

## Implant Summary Report for:

Heraeus Medical

## Knees using Palacos 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 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**

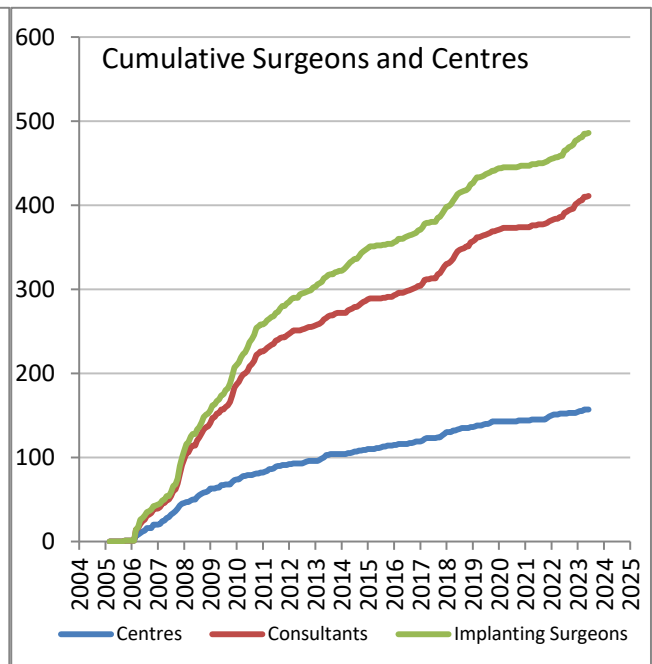
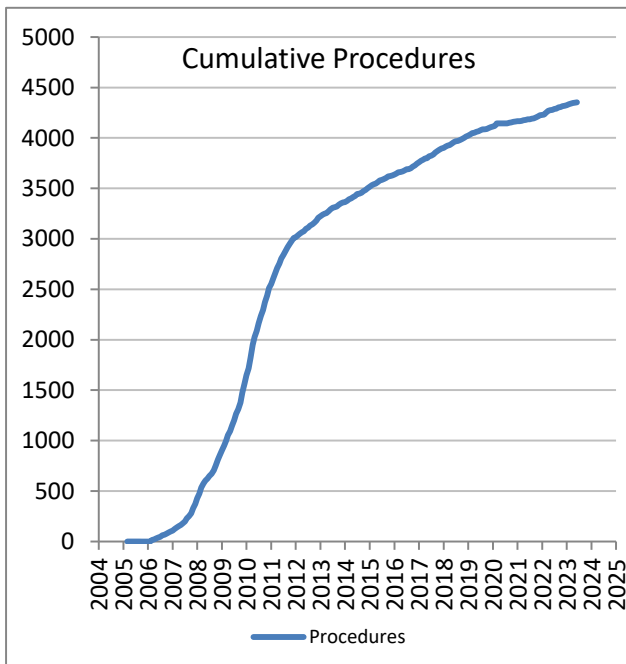
Date of first recorded usage in the NJR: **26 September 2005**

Date of last recorded usage in this dataset: **25 May 2023**

Maximum implantation time: 17.3 years

Mean implantation time: 9.4 years

Totals Recorded in NJR	Cumulative Total
Procedures	4,353
Patients	4,057
Centres	157
Consultants	411
Implanting Surgeons	486



Current Outcome	Year of implantation													Total	%
	Pre-2012	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023		
<b>Death</b>	1215	54	43	44	22	17	22	10	8	3	3	0	0	1441	33.1%
<b>Revised</b>	185	14	6	7	8	8	8	7	4	1	0	1	0	249	5.7%
<b>Unrevised</b>	1616	140	91	100	92	96	113	104	79	48	61	95	28	2663	61.2%
<b>Total</b>	<b>3016</b>	<b>208</b>	<b>140</b>	<b>151</b>	<b>122</b>	<b>121</b>	<b>143</b>	<b>121</b>	<b>91</b>	<b>52</b>	<b>64</b>	<b>96</b>	<b>28</b>	<b>4353</b>	<b>100%</b>

