

Implant Summary Report for:

Heraeus Medical

Hips using Palacos 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 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

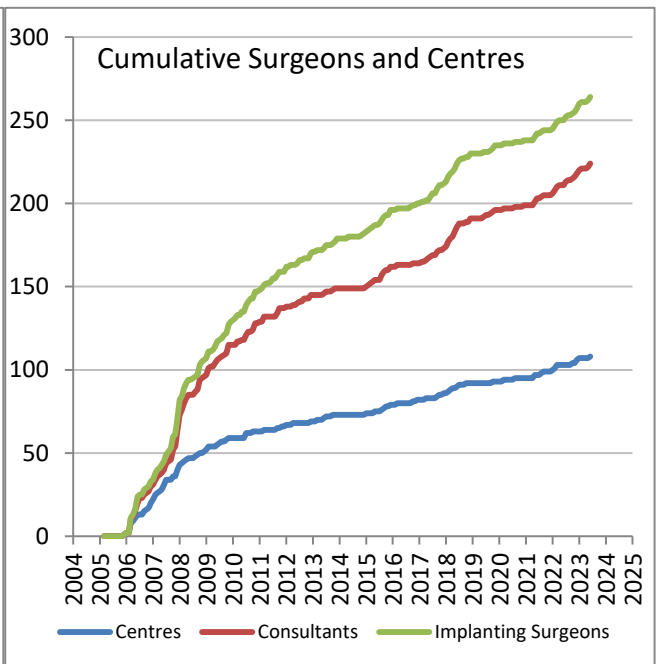
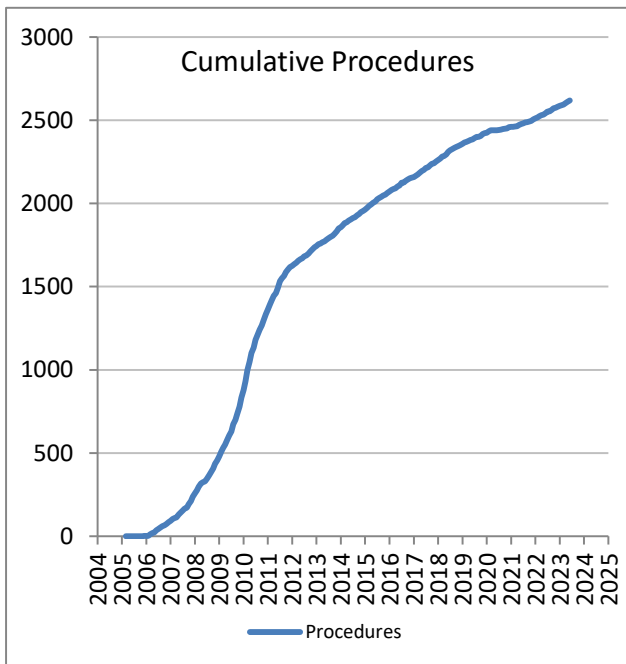
Date of first recorded usage in the NJR: **15 November 2005**

Date of last recorded usage in this dataset **25 May 2023**

Maximum implantation time: 17.5 years

Mean implantation time: 8.6 years

Totals Recorded in NJR	Cumulative Total
Procedures	2,619
Patients	2,483
Centres	108
Consultants	224
Implanting Surgeons	264



Current Outcome	Year of implantation													Total	%
	Pre-2012	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023		
Death	826	41	43	28	32	17	19	10	4	5	3	0	0	1028	39.3%
Revised	51	4	4	4	4	3	3	4	1	2	1	0	1	82	3.1%
Unrevised	749	73	66	74	74	66	79	85	60	30	46	76	31	1509	57.6%
Total	1626	118	113	106	110	86	101	99	65	37	50	76	32	2619	100%

Patient / Procedure Details

Patient Details

	Hips using Palacos Cement	All other cement brands in NJR	All NJR hip replacement
Total Procedures	2,619	883,637	1,522,840
Total Patients	2,483	766,117	1,266,846
Demographics			
Mean age	73.8	71.1	68.7
< 50	1.5%	4.1%	6.2%
50 – 59	5.8%	10.4%	14.6%
60 – 69	21.9%	25.6%	29.3%
70 – 79	45.5%	39.6%	34.6%
≥ 80	25.3%	20.3%	15.4%
Median BMI	27	28	28
% BMI information available	56.0%	67.0%	65.3%
Underweight (BMI < 18.5)	1.4%	1.0%	0.9%
Normal (18.5 ≤ BMI < 25)	25.0%	22.0%	20.9%
Overweight (25 ≤ BMI < 30)	41.7%	39.5%	39.3%
Obese I (30 ≤ BMI < 35)	21.2%	25.1%	25.8%
Obese II (35 ≤ BMI < 40)	7.8%	9.3%	9.9%
Obese III (BMI ≥ 40)	2.9%	3.1%	3.3%
% Male	33.7%	36.9%	40.2%
ASA Grades			
P1 - Fit and healthy	12.8%	12.1%	14.6%
P2 - Mild disease not incapacitating	67.8%	67.2%	67.9%
P3 - Incapacitating systemic disease	18.7%	20.0%	16.9%
P4 / P5	0.7%	0.7%	0.6%
Indications			
Osteoarthritis	93.47%	89.74%	91.15%
Rheumatoid Arthritis	0.95%	1.40%	1.30%
Avascular Necrosis	3.02%	2.59%	2.61%
Fractured Neck of Femur	3.40%	5.33%	3.88%
CDH/DDH	2.94%	1.19%	1.59%
Other	1.45%	2.26%	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	7	6.92	0.849
Dislocation / Subluxation	24	15.82	0.057
Adverse Soft Tissue Reaction	4	5.50	0.671
Infection	10	11.89	0.77
Aseptic Loosening - Stem	12	7.82	0.147
Aseptic Loosening - Socket	8	14.39	0.11
Periprosthetic Fracture Stem	16	14.26	0.595
Periprosthetic Fracture Socket	0	1.31	0.646
Malalignment Stem	7	1.52	<0.001
Malalignment Socket	1	3.10	0.386
Wear Of Acetabular Component	4	3.54	0.785
Lysis Stem	4	2.43	0.315
Lysis Socket	4	3.53	0.785
Implant Fracture Stem	1	1.59	1
Implant Fracture Socket	0	0.30	1
Implant Fracture Head	0	0.31	1
Dissociation of Liner	0	0.65	1
Other / reason not recorded	4	2.79	0.367
Total Revised	82	74.10	0.351

