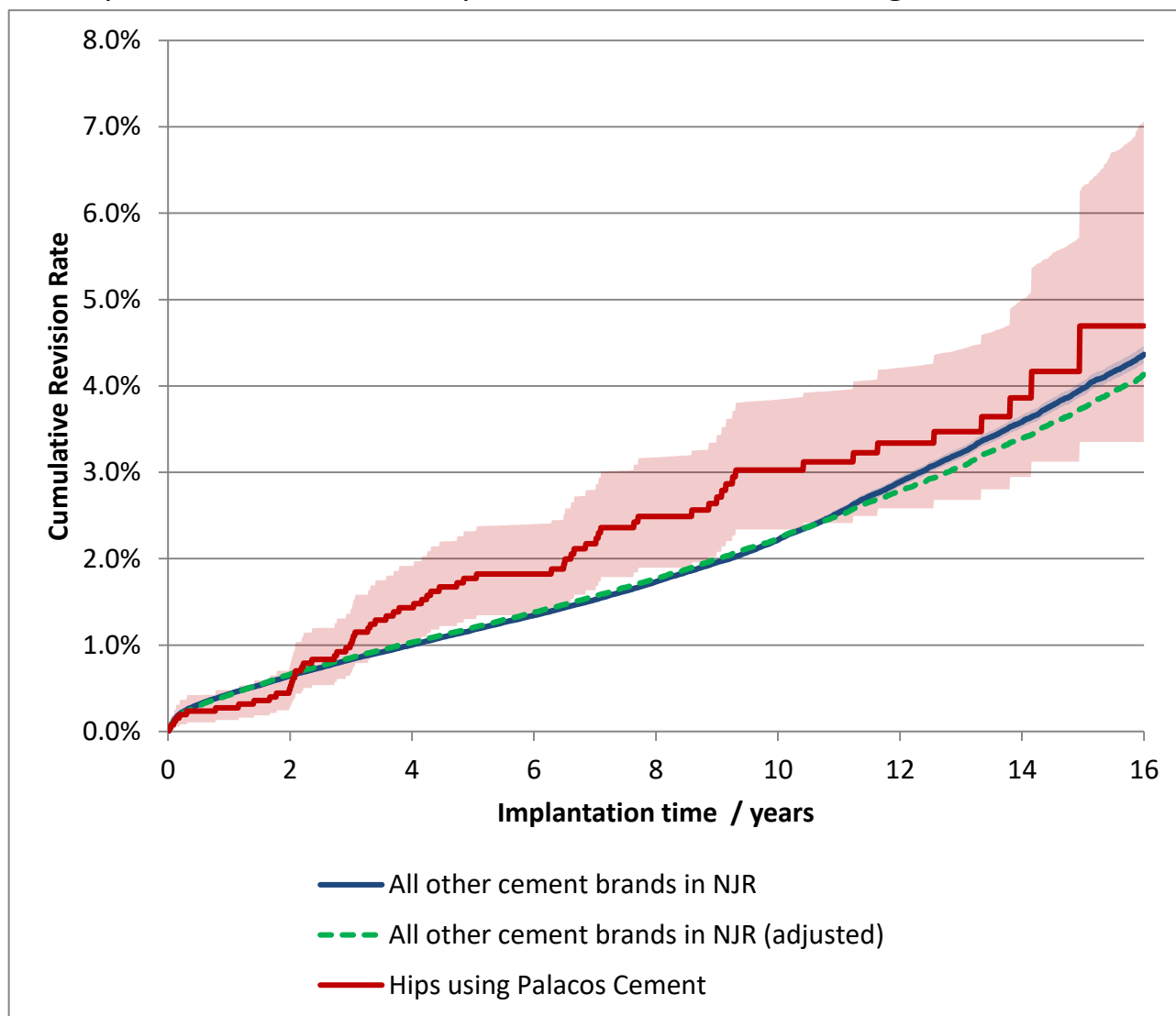
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	1.13 (0.90 - 1.41)	0.293
All bearings. Adjusted for age, gender, year cohort and indications.	1.21 (0.97 - 1.51)	0.098

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Cemented Component Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	1.20 (0.94 - 1.53)	0.137
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.22 (0.96 - 1.56)	0.100

