

Implant Summary Report for:

Heraeus Medical

Knees using Palacos Cement

Comprising PRIMARY knees implanted up to:
NJR Database extract:

01 November 2022
31 December 2022

Produced on:
Licensed for use until:

15 February 2023
15 February 2024

Contents

Recorded Usage in NJR	2
Patient and Procedure Details	3
Revision and Survivorship	4
Patient Reported Outcomes	7
APPENDICES – Component Lists	12

This report has been produced by the National Joint Registry (NJR). It summarises usage and outcomes associated with the Knees 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 components listed in the appendices.

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NJR Recorded Usage

Implant Usage

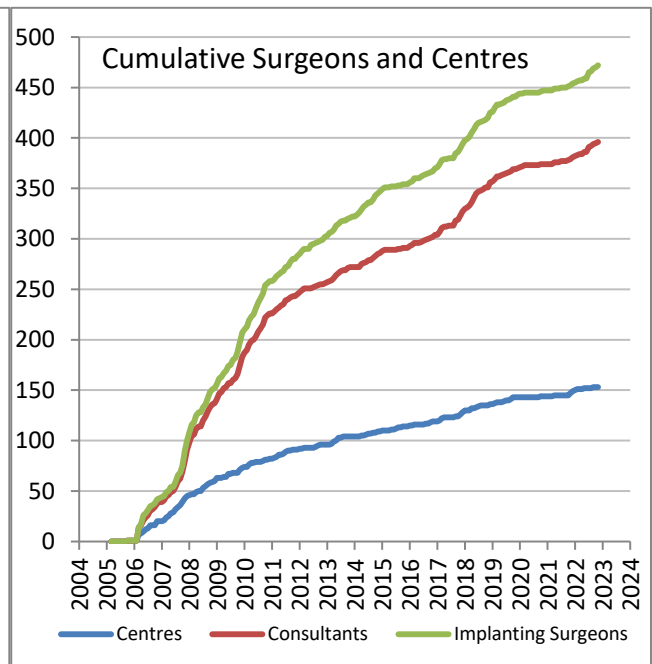
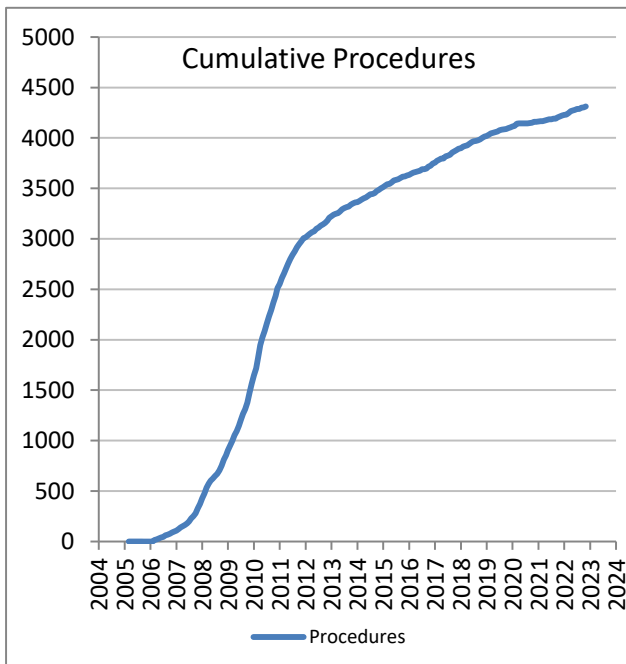
Date of first recorded usage in the NJR: **26 September 2005**

Date of last recorded usage in this dataset: **27 October 2022**

Maximum implantation time: 16.7 years

Mean implantation time: 9.1 years

Totals Recorded in NJR	Cumulative Total
Procedures	4,312
Patients	4,020
Centres	153
Consultants	396
Implanting Surgeons	472



Current Outcome	Year of implantation													Total	%
	Pre-2011	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022		
Death	972	138	48	38	39	20	17	15	8	5	2	2	0	1304	30.2%
Revised	156	24	14	6	6	8	8	8	7	2	1	0	1	241	5.6%
Unrevised	1424	301	146	96	106	94	96	120	106	84	49	62	83	2767	64.2%
Total	2552	463	208	140	151	122	121	143	121	91	52	64	84	4312	100%

