

Implant Summary Report for:

Biomet

Avantage Cemented Cup

Comprising PRIMARY hips implanted up to:
NJR Database extract:

06 June 2014
05 August 2014

Produced on:
Licenced for use until:

14 August 2014
14 August 2015

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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 Avantage Cemented Cup, based on data collected by the NJR up to the specified date, for the following combinations of products:

Acetabular Components

All Avantage Cemented Cups

Femoral Components

Any Femoral Components manufactured by Biomet

Appendix A lists details of all Avantage Cemented Cup components included in this report.

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NJR Recorded Usage

Implant Usage

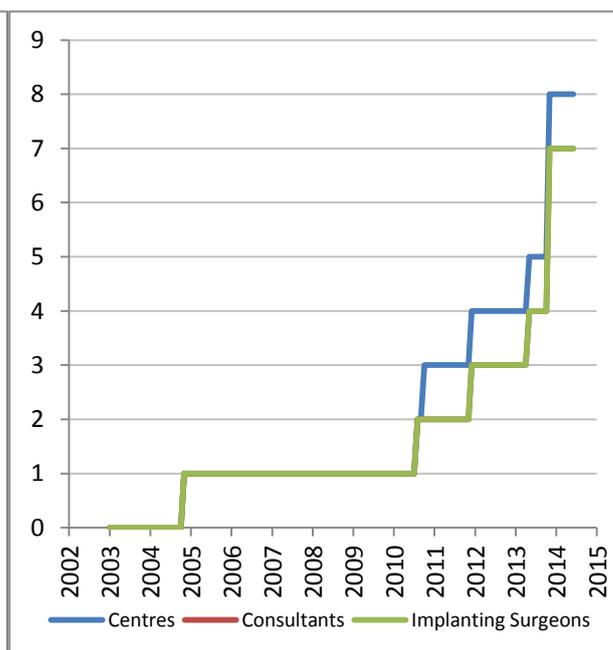
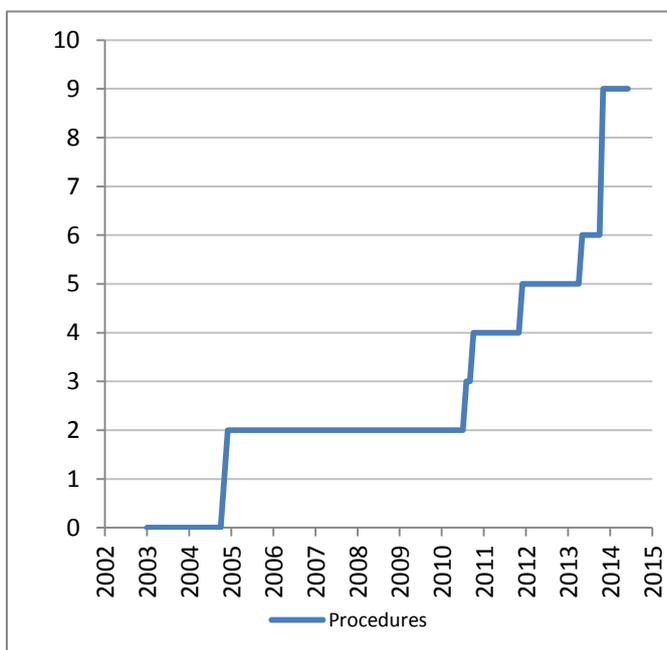
Date of first recorded usage in the NJR: **08 October 2004**

Date of last recorded usage in this dataset: **23 October 2013**

Maximum implantation time: 9.8 years

Mean implantation time: 3.7 years

Totals Recorded in NJR	Cumulative Total
Procedures	9
Centres	8
Consultants	7
Implanting Surgeons	7



Outcome	Year of implantation												Total	%
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014		
Death	0	0	0	0	0	0	0	0	0	0	1	0	1	11.1%
Revised	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0%
Unrevised	0	2	0	0	0	0	0	2	1	0	3	0	8	88.9%
Total	0	2	0	0	0	0	0	2	1	0	4	0	9	100%

