

Implant Summary Report for:

Heraeus Medical

Knees using Palacos Cement

Comprising PRIMARY knees implanted up to:	13 January 2024
NJR Database extract:	12 February 2024
Produced on:	22 February 2024
Licensed for use until:	22 February 2025

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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

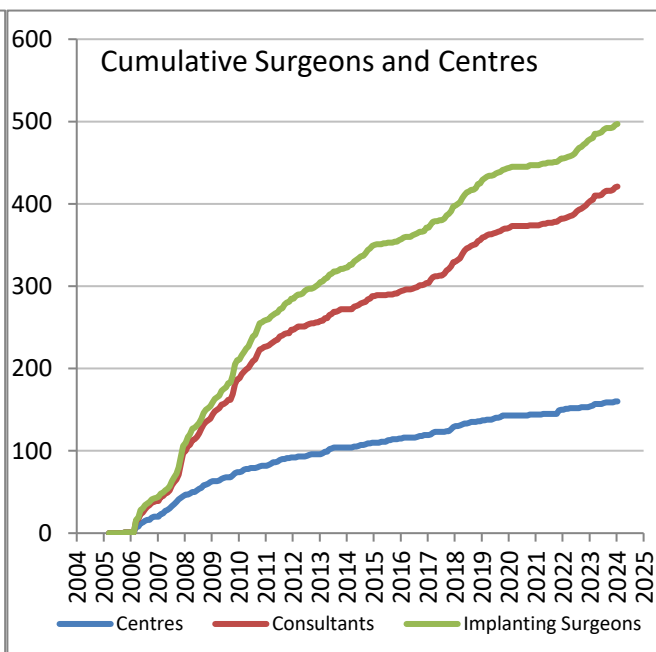
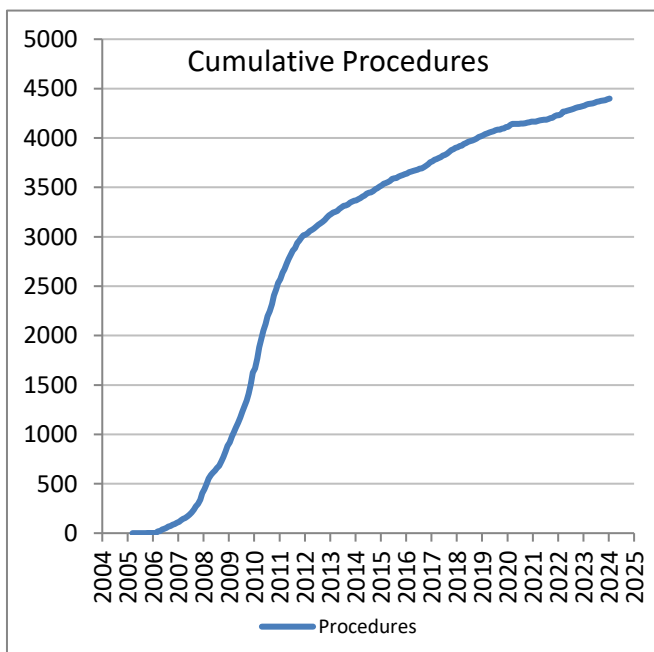
Date of first recorded usage in the NJR: **26 September 2005**

Date of last recorded usage in this dataset: **09 January 2024**

Maximum implantation time: 17.9 years

Mean implantation time: 9.7 years

Totals Recorded in NJR	Cumulative Total
Procedures	4,399
Patients	4,100
Centres	160
Consultants	421
Implanting Surgeons	497



Current Outcome	Year of implantation														Total	%
	Pre-2013	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024			
Death	1269	43	44	22	17	22	10	8	3	3	0	0	0	1441	32.8%	
Revised	203	6	7	9	8	8	7	4	1	0	1	0	0	254	5.8%	
Unrevised	1752	91	100	91	96	113	104	79	48	61	95	72	2	2704	61.5%	
Total	3224	140	151	122	121	143	121	91	52	64	96	72	2	4399	100%	

