

Implant Summary Report for:

Heraeus Medical

Knees using Palacos Antibiotic Cement

Comprising PRIMARY knees implanted up to:	10 December 2020
NJR Database extract:	08 February 2021
Produced on:	16 February 2021
Licensed for use until:	16 June 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

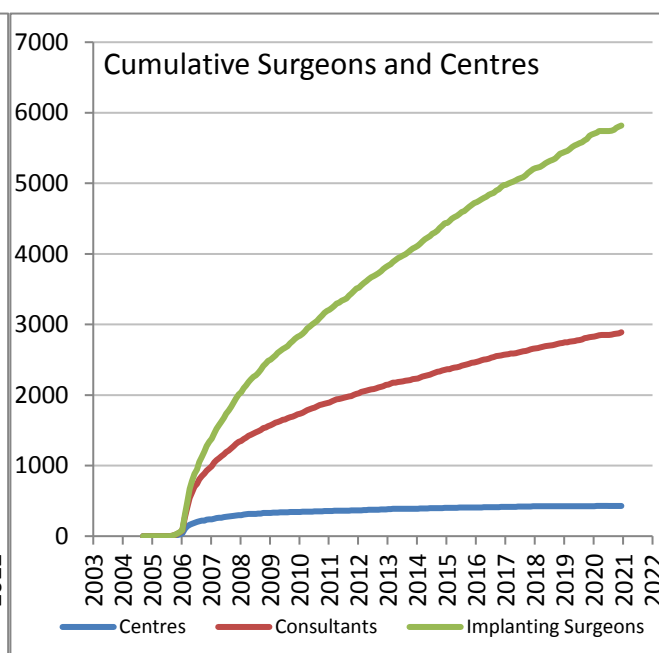
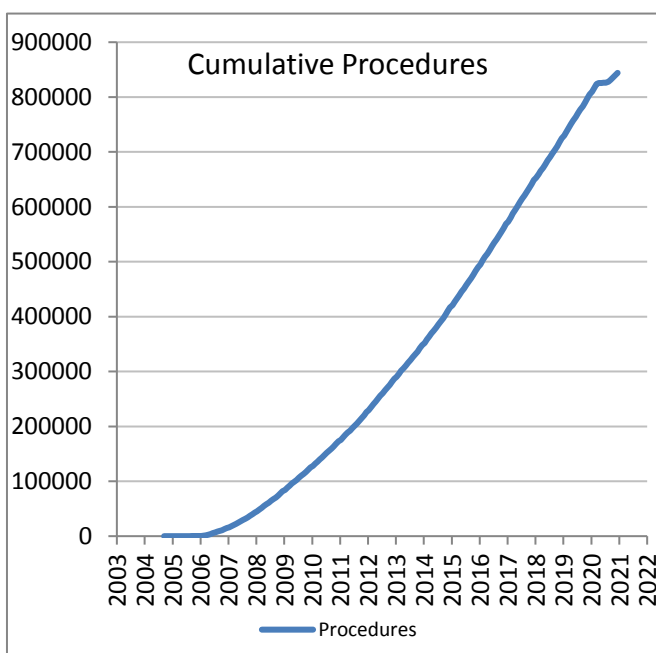
Date of first recorded usage in the NJR: **01 September 2005**

Date of last recorded usage in this dataset: **10 December 2020**

Maximum implantation time: 15.3 years

Mean implantation time: 5.7 years

Totals Recorded in NJR	Cumulative Total
Procedures	844,284
Patients	699,522
Centres	428
Consultants	2,889
Implanting Surgeons	5,819



Current Outcome	Year of implantation														Total	%
	Pre-2009	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020			
Death	30083	12036	11520	11011	10252	8262	7273	5865	4381	2838	1638	801	88	106048	12.6%	
Revised	3946	1874	1867	1915	2004	1962	1898	1745	1416	1168	671	381	73	20920	2.5%	
Unrevised	49460	29649	34237	40671	48356	51486	59792	66338	72635	75496	74466	78578	36152	717316	85.0%	
Total	83489	43559	47624	53597	60612	61710	68963	73948	78432	79502	76775	79760	36313	844284	100%	