Patient / Procedure Details

Patient Details

	Avantage Cemented Cup	All NJR Cemented Cups	All NJR hip replacement
Demographics			
Mean age	72.0	73.3	68.4
< 50	0.0%	1.4%	6.1%
50 – 59	0.0%	5.2%	13.7%
60 – 69	33.3%	23.6%	29.9%
70 – 79	55.6%	44.7%	34.3%
≥ 80	11.1%	25.1%	16.0%
Median BMI	30.5	28	28
% BMI information available	66.7%	46.7%	49.6%
Underweight (BMI < 18.5)	0.0%	1.2%	0.9%
Normal (18.5 ≤ BMI < 25)	33.3%	22.9%	21.3%
Overweight (25 ≤ BMI < 30)	16.7%	40.5%	40.2%
Obese I (30 ≤ BMI < 35)	50.0%	24.5%	25.2%
Obese II (35 ≤ BMI < 40)	0.0%	8.3%	9.2%
Obese III (BMI ≥ 40)	0.0%	2.7%	3.2%
% Male	33.3%	33.9%	40.3%
ASA Grades			
P1 - Fit and healthy	0.0%	12.6%	18.1%
P2 - Mild disease not incapacitating	77.8%	68.7%	67.2%
P3 - Incapacitating systemic disease	11.1%	18.0%	14.1%
P4 / P5	11.1%	0.7%	0.5%
Indications			
Osteoarthritis	77.78%	93.18%	92.86%
Rheumatoid Arthritis	0.00%	1.42%	1.33%
Avascular Necrosis	0.00%	2.27%	2.54%
Fractured Neck of Femur	11.11%	2.42%	2.08%
CDH/DDH	0.00%	0.61%	1.52%
Other	11.11%	2.12%	2.13%

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	Number of procedures †	Crude Revision Rate		
		Avantage Cemented Cup	All NJR Cemented Cups	All NJR hip replacement
Pain	0	0.00%	0.21%	0.57%
Dislocation / Subluxation	0	0.00%	0.40%	0.42%
Adverse Soft Tissue Reaction	0	0.00%	0.01%	0.39%
Infection	0	0.00%	0.34%	0.34%
Aseptic Loosening - Stem	0	0.00%	0.21%	0.34%
Aseptic Loosening - Socket	0	0.00%	0.31%	0.33%
Periprosthetic Fracture Stem	0	0.00%	0.15%	0.25%
Periprosthetic Fracture Socket	0	0.00%	0.01%	0.03%
Malalignment Socket	0	0.00%	0.08%	0.14%
Wear Of Acetabular Component	0	0.00%	0.05%	0.10%
Lysis Socket	0	0.00%	0.06%	0.08%
Lysis Stem	0	0.00%	0.05%	0.08%
Malalignment Stem	0	0.00%	0.04%	0.06%
Implant Fracture Stem	0	0.00%	0.02%	0.03%
Dissociation Of Liner	0	0.00%	0.01%	0.03%
Implant Fracture Socket	0	0.00%	0.01%	0.03%
Other / reason not recorded	0	0.00%	0.05%	0.16%