Patient / Procedure Details

Patient Details

	Knees using Palacos Cement	All other cement brands in NJR
Total Procedures	4,312	1,339,411
Total Patients	4,020	1,080,193
Demographics		
Mean age	70.4	69.6
< 50	2.2%	2.5%
50 – 59	11.8%	13.7%
60 – 69	32.4%	32.9%
70 – 79	36.9%	37.1%
≥ 80	16.7%	13.9%
Median BMI	30	30
% BMI information available	50.6%	69.7%
Underweight (BMI < 18.5)	0.3%	0.2%
Normal (18.5 ≤ BMI < 25)	11.6%	10.4%
Overweight (25 ≤ BMI < 30)	34.6%	34.4%
Obese I (30 ≤ BMI < 35)	29.0%	32.3%
Obese II (35 ≤ BMI < 40)	16.9%	16.2%
Obese III (BMI ≥ 40)	7.7%	6.5%
% Male	42.0%	43.2%
ASA Grades		
P1 - Fit and healthy	11.2%	10.2%
P2 - Mild disease not incapacitating	70.3%	72.4%
P3 - Incapacitating systemic disease	18.0%	17.1%
P4 / P5	0.4%	0.3%
Indications		
Osteoarthritis	97.91%	97.43%
Rheumatoid Arthritis	1.18%	1.35%
Other Inflammatory Arthropathy	0.51%	0.67%
Previous Trauma	0.74%	0.66%
Avascular Necrosis	0.35%	0.39%
Other	0.32%	0.40%

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

Reasons for revision of primary procedures in which the implant was used.

Reason for Revision	Revised †	Expected Revisions *	p value
Infection	70	29.11	<0.001
Progressive Arthritis Remaining	18	27.86	0.07
Aseptic Loosening Femur	34	16.95	<0.001
Aseptic Loosening Tibia	43	30.09	0.022
Aseptic Loosening Patella	1	5.27	0.074
Unexplained Pain	27	24.13	0.539
Stiffness	11	9.24	0.508
Malalignment	23	11.00	0.001
Instability	34	22.58	0.02
Dislocation / Subluxation	5	5.32	1
Periprosthetic Fracture	16	6.84	0.003
Wear of Polyethylene Component	9	9.60	1
Lysis - Tibia	15	7.12	0.007
Lysis - Femur	7	4.87	0.354
Component Dissociation	3	2.10	0.472
Implant Fracture	0	0.97	1
Other / Not recorded	10	12.01	0.665
Total Revised	241	161.08	<0.001

† multiple reasons may be listed for one revision procedure

* Based on All NJR Knees 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 $p < 0.001$