## Patient / Procedure Details

## Patient Details

	Knees using Palacos Cement	All other cement brands in NJR
<b>Total Procedures</b>	4,353	1,403,484
<b>Total Patients</b>	4,057	1,128,079
<b>Demographics</b>		
Mean age	<b>70.4</b>	<b>69.6</b>
< 50	2.3%	2.4%
50 – 59	11.8%	13.7%
60 – 69	32.4%	32.9%
70 – 79	36.9%	37.2%
≥ 80	16.7%	13.8%
Median BMI	<b>30</b>	<b>30</b>
% BMI information available	50.9%	70.2%
Underweight ( BMI < 18.5)	0.3%	0.2%
Normal (18.5 ≤ BMI < 25)	11.8%	10.4%
Overweight (25 ≤ BMI < 30)	34.6%	34.3%
Obese I (30 ≤ BMI < 35)	29.0%	32.3%
Obese II (35 ≤ BMI < 40)	16.7%	16.2%
Obese III (BMI ≥ 40)	7.6%	6.5%
% Male	42.0%	43.2%
<b>ASA Grades</b>		
P1 - Fit and healthy	11.2%	10.0%
P2 - Mild disease not incapacitating	70.4%	72.3%
P3 - Incapacitating systemic disease	17.9%	17.3%
P4 / P5	0.4%	0.3%
<b>Indications</b>		
Osteoarthritis	97.93%	97.45%
Rheumatoid Arthritis	1.19%	1.33%
Other Inflammatory Arthropathy	0.51%	0.68%
Previous Trauma	0.78%	0.67%
Avascular Necrosis	0.37%	0.40%
Other	0.32%	0.39%

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	71	29.82	<0.001
Progressive Arthritis Remaining	20	29.29	0.095
Aseptic Loosening Femur	34	17.73	<0.001
Aseptic Loosening Tibia	46	31.48	0.015
Aseptic Loosening Patella	1	5.40	0.051
Unexplained Pain	27	24.34	0.542
Stiffness	12	9.38	0.409
Malalignment	24	11.18	<0.001
Instability	34	23.37	0.037
Dislocation / Subluxation	5	5.52	1
Periprosthetic Fracture	16	7.26	0.004
Wear of Polyethylene Component	9	10.46	0.876
Lysis - Tibia	15	7.61	0.016
Lysis - Femur	7	5.22	0.377
Component Dissociation	3	2.13	0.477
Implant Fracture	0	1.04	0.632
Other / Not recorded	10	12.17	0.665
<b>Total Revised</b>	<b>249</b>	<b>166.27</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

