

## Implant Summary Report for:

Heraeus Medical

### Hips using Palacos Antibiotic Cement

Comprising PRIMARY hips implanted up to:  
NJR Database extract:

01 November 2022  
31 December 2022

Produced on:  
Licensed for use until:

15 February 2023  
15 February 2024

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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**

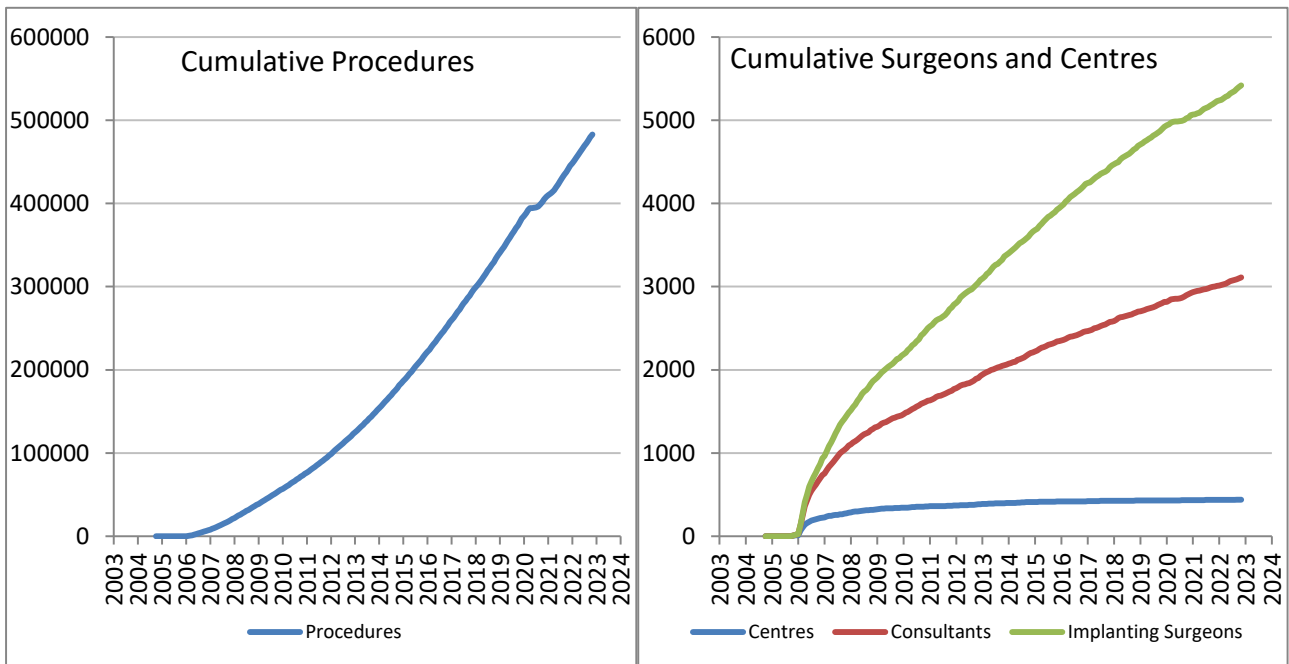
Date of first recorded usage in the NJR: **06 September 2005**

Date of last recorded usage in this dataset **01 November 2022**

Maximum implantation time: 17.1 years

Mean implantation time: 5.8 years

Totals Recorded in NJR	Cumulative Total
Procedures	483,018
Patients	428,307
Centres	439
Consultants	3,111
Implanting Surgeons	5,421



Current Outcome	Year of implantation													Total	%
	Pre-2011	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022		
<b>Death</b>	35462	7951	8119	7739	7387	6582	5745	4567	3510	2506	877	587	120	91152	18.9%
<b>Revised</b>	2949	578	633	626	654	684	646	604	542	505	246	292	131	9090	1.9%
<b>Unrevised</b>	38069	13766	17106	20866	24634	27750	31873	34444	37393	40963	24005	37435	34472	382776	79.2%
<b>Total</b>	<b>76480</b>	<b>22295</b>	<b>25858</b>	<b>29231</b>	<b>32675</b>	<b>35016</b>	<b>38264</b>	<b>39615</b>	<b>41445</b>	<b>43974</b>	<b>25128</b>	<b>38314</b>	<b>34723</b>	<b>483018</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>	483,018	360,457	1,453,930
<b>Total Patients</b>	428,307	321,339	1,213,439
<b>Demographics</b>			
Mean age	<b>71.6</b>	<b>70.4</b>	<b>68.7</b>
< 50	3.3%	5.2%	6.2%
50 – 59	9.5%	11.6%	14.5%
60 – 69	25.5%	25.8%	29.4%
70 – 79	40.7%	38.0%	34.5%
≥ 80	21.0%	19.4%	15.4%
Median BMI	<b>28</b>	<b>28</b>	<b>28</b>
% BMI information available	71.5%	59.5%	64.6%
Underweight ( BMI < 18.5)	1.0%	1.0%	0.9%
Normal (18.5 ≤ BMI < 25)	21.7%	22.5%	20.9%
Overweight (25 ≤ BMI < 30)	39.4%	40.0%	39.4%
Obese I (30 ≤ BMI < 35)	25.4%	24.6%	25.8%
Obese II (35 ≤ BMI < 40)	9.4%	9.0%	9.9%
Obese III (BMI ≥ 40)	3.1%	2.9%	3.3%
% Male	35.8%	38.4%	40.2%
<b>ASA Grades</b>			
P1 - Fit and healthy	10.2%	15.2%	14.9%
P2 - Mild disease not incapacitating	68.8%	65.1%	67.8%
P3 - Incapacitating systemic disease	20.3%	19.0%	16.7%
P4 / P5	0.7%	0.8%	0.6%
<b>Indications</b>			
Osteoarthritis	89.81%	89.76%	91.15%
Rheumatoid Arthritis	1.40%	1.41%	1.30%
Avascular Necrosis	2.57%	2.54%	2.59%
Fractured Neck of Femur	5.52%	4.92%	3.85%
CDH/DDH	1.10%	1.31%	1.58%
Other	2.08%	2.55%	2.09%

