

Implant Summary Report for:

Heraeus Medical

Knees using Palacos 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 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

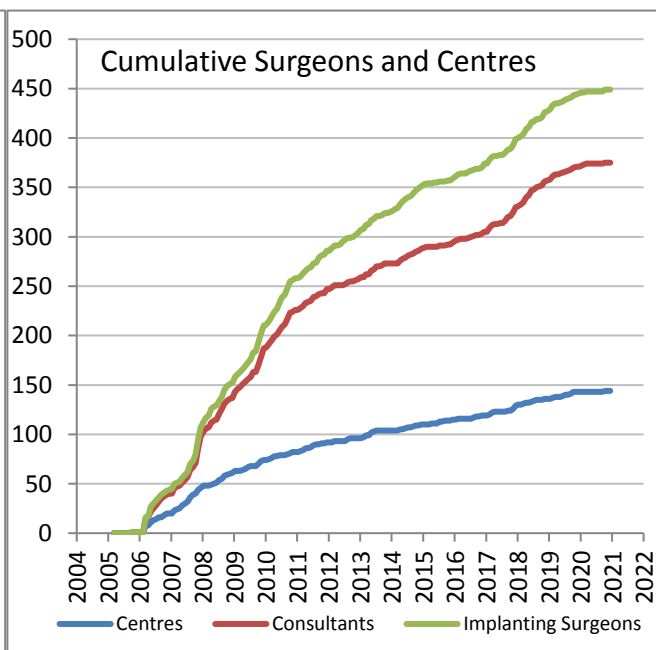
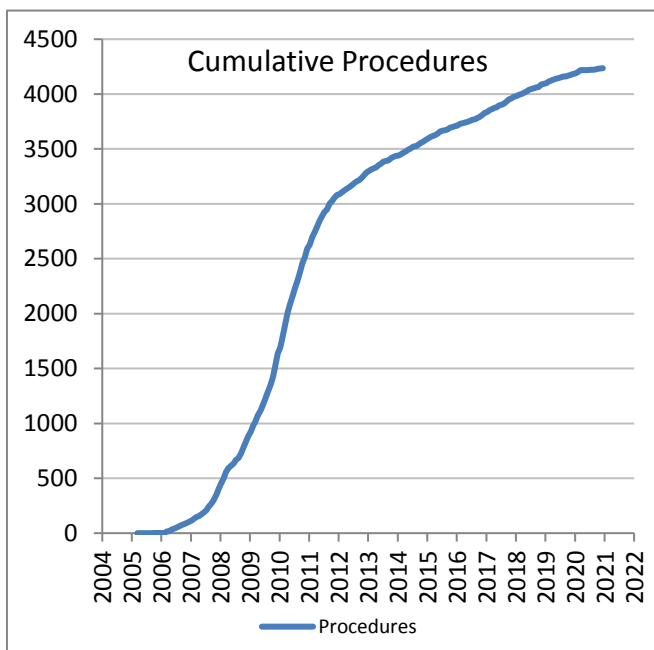
Date of first recorded usage in the NJR: **26 September 2005**

Date of last recorded usage in this dataset: **01 December 2020**

Maximum implantation time: 14.8 years

Mean implantation time: 8.2 years

Totals Recorded in NJR	Cumulative Total
Procedures	4,236
Patients	3,953
Centres	144
Consultants	375
Implanting Surgeons	449



Current Outcome	Year of implantation														Total	%
	Pre-2009	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020			
Death	329	229	233	101	33	29	26	13	9	9	4	0	0	1015	24.0%	
Revised	53	48	52	21	12	6	6	8	7	5	4	2	0	224	5.3%	
Unrevised	528	490	658	342	165	108	121	102	105	130	112	89	47	2997	70.8%	
Total	910	767	943	464	210	143	153	123	121	144	120	91	47	4236	100%	

