

Implant Summary Report for:

Heraeus Medical

Knees using Palacos Antibiotic Cement

Comprising PRIMARY knees implanted up to:	13 January 2024
NJR Database extract:	12 February 2024
Produced on:	22 February 2024
Licensed for use until:	22 February 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 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 components listed in the appendices.

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NJR Recorded Usage

Implant Usage

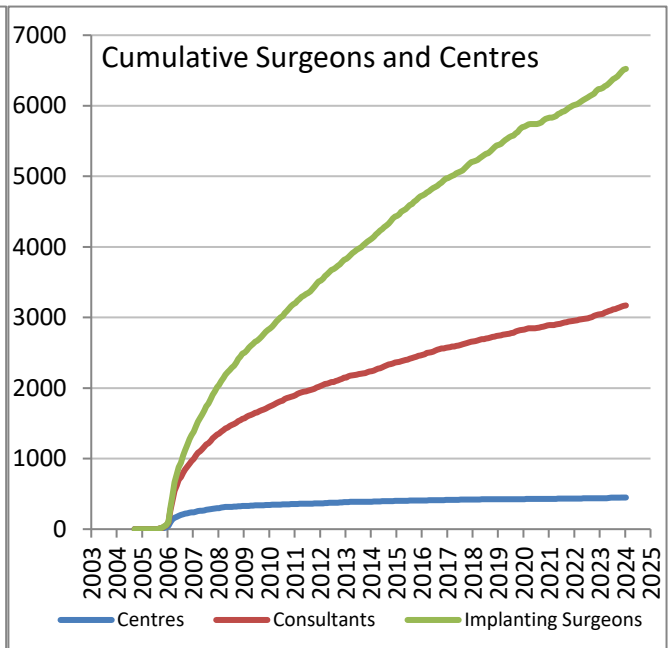
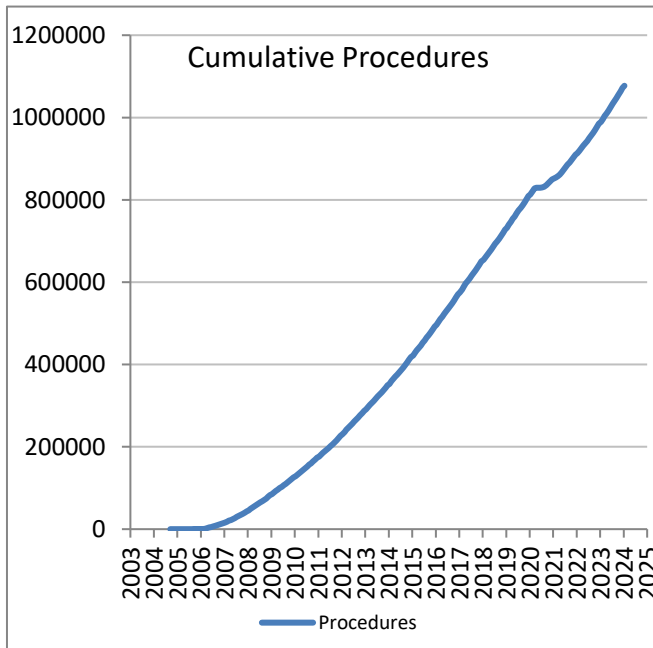
Date of first recorded usage in the NJR: **01 September 2005**

Date of last recorded usage in this dataset: **13 January 2024**

Maximum implantation time: 18.4 years

Mean implantation time: 6.7 years

Totals Recorded in NJR	Cumulative Total
Procedures	1,077,405
Patients	879,244
Centres	448
Consultants	3,170
Implanting Surgeons	6,523



Current Outcome	Year of implantation														Total	%
	Pre-2013	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024			
Death	1E+05	14191	13551	11940	10296	7989	5941	4581	1395	1100	570	98	0	178377	16.6%	
Revised	13239	2335	2318	2216	1965	1750	1403	1115	451	506	406	228	0	27932	2.6%	
Unrevised	2E+05	45276	53195	59886	66284	69914	70262	75314	37997	58996	74526	87355	2721	871096	80.9%	
Total	3E+05	61802	69064	74042	78545	79653	77606	81010	39843	60602	75502	87681	2721	1077405	100%	