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	578	679.34	<0.001
Dislocation / Subluxation	2232	2214.93	0.598
Adverse Soft Tissue Reaction	377	492.43	<0.001
Infection	2005	2050.12	0.144
Aseptic Loosening - Stem	697	801.01	<0.001
Aseptic Loosening - Socket	1319	1362.43	0.135
Periprosthetic Fracture Stem	1792	1874.61	0.006
Periprosthetic Fracture Socket	169	179.03	0.281
Malalignment Stem	201	214.85	0.197
Malalignment Socket	417	392.36	0.09
Wear Of Acetabular Component	317	304.74	0.388
Lysis Stem	203	216.31	0.281
Lysis Socket	302	301.64	0.972
Implant Fracture Stem	176	174.68	0.921
Implant Fracture Socket	41	42.09	0.836
Implant Fracture Head	42	42.77	0.92
Dissociation of Liner	105	95.72	0.187
Other / reason not recorded	336	354.89	0.198
<b>Total Revised</b>	<b>9090</b>	<b>9489.19</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	2193	24%	18%
Acetabular only	1905	21%	17%
Both femoral and acetabular	3857	42%	59%
Neither femoral nor acetabular revision recorded *	1135	12%	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	441	446.83	0.724
Dislocation / Subluxation	2213	2224.47	0.717
Adverse Soft Tissue Reaction	128	112.60	0.049
Infection	1973	2047.62	0.012
Aseptic Loosening - Stem	630	733.58	<0.001
Aseptic Loosening - Socket	1269	1323.19	0.048
Periprosthetic Fracture Stem	1724	1772.65	0.083
Periprosthetic Fracture Socket	168	174.10	0.494
Malalignment Stem	194	202.61	0.374
Malalignment Socket	388	363.41	0.062
Wear Of Acetabular Component	309	303.96	0.711
Lysis Stem	169	176.40	0.503
Lysis Socket	264	259.96	0.747
Implant Fracture Stem	166	173.01	0.496
Implant Fracture Socket	41	41.10	1
Implant Fracture Head	37	38.57	0.722
Dissociation of Liner	104	92.72	0.085
Other / reason not recorded	275	264.22	0.334
<b>Total Revised</b>	<b>8475</b>	<b>8701.30</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