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Hips using Palacos Cement	All other cement brands in NJR	All THR	At Risk	Hips using Palacos Cement	All other cement brands in NJR	All THR
0	2,656	-	-	-	2,578	-	-	-
1	2,516	0.5% (0.3% - 0.7%)	0.7% (0.7% - 0.7%)	0.8% (0.8% - 0.8%)	2,440	0.4% (0.2% - 0.6%)	0.7% (0.7% - 0.7%)	0.8% (0.7% - 0.8%)
2	2,382	0.8% (0.5% - 1.1%)	1.0% (1.0% - 1.0%)	1.1% (1.1% - 1.1%)	2,307	0.7% (0.4% - 1.0%)	0.9% (0.9% - 1.0%)	1.0% (1.0% - 1.1%)
3	2,250	1.4% (1.0% - 1.9%)	1.2% (1.2% - 1.3%)	1.4% (1.4% - 1.4%)	2,175	1.3% (1.0% - 1.8%)	1.2% (1.1% - 1.2%)	1.3% (1.3% - 1.3%)
4	2,139	1.9% (1.4% - 2.4%)	1.5% (1.5% - 1.5%)	1.7% (1.6% - 1.7%)	2,066	1.8% (1.3% - 2.3%)	1.4% (1.3% - 1.4%)	1.5% (1.5% - 1.5%)
5	2,005	2.2% (1.7% - 2.8%)	1.7% (1.7% - 1.8%)	2.0% (1.9% - 2.0%)	1,936	2.1% (1.6% - 2.7%)	1.6% (1.5% - 1.6%)	1.7% (1.7% - 1.7%)
6	1,833	2.4% (1.8% - 3.0%)	2.0% (2.0% - 2.0%)	2.3% (2.3% - 2.3%)	1,766	2.2% (1.6% - 2.8%)	1.8% (1.7% - 1.8%)	1.9% (1.9% - 1.9%)
7	1,663	2.7% (2.1% - 3.4%)	2.3% (2.2% - 2.3%)	2.6% (2.6% - 2.6%)	1,596	2.5% (1.9% - 3.2%)	2.0% (1.9% - 2.0%)	2.1% (2.1% - 2.1%)
8	1,510	3.2% (2.5% - 3.9%)	2.6% (2.5% - 2.6%)	3.0% (2.9% - 3.0%)	1,446	2.8% (2.2% - 3.5%)	2.2% (2.2% - 2.2%)	2.4% (2.3% - 2.4%)
9	1,334	3.4% (2.7% - 4.2%)	2.9% (2.9% - 2.9%)	3.3% (3.3% - 3.4%)	1,273	3.0% (2.4% - 3.8%)	2.5% (2.4% - 2.5%)	2.6% (2.6% - 2.6%)
10	1,160	3.8% (3.1% - 4.7%)	3.2% (3.2% - 3.3%)	3.7% (3.6% - 3.7%)	1,101	3.4% (2.6% - 4.2%)	2.7% (2.7% - 2.8%)	2.9% (2.8% - 2.9%)
11	1,010	3.9% (3.1% - 4.8%)	3.6% (3.6% - 3.7%)	4.1% (4.0% - 4.1%)	951	3.4% (2.7% - 4.3%)	3.1% (3.0% - 3.2%)	3.2% (3.2% - 3.2%)
12	878	4.2% (3.4% - 5.2%)	4.1% (4.0% - 4.1%)	4.5% (4.5% - 4.6%)	819	3.8% (3.0% - 4.7%)	3.5% (3.4% - 3.6%)	3.6% (3.5% - 3.6%)
13	689	4.3% (3.5% - 5.4%)	4.5% (4.4% - 4.6%)	5.0% (4.9% - 5.1%)	632	3.9% (3.1% - 4.9%)	3.9% (3.8% - 3.9%)	3.9% (3.9% - 4.0%)
14	410	4.7% (3.7% - 5.8%)	4.9% (4.9% - 5.0%)	5.5% (5.4% - 5.5%)	365	4.3% (3.3% - 5.5%)	4.3% (4.2% - 4.3%)	4.3% (4.3% - 4.4%)
15	196	5.4% (4.1% - 6.9%)	5.4% (5.3% - 5.5%)	6.0% (5.9% - 6.0%)	170	5.1% (3.7% - 6.8%)	4.7% (4.6% - 4.8%)	4.8% (4.7% - 4.8%)

