

Implant Summary Report for:

Heraeus Medical

Knees using Palacos Antibiotic Cement

Comprising PRIMARY knees implanted up to: 30 May 2021
NJR Database extract: 29 July 2021

Produced on: 16 August 2021
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This report has been produced by the National Joint Registry of England, Wales and Northern Ireland (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

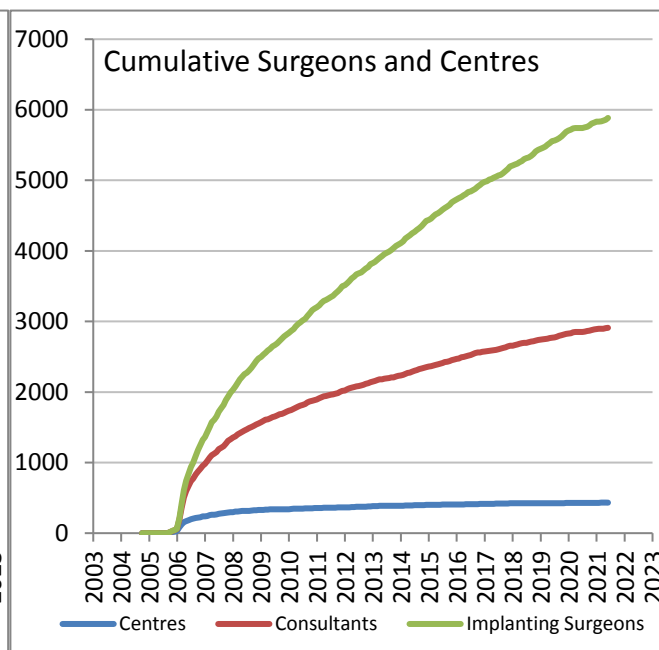
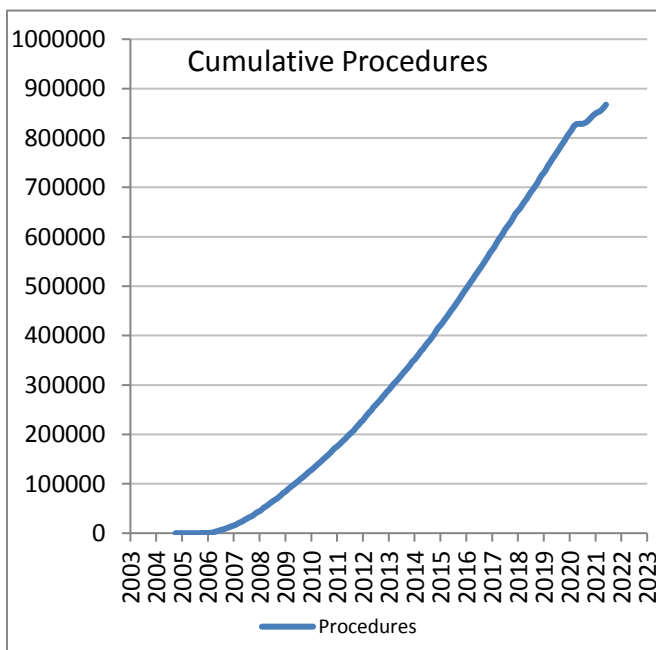
Date of first recorded usage in the NJR: **01 September 2005**

Date of last recorded usage in this dataset: **30 May 2021**

Maximum implantation time: 15.7 years

Mean implantation time: 6.0 years

Totals Recorded in NJR	Cumulative Total
Procedures	867,557
Patients	717,550
Centres	432
Consultants	2,910
Implanting Surgeons	5,884



Current Outcome	Year of implantation														Total	%
	Pre-2010	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021			
Death	45176	12544	12156	11501	9431	8500	6999	5402	3703	2358	1424	270	8	119472	13.8%	
Revised	5932	1912	1947	2049	2010	1955	1819	1500	1261	796	495	126	15	21817	2.5%	
Unrevised	76449	33189	39542	47111	50323	58557	65179	71593	74581	74251	78516	38669	18308	726268	83.7%	
Total	1E+05	47645	53645	60661	61764	69012	73997	78495	79545	77405	80435	39065	18331	867557	100%	