[†] multiple reasons may be listed for one revision procedure^{*} Based on All NJR Hips with Cement, adjusted for agegroup, gender, indications, and implantation yearSignificantly 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	18	22%	21%
Acetabular only	23	28%	19%
Both femoral and acetabular	39	48%	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	4.15	1
Dislocation / Subluxation	24	15.65	0.042
Adverse Soft Tissue Reaction	1	0.92	0.601
Infection	10	11.56	0.768
Aseptic Loosening - Stem	9	6.85	0.438
Aseptic Loosening - Socket	8	13.68	0.136
Periprosthetic Fracture Stem	15	13.06	0.577
Periprosthetic Fracture Socket	0	1.23	0.64
Malalignment Stem	7	1.34	<0.001
Malalignment Socket	1	2.73	0.535
Wear Of Acetabular Component	4	3.46	0.783
Lysis Stem	3	1.90	0.446
Lysis Socket	4	3.00	0.551
Implant Fracture Stem	0	1.51	0.414
Implant Fracture Socket	0	0.28	1
Implant Fracture Head	0	0.26	1
Dissociation of Liner	0	0.60	1
Other / reason not recorded	2	1.79	0.7
Total Revised	71	63.90	0.38

* 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



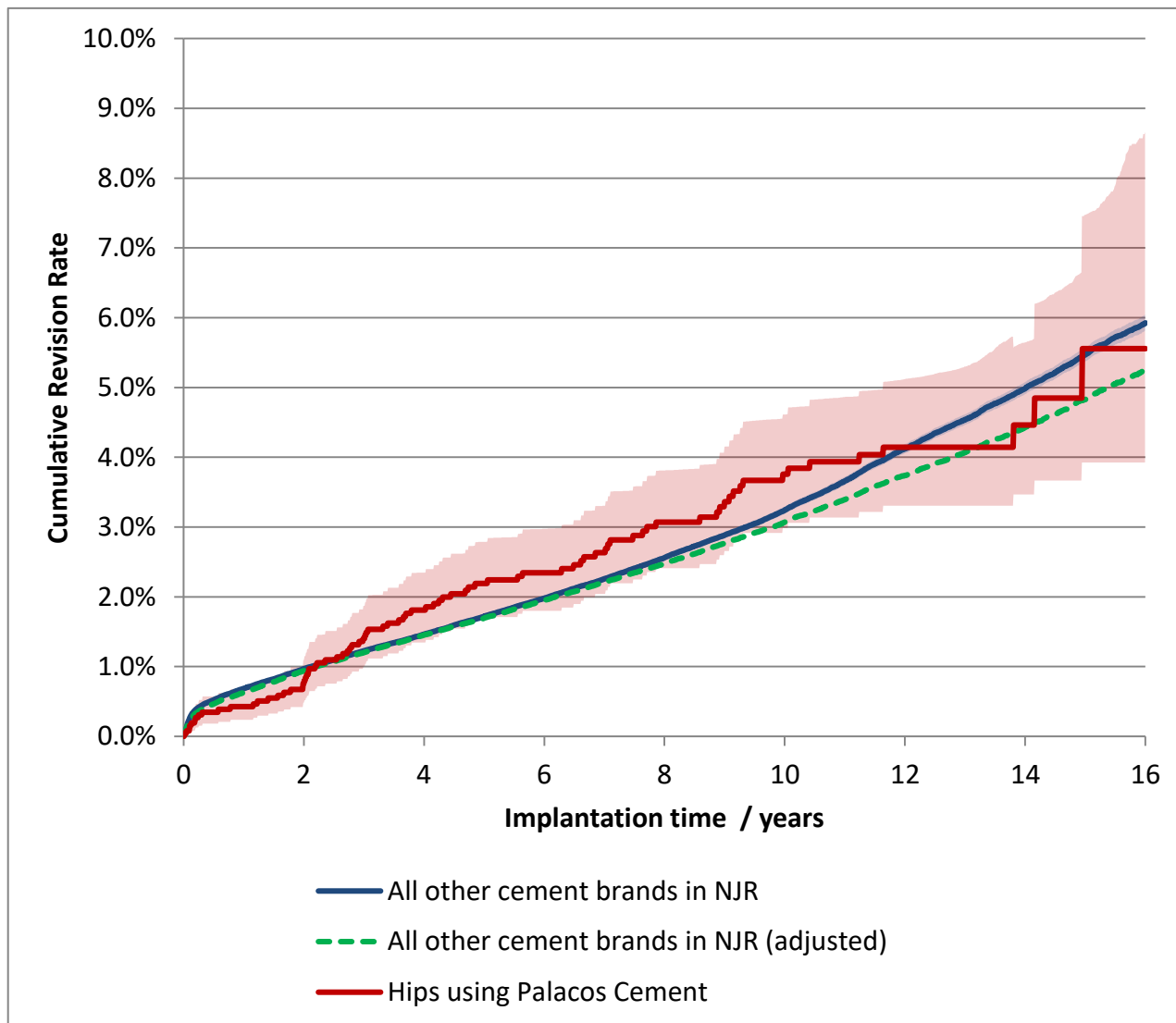
Components Revised	Number of procedures	Hips using Palacos Cement	All other cement brands in NJR
Femoral only	17	24%	24%
Acetabular only	23	32%	22%
Both femoral and acetabular	29	41%	43%
Neither femoral nor acetabular revision recorded *	2	3%	11%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