Patient / Procedure Details

Patient Details

	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Total Procedures	1,077,405	467,370
Total Patients	879,244	398,330
Demographics		
Mean age	69.6	69.7
< 50	2.3%	2.6%
50 – 59	13.8%	13.2%
60 – 69	33.0%	32.4%
70 – 79	37.2%	37.6%
≥ 80	13.7%	14.2%
Median BMI	30	30
% BMI information available	73.5%	57.9%
Underweight (BMI < 18.5)	0.2%	0.2%
Normal (18.5 ≤ BMI < 25)	10.3%	11.1%
Overweight (25 ≤ BMI < 30)	34.2%	34.8%
Obese I (30 ≤ BMI < 35)	32.5%	31.4%
Obese II (35 ≤ BMI < 40)	16.4%	16.0%
Obese III (BMI ≥ 40)	6.5%	6.6%
% Male	43.5%	42.9%
ASA Grades		
P1 - Fit and healthy	9.1%	12.5%
P2 - Mild disease not incapacitating	72.9%	70.4%
P3 - Incapacitating systemic disease	17.6%	16.7%
P4 / P5	0.3%	0.4%
Indications		
Osteoarthritis	97.64%	97.00%
Rheumatoid Arthritis	1.20%	1.69%
Other Inflammatory Arthropathy	0.71%	0.66%
Previous Trauma	0.60%	0.71%
Avascular Necrosis	0.38%	0.40%
Other	0.36%	0.52%

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	6114	6230.00	0.011
Progressive Arthritis Remaining	4648	4857.67	<0.001
Aseptic Loosening Femur	2429	2533.19	0.003
Aseptic Loosening Tibia	5060	5064.23	0.931
Aseptic Loosening Patella	829	833.03	0.822
Unexplained Pain	3438	3495.72	0.129
Stiffness	1788	1807.04	0.444
Malalignment	1913	1973.71	0.025
Instability	4006	4106.01	0.011
Dislocation / Subluxation	868	917.41	0.01
Periprosthetic Fracture	1265	1285.90	0.35
Wear of Polyethylene Component	1265	1381.20	<0.001
Lysis - Tibia	1170	1192.82	0.322
Lysis - Femur	705	755.56	0.007
Component Dissociation	312	333.22	0.075
Implant Fracture	157	163.55	0.446
Other / Not recorded	1831	1835.52	0.867
Total Revised	27932	28508.07	<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

