

## Implant Summary Report for:

Heraeus Medical

### Hips using Palacos Antibiotic Cement

Comprising PRIMARY hips implanted up to:	01 July 2024
NJR Database extract:	31 July 2024
Produced on:	16 August 2024
Licensed for use until:	16 August 2025

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

Appendix A lists details of all Palacos Antibiotic Cement products included in this report.

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**NJR Recorded Usage**

**Implant Usage**

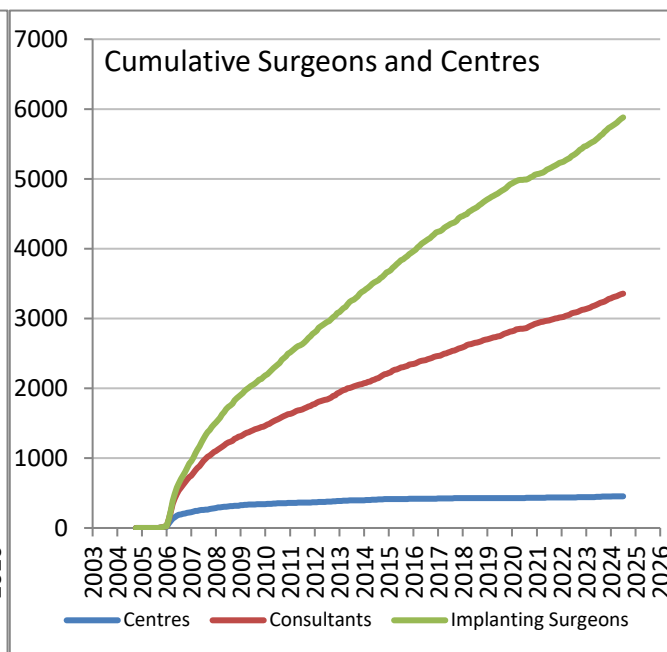
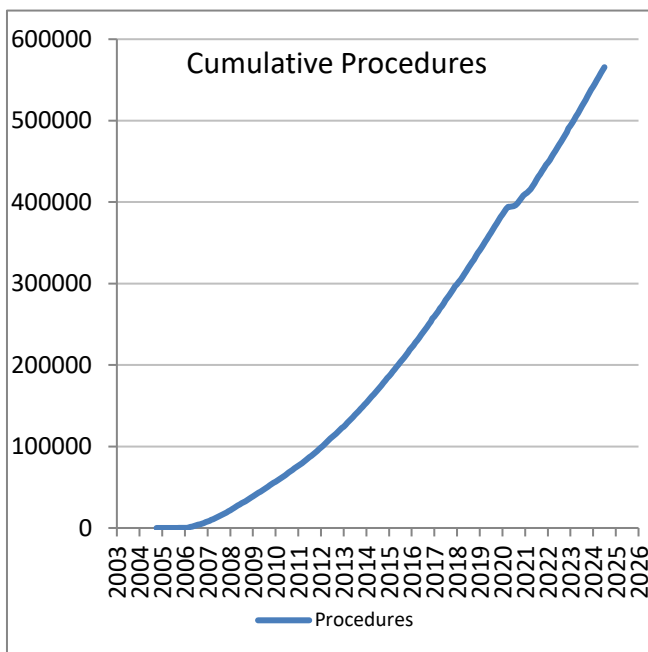
Date of first recorded usage in the NJR: **06 September 2005**

Date of last recorded usage in this dataset: **01 July 2024**

Maximum implantation time: 18.8 years

Mean implantation time: 6.2 years

Totals Recorded in NJR	Cumulative Total
Procedures	565,745
Patients	498,336
Centres	453
Consultants	3,357
Implanting Surgeons	5,880



Current Outcome	Year of implantation													Total	%
	Pre-2013	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024		
Death	59448	9653	9402	8676	7887	6609	5428	4306	1708	1698	1065	406	20	116306	20.6%
Revised	4577	711	731	774	732	700	632	592	305	418	367	286	99	10924	1.9%
Unrevised	60435	18871	22550	25571	29653	32320	35410	39120	23206	36475	43676	47175	24053	438515	77.5%
<b>Total</b>	<b>1E+05</b>	<b>29235</b>	<b>32683</b>	<b>35021</b>	<b>38272</b>	<b>39629</b>	<b>41470</b>	<b>44018</b>	<b>25219</b>	<b>38591</b>	<b>45108</b>	<b>47867</b>	<b>24172</b>	<b>565745</b>	<b>100%</b>