Patient / Procedure Details

Patient Details

	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Total Procedures	867,557	346,808
Total Patients	717,550	297,946
Demographics		
Mean age	69.5	69.7
< 50	2.2%	2.5%
50 – 59	12.9%	12.5%
60 – 69	32.5%	31.6%
70 – 79	37.3%	37.8%
≥ 80	15.1%	15.7%
Median BMI	30	30
% BMI information available	71.6%	59.9%
Underweight (BMI < 18.5)	0.2%	0.3%
Normal (18.5 ≤ BMI < 25)	10.1%	10.8%
Overweight (25 ≤ BMI < 30)	34.3%	34.8%
Obese I (30 ≤ BMI < 35)	32.6%	31.6%
Obese II (35 ≤ BMI < 40)	16.2%	16.0%
Obese III (BMI ≥ 40)	6.6%	6.6%
% Male	43.2%	42.8%
ASA Grades		
P1 - Fit and healthy	9.9%	12.4%
P2 - Mild disease not incapacitating	73.0%	70.8%
P3 - Incapacitating systemic disease	16.8%	16.5%
P4 / P5	0.3%	0.4%
Indications		
Osteoarthritis	97.55%	97.06%
Rheumatoid Arthritis	1.26%	1.68%
Other Inflammatory Arthropathy	0.66%	0.65%
Previous Trauma	0.62%	0.73%
Avascular Necrosis	0.39%	0.41%
Other	0.38%	0.46%

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	4706	4818.07	0.004
Progressive Arthritis Remaining	3384	3532.07	<0.001
Aseptic Loosening Femur	1797	1891.65	<0.001
Aseptic Loosening Tibia	3729	3781.16	0.17
Aseptic Loosening Patella	664	664.45	0.973
Unexplained Pain	3099	3141.44	0.203
Stiffness	1468	1493.77	0.237
Malalignment	1559	1607.41	0.038
Instability	3104	3208.05	0.002
Dislocation / Subluxation	684	730.58	0.004
Periprosthetic Fracture	813	823.23	0.549
Wear of Polyethylene Component	808	883.87	<0.001
Lysis - Tibia	797	835.40	0.036
Lysis - Femur	473	520.20	0.002
Component Dissociation	251	274.07	0.024
Implant Fracture	107	111.60	0.498
Other / Not recorded	1620	1635.88	0.499
Total Revised	21817	22307.49	<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