Patient / Procedure Details

Patient Details

	Knees using Palacos Cement	All other cement brands in NJR
Total Procedures	4,399	1,540,376
Total Patients	4,100	1,226,275
Demographics		
Mean age	70.4	69.6
< 50	2.2%	2.4%
50 – 59	11.8%	13.6%
60 – 69	32.5%	32.8%
70 – 79	36.8%	37.3%
≥ 80	16.8%	13.8%
Median BMI	30	30
% BMI information available	51.3%	68.9%
Underweight (BMI < 18.5)	0.3%	0.2%
Normal (18.5 ≤ BMI < 25)	11.6%	10.5%
Overweight (25 ≤ BMI < 30)	34.7%	34.3%
Obese I (30 ≤ BMI < 35)	29.3%	32.2%
Obese II (35 ≤ BMI < 40)	16.6%	16.3%
Obese III (BMI ≥ 40)	7.6%	6.5%
% Male	42.1%	43.3%
ASA Grades		
P1 - Fit and healthy	11.1%	10.1%
P2 - Mild disease not incapacitating	70.5%	72.2%
P3 - Incapacitating systemic disease	17.9%	17.3%
P4 / P5	0.5%	0.3%
Indications		
Osteoarthritis	97.95%	97.44%
Rheumatoid Arthritis	1.18%	1.35%
Other Inflammatory Arthropathy	0.50%	0.69%
Previous Trauma	0.77%	0.63%
Avascular Necrosis	0.36%	0.39%
Other	0.32%	0.41%

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	30.49	<0.001
Progressive Arthritis Remaining	20	30.99	0.047
Aseptic Loosening Femur	36	18.54	<0.001
Aseptic Loosening Tibia	49	32.68	0.006
Aseptic Loosening Patella	1	5.57	0.052
Unexplained Pain	27	24.78	0.614
Stiffness	13	9.63	0.256
Malalignment	24	11.55	<0.001
Instability	34	24.12	0.052
Dislocation / Subluxation	5	5.64	1
Periprosthetic Fracture	16	7.87	0.01
Wear of Polyethylene Component	11	11.53	1
Lysis - Tibia	15	8.05	0.021
Lysis - Femur	8	5.49	0.278
Component Dissociation	3	2.19	0.486
Implant Fracture	0	1.10	0.633
Other / Not recorded	10	12.14	0.665
Total Revised	254	171.91	<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