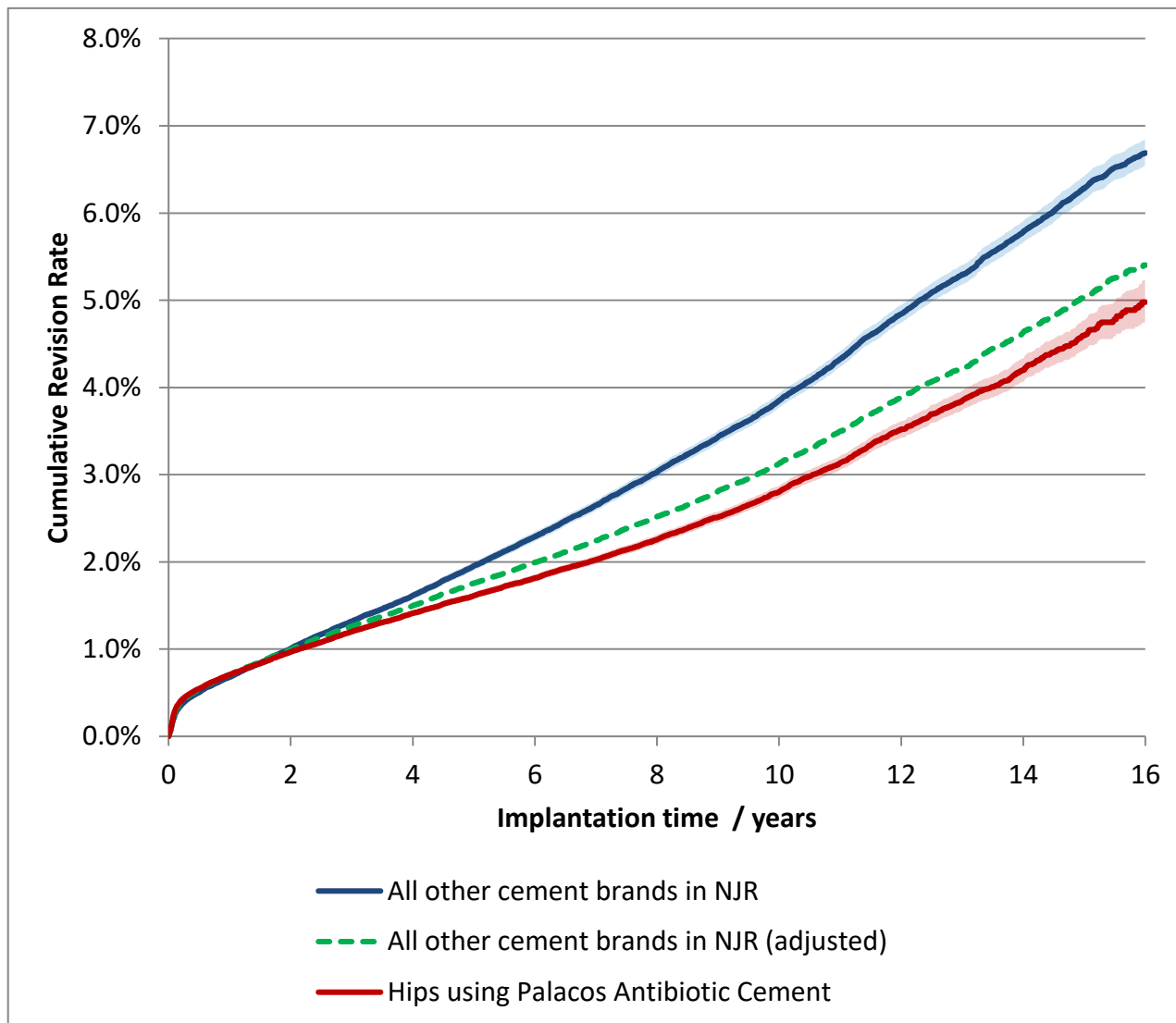
Components Revised	Number of procedures	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral only	2140	25%	22%
Acetabular only	1846	22%	23%
Both femoral and acetabular	3363	40%	47%
Neither femoral nor acetabular revision recorded *	1126	13%	8%

\* 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.

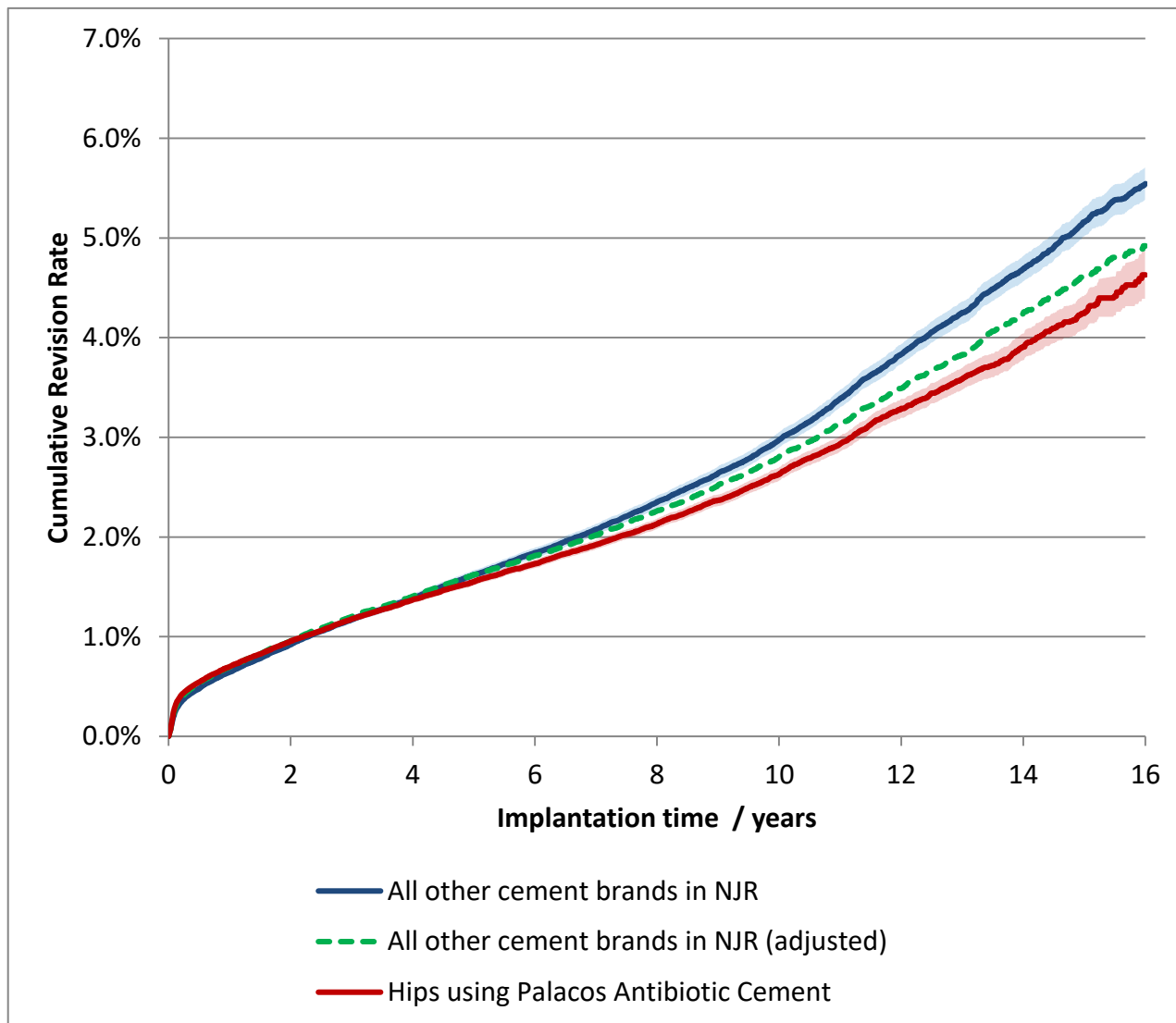
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.77 ‡ (0.75 - 0.79)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.91 (0.88 - 0.94)	<0.001