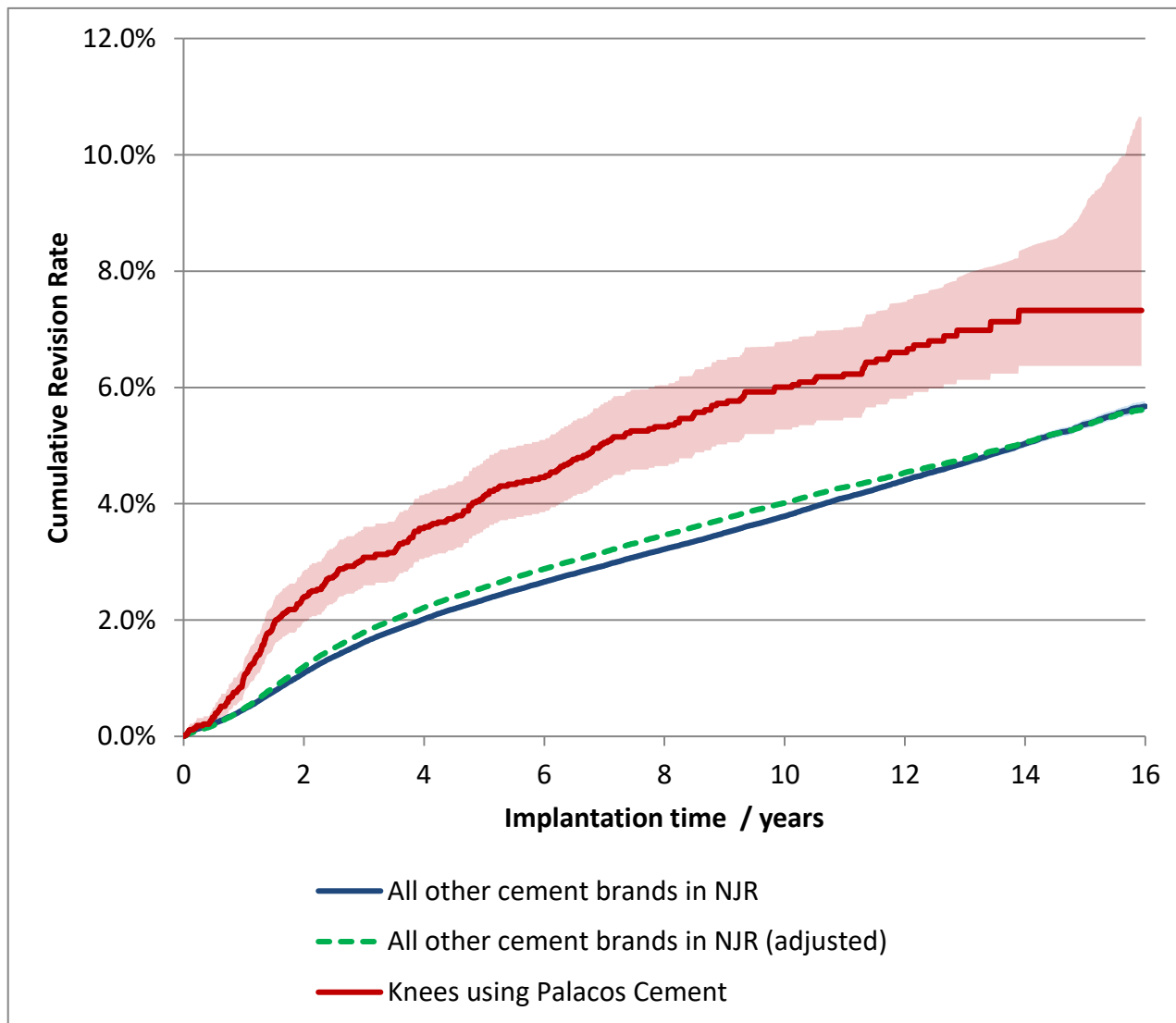


Components Revised	Number of procedures	Knees using Palacos Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	204	84.6%	74.2%
Isolated bearing exchange	20	8.3%	12.7%
Patella revision / resurfacing only	16	6.6%	12.2%
No component revision recorded	1	0.4%	0.9%

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision



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

Adjustment	Hazard Ratio (95% CI)	p-value
Unadjusted.	1.57 ‡ (1.38 - 1.78)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	1.50 (1.32 - 1.71)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	At Risk	Knees using Palacos Cement	All other cement brands in NJR
0	4312	-	-
1	4124	1.0% (0.7% - 1.3%)	0.5% (0.5% - 0.5%)
2	3956	2.4% (2.0% - 2.8%)	1.1% (1.1% - 1.1%)
3	3801	3.1% (2.6% - 3.6%)	1.6% (1.6% - 1.6%)
4	3602	3.6% (3.1% - 4.1%)	2.0% (2.0% - 2.0%)
5	3371	4.1% (3.6% - 4.7%)	2.4% (2.3% - 2.4%)
6	3122	4.5% (3.9% - 5.1%)	2.7% (2.6% - 2.7%)
7	2919	5.1% (4.4% - 5.7%)	2.9% (2.9% - 3.0%)
8	2688	5.3% (4.7% - 6.0%)	3.2% (3.2% - 3.3%)
9	2462	5.7% (5.0% - 6.5%)	3.5% (3.5% - 3.5%)
10	2215	6.0% (5.3% - 6.8%)	3.8% (3.7% - 3.8%)
11	1965	6.2% (5.5% - 7.0%)	4.1% (4.1% - 4.2%)
12	1499	6.6% (5.8% - 7.5%)	4.4% (4.4% - 4.5%)
13	839	7.0% (6.1% - 7.9%)	4.7% (4.6% - 4.8%)
14	433	7.3% (6.4% - 8.4%)	5.0% (5.0% - 5.1%)
15	153	7.3% (6.4% - 9.1%)	5.4% (5.3% - 5.4%)