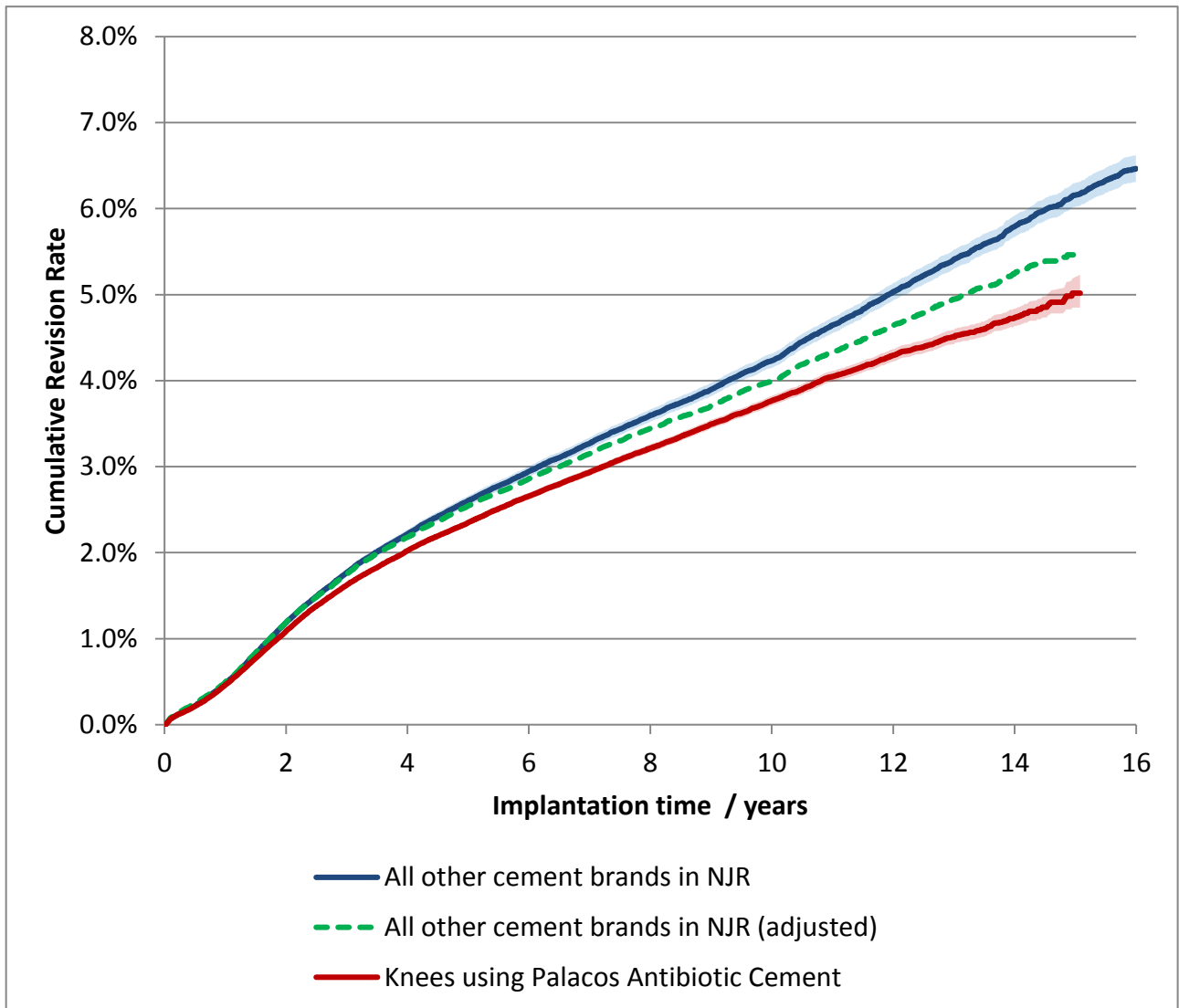


Components Revised	Number of procedures	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	15642	71.7%	79.1%
Isolated bearing exchange	2950	13.5%	10.1%
Patella revision / resurfacing only	3000	13.8%	10.2%
No component revision recorded	225	1.0%	0.7%

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.	0.92 (0.90 - 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	867557	-	-
1	817107	0.5% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)
2	739013	1.1% (1.1% - 1.1%)	1.2% (1.2% - 1.2%)
3	646708	1.6% (1.6% - 1.7%)	1.8% (1.7% - 1.8%)
4	559165	2.0% (2.0% - 2.1%)	2.2% (2.2% - 2.3%)
5	471081	2.4% (2.3% - 2.4%)	2.6% (2.5% - 2.7%)
6	389328	2.7% (2.6% - 2.7%)	2.9% (2.9% - 3.0%)
7	315469	2.9% (2.9% - 3.0%)	3.3% (3.2% - 3.3%)
8	251180	3.2% (3.2% - 3.3%)	3.6% (3.5% - 3.7%)
9	193417	3.5% (3.4% - 3.5%)	3.9% (3.8% - 4.0%)
10	140687	3.8% (3.7% - 3.8%)	4.2% (4.1% - 4.3%)
11	99424	4.0% (4.0% - 4.1%)	4.6% (4.6% - 4.7%)
12	64496	4.3% (4.2% - 4.4%)	5.0% (4.9% - 5.1%)
13	35399	4.5% (4.4% - 4.6%)	5.4% (5.3% - 5.5%)
14	14164	4.7% (4.6% - 4.8%)	5.8% (5.7% - 5.9%)
15	2427	5.0% (4.9% - 5.2%)	6.2% (6.0% - 6.3%)

