

Implant Summary Report for:

Heraeus Medical

Hips using Palacos 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 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

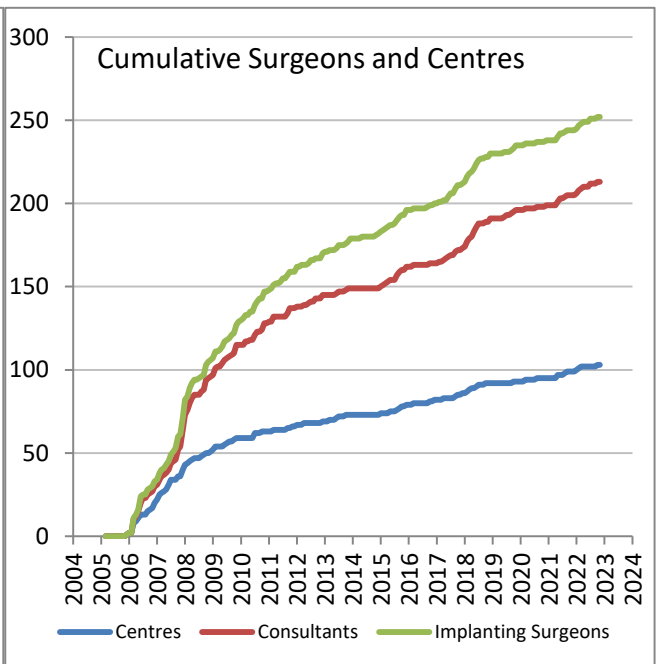
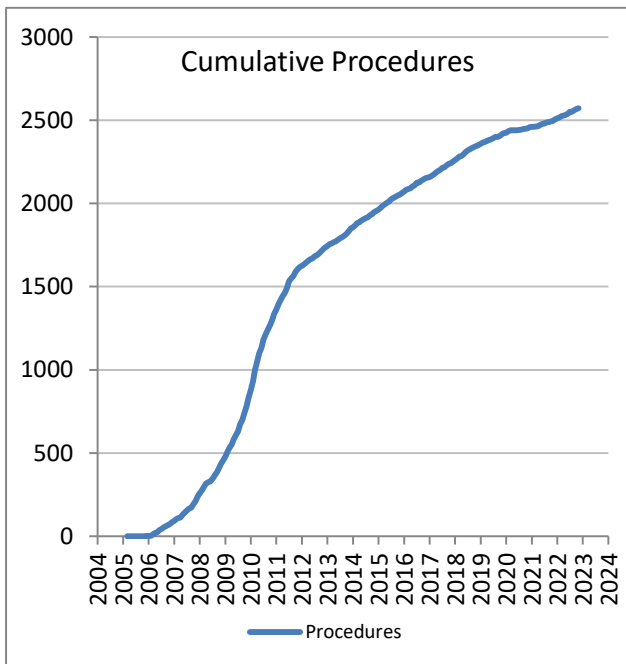
Date of first recorded usage in the NJR: **15 November 2005**

Date of last recorded usage in this dataset **17 October 2022**

Maximum implantation time: 17.0 years

Mean implantation time: 8.4 years

Totals Recorded in NJR	Cumulative Total
Procedures	2,572
Patients	2,439
Centres	103
Consultants	213
Implanting Surgeons	252



Current Outcome	Year of implantation													Total	%
	Pre-2011	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022		
Death	657	100	36	39	23	28	14	15	8	4	3	0	0	927	36.0%
Revised	37	13	4	4	4	3	3	3	4	1	1	1	0	78	3.0%
Unrevised	668	151	78	70	79	79	69	83	87	60	33	49	61	1567	60.9%
Total	1362	264	118	113	106	110	86	101	99	65	37	50	61	2572	100%

Patient / Procedure Details

Patient Details

	Hips using Palacos Cement	All other cement brands in NJR	All NJR hip replacement
Total Procedures	2,572	840,903	1,453,930
Total Patients	2,439	730,899	1,213,439
Demographics			
Mean age	73.8	71.1	68.7
< 50	1.6%	4.1%	6.2%
50 – 59	5.7%	10.4%	14.5%
60 – 69	22.0%	25.6%	29.4%
70 – 79	45.5%	39.6%	34.5%
≥ 80	25.3%	20.3%	15.4%
Median BMI	27	28	28
% BMI information available	55.3%	66.4%	64.6%
Underweight (BMI < 18.5)	1.3%	1.0%	0.9%
Normal (18.5 ≤ BMI < 25)	25.2%	22.0%	20.9%
Overweight (25 ≤ BMI < 30)	41.5%	39.6%	39.4%
Obese I (30 ≤ BMI < 35)	21.1%	25.1%	25.8%
Obese II (35 ≤ BMI < 40)	8.0%	9.2%	9.9%
Obese III (BMI ≥ 40)	3.0%	3.0%	3.3%
% Male	33.4%	36.9%	40.2%
ASA Grades			
P1 - Fit and healthy	12.6%	12.3%	14.9%
P2 - Mild disease not incapacitating	68.0%	67.2%	67.8%
P3 - Incapacitating systemic disease	18.7%	19.7%	16.7%
P4 / P5	0.7%	0.7%	0.6%
Indications			
Osteoarthritis	93.39%	89.78%	91.15%
Rheumatoid Arthritis	0.97%	1.41%	1.30%
Avascular Necrosis	3.03%	2.56%	2.59%
Fractured Neck of Femur	3.42%	5.27%	3.85%
CDH/DDH	2.99%	1.18%	1.58%
Other	1.48%	2.28%	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 [†]	Expected Revisions [*]	p value
Unexplained Pain	7	7.02	1
Dislocation / Subluxation	22	15.32	0.094
Adverse Soft Tissue Reaction	4	5.32	0.826
Infection	10	11.49	0.768
Aseptic Loosening - Stem	11	7.58	0.2
Aseptic Loosening - Socket	8	13.51	0.17
Periprosthetic Fracture Stem	14	13.75	0.892
Periprosthetic Fracture Socket	0	1.22	0.639
Malalignment Stem	6	1.51	0.005
Malalignment Socket	1	3.15	0.387
Wear Of Acetabular Component	4	3.23	0.571
Lysis Stem	4	2.25	0.295
Lysis Socket	4	3.17	0.566
Implant Fracture Stem	1	1.52	1
Implant Fracture Socket	0	0.30	1
Implant Fracture Head	0	0.31	1
Dissociation of Liner	0	0.61	1
Other / reason not recorded	4	2.80	0.369
Total Revised	78	71.74	0.442