## Patient / Procedure Details

## Patient Details

	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All NJR hip replacement
<b>Total Procedures</b>	565,745	432,924	1,649,604
<b>Total Patients</b>	498,336	384,124	1,364,179
<b>Demographics</b>			
Mean age	<b>71.6</b>	<b>70.5</b>	<b>68.7</b>
< 50	3.2%	4.9%	6.1%
50 – 59	9.6%	11.4%	14.6%
60 – 69	25.3%	25.7%	29.3%
70 – 79	40.9%	38.5%	34.6%
≥ 80	21.0%	19.5%	15.4%
Median BMI	<b>28</b>	<b>28</b>	<b>28</b>
% BMI information available	72.5%	58.5%	66.4%
Underweight ( BMI < 18.5)	1.0%	1.1%	0.9%
Normal (18.5 ≤ BMI < 25)	21.8%	22.6%	20.9%
Overweight (25 ≤ BMI < 30)	39.2%	39.7%	39.1%
Obese I (30 ≤ BMI < 35)	25.4%	24.6%	25.8%
Obese II (35 ≤ BMI < 40)	9.5%	9.1%	10.0%
Obese III (BMI ≥ 40)	3.2%	2.9%	3.3%
% Male	35.7%	38.1%	40.2%
<b>ASA Grades</b>			
P1 - Fit and healthy	9.6%	14.8%	14.1%
P2 - Mild disease not incapacitating	68.5%	65.1%	67.9%
P3 - Incapacitating systemic disease	21.2%	19.3%	17.4%
P4 / P5	0.7%	0.8%	0.6%
<b>Indications</b>			
Osteoarthritis	89.88%	89.92%	91.20%
Rheumatoid Arthritis	1.41%	1.40%	1.29%
Avascular Necrosis	2.70%	2.63%	2.65%
Fractured Neck of Femur	5.07%	4.54%	3.63%
CDH/DDH	1.13%	1.30%	1.61%
Other	2.42%	2.78%	2.26%

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 <sup>†</sup>	Expected Revisions <sup>*</sup>	p value
Unexplained Pain	616	717.81	<0.001
Dislocation / Subluxation	2678	2697.05	0.599
Adverse Soft Tissue Reaction	419	544.27	<0.001
Infection	2482	2562.03	0.021
Aseptic Loosening - Stem	865	988.41	<0.001
Aseptic Loosening - Socket	1697	1729.01	0.34
Periprosthetic Fracture Stem	1941	2025.55	0.008
Periprosthetic Fracture Socket	192	202.23	0.319
Malalignment Stem	236	257.65	0.065
Malalignment Socket	481	462.31	0.247
Wear Of Acetabular Component	426	400.15	0.117
Lysis Stem	267	279.12	0.406
Lysis Socket	406	390.60	0.341
Implant Fracture Stem	195	195.61	0.963
Implant Fracture Socket	41	43.73	0.625
Implant Fracture Head	44	46.24	0.705
Dissociation of Liner	129	118.46	0.178
Other / reason not recorded	566	592.09	0.151
<b>Total Revised</b>	<b>10924</b>	<b>11417.30</b>	<b>&lt;0.001</b>

† 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 Antibiotic Cement	All other cement brands in NJR
Femoral only	2622	24%	18%
Acetabular only	2274	21%	18%
Both femoral and acetabular	4606	42%	58%
Neither femoral nor acetabular revision recorded *	1422	13%	6%

\* 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 <sup>†</sup>	Expected Revisions <sup>*</sup>	p value
Unexplained Pain	478	484.71	0.699
Dislocation / Subluxation	2659	2706.99	0.178
Adverse Soft Tissue Reaction	155	143.72	0.218
Infection	2446	2556.74	<0.001
Aseptic Loosening - Stem	792	913.07	<0.001
Aseptic Loosening - Socket	1645	1687.43	0.185
Periprosthetic Fracture Stem	1870	1926.49	0.062
Periprosthetic Fracture Socket	190	196.11	0.527
Malalignment Stem	227	244.12	0.113
Malalignment Socket	451	433.09	0.233
Wear Of Acetabular Component	418	403.38	0.363
Lysis Stem	230	234.85	0.712
Lysis Socket	365	349.18	0.293
Implant Fracture Stem	185	193.11	0.438
Implant Fracture Socket	41	41.99	0.917
Implant Fracture Head	39	42.32	0.511
Dissociation of Liner	127	114.34	0.089
Other / reason not recorded	504	501.62	0.892
<b>Total Revised</b>	<b>10278</b>	<b>10608.08</b>	<b>&lt;0.001</b>

