

Implant Summary Report for:

Heraeus Medical

Knees using Palacos Cement

Comprising PRIMARY knees implanted up to:	01 July 2024
NJR Database extract:	31 July 2024
Produced on:	15 August 2024
Licensed for use until:	15 August 2025

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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

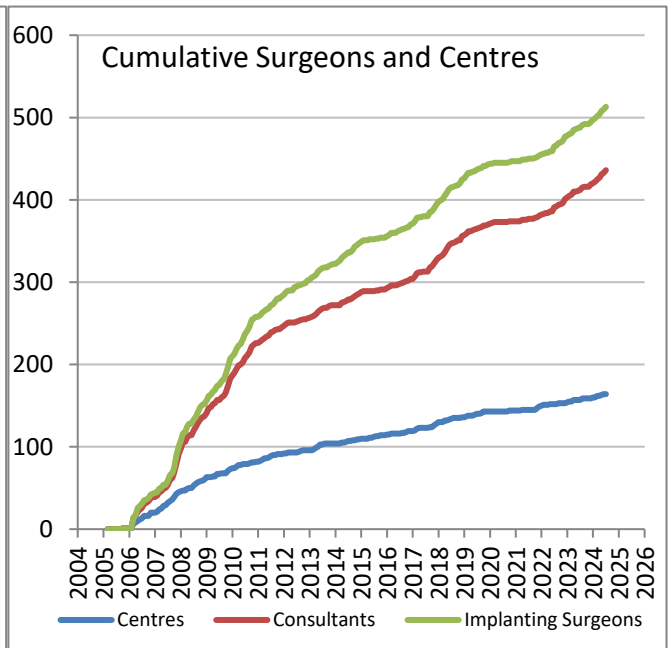
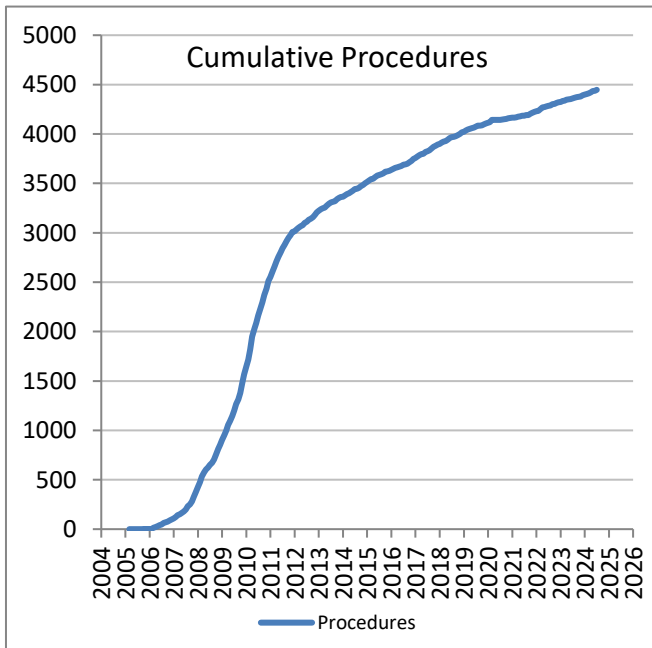
Date of first recorded usage in the NJR: **26 September 2005**

Date of last recorded usage in this dataset: **18 June 2024**

Maximum implantation time: 18.4 years

Mean implantation time: 9.8 years

Totals Recorded in NJR	Cumulative Total
Procedures	4,447
Patients	4,143
Centres	164
Consultants	436
Implanting Surgeons	513



Current Outcome	Year of implantation													Total	%
	Pre-2013	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024		
Death	1351	52	45	24	18	27	12	10	3	3	0	0	0	1545	34.7%
Revised	206	6	7	10	8	8	7	4	1	0	1	0	0	258	5.8%
Unrevised	1667	82	99	88	95	108	102	77	48	61	95	73	49	2644	59.5%
Total	3224	140	151	122	121	143	121	91	52	64	96	73	49	4447	100%

