

Implant Summary Report for:

Heraeus Medical

Hips using Palacos Antibiotic Cement

Comprising PRIMARY hips implanted up to:	01 June 2023
NJR Database extract:	31 July 2023
Produced on:	08 August 2023
Licensed for use until:	08 August 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

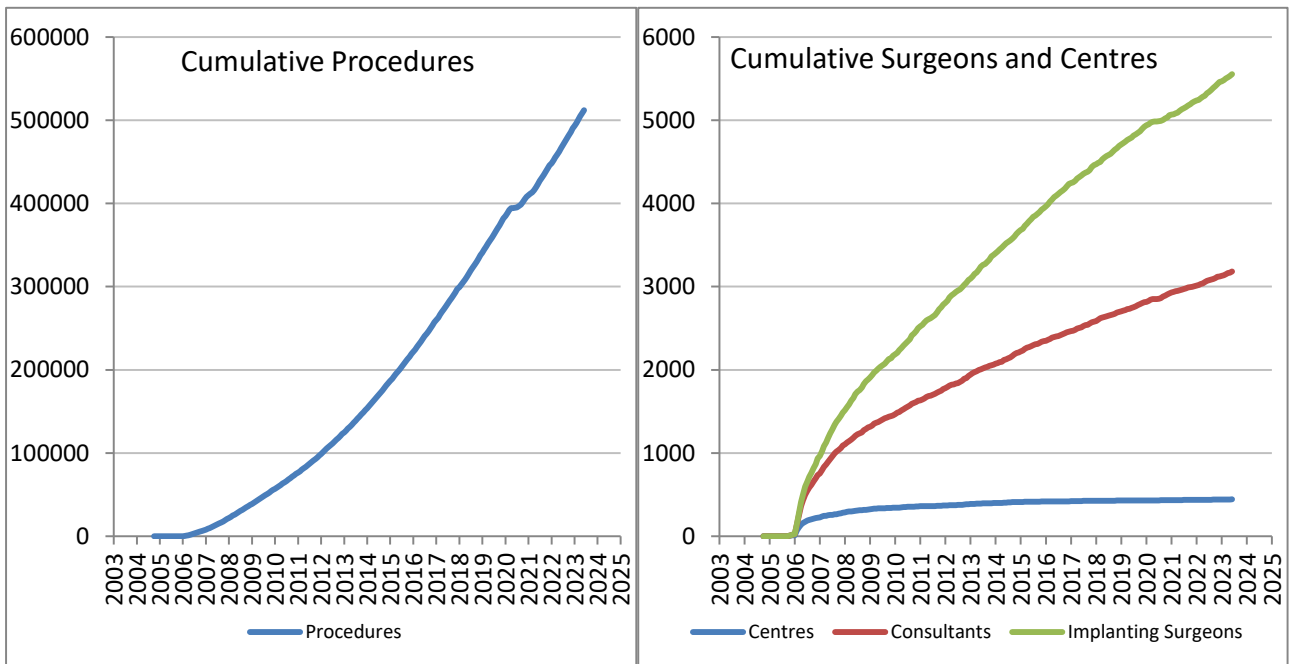
Date of first recorded usage in the NJR: **06 September 2005**

Date of last recorded usage in this dataset **01 June 2023**

Maximum implantation time: 17.7 years

Mean implantation time: 6.0 years

Totals Recorded in NJR	Cumulative Total
Procedures	512,224
Patients	453,153
Centres	444
Consultants	3,182
Implanting Surgeons	5,555



	Year of implantation														
Current Outcome	Pre-2012	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total	%
Death	46942	9135	8814	8516	7730	6934	5696	4569	3470	1338	1150	560	69	104923	20.5%
Revised	3629	668	665	681	725	678	634	575	532	272	335	276	69	9739	1.9%
Unrevised	48216	16060	19754	23483	26562	30653	33295	36312	39984	23547	36993	43798	18905	397562	77.6%
Total	98787	25863	29233	32680	35017	38265	39625	41456	43986	25157	38478	44634	19043	512224	100%