Cumulative revision rate with 95% confidence intervals

Rate is only reported for times where more than 40 remain at risk

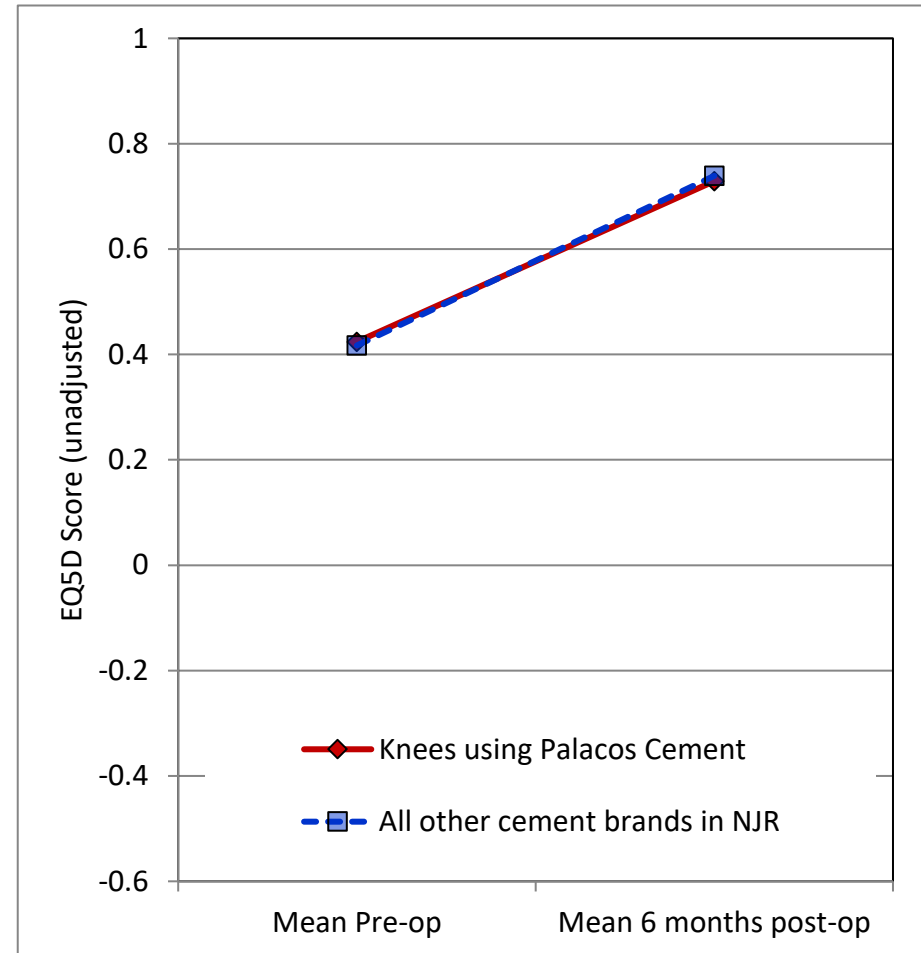
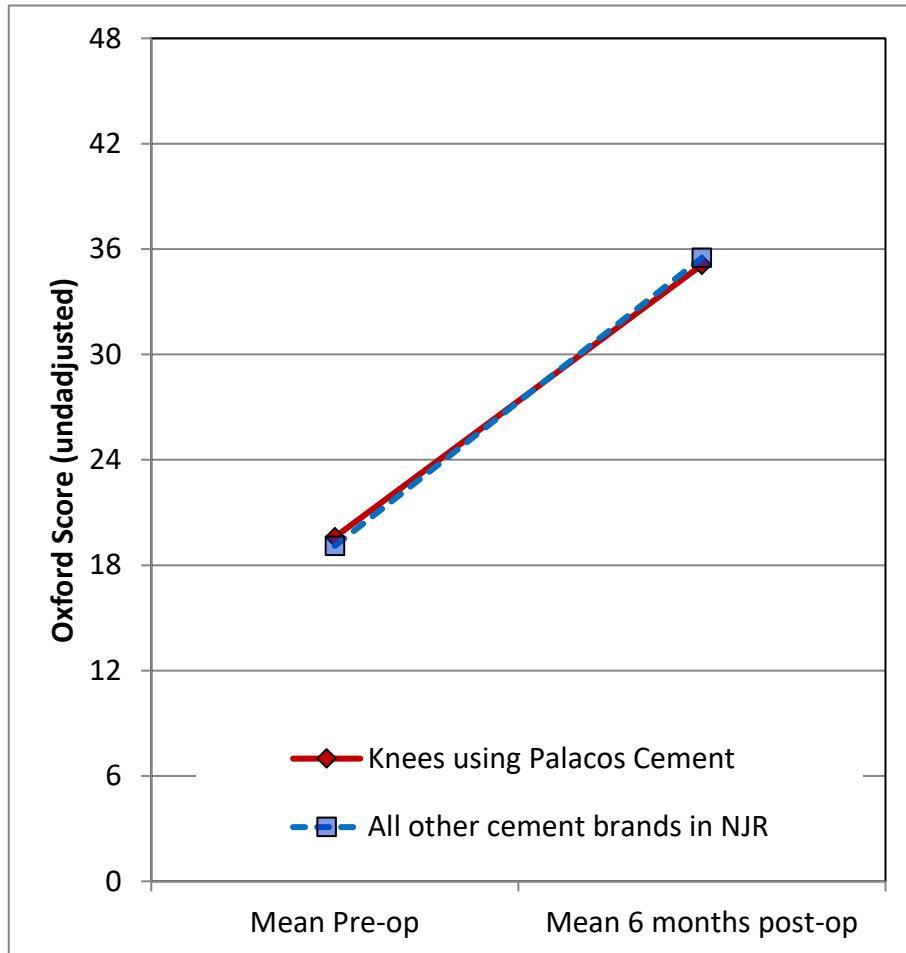
Summary Report for:

Knees using Palacos Cement

Patient Reported Outcomes

Comprising PROMs data up to and including: 31/12/2020

PROMs Analysis



Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/12/2020

Oxford Knee Score (0 - 48)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	1,093	359,916	382,034
PreOp score	19.6 (19.1 - 20.1)	19.1 (19.1 - 19.1)	19.1 (19.1 - 19.1)
6 month score	35.1 (34.5 - 35.7)	35.5 (35.5 - 35.5)	35.5 (35.5 - 35.5)
6 month score (adjusted)	34.8 (34.3 - 35.3)	35.5 (35.5 - 35.5)	35.5 (35.5 - 35.5)
Health gain	15.5 (15.0 - 16.1)	16.4 (16.4 - 16.4)	16.4 (16.4 - 16.4)
Health gain (adjusted)	15.7 (15.2 - 16.2)	16.4 (16.4 - 16.4)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	0.005		
Score Improved	93.2%	94.0%	93.9%

EQ-5D Index (-0.59 - 1.00)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	1,002	333,933	354,535
PreOp score	0.424 (0.405 - 0.443)	0.417 (0.416 - 0.418)	0.417 (0.416 - 0.418)
6 month score	0.729 (0.713 - 0.746)	0.739 (0.738 - 0.740)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.723 (0.709 - 0.738)	0.739 (0.739 - 0.740)	0.739 (0.738 - 0.740)
Health gain	0.305 (0.285 - 0.325)	0.322 (0.321 - 0.323)	0.322 (0.321 - 0.323)
Health gain (adjusted)	0.306 (0.292 - 0.320)	0.322 (0.321 - 0.323)	0.322 (0.321 - 0.322)
p value (adjusted health gain)	0.047		
Score Improved	81.1%	81.4%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	954	320,182	340,143
PreOp score	68.9 (67.6 - 70.2)	68.0 (67.9 - 68.0)	68.0 (67.9 - 68.1)
6 month score	72.5 (71.2 - 73.7)	74.2 (74.1 - 74.2)	74.1 (74.1 - 74.2)
6 month score (adjusted)	72.1 (71.0 - 73.2)	74.2 (74.1 - 74.2)	74.1 (74.1 - 74.2)
Health gain	3.5 (2.1 - 5.0)	6.2 (6.1 - 6.3)	6.2 (6.1 - 6.2)
Health gain (adjusted)	4.1 (3.0 - 5.2)	6.2 (6.1 - 6.2)	6.2 (6.1 - 6.2)
p value (adjusted health gain)	< 0.001		
Score Improved	50.2%	56.5%	56.4%

Adjusted scores correspond to the NHS Digital version 3 casemix-adjustment model. This includes patient variables from PROMs, HES, and IMD data.

