

Implant Summary Report for:

Heraeus Medical

Knees using Palacos 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 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

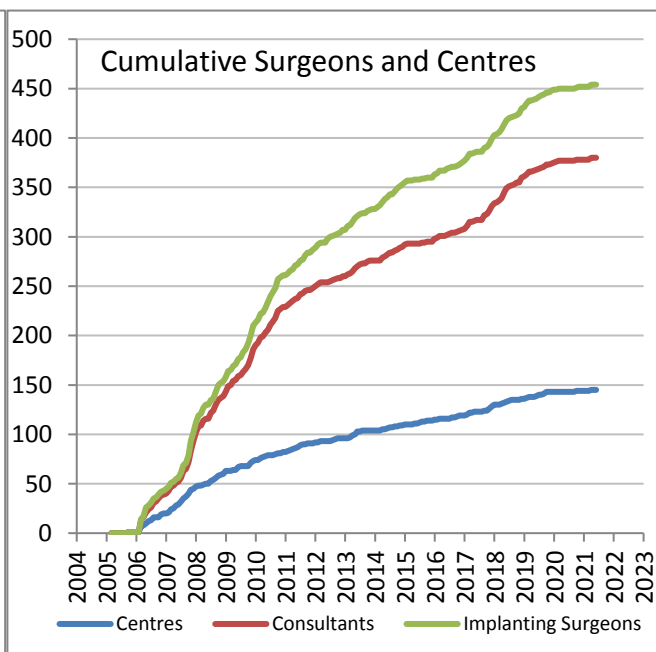
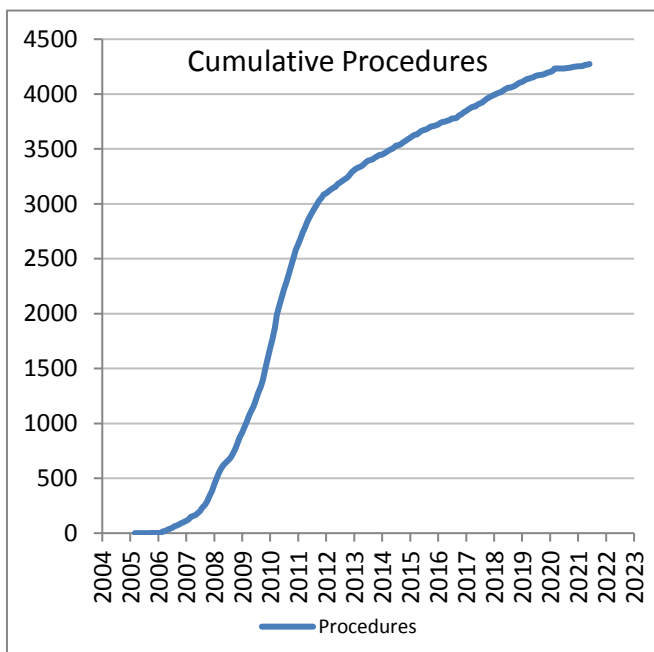
Date of first recorded usage in the NJR: **26 September 2005**

Date of last recorded usage in this dataset: **17 May 2021**

Maximum implantation time: 15.3 years

Mean implantation time: 8.5 years

Totals Recorded in NJR	Cumulative Total
Procedures	4,274
Patients	3,989
Centres	145
Consultants	380
Implanting Surgeons	454



Current Outcome	Year of implantation														Total	%
	Pre-2010	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021			
Death	597	254	115	38	30	28	18	10	10	4	3	0	0	1107	25.9%	
Revised	101	52	21	12	6	6	8	8	7	4	2	0	0	227	5.3%	
Unrevised	990	637	329	160	107	119	97	103	127	113	86	52	20	2940	68.8%	
Total	1688	943	465	210	143	153	123	121	144	121	91	52	20	4274	100%	