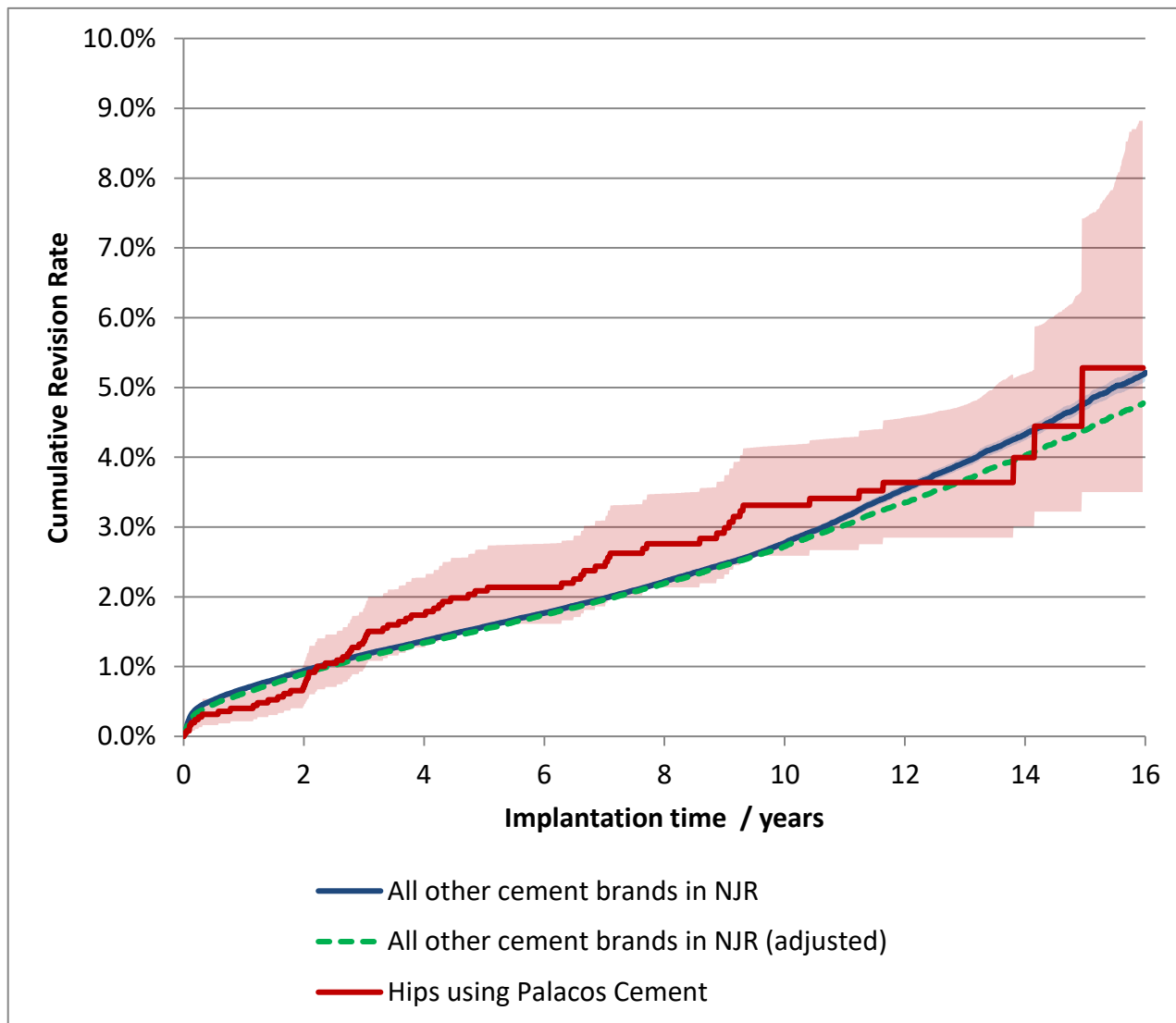
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	1.02 (0.83 - 1.27)	0.824
All bearings. Adjusted for age, gender, year cohort and indications.	1.11 (0.89 - 1.38)	0.357