Patient / Procedure Details

Patient Details

	Knees using Palacos Cement	All other cement brands in NJR
Total Procedures	4,236	1,180,090
Total Patients	3,953	960,416
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	48.4%	68.2%
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)	16.6%	16.1%
Obese III (BMI ≥ 40)	8.0%	6.6%
% Male	42.2%	43.0%
ASA Grades		
P1 - Fit and healthy	11.2%	10.6%
P2 - Mild disease not incapacitating	70.4%	72.4%
P3 - Incapacitating systemic disease	17.9%	16.7%
P4 / P5	0.5%	0.3%
Indications		
Osteoarthritis	97.88%	97.41%
Rheumatoid Arthritis	1.18%	1.39%
Other Inflammatory Arthropathy	0.52%	0.66%
Previous Trauma	0.73%	0.64%
Avascular Necrosis	0.35%	0.39%
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	66	27.44	<0.001
Progressive Arthritis Remaining	15	24.17	0.065
Aseptic Loosening Femur	28	15.20	0.003
Aseptic Loosening Tibia	37	27.29	0.068
Aseptic Loosening Patella	1	4.91	0.105
Unexplained Pain	27	23.99	0.538
Stiffness	10	8.92	0.616
Malalignment	22	10.59	0.002
Instability	32	21.06	0.021
Dislocation / Subluxation	4	4.93	1
Periprosthetic Fracture	14	5.44	0.001
Wear of Polyethylene Component	6	7.73	0.717
Lysis - Tibia	15	6.11	0.002
Lysis - Femur	5	4.07	0.612
Component Dissociation	3	2.00	0.458
Implant Fracture	0	0.80	1
Other / Not recorded	11	11.60	1
Total Revised	224	149.02	<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