Patient / Procedure Details

Patient Details

	Knees using Palacos Cement	All other cement brands in NJR
Total Procedures	4,447	1,600,995
Total Patients	4,143	1,271,049
Demographics		
Mean age	70.4	69.7
< 50	2.2%	2.4%
50 – 59	11.7%	13.6%
60 – 69	32.6%	32.8%
70 – 79	36.8%	37.4%
≥ 80	16.7%	13.8%
Median BMI	30	30
% BMI information available	51.7%	69.4%
Underweight (BMI < 18.5)	0.3%	0.2%
Normal (18.5 ≤ BMI < 25)	11.6%	10.5%
Overweight (25 ≤ BMI < 30)	34.6%	34.3%
Obese I (30 ≤ BMI < 35)	29.5%	32.3%
Obese II (35 ≤ BMI < 40)	16.6%	16.3%
Obese III (BMI ≥ 40)	7.5%	6.5%
% Male	42.0%	43.3%
ASA Grades		
P1 - Fit and healthy	11.1%	9.9%
P2 - Mild disease not incapacitating	70.5%	72.1%
P3 - Incapacitating systemic disease	17.9%	17.6%
P4 / P5	0.4%	0.3%
Indications		
Osteoarthritis	97.91%	97.47%
Rheumatoid Arthritis	1.21%	1.33%
Other Inflammatory Arthropathy	0.56%	0.70%
Previous Trauma	0.76%	0.61%
Avascular Necrosis	0.36%	0.38%
Other	0.31%	0.42%

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	71	31.07	<0.001
Progressive Arthritis Remaining	22	32.45	0.065
Aseptic Loosening Femur	36	19.31	<0.001
Aseptic Loosening Tibia	51	33.92	0.006
Aseptic Loosening Patella	1	5.68	0.053
Unexplained Pain	27	24.95	0.617
Stiffness	13	9.75	0.262
Malalignment	24	11.69	0.001
Instability	34	24.76	0.069
Dislocation / Subluxation	5	5.81	1
Periprosthetic Fracture	16	8.40	0.014
Wear of Polyethylene Component	12	12.30	1
Lysis - Tibia	15	8.60	0.038
Lysis - Femur	8	5.90	0.402
Component Dissociation	3	2.28	0.5
Implant Fracture	0	1.19	0.637
Other / Not recorded	10	12.18	0.666
Total Revised	258	176.55	<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