[†] 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	23%	21%
Acetabular only	22	28%	19%
Both femoral and acetabular	36	46%	52%
Neither femoral nor acetabular revision recorded [*]	2	3%	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	4.11	1
Dislocation / Subluxation	22	15.11	0.091
Adverse Soft Tissue Reaction	1	0.88	0.585
Infection	10	11.17	0.881
Aseptic Loosening - Stem	8	6.53	0.551
Aseptic Loosening - Socket	8	12.69	0.257
Periprosthetic Fracture Stem	13	12.41	0.776
Periprosthetic Fracture Socket	0	1.13	0.635
Malalignment Stem	6	1.31	0.002
Malalignment Socket	1	2.71	0.534
Wear Of Acetabular Component	4	3.15	0.563
Lysis Stem	3	1.75	0.256
Lysis Socket	4	2.67	0.347
Implant Fracture Stem	0	1.43	0.412
Implant Fracture Socket	0	0.28	1
Implant Fracture Head	0	0.24	1
Dissociation of Liner	0	0.56	1
Other / reason not recorded	2	1.74	0.695
Total Revised	67	61.10	0.441

* 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



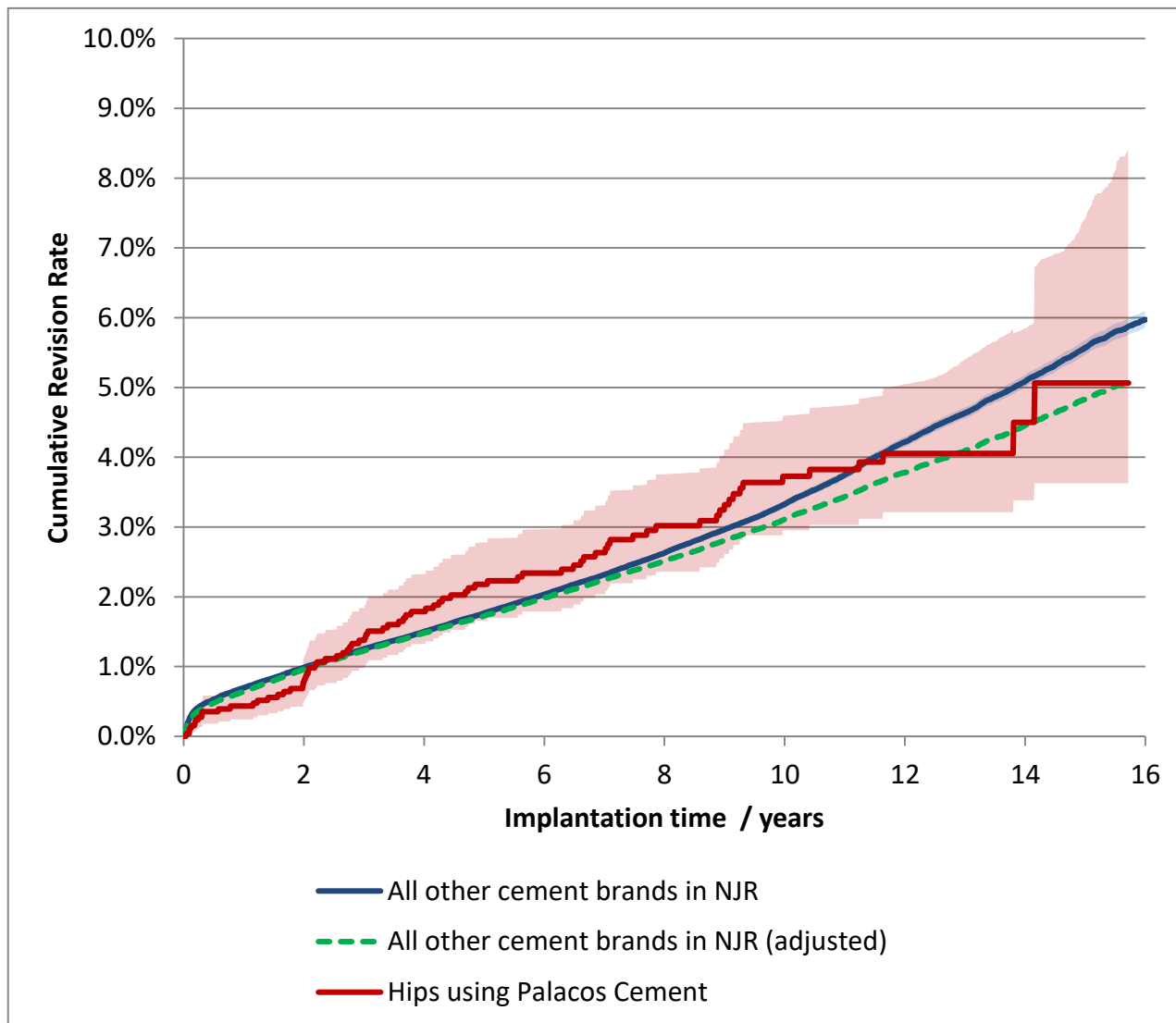
Components Revised	Number of procedures	Hips using Palacos Cement	All other cement brands in NJR
Femoral only	16	24%	24%
Acetabular only	22	33%	23%
Both femoral and acetabular	27	40%	43%
Neither femoral nor acetabular revision recorded *	2	3%	11%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



