

## Implant Summary Report for:

Heraeus Medical

### Knees using Palacos Antibiotic Cement

Comprising PRIMARY knees implanted up to: 01 June 2023  
NJR Database extract: 31 July 2023

Produced on: 07 August 2023  
Licensed for use until: 07 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 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**

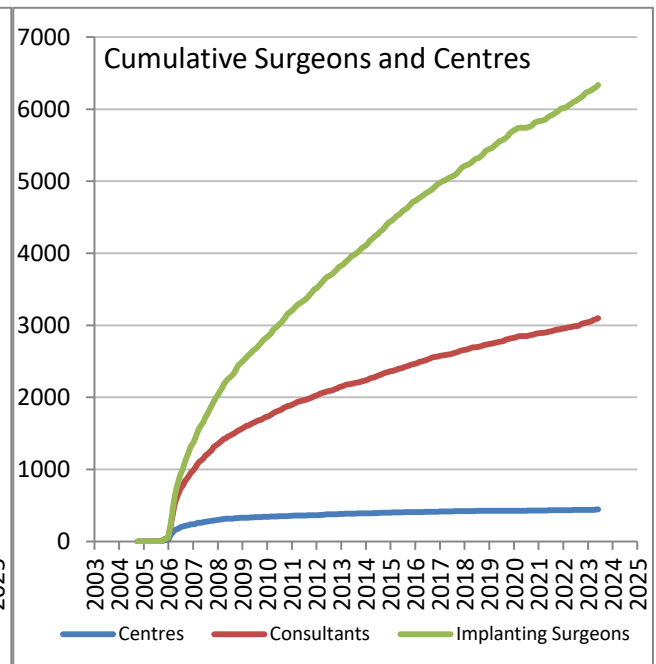
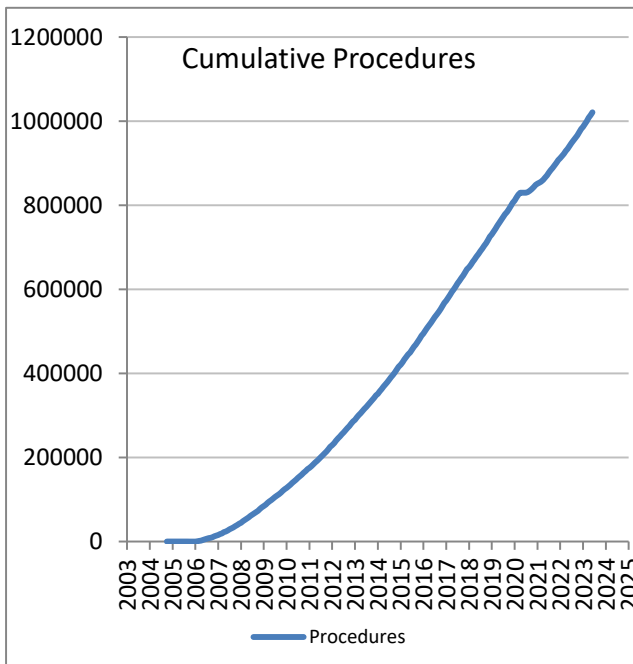
Date of first recorded usage in the NJR: **01 September 2005**

Date of last recorded usage in this dataset: **01 June 2023**

Maximum implantation time: 17.7 years

Mean implantation time: 6.6 years

Totals Recorded in NJR	Cumulative Total
Procedures	1,021,305
Patients	836,047
Centres	446
Consultants	3,100
Implanting Surgeons	6,335



	Year of implantation													Total	%
	Current Outcome	Pre-2012	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022		
<b>Death</b>	90269	16538	14171	13545	11920	10274	7974	5927	4567	1385	1091	561	61	178283	17.5%
<b>Revised</b>	10642	2313	2270	2237	2135	1865	1656	1290	1017	382	408	277	51	26543	2.6%
<b>Unrevised</b>	1E+05	41839	45356	53285	59989	66402	70020	70384	75401	38030	59045	73986	34722	816479	79.9%
<b>Total</b>	2E+05	60690	61797	69067	74044	78541	79650	77601	80985	39797	60544	74824	34834	1021305	100%