Patient / Procedure Details

Patient Details

	Hips using Palacos Antibiotic Cement	All other cement brands in NJR	All NJR hip replacement
Total Procedures	512,224	374,032	1,522,840
Total Patients	453,153	332,862	1,266,846
Demographics			
Mean age	71.6	70.4	68.7
< 50	3.3%	5.1%	6.2%
50 – 59	9.5%	11.6%	14.6%
60 – 69	25.4%	25.7%	29.3%
70 – 79	40.8%	38.2%	34.6%
≥ 80	21.0%	19.4%	15.4%
Median BMI	28	28	28
% BMI information available	71.8%	60.3%	65.3%
Underweight (BMI < 18.5)	1.0%	1.0%	0.9%
Normal (18.5 ≤ BMI < 25)	21.7%	22.6%	20.9%
Overweight (25 ≤ BMI < 30)	39.3%	39.8%	39.3%
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)	3.2%	2.9%	3.3%
% Male	35.8%	38.3%	40.2%
ASA Grades			
P1 - Fit and healthy	10.0%	15.0%	14.6%
P2 - Mild disease not incapacitating	68.7%	65.1%	67.9%
P3 - Incapacitating systemic disease	20.6%	19.2%	16.9%
P4 / P5	0.7%	0.8%	0.6%
Indications			
Osteoarthritis	89.81%	89.66%	91.15%
Rheumatoid Arthritis	1.40%	1.40%	1.30%
Avascular Necrosis	2.62%	2.57%	2.61%
Fractured Neck of Femur	5.53%	5.04%	3.88%
CDH/DDH	1.11%	1.31%	1.59%
Other	2.05%	2.53%	2.06%

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	584	676.75	<0.001
Dislocation / Subluxation	2382	2366.64	0.65
Adverse Soft Tissue Reaction	386	511.51	<0.001
Infection	2181	2229.69	0.128
Aseptic Loosening - Stem	742	844.80	<0.001
Aseptic Loosening - Socket	1457	1484.39	0.365
Periprosthetic Fracture Stem	1921	1996.89	0.014
Periprosthetic Fracture Socket	189	198.63	0.322
Malalignment Stem	212	227.02	0.159
Malalignment Socket	432	405.04	0.068
Wear Of Acetabular Component	347	332.63	0.333
Lysis Stem	224	238.06	0.282
Lysis Socket	340	332.88	0.634
Implant Fracture Stem	192	191.52	0.962
Implant Fracture Socket	42	42.19	1
Implant Fracture Head	44	43.44	0.919
Dissociation of Liner	110	100.26	0.174
Other / reason not recorded	339	358.78	0.174
Total Revised	9739	10117.85	<0.001

† 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	2337	24%	18%
Acetabular only	2036	21%	18%
Both femoral and acetabular	4118	42%	58%
Neither femoral nor acetabular revision recorded *	1248	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 [†]	Expected Revisions*	p value
Unexplained Pain	451	455.70	0.774
Dislocation / Subluxation	2365	2379.35	0.668
Adverse Soft Tissue Reaction	132	118.91	0.097
Infection	2148	2226.73	0.011
Aseptic Loosening - Stem	675	779.90	<0.001
Aseptic Loosening - Socket	1411	1460.22	0.086
Periprosthetic Fracture Stem	1854	1907.87	0.064
Periprosthetic Fracture Socket	188	193.62	0.548
Malalignment Stem	205	215.88	0.285
Malalignment Socket	404	383.22	0.126
Wear Of Acetabular Component	339	333.92	0.722
Lysis Stem	189	196.80	0.492
Lysis Socket	301	291.77	0.49
Implant Fracture Stem	183	191.45	0.421
Implant Fracture Socket	42	41.72	1
Implant Fracture Head	39	41.63	0.566
Dissociation of Liner	108	97.07	0.109
Other / reason not recorded	283	275.82	0.528
Total Revised	9134	9372.43	<0.001

