

## Implant Summary Report for:

Implantcast GmbH

### EcoFit Cup cpTi

Comprising PRIMARY hips implanted up to:  
NJR Database extract:

06 December 2019  
04 February 2020

Produced on:  
Licensed for use until:

15 February 2020  
15 June 2020

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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 EcoFit Cup cpTi up to the specified dates. This analysis is based on data collected by the NJR and PROMs data collected by NHS Digital for the following combinations of products:

<b>Acetabular components</b>	<b>EcoFit Cup cpTi</b>
<b>Femoral Component</b>	<b>Any Femoral Components manufactured by Implantcast GmbH</b>

Appendix A lists details of all EcoFit Cup cpTi components included in this report.

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## NJR Recorded Usage

### Implant Usage

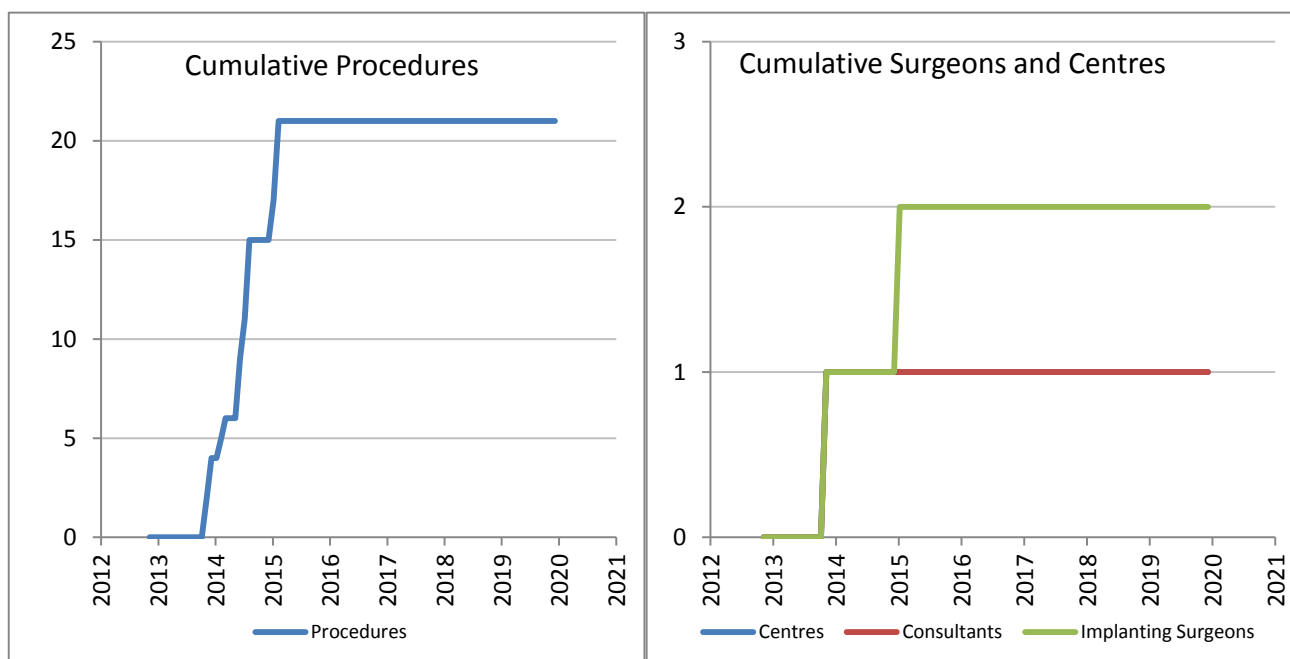
Date of first recorded usage in the NJR: **22 October 2013**

Date of last recorded usage in this dataset: **03 February 2015**

Maximum implantation time: 6.1 years

Mean implantation time: 5.2 years

Totals Recorded in NJR	Cumulative Total
Procedures	21
Patients	21
Centres	1
Consultants	1
Implanting Surgeons	2



Current Outcome	Pre-2008	Year of implantation													Total	%
		2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019			
Death	0	0	0	0	0	0	1	0	0	0	0	0	0	1	4.8%	
Revised	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0%	
Unrevised	0	0	0	0	0	0	3	13	4	0	0	0	0	20	95.2%	
Total	0	0	0	0	0	0	4	13	4	0	0	0	0	21	100%	