Patient / Procedure Details

Patient Details

	Knees using Palacos Cement	All other cement brands in NJR
Total Procedures	4,274	1,210,091
Total Patients	3,989	983,111
Demographics		
Mean age	70.4	69.6
< 50	2.1%	2.3%
50 – 59	11.0%	12.8%
60 – 69	31.4%	32.2%
70 – 79	37.0%	37.4%
≥ 80	18.5%	15.3%
Median BMI	30	30
% BMI information available	48.6%	68.4%
Underweight (BMI < 18.5)	0.4%	0.2%
Normal (18.5 ≤ BMI < 25)	11.8%	10.3%
Overweight (25 ≤ BMI < 30)	34.2%	34.4%
Obese I (30 ≤ BMI < 35)	28.9%	32.3%
Obese II (35 ≤ BMI < 40)	16.8%	16.1%
Obese III (BMI ≥ 40)	7.9%	6.6%
% Male	42.2%	43.1%
ASA Grades		
P1 - Fit and healthy	11.3%	10.6%
P2 - Mild disease not incapacitating	70.3%	72.3%
P3 - Incapacitating systemic disease	17.9%	16.7%
P4 / P5	0.5%	0.3%
Indications		
Osteoarthritis	97.85%	97.41%
Rheumatoid Arthritis	1.22%	1.38%
Other Inflammatory Arthropathy	0.56%	0.66%
Previous Trauma	0.75%	0.65%
Avascular Necrosis	0.35%	0.40%
Other	0.33%	0.40%

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	67	27.96	<0.001
Progressive Arthritis Remaining	15	25.24	0.045
Aseptic Loosening Femur	29	15.63	0.002
Aseptic Loosening Tibia	37	27.94	0.088
Aseptic Loosening Patella	1	5.03	0.072
Unexplained Pain	27	24.24	0.541
Stiffness	10	9.04	0.737
Malalignment	23	10.68	<0.001
Instability	33	21.49	0.017
Dislocation / Subluxation	5	5.09	1
Periprosthetic Fracture	14	5.81	0.003
Wear of Polyethylene Component	6	8.17	0.597
Lysis - Tibia	15	6.35	0.002
Lysis - Femur	5	4.25	0.623
Component Dissociation	3	2.05	0.465
Implant Fracture	0	0.85	1
Other / Not recorded	11	11.78	1
Total Revised	227	152.82	<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

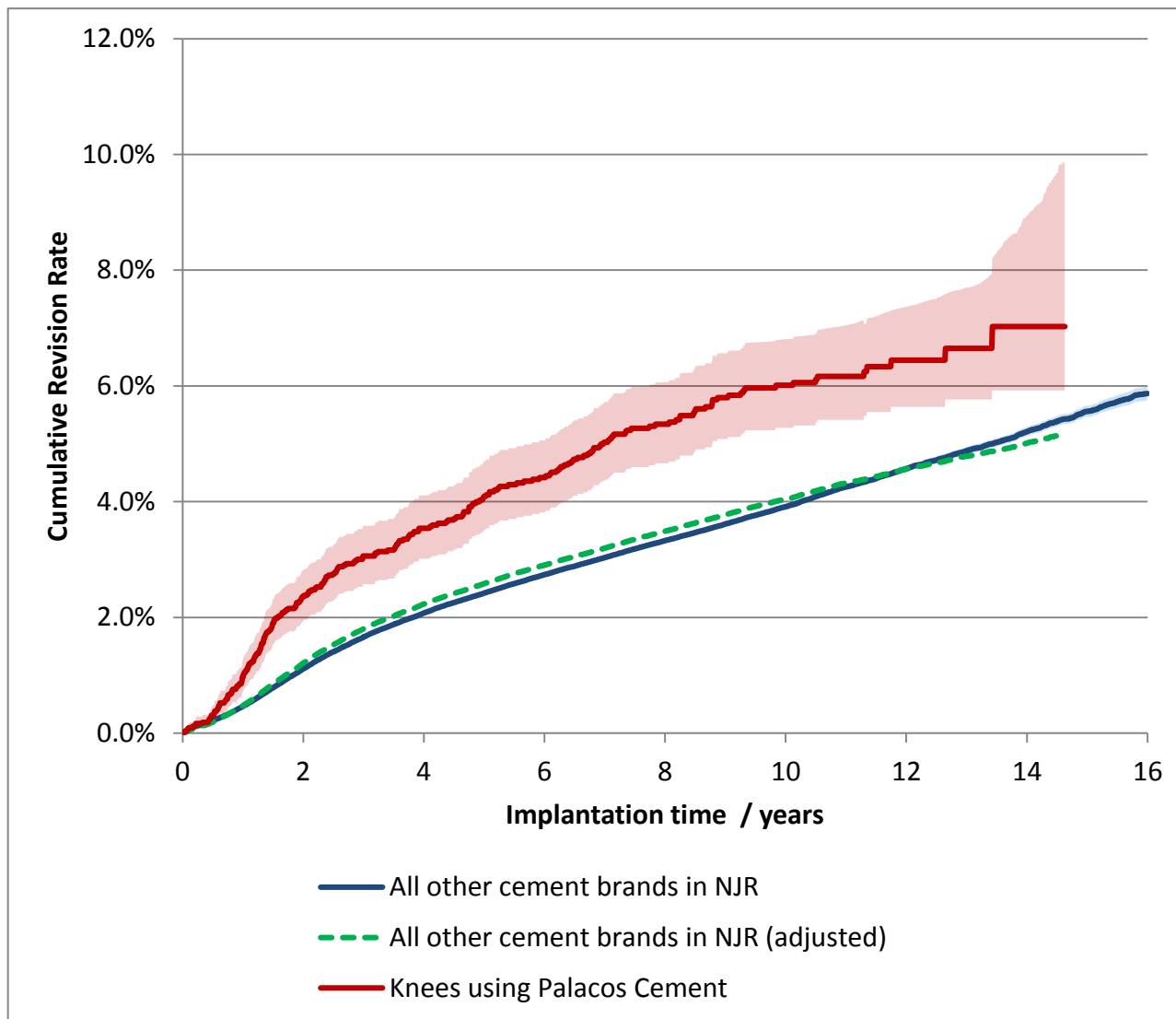
Significantly better, $p < 0.001$ Significantly better, $p < 0.05$ Significantly worse $p < 0.05$ Significantly worse $p < 0.001$ 