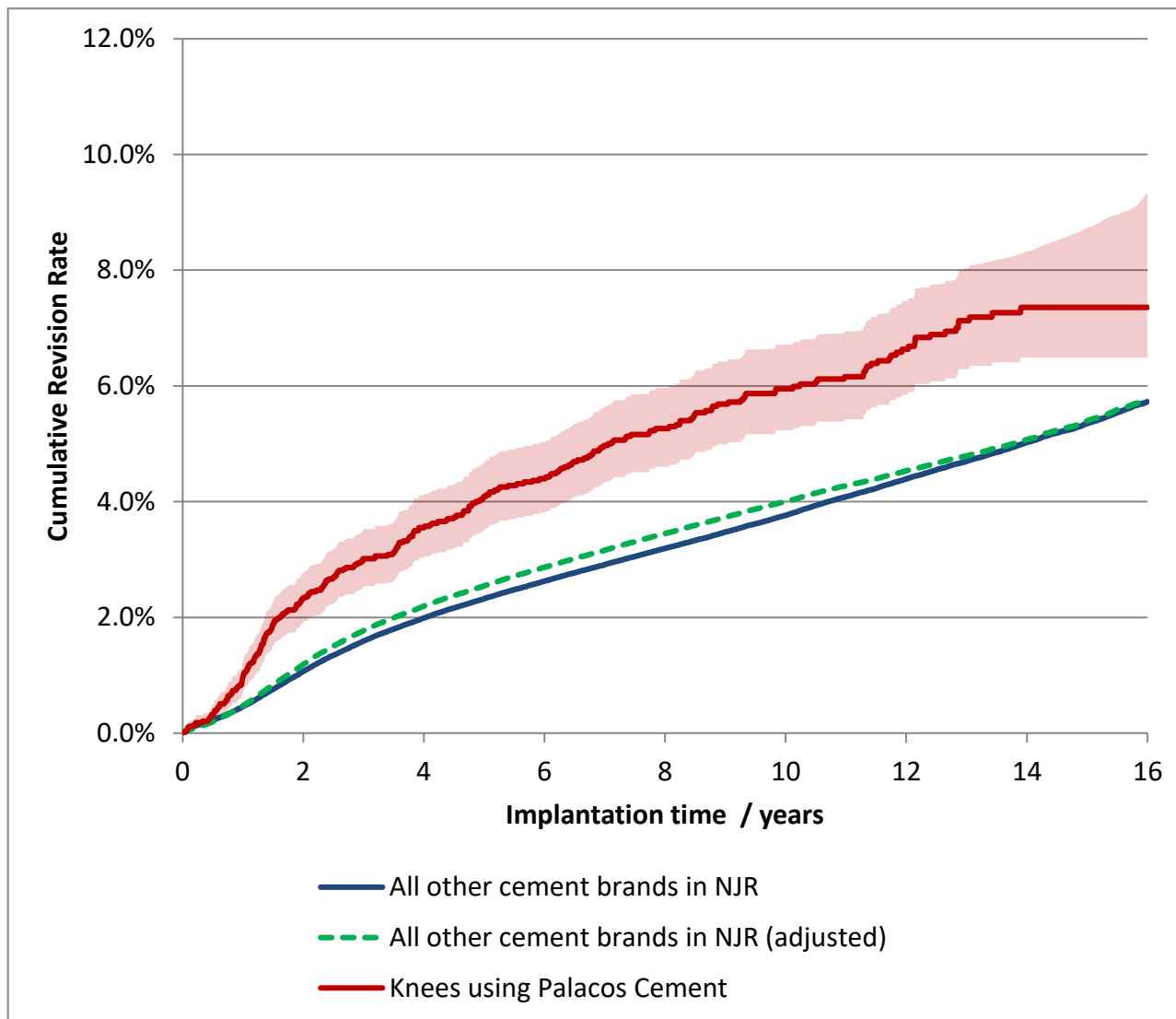


Components Revised	Number of procedures	Knees using Palacos Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	216	85.0%	75.0%
Isolated bearing exchange	21	8.3%	12.5%
Patella revision / resurfacing only	16	6.3%	11.6%
No component revision recorded	1	0.4%	0.9%

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.	1.54 ‡ (1.36 - 1.75)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	1.48 (1.31 - 1.68)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