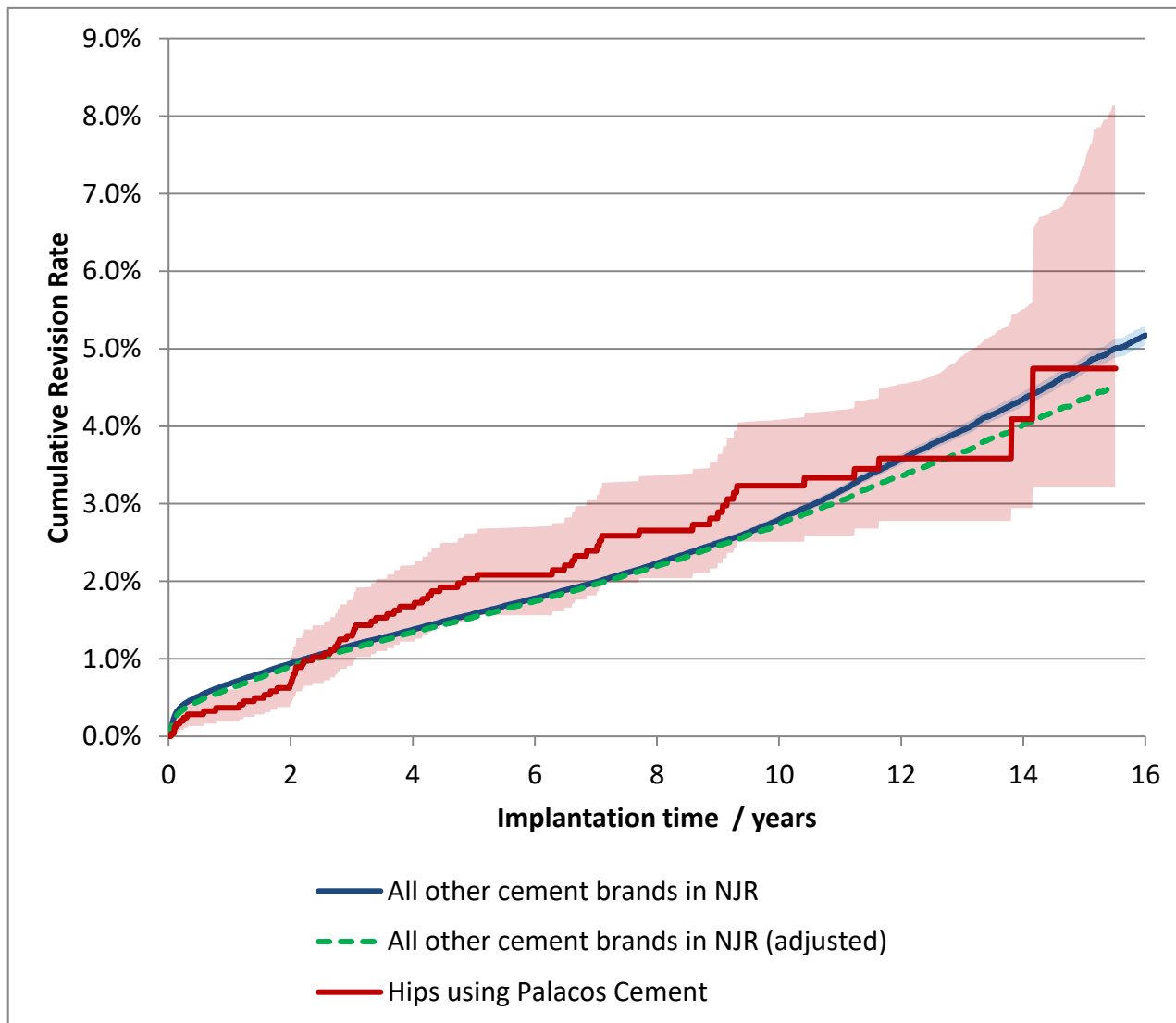
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	1.00 (0.80 - 1.25)	0.982
All bearings. Adjusted for age, gender, year cohort and indications.	1.09 (0.87 - 1.36)	0.458