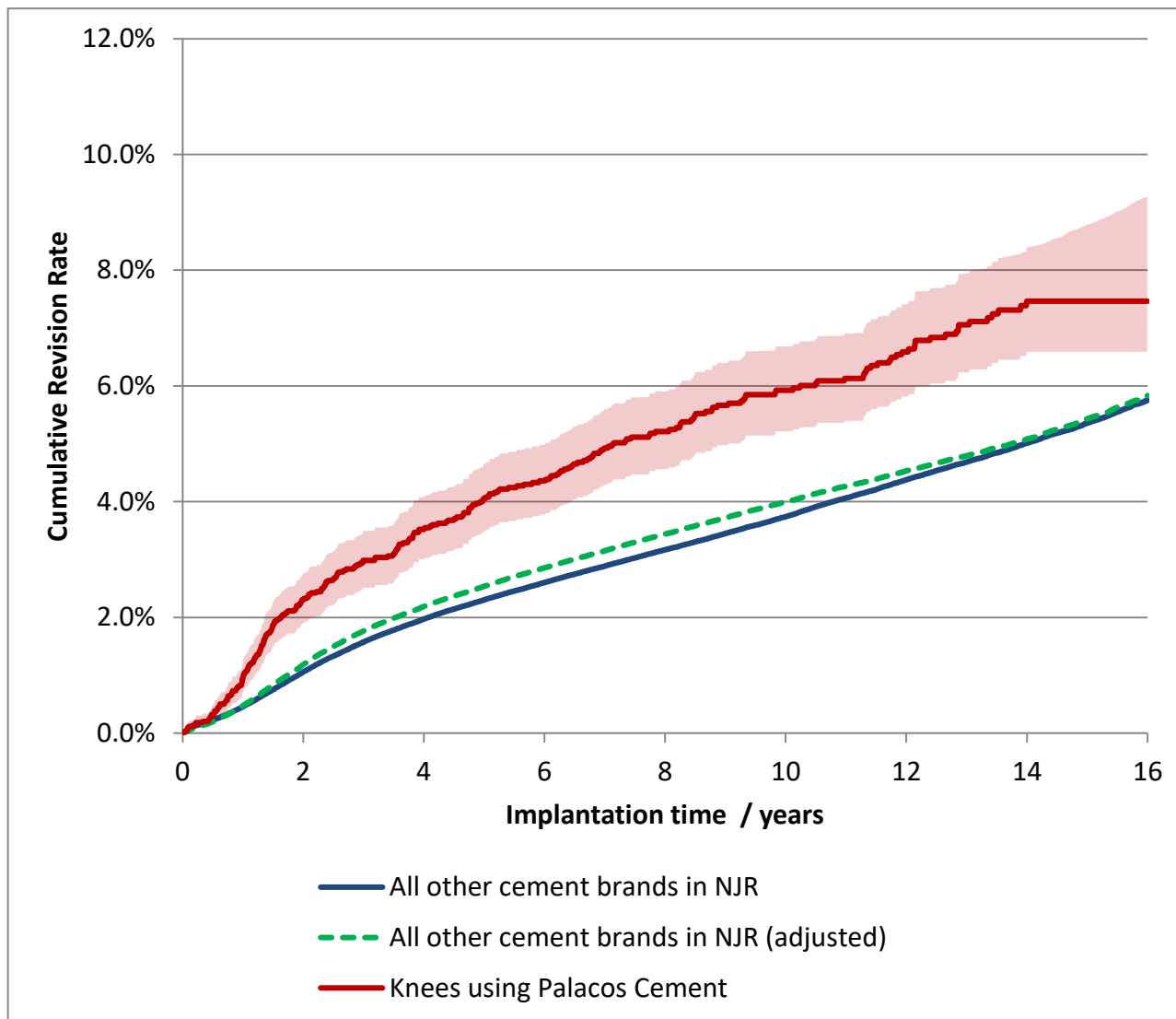


Components Revised	Number of procedures	Knees using Palacos Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	220	85.3%	75.0%
Isolated bearing exchange	21	8.1%	12.7%
Patella revision / resurfacing only	16	6.2%	11.5%
No component revision recorded	1	0.4%	0.9%

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.	1.53 ‡ (1.36 - 1.73)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	1.47 (1.30 - 1.66)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