Revision and Survivorship

Cumulative Revision Rate

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



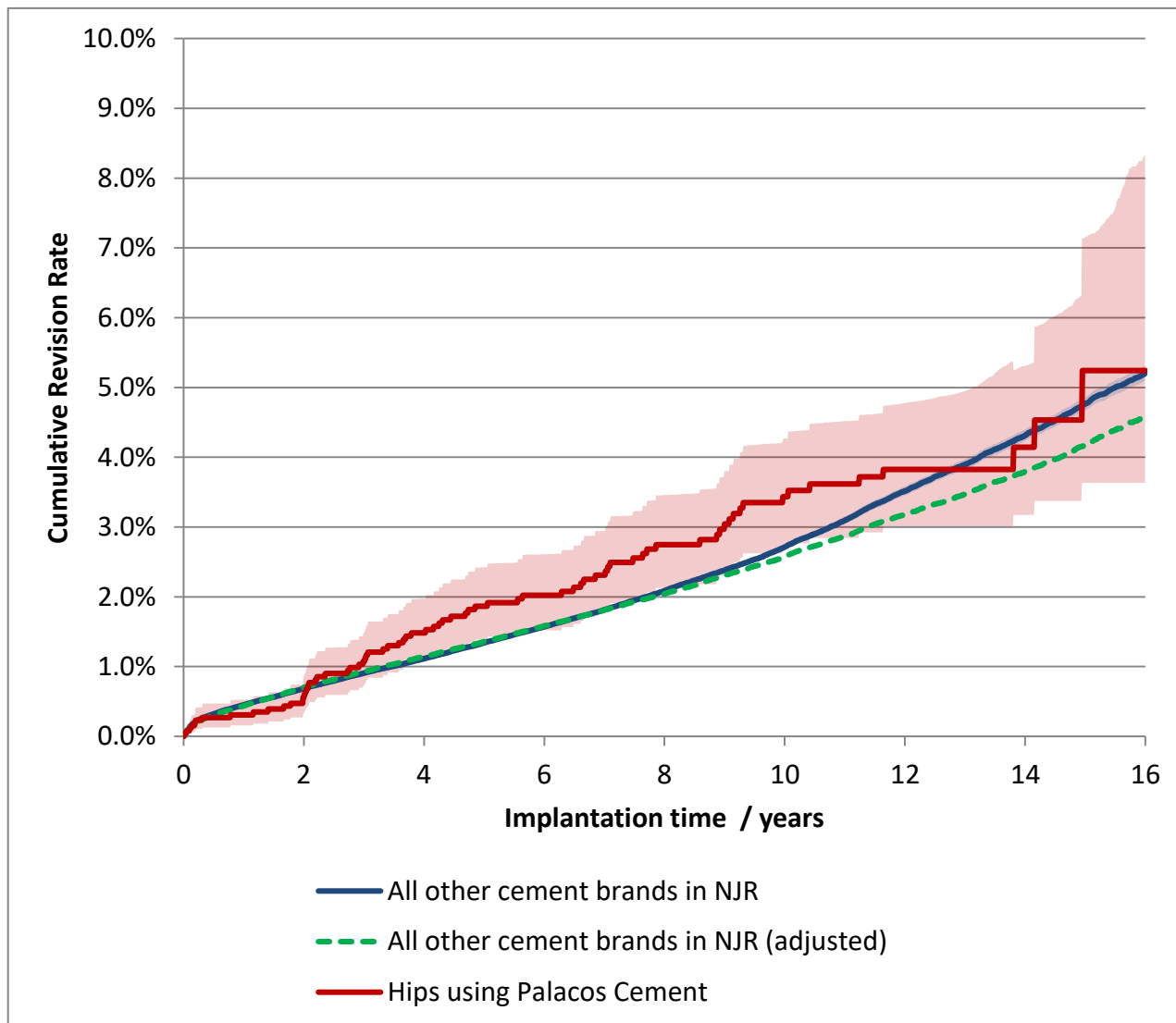
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	1.06 (0.84 - 1.34)	0.604
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.11 (0.88 - 1.41)	0.373

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Cemented Component Revision. All Bearing types