Revision and Survivorship

Cumulative Revision Rate

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



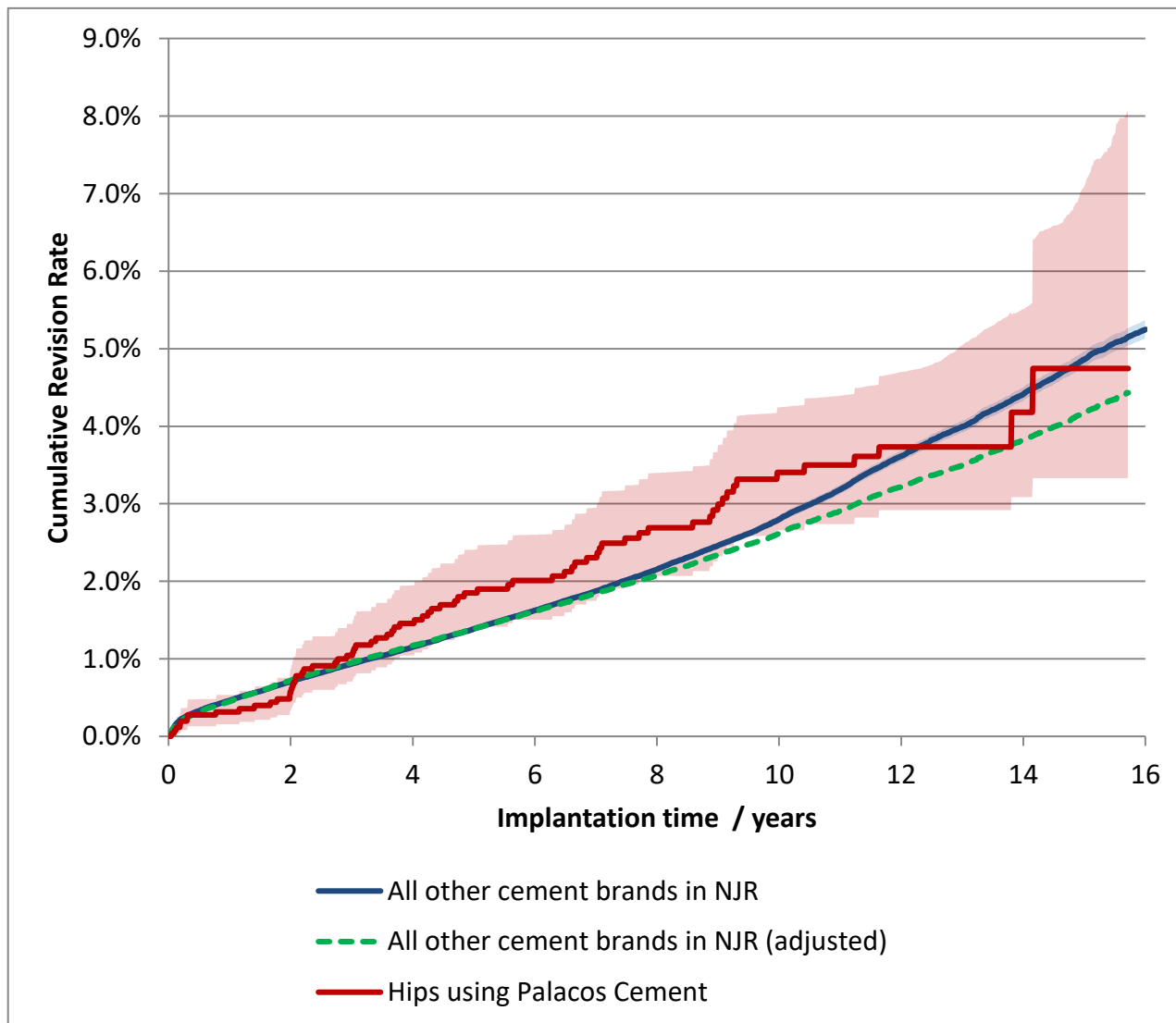
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	1.05 (0.82 - 1.33)	0.715
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.10 (0.86 - 1.40)	0.449

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Cemented Component Revision. All Bearing types