† multiple reasons may be listed for one revision procedure

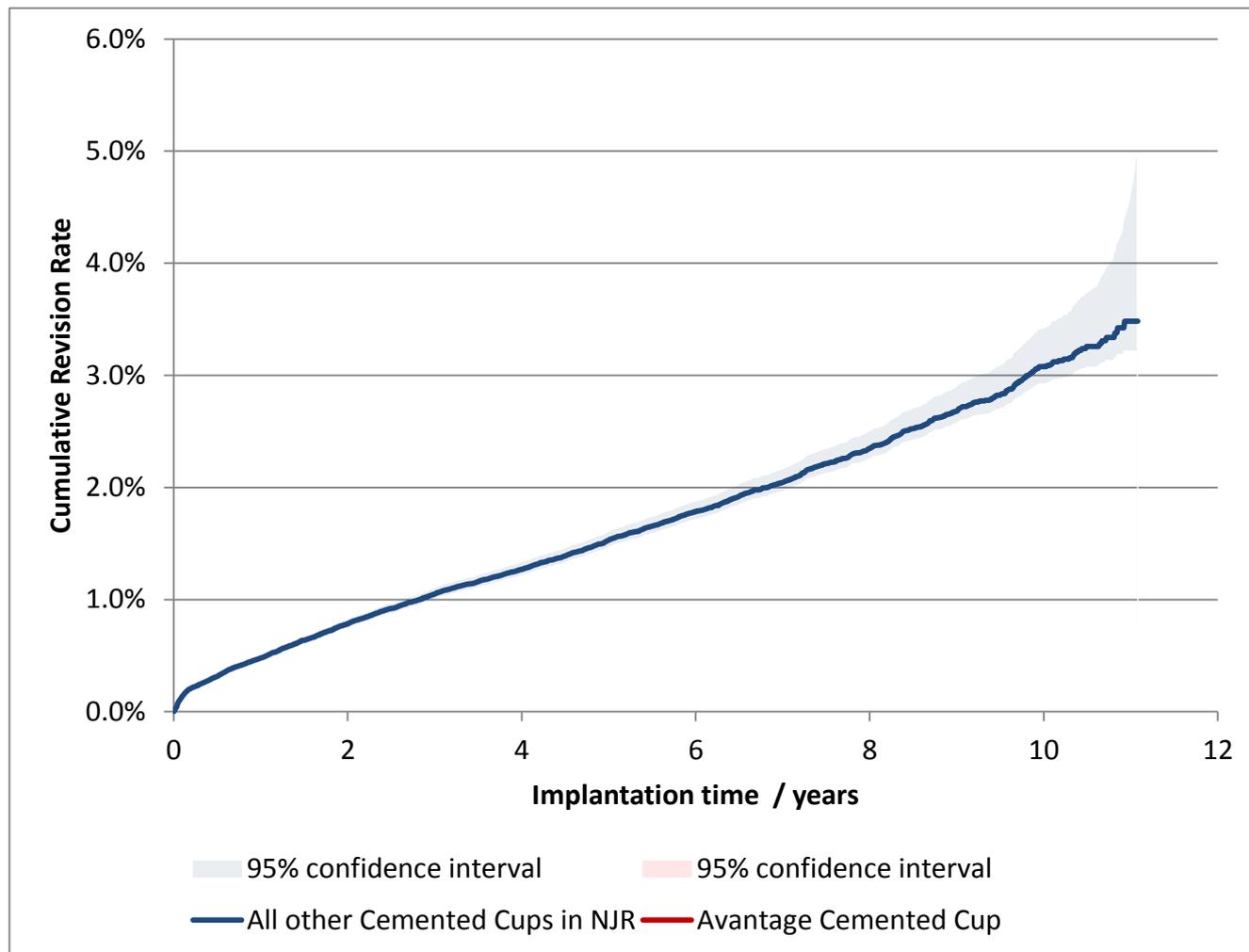
Components Revised	Number of procedures	Avantage Cemented Cup	All NJR Cemented Cups	All NJR hip replacement
Femoral only	0	NaN	15%	18%
Acetabular only	0	NaN	27%	29%
Both femoral and acetabular	0	NaN	51%	46%
Neither femoral nor acetabular revision recorded *	0	NaN	6%	8%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All articulation types