## Patient / Procedure Details

## Patient Details

	EcoFit Cup cpTi	All other Cementless Cups in NJR	All NJR hip replacement
<b>Total Procedures</b>	21	772,705	1,204,099
<b>Total Patients</b>	21	658,643	1,017,482
<b>Demographics</b>			
Mean age	<b>70.9</b>	<b>66.1</b>	<b>68.6</b>
< 50	0.0%	8.3%	5.9%
50 – 59	9.5%	18.1%	13.8%
60 – 69	47.6%	32.4%	29.0%
70 – 79	23.8%	29.7%	34.7%
≥ 80	19.0%	11.5%	16.6%
Median BMI	<b>27</b>	<b>28</b>	<b>28</b>
% BMI information available	42.9%	64.0%	62.0%
Underweight ( BMI < 18.5)	0.0%	0.8%	0.9%
Normal (18.5 ≤ BMI < 25)	22.2%	19.9%	20.7%
Overweight (25 ≤ BMI < 30)	33.3%	39.4%	39.6%
Obese I (30 ≤ BMI < 35)	33.3%	26.2%	25.8%
Obese II (35 ≤ BMI < 40)	11.1%	10.2%	9.7%
Obese III (BMI ≥ 40)	0.0%	3.5%	3.3%
% Male	47.6%	43.7%	40.2%
<b>ASA Grades</b>			
P1 - Fit and healthy	28.6%	18.4%	15.7%
P2 - Mild disease not incapacitating	57.1%	67.5%	67.6%
P3 - Incapacitating systemic disease	14.3%	13.7%	16.1%
P4 / P5	0.0%	0.4%	0.6%
<b>Indications</b>			
Osteoarthritis	90.48%	91.81%	91.50%
Rheumatoid Arthritis	4.76%	1.28%	1.32%
Avascular Necrosis	19.05%	2.64%	2.50%
Fractured Neck of Femur	0.00%	2.94%	3.45%
CDH/DDH	4.76%	2.08%	1.57%
Other	0.00%	1.97%	2.12%

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 - all bearing types

Reasons for revision of primary procedures in which the implant was used.

Reason for Revision	Revised <sup>†</sup>	Expected Revisions <sup>*</sup>	p value
Unexplained Pain	0	0.02	1
Dislocation / Subluxation	0	0.09	1
Adverse Soft Tissue Reaction	0	0.01	1
Infection	0	0.08	1
Aseptic Loosening - Stem	0	0.05	1
Aseptic Loosening - Socket	0	0.02	1
Periprosthetic Fracture Stem	0	0.08	1
Periprosthetic Fracture Socket	0	0.01	1
Malalignment Stem	0	0.01	1
Malalignment Socket	0	0.02	1
Wear Of Acetabular Component	0	0.01	1
Lysis Stem	0	0.01	1
Lysis Socket	0	0.00	1
Implant Fracture Stem	0	0.00	1
Implant Fracture Socket	0	0.01	1
Implant Fracture Head	0	0.00	1
Dissociation of Liner	0	0.01	1
Other / reason not recorded	0	0.02	1
<b>Total Revised</b>	<b>0</b>	<b>0.38</b>	<b>1</b>

<sup>†</sup> multiple reasons may be listed for one revision procedure<sup>\*</sup> Based on All NJR Cementless Cups, adjusted for agegroup, gender, indications, and implantation yearSignificantly better,  $p < 0.001$ Significantly better,  $p < 0.05$ Significantly worse  $p < 0.05$ Significantly worse  $p < 0.001$ 

Components Revised	Number of procedures	EcoFit Cup cpTi	All other Cementless Cups in NJR
Femoral only	0	NaN	22%
Acetabular only	0	NaN	25%
Both femoral and acetabular	0	NaN	43%
Neither femoral nor acetabular revision recorded <sup>*</sup>	0	NaN	10%

<sup>\*</sup> includes isolated head and/or liner exchange

## Revision and Survivorship

## Reasons for Revision - excluding Metal on Metal

Reasons for revision of non-MoM primary procedures in which the implant was used.

Reason for Revision	Revised <sup>†</sup>	Expected Revisions <sup>*</sup>	p value
Unexplained Pain	0	0.02	1
Dislocation / Subluxation	0	0.09	1
Adverse Soft Tissue Reaction	0	0.01	1
Infection	0	0.08	1
Aseptic Loosening - Stem	0	0.05	1
Aseptic Loosening - Socket	0	0.02	1
Periprosthetic Fracture Stem	0	0.08	1
Periprosthetic Fracture Socket	0	0.01	1
Malalignment Stem	0	0.01	1
Malalignment Socket	0	0.02	1
Wear Of Acetabular Component	0	0.01	1
Lysis Stem	0	0.01	1
Lysis Socket	0	0.00	1
Implant Fracture Stem	0	0.00	1
Implant Fracture Socket	0	0.01	1
Implant Fracture Head	0	0.00	1
Dissociation of Liner	0	0.01	1
Other / reason not recorded	0	0.02	1
<b>Total Revised</b>	<b>0</b>	<b>0.38</b>	<b>1</b>

\* Based on All NJR Cementless Cups (excluding metal on metal), adjusted for agegroup, gender, indications, and implantation year