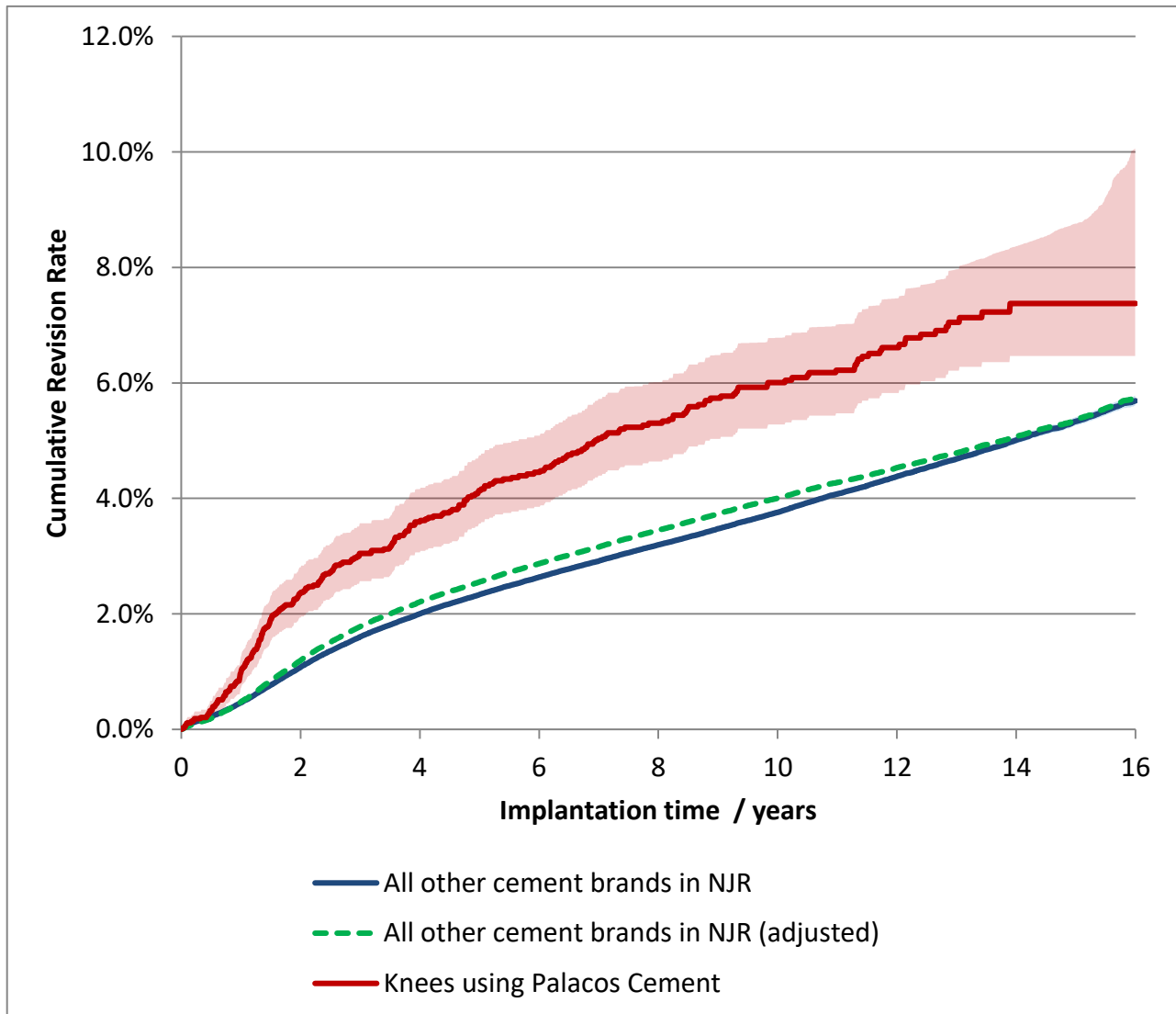


Components Revised	Number of procedures	Knees using Palacos Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	211	84.7%	74.3%
Isolated bearing exchange	21	8.4%	12.8%
Patella revision / resurfacing only	16	6.4%	12.0%
No component revision recorded	1	0.4%	0.9%

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.	1.57 ‡ (1.39 - 1.78)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	1.50 (1.33 - 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	4353	-	-
1	4189	1.0% (0.7% - 1.3%)	0.5% (0.5% - 0.5%)
2	3981	2.4% (1.9% - 2.8%)	1.1% (1.1% - 1.1%)
3	3846	3.0% (2.6% - 3.6%)	1.6% (1.6% - 1.6%)
4	3659	3.6% (3.1% - 4.2%)	2.0% (2.0% - 2.0%)
5	3434	4.1% (3.6% - 4.7%)	2.3% (2.3% - 2.4%)
6	3197	4.5% (3.9% - 5.1%)	2.6% (2.6% - 2.7%)
7	2962	5.0% (4.4% - 5.7%)	2.9% (2.9% - 2.9%)
8	2757	5.3% (4.6% - 6.0%)	3.2% (3.2% - 3.2%)
9	2507	5.7% (5.0% - 6.5%)	3.5% (3.4% - 3.5%)
10	2285	6.0% (5.3% - 6.8%)	3.8% (3.7% - 3.8%)
11	2050	6.2% (5.5% - 7.0%)	4.1% (4.0% - 4.1%)
12	1726	6.6% (5.8% - 7.5%)	4.4% (4.3% - 4.4%)
13	1198	7.1% (6.2% - 8.0%)	4.7% (4.6% - 4.7%)
14	602	7.4% (6.5% - 8.4%)	5.0% (4.9% - 5.1%)
15	308	7.4% (6.5% - 8.8%)	5.3% (5.3% - 5.4%)

Cumulative revision rate with 95% confidence intervals  
 Rate is only reported for times where more than 40 remain at risk