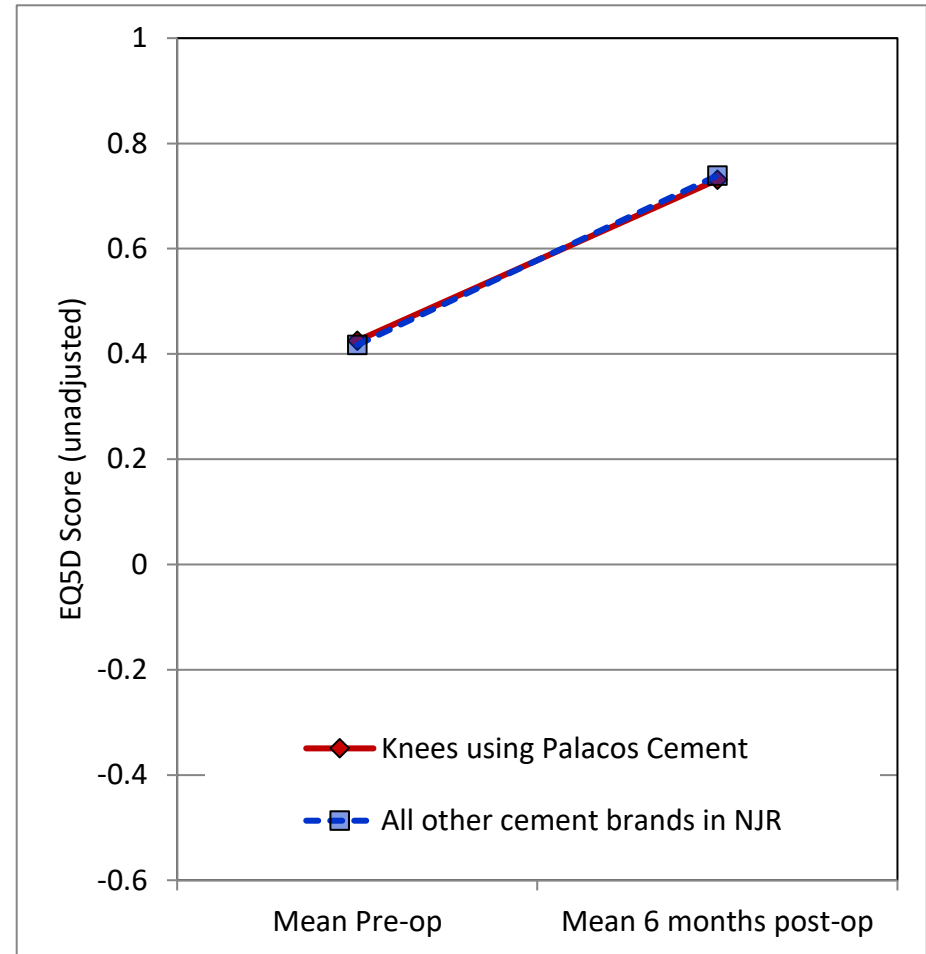
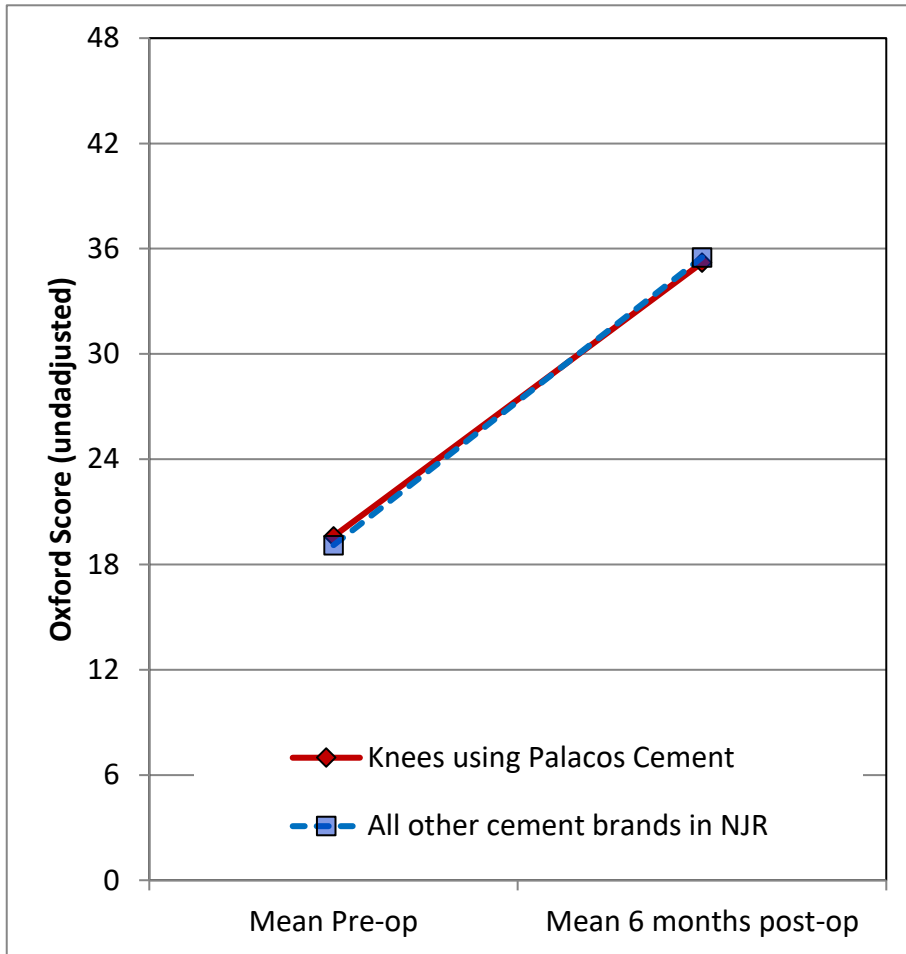
Period /years	At Risk	Knees using Palacos Cement	All other cement brands in NJR
0	4447	-	-
1	4270	1.0% (0.7% - 1.3%)	0.5% (0.4% - 0.5%)
2	4080	2.3% (1.9% - 2.7%)	1.1% (1.0% - 1.1%)
3	3885	3.0% (2.5% - 3.5%)	1.6% (1.6% - 1.6%)
4	3728	3.5% (3.0% - 4.1%)	2.0% (1.9% - 2.0%)
5	3536	4.1% (3.5% - 4.7%)	2.3% (2.3% - 2.3%)
6	3318	4.4% (3.8% - 5.0%)	2.6% (2.6% - 2.6%)
7	3074	4.9% (4.3% - 5.6%)	2.9% (2.9% - 2.9%)
8	2840	5.2% (4.6% - 5.9%)	3.2% (3.1% - 3.2%)
9	2624	5.7% (5.0% - 6.4%)	3.4% (3.4% - 3.5%)
10	2384	5.9% (5.2% - 6.7%)	3.7% (3.7% - 3.8%)
11	2179	6.1% (5.4% - 6.9%)	4.1% (4.0% - 4.1%)
12	1918	6.6% (5.8% - 7.4%)	4.4% (4.3% - 4.4%)
13	1622	7.1% (6.2% - 7.9%)	4.7% (4.6% - 4.7%)
14	1161	7.5% (6.6% - 8.4%)	5.0% (5.0% - 5.1%)
15	572	7.5% (6.6% - 8.8%)	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