† multiple reasons may be listed for one revision procedure

Significantly better,  $p < 0.001$

Significantly better,  $p < 0.05$

Significantly worse  $p < 0.05$

Significantly worse  $p < 0.001$



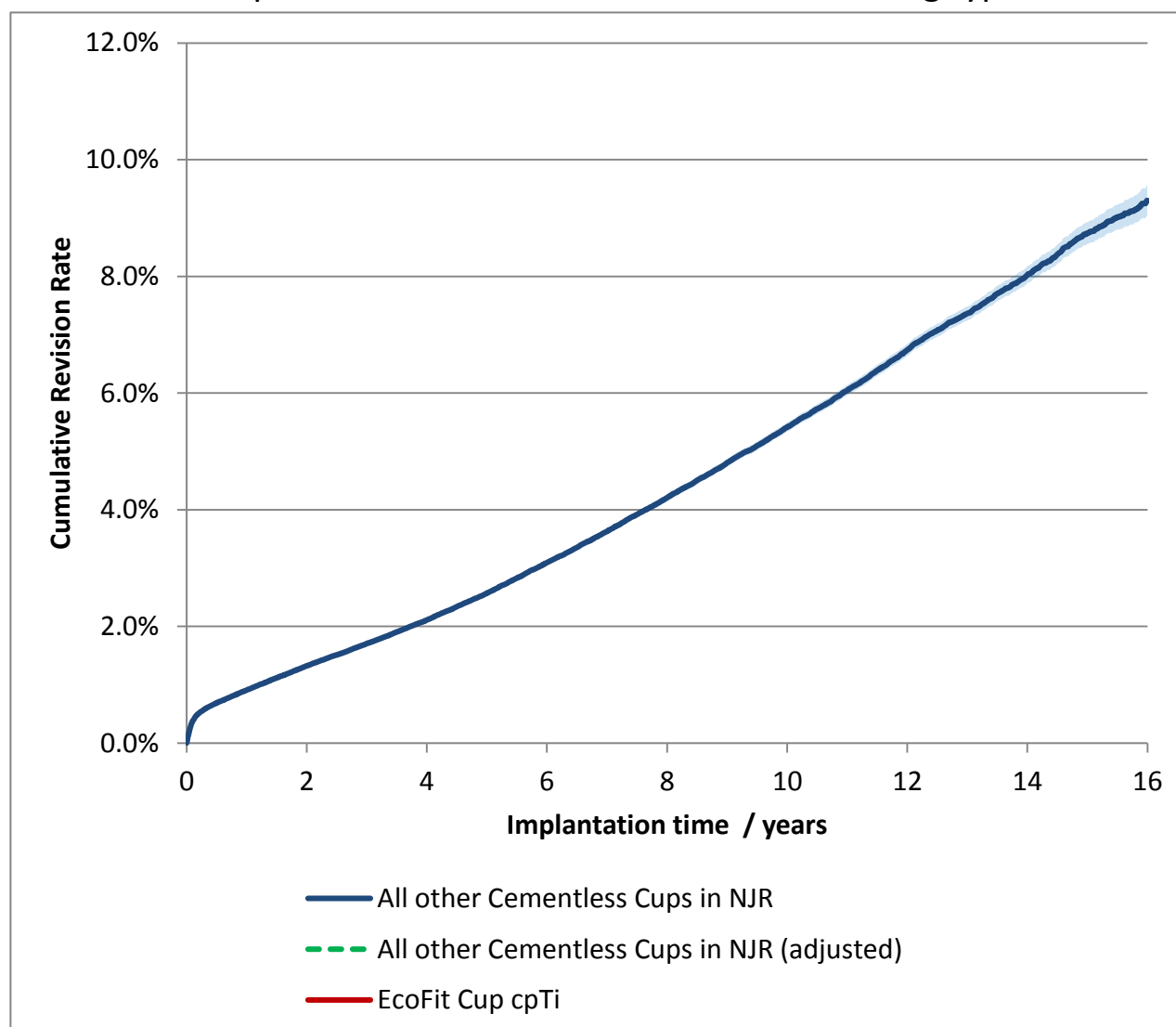
Components Revised	Number of procedures	EcoFit Cup cpTi	All other Cementless Cups in NJR
Femoral only	0	NaN	31%
Acetabular only	0	NaN	24%
Both femoral and acetabular	0	NaN	33%
Neither femoral nor acetabular revision recorded *	0	NaN	13%