Cumulative revision rate with 95% confidence intervals

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

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Cemented Component Revision

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Hips using Palacos Cement	All other cement brands in NJR	All THR	At Risk	Hips using Palacos Cement	All other cement brands in NJR	All THR
0	2,656	-	-	-	2,578	-	-	-
1	2,516	0.3% (0.2% - 0.6%)	0.5% (0.4% - 0.5%)	(-)	2,440	0.3% (0.1% - 0.5%)	0.4% (0.4% - 0.4%)	(-)
2	2,382	0.6% (0.4% - 0.9%)	0.7% (0.7% - 0.7%)	(-)	2,307	0.5% (0.3% - 0.8%)	0.6% (0.6% - 0.7%)	(-)
3	2,250	1.1% (0.8% - 1.5%)	0.9% (0.9% - 0.9%)	(-)	2,175	1.0% (0.7% - 1.4%)	0.8% (0.8% - 0.9%)	(-)
4	2,139	1.5% (1.1% - 2.0%)	1.1% (1.1% - 1.1%)	(-)	2,066	1.4% (1.0% - 1.9%)	1.0% (1.0% - 1.0%)	(-)
5	2,005	1.9% (1.4% - 2.5%)	1.4% (1.3% - 1.4%)	(-)	1,936	1.8% (1.3% - 2.3%)	1.2% (1.2% - 1.2%)	(-)
6	1,833	2.1% (1.6% - 2.7%)	1.6% (1.6% - 1.6%)	(-)	1,766	1.8% (1.3% - 2.4%)	1.3% (1.3% - 1.4%)	(-)
7	1,663	2.4% (1.8% - 3.1%)	1.8% (1.8% - 1.9%)	(-)	1,596	2.2% (1.6% - 2.8%)	1.5% (1.5% - 1.6%)	(-)
8	1,510	2.8% (2.2% - 3.6%)	2.1% (2.1% - 2.1%)	(-)	1,446	2.5% (1.9% - 3.2%)	1.7% (1.7% - 1.8%)	(-)
9	1,334	3.1% (2.4% - 3.9%)	2.4% (2.3% - 2.4%)	(-)	1,273	2.7% (2.1% - 3.4%)	2.0% (1.9% - 2.0%)	(-)
10	1,160	3.5% (2.8% - 4.3%)	2.7% (2.6% - 2.7%)	(-)	1,101	3.0% (2.3% - 3.8%)	2.2% (2.2% - 2.3%)	(-)
11	1,010	3.6% (2.8% - 4.5%)	3.1% (3.0% - 3.1%)	(-)	951	3.1% (2.4% - 3.9%)	2.5% (2.5% - 2.6%)	(-)
12	878	3.8% (3.0% - 4.7%)	3.5% (3.4% - 3.5%)	(-)	819	3.3% (2.6% - 4.2%)	2.9% (2.8% - 2.9%)	(-)
13	689	3.9% (3.1% - 4.9%)	3.8% (3.8% - 3.9%)	(-)	632	3.5% (2.7% - 4.4%)	3.2% (3.2% - 3.3%)	(-)
14	410	4.3% (3.3% - 5.4%)	4.2% (4.2% - 4.3%)	(-)	365	3.9% (2.9% - 5.0%)	3.6% (3.5% - 3.7%)	(-)
15	196	5.0% (3.7% - 6.5%)	4.7% (4.6% - 4.7%)	(-)	170	4.7% (3.4% - 6.3%)	4.0% (3.9% - 4.1%)	(-)