\* 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



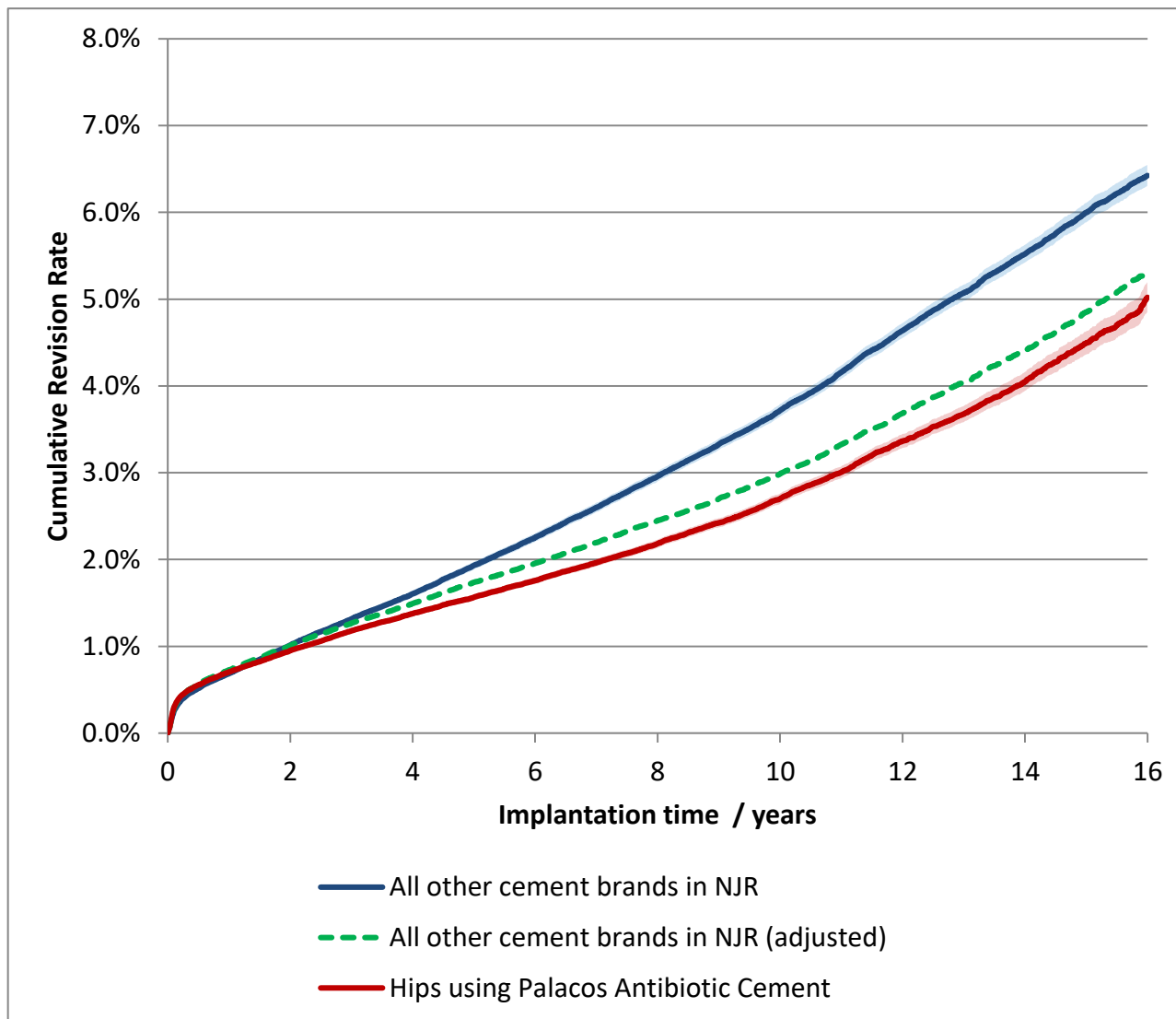
Components Revised	Number of procedures	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral only	2569	25%	21%
Acetabular only	2213	22%	24%
Both femoral and acetabular	4085	40%	47%
Neither femoral nor acetabular revision recorded *	1411	14%	8%

\* 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 Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

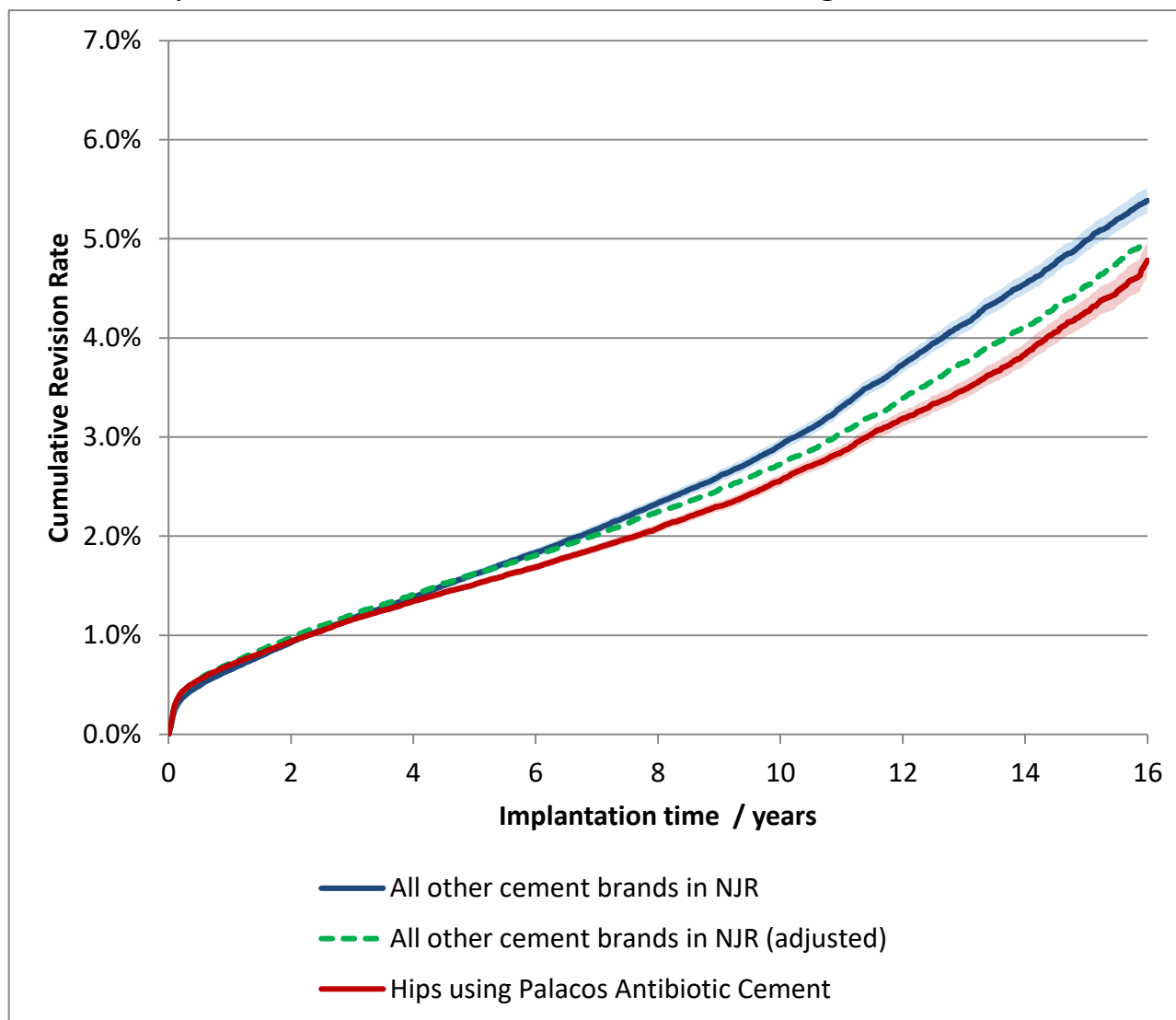
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.77 ‡ (0.75 - 0.79)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.91 (0.88 - 0.93)	<0.001