## Patient / Procedure Details

## Patient Details

	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
<b>Total Procedures</b>	1,021,305	386,532
<b>Total Patients</b>	836,047	330,301
<b>Demographics</b>		
Mean age	<b>69.6</b>	<b>69.7</b>
< 50	2.4%	2.6%
50 – 59	13.8%	13.3%
60 – 69	33.1%	32.3%
70 – 79	37.1%	37.5%
≥ 80	13.7%	14.2%
Median BMI	<b>30</b>	<b>30</b>
% BMI information available	73.1%	62.6%
Underweight ( BMI < 18.5)	0.2%	0.2%
Normal (18.5 ≤ BMI < 25)	10.2%	10.9%
Overweight (25 ≤ BMI < 30)	34.2%	34.7%
Obese I (30 ≤ BMI < 35)	32.6%	31.5%
Obese II (35 ≤ BMI < 40)	16.3%	16.1%
Obese III (BMI ≥ 40)	6.5%	6.6%
% Male	43.4%	42.9%
<b>ASA Grades</b>		
P1 - Fit and healthy	9.4%	11.8%
P2 - Mild disease not incapacitating	73.0%	70.7%
P3 - Incapacitating systemic disease	17.4%	17.1%
P4 / P5	0.3%	0.4%
<b>Indications</b>		
Osteoarthritis	97.60%	97.06%
Rheumatoid Arthritis	1.22%	1.63%
Other Inflammatory Arthropathy	0.69%	0.66%
Previous Trauma	0.63%	0.76%
Avascular Necrosis	0.39%	0.41%
Other	0.36%	0.48%

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	5774	5902.01	0.002
Progressive Arthritis Remaining	4342	4520.42	<0.001
Aseptic Loosening Femur	2276	2378.43	<0.001
Aseptic Loosening Tibia	4786	4791.17	0.904
Aseptic Loosening Patella	794	795.16	0.95
Unexplained Pain	3366	3408.39	0.222
Stiffness	1719	1730.14	0.63
Malalignment	1827	1876.99	0.043
Instability	3800	3892.38	0.01
Dislocation / Subluxation	816	859.68	0.012
Periprosthetic Fracture	1129	1138.46	0.621
Wear of Polyethylene Component	1156	1232.11	0.001
Lysis - Tibia	1090	1112.37	0.28
Lysis - Femur	651	699.58	0.004
Component Dissociation	298	321.02	0.034
Implant Fracture	147	148.21	0.894
Other / Not recorded	1810	1821.42	0.641
<b>Total Revised</b>	<b>26543</b>	<b>27033.22</b>	<b>&lt;0.001</b>