Patient / Procedure Details

Patient Details

	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Total Procedures	844,284	340,042
Total Patients	699,522	292,305
Demographics		
Mean age	69.6	69.7
< 50	2.2%	2.5%
50 – 59	12.9%	12.5%
60 – 69	32.5%	31.6%
70 – 79	37.2%	37.7%
≥ 80	15.1%	15.7%
Median BMI	30	30
% BMI information available	71.4%	59.8%
Underweight (BMI < 18.5)	0.2%	0.3%
Normal (18.5 ≤ BMI < 25)	10.1%	10.8%
Overweight (25 ≤ BMI < 30)	34.3%	34.7%
Obese I (30 ≤ BMI < 35)	32.6%	31.6%
Obese II (35 ≤ BMI < 40)	16.2%	16.0%
Obese III (BMI ≥ 40)	6.6%	6.7%
% Male	43.1%	42.8%
ASA Grades		
P1 - Fit and healthy	10.0%	12.3%
P2 - Mild disease not incapacitating	73.0%	70.8%
P3 - Incapacitating systemic disease	16.7%	16.5%
P4 / P5	0.3%	0.4%
Indications		
Osteoarthritis	97.54%	97.08%
Rheumatoid Arthritis	1.27%	1.69%
Other Inflammatory Arthropathy	0.66%	0.64%
Previous Trauma	0.61%	0.73%
Avascular Necrosis	0.38%	0.41%
Other	0.38%	0.44%

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	4494	4605.47	0.003
Progressive Arthritis Remaining	3198	3341.04	<0.001
Aseptic Loosening Femur	1733	1810.30	0.005
Aseptic Loosening Tibia	3569	3610.99	0.259
Aseptic Loosening Patella	638	642.52	0.76
Unexplained Pain	3032	3076.86	0.179
Stiffness	1428	1452.45	0.252
Malalignment	1512	1563.68	0.024
Instability	2978	3084.25	0.001
Dislocation / Subluxation	659	705.26	0.004
Periprosthetic Fracture	740	751.35	0.493
Wear of Polyethylene Component	758	833.03	<0.001
Lysis - Tibia	757	787.13	0.09
Lysis - Femur	447	488.85	0.004
Component Dissociation	241	261.76	0.035
Implant Fracture	101	105.80	0.485
Other / Not recorded	1578	1588.93	0.638
Total Revised	20920	21391.44	<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