‡ Hazard ratio varies with time

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 Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

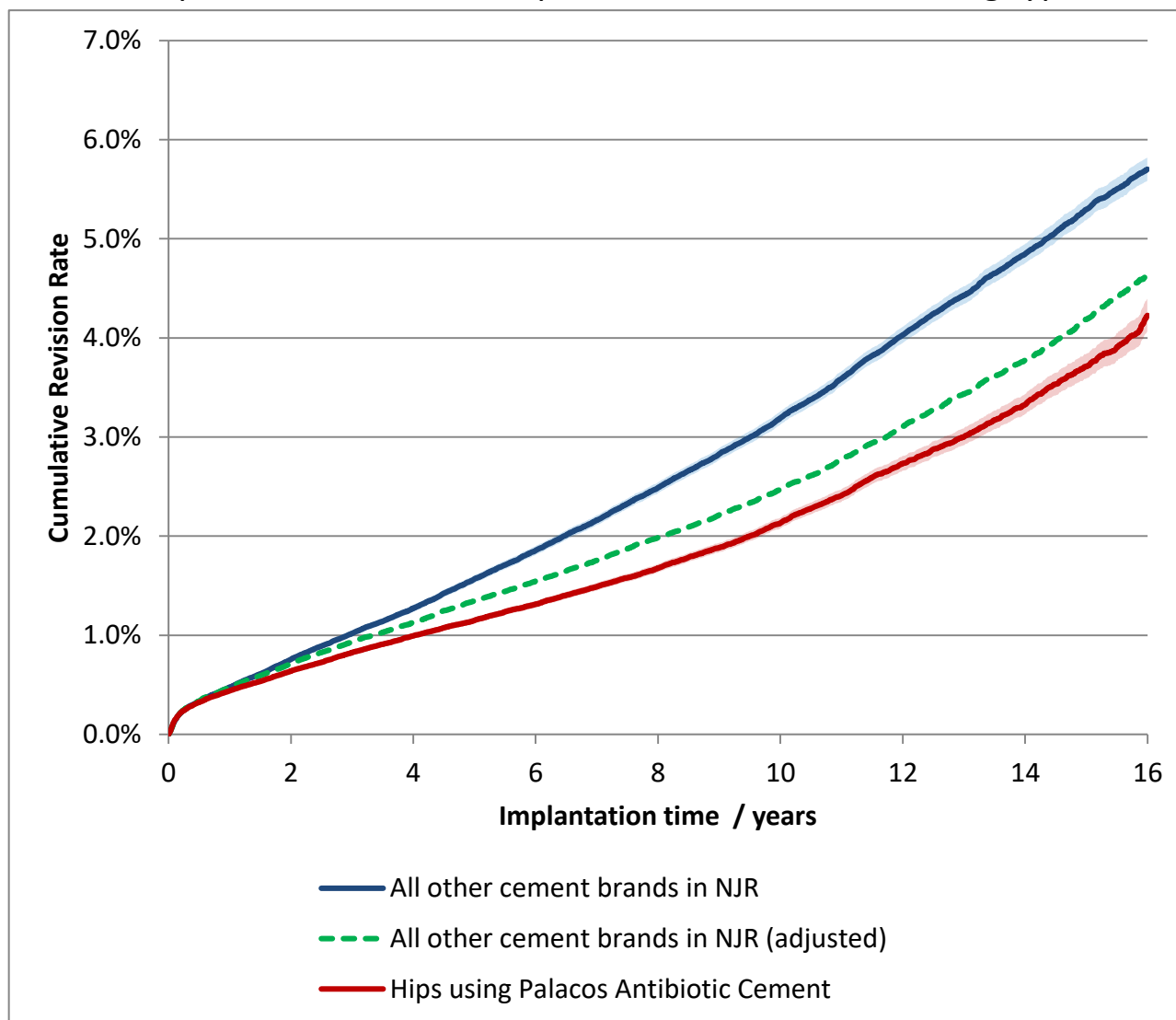
Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	0.90 ‡ (0.87 - 0.92)	<0.001 ‡
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.93 (0.90 - 0.95)	<0.001

‡ Hazard ratio varies with time

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 Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.71 ‡ (0.69 - 0.73)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.87 (0.84 - 0.89)	<0.001