* 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



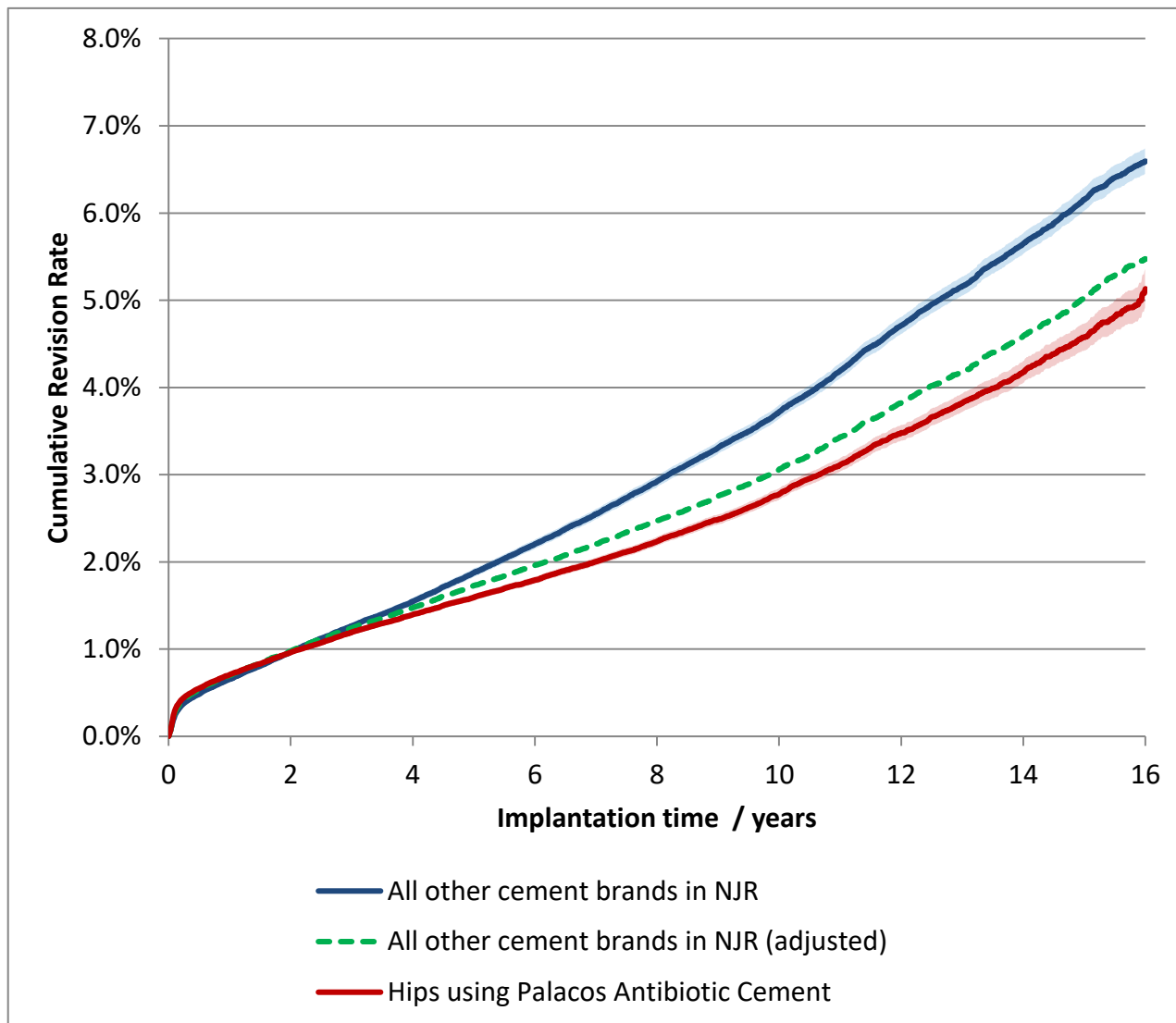
Components Revised	Number of procedures	Hips using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral only	2291	25%	22%
Acetabular only	1978	22%	23%
Both femoral and acetabular	3626	40%	47%
Neither femoral nor acetabular revision recorded *	1239	14%	8%

* 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.

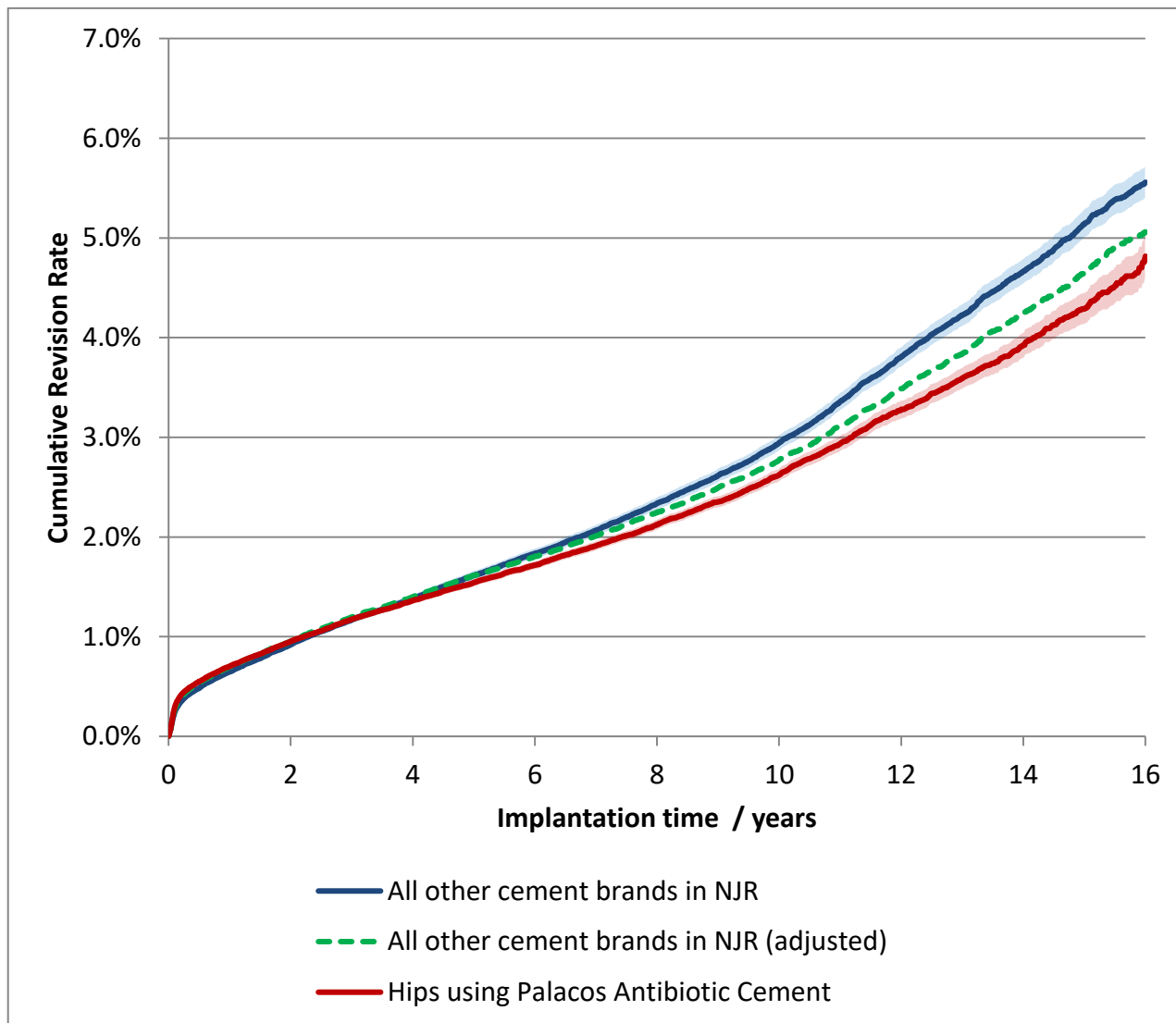
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.79 ‡ (0.77 - 0.81)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.92 (0.89 - 0.94)	<0.001