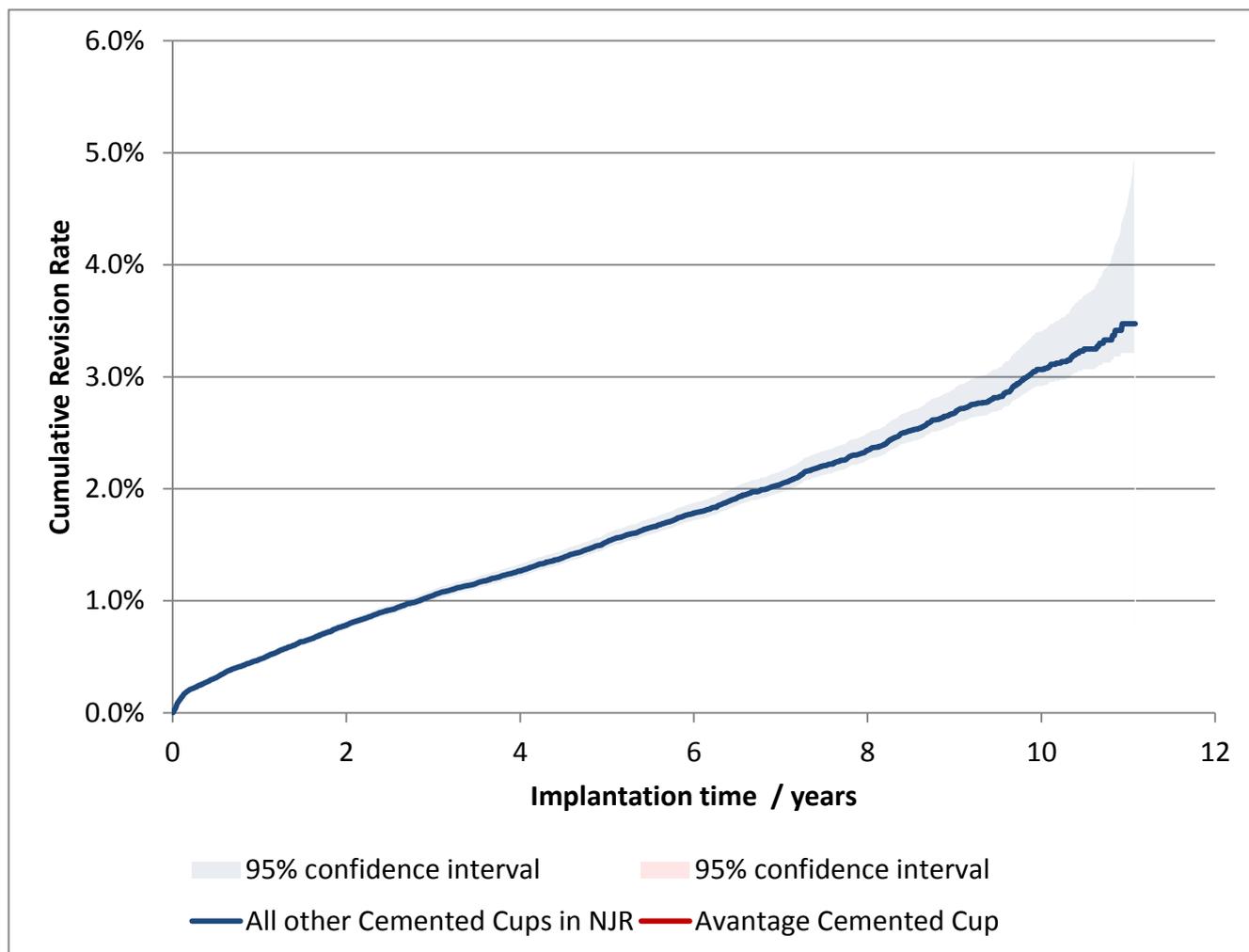
Cox Proportional Hazards model for revision risk ratio of Avantage Cemented Cup / all other Cemented Cups, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	Insufficient data	
All bearings. Adjusted for age, gender, year cohort and indications.	Insufficient data	