\* includes isolated head and/or liner exchange

## Revision and Survivorship

## Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



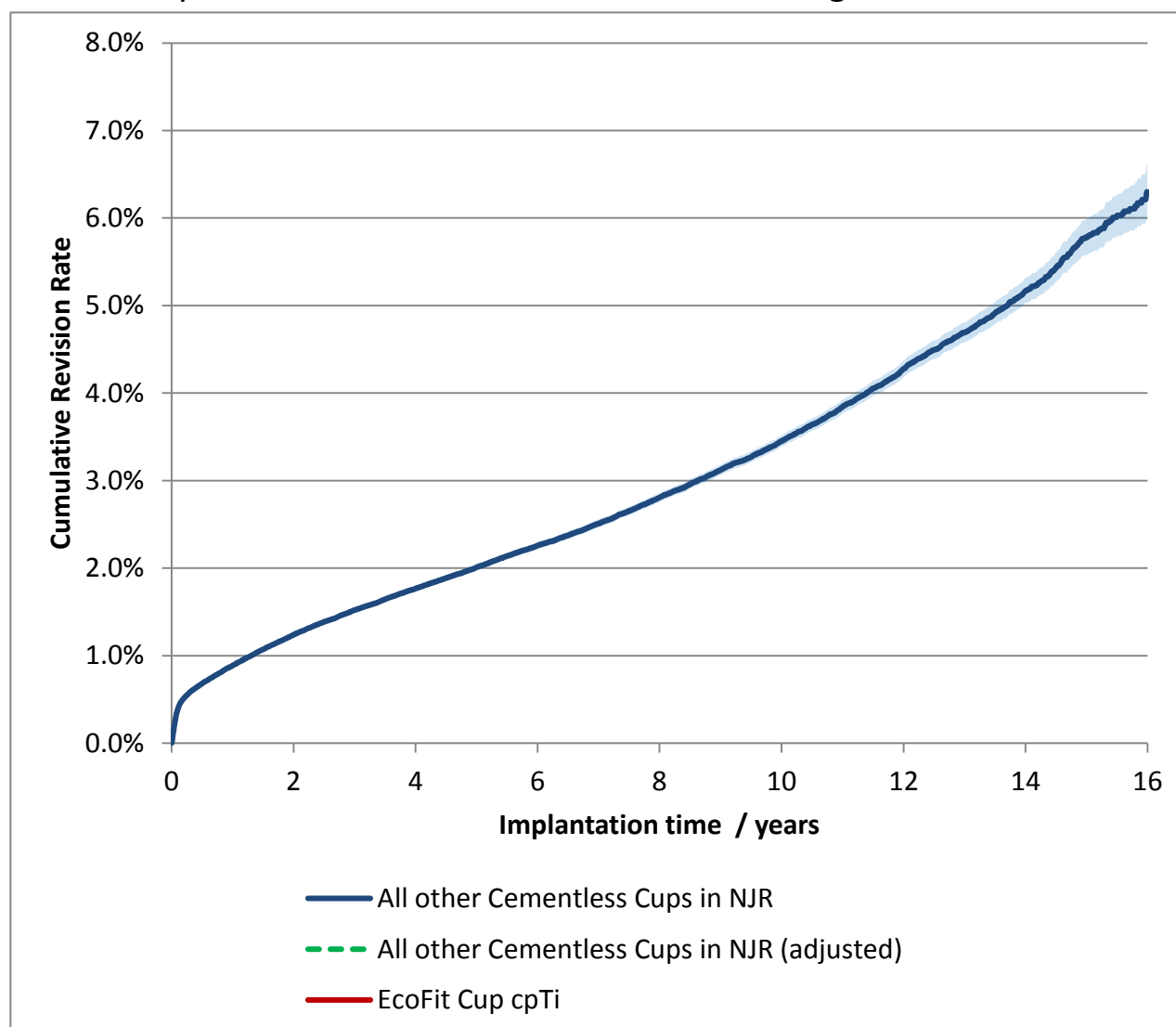
Cox Proportional Hazards model for revision risk ratio of EcoFit Cup cpTi / All other Cementless Cups in NJR, with endpoint as any revision.

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



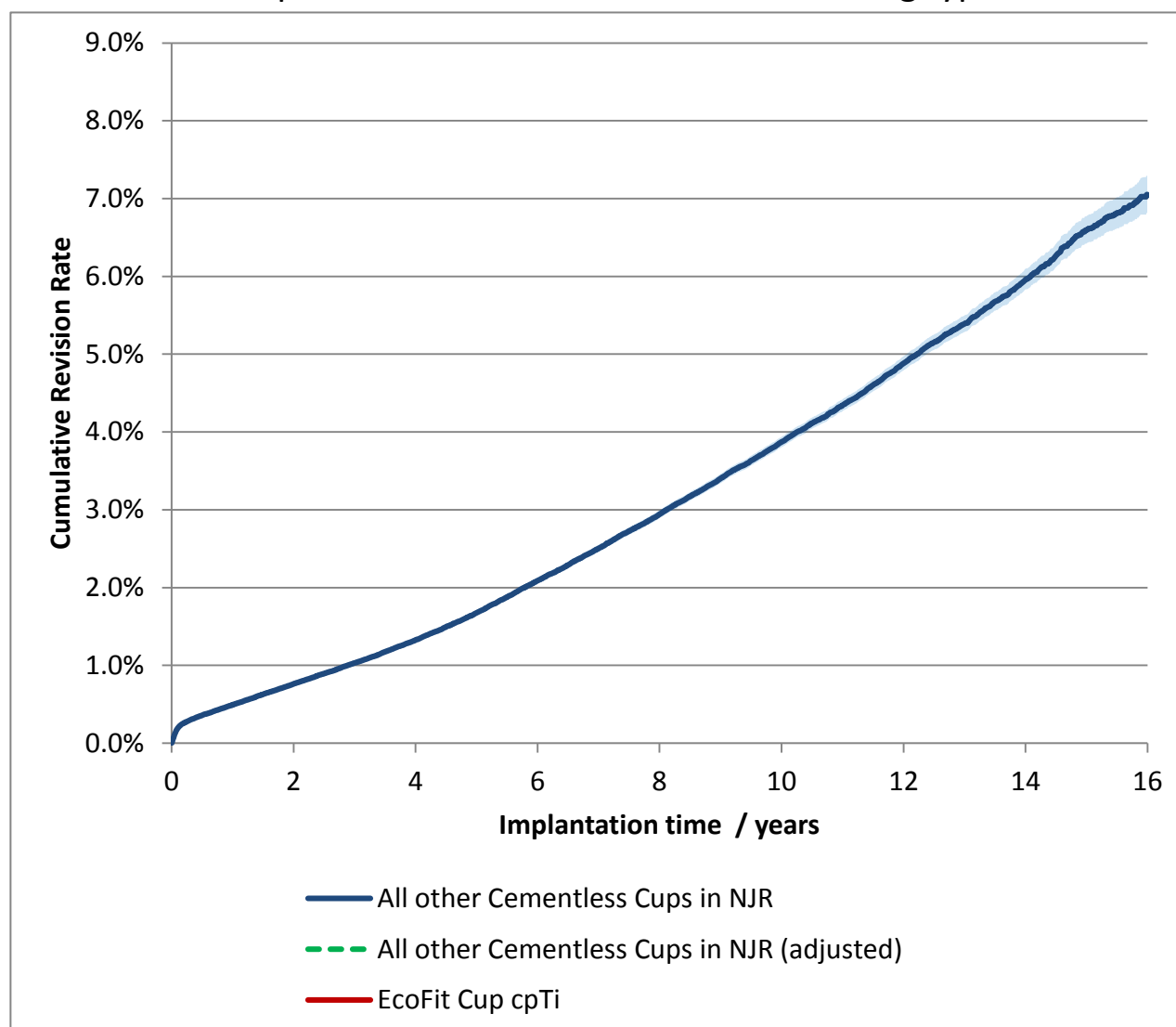
Cox Proportional Hazards model for revision risk ratio of EcoFit Cup cpTi / All other Cementless Cups in NJR, with endpoint as any revision.