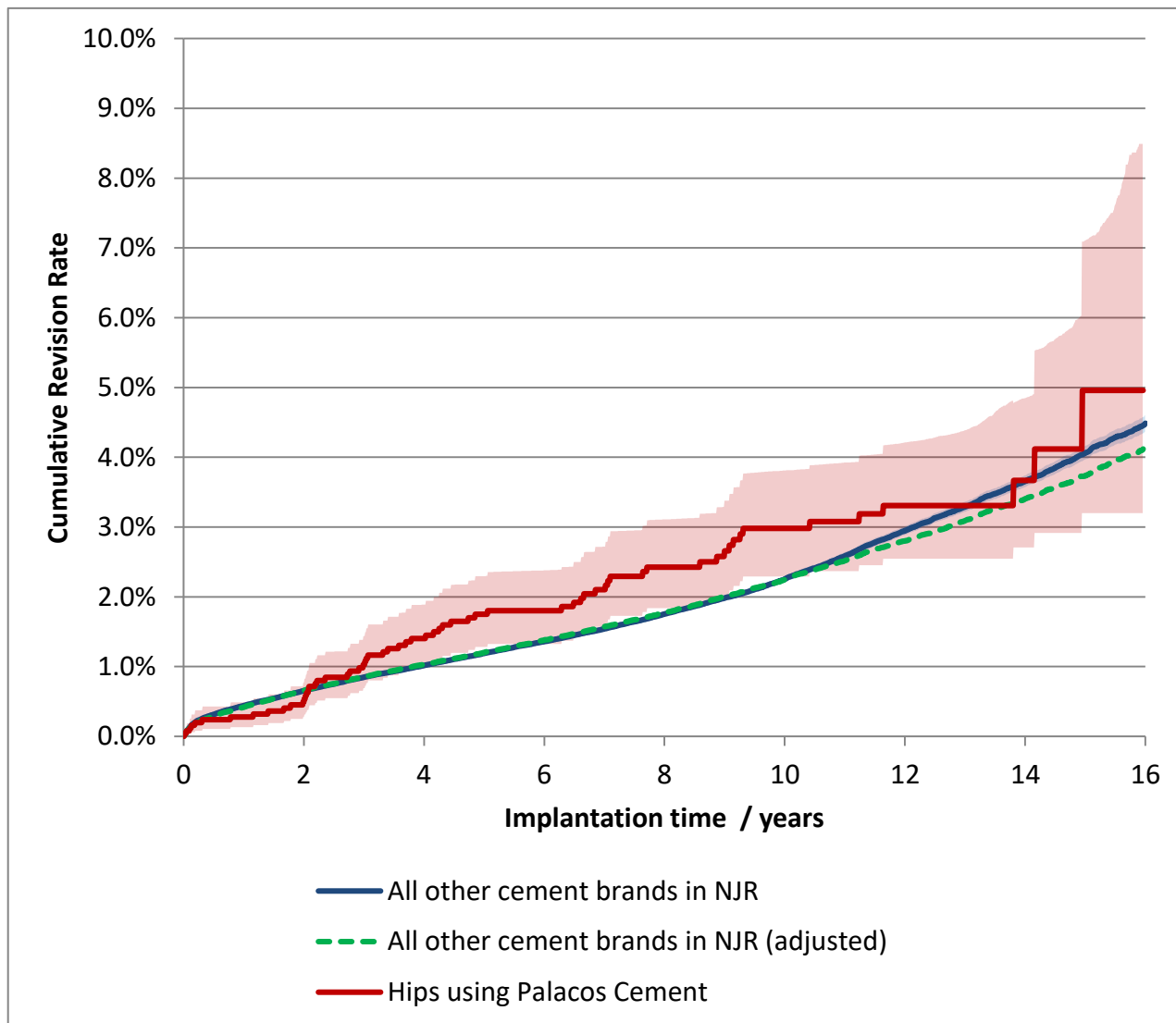
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	1.11 (0.88 - 1.39)	0.376
All bearings. Adjusted for age, gender, year cohort and indications.	1.20 (0.95 - 1.50)	0.126

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.	1.16 (0.91 - 1.49)	0.227
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.20 (0.94 - 1.54)	0.148