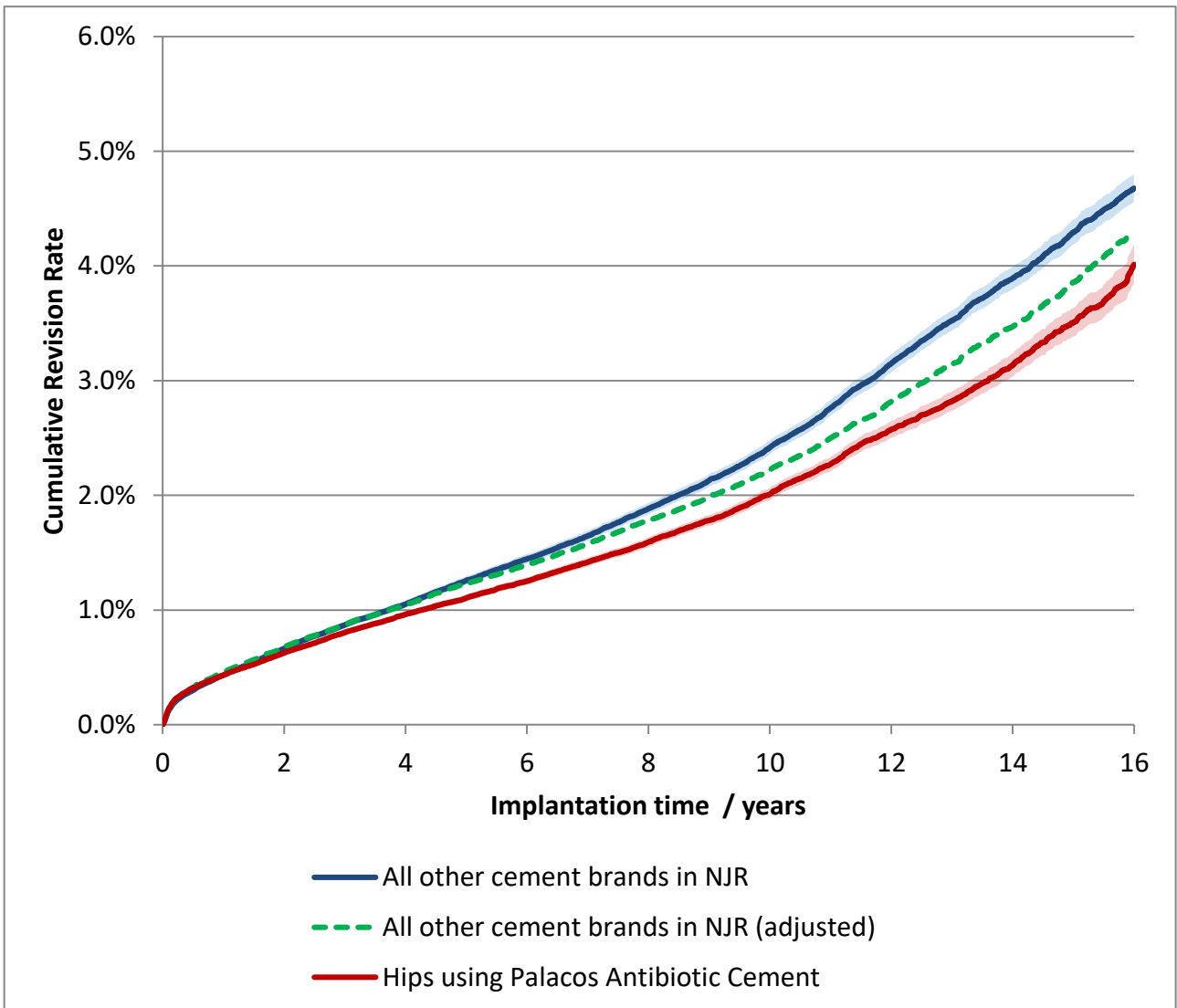
‡ Hazard ratio varies with time



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 Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	0.85 ‡ (0.82 - 0.88)	<0.001 ‡
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.90 (0.87 - 0.93)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR	At Risk	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR
0	565,745	-	-	-	560,437	-	-	-
1	505,672	0.7% (0.7% - 0.7%)	0.7% (0.7% - 0.7%)	0.8% (0.8% - 0.8%)	500,594	0.7% (0.7% - 0.7%)	0.6% (0.6% - 0.7%)	0.8% (0.7% - 0.8%)
2	449,878	1.0% (0.9% - 1.0%)	1.0% (1.0% - 1.0%)	1.1% (1.1% - 1.1%)	445,003	0.9% (0.9% - 1.0%)	0.9% (0.9% - 1.0%)	1.0% (1.0% - 1.1%)
3	397,888	1.2% (1.1% - 1.2%)	1.3% (1.3% - 1.4%)	1.4% (1.4% - 1.4%)	393,172	1.2% (1.1% - 1.2%)	1.2% (1.1% - 1.2%)	1.3% (1.3% - 1.3%)
4	356,482	1.4% (1.3% - 1.4%)	1.6% (1.6% - 1.6%)	1.7% (1.6% - 1.7%)	351,920	1.3% (1.3% - 1.4%)	1.4% (1.3% - 1.4%)	1.5% (1.5% - 1.5%)
5	315,840	1.6% (1.5% - 1.6%)	1.9% (1.9% - 2.0%)	2.0% (1.9% - 2.0%)	311,452	1.5% (1.5% - 1.5%)	1.6% (1.6% - 1.7%)	1.7% (1.7% - 1.7%)
6	266,437	1.8% (1.7% - 1.8%)	2.3% (2.2% - 2.3%)	2.3% (2.2% - 2.3%)	262,212	1.7% (1.6% - 1.7%)	1.8% (1.8% - 1.9%)	1.9% (1.9% - 1.9%)
7	222,880	2.0% (1.9% - 2.0%)	2.6% (2.5% - 2.7%)	2.6% (2.6% - 2.6%)	218,795	1.9% (1.8% - 1.9%)	2.1% (2.0% - 2.1%)	2.1% (2.1% - 2.1%)
8	181,681	2.2% (2.1% - 2.2%)	3.0% (2.9% - 3.0%)	2.9% (2.9% - 3.0%)	177,763	2.1% (2.0% - 2.1%)	2.3% (2.3% - 2.4%)	2.3% (2.3% - 2.4%)
9	145,093	2.4% (2.4% - 2.5%)	3.3% (3.3% - 3.4%)	3.3% (3.2% - 3.3%)	141,357	2.3% (2.3% - 2.4%)	2.6% (2.5% - 2.7%)	2.6% (2.6% - 2.6%)
10	113,272	2.7% (2.6% - 2.8%)	3.7% (3.6% - 3.8%)	3.6% (3.6% - 3.7%)	109,715	2.6% (2.5% - 2.6%)	2.9% (2.9% - 3.0%)	2.9% (2.8% - 2.9%)
11	86,124	3.0% (2.9% - 3.1%)	4.2% (4.1% - 4.2%)	4.0% (4.0% - 4.1%)	82,735	2.8% (2.8% - 2.9%)	3.3% (3.2% - 3.4%)	3.2% (3.1% - 3.2%)
12	64,048	3.4% (3.3% - 3.4%)	4.6% (4.6% - 4.7%)	4.5% (4.4% - 4.5%)	60,836	3.2% (3.1% - 3.3%)	3.7% (3.6% - 3.8%)	3.5% (3.5% - 3.6%)