Components Revised	Number of procedures	Knees using Palacos Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	189	83.3%	74.3%
Isolated bearing exchange	21	9.3%	12.3%
Patella revision / resurfacing only	16	7.0%	12.5%
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 ‡ (1.34 - 1.74)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	1.49 (1.31 - 1.70)	<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	4274	-	-
1	4143	1.0% (0.7% - 1.3%)	0.5% (0.5% - 0.5%)
2	3952	2.4% (1.9% - 2.8%)	1.1% (1.1% - 1.1%)
3	3748	3.1% (2.6% - 3.6%)	1.7% (1.6% - 1.7%)
4	3511	3.5% (3.0% - 4.1%)	2.1% (2.0% - 2.1%)
5	3268	4.1% (3.5% - 4.7%)	2.4% (2.4% - 2.5%)
6	3077	4.4% (3.8% - 5.1%)	2.7% (2.7% - 2.8%)
7	2827	5.0% (4.4% - 5.7%)	3.0% (3.0% - 3.1%)
8	2603	5.3% (4.7% - 6.1%)	3.3% (3.3% - 3.4%)
9	2340	5.8% (5.1% - 6.6%)	3.6% (3.6% - 3.7%)
10	1992	6.0% (5.3% - 6.8%)	3.9% (3.9% - 4.0%)
11	1414	6.2% (5.4% - 7.0%)	4.3% (4.2% - 4.3%)
12	709	6.4% (5.6% - 7.4%)	4.6% (4.5% - 4.6%)
13	374	6.6% (5.8% - 7.7%)	4.9% (4.8% - 4.9%)
14	94	7.0% (5.9% - 8.9%)	5.2% (5.1% - 5.3%)
15		(-)	5.6% (5.5% - 5.7%)