‡ 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.

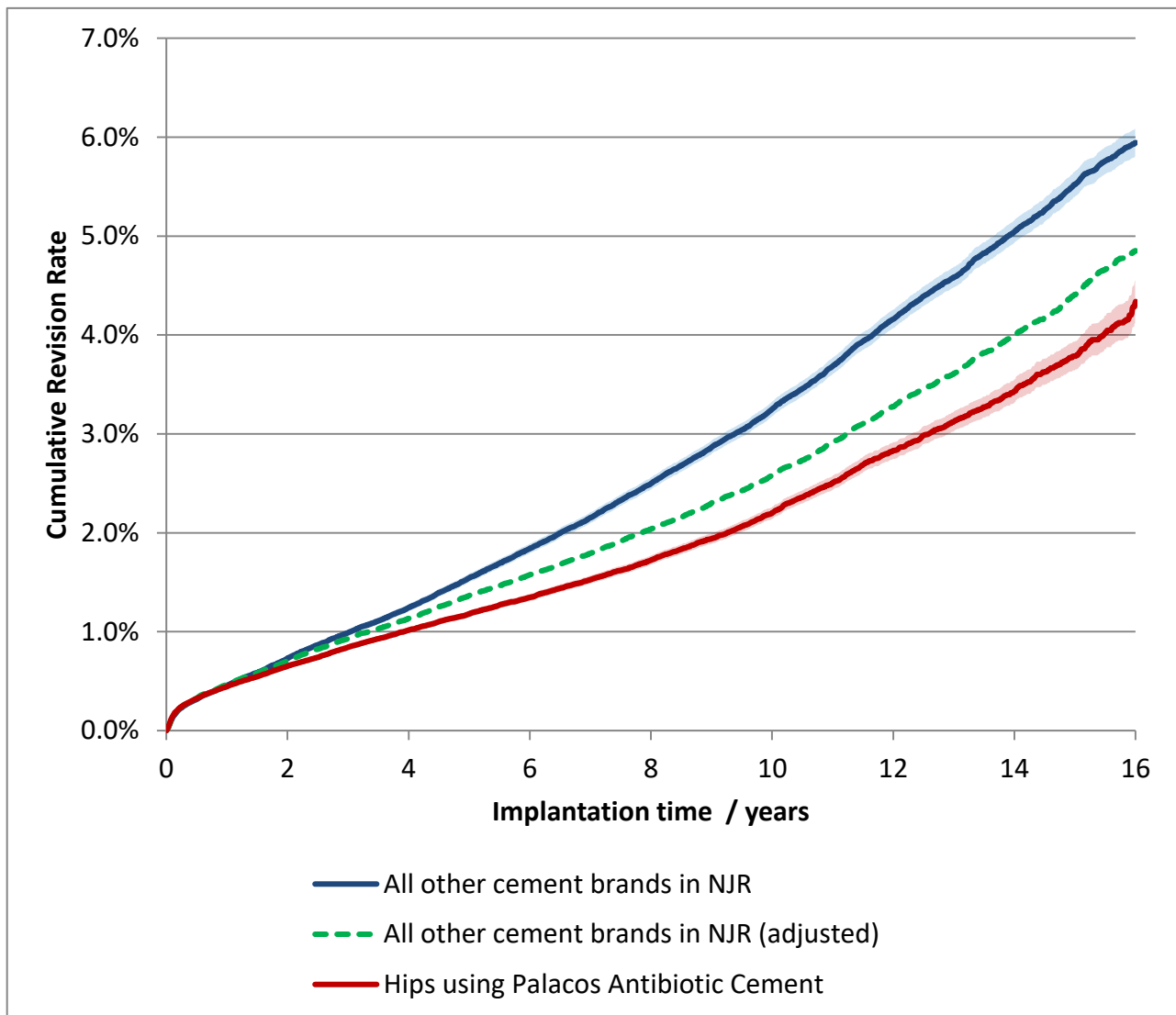
Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	0.91 ‡ (0.88 - 0.94)	<0.001 ‡
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.94 (0.91 - 0.97)	<0.001