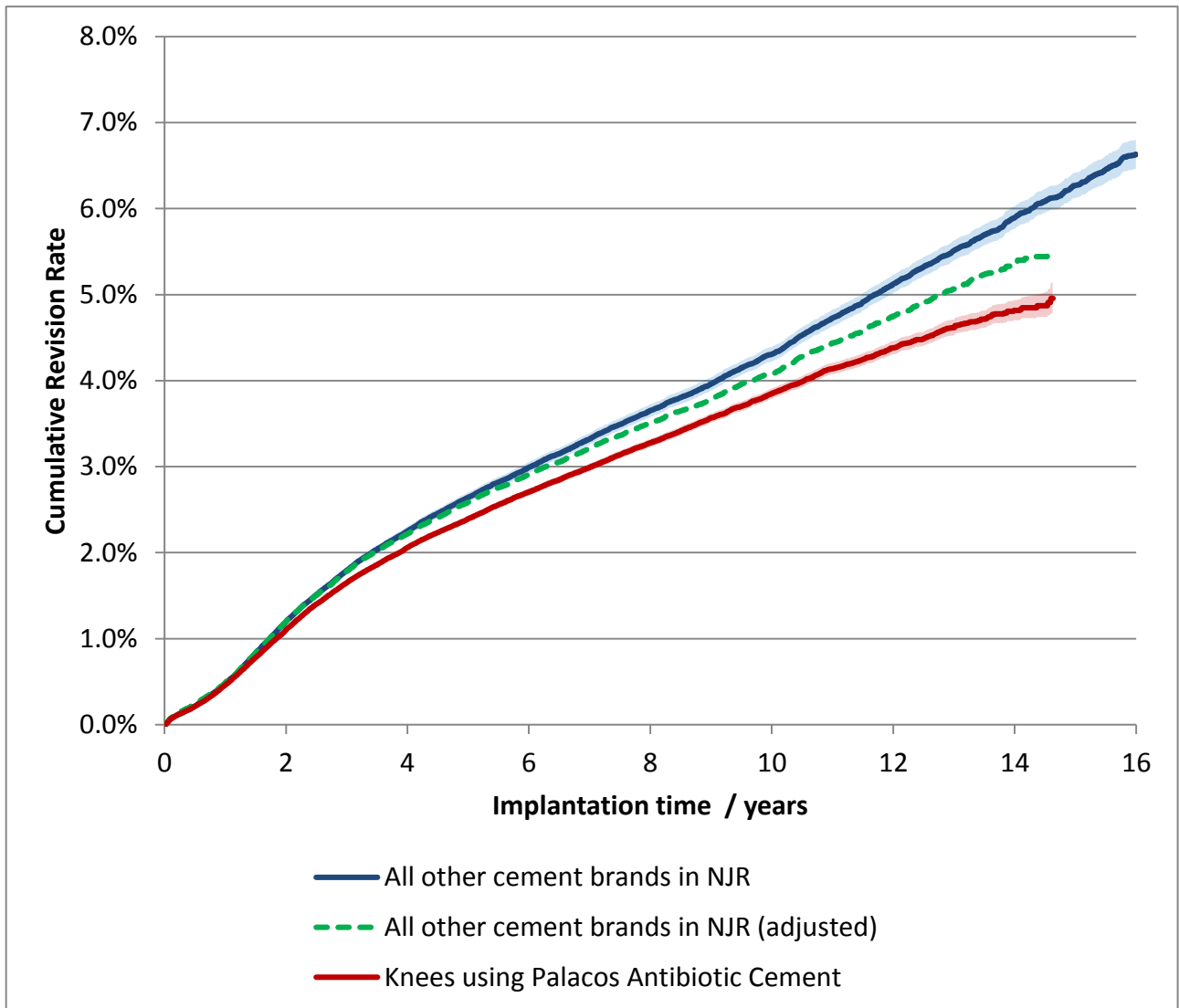


Components Revised	Number of procedures	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	14988	71.6%	79.0%
Isolated bearing exchange	2814	13.5%	10.0%
Patella revision / resurfacing only	2902	13.9%	10.3%
No component revision recorded	216	1.0%	0.7%

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.	0.93 (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	844284	-	-
1	794390	0.5% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)
2	701876	1.1% (1.1% - 1.1%)	1.2% (1.2% - 1.2%)
3	613723	1.7% (1.6% - 1.7%)	1.8% (1.7% - 1.8%)
4	524802	2.1% (2.0% - 2.1%)	2.2% (2.2% - 2.3%)
5	439062	2.4% (2.4% - 2.4%)	2.6% (2.6% - 2.7%)
6	360851	2.7% (2.7% - 2.7%)	3.0% (2.9% - 3.1%)
7	289973	3.0% (2.9% - 3.0%)	3.3% (3.3% - 3.4%)
8	228550	3.3% (3.2% - 3.3%)	3.7% (3.6% - 3.7%)
9	171512	3.6% (3.5% - 3.6%)	4.0% (3.9% - 4.0%)
10	124241	3.8% (3.8% - 3.9%)	4.3% (4.2% - 4.4%)
11	84796	4.1% (4.1% - 4.2%)	4.7% (4.6% - 4.8%)
12	51558	4.4% (4.3% - 4.5%)	5.1% (5.0% - 5.2%)
13	25171	4.6% (4.5% - 4.7%)	5.5% (5.4% - 5.6%)
14	7884	4.8% (4.7% - 4.9%)	5.9% (5.8% - 6.0%)
15		(-)	6.3% (6.1% - 6.4%)