13	45,964	3.7% (3.6% - 3.8%)	5.1% (5.0% - 5.2%)	4.9% (4.9% - 5.0%)	43,056	3.5% (3.4% - 3.6%)	4.1% (4.0% - 4.2%)	3.9% (3.9% - 3.9%)
14	32,193	4.1% (3.9% - 4.2%)	5.5% (5.4% - 5.6%)	5.4% (5.3% - 5.4%)	29,639	3.8% (3.7% - 3.9%)	4.5% (4.4% - 4.6%)	4.3% (4.2% - 4.3%)
15	21,289	4.5% (4.4% - 4.6%)	6.0% (5.9% - 6.1%)	5.9% (5.8% - 5.9%)	19,212	4.3% (4.1% - 4.4%)	5.0% (4.9% - 5.1%)	4.7% (4.6% - 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 Antibiotic Cement	All other cement brands in NJR	All THR	At Risk	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR
0	565,745	-	-	-	560,437	-	-	-
1	505,672	0.4% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)	(-)	500,594	0.4% (0.4% - 0.4%)	0.4% (0.4% - 0.5%)	(-)
2	449,878	0.6% (0.6% - 0.7%)	0.8% (0.7% - 0.8%)	(-)	445,003	0.6% (0.6% - 0.6%)	0.7% (0.6% - 0.7%)	(-)
3	397,888	0.8% (0.8% - 0.9%)	1.0% (1.0% - 1.0%)	(-)	393,172	0.8% (0.8% - 0.8%)	0.9% (0.8% - 0.9%)	(-)
4	356,482	1.0% (1.0% - 1.0%)	1.3% (1.2% - 1.3%)	(-)	351,920	1.0% (0.9% - 1.0%)	1.1% (1.0% - 1.1%)	(-)
5	315,840	1.2% (1.1% - 1.2%)	1.6% (1.5% - 1.6%)	(-)	311,452	1.1% (1.1% - 1.1%)	1.3% (1.2% - 1.3%)	(-)
6	266,437	1.3% (1.3% - 1.3%)	1.9% (1.8% - 1.9%)	(-)	262,212	1.3% (1.2% - 1.3%)	1.4% (1.4% - 1.5%)	(-)
7	222,880	1.5% (1.5% - 1.5%)	2.2% (2.1% - 2.2%)	(-)	218,795	1.4% (1.4% - 1.5%)	1.6% (1.6% - 1.7%)	(-)
8	181,681	1.7% (1.6% - 1.7%)	2.5% (2.4% - 2.5%)	(-)	177,763	1.6% (1.6% - 1.6%)	1.9% (1.8% - 1.9%)	(-)
9	145,093	1.9% (1.8% - 1.9%)	2.8% (2.8% - 2.9%)	(-)	141,357	1.8% (1.7% - 1.8%)	2.1% (2.1% - 2.2%)	(-)
10	113,272	2.1% (2.1% - 2.2%)	3.2% (3.1% - 3.3%)	(-)	109,715	2.0% (2.0% - 2.1%)	2.4% (2.4% - 2.5%)	(-)
11	86,124	2.4% (2.3% - 2.5%)	3.6% (3.5% - 3.7%)	(-)	82,735	2.3% (2.2% - 2.3%)	2.8% (2.7% - 2.8%)	(-)
12	64,048	2.7% (2.7% - 2.8%)	4.0% (3.9% - 4.1%)	(-)	60,836	2.6% (2.5% - 2.6%)	3.1% (3.1% - 3.2%)	(-)
13	45,964	3.0% (2.9% - 3.1%)	4.4% (4.3% - 4.5%)	(-)	43,056	2.8% (2.7% - 2.9%)	3.5% (3.4% - 3.6%)	(-)
14	32,193	3.3% (3.2% - 3.4%)	4.8% (4.8% - 4.9%)	(-)	29,639	3.1% (3.0% - 3.2%)	3.9% (3.8% - 4.0%)	(-)
15	21,289	3.7% (3.6% - 3.8%)	5.3% (5.2% - 5.4%)	(-)	19,212	3.5% (3.4% - 3.6%)	4.3% (4.2% - 4.4%)	(-)