‡ 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.

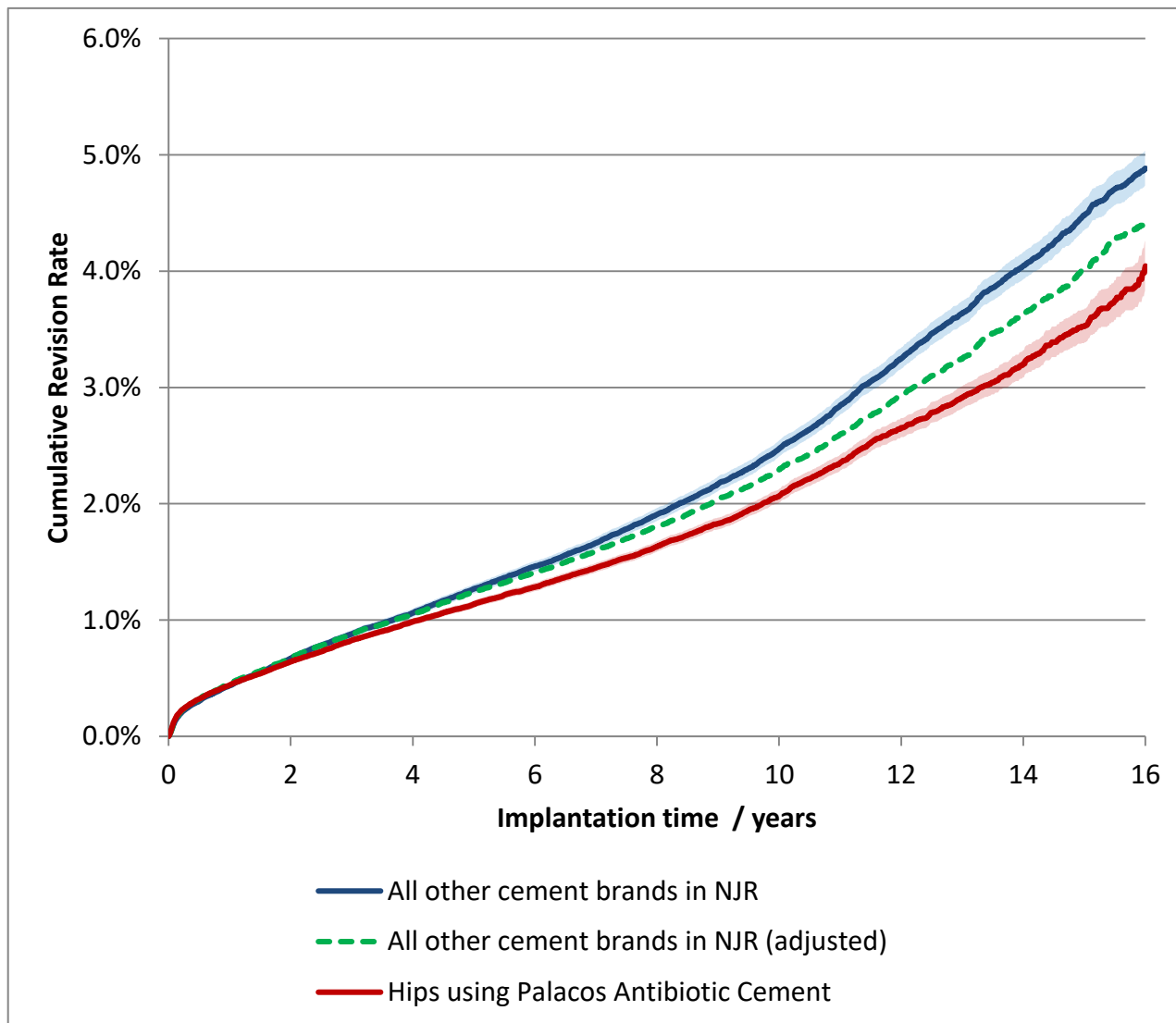
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.72 ‡ (0.70 - 0.74)	<0.001 ‡
All bearings. Adjusted for age, gender, year cohort and indications.	0.86 (0.83 - 0.89)	<0.001