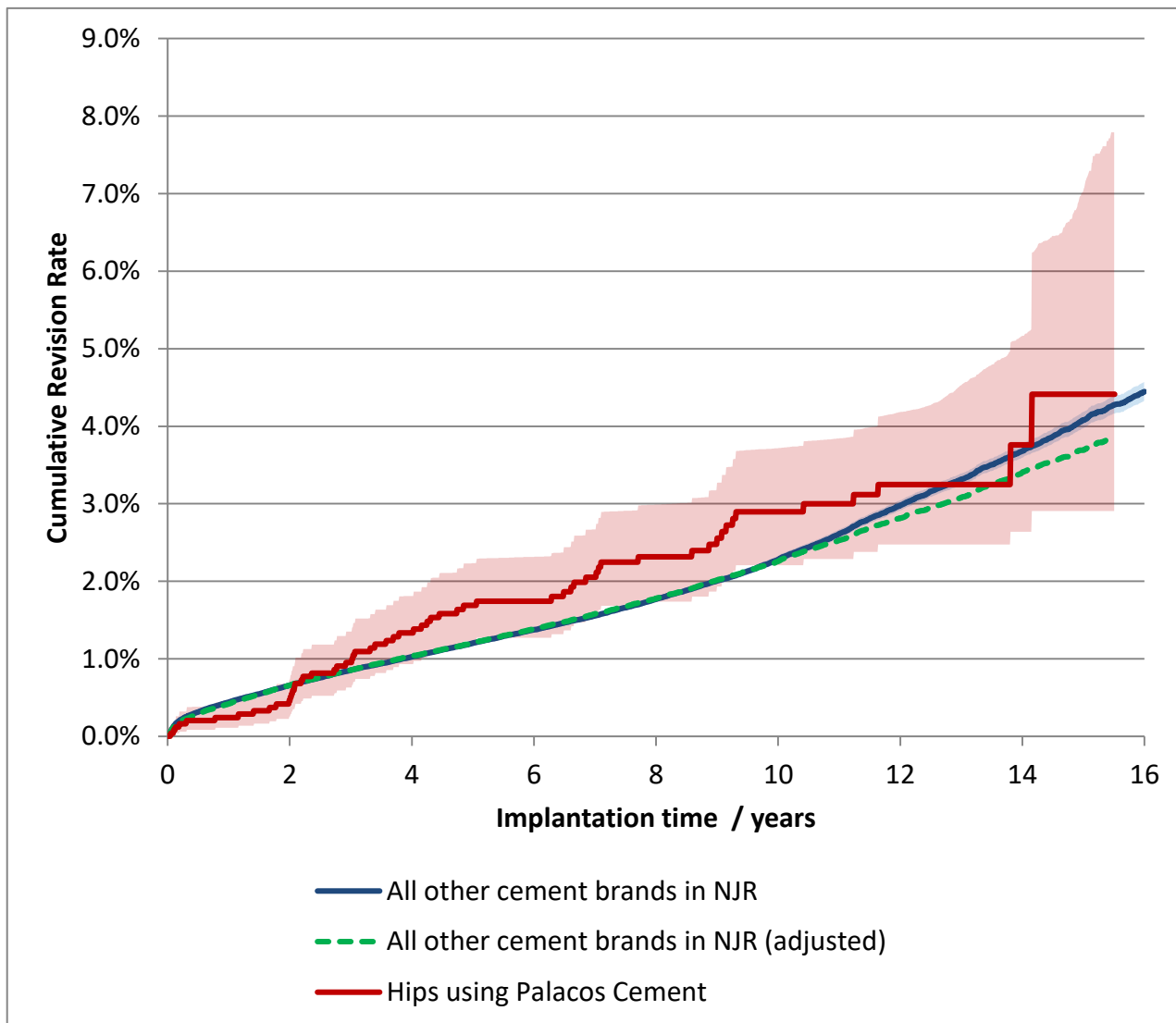
Cox Proportional Hazards model for revision risk ratio of Hips using Palacos Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	1.07 (0.85 - 1.36)	0.564
All bearings. Adjusted for age, gender, year cohort and indications.	1.17 (0.92 - 1.48)	0.195

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.	1.14 (0.88 - 1.47)	0.326
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.18 (0.91 - 1.52)	0.211