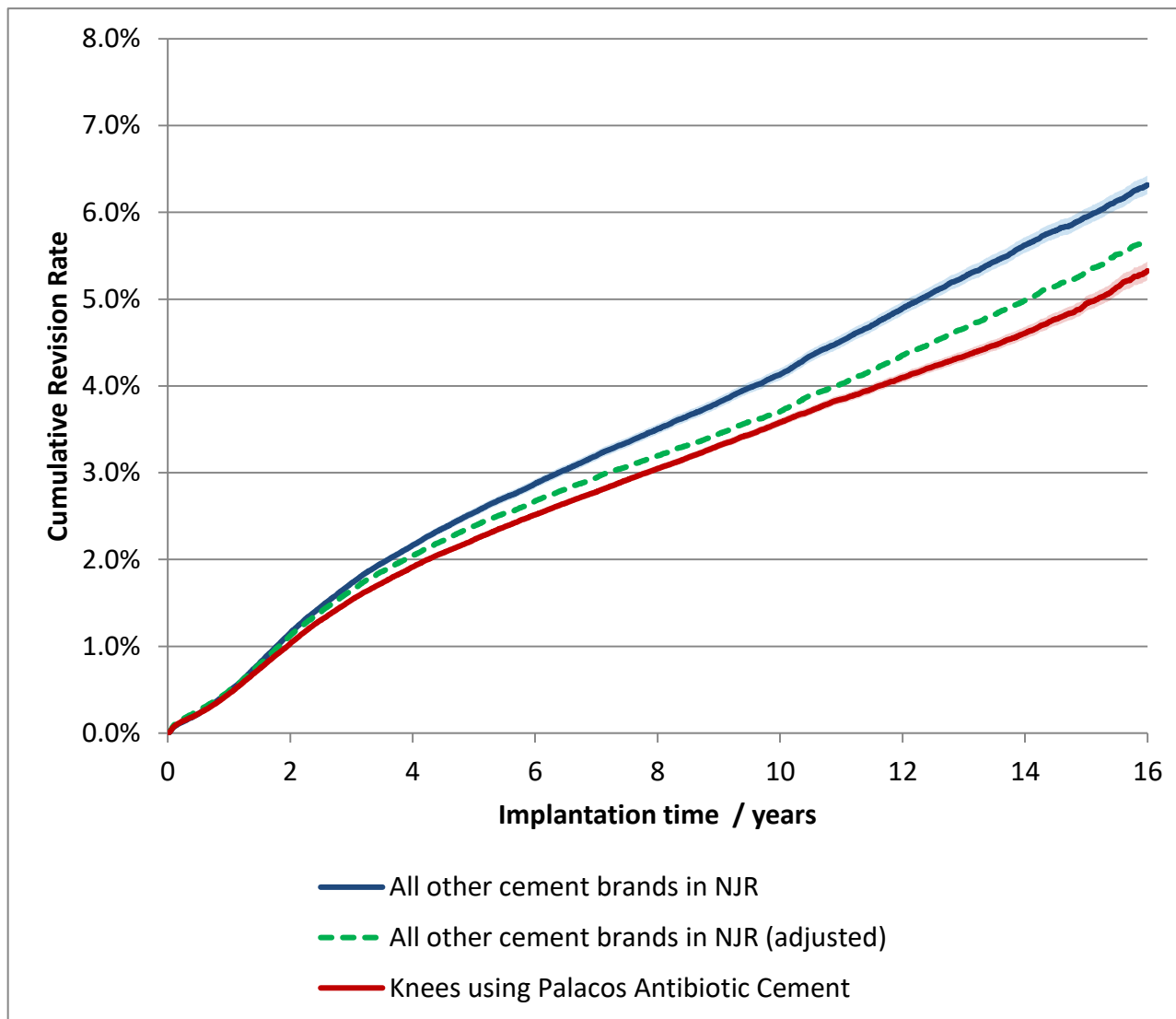


Components Revised	Number of procedures	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	20083	71.9%	79.9%
Isolated bearing exchange	3975	14.2%	9.8%
Patella revision / resurfacing only	3611	12.9%	9.6%
No component revision recorded	263	0.9%	0.7%

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision



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

Adjustment	Hazard Ratio (95% CI)	p-value
Unadjusted.	0.85 ‡ (0.84 - 0.87)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	0.93 (0.92 - 0.95)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	At Risk	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
0	1077405	-	-
1	976259	0.5% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)
2	884616	1.0% (1.0% - 1.1%)	1.2% (1.1% - 1.2%)
3	807275	1.5% (1.5% - 1.6%)	1.7% (1.7% - 1.8%)
4	752025	1.9% (1.9% - 1.9%)	2.2% (2.1% - 2.2%)
5	657719	2.2% (2.2% - 2.3%)	2.5% (2.5% - 2.6%)
6	568605	2.5% (2.5% - 2.5%)	2.9% (2.8% - 2.9%)
7	480827	2.8% (2.7% - 2.8%)	3.2% (3.1% - 3.3%)
8	397814	3.0% (3.0% - 3.1%)	3.5% (3.4% - 3.6%)
9	322009	3.3% (3.3% - 3.4%)	3.8% (3.7% - 3.9%)
10	255379	3.6% (3.5% - 3.6%)	4.1% (4.1% - 4.2%)
11	198637	3.8% (3.8% - 3.9%)	4.5% (4.4% - 4.6%)
12	147690	4.1% (4.0% - 4.2%)	4.9% (4.8% - 5.0%)
13	105089	4.3% (4.3% - 4.4%)	5.3% (5.2% - 5.3%)
14	70887	4.6% (4.5% - 4.7%)	5.6% (5.5% - 5.7%)
15	42846	4.9% (4.9% - 5.0%)	5.9% (5.8% - 6.0%)

Cumulative revision rate with 95% confidence intervals
 Rate is only reported for times where more than 40 remain at risk