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 Bearing types



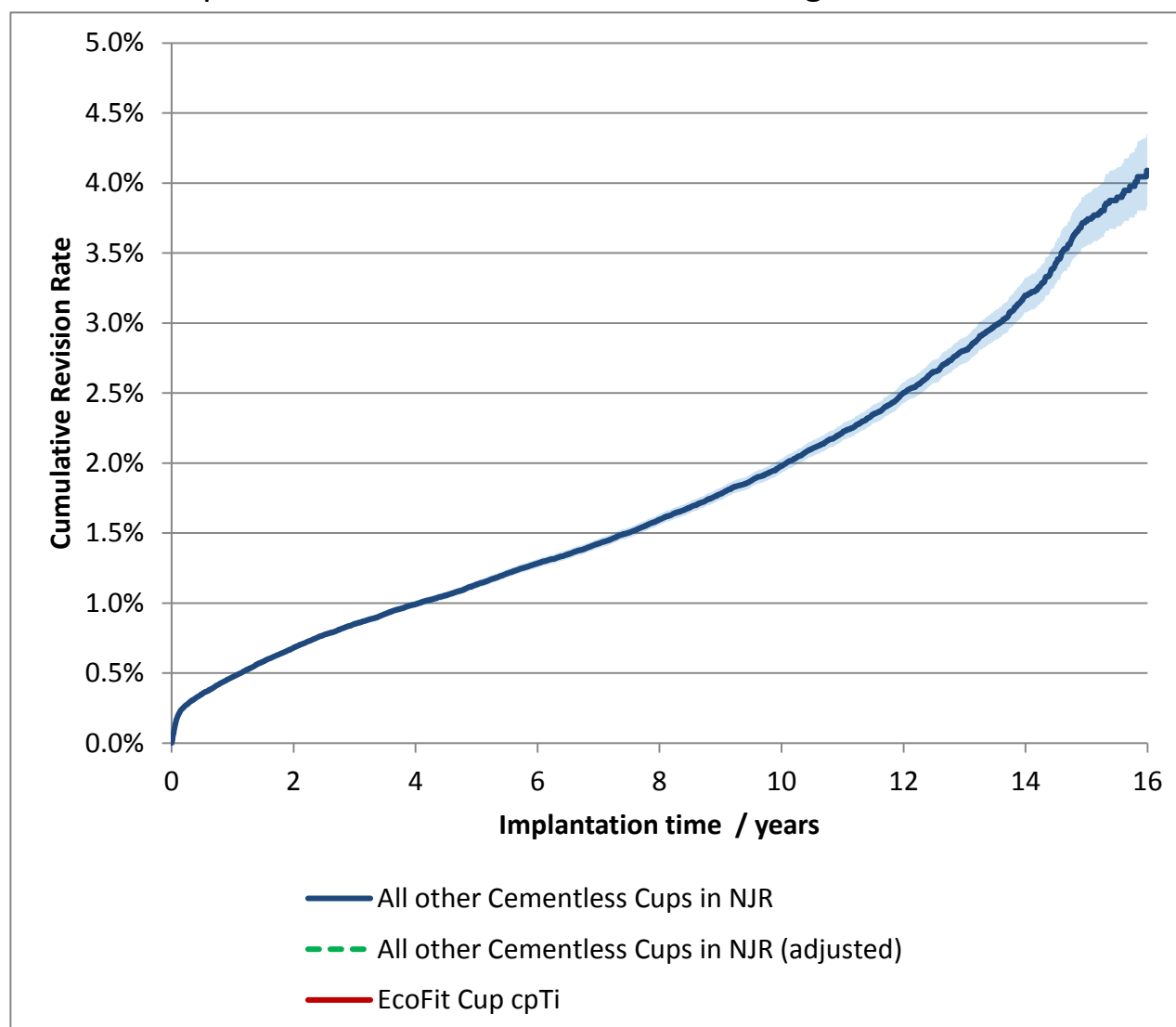
Cox Proportional Hazards model for revision risk ratio of EcoFit Cup cpTi / All other Cementless Cups in NJR, with endpoint as any revision.