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	2,619	-	-	-	2,541	-	-	-
1	2,472	0.4% (0.2% - 0.7%)	0.7% (0.7% - 0.7%)	0.8% (0.8% - 0.8%)	2,395	0.4% (0.2% - 0.6%)	0.7% (0.7% - 0.7%)	0.8% (0.7% - 0.8%)
2	2,351	0.8% (0.5% - 1.1%)	1.0% (0.9% - 1.0%)	1.1% (1.1% - 1.1%)	2,275	0.7% (0.4% - 1.0%)	0.9% (0.9% - 1.0%)	1.1% (1.0% - 1.1%)
3	2,235	1.4% (1.0% - 1.9%)	1.2% (1.2% - 1.2%)	1.4% (1.4% - 1.4%)	2,159	1.4% (1.0% - 1.8%)	1.2% (1.1% - 1.2%)	1.3% (1.3% - 1.3%)
4	2,104	1.8% (1.3% - 2.3%)	1.5% (1.4% - 1.5%)	1.7% (1.7% - 1.7%)	2,030	1.7% (1.3% - 2.3%)	1.4% (1.3% - 1.4%)	1.5% (1.5% - 1.5%)
5	1,961	2.2% (1.7% - 2.8%)	1.7% (1.7% - 1.8%)	2.0% (2.0% - 2.0%)	1,891	2.1% (1.6% - 2.7%)	1.6% (1.5% - 1.6%)	1.7% (1.7% - 1.7%)
6	1,789	2.3% (1.8% - 3.0%)	2.0% (1.9% - 2.0%)	2.3% (2.3% - 2.3%)	1,721	2.1% (1.6% - 2.8%)	1.8% (1.7% - 1.8%)	1.9% (1.9% - 2.0%)
7	1,628	2.6% (2.0% - 3.3%)	2.3% (2.2% - 2.3%)	2.6% (2.6% - 2.7%)	1,560	2.4% (1.9% - 3.1%)	2.0% (1.9% - 2.0%)	2.1% (2.1% - 2.2%)
8	1,463	3.1% (2.4% - 3.8%)	2.6% (2.5% - 2.6%)	3.0% (3.0% - 3.0%)	1,399	2.8% (2.1% - 3.5%)	2.2% (2.2% - 2.3%)	2.4% (2.4% - 2.4%)
9	1,293	3.4% (2.7% - 4.2%)	2.9% (2.8% - 2.9%)	3.4% (3.3% - 3.4%)	1,231	3.0% (2.3% - 3.7%)	2.5% (2.4% - 2.5%)	2.6% (2.6% - 2.7%)
10	1,112	3.8% (3.0% - 4.6%)	3.2% (3.2% - 3.3%)	3.8% (3.7% - 3.8%)	1,052	3.3% (2.6% - 4.2%)	2.8% (2.7% - 2.8%)	2.9% (2.9% - 3.0%)
11	961	3.9% (3.1% - 4.9%)	3.7% (3.6% - 3.7%)	4.2% (4.1% - 4.2%)	902	3.4% (2.7% - 4.3%)	3.1% (3.1% - 3.2%)	3.3% (3.2% - 3.3%)
12	807	4.1% (3.3% - 5.1%)	4.1% (4.1% - 4.2%)	4.7% (4.6% - 4.7%)	748	3.6% (2.8% - 4.6%)	3.5% (3.5% - 3.6%)	3.6% (3.6% - 3.7%)
13	574	4.1% (3.3% - 5.3%)	4.5% (4.5% - 4.6%)	5.1% (5.1% - 5.2%)	521	3.6% (2.8% - 4.8%)	3.9% (3.9% - 4.0%)	4.0% (4.0% - 4.1%)
14	267	4.5% (3.5% - 5.6%)	5.0% (4.9% - 5.1%)	5.6% (5.5% - 5.7%)	235	4.0% (3.0% - 5.2%)	4.3% (4.2% - 4.4%)	4.4% (4.4% - 4.5%)
15	132	5.6% (3.9% - 7.5%)	5.5% (5.4% - 5.6%)	6.1% (6.0% - 6.2%)	112	5.3% (3.5% - 7.4%)	4.8% (4.7% - 4.9%)	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 Cement	All other cement brands in NJR	All THR	At Risk	Hips using Palacos Cement	All other cement brands in NJR	All THR
0	2,619	-	-	-	2,541	-	-	-
1	2,472	0.3% (0.2% - 0.5%)	0.5% (0.4% - 0.5%)	(-)	2,395	0.3% (0.1% - 0.5%)	0.4% (0.4% - 0.5%)	(-)
2	2,351	0.6% (0.3% - 0.9%)	0.7% (0.7% - 0.7%)	(-)	2,275	0.5% (0.3% - 0.8%)	0.7% (0.6% - 0.7%)	(-)
3	2,235	1.1% (0.7% - 1.5%)	0.9% (0.9% - 0.9%)	(-)	2,159	1.0% (0.7% - 1.4%)	0.8% (0.8% - 0.9%)	(-)
4	2,104	1.5% (1.1% - 2.0%)	1.1% (1.1% - 1.1%)	(-)	2,030	1.4% (1.0% - 1.9%)	1.0% (1.0% - 1.0%)	(-)
5	1,961	1.9% (1.4% - 2.4%)	1.3% (1.3% - 1.4%)	(-)	1,891	1.7% (1.3% - 2.3%)	1.2% (1.2% - 1.2%)	(-)
6	1,789	2.0% (1.5% - 2.6%)	1.6% (1.5% - 1.6%)	(-)	1,721	1.8% (1.3% - 2.4%)	1.4% (1.3% - 1.4%)	(-)
7	1,628	2.3% (1.8% - 2.9%)	1.8% (1.8% - 1.8%)	(-)	1,560	2.1% (1.6% - 2.7%)	1.5% (1.5% - 1.6%)	(-)
8	1,463	2.7% (2.1% - 3.5%)	2.1% (2.1% - 2.1%)	(-)	1,399	2.4% (1.8% - 3.1%)	1.8% (1.7% - 1.8%)	(-)
9	1,293	3.0% (2.4% - 3.8%)	2.4% (2.3% - 2.4%)	(-)	1,231	2.7% (2.0% - 3.4%)	2.0% (1.9% - 2.0%)	(-)
10	1,112	3.4% (2.7% - 4.3%)	2.7% (2.7% - 2.8%)	(-)	1,052	3.0% (2.3% - 3.8%)	2.3% (2.2% - 2.3%)	(-)
11	961	3.6% (2.8% - 4.5%)	3.1% (3.0% - 3.2%)	(-)	902	3.1% (2.4% - 3.9%)	2.6% (2.5% - 2.6%)	(-)
12	807	3.8% (3.0% - 4.8%)	3.5% (3.5% - 3.6%)	(-)	748	3.3% (2.5% - 4.2%)	3.0% (2.9% - 3.0%)	(-)
13	574	3.8% (3.0% - 5.0%)	3.9% (3.8% - 4.0%)	(-)	521	3.3% (2.5% - 4.4%)	3.3% (3.2% - 3.4%)	(-)
14	267	4.1% (3.2% - 5.3%)	4.3% (4.2% - 4.4%)	(-)	235	3.7% (2.7% - 4.8%)	3.7% (3.6% - 3.7%)	(-)
15	132	5.2% (3.6% - 7.2%)	4.8% (4.7% - 4.9%)	(-)	112	5.0% (3.2% - 7.1%)	4.1% (4.0% - 4.2%)	(-)