† 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

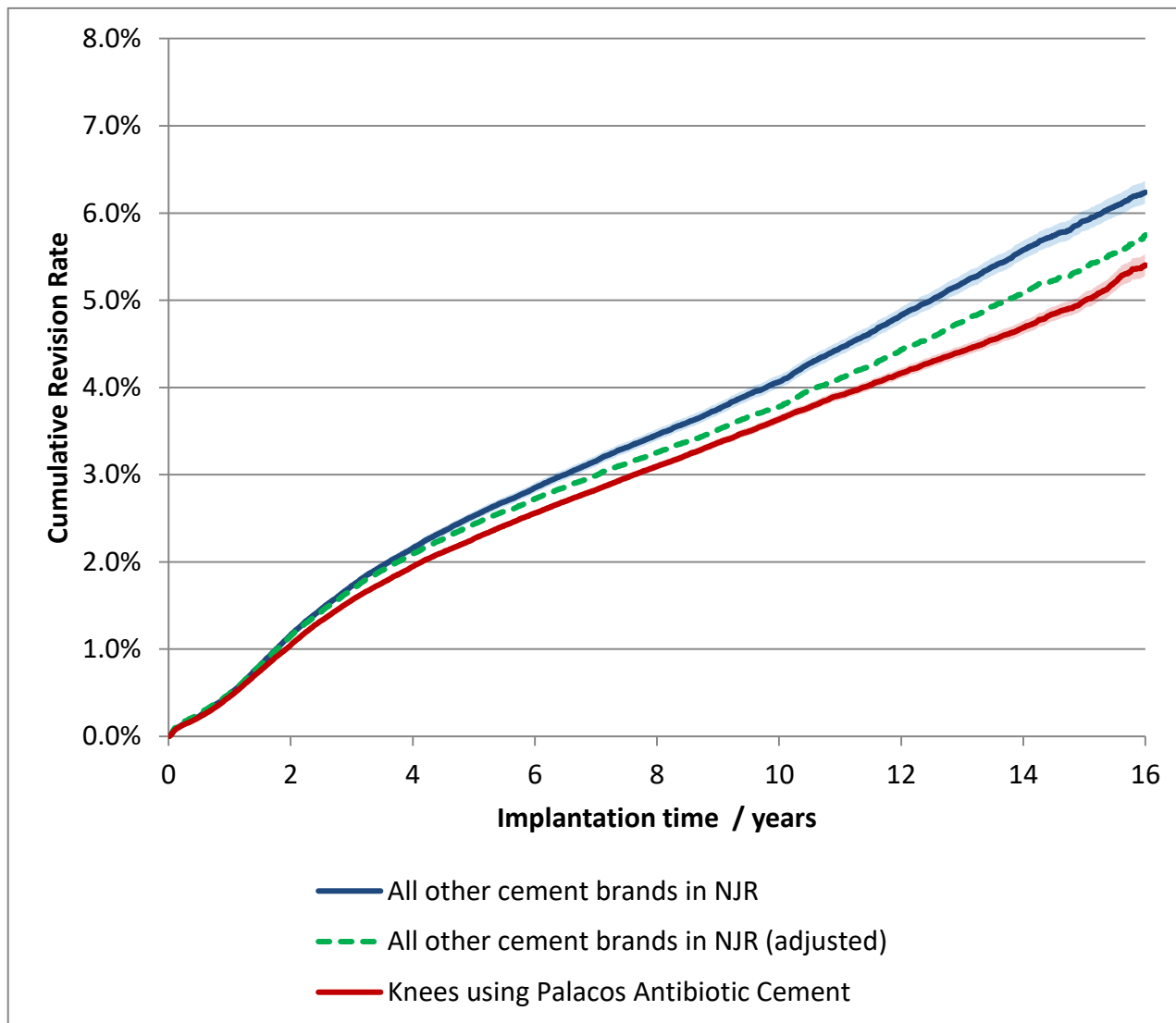


Components Revised	Number of procedures	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	19100	72.0%	78.9%
Isolated bearing exchange	3718	14.0%	10.5%
Patella revision / resurfacing only	3473	13.1%	9.9%
No component revision recorded	252	0.9%	0.7%

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.	0.88 ‡ (0.86 - 0.90)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	0.94 (0.91 - 0.96)	<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	1021305	-	-
1	928389	0.5% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)
2	843291	1.0% (1.0% - 1.1%)	1.2% (1.1% - 1.2%)
3	785915	1.6% (1.5% - 1.6%)	1.7% (1.7% - 1.8%)
4	706388	1.9% (1.9% - 2.0%)	2.2% (2.1% - 2.2%)
5	613690	2.3% (2.2% - 2.3%)	2.5% (2.5% - 2.6%)
6	526384	2.6% (2.5% - 2.6%)	2.9% (2.8% - 2.9%)
7	439842	2.8% (2.8% - 2.9%)	3.2% (3.1% - 3.2%)
8	360167	3.1% (3.1% - 3.1%)	3.5% (3.4% - 3.5%)
9	288647	3.4% (3.3% - 3.4%)	3.8% (3.7% - 3.8%)
10	227452	3.6% (3.6% - 3.7%)	4.1% (4.0% - 4.1%)
11	173600	3.9% (3.9% - 4.0%)	4.5% (4.4% - 4.5%)
12	124952	4.2% (4.1% - 4.2%)	4.8% (4.7% - 4.9%)
13	87056	4.4% (4.3% - 4.5%)	5.2% (5.1% - 5.3%)
14	55754	4.7% (4.6% - 4.8%)	5.6% (5.5% - 5.7%)
15	30259	5.0% (4.9% - 5.1%)	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