Patient Reported Outcomes

Comprising PROMs data up to and including: 31/03/2022

PROMs Analysis



Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/03/2022

Oxford Knee Score (0 - 48)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	1,105	380,958	400,237
PreOp score	19.6 (19.2 - 20.1)	19.1 (19.1 - 19.1)	19.1 (19.1 - 19.1)
6 month score	35.2 (34.6 - 35.7)	35.5 (35.5 - 35.6)	35.5 (35.5 - 35.6)
6 month score (adjusted)	34.9 (34.4 - 35.4)	35.5 (35.5 - 35.6)	35.5 (35.5 - 35.6)
Health gain	15.5 (15.0 - 16.1)	16.4 (16.4 - 16.5)	16.4 (16.4 - 16.5)
Health gain (adjusted)	15.8 (15.3 - 16.3)	16.4 (16.4 - 16.4)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	0.006		
Score Improved	93.3%	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	1,012	353,582	371,558
PreOp score	0.425 (0.406 - 0.444)	0.417 (0.416 - 0.418)	0.418 (0.417 - 0.419)
6 month score	0.731 (0.714 - 0.747)	0.739 (0.738 - 0.740)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.725 (0.711 - 0.739)	0.739 (0.739 - 0.740)	0.739 (0.738 - 0.740)
Health gain	0.306 (0.286 - 0.326)	0.322 (0.321 - 0.323)	0.322 (0.320 - 0.323)
Health gain (adjusted)	0.307 (0.293 - 0.322)	0.322 (0.321 - 0.322)	0.322 (0.321 - 0.322)
p value (adjusted health gain)	0.074		
Score Improved	80.8%	81.4%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	964	338,592	355,986
PreOp score	68.9 (67.6 - 70.2)	67.9 (67.8 - 68.0)	67.9 (67.9 - 68.0)
6 month score	72.5 (71.2 - 73.7)	74.1 (74.0 - 74.2)	74.1 (74.1 - 74.2)
6 month score (adjusted)	72.1 (71.0 - 73.2)	74.1 (74.1 - 74.2)	74.1 (74.1 - 74.2)
Health gain	3.6 (2.2 - 5.0)	6.2 (6.1 - 6.3)	6.2 (6.1 - 6.3)
Health gain (adjusted)	4.2 (3.1 - 5.3)	6.2 (6.2 - 6.3)	6.2 (6.2 - 6.3)
p value (adjusted health gain)	< 0.001		
Score Improved	50.3%	56.5%	56.5%