‡ 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 - 0.93)	<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	512,224	-	-	-	507,077	-	-	-
1	455,451	0.7% (0.7% - 0.7%)	0.7% (0.6% - 0.7%)	0.8% (0.8% - 0.8%)	450,492	0.7% (0.7% - 0.7%)	0.6% (0.6% - 0.7%)	0.8% (0.7% - 0.8%)
2	404,167	1.0% (0.9% - 1.0%)	1.0% (0.9% - 1.0%)	1.1% (1.1% - 1.1%)	399,357	1.0% (0.9% - 1.0%)	0.9% (0.9% - 1.0%)	1.1% (1.0% - 1.1%)
3	367,386	1.2% (1.2% - 1.2%)	1.3% (1.2% - 1.3%)	1.4% (1.4% - 1.4%)	362,706	1.2% (1.1% - 1.2%)	1.2% (1.1% - 1.2%)	1.3% (1.3% - 1.3%)
4	323,809	1.4% (1.4% - 1.4%)	1.5% (1.5% - 1.6%)	1.7% (1.7% - 1.7%)	319,307	1.4% (1.3% - 1.4%)	1.4% (1.3% - 1.4%)	1.5% (1.5% - 1.5%)
5	274,439	1.6% (1.6% - 1.6%)	1.9% (1.8% - 1.9%)	2.0% (2.0% - 2.0%)	270,099	1.5% (1.5% - 1.6%)	1.6% (1.6% - 1.7%)	1.7% (1.7% - 1.7%)
6	230,488	1.8% (1.7% - 1.8%)	2.2% (2.2% - 2.3%)	2.3% (2.3% - 2.3%)	226,304	1.7% (1.7% - 1.8%)	1.8% (1.8% - 1.9%)	1.9% (1.9% - 2.0%)
7	188,673	2.0% (2.0% - 2.0%)	2.5% (2.5% - 2.6%)	2.6% (2.6% - 2.7%)	184,651	1.9% (1.9% - 2.0%)	2.1% (2.0% - 2.1%)	2.1% (2.1% - 2.2%)
8	151,555	2.2% (2.2% - 2.3%)	2.9% (2.9% - 3.0%)	3.0% (3.0% - 3.0%)	147,710	2.1% (2.1% - 2.2%)	2.3% (2.3% - 2.4%)	2.4% (2.4% - 2.4%)
9	118,781	2.5% (2.4% - 2.5%)	3.3% (3.2% - 3.4%)	3.4% (3.3% - 3.4%)	115,114	2.4% (2.3% - 2.4%)	2.6% (2.6% - 2.7%)	2.6% (2.6% - 2.7%)
10	90,779	2.8% (2.7% - 2.8%)	3.7% (3.6% - 3.8%)	3.8% (3.7% - 3.8%)	87,290	2.6% (2.6% - 2.7%)	2.9% (2.9% - 3.0%)	2.9% (2.9% - 3.0%)
11	67,950	3.1% (3.0% - 3.2%)	4.2% (4.1% - 4.3%)	4.2% (4.1% - 4.2%)	64,637	2.9% (2.9% - 3.0%)	3.4% (3.3% - 3.4%)	3.3% (3.2% - 3.3%)
12	48,823	3.5% (3.4% - 3.6%)	4.7% (4.6% - 4.8%)	4.7% (4.6% - 4.7%)	45,812	3.3% (3.2% - 3.4%)	3.8% (3.7% - 3.9%)	3.6% (3.6% - 3.7%)
13	34,196	3.8% (3.7% - 3.9%)	5.2% (5.1% - 5.3%)	5.1% (5.1% - 5.2%)	31,583	3.6% (3.5% - 3.7%)	4.2% (4.1% - 4.3%)	4.0% (4.0% - 4.1%)
14	22,528	4.2% (4.1% - 4.3%)	5.6% (5.5% - 5.8%)	5.6% (5.5% - 5.7%)	20,420	3.9% (3.8% - 4.1%)	4.7% (4.5% - 4.8%)	4.4% (4.4% - 4.5%)
15	12,889	4.6% (4.4% - 4.7%)	6.2% (6.0% - 6.3%)	6.1% (6.0% - 6.2%)	11,538	4.3% (4.1% - 4.4%)	5.1% (5.0% - 5.3%)	4.8% (4.8% - 4.9%)