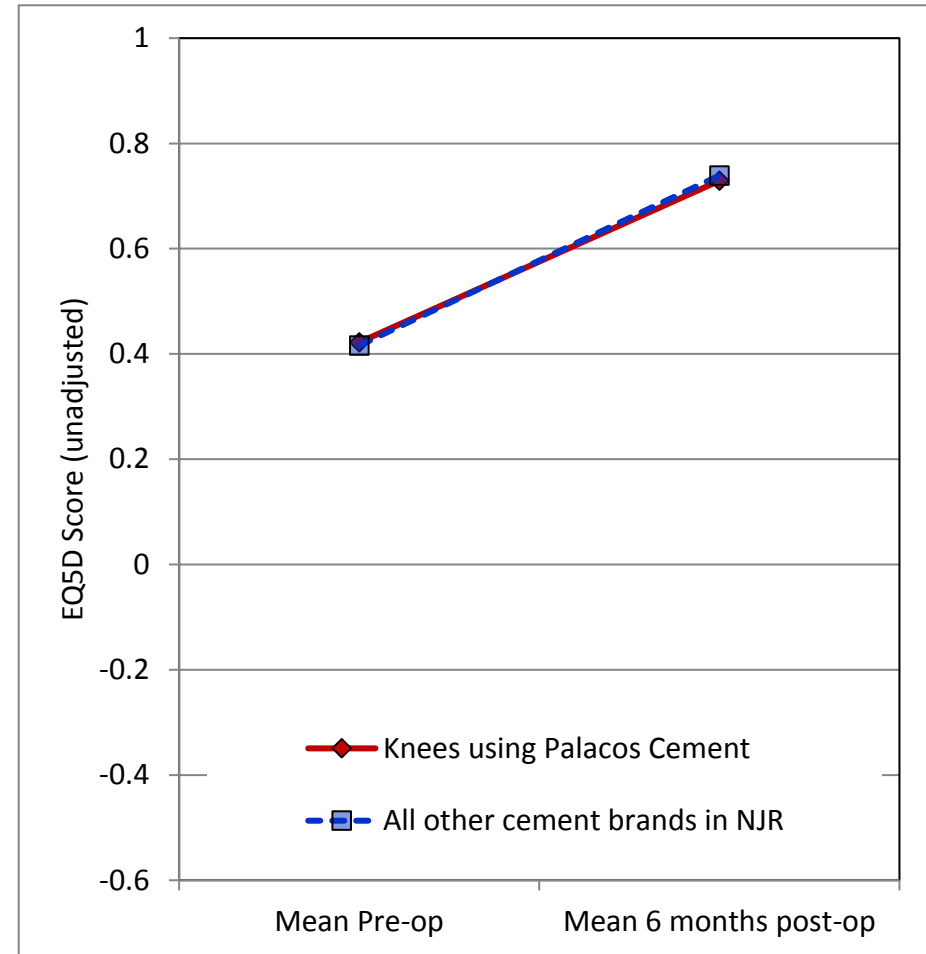
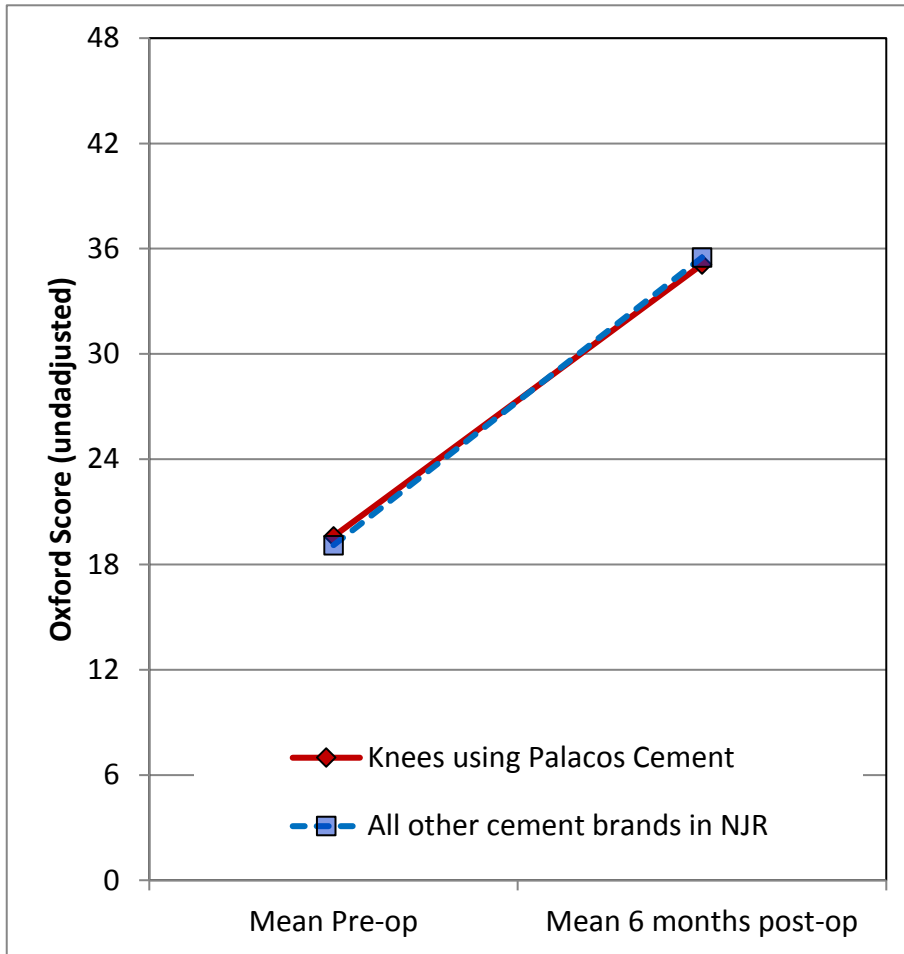
Cumulative revision rate with 95% confidence intervals