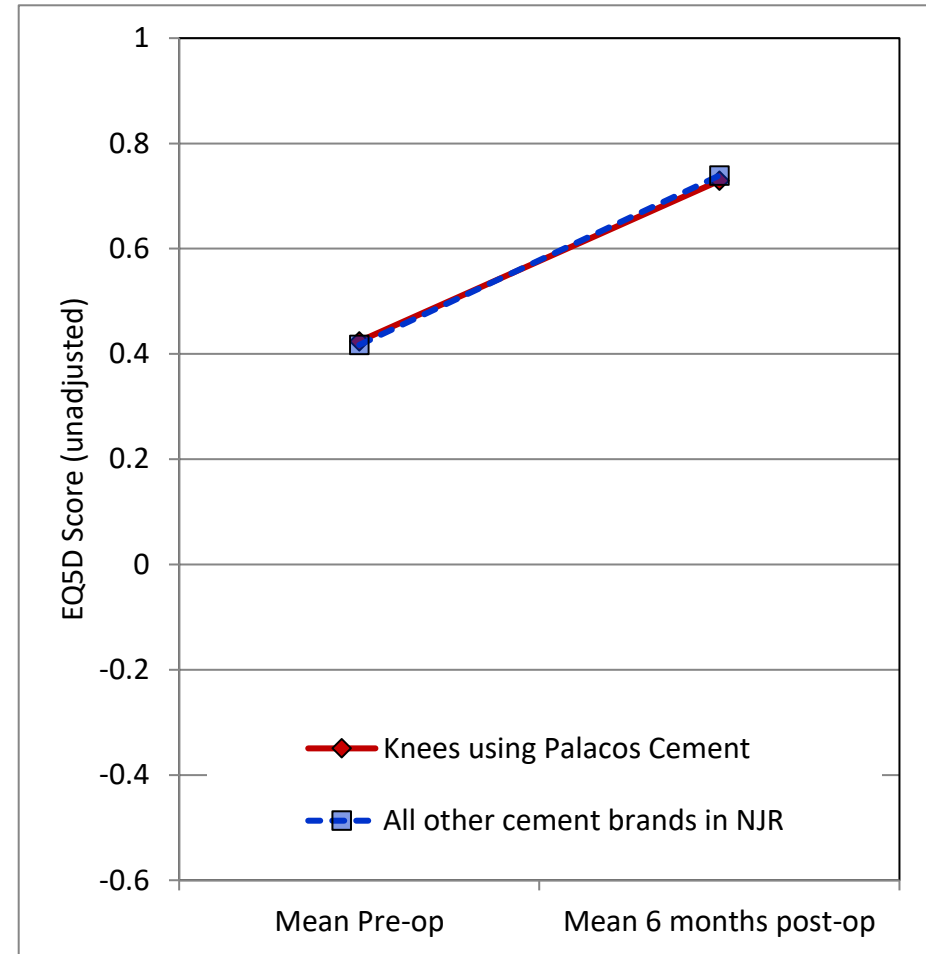
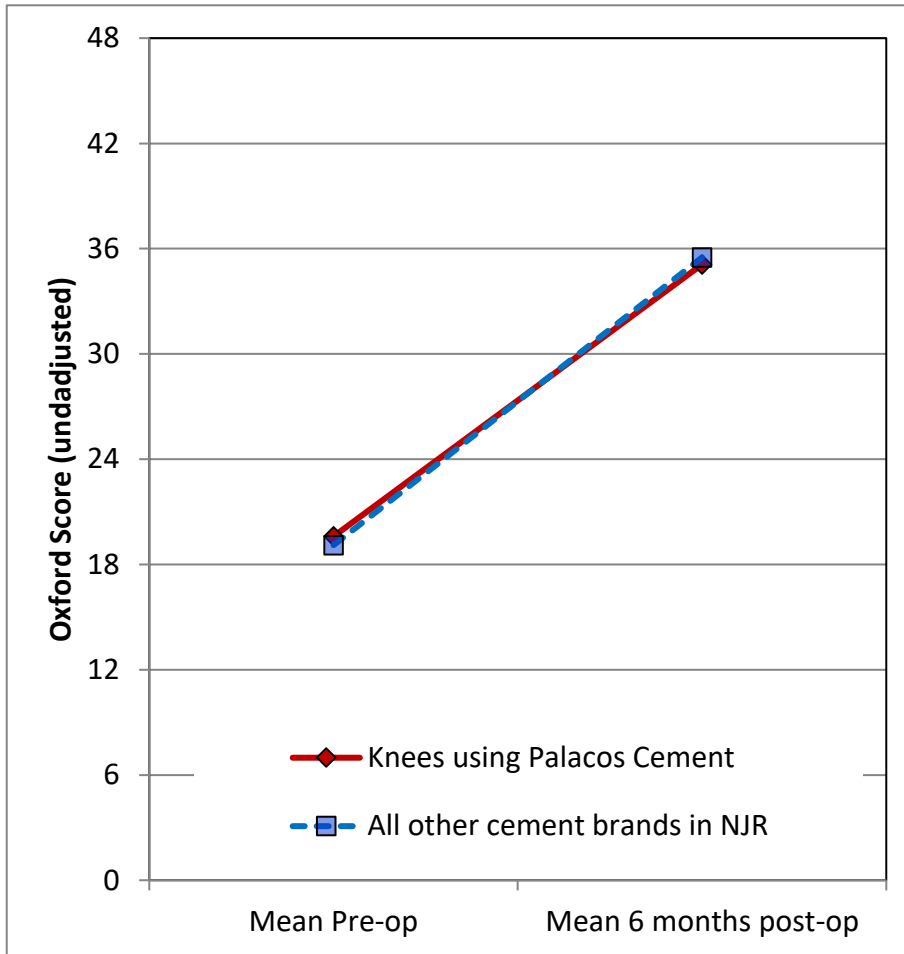
Period /years	At Risk	Knees using Palacos Cement	All other cement brands in NJR
0	4399	-	-
1	4239	1.0% (0.7% - 1.3%)	0.5% (0.4% - 0.5%)
2	4023	2.3% (1.9% - 2.8%)	1.1% (1.0% - 1.1%)
3	3865	3.0% (2.5% - 3.5%)	1.6% (1.6% - 1.6%)
4	3700	3.6% (3.0% - 4.1%)	2.0% (2.0% - 2.0%)
5	3495	4.1% (3.5% - 4.7%)	2.3% (2.3% - 2.3%)
6	3268	4.4% (3.8% - 5.0%)	2.6% (2.6% - 2.7%)
7	3032	5.0% (4.3% - 5.6%)	2.9% (2.9% - 2.9%)
8	2804	5.3% (4.6% - 6.0%)	3.2% (3.2% - 3.2%)
9	2574	5.7% (5.0% - 6.4%)	3.5% (3.4% - 3.5%)
10	2335	6.0% (5.2% - 6.7%)	3.8% (3.7% - 3.8%)
11	2138	6.2% (5.4% - 6.9%)	4.1% (4.0% - 4.1%)
12	1859	6.6% (5.8% - 7.5%)	4.4% (4.4% - 4.4%)
13	1471	7.1% (6.3% - 8.0%)	4.7% (4.6% - 4.7%)
14	891	7.4% (6.5% - 8.3%)	5.0% (5.0% - 5.1%)
15	438	7.4% (6.5% - 8.7%)	5.4% (5.3% - 5.4%)

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	1,093	363,804	382,040
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)	0.006		
Score Improved	93.2%	93.9%	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	337,546	354,540
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 (0.738 - 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)	0.051		
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	323,684	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)	74.1 (74.1 - 74.2)	74.1 (74.1 - 74.2)
6 month score (adjusted)	72.1 (71.0 - 73.2)	74.1 (74.1 - 74.2)	74.1 (74.1 - 74.2)
Health gain	3.5 (2.1 - 5.0)	6.2 (6.1 - 6.2)	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%	56.4%	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	276366
A little better	186	59565
About the same	53	16750
A little worse	44	12682
Much worse	26	8375

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	97229
Very Good	384	133599
Good	290	89606
Fair	138	40494
Poor	40	12040

Answer to 6-months general health question:

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

Disclaimer

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
Cement		
66017777	PALACOS R 2x40 g	3849
66017778	PALACOS R 1x40 g	120
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