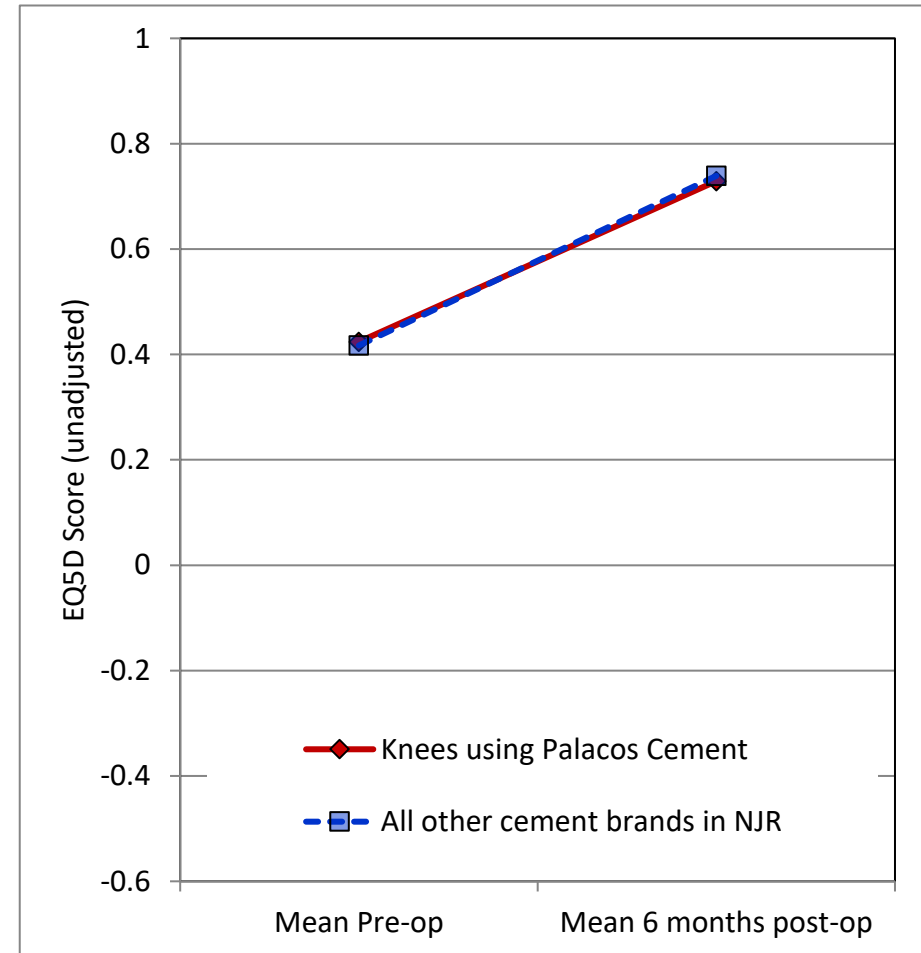
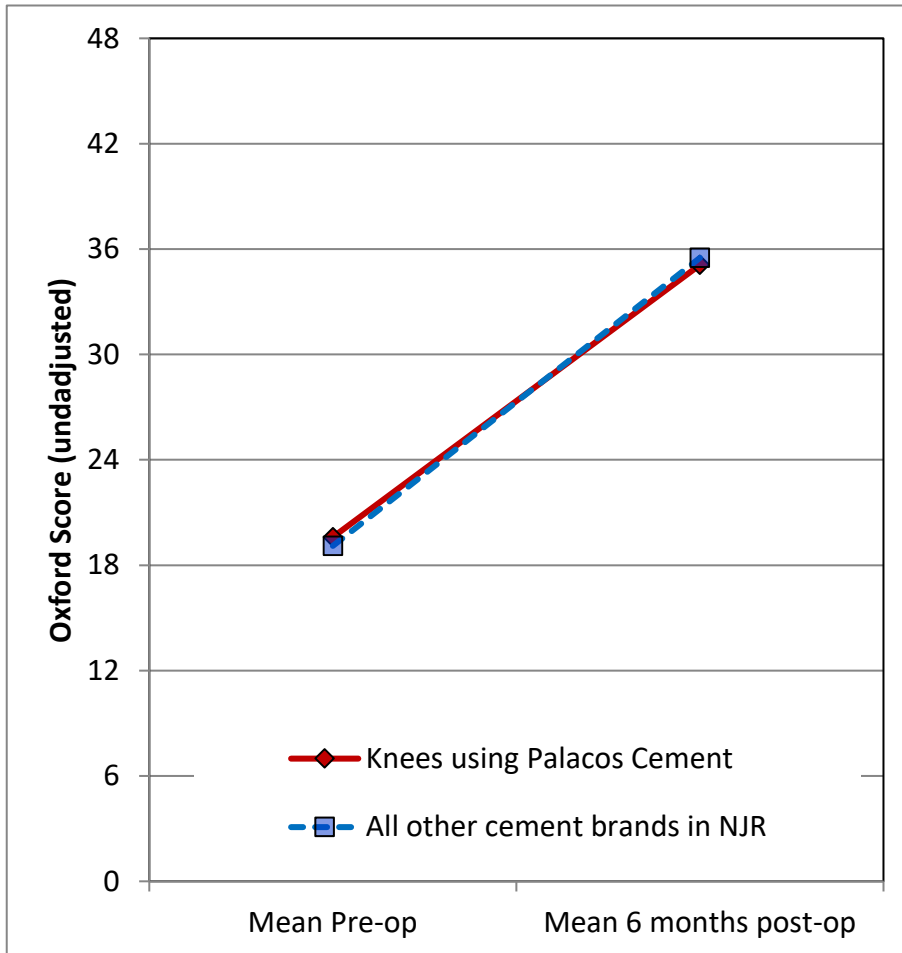
Summary Report for:

Knees using Palacos Cement

## PROMs Analysis

## Patient Reported Outcomes

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



## 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	1,093	359,925	382,041
PreOp score	19.6 (19.1 - 20.1)	19.1 (19.1 - 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 (15.0 - 16.1)	16.4 (16.4 - 16.4)	16.4 (16.4 - 16.4)
Health gain (adjusted)	15.7 (15.2 - 16.2)	16.4 (16.4 - 16.4)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	0.005		
Score Improved	93.2%	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	1,002	333,941	354,541
PreOp score	0.424 (0.405 - 0.443)	0.417 (0.416 - 0.418)	0.417 (0.416 - 0.418)
6 month score	0.729 (0.713 - 0.746)	0.739 (0.738 - 0.740)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.723 (0.709 - 0.738)	0.739 (0.739 - 0.740)	0.739 (0.738 - 0.740)
Health gain	0.305 (0.285 - 0.325)	0.322 (0.321 - 0.323)	0.322 (0.321 - 0.323)
Health gain (adjusted)	0.306 (0.292 - 0.320)	0.322 (0.321 - 0.323)	0.322 (0.321 - 0.322)
p value (adjusted health gain)	0.047		
Score Improved	81.1%	81.4%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	954	320,191	340,151
PreOp score	68.9 (67.6 - 70.2)	68.0 (67.9 - 68.0)	68.0 (67.9 - 68.1)
6 month score	72.5 (71.2 - 73.7)	74.2 (74.1 - 74.2)	74.1 (74.1 - 74.2)
6 month score (adjusted)	72.1 (71.0 - 73.2)	74.2 (74.1 - 74.2)	74.1 (74.1 - 74.2)
Health gain	3.5 (2.1 - 5.0)	6.2 (6.1 - 6.3)	6.2 (6.1 - 6.2)
Health gain (adjusted)	4.1 (3.0 - 5.2)	6.2 (6.1 - 6.2)	6.2 (6.1 - 6.2)
p value (adjusted health gain)	< 0.001		
Score Improved	50.2%	56.5%	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