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: Acetabular Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of EcoFit Cup cpTi / All other Cementless Cups in NJR, 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: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	EcoFit Cup cpTi	All other Cementless Cups in NJR	All THR	At Risk	EcoFit Cup cpTi	All other Cementless Cups in NJR	All THR
0	21	-	-	-	21	-	-	-
1		( - )	0.9% (0.9% - 0.9%)	0.8% (0.8% - 0.8%)		( - )	0.9% (0.9% - 0.9%)	0.8% (0.8% - 0.8%)
2		( - )	1.3% (1.3% - 1.4%)	1.2% (1.1% - 1.2%)		( - )	1.2% (1.2% - 1.3%)	1.1% (1.1% - 1.1%)
3		( - )	1.7% (1.7% - 1.7%)	1.5% (1.5% - 1.5%)		( - )	1.5% (1.5% - 1.6%)	1.4% (1.4% - 1.4%)
4		( - )	2.1% (2.1% - 2.1%)	1.8% (1.8% - 1.9%)		( - )	1.8% (1.7% - 1.8%)	1.6% (1.6% - 1.6%)
5		( - )	2.6% (2.5% - 2.6%)	2.2% (2.2% - 2.3%)		( - )	2.0% (2.0% - 2.0%)	1.9% (1.8% - 1.9%)
6		( - )	3.1% (3.0% - 3.1%)	2.6% (2.6% - 2.7%)		( - )	2.3% (2.2% - 2.3%)	2.1% (2.1% - 2.1%)
7		( - )	3.6% (3.6% - 3.7%)	3.1% (3.0% - 3.1%)		( - )	2.5% (2.5% - 2.6%)	2.4% (2.3% - 2.4%)
8		( - )	4.2% (4.1% - 4.3%)	3.5% (3.5% - 3.6%)		( - )	2.8% (2.8% - 2.9%)	2.7% (2.6% - 2.7%)
9		( - )	4.8% (4.7% - 4.9%)	4.0% (4.0% - 4.1%)		( - )	3.1% (3.1% - 3.2%)	3.0% (2.9% - 3.0%)
10		( - )	5.4% (5.3% - 5.5%)	4.6% (4.5% - 4.6%)		( - )	3.5% (3.4% - 3.5%)	3.3% (3.3% - 3.4%)
11		( - )	6.0% (6.0% - 6.1%)	5.1% (5.1% - 5.2%)		( - )	3.8% (3.8% - 3.9%)	3.7% (3.7% - 3.8%)
12		( - )	6.7% (6.6% - 6.8%)	5.7% (5.7% - 5.8%)		( - )	4.3% (4.2% - 4.4%)	4.2% (4.1% - 4.3%)
13		( - )	7.4% (7.2% - 7.5%)	6.3% (6.2% - 6.4%)		( - )	4.7% (4.6% - 4.8%)	4.7% (4.6% - 4.8%)
14		( - )	8.0% (7.9% - 8.2%)	6.9% (6.8% - 7.0%)		( - )	5.2% (5.0% - 5.3%)	5.1% (5.0% - 5.3%)
15		( - )	8.7% (8.5% - 8.9%)	7.6% (7.4% - 7.7%)		( - )	5.8% (5.6% - 6.0%)	5.8% (5.6% - 5.9%)