Cumulative revision rate with 95% confidence intervals

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

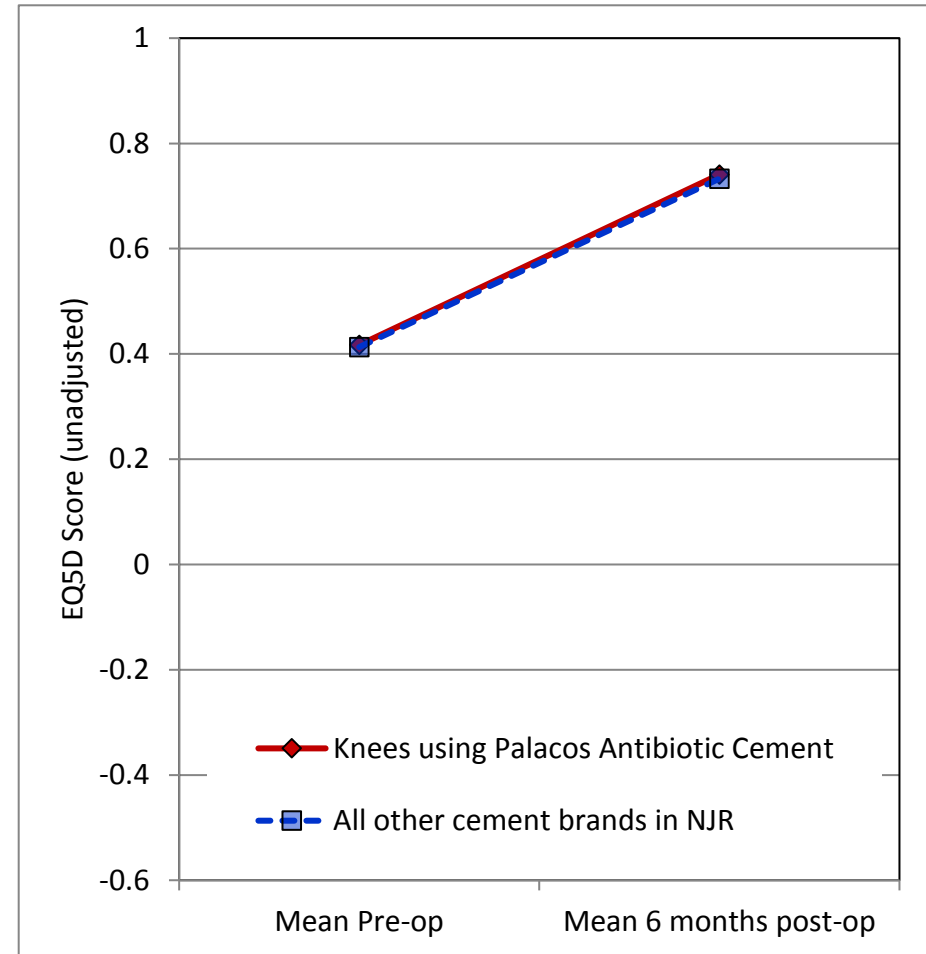
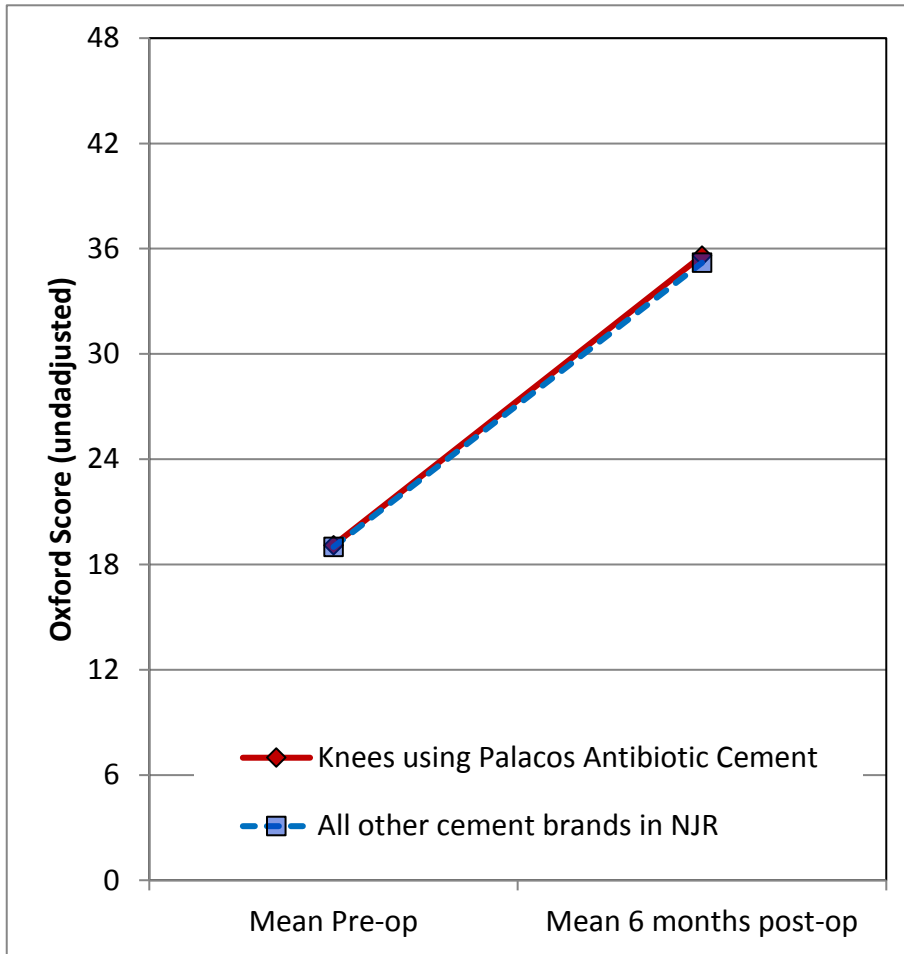
Summary Report for:

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	241,254	82,305	343,495
PreOp score	19.1 (19.1 - 19.1)	19.0 (18.9 - 19.0)	19.1 (19.1 - 19.1)
6 month score	35.6 (35.6 - 35.6)	35.2 (35.1 - 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 (16.5 - 16.5)	16.2 (16.2 - 16.3)	16.4 (16.4 - 16.4)
Health gain (adjusted)	16.5 (16.5 - 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	223,976	76,202	318,748
PreOp score	0.417 (0.416 - 0.418)	0.413 (0.411 - 0.416)	0.416 (0.415 - 0.417)
6 month score	0.741 (0.740 - 0.742)	0.733 (0.731 - 0.734)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.740 (0.739 - 0.741)	0.735 (0.733 - 0.737)	0.739 (0.738 - 0.739)
Health gain	0.324 (0.323 - 0.326)	0.319 (0.317 - 0.322)	0.322 (0.321 - 0.324)
Health gain (adjusted)	0.324 (0.323 - 0.325)	0.319 (0.317 - 0.320)	0.322 (0.322 - 0.323)
p value (adjusted health gain)	< 0.001		
Score Improved	81.6%	81.0%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	214,679	73,453	306,152
PreOp score	67.9 (67.8 - 67.9)	67.9 (67.8 - 68.1)	67.9 (67.8 - 68.0)
6 month score	74.3 (74.2 - 74.3)	73.7 (73.5 - 73.8)	74.1 (74.0 - 74.2)
6 month score (adjusted)	74.2 (74.2 - 74.3)	73.8 (73.7 - 73.9)	74.1 (74.0 - 74.2)
Health gain	6.4 (6.3 - 6.5)	5.7 (5.6 - 5.9)	6.2 (6.1 - 6.3)
Health gain (adjusted)	6.3 (6.3 - 6.4)	5.9 (5.8 - 6.0)	6.2 (6.1 - 6.3)
p value (adjusted health gain)	< 0.001		
Score Improved	57.0%	55.3%	56.5%