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. Excluding Metal-on-Metal



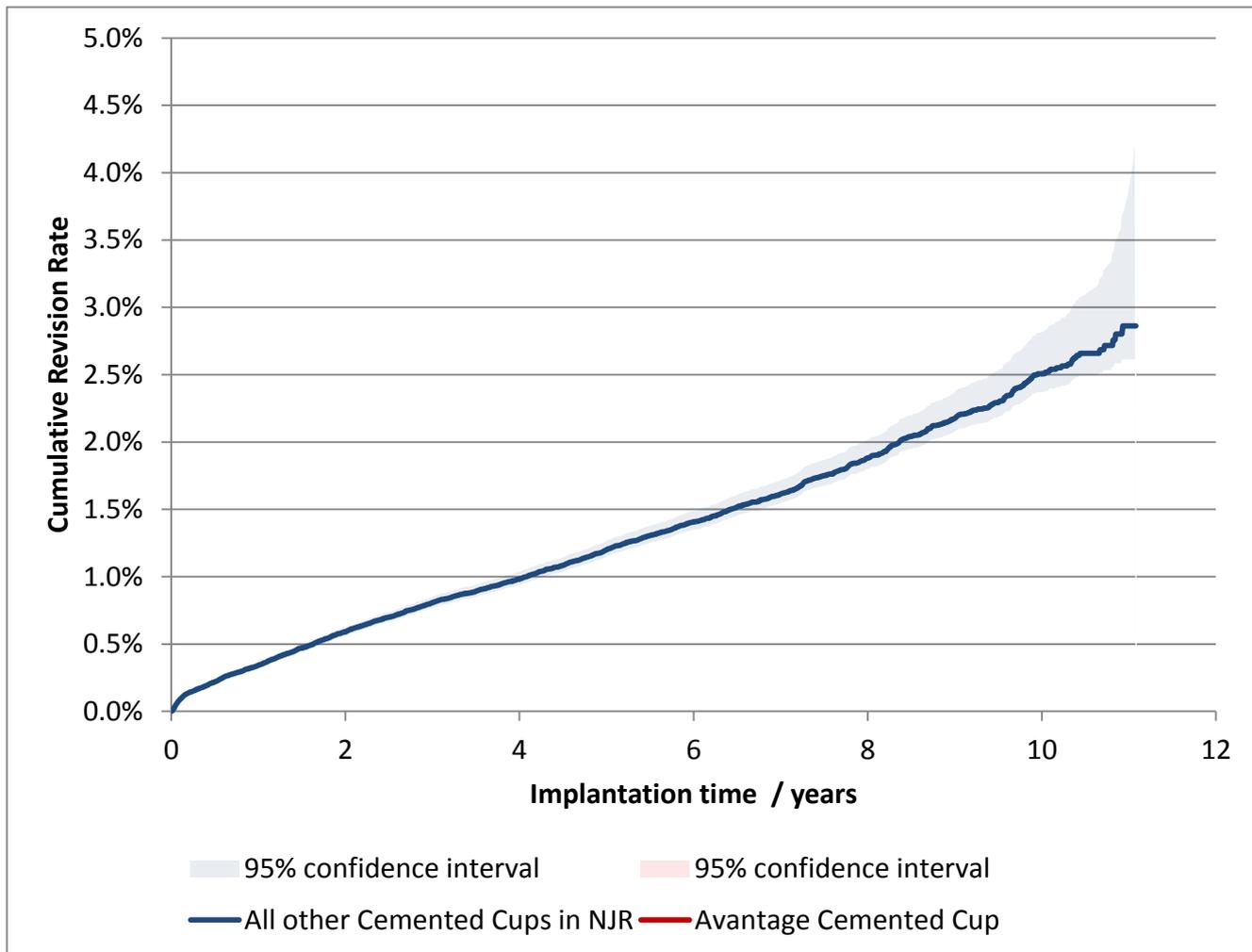
Cox Proportional Hazards model for revision risk ratio of Avantage Cemented Cup / all other Cemented Cups, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	Insufficient data	
Excluding MoM. Adjusted for age, gender, year cohort and indications.	Insufficient data	

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Acetabular Revision. All articulation types