Cumulative revision rate with 95% confidence intervals

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

## Revision and Survivorship

## Cumulative Revision Rate

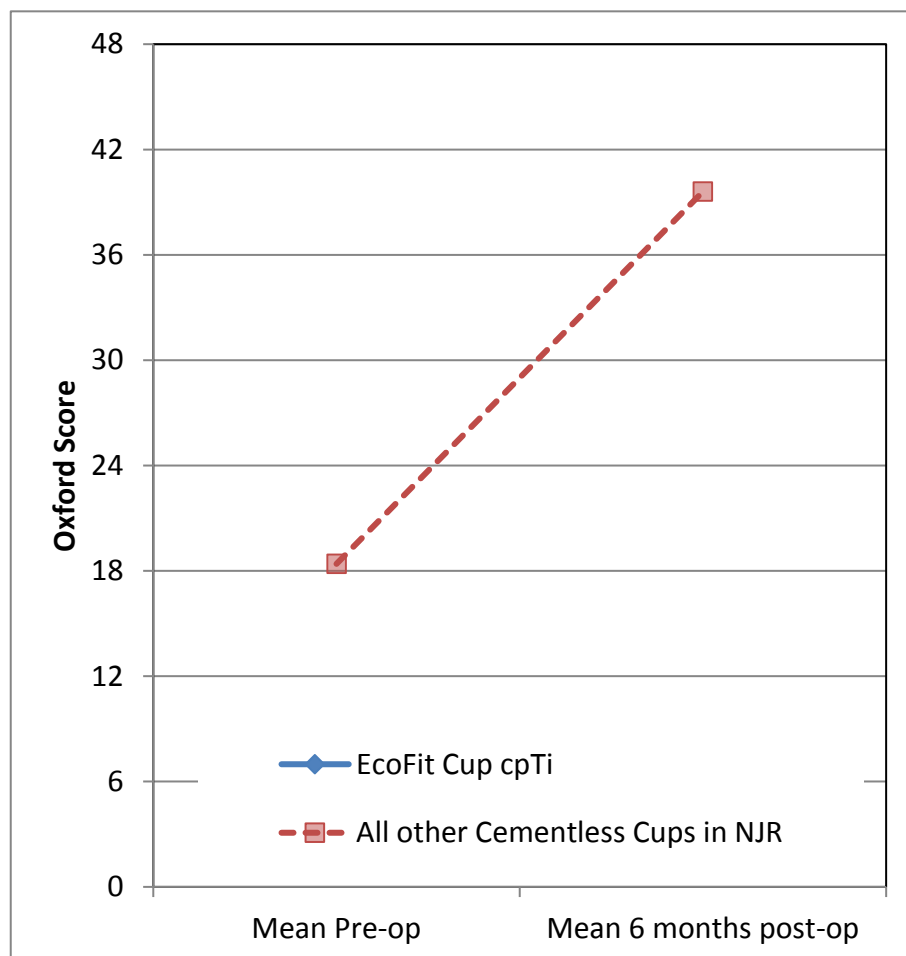
Endpoint: Acetabular Revision

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	EcoFit Cup cpTi	All other Cementless Cups	All THR	At Risk	EcoFit Cup cpTi	All other Cementless Cups	All THR
0	21	-	-	-	21	-	-	-
1		( - )	0.5% (0.5% - 0.5%)	0.4% (0.4% - 0.5%)		( - )	0.5% (0.5% - 0.5%)	0.4% (0.4% - 0.4%)
2		( - )	0.8% (0.7% - 0.8%)	0.7% (0.7% - 0.7%)		( - )	0.7% (0.7% - 0.7%)	0.6% (0.6% - 0.7%)
3		( - )	1.0% (1.0% - 1.1%)	0.9% (0.9% - 1.0%)		( - )	0.9% (0.8% - 0.9%)	0.8% (0.8% - 0.9%)
4		( - )	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)		( - )	1.0% (1.0% - 1.0%)	1.0% (1.0% - 1.0%)
5		( - )	1.7% (1.6% - 1.7%)	1.5% (1.5% - 1.5%)		( - )	1.1% (1.1% - 1.2%)	1.1% (1.1% - 1.2%)
6		( - )	2.1% (2.0% - 2.1%)	1.8% (1.8% - 1.8%)		( - )	1.3% (1.3% - 1.3%)	1.3% (1.3% - 1.3%)
7		( - )	2.5% (2.5% - 2.5%)	2.2% (2.1% - 2.2%)		( - )	1.4% (1.4% - 1.5%)	1.5% (1.5% - 1.5%)
8		( - )	2.9% (2.9% - 3.0%)	2.5% (2.5% - 2.6%)		( - )	1.6% (1.6% - 1.6%)	1.7% (1.7% - 1.7%)
9		( - )	3.4% (3.3% - 3.5%)	2.9% (2.9% - 2.9%)		( - )	1.8% (1.7% - 1.8%)	1.9% (1.9% - 1.9%)
10		( - )	3.9% (3.8% - 3.9%)	3.3% (3.3% - 3.4%)		( - )	2.0% (1.9% - 2.0%)	2.2% (2.1% - 2.2%)
11		( - )	4.3% (4.3% - 4.4%)	3.8% (3.7% - 3.8%)		( - )	2.2% (2.2% - 2.3%)	2.5% (2.4% - 2.5%)
12		( - )	4.9% (4.8% - 5.0%)	4.3% (4.2% - 4.3%)		( - )	2.5% (2.4% - 2.6%)	2.8% (2.8% - 2.9%)
13		( - )	5.4% (5.3% - 5.5%)	4.7% (4.7% - 4.8%)		( - )	2.8% (2.7% - 2.9%)	3.2% (3.1% - 3.3%)
14		( - )	6.0% (5.8% - 6.1%)	5.2% (5.1% - 5.3%)		( - )	3.2% (3.1% - 3.3%)	3.6% (3.5% - 3.7%)
15		( - )	6.6% (6.4% - 6.8%)	5.8% (5.7% - 6.0%)		( - )	3.7% (3.5% - 3.9%)	4.2% (4.0% - 4.3%)