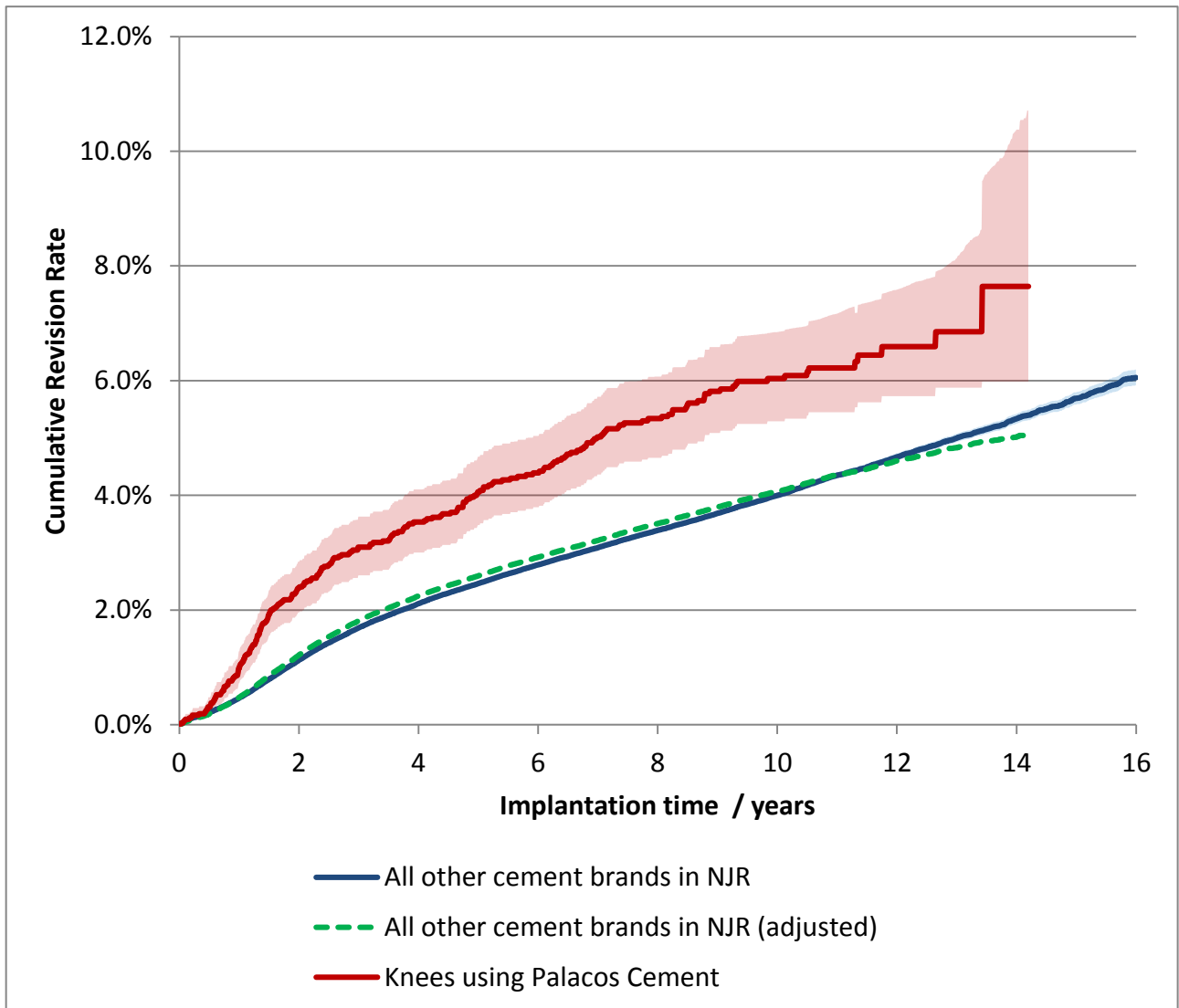


Components Revised	Number of procedures	Knees using Palacos Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	186	83.0%	74.2%
Isolated bearing exchange	21	9.4%	12.2%
Patella revision / resurfacing only	16	7.1%	12.6%
No component revision recorded	1	0.4%	0.9%

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 - 1.75)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	1.51 (1.32 - 1.72)	<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	4236	-	-
1	4096	1.0% (0.7% - 1.3%)	0.5% (0.5% - 0.5%)
2	3894	2.4% (2.0% - 2.8%)	1.1% (1.1% - 1.1%)
3	3683	3.1% (2.6% - 3.6%)	1.7% (1.7% - 1.7%)
4	3444	3.5% (3.0% - 4.1%)	2.1% (2.1% - 2.1%)
5	3224	4.1% (3.5% - 4.7%)	2.5% (2.4% - 2.5%)
6	3008	4.4% (3.8% - 5.0%)	2.8% (2.8% - 2.8%)
7	2769	5.0% (4.4% - 5.7%)	3.1% (3.1% - 3.1%)
8	2539	5.3% (4.7% - 6.1%)	3.4% (3.3% - 3.4%)
9	2261	5.8% (5.1% - 6.6%)	3.7% (3.6% - 3.7%)
10	1794	6.0% (5.3% - 6.8%)	4.0% (3.9% - 4.0%)
11	1070	6.2% (5.4% - 7.2%)	4.3% (4.3% - 4.4%)
12	545	6.6% (5.7% - 7.6%)	4.7% (4.6% - 4.7%)
13	238	6.9% (5.9% - 8.1%)	5.0% (4.9% - 5.1%)
14	51	7.6% (6.0% - 10.4%)	5.3% (5.2% - 5.4%)
15		(-)	5.7% (5.6% - 5.8%)