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

Patient Reported Outcomes

Comprising PROMs data up to and including: 31/12/2020

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 Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	1,050	322,509	343,495
PreOp score	19.6 (19.1 - 20.1)	19.1 (19.0 - 19.1)	19.1 (19.1 - 19.1)
6 month score	35.1 (34.5 - 35.7)	35.5 (35.5 - 35.5)	35.5 (35.5 - 35.5)
6 month score (adjusted)	34.8 (34.3 - 35.3)	35.5 (35.5 - 35.5)	35.5 (35.5 - 35.5)
Health gain	15.5 (14.9 - 16.0)	16.4 (16.4 - 16.5)	16.4 (16.4 - 16.4)
Health gain (adjusted)	15.7 (15.2 - 16.2)	16.4 (16.4 - 16.5)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	0.003		
Score Improved	93.0%	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	954	299,224	318,748
PreOp score	0.422 (0.402 - 0.442)	0.416 (0.415 - 0.417)	0.416 (0.415 - 0.417)
6 month score	0.729 (0.712 - 0.746)	0.739 (0.738 - 0.740)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.723 (0.708 - 0.737)	0.739 (0.738 - 0.740)	0.739 (0.738 - 0.739)
Health gain	0.307 (0.286 - 0.327)	0.323 (0.322 - 0.324)	0.322 (0.321 - 0.324)
Health gain (adjusted)	0.307 (0.292 - 0.321)	0.323 (0.322 - 0.324)	0.322 (0.322 - 0.323)
p value (adjusted health gain)	0.047		
Score Improved	81.2%	81.5%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	910	287,222	306,152
PreOp score	69.1 (67.8 - 70.4)	67.9 (67.8 - 68.0)	67.9 (67.8 - 68.0)
6 month score	72.5 (71.2 - 73.8)	74.1 (74.0 - 74.2)	74.1 (74.0 - 74.2)
6 month score (adjusted)	72.1 (70.9 - 73.2)	74.1 (74.1 - 74.2)	74.1 (74.0 - 74.2)
Health gain	3.5 (2.0 - 4.9)	6.2 (6.2 - 6.3)	6.2 (6.1 - 6.3)
Health gain (adjusted)	4.2 (3.0 - 5.3)	6.2 (6.2 - 6.3)	6.2 (6.1 - 6.3)
p value (adjusted health gain)	< 0.001		
Score Improved	50.1%	56.6%	56.5%