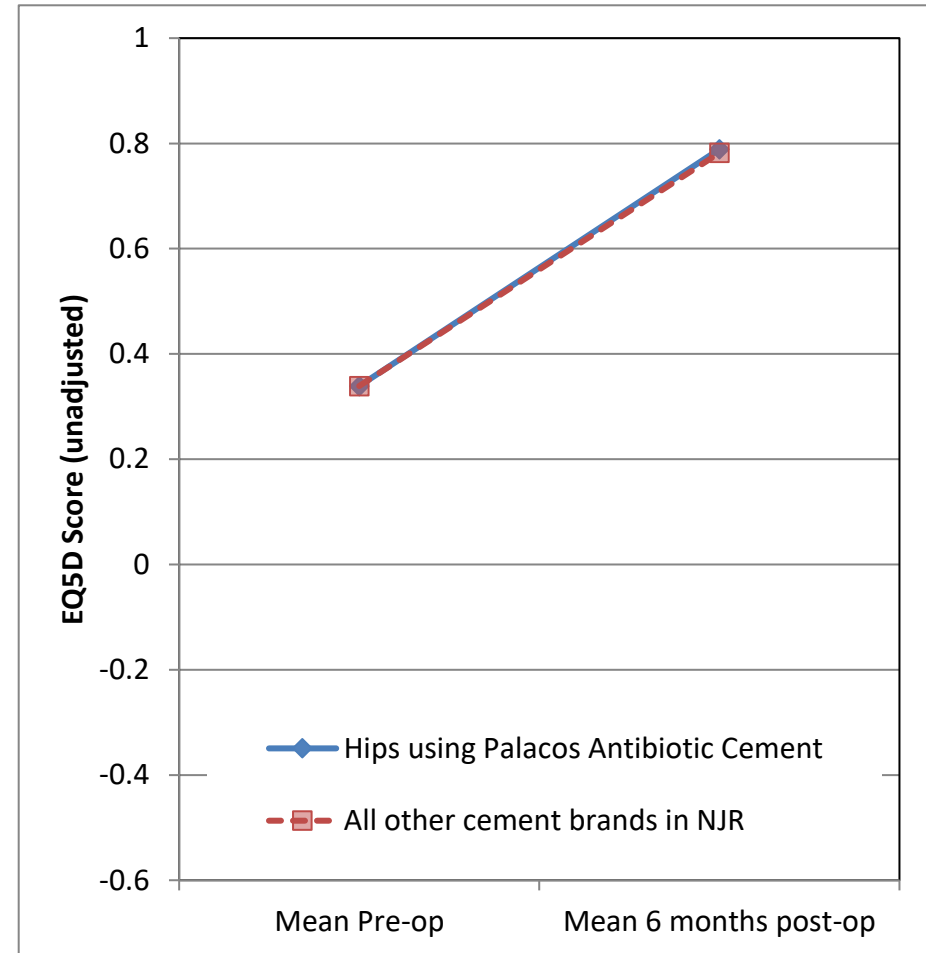
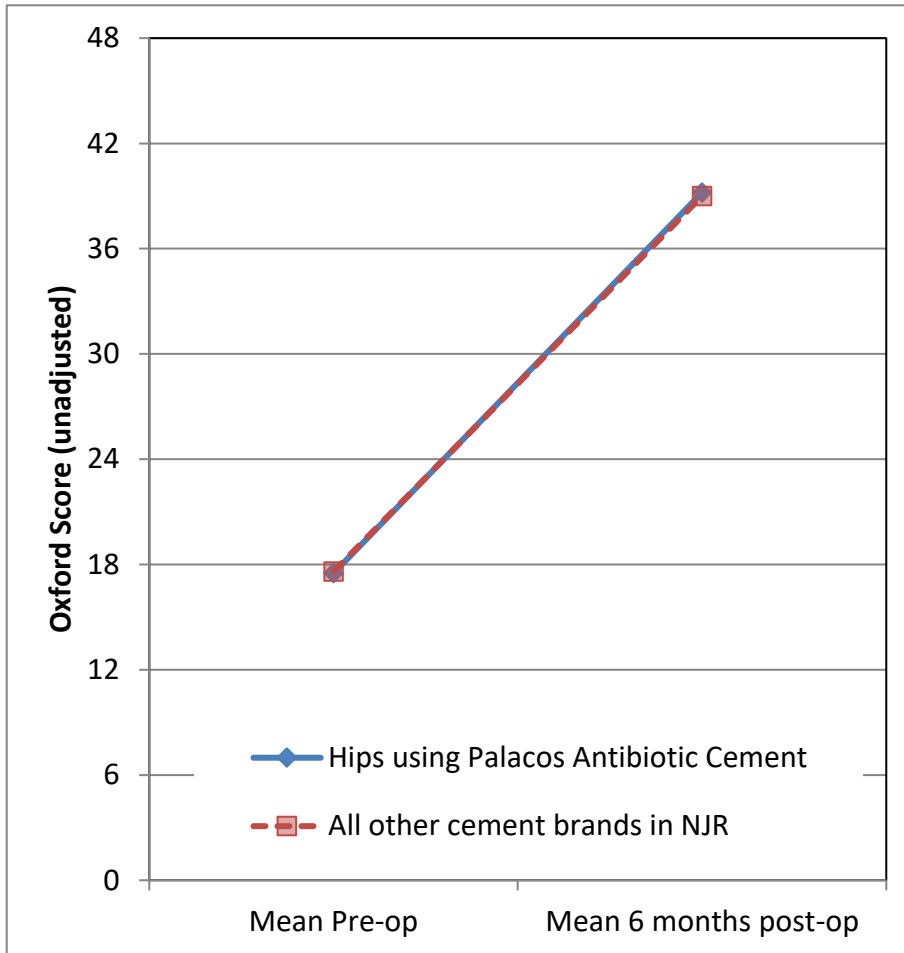
Cumulative revision rate with 95% confidence intervals