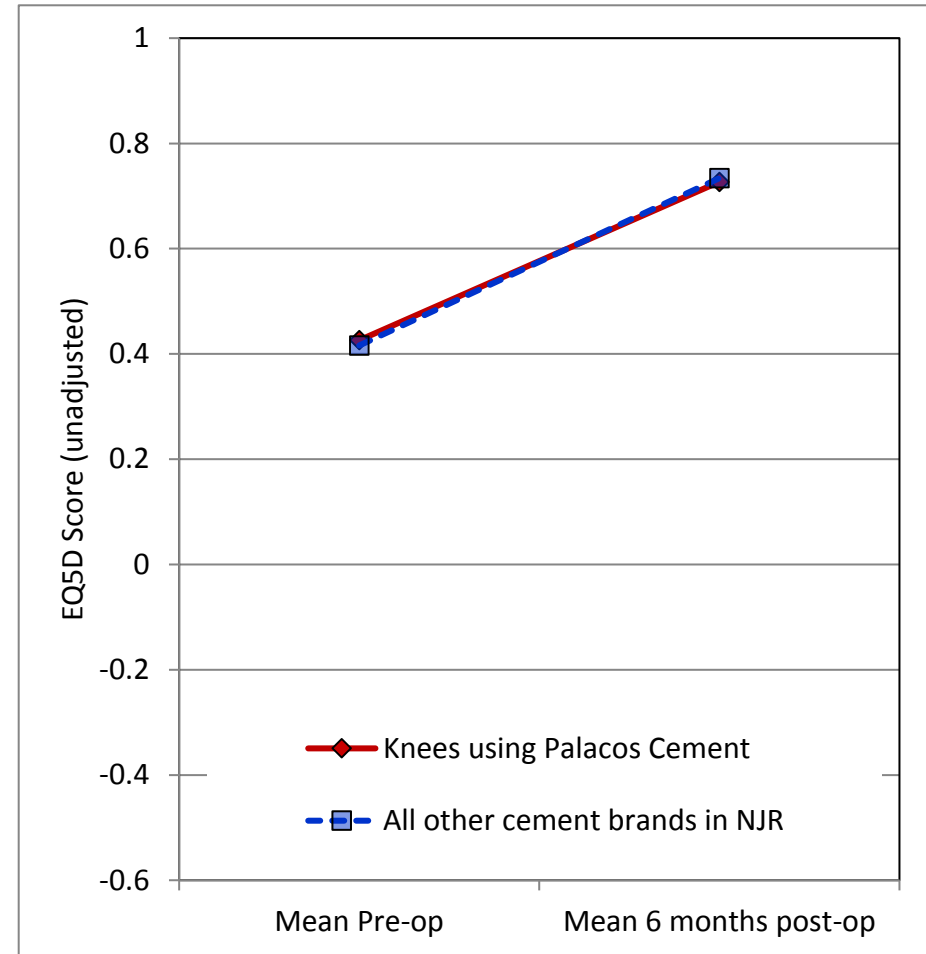
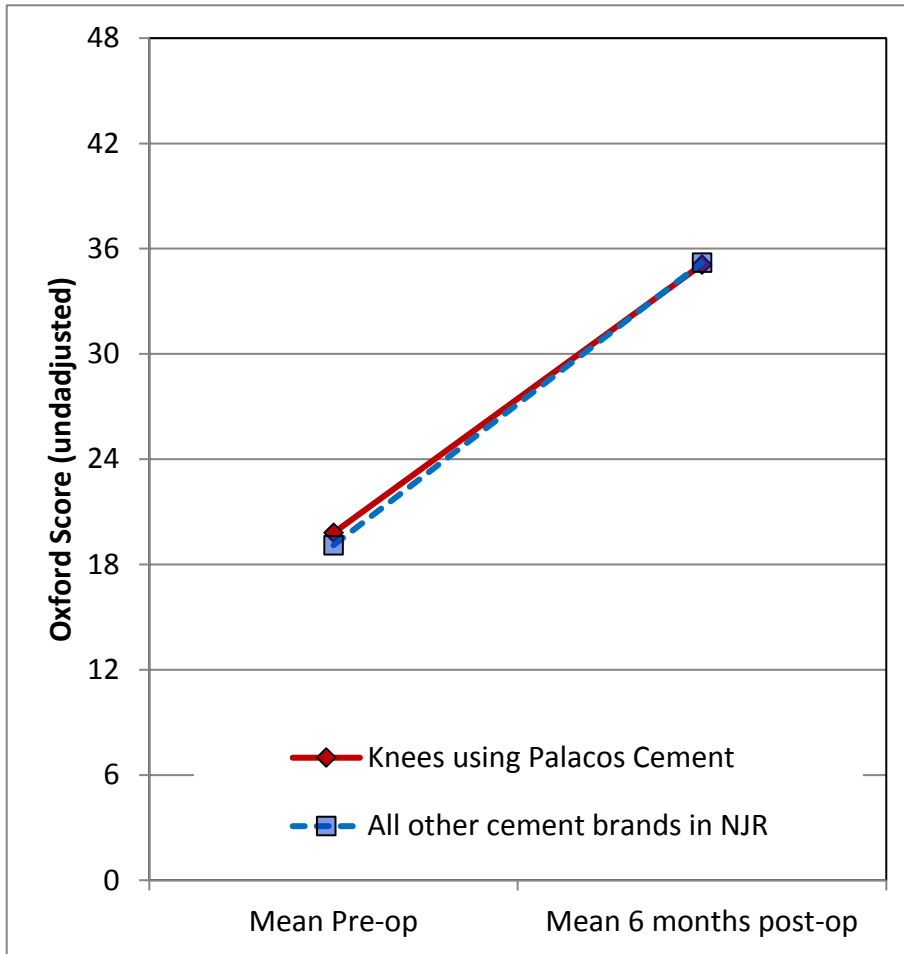
Cumulative revision rate with 95% confidence intervals