‡ 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.

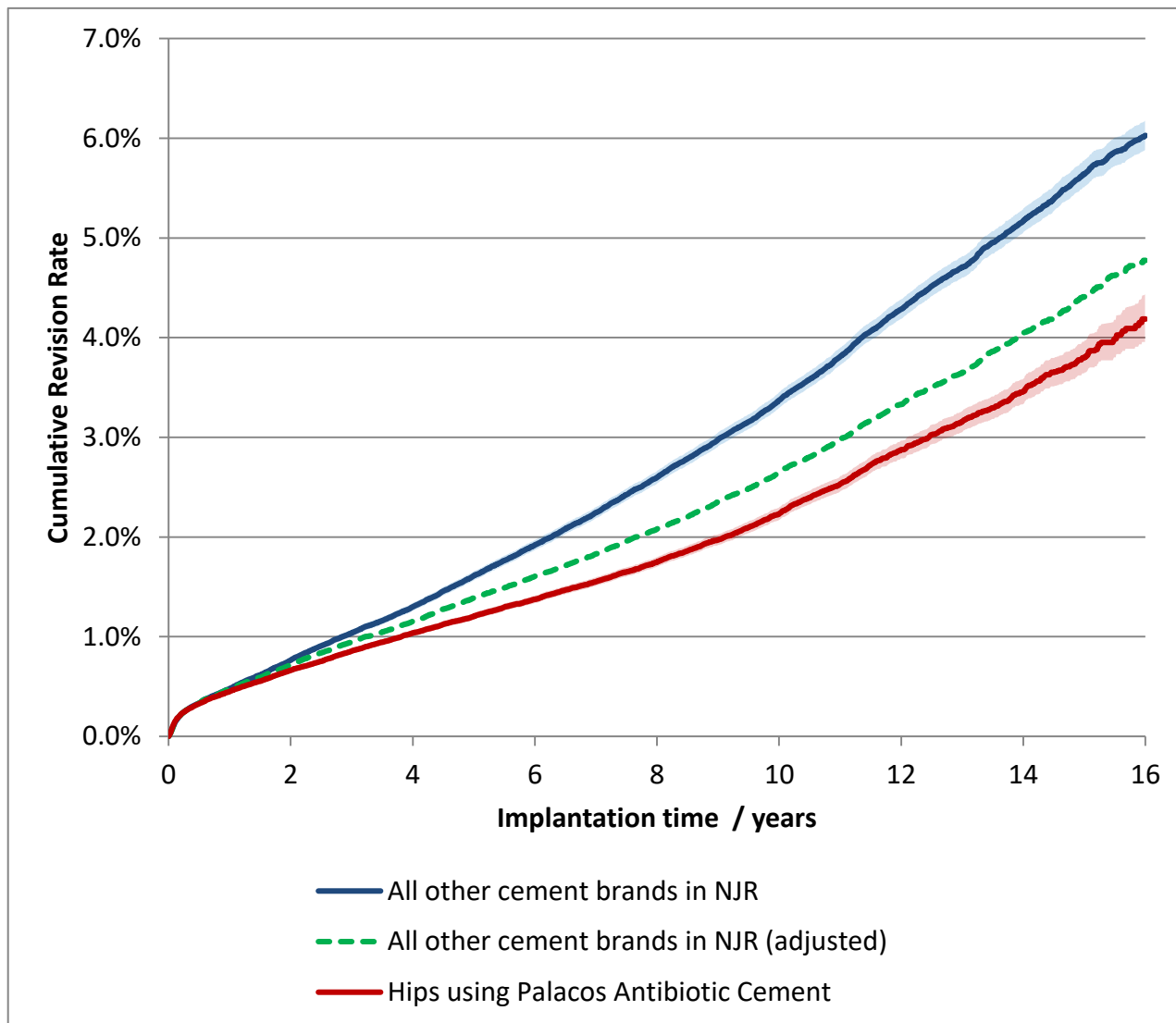
Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	0.91 ‡ (0.88 - 0.94)	<0.001 ‡
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.94 (0.91 - 0.97)	<0.001

‡ 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.	0.70 ‡ (0.68 - 0.72)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.86 (0.83 - 0.89)	<0.001