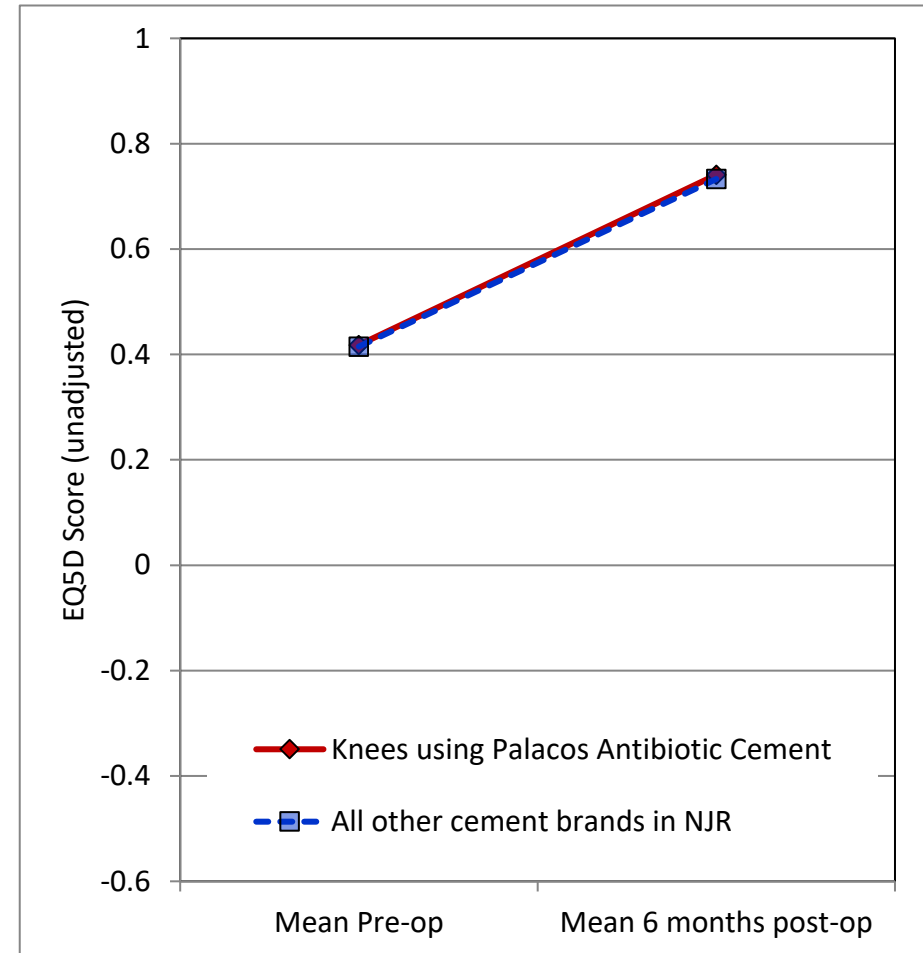
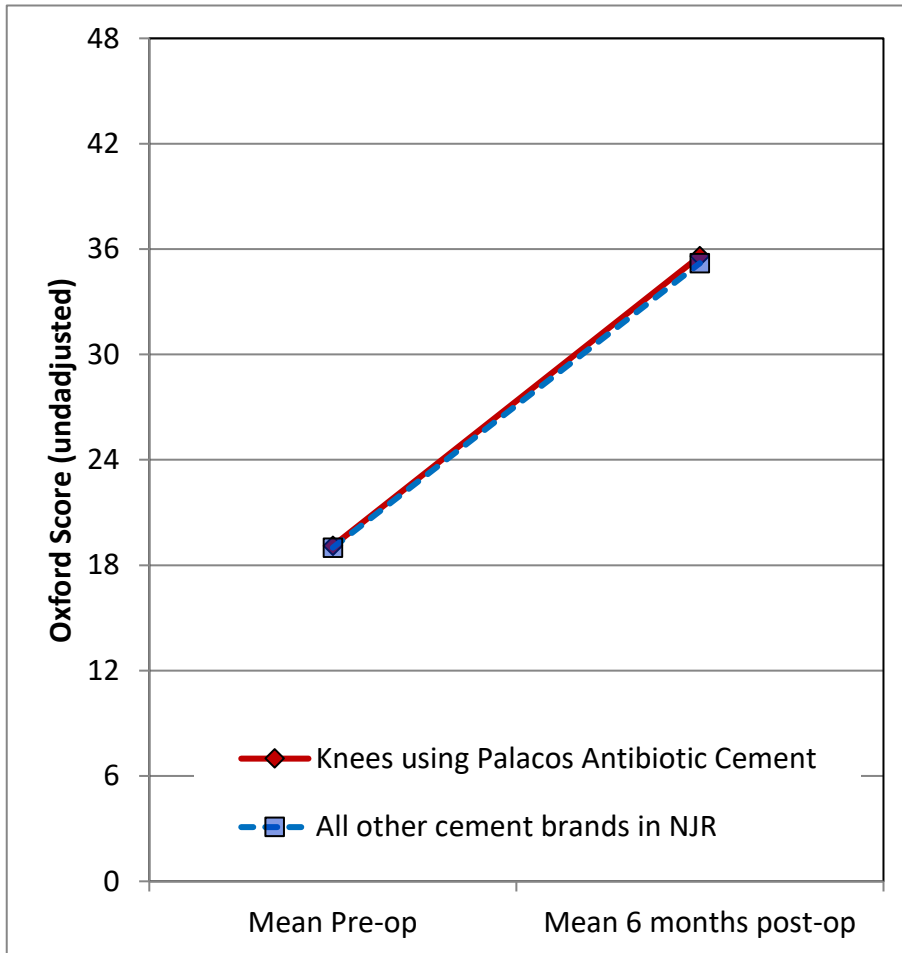
Summary Report for:

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	269,027	91,991	382,041
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 (35.2 - 35.3)	35.5 (35.5 - 35.5)
6 month score (adjusted)	35.6 (35.5 - 35.6)	35.3 (35.3 - 35.4)	35.5 (35.5 - 35.5)
Health gain	16.5 (16.4 - 16.5)	16.2 (16.1 - 16.3)	16.4 (16.4 - 16.4)
Health gain (adjusted)	16.5 (16.4 - 16.5)	16.2 (16.2 - 16.3)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	< 0.001		
Score Improved	94.1%	93.7%	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	249,782	85,161	354,541
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)	0.733 (0.731 - 0.735)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.741 (0.740 - 0.742)	0.735 (0.734 - 0.737)	0.739 (0.738 - 0.740)
Health gain	0.324 (0.322 - 0.325)	0.318 (0.316 - 0.320)	0.322 (0.321 - 0.323)
Health gain (adjusted)	0.323 (0.323 - 0.324)	0.318 (0.316 - 0.319)	0.322 (0.321 - 0.322)
p value (adjusted health gain)	< 0.001		
Score Improved	81.6%	80.9%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	239,150	81,995	340,151
PreOp score	68.0 (67.9 - 68.0)	68.0 (67.9 - 68.2)	68.0 (67.9 - 68.1)
6 month score	74.3 (74.2 - 74.4)	73.7 (73.6 - 73.8)	74.1 (74.1 - 74.2)
6 month score (adjusted)	74.3 (74.2 - 74.3)	73.8 (73.7 - 74.0)	74.1 (74.1 - 74.2)
Health gain	6.3 (6.3 - 6.4)	5.7 (5.6 - 5.8)	6.2 (6.1 - 6.2)
Health gain (adjusted)	6.3 (6.2 - 6.4)	5.9 (5.7 - 6.0)	6.2 (6.1 - 6.2)
p value (adjusted health gain)	< 0.001		
Score Improved	56.9%	55.3%	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