Cumulative revision rate with 95% confidence intervals

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

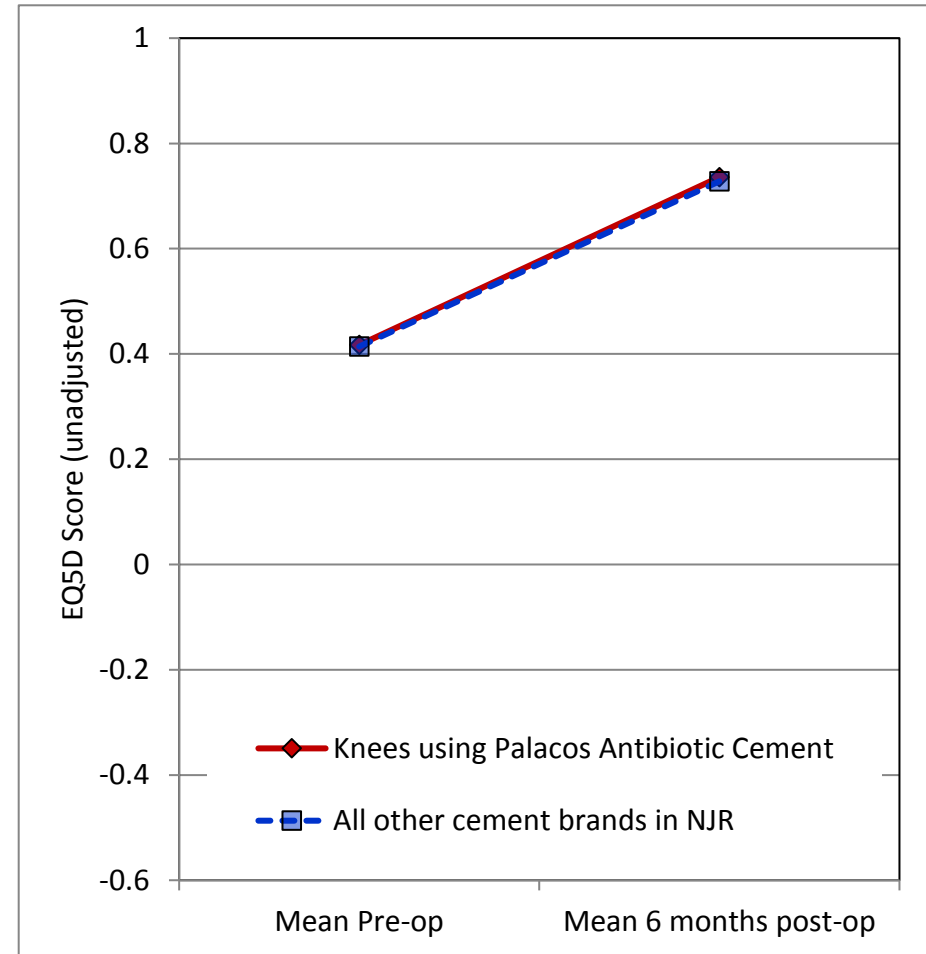
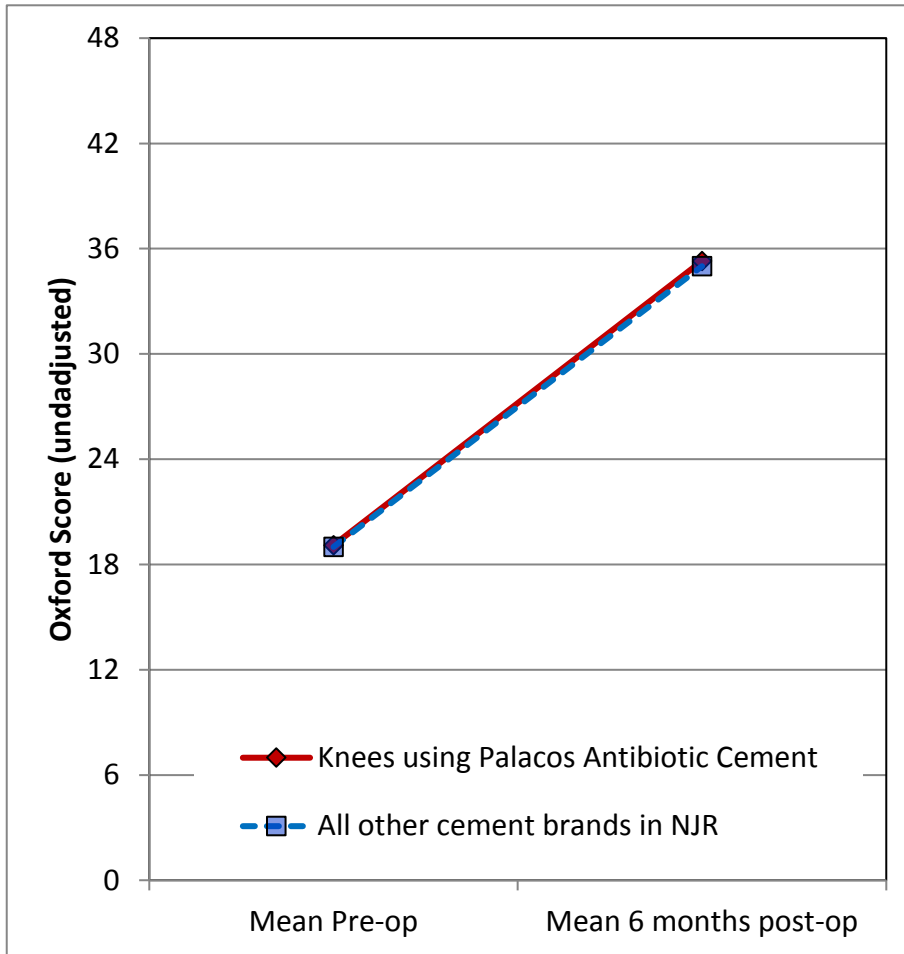
Summary Report for:

Knees using Palacos Antibiotic Cement

Patient Reported Outcomes

Comprising PROMs data up to and including: 19/05/2018

PROMs Analysis



Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 19/05/2018

Oxford Knee Score (0 - 48)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	218,327	78,394	313,694
PreOp score	19.1 (19.1 - 19.1)	19.0 (18.9 - 19.0)	19.1 (19.0 - 19.1)
6 month score	35.3 (35.3 - 35.3)	35.0 (34.9 - 35.0)	35.2 (35.1 - 35.2)
6 month score (adjusted)	35.3 (35.2 - 35.3)	35.0 (35.0 - 35.1)	35.2 (35.1 - 35.2)
Health gain	16.2 (16.2 - 16.2)	16.0 (15.9 - 16.0)	16.1 (16.1 - 16.1)
Health gain (adjusted)	16.2 (16.2 - 16.2)	16.0 (15.9 - 16.0)	16.1 (16.1 - 16.1)
p value (adjusted health gain)	< 0.001		
Score Improved	93.8%	93.4%	93.6%

EQ-5D Index (-0.59 - 1.00)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	201,918	72,345	289,980
PreOp score	0.417 (0.415 - 0.418)	0.414 (0.412 - 0.416)	0.416 (0.415 - 0.417)
6 month score	0.736 (0.735 - 0.737)	0.728 (0.726 - 0.730)	0.733 (0.732 - 0.734)
6 month score (adjusted)	0.736 (0.735 - 0.737)	0.730 (0.728 - 0.732)	0.733 (0.732 - 0.734)
Health gain	0.320 (0.318 - 0.321)	0.314 (0.312 - 0.317)	0.318 (0.316 - 0.319)
Health gain (adjusted)	0.320 (0.319 - 0.321)	0.314 (0.312 - 0.316)	0.318 (0.317 - 0.318)
p value (adjusted health gain)	< 0.001		
Score Improved	81.1%	80.5%	80.9%

EQ-VAS (0 - 100)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	192,419	69,305	276,892
PreOp score	68.0 (67.9 - 68.1)	68.1 (68.0 - 68.3)	68.0 (67.9 - 68.1)
6 month score	73.9 (73.8 - 74.0)	73.4 (73.2 - 73.5)	73.7 (73.6 - 73.8)
6 month score (adjusted)	73.9 (73.8 - 73.9)	73.4 (73.3 - 73.5)	73.7 (73.6 - 73.8)
Health gain	5.9 (5.8 - 6.0)	5.3 (5.1 - 5.4)	5.7 (5.6 - 5.8)
Health gain (adjusted)	5.9 (5.8 - 5.9)	5.4 (5.3 - 5.5)	5.7 (5.6 - 5.8)
p value (adjusted health gain)	< 0.001		
Score Improved	56.0%	54.3%	55.5%