Cumulative revision rate with 95% confidence intervals

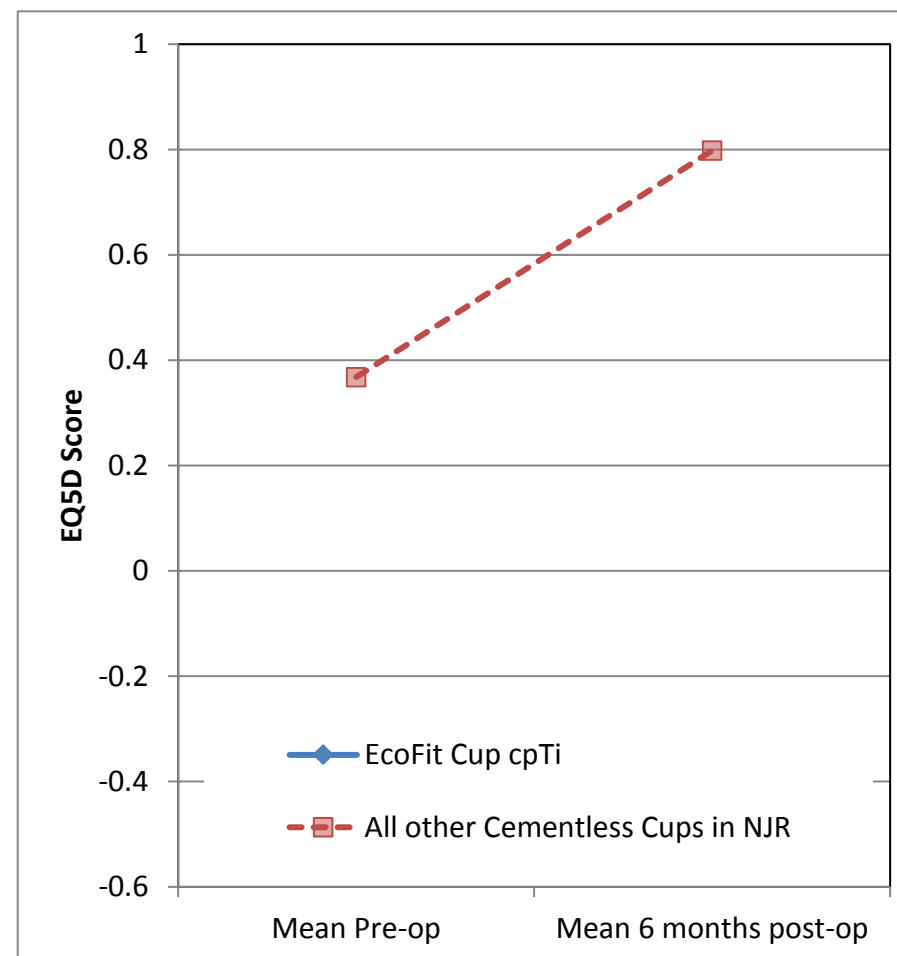
Rate is only reported for times where more than 40 remain at risk

## PROMs Analysis



## Patient Reported Outcomes

Comprising PROMs data up to and including: 29/03/2018



## Patient Reported Outcomes

### PROMs Analysis

Comprising PROMs data up to and including: 29/03/2018

Oxford Hip Score (0 - 48)	EcoFit Cup cpTi	All other Cementless Cups in NJR	All THR in NJR
Paired Records	0	185,466	291,075
PreOp score		18.4 (18.4 - 18.4)	18.0 (18.0 - 18.0)
6 month score		40.0 (39.9 - 40.0)	39.3 (39.3 - 39.4)
6 month score (adjusted)		39.6 (39.6 - 39.7)	39.3 (39.3 - 39.4)
Health gain		21.6 (21.5 - 21.6)	21.3 (21.3 - 21.4)
Health gain (adjusted)		21.6 (21.6 - 21.7)	21.3 (21.3 - 21.4)
p value (adjusted health gain)			
Score Improved	0.0%	97.3%	97.2%

EQ-5D Index (-0.59 - 1.00)	EcoFit Cup cpTi	All other Cementless Cups in NJR	All THR in NJR
Paired Records	0	171,275	267,683
PreOp score		0.368 (0.367 - 0.370)	0.355 (0.354 - 0.356)
6 month score		0.804 (0.803 - 0.805)	0.792 (0.791 - 0.792)
6 month score (adjusted)		0.798 (0.797 - 0.799)	0.792 (0.791 - 0.792)
Health gain		0.436 (0.434 - 0.437)	0.437 (0.435 - 0.438)
Health gain (adjusted)		0.443 (0.442 - 0.444)	0.437 (0.436 - 0.437)
p value (adjusted health gain)			
Score Improved	0.0%	89.8%	89.4%

EQ-VAS (0 - 100)	EcoFit Cup cpTi	All other Cementless Cups in NJR	All THR in NJR
Paired Records	0	164,796	256,675
PreOp score		65.4 (65.3 - 65.5)	65.0 (64.9 - 65.1)
6 month score		77.7 (77.6 - 77.8)	76.8 (76.7 - 76.9)
6 month score (adjusted)		77.1 (77.0 - 77.2)	76.8 (76.7 - 76.8)
Health gain		12.3 (12.2 - 12.4)	11.8 (11.7 - 11.9)
Health gain (adjusted)		12.1 (12.0 - 12.2)	11.8 (11.7 - 11.8)
p value (adjusted health gain)			
Score Improved	0.0%	66.8%	65.6%