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	512,224	-	-	-	507,077	-	-	-
1	455,451	0.4% (0.4% - 0.5%)	0.5% (0.4% - 0.5%)	(-)	450,492	0.4% (0.4% - 0.5%)	0.4% (0.4% - 0.5%)	(-)
2	404,167	0.7% (0.6% - 0.7%)	0.7% (0.7% - 0.8%)	(-)	399,357	0.6% (0.6% - 0.7%)	0.7% (0.6% - 0.7%)	(-)
3	367,386	0.8% (0.8% - 0.9%)	1.0% (1.0% - 1.0%)	(-)	362,706	0.8% (0.8% - 0.9%)	0.9% (0.8% - 0.9%)	(-)
4	323,809	1.0% (1.0% - 1.0%)	1.2% (1.2% - 1.3%)	(-)	319,307	1.0% (1.0% - 1.0%)	1.1% (1.0% - 1.1%)	(-)
5	274,439	1.2% (1.1% - 1.2%)	1.5% (1.5% - 1.6%)	(-)	270,099	1.1% (1.1% - 1.2%)	1.3% (1.2% - 1.3%)	(-)
6	230,488	1.3% (1.3% - 1.4%)	1.8% (1.8% - 1.9%)	(-)	226,304	1.3% (1.2% - 1.3%)	1.5% (1.4% - 1.5%)	(-)
7	188,673	1.5% (1.5% - 1.6%)	2.2% (2.1% - 2.2%)	(-)	184,651	1.5% (1.4% - 1.5%)	1.7% (1.6% - 1.7%)	(-)
8	151,555	1.7% (1.7% - 1.8%)	2.5% (2.4% - 2.6%)	(-)	147,710	1.6% (1.6% - 1.7%)	1.9% (1.9% - 2.0%)	(-)
9	118,781	1.9% (1.9% - 2.0%)	2.9% (2.8% - 2.9%)	(-)	115,114	1.8% (1.8% - 1.9%)	2.2% (2.1% - 2.2%)	(-)
10	90,779	2.2% (2.1% - 2.3%)	3.3% (3.2% - 3.3%)	(-)	87,290	2.1% (2.0% - 2.1%)	2.5% (2.4% - 2.5%)	(-)
11	67,950	2.5% (2.4% - 2.6%)	3.7% (3.6% - 3.8%)	(-)	64,637	2.4% (2.3% - 2.4%)	2.8% (2.8% - 2.9%)	(-)
12	48,823	2.8% (2.7% - 2.9%)	4.2% (4.1% - 4.3%)	(-)	45,812	2.7% (2.6% - 2.7%)	3.2% (3.2% - 3.3%)	(-)
13	34,196	3.1% (3.0% - 3.2%)	4.6% (4.5% - 4.7%)	(-)	31,583	2.9% (2.8% - 3.0%)	3.6% (3.5% - 3.7%)	(-)
14	22,528	3.4% (3.3% - 3.5%)	5.0% (4.9% - 5.2%)	(-)	20,420	3.2% (3.1% - 3.3%)	4.0% (3.9% - 4.2%)	(-)
15	12,889	3.8% (3.6% - 3.9%)	5.5% (5.4% - 5.6%)	(-)	11,538	3.5% (3.4% - 3.7%)	4.5% (4.3% - 4.6%)	(-)