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

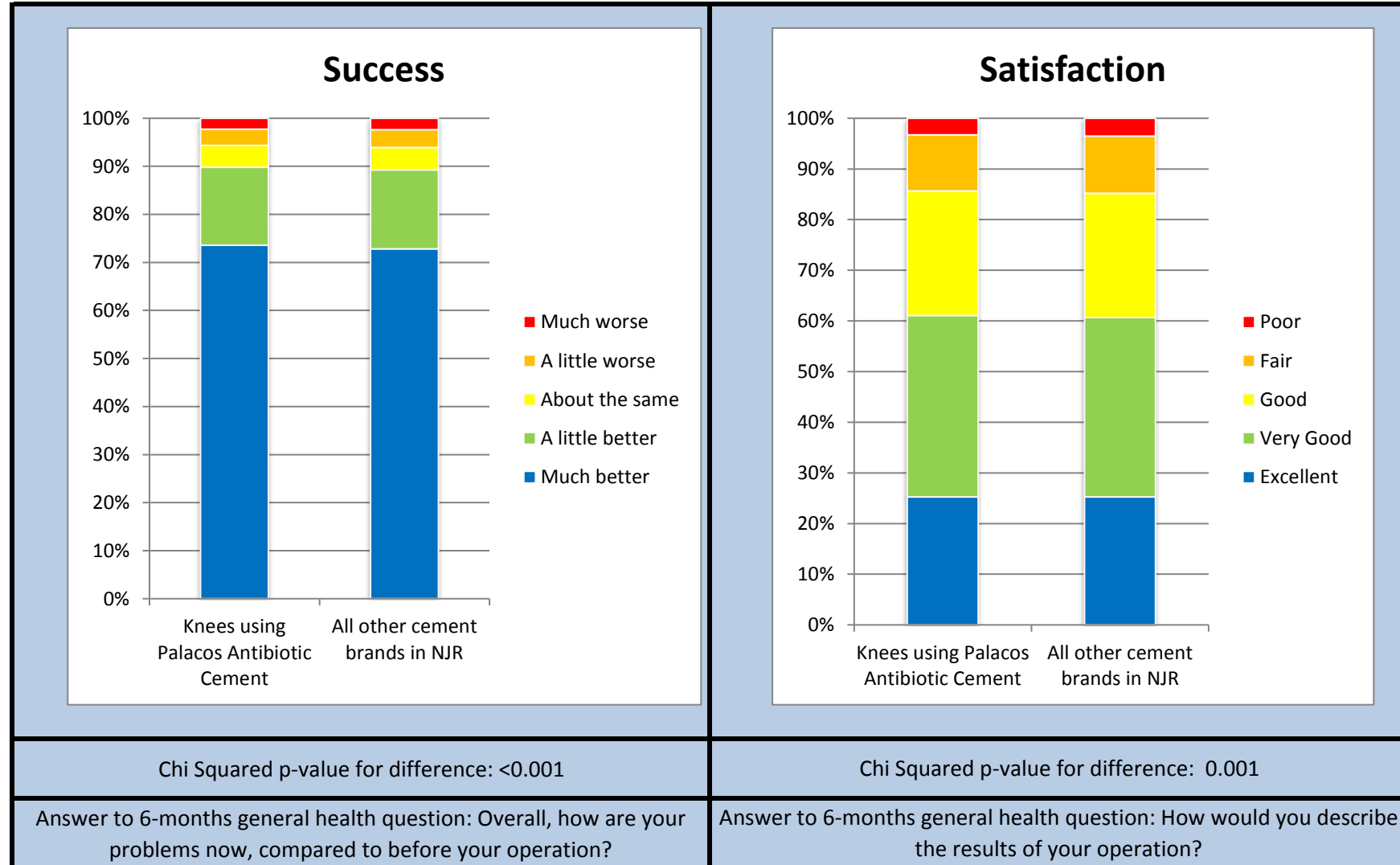
Figures in parentheses represent the 95% confidence interval for the mean

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	164791	58795
A little better	36363	13297
About the same	10177	3742
A little worse	7636	2967
Much worse	5035	1938

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	56438	20341
Very Good	80113	28503
Good	54886	19765
Fair	24820	9066
Poor	7278	2844

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	683125
66017771	Palacos R +G 1x40 g	19883
66017772	Palacos R +G 1x60 g	30432
66017773	Palacos R +G 2x20 g	32664
66017776	Palacos R +G 2x10 g	30
66017783	Palamed G 1x20 g	6
66017787	Palacos LV +G 1x40 g	1796
66031993	PALACOS MV+G 1x40g	246
66031995	Palacos MV+G 2x40 g	2287
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	73772