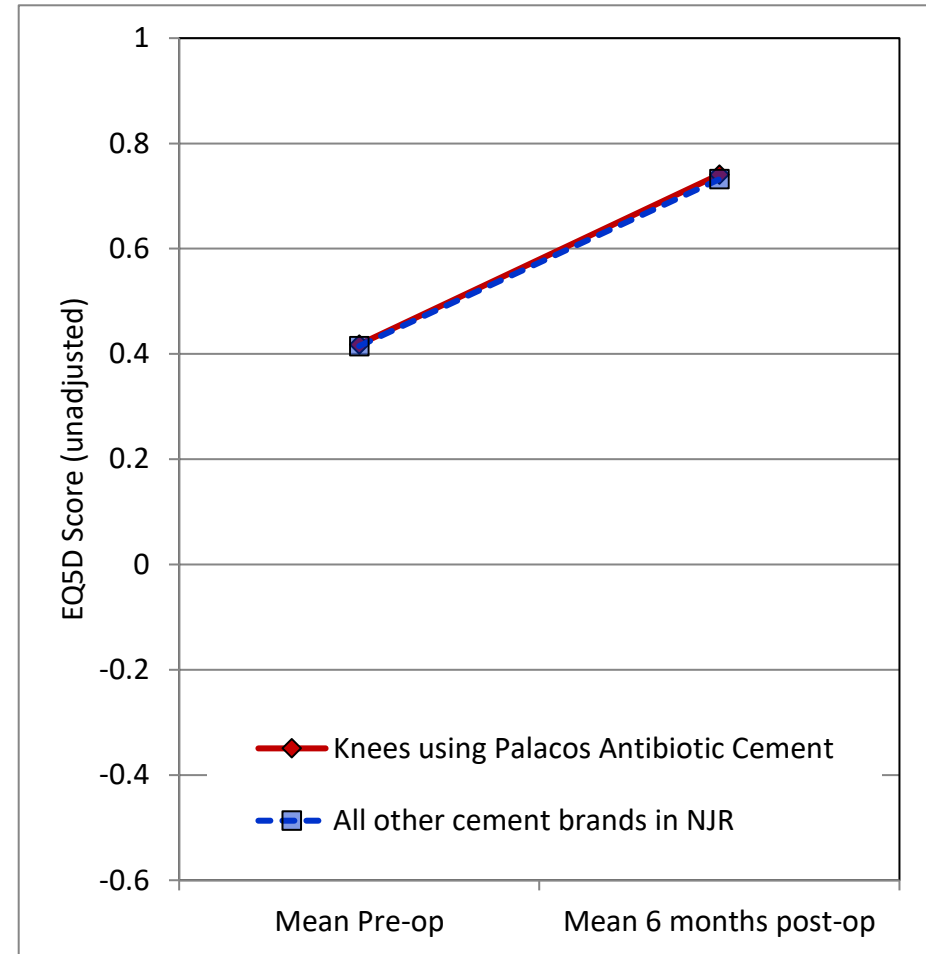
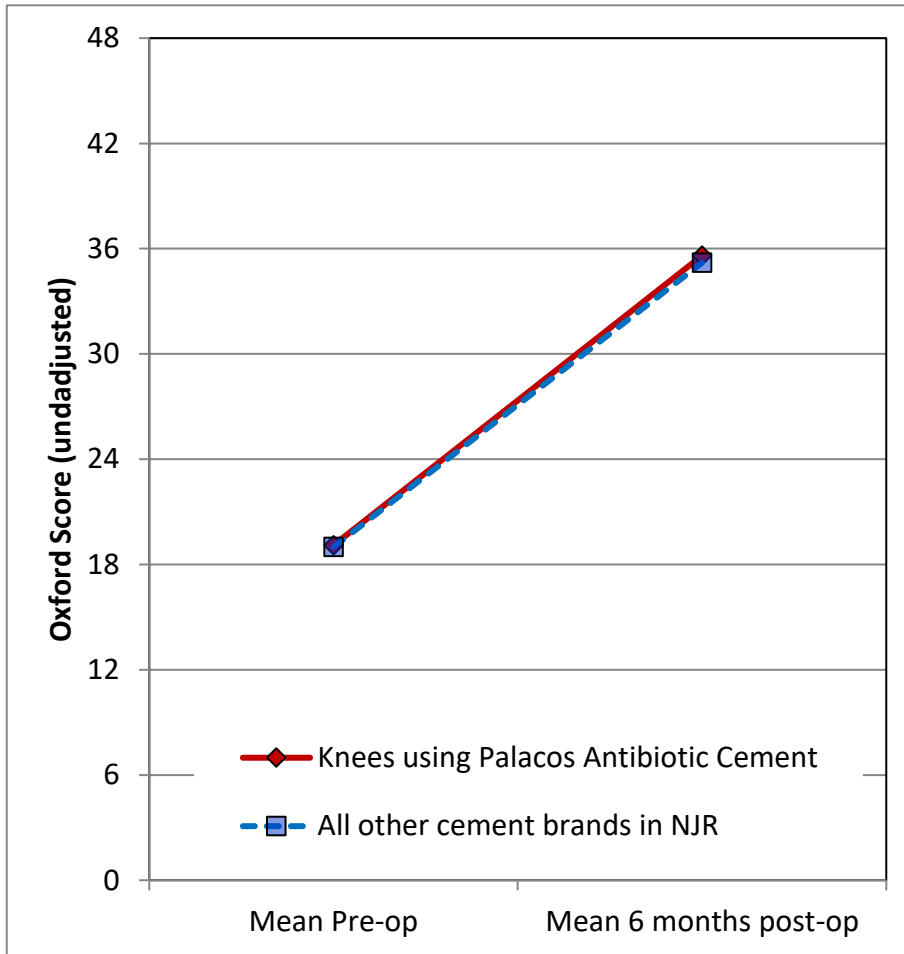
Summary Report for:

Knees using Palacos Antibiotic 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 Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	268,981	95,916	382,040
PreOp score	19.1 (19.1 - 19.1)	19.0 (19.0 - 19.1)	19.1 (19.1 - 19.1)
6 month score	35.6 (35.6 - 35.6)	35.2 (35.1 - 35.2)	35.5 (35.5 - 35.5)
6 month score (adjusted)	35.6 (35.5 - 35.6)	35.3 (35.2 - 35.3)	35.5 (35.5 - 35.5)
Health gain	16.5 (16.4 - 16.5)	16.2 (16.1 - 16.2)	16.4 (16.4 - 16.4)
Health gain (adjusted)	16.5 (16.4 - 16.5)	16.2 (16.1 - 16.2)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	< 0.001		
Score Improved	94.1%	93.6%	93.9%

EQ-5D Index (-0.59 - 1.00)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	249,739	88,809	354,540
PreOp score	0.418 (0.416 - 0.419)	0.415 (0.413 - 0.417)	0.417 (0.416 - 0.418)
6 month score	0.741 (0.740 - 0.742)	0.732 (0.730 - 0.734)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.741 (0.740 - 0.742)	0.734 (0.733 - 0.736)	0.739 (0.738 - 0.740)
Health gain	0.324 (0.322 - 0.325)	0.317 (0.315 - 0.319)	0.322 (0.321 - 0.323)
Health gain (adjusted)	0.323 (0.323 - 0.324)	0.317 (0.316 - 0.319)	0.322 (0.321 - 0.322)
p value (adjusted health gain)	< 0.001		
Score Improved	81.6%	80.8%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	239,110	85,528	340,151
PreOp score	68.0 (67.9 - 68.0)	68.0 (67.9 - 68.1)	68.0 (67.9 - 68.1)
6 month score	74.3 (74.2 - 74.4)	73.6 (73.5 - 73.7)	74.1 (74.1 - 74.2)
6 month score (adjusted)	74.3 (74.2 - 74.3)	73.8 (73.6 - 73.9)	74.1 (74.1 - 74.2)
Health gain	6.3 (6.3 - 6.4)	5.6 (5.5 - 5.7)	6.2 (6.1 - 6.2)
Health gain (adjusted)	6.3 (6.2 - 6.4)	5.8 (5.7 - 5.9)	6.2 (6.1 - 6.2)
p value (adjusted health gain)	< 0.001		
Score Improved	56.9%	55.1%	56.4%