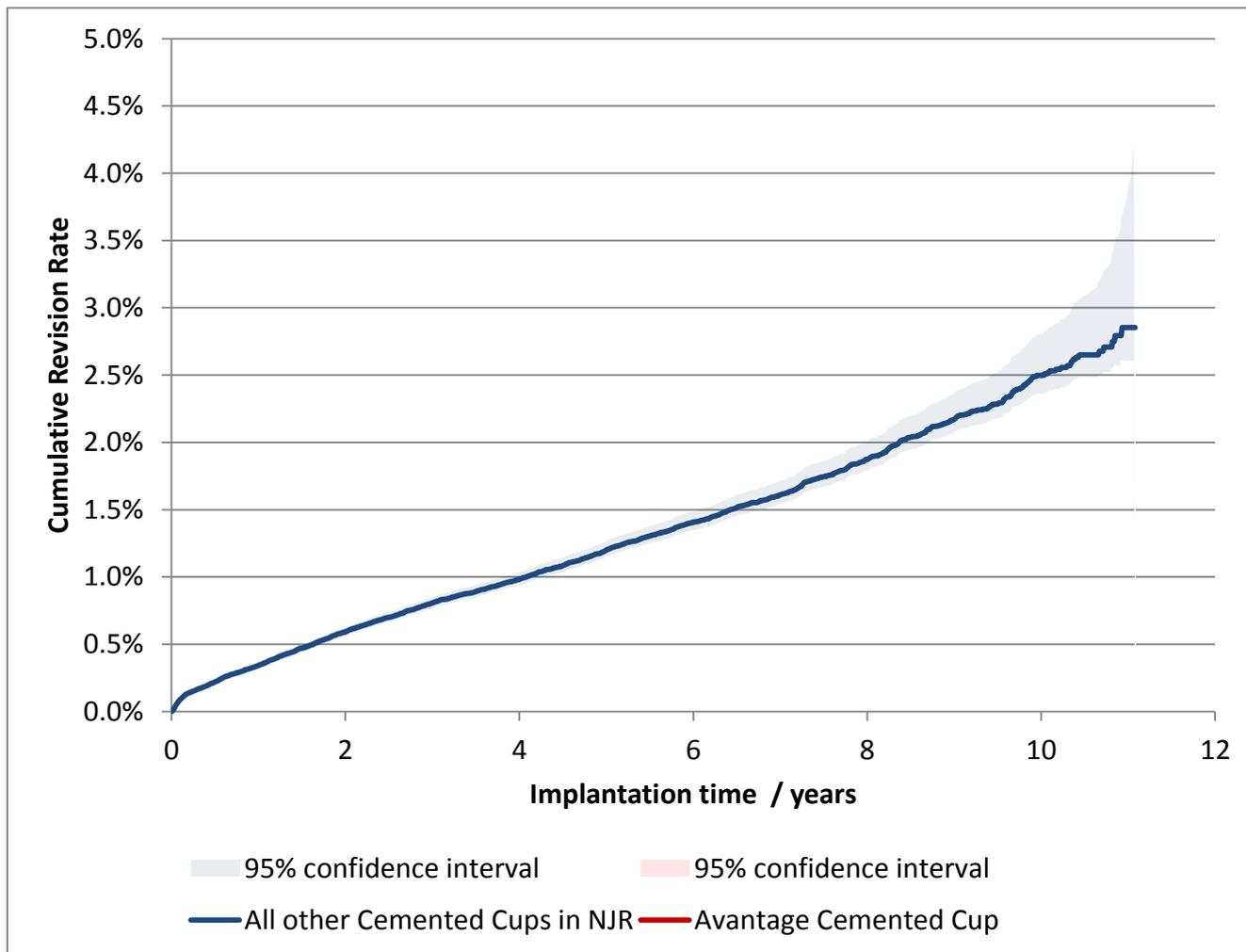
Cox Proportional Hazards model for revision risk ratio of Avantage Cemented Cup / all other Cemented Cups, with endpoint as Acetabular revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	Insufficient data	
All bearings. Adjusted for age, gender, year cohort and indications.	Insufficient data	

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Acetabular Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Avantage Cemented Cup / all other Cemented Cups, with endpoint as Acetabular revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted	Insufficient data	
Excluding MoM. Adjusted for age, gender, year cohort and indications.	Insufficient data	

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	All articulation types				Excluding Metal on Metal articulations			
	At Risk	Avantage Cemented Cup	All NJR Cemented Cups	All THR	At Risk	Avantage Cemented Cup	All NJR Cemented Cups	All THR
0	9	0.0% (0.0% - 0.0%)	0.0% (0.0% - 0.0%)	0.0% (0.0% - 0.0%)	9	0.0% (0.0% - 0.0%)	0.0% (0.0% - 0.0%)	0.0% (0.0% - 0.0%)
1		(-)	0.5% (0.5% - 0.5%)	0.7% (0.7% - 0.8%)		(-)	0.5% (0.4% - 0.5%)	0.7% (0.7% - 0.7%)
2		(-)	0.8% (0.7% - 0.8%)	1.2% (1.2% - 1.2%)		(-)	0.8% (0.7% - 0.8%)	1.1% (1.0% - 1.1%)
3		(-)	1.0% (1.0% - 1.1%)	1.6% (1.6% - 1.7%)		(-)	1.0% (1.0% - 1.1%)	1.4% (1.3% - 1.4%)
4		(-)	1.3% (1.2% - 1.3%)	2.1% (2.1% - 2.1%)		(-)	1.3% (1.2% - 1.3%)	1.6% (1.6% - 1.7%)
5		(-)	1.5% (1.5% - 1.6%)	2.7% (2.6% - 2.7%)		(-)	1.5% (1.5% - 1.6%)	1.9% (1.9% - 2.0%)
6		(-)	1.8% (1.7% - 1.9%)	3.3% (3.3% - 3.4%)		(-)	1.8% (1.7% - 1.9%)	2.2% (2.2% - 2.3%)
7		(-)	2.0% (2.0% - 2.2%)	4.0% (3.9% - 4.1%)		(-)	2.0% (2.0% - 2.2%)	2.5% (2.5% - 2.6%)
8		(-)	2.3% (2.3% - 2.5%)	4.6% (4.5% - 4.7%)		(-)	2.3% (2.3% - 2.5%)	2.8% (2.8% - 3.0%)
9		(-)	2.7% (2.6% - 2.9%)	5.2% (5.1% - 5.4%)		(-)	2.7% (2.6% - 2.9%)	3.2% (3.1% - 3.4%)
10		(-)	3.1% (2.9% - 3.4%)	5.7% (5.6% - 6.1%)		(-)	3.1% (2.9% - 3.4%)	3.6% (3.4% - 3.9%)