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	2,572	-	-	-	2,494	-	-	-
1	2,428	0.4% (0.2% - 0.7%)	0.7% (0.7% - 0.7%)	0.8% (0.8% - 0.8%)	2,352	0.4% (0.2% - 0.6%)	0.7% (0.7% - 0.7%)	0.8% (0.7% - 0.8%)
2	2,327	0.8% (0.5% - 1.1%)	1.0% (1.0% - 1.0%)	1.1% (1.1% - 1.1%)	2,252	0.7% (0.4% - 1.0%)	0.9% (0.9% - 1.0%)	1.1% (1.0% - 1.1%)
3	2,215	1.4% (1.0% - 1.8%)	1.3% (1.2% - 1.3%)	1.4% (1.4% - 1.4%)	2,140	1.3% (0.9% - 1.8%)	1.2% (1.1% - 1.2%)	1.3% (1.3% - 1.3%)
4	2,066	1.8% (1.3% - 2.3%)	1.5% (1.5% - 1.5%)	1.7% (1.7% - 1.7%)	1,993	1.7% (1.2% - 2.2%)	1.4% (1.3% - 1.4%)	1.5% (1.5% - 1.5%)
5	1,901	2.2% (1.7% - 2.8%)	1.8% (1.7% - 1.8%)	2.0% (2.0% - 2.0%)	1,832	2.0% (1.5% - 2.6%)	1.6% (1.6% - 1.6%)	1.7% (1.7% - 1.8%)
6	1,748	2.3% (1.8% - 3.0%)	2.0% (2.0% - 2.1%)	2.4% (2.3% - 2.4%)	1,681	2.1% (1.6% - 2.7%)	1.8% (1.7% - 1.8%)	1.9% (1.9% - 2.0%)
7	1,581	2.6% (2.0% - 3.3%)	2.3% (2.3% - 2.4%)	2.7% (2.7% - 2.7%)	1,515	2.4% (1.8% - 3.0%)	2.0% (2.0% - 2.0%)	2.2% (2.1% - 2.2%)
8	1,424	3.0% (2.4% - 3.8%)	2.6% (2.6% - 2.7%)	3.1% (3.0% - 3.1%)	1,361	2.7% (2.0% - 3.4%)	2.2% (2.2% - 2.3%)	2.4% (2.4% - 2.4%)
9	1,248	3.3% (2.6% - 4.1%)	3.0% (2.9% - 3.0%)	3.5% (3.4% - 3.5%)	1,187	2.9% (2.2% - 3.6%)	2.5% (2.4% - 2.5%)	2.7% (2.6% - 2.7%)
10	1,081	3.7% (3.0% - 4.6%)	3.3% (3.3% - 3.4%)	3.9% (3.8% - 3.9%)	1,022	3.2% (2.5% - 4.1%)	2.8% (2.7% - 2.8%)	3.0% (2.9% - 3.0%)
11	923	3.8% (3.0% - 4.7%)	3.7% (3.7% - 3.8%)	4.3% (4.3% - 4.4%)	864	3.3% (2.6% - 4.2%)	3.2% (3.1% - 3.2%)	3.3% (3.3% - 3.3%)
12	704	4.1% (3.2% - 5.0%)	4.2% (4.2% - 4.3%)	4.8% (4.7% - 4.9%)	647	3.6% (2.8% - 4.5%)	3.6% (3.5% - 3.6%)	3.7% (3.6% - 3.7%)
13	382	4.1% (3.2% - 5.4%)	4.6% (4.6% - 4.7%)	5.3% (5.2% - 5.3%)	342	3.6% (2.8% - 4.9%)	3.9% (3.9% - 4.0%)	4.1% (4.0% - 4.1%)
14	190	4.5% (3.4% - 5.8%)	5.1% (5.0% - 5.2%)	5.8% (5.7% - 5.8%)	166	4.1% (2.9% - 5.5%)	4.3% (4.3% - 4.4%)	4.5% (4.4% - 4.5%)
15	84	5.1% (3.6% - 7.4%)	5.6% (5.5% - 5.7%)	6.3% (6.2% - 6.3%)	70	4.7% (3.2% - 7.4%)	4.8% (4.7% - 4.9%)	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 Cement	All other cement brands in NJR	All THR	At Risk	Hips using Palacos Cement	All other cement brands in NJR	All THR
0	2,572	-	-	-	2,494	-	-	-
1	2,428	0.3% (0.2% - 0.5%)	0.5% (0.4% - 0.5%)	(-)	2,352	0.2% (0.1% - 0.4%)	0.4% (0.4% - 0.5%)	(-)
2	2,327	0.6% (0.3% - 0.9%)	0.7% (0.7% - 0.7%)	(-)	2,252	0.5% (0.3% - 0.7%)	0.7% (0.6% - 0.7%)	(-)
3	2,215	1.0% (0.7% - 1.5%)	0.9% (0.9% - 1.0%)	(-)	2,140	1.0% (0.6% - 1.4%)	0.9% (0.8% - 0.9%)	(-)
4	2,066	1.5% (1.0% - 1.9%)	1.2% (1.1% - 1.2%)	(-)	1,993	1.3% (0.9% - 1.8%)	1.0% (1.0% - 1.1%)	(-)
5	1,901	1.8% (1.4% - 2.4%)	1.4% (1.4% - 1.4%)	(-)	1,832	1.7% (1.2% - 2.2%)	1.2% (1.2% - 1.2%)	(-)
6	1,748	2.0% (1.5% - 2.6%)	1.6% (1.6% - 1.7%)	(-)	1,681	1.7% (1.3% - 2.3%)	1.4% (1.3% - 1.4%)	(-)
7	1,581	2.3% (1.7% - 2.9%)	1.9% (1.8% - 1.9%)	(-)	1,515	2.1% (1.5% - 2.7%)	1.6% (1.5% - 1.6%)	(-)
8	1,424	2.7% (2.1% - 3.4%)	2.2% (2.1% - 2.2%)	(-)	1,361	2.3% (1.7% - 3.0%)	1.8% (1.7% - 1.8%)	(-)
9	1,248	3.0% (2.3% - 3.8%)	2.5% (2.4% - 2.5%)	(-)	1,187	2.6% (1.9% - 3.3%)	2.0% (2.0% - 2.0%)	(-)
10	1,081	3.4% (2.7% - 4.2%)	2.8% (2.7% - 2.9%)	(-)	1,022	2.9% (2.2% - 3.7%)	2.3% (2.2% - 2.3%)	(-)
11	923	3.5% (2.7% - 4.4%)	3.2% (3.1% - 3.2%)	(-)	864	3.0% (2.3% - 3.8%)	2.6% (2.6% - 2.7%)	(-)
12	704	3.7% (2.9% - 4.7%)	3.6% (3.5% - 3.7%)	(-)	647	3.2% (2.5% - 4.2%)	3.0% (2.9% - 3.0%)	(-)
13	382	3.7% (2.9% - 5.0%)	4.0% (3.9% - 4.1%)	(-)	342	3.2% (2.5% - 4.5%)	3.3% (3.2% - 3.4%)	(-)
14	190	4.2% (3.1% - 5.5%)	4.4% (4.3% - 4.5%)	(-)	166	3.8% (2.6% - 5.2%)	3.7% (3.6% - 3.8%)	(-)
15	84	4.7% (3.3% - 7.1%)	4.9% (4.8% - 5.0%)	(-)	70	4.4% (2.9% - 7.0%)	4.1% (4.0% - 4.2%)	(-)