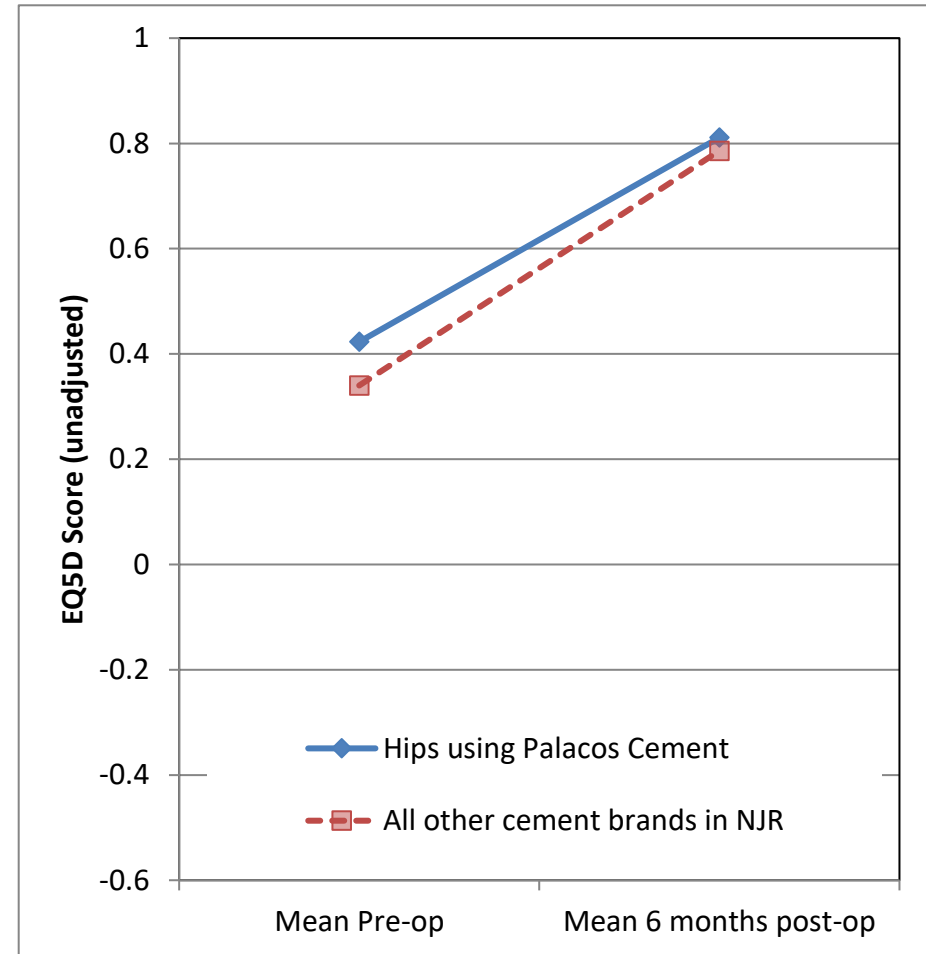
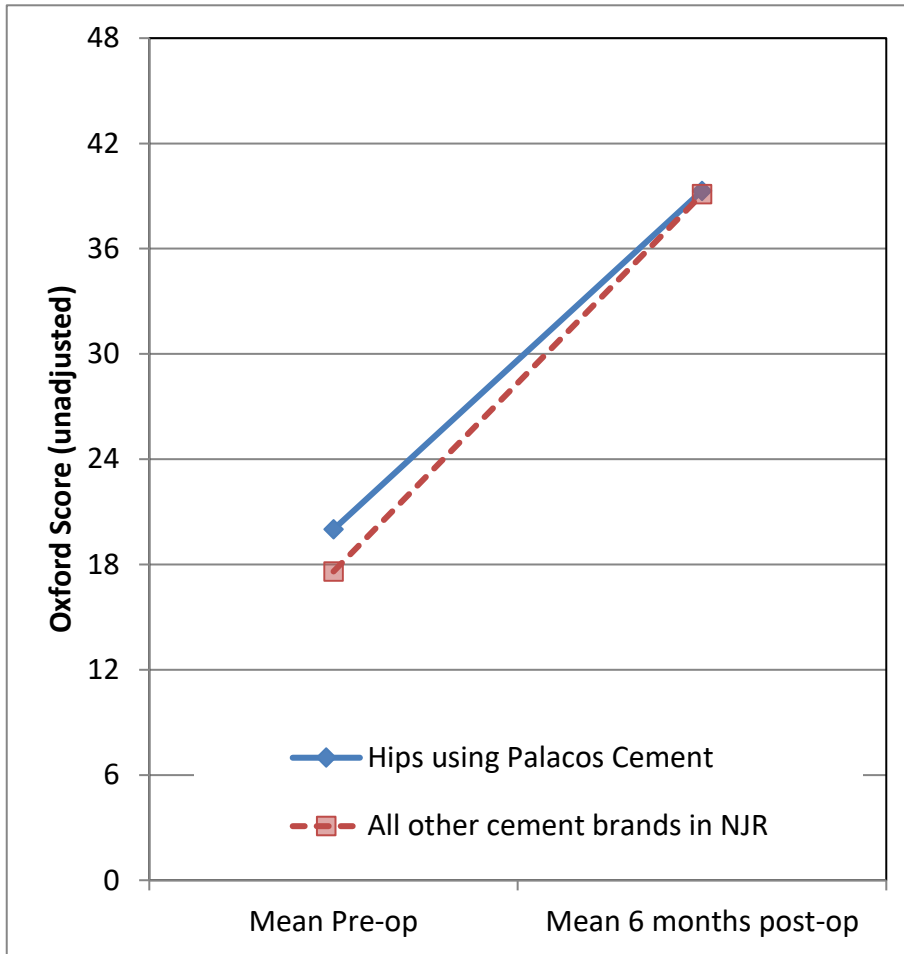
Cumulative revision rate with 95% confidence intervals