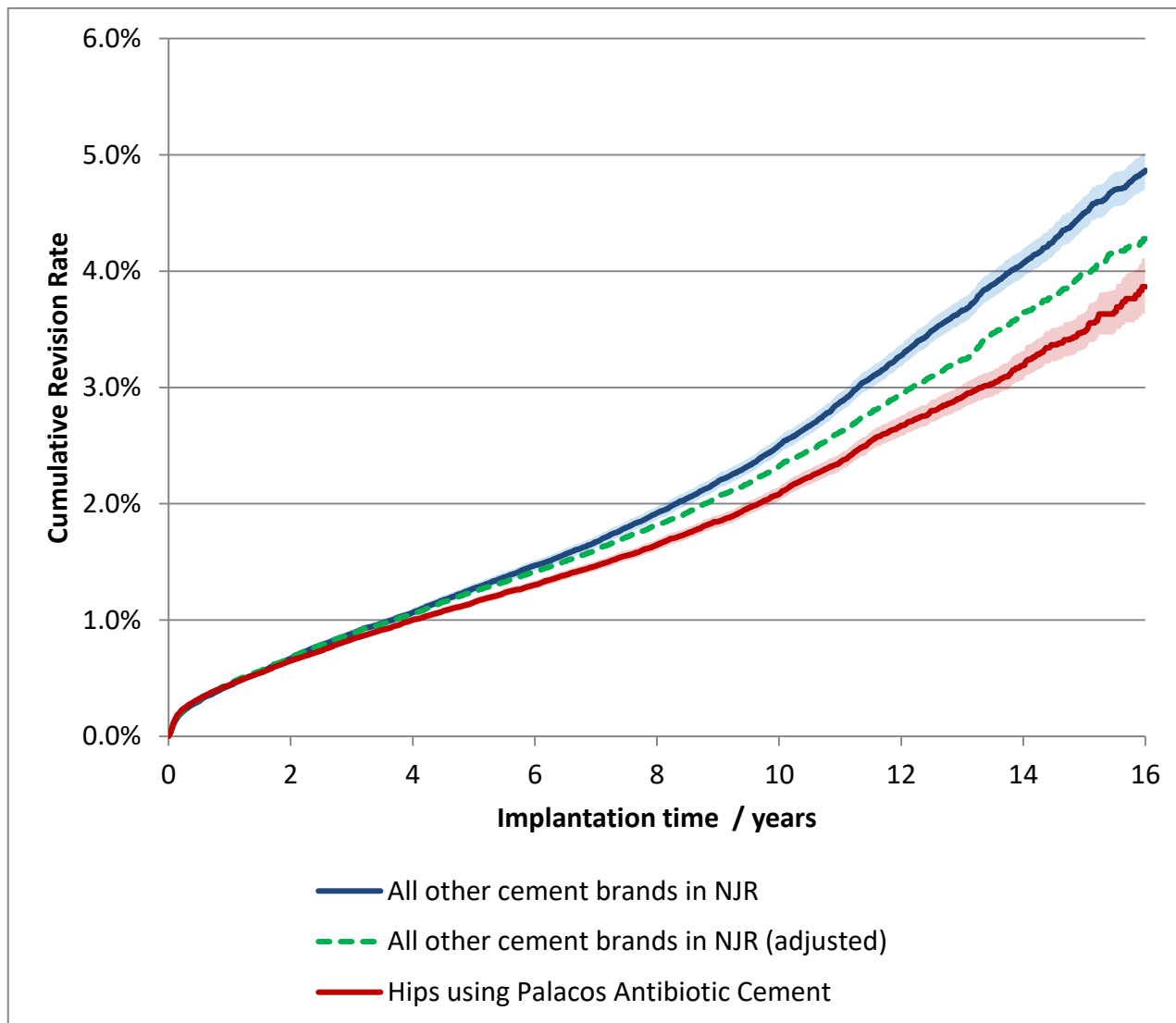
‡ Hazard ratio varies with time



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 - 0.94)	<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	483,018	-	-	-	477,939	-	-	-
1	431,100	0.7% (0.7% - 0.7%)	0.7% (0.7% - 0.7%)	0.8% (0.8% - 0.8%)	426,203	0.7% (0.7% - 0.7%)	0.6% (0.6% - 0.7%)	0.8% (0.7% - 0.8%)
2	386,882	1.0% (0.9% - 1.0%)	1.0% (1.0% - 1.0%)	1.1% (1.1% - 1.1%)	382,121	1.0% (0.9% - 1.0%)	0.9% (0.9% - 1.0%)	1.1% (1.0% - 1.1%)
3	351,849	1.2% (1.2% - 1.2%)	1.3% (1.3% - 1.4%)	1.4% (1.4% - 1.4%)	347,234	1.2% (1.1% - 1.2%)	1.2% (1.1% - 1.2%)	1.3% (1.3% - 1.3%)
4	300,985	1.4% (1.4% - 1.4%)	1.6% (1.6% - 1.7%)	1.7% (1.7% - 1.7%)	296,540	1.4% (1.3% - 1.4%)	1.4% (1.3% - 1.4%)	1.5% (1.5% - 1.5%)
5	254,803	1.6% (1.6% - 1.7%)	2.0% (1.9% - 2.0%)	2.0% (2.0% - 2.0%)	250,515	1.6% (1.5% - 1.6%)	1.6% (1.6% - 1.7%)	1.7% (1.7% - 1.8%)
6	211,361	1.8% (1.8% - 1.9%)	2.3% (2.2% - 2.3%)	2.4% (2.3% - 2.4%)	207,248	1.7% (1.7% - 1.8%)	1.8% (1.8% - 1.9%)	1.9% (1.9% - 2.0%)
7	171,611	2.0% (2.0% - 2.1%)	2.7% (2.6% - 2.7%)	2.7% (2.7% - 2.7%)	167,659	1.9% (1.9% - 2.0%)	2.1% (2.0% - 2.1%)	2.2% (2.1% - 2.2%)
8	136,810	2.3% (2.2% - 2.3%)	3.0% (3.0% - 3.1%)	3.1% (3.0% - 3.1%)	133,032	2.1% (2.1% - 2.2%)	2.4% (2.3% - 2.4%)	2.4% (2.4% - 2.4%)
9	105,962	2.5% (2.5% - 2.6%)	3.4% (3.4% - 3.5%)	3.5% (3.4% - 3.5%)	102,358	2.4% (2.3% - 2.4%)	2.6% (2.6% - 2.7%)	2.7% (2.6% - 2.7%)
10	80,014	2.8% (2.7% - 2.9%)	3.9% (3.8% - 3.9%)	3.9% (3.8% - 3.9%)	76,598	2.6% (2.6% - 2.7%)	3.0% (2.9% - 3.1%)	3.0% (2.9% - 3.0%)
11	58,716	3.1% (3.1% - 3.2%)	4.3% (4.2% - 4.4%)	4.3% (4.3% - 4.4%)	55,542	2.9% (2.9% - 3.0%)	3.4% (3.3% - 3.5%)	3.3% (3.3% - 3.3%)
12	41,995	3.5% (3.4% - 3.6%)	4.8% (4.7% - 4.9%)	4.8% (4.7% - 4.9%)	39,184	3.3% (3.2% - 3.4%)	3.8% (3.7% - 3.9%)	3.7% (3.6% - 3.7%)
13	28,671	3.8% (3.7% - 4.0%)	5.3% (5.2% - 5.4%)	5.3% (5.2% - 5.3%)	26,305	3.6% (3.5% - 3.7%)	4.3% (4.1% - 4.4%)	4.1% (4.0% - 4.1%)