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

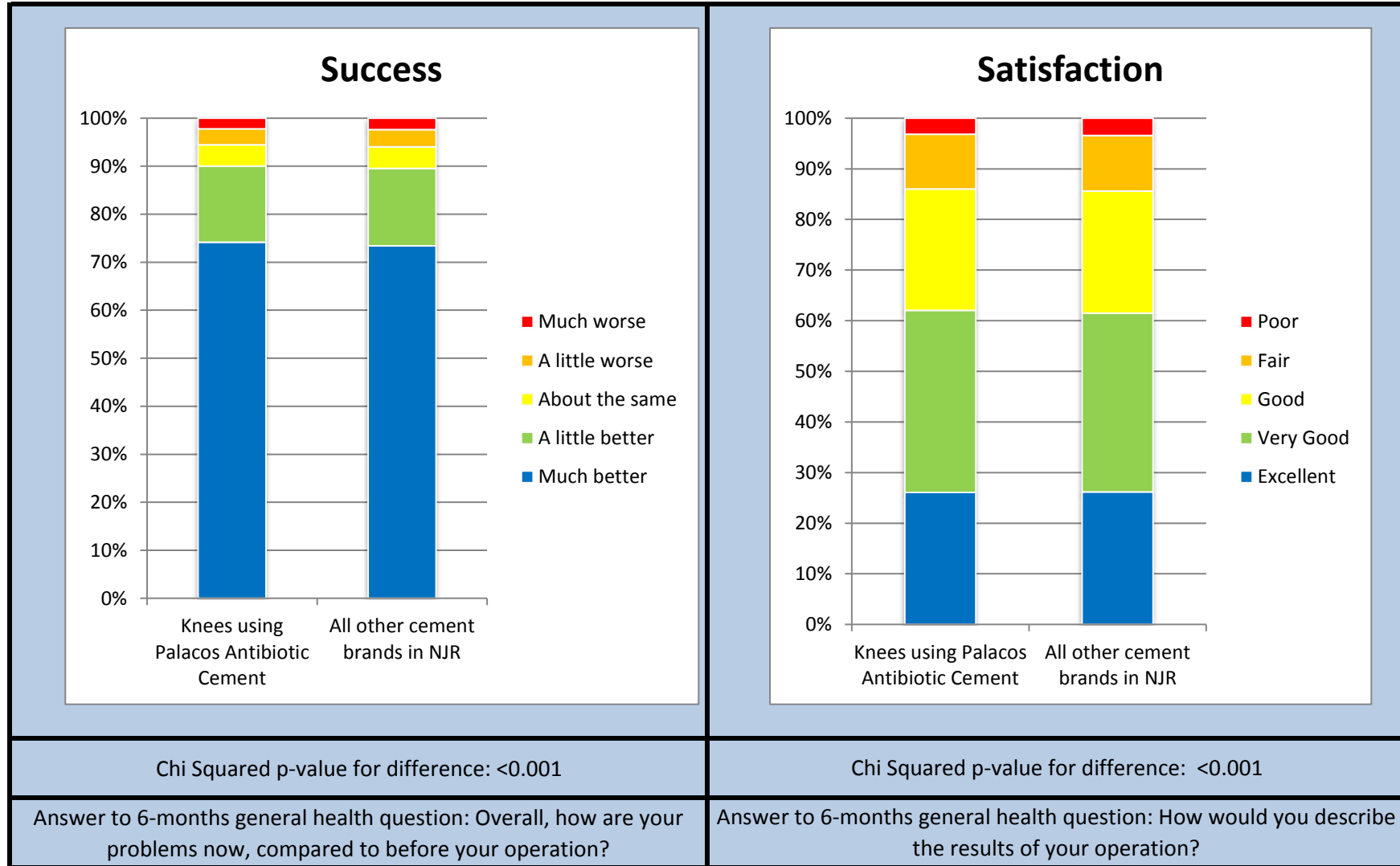
Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Knees using Palacos 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	183412	62131
A little better	39155	13658
About the same	11032	3826
A little worse	8192	3030
Much worse	5466	2006

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	64303	22086
Very Good	88804	29847
Good	59169	20374
Fair	26641	9246
Poor	7844	2895

Answer to 6-months general health question:

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

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Appendix A: Cement Components

Catalogue Number	Description	Number Implanted
66017569	Palacos R +G 2x40 g	702281
66017771	Palacos R +G 1x40 g	20404
66017772	Palacos R +G 1x60 g	31507
66017773	Palacos R +G 2x20 g	33348
66017776	Palacos R +G 2x10 g	30
66017783	Palamed G 1x20 g	6
66017787	Palacos LV +G 1x40 g	1807
66031993	PALACOS MV+G 1x40g	268
66031995	Palacos MV+G 2x40 g	2366
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	1
Multiple Found	Multiple Found	75497