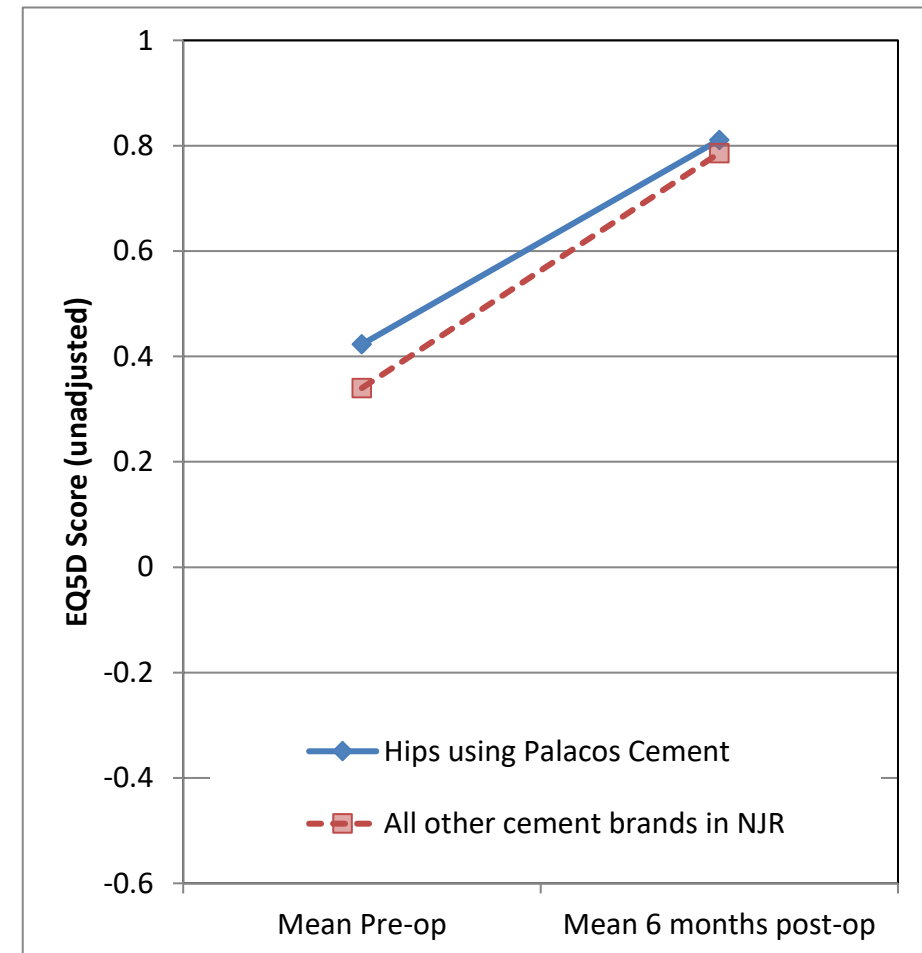
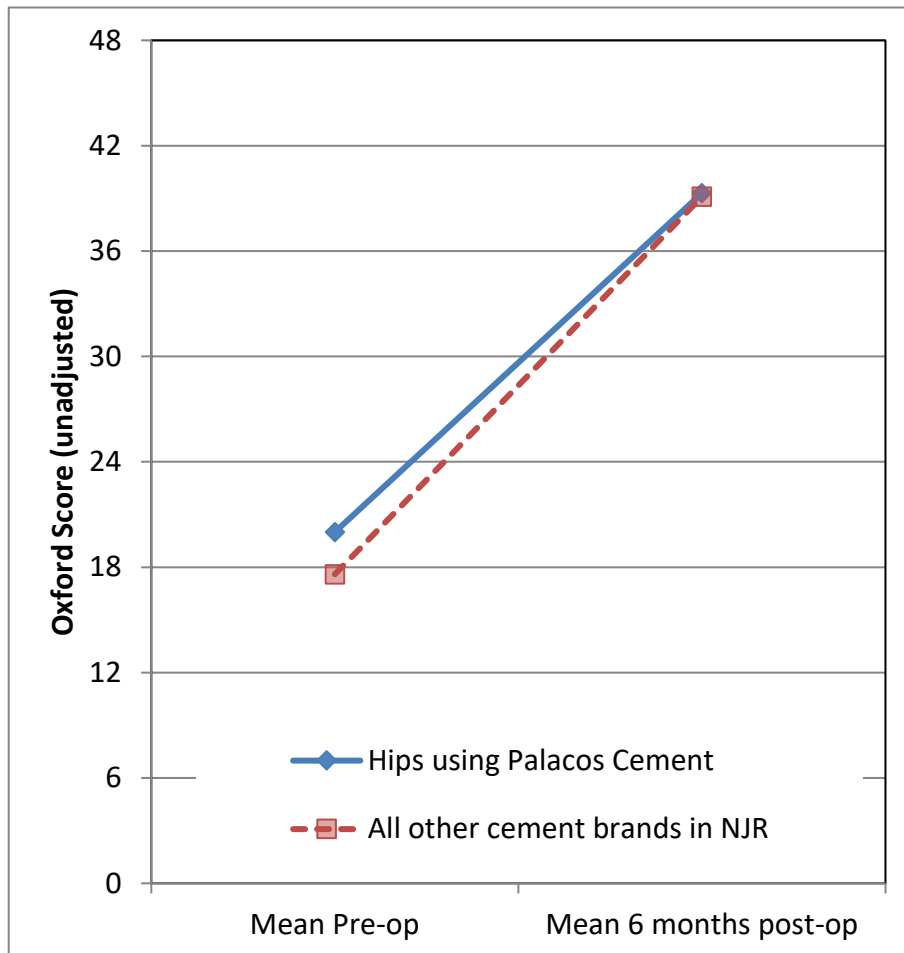
Cumulative revision rate with 95% confidence intervals

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	206,207	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	323,118
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	181,844	310,933
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.