14	17,581	4.2% (4.1% - 4.3%)	5.8% (5.7% - 5.9%)	5.8% (5.7% - 5.8%)	15,889	3.9% (3.8% - 4.0%)	4.7% (4.6% - 4.8%)	4.5% (4.4% - 4.5%)
15	8,588	4.6% (4.4% - 4.8%)	6.3% (6.1% - 6.4%)	6.3% (6.2% - 6.3%)	7,804	4.2% (4.1% - 4.4%)	5.2% (5.0% - 5.3%)	4.9% (4.8% - 5.0%)

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	483,018	-	-	-	477,939	-	-	-
1	431,100	0.5% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)	(-)	426,203	0.4% (0.4% - 0.5%)	0.4% (0.4% - 0.5%)	(-)
2	386,882	0.7% (0.6% - 0.7%)	0.8% (0.7% - 0.8%)	(-)	382,121	0.7% (0.6% - 0.7%)	0.7% (0.6% - 0.7%)	(-)
3	351,849	0.9% (0.8% - 0.9%)	1.0% (1.0% - 1.1%)	(-)	347,234	0.8% (0.8% - 0.9%)	0.9% (0.8% - 0.9%)	(-)
4	300,985	1.0% (1.0% - 1.1%)	1.3% (1.3% - 1.3%)	(-)	296,540	1.0% (1.0% - 1.0%)	1.1% (1.0% - 1.1%)	(-)
5	254,803	1.2% (1.2% - 1.2%)	1.6% (1.6% - 1.7%)	(-)	250,515	1.2% (1.1% - 1.2%)	1.3% (1.2% - 1.3%)	(-)
6	211,361	1.4% (1.3% - 1.4%)	1.9% (1.9% - 2.0%)	(-)	207,248	1.3% (1.3% - 1.3%)	1.5% (1.4% - 1.5%)	(-)
7	171,611	1.6% (1.5% - 1.6%)	2.2% (2.2% - 2.3%)	(-)	167,659	1.5% (1.4% - 1.5%)	1.7% (1.6% - 1.7%)	(-)
8	136,810	1.8% (1.7% - 1.8%)	2.6% (2.5% - 2.7%)	(-)	133,032	1.6% (1.6% - 1.7%)	1.9% (1.9% - 2.0%)	(-)
9	105,962	2.0% (1.9% - 2.0%)	3.0% (2.9% - 3.0%)	(-)	102,358	1.8% (1.8% - 1.9%)	2.2% (2.1% - 2.3%)	(-)
10	80,014	2.2% (2.2% - 2.3%)	3.4% (3.3% - 3.5%)	(-)	76,598	2.1% (2.0% - 2.1%)	2.5% (2.4% - 2.6%)	(-)
11	58,716	2.5% (2.5% - 2.6%)	3.8% (3.7% - 3.9%)	(-)	55,542	2.4% (2.3% - 2.4%)	2.9% (2.8% - 3.0%)	(-)
12	41,995	2.9% (2.8% - 3.0%)	4.3% (4.2% - 4.4%)	(-)	39,184	2.7% (2.6% - 2.8%)	3.3% (3.2% - 3.4%)	(-)
13	28,671	3.2% (3.1% - 3.3%)	4.7% (4.6% - 4.8%)	(-)	26,305	2.9% (2.8% - 3.0%)	3.7% (3.6% - 3.8%)	(-)
14	17,581	3.5% (3.3% - 3.6%)	5.2% (5.0% - 5.3%)	(-)	15,889	3.2% (3.1% - 3.3%)	4.1% (3.9% - 4.2%)	(-)
15	8,588	3.8% (3.6% - 4.0%)	5.6% (5.5% - 5.8%)	(-)	7,804	3.5% (3.3% - 3.6%)	4.5% (4.4% - 4.6%)	(-)