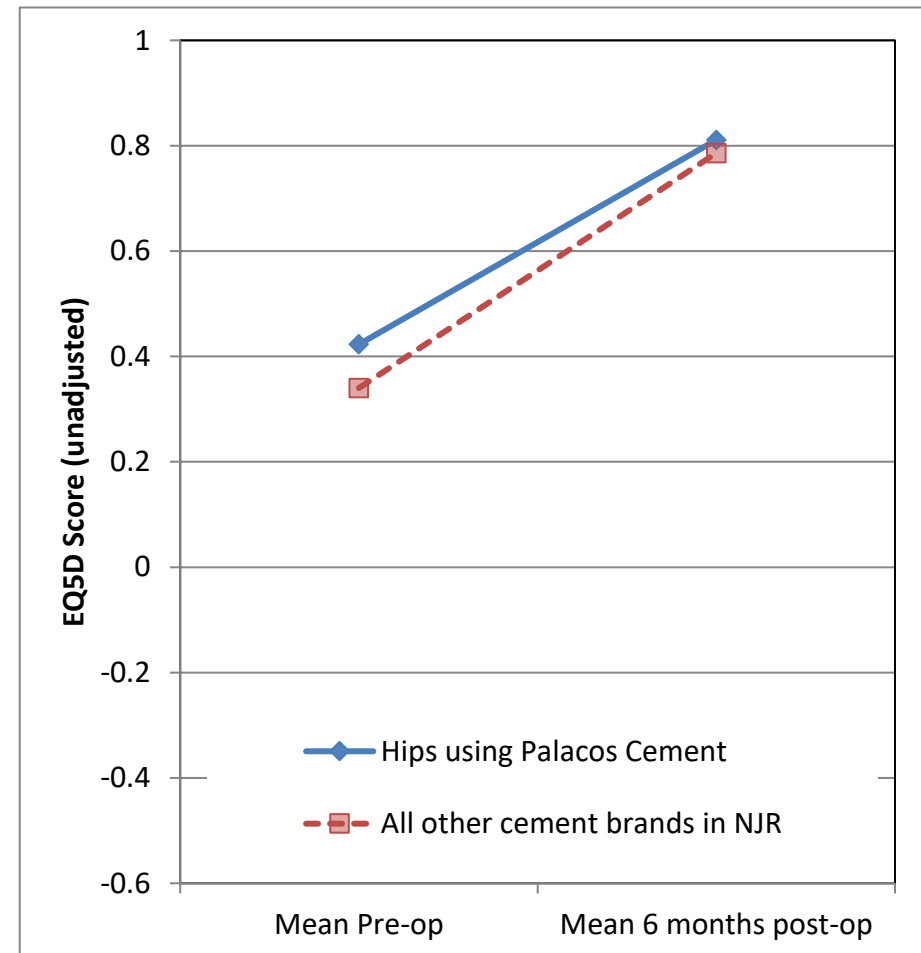
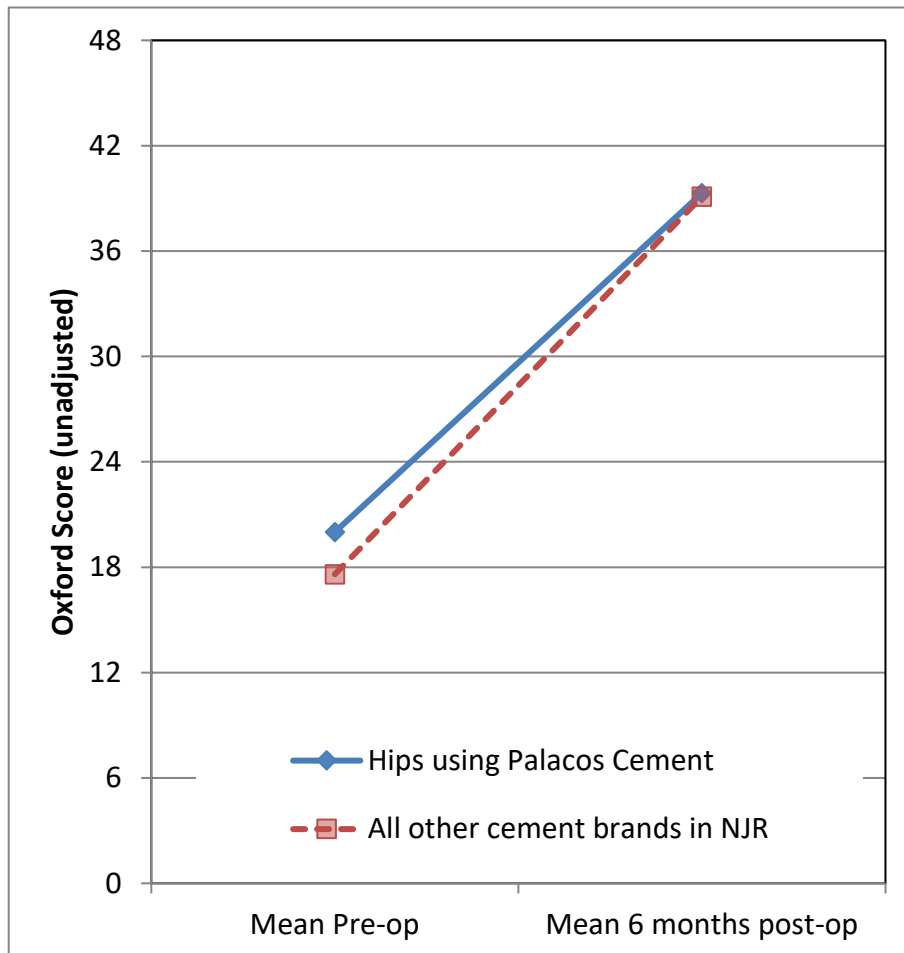
Cumulative revision rate with 95% confidence intervals

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	206,210	350,456
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	189,450	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 - 0.788)	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)	0.73		
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	181,846	310,932
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)	0.03		
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.