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

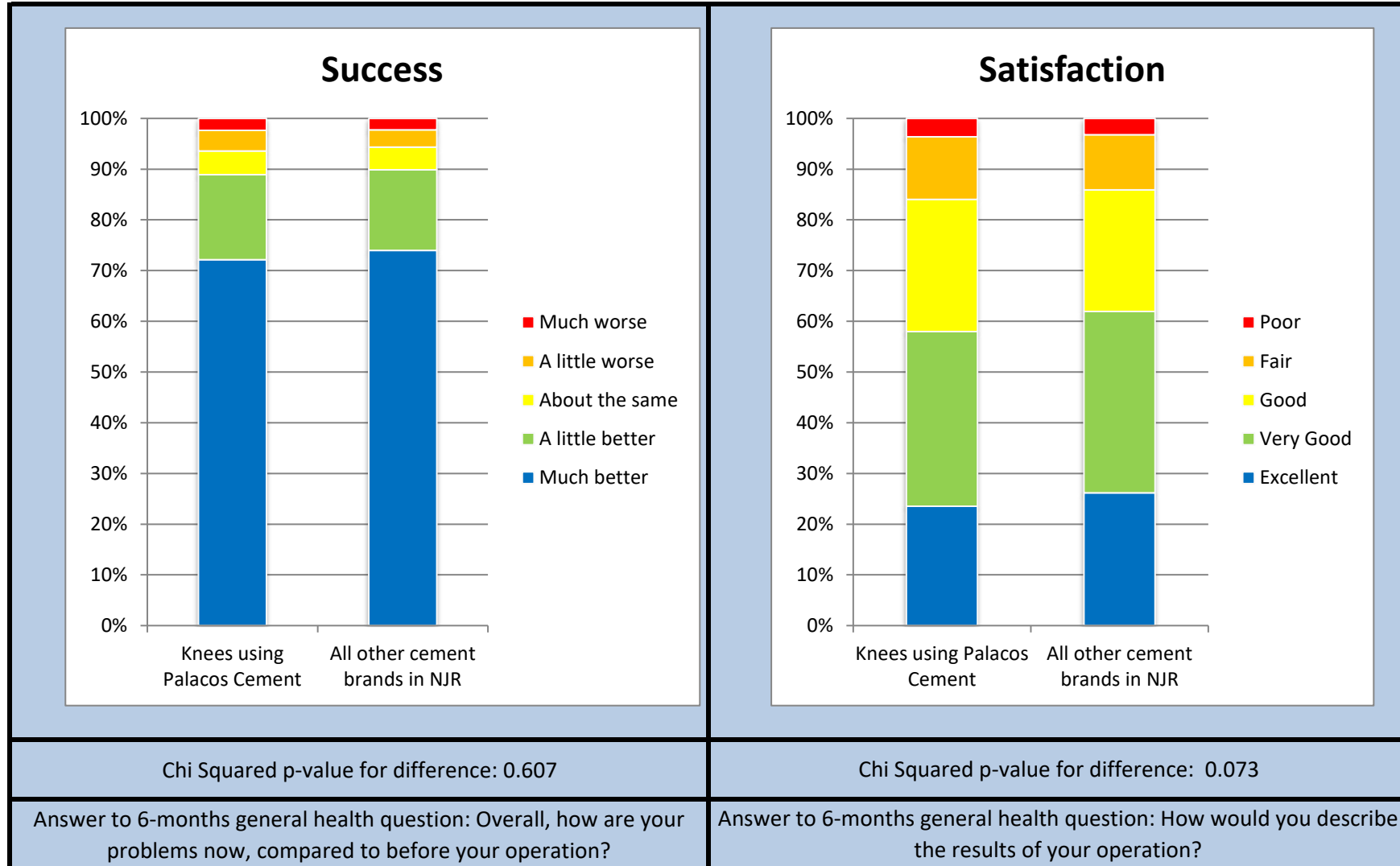
Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Knees using Palacos Cement

Patient Reported Outcomes

Responses are not case mix adjusted



Patient Reported Outcomes

Success

Response	Knees using Palacos Cement	All other cement brands in NJR
Much better	834	291250
A little better	194	62648
About the same	54	17614
A little worse	47	13384
Much worse	27	8855

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	271	102758
Very Good	396	140574
Good	300	94219
Fair	142	42672
Poor	42	12720

Answer to 6-months general health question:

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

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