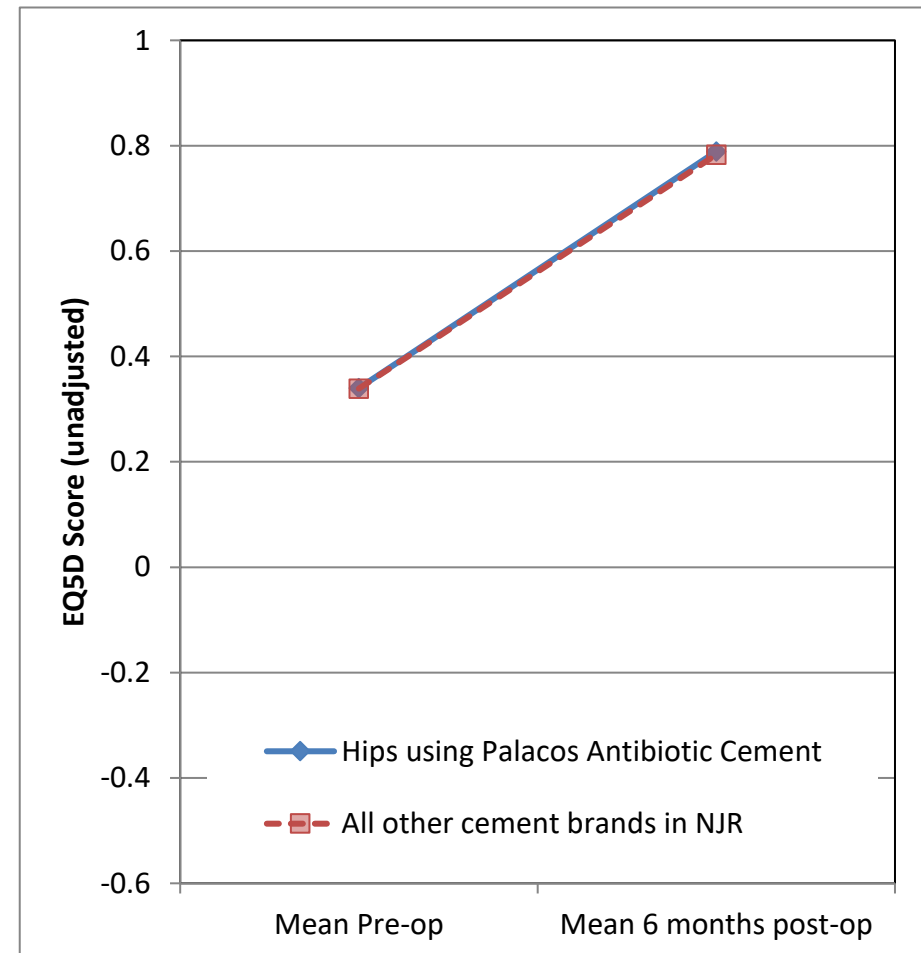
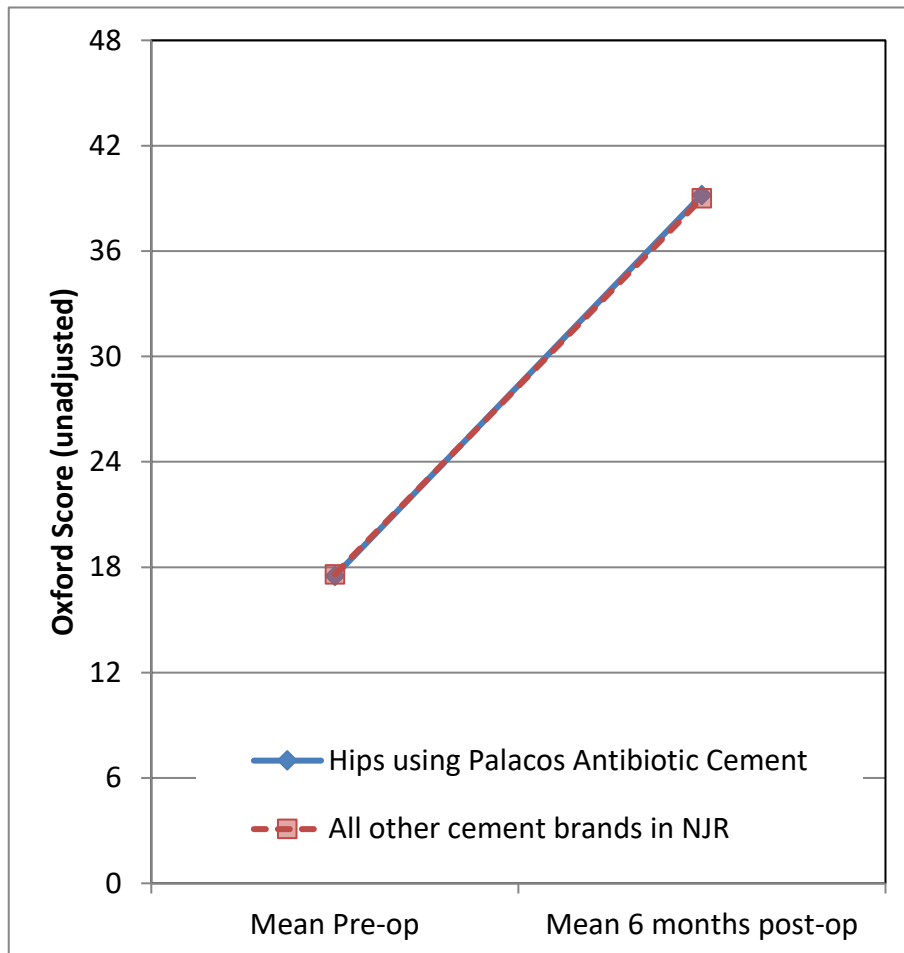
Cumulative revision rate with 95% confidence intervals

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	81,578	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	115,112	74,998	323,116
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)	0.29		
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	110,280	72,189	310,932
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: 0.245

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	110408	71613
A little better	11050	7356
About the same	2985	2026
A little worse	1721	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	51610	33735
Very Good	44548	28725
Good	21809	14152
Fair	7212	4763
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	448391
66017771	PALACOS R +G 1x40 g	3337
66017772	PALACOS R +G 1x60 g	6793
66017773	PALACOS R +G 2x20 g	5056
66017776	PALACOS R +G 2x10 g	7
66017787	PALACOS LV +G 1x40 g	4792
66031993	PALACOS MV+G 1x40g	209
66031995	PALACOS MV+G 2x40 g	2272
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	169
66044274	PALACOS R+G Pro 75 cement	641
Multiple Found	Multiple Found	40548