Cumulative revision rate with 95% confidence intervals

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Acetabular Revision

Period /years	All articulation types				Excluding Metal on Metal articulations			
	At Risk	Avantage Cemented Cup	All NJR Cemented Cups	All THR	At Risk	Avantage Cemented Cup	All NJR Cemented Cups	All THR
0	9	0.0% (0.0% - 0.0%)	0.0% (0.0% - 0.0%)	0.0% (0.0% - 0.0%)	9	0.0% (0.0% - 0.0%)	0.0% (0.0% - 0.0%)	0.0% (0.0% - 0.0%)
1		(-)	0.3% (0.3% - 0.4%)	0.5% (0.4% - 0.5%)		(-)	0.3% (0.3% - 0.4%)	0.4% (0.4% - 0.4%)
2		(-)	0.6% (0.6% - 0.6%)	0.8% (0.8% - 0.8%)		(-)	0.6% (0.6% - 0.6%)	0.7% (0.7% - 0.7%)
3		(-)	0.8% (0.8% - 0.9%)	1.1% (1.1% - 1.1%)		(-)	0.8% (0.8% - 0.8%)	0.9% (0.9% - 0.9%)
4		(-)	1.0% (0.9% - 1.0%)	1.5% (1.5% - 1.5%)		(-)	1.0% (0.9% - 1.0%)	1.1% (1.1% - 1.1%)
5		(-)	1.2% (1.1% - 1.3%)	2.0% (1.9% - 2.0%)		(-)	1.2% (1.1% - 1.3%)	1.3% (1.3% - 1.4%)
6		(-)	1.4% (1.3% - 1.5%)	2.5% (2.5% - 2.6%)		(-)	1.4% (1.3% - 1.5%)	1.5% (1.5% - 1.6%)
7		(-)	1.6% (1.5% - 1.7%)	3.1% (3.0% - 3.2%)		(-)	1.6% (1.5% - 1.7%)	1.7% (1.7% - 1.8%)
8		(-)	1.9% (1.8% - 2.0%)	3.6% (3.6% - 3.8%)		(-)	1.9% (1.8% - 2.0%)	2.0% (1.9% - 2.1%)
9		(-)	2.2% (2.1% - 2.4%)	4.2% (4.1% - 4.4%)		(-)	2.2% (2.1% - 2.4%)	2.3% (2.2% - 2.4%)
10		(-)	2.5% (2.4% - 2.8%)	4.7% (4.5% - 5.0%)		(-)	2.5% (2.4% - 2.8%)	2.6% (2.5% - 2.8%)