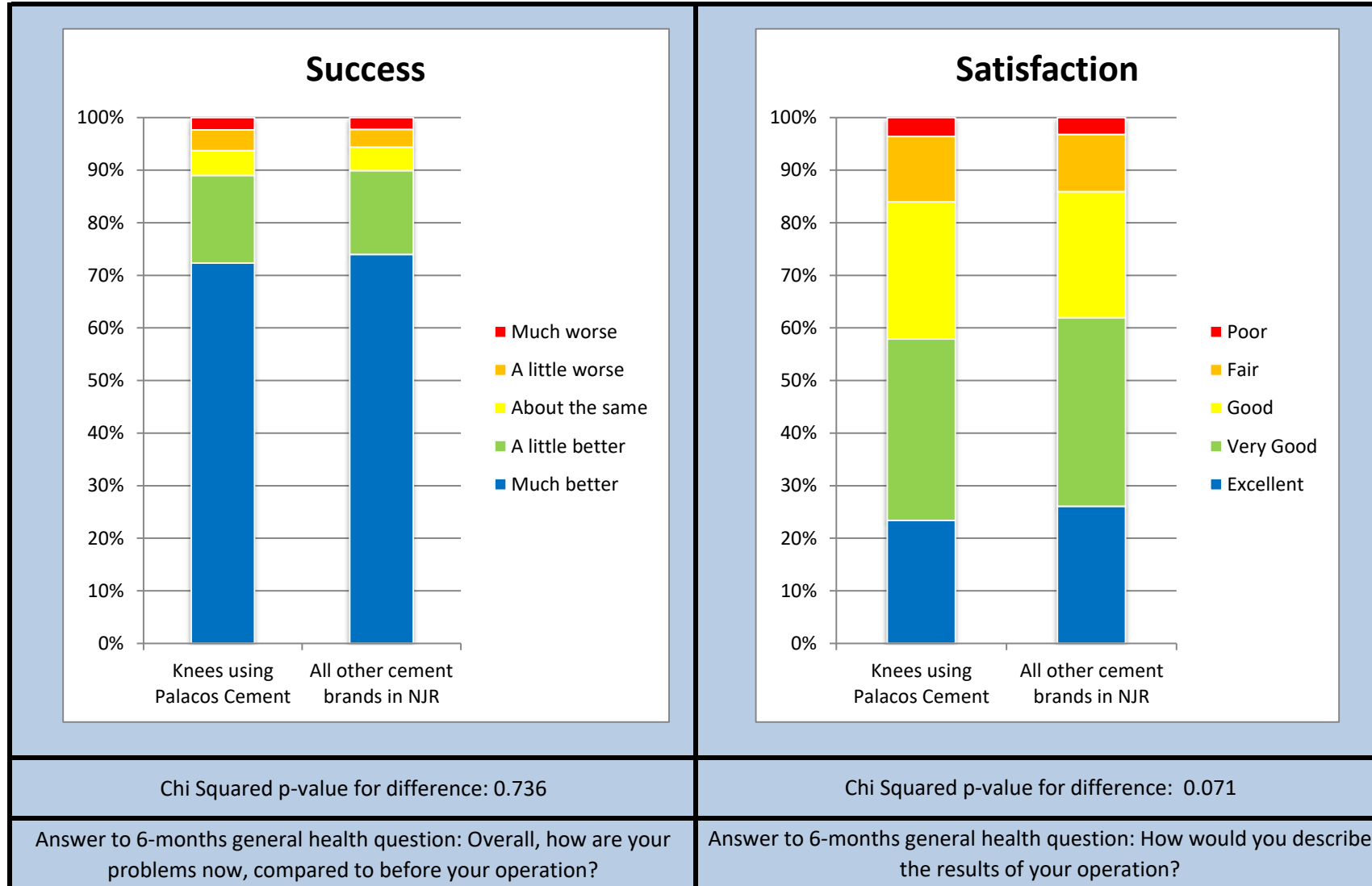


Summary Report for:

Knees using Palacos 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	808	273290
A little better	186	58815
About the same	53	16537
A little worse	44	12516
Much worse	26	8253

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	260	96187
Very Good	384	132109
Good	290	88519
Fair	138	39942
Poor	40	11893

Answer to 6-months general health question:

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

## Disclaimer

### Disclaimer

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# Appendix A: Component List

Catalogue Number	Description	Number Implanted
Cement		
66017777	PALACOS R 2x40 g	3804
66017778	PALACOS R 1x40 g	119
66017788	PALACOS LV 1x40 g	13
66031982	PALACOS MV 1x40 g	413
66031984	PALACOS MV plain 2x40g	2
66037893	PALACOS LV 1x20g	1
Multiple Found	Multiple Found	1