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: 31/03/2022



## Patient Reported Outcomes

## PROMs Analysis

Comprising PROMs data up to and including: 31/03/2022

Oxford Hip Score (0 - 48)	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR in NJR
Paired Records	132,412	87,043	367,524
PreOp score	17.5 (17.5 - 17.6)	17.6 (17.5 - 17.6)	17.9 (17.9 - 17.9)
6 month score	39.2 (39.2 - 39.3)	39.0 (38.9 - 39.0)	39.6 (39.5 - 39.6)
6 month score (adjusted)	39.5 (39.5 - 39.6)	39.4 (39.3 - 39.4)	39.6 (39.5 - 39.6)
Health gain	21.7 (21.7 - 21.8)	21.4 (21.3 - 21.5)	21.7 (21.6 - 21.7)
Health gain (adjusted)	21.6 (21.6 - 21.7)	21.5 (21.4 - 21.5)	21.7 (21.6 - 21.7)
p value (adjusted health gain)	< 0.001		
Score Improved	97.4%	97.2%	97.3%

EQ-5D Index (-0.59 - 1.00)	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR in NJR
Paired Records	121,692	80,015	338,993
PreOp score	0.339 (0.338 - 0.341)	0.339 (0.337 - 0.341)	0.353 (0.351 - 0.354)
6 month score	0.789 (0.787 - 0.790)	0.782 (0.780 - 0.784)	0.795 (0.794 - 0.796)
6 month score (adjusted)	0.793 (0.792 - 0.794)	0.790 (0.789 - 0.792)	0.795 (0.794 - 0.796)
Health gain	0.449 (0.447 - 0.451)	0.443 (0.441 - 0.446)	0.442 (0.441 - 0.444)
Health gain (adjusted)	0.440 (0.439 - 0.442)	0.438 (0.436 - 0.439)	0.442 (0.442 - 0.443)
p value (adjusted health gain)	0.17		
Score Improved	89.8%	89.5%	89.7%

EQ-VAS (0 - 100)	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All THR in NJR
Paired Records	116,447	76,978	325,935
PreOp score	64.2 (64.1 - 64.3)	64.3 (64.1 - 64.4)	64.6 (64.5 - 64.7)
6 month score	76.5 (76.4 - 76.6)	76.0 (75.9 - 76.1)	77.0 (76.9 - 77.1)
6 month score (adjusted)	76.9 (76.8 - 77.0)	76.7 (76.6 - 76.8)	77.0 (76.9 - 77.1)
Health gain	12.3 (12.2 - 12.4)	11.7 (11.6 - 11.9)	12.4 (12.3 - 12.5)
Health gain (adjusted)	12.3 (12.2 - 12.4)	12.1 (12.0 - 12.2)	12.4 (12.3 - 12.5)
p value (adjusted health gain)	0.002		
Score Improved	66.3%	65.3%	66.7%

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 Antibiotic Cement

Responses are not case mix adjusted

**Patient Reported Outcomes**



**Patient Reported Outcomes**

**Success**

Response	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Much better	117112	76905
A little better	11752	7908
About the same	3180	2191
A little worse	1824	1208
Much worse	1236	774

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

**Satisfaction**

Response	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Excellent	54871	36221
Very Good	47145	30810
Good	23133	15262
Fair	7670	5114
Poor	2107	1420

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

## Disclaimer

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# Appendix A: Component List

Catalogue Number Description Number Implanted

Catalogue Num	Description	Number
Cement		
66017569	PALACOS R +G 2x40 g	497620
66017771	PALACOS R +G 1x40 g	3642
66017772	PALACOS R +G 1x60 g	7643
66017773	PALACOS R +G 2x20 g	5279
66017776	PALACOS R +G 2x10 g	7
66017787	PALACOS LV +G 1x40 g	4998
66031993	PALACOS MV+G 1x40g	229
66031995	PALACOS MV+G 2x40 g	2553
66031996	PALACOS MV+G 1x20g	3
66031998	PALACOS MV+G 2x20 g	9
66032000	PALACOS MV+G 1x60 g	1
66037894	PALACOS LV+G 1x20g	1
66044273	PALACOS R+G Pro 55 cement	179
66044274	PALACOS R+G Pro 75 cement	757
Multiple Found	Multiple Found	42824