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

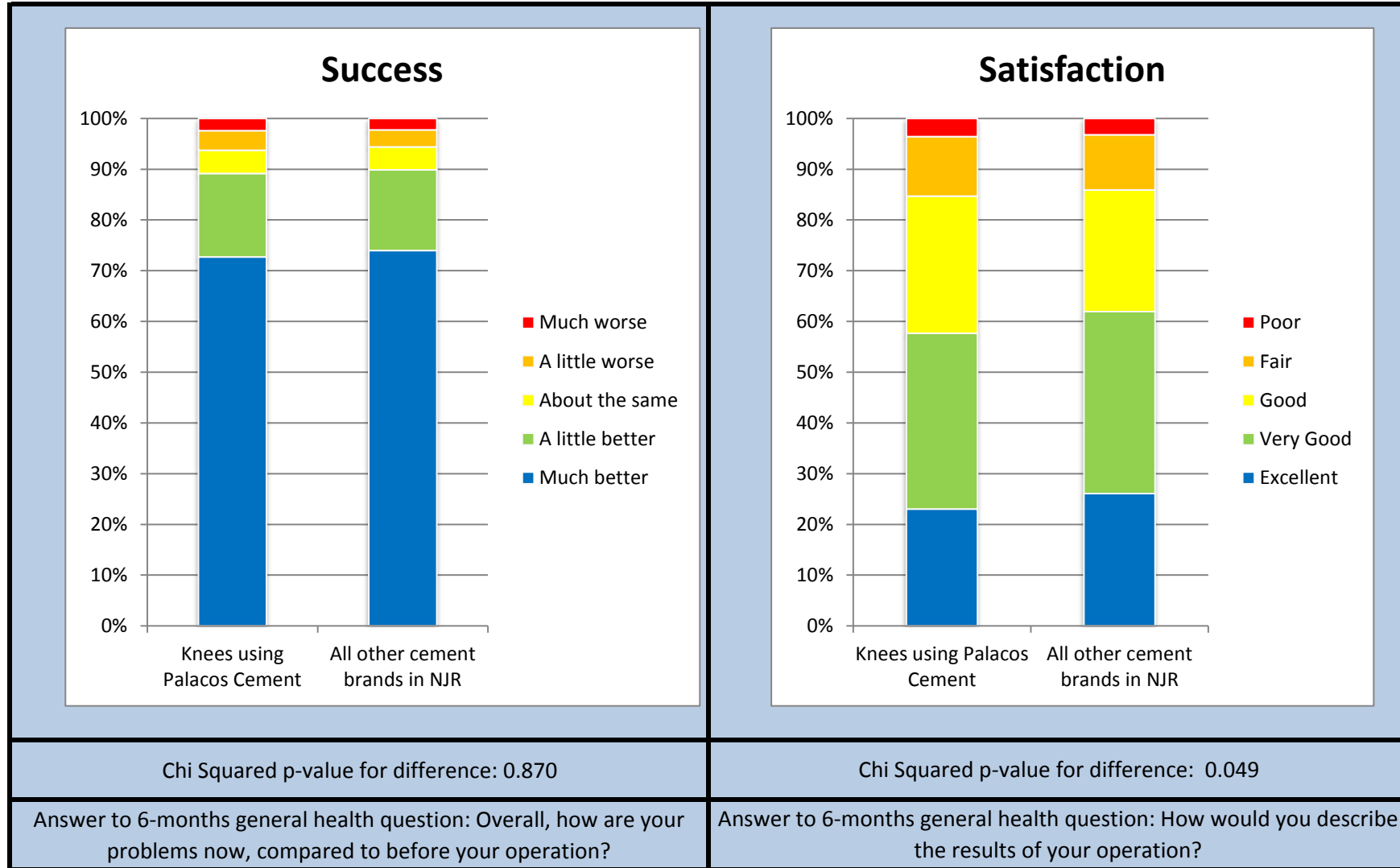
Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Knees using Palacos Cement

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Knees using Palacos Cement	All other cement brands in NJR
Much better	778	244765
A little better	176	52637
About the same	49	14809
A little worse	41	11181
Much worse	26	7446

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	245	86144
Very Good	369	118282
Good	288	79255
Fair	125	35762
Poor	38	10701

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
66017777	Palacos R 2x40 g	3644
66017778	Palacos R 1x40 g	111
66017784	Palamed 2x40 g	68
66017786	Palamed 1x40 g	20
66017788	Palacos LV 1x40 g	13
66031982	Palacos MV 1x40 g	412
66031984	PALACOS MV plain 2x40g	2
66037893	PALACOS LV 1x20g	1
Multiple Found	Multiple Found	3