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

Patient Reported Outcomes

Comprising PROMs data up to and including: 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 Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	1,061	295,660	313,694
PreOp score	19.8 (19.3 - 20.2)	19.1 (19.0 - 19.1)	19.1 (19.0 - 19.1)
6 month score	35.1 (34.6 - 35.7)	35.2 (35.2 - 35.2)	35.2 (35.1 - 35.2)
6 month score (adjusted)	34.7 (34.2 - 35.2)	35.2 (35.2 - 35.2)	35.2 (35.1 - 35.2)
Health gain	15.4 (14.8 - 16.0)	16.1 (16.1 - 16.2)	16.1 (16.1 - 16.1)
Health gain (adjusted)	15.6 (15.1 - 16.1)	16.1 (16.1 - 16.2)	16.1 (16.1 - 16.1)
p value (adjusted health gain)	0.025		
Score Improved	93.2%	93.7%	93.6%

EQ-5D Index (-0.59 - 1.00)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	971	273,292	289,980
PreOp score	0.426 (0.407 - 0.445)	0.416 (0.415 - 0.417)	0.416 (0.415 - 0.417)
6 month score	0.727 (0.710 - 0.743)	0.734 (0.733 - 0.735)	0.733 (0.732 - 0.734)
6 month score (adjusted)	0.716 (0.702 - 0.731)	0.734 (0.733 - 0.735)	0.733 (0.732 - 0.734)
Health gain	0.301 (0.280 - 0.321)	0.318 (0.317 - 0.319)	0.318 (0.316 - 0.319)
Health gain (adjusted)	0.301 (0.286 - 0.315)	0.318 (0.317 - 0.319)	0.318 (0.317 - 0.318)
p value (adjusted health gain)	0.015		
Score Improved	80.3%	81.0%	80.9%

EQ-VAS (0 - 100)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	927	260,797	276,892
PreOp score	69.2 (67.9 - 70.5)	68.0 (67.9 - 68.1)	68.0 (67.9 - 68.1)
6 month score	72.7 (71.4 - 73.9)	73.8 (73.7 - 73.8)	73.7 (73.6 - 73.8)
6 month score (adjusted)	71.9 (70.8 - 73.0)	73.8 (73.7 - 73.8)	73.7 (73.6 - 73.8)
Health gain	3.5 (2.1 - 4.9)	5.8 (5.7 - 5.8)	5.7 (5.6 - 5.8)
Health gain (adjusted)	3.9 (2.8 - 5.0)	5.8 (5.7 - 5.8)	5.7 (5.6 - 5.8)
p value (adjusted health gain)	< 0.001		
Score Improved	50.3%	55.6%	55.5%