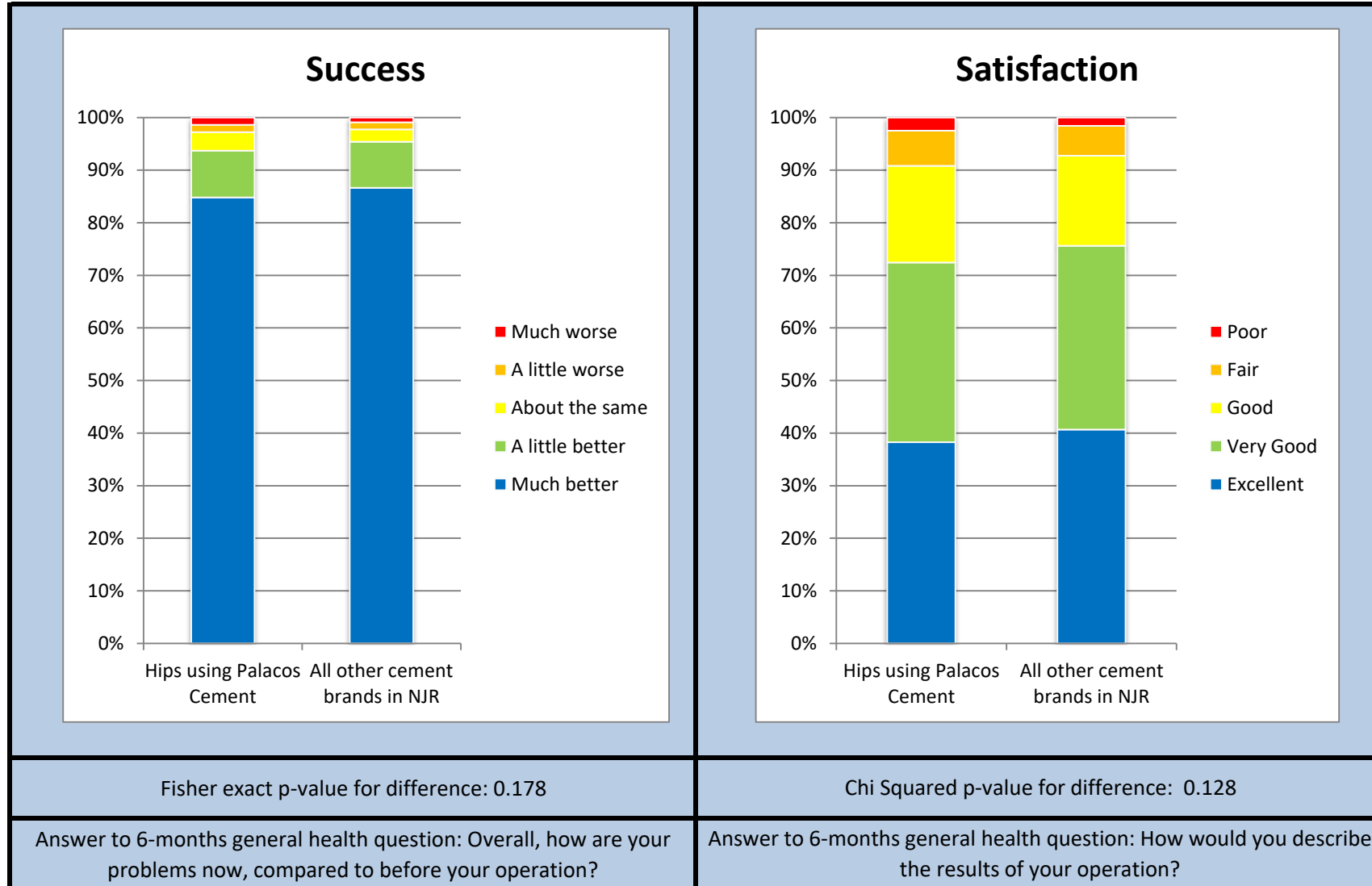
Figures in parentheses represent the 95% confidence interval for the mean

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	181413
A little better	64	18342
About the same	25	4986
A little worse	10	2819
Much worse	10	1851

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	85070
Very Good	246	73027
Good	132	35829
Fair	48	11927
Poor	18	3243

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		
66017777	PALACOS R 2x40 g	2230
66017778	PALACOS R 1x40 g	25
66017788	PALACOS LV 1x40 g	61
66031982	PALACOS MV 1x40 g	300
66031984	PALACOS MV plain 2x40g	1
Multiple Found	Multiple Found	2