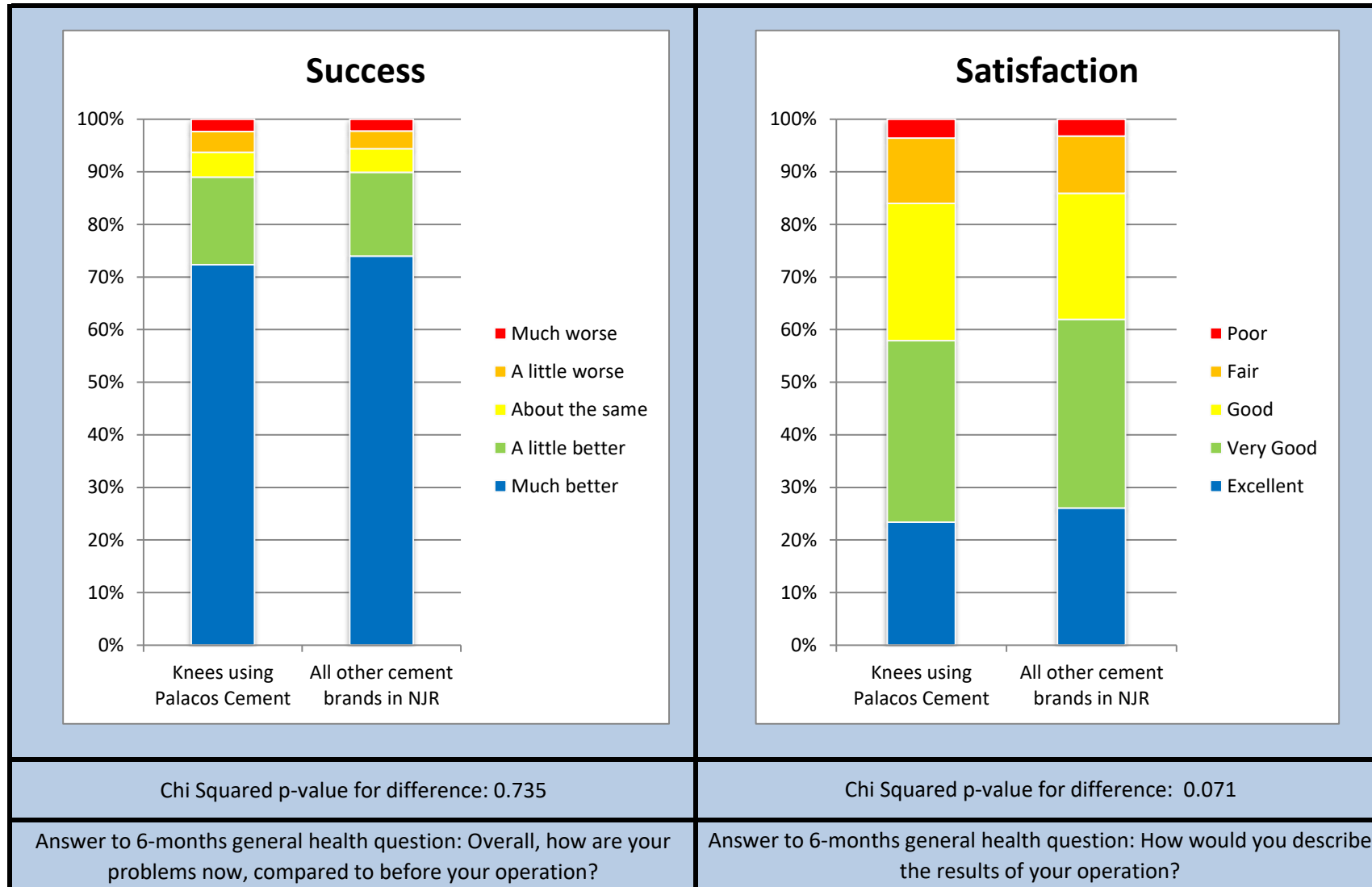
Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Knees using Palacos Cement

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Knees using Palacos Cement	All other cement brands in NJR
Much better	808	273288
A little better	186	58814
About the same	53	16534
A little worse	44	12514
Much worse	26	8253

Answer to 6-months general health question:

"Overall, how are your problems now, compared to before your operation?"

Satisfaction

Response	Knees using Palacos Cement	All other cement brands in NJR
Excellent	260	96182
Very Good	384	132110
Good	290	88518
Fair	138	39940
Poor	40	11892

Answer to 6-months general health question:

"How would you describe the results of your operation?"

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