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

PROMs Analysis

Patient Reported Outcomes

Comprising PROMs data up to and including: 31/12/2020



Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/12/2020

Oxford Hip Score (0 - 48)	Hips using Palacos Cement	All other cement brands in NJR	All THR in NJR
Paired Records	710	207,711	350,453
PreOp score	20.0 (19.4 - 20.6)	17.6 (17.5 - 17.6)	17.9 (17.9 - 18.0)
6 month score	39.3 (38.7 - 40.0)	39.1 (39.1 - 39.2)	39.6 (39.5 - 39.6)
6 month score (adjusted)	38.7 (38.1 - 39.3)	39.5 (39.4 - 39.5)	39.6 (39.5 - 39.6)
Health gain	19.4 (18.6 - 20.1)	21.6 (21.5 - 21.6)	21.6 (21.6 - 21.7)
Health gain (adjusted)	20.8 (20.2 - 21.3)	21.5 (21.5 - 21.6)	21.6 (21.6 - 21.7)
p value (adjusted health gain)	0.002		
Score Improved	95.5%	97.3%	97.3%

EQ-5D Index (-0.59 - 1.00)	Hips using Palacos Cement	All other cement brands in NJR	All THR in NJR
Paired Records	660	190,801	323,116
PreOp score	0.423 (0.400 - 0.446)	0.340 (0.338 - 0.341)	0.353 (0.352 - 0.354)
6 month score	0.811 (0.793 - 0.829)	0.786 (0.785 - 0.787)	0.795 (0.794 - 0.796)
6 month score (adjusted)	0.791 (0.774 - 0.807)	0.792 (0.791 - 0.793)	0.795 (0.794 - 0.796)
Health gain	0.388 (0.362 - 0.414)	0.447 (0.445 - 0.448)	0.442 (0.441 - 0.443)
Health gain (adjusted)	0.438 (0.421 - 0.454)	0.439 (0.438 - 0.440)	0.442 (0.441 - 0.443)
p value (adjusted health gain)	0.74		
Score Improved	87.3%	89.7%	89.7%

EQ-VAS (0 - 100)	Hips using Palacos Cement	All other cement brands in NJR	All THR in NJR
Paired Records	623	183,153	310,929
PreOp score	67.0 (65.4 - 68.5)	64.4 (64.3 - 64.5)	64.7 (64.7 - 64.8)
6 month score	76.6 (75.3 - 78.0)	76.4 (76.3 - 76.4)	77.0 (77.0 - 77.1)
6 month score (adjusted)	75.8 (74.6 - 77.0)	76.9 (76.8 - 77.0)	77.0 (77.0 - 77.1)
Health gain	9.7 (7.9 - 11.4)	12.0 (11.9 - 12.1)	12.3 (12.2 - 12.4)
Health gain (adjusted)	11.0 (9.8 - 12.3)	12.2 (12.1 - 12.2)	12.3 (12.3 - 12.4)
p value (adjusted health gain)	0.032		
Score Improved	61.3%	65.8%	66.6%

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

Summary Report for:

Hips using Palacos Cement

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Hips using Palacos Cement	All other cement brands in NJR
Much better	608	182801
A little better	64	18490
About the same	25	5028
A little worse	10	2841
Much worse	10	1864

Answer to 6-months general health question:

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

Satisfaction

Response	Hips using Palacos Cement	All other cement brands in NJR
Excellent	275	85685
Very Good	246	73599
Good	132	36123
Fair	48	12033
Poor	18	3267

Answer to 6-months general health question:

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

Disclaimer

Disclaimer

The data used for this analysis was obtained from the National Joint Registry ("NJR"), part of the Healthcare Quality Improvement Partnership ("HQIP"). HQIP, the NJR and/or its contractor, NEC Software Solutions (UK) Limited ("NEC") take no responsibility (except as prohibited by law) 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 including any duty of care to third party readers of the data analysis.

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
Cement		
66017777	PALACOS R 2x40 g	2267
66017778	PALACOS R 1x40 g	26
66017788	PALACOS LV 1x40 g	60
66031982	PALACOS MV 1x40 g	300
66031984	PALACOS MV plain 2x40g	1
Multiple Found	Multiple Found	2