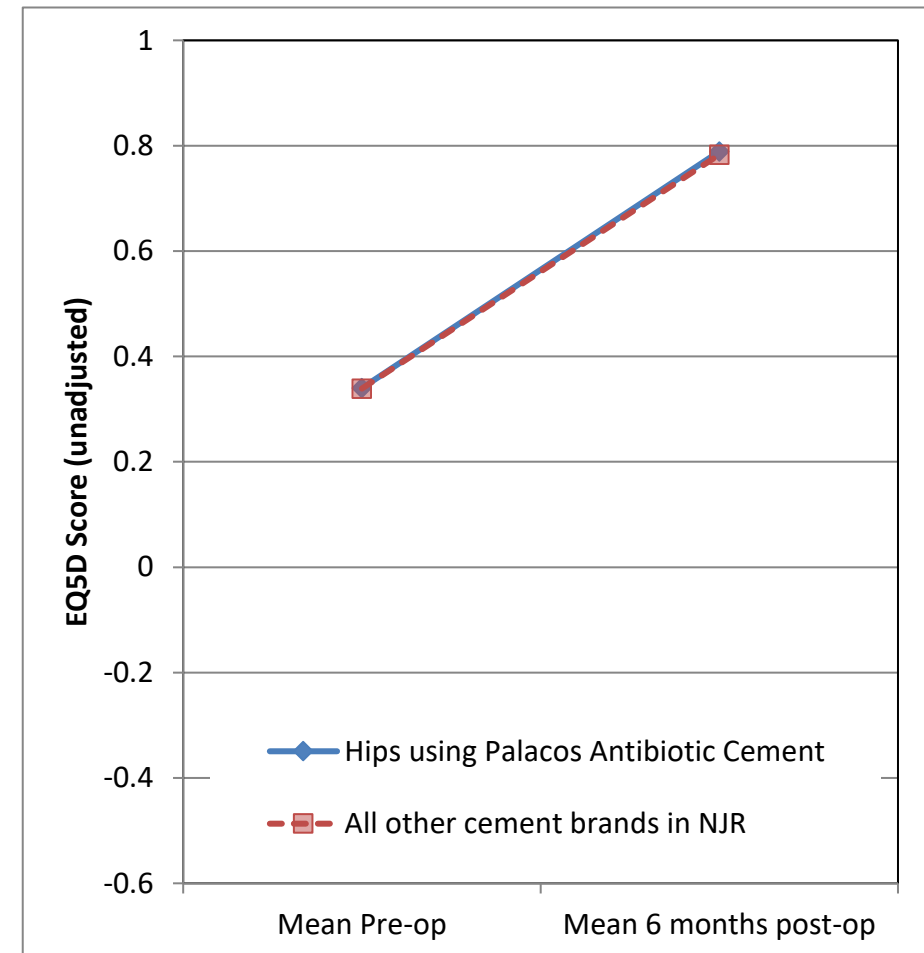
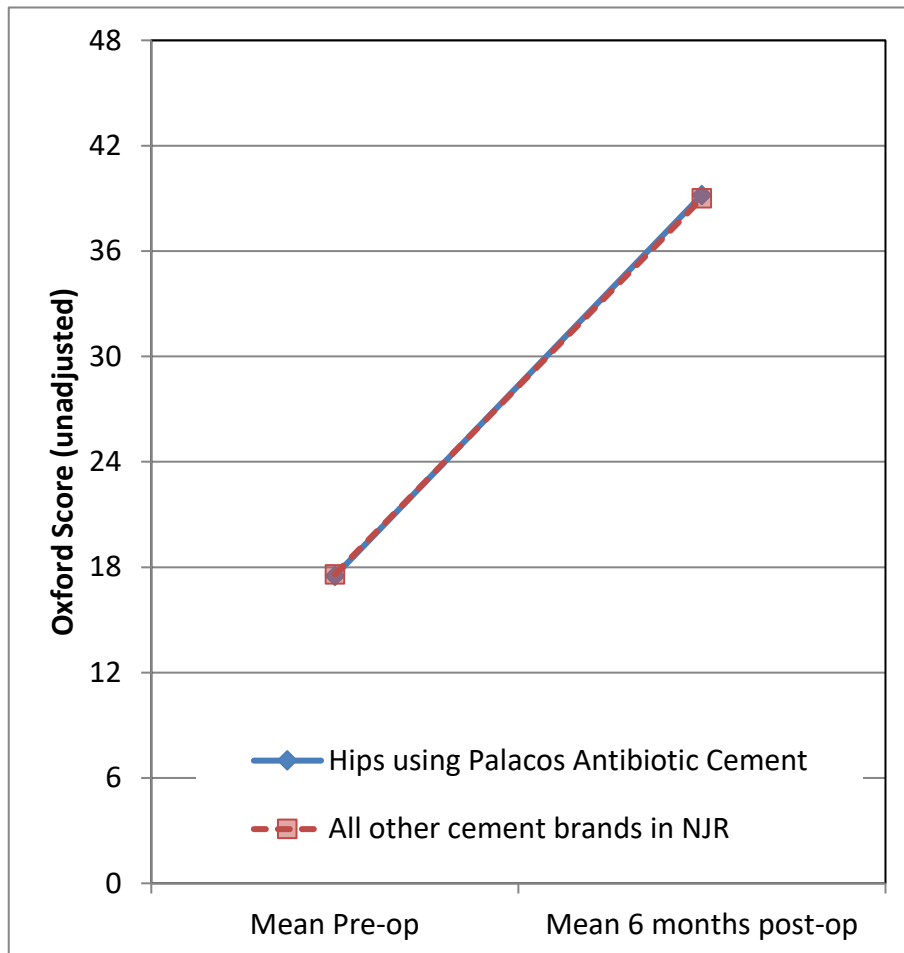
Cumulative revision rate with 95% confidence intervals