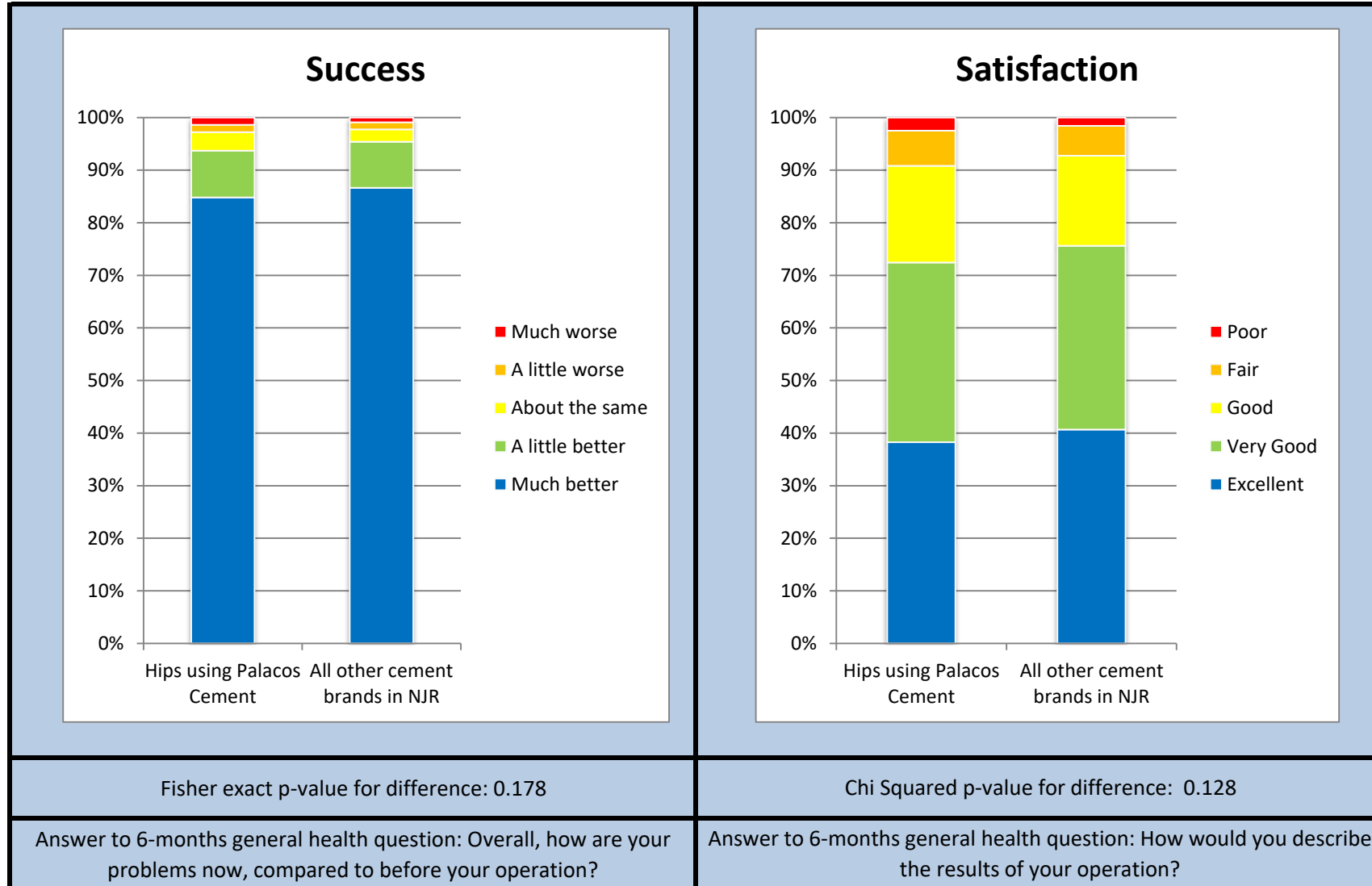
Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Hips using Palacos Cement

Responses are not case mix adjusted

Patient Reported Outcomes



Fisher exact p-value for difference: 0.178

Chi Squared p-value for difference: 0.128

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 Cement	All other cement brands in NJR
Much better	608	181412
A little better	64	18341
About the same	25	4986
A little worse	10	2818
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	85071
Very Good	246	73028
Good	132	35826
Fair	48	11925
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	2189
66017778	PALACOS R 1x40 g	20
66017788	PALACOS LV 1x40 g	61
66031982	PALACOS MV 1x40 g	300
66031984	PALACOS MV plain 2x40g	1
Multiple Found	Multiple Found	1