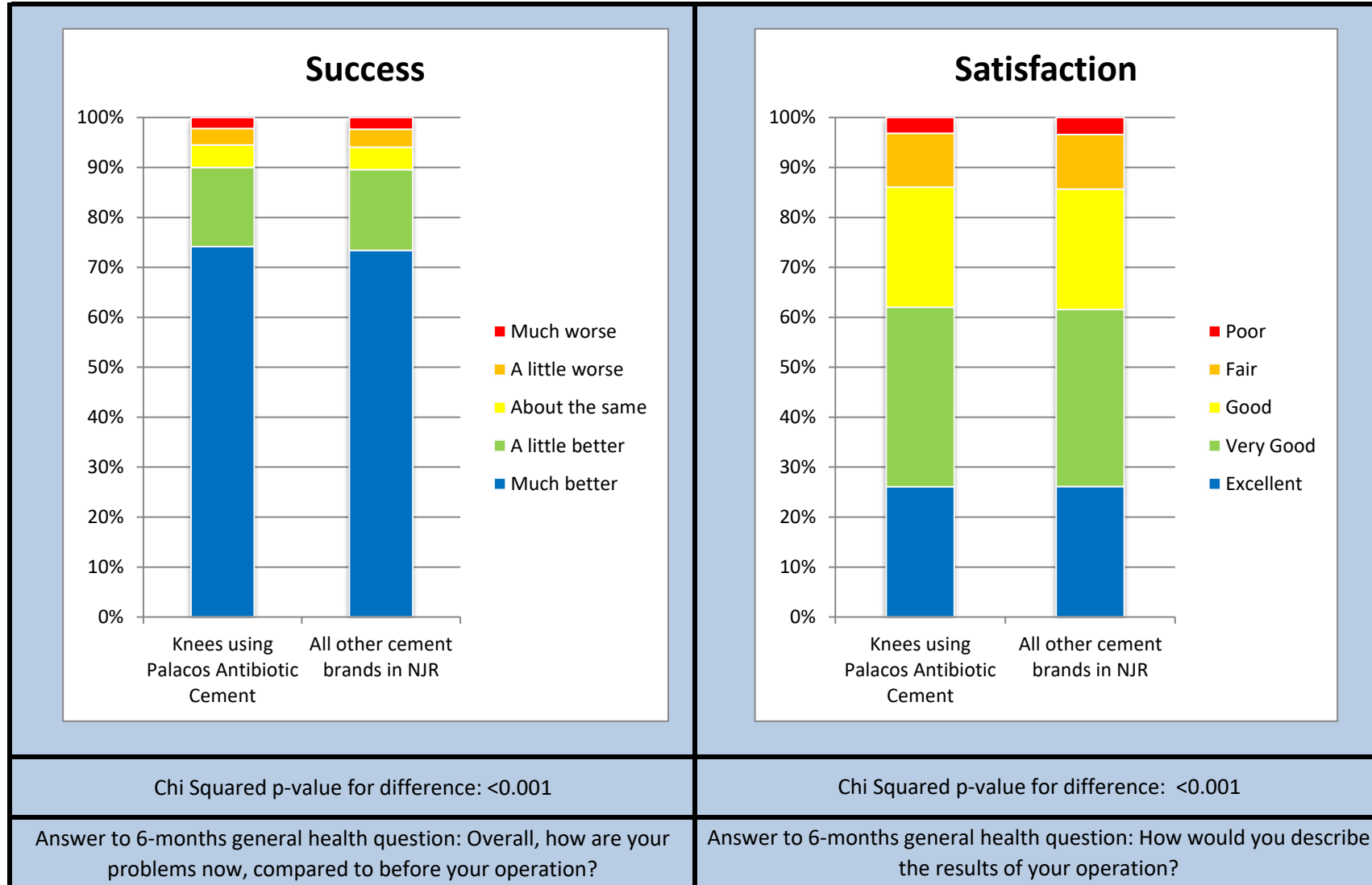


Summary Report for:

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	204586	69512
A little better	43740	15261
About the same	12299	4291
A little worse	9183	3377
Much worse	6037	2242

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	71794	24653
Very Good	99000	33493
Good	66078	22731
Fair	29739	10341
Poor	8712	3221

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	830049
66017771	PALACOS R +G 1x40 g	22974
66017772	PALACOS R +G 1x60 g	38687
66017773	PALACOS R +G 2x20 g	37365
66017776	PALACOS R +G 2x10 g	32
66017787	PALACOS LV +G 1x40 g	1860
66031993	PALACOS MV+G 1x40g	380
66031995	PALACOS MV+G 2x40 g	3112
66031996	PALACOS MV+G 1x20g	7
66031998	PALACOS MV+G 2x20 g	32
66032000	PALACOS MV+G 1x60 g	1
66037894	PALACOS LV+G 1x20g	2
66044274	PALACOS R+G Pro 75 cement	2
Multiple Found	Multiple Found	86802