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

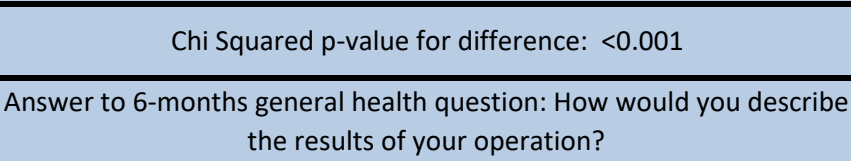
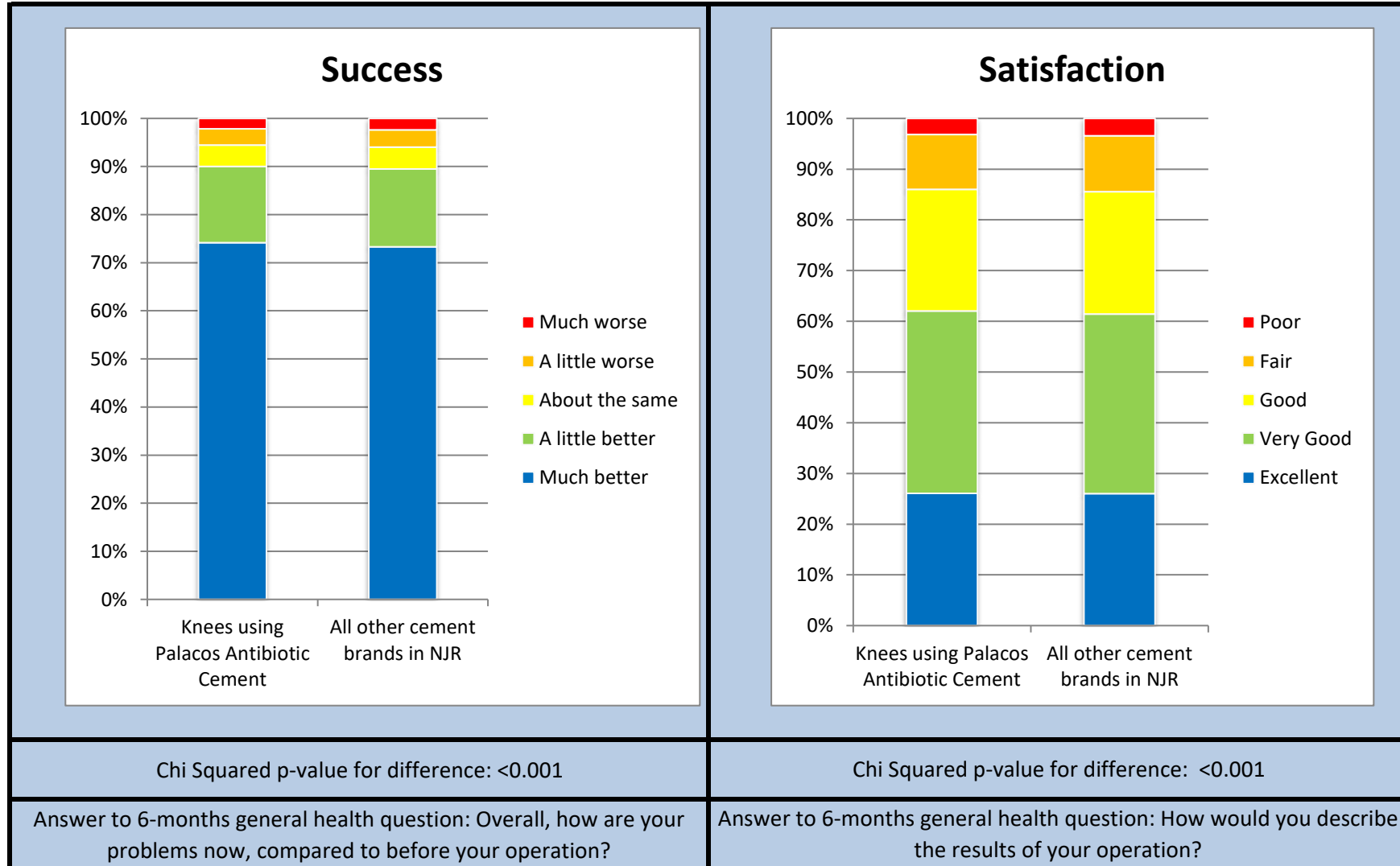
Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Knees using Palacos Antibiotic Cement

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Much better	204556	72618
A little better	43732	16019
About the same	12295	4508
A little worse	9180	3546
Much worse	6035	2366

Answer to 6-months general health question:

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

Satisfaction

Response	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Excellent	71787	25702
Very Good	98982	35001
Good	66063	23833
Fair	29734	10898
Poor	8710	3370

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	876967
66017771	PALACOS R +G 1x40 g	23742
66017772	PALACOS R +G 1x60 g	41527
66017773	PALACOS R +G 2x20 g	38763
66017776	PALACOS R +G 2x10 g	32
66017787	PALACOS LV +G 1x40 g	1862
66031993	PALACOS MV+G 1x40g	440
66031995	PALACOS MV+G 2x40 g	3416
66031996	PALACOS MV+G 1x20g	9
66031998	PALACOS MV+G 2x20 g	36
66032000	PALACOS MV+G 1x60 g	1
66037894	PALACOS LV+G 1x20g	2
66044274	PALACOS R+G Pro 75 cement	6
Multiple Found	Multiple Found	90602