Cumulative revision rate with 95% confidence intervals

Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 30th November 2012

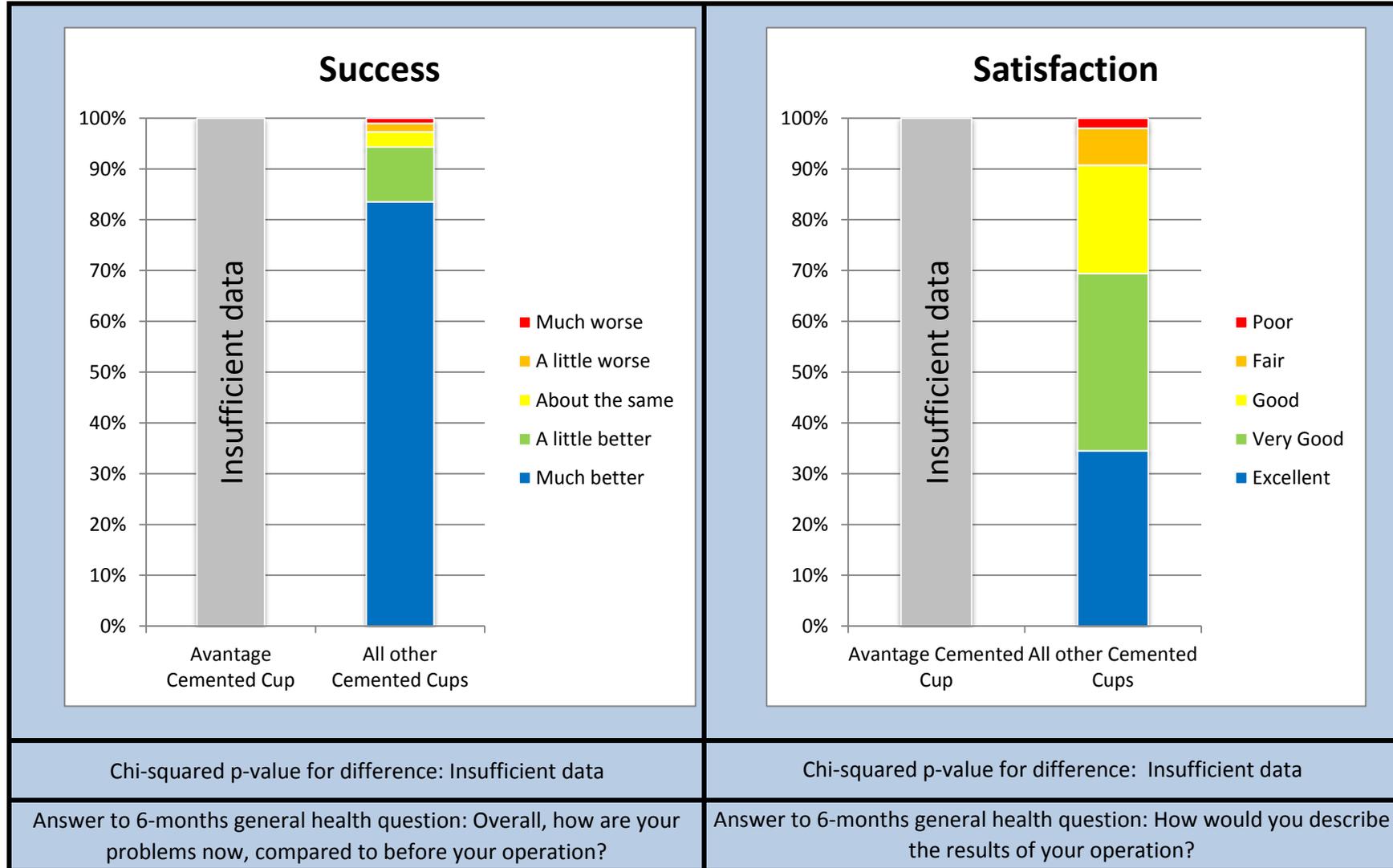
Measure	Product Group	Pre-Op Records	Mean Pre-Op Score	6-month records	Mean 6 month Score	Health Gain	Improved	Unchanged / Worsened
Oxford Hip Score	Avantage Cemented Cup	0	NaN	0	NaN	NaN	NaN	NaN
	All Cemented Cups	26,222	16.6	19,628	37.2	20.6	96%	4%
EQ-5D Index	Avantage Cemented Cup	0	NaN	0	NaN	NaN	NaN	NaN
	All Cemented Cups	24,843	0.30	18,468	0.75	0.45	88%	12%
EQ-VAS	Avantage Cemented Cup	0	NaN	0	NaN	NaN	NaN	NaN
	All Cemented Cups	23,516	63.5	18,459	73.5	10.0	61%	39%

Summary Report for:

Avantage Cemented Cup

Responses are not case mix adjusted

Patient Reported Outcomes



Chi-squared p-value for difference: Insufficient data

Chi-squared p-value for difference: Insufficient data

Answer to 6-months general health question: Overall, how are your problems now, compared to before your operation?

Answer to 6-months general health question: How would you describe the results of your operation?

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
P0463044	AVANTAGE CEMENTED SHELL SS Ø44MM	1
P0463046	AVANTAGE CEMENTED SHELL SS Ø46MM	1
P0463050	AVANTAGE CEMENTED SHELL SS Ø50MM	3
P0463054	AVANTAGE CEMENTED SHELL SS Ø54MM	2
P0463056	AVANTAGE CEMENTED SHELL SS Ø56MM	1
P0463060	AVANTAGE CEMENTED SHELL SS Ø60MM	1