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

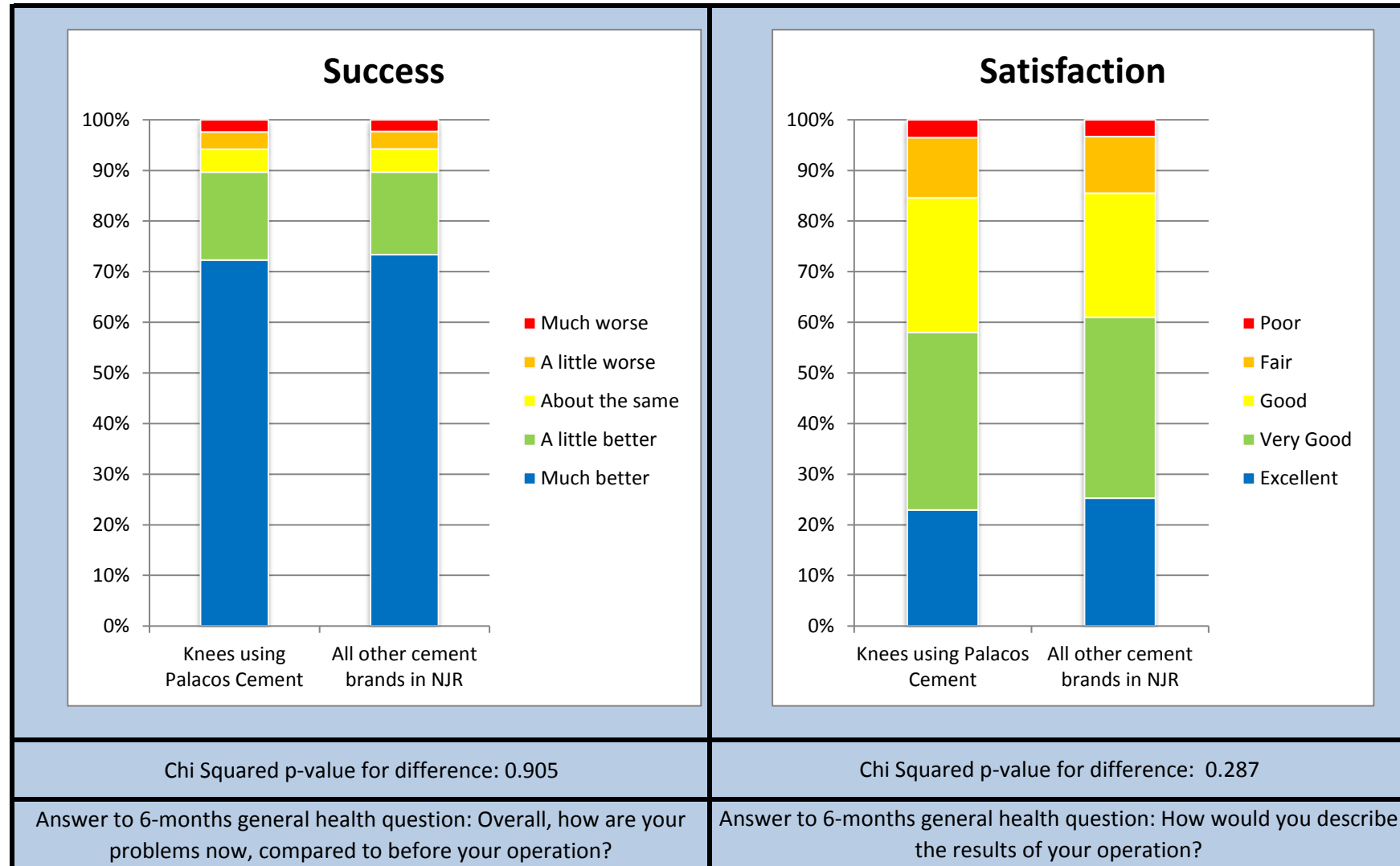
Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Knees using Palacos 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	782	222804
A little better	188	49472
About the same	49	13870
A little worse	37	10566
Much worse	26	6947

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	247	76532
Very Good	378	108238
Good	287	74364
Fair	128	33758
Poor	38	10084

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	3607
66017778	Palacos R 1x40 g	110
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