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 Antibiotic Cement	All other cement brands in NJR	All THR in NJR
Paired Records	125,342	81,575	350,456
PreOp score	17.5 (17.5 - 17.6)	17.6 (17.5 - 17.6)	17.9 (17.9 - 18.0)
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 - 39.5)	39.4 (39.3 - 39.4)	39.6 (39.5 - 39.6)
Health gain	21.7 (21.6 - 21.7)	21.4 (21.3 - 21.5)	21.6 (21.6 - 21.7)
Health gain (adjusted)	21.6 (21.5 - 21.6)	21.4 (21.4 - 21.5)	21.6 (21.6 - 21.7)
p value (adjusted health gain)	0.006		
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	115,114	74,996	323,118
PreOp score	0.340 (0.339 - 0.342)	0.339 (0.337 - 0.341)	0.353 (0.352 - 0.354)
6 month score	0.789 (0.788 - 0.790)	0.783 (0.781 - 0.785)	0.795 (0.794 - 0.796)
6 month score (adjusted)	0.793 (0.792 - 0.795)	0.791 (0.789 - 0.793)	0.795 (0.794 - 0.796)
Health gain	0.449 (0.447 - 0.451)	0.444 (0.441 - 0.446)	0.442 (0.441 - 0.443)
Health gain (adjusted)	0.440 (0.439 - 0.441)	0.438 (0.436 - 0.439)	0.442 (0.441 - 0.443)
p value (adjusted health gain)	0.3		
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	110,281	72,186	310,933
PreOp score	64.4 (64.3 - 64.5)	64.3 (64.2 - 64.5)	64.7 (64.7 - 64.8)
6 month score	76.6 (76.5 - 76.7)	76.0 (75.9 - 76.2)	77.0 (77.0 - 77.1)
6 month score (adjusted)	77.0 (76.9 - 77.1)	76.8 (76.6 - 76.9)	77.0 (77.0 - 77.1)
Health gain	12.2 (12.1 - 12.3)	11.7 (11.5 - 11.9)	12.3 (12.2 - 12.4)
Health gain (adjusted)	12.3 (12.2 - 12.4)	12.0 (11.9 - 12.1)	12.3 (12.3 - 12.4)
p value (adjusted health gain)	0.004		
Score Improved	66.2%	65.2%	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 Antibiotic Cement

Responses are not case mix adjusted

**Patient Reported Outcomes**



Chi Squared p-value for difference: 0.247

Chi Squared p-value for difference: 0.561

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?

## Patient Reported Outcomes

### Success

Response	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Much better	110409	71611
A little better	11050	7355
About the same	2985	2026
A little worse	1720	1108
Much worse	1142	719

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	51611	33735
Very Good	44549	28725
Good	21808	14150
Fair	7211	4762
Poor	1957	1304

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
Cement		
66017569	PALACOS R +G 2x40 g	421635
66017771	PALACOS R +G 1x40 g	3195
66017772	PALACOS R +G 1x60 g	6306
66017773	PALACOS R +G 2x20 g	4843
66017776	PALACOS R +G 2x10 g	7
66017787	PALACOS LV +G 1x40 g	4685
66031993	PALACOS MV+G 1x40g	199
66031995	PALACOS MV+G 2x40 g	2107
66031996	PALACOS MV+G 1x20g	2
66031998	PALACOS MV+G 2x20 g	5
66032000	PALACOS MV+G 1x60 g	1
66037894	PALACOS LV+G 1x20g	1
66044273	PALACOS R+G Pro 55 cement	168
66044274	PALACOS R+G Pro 75 cement	534
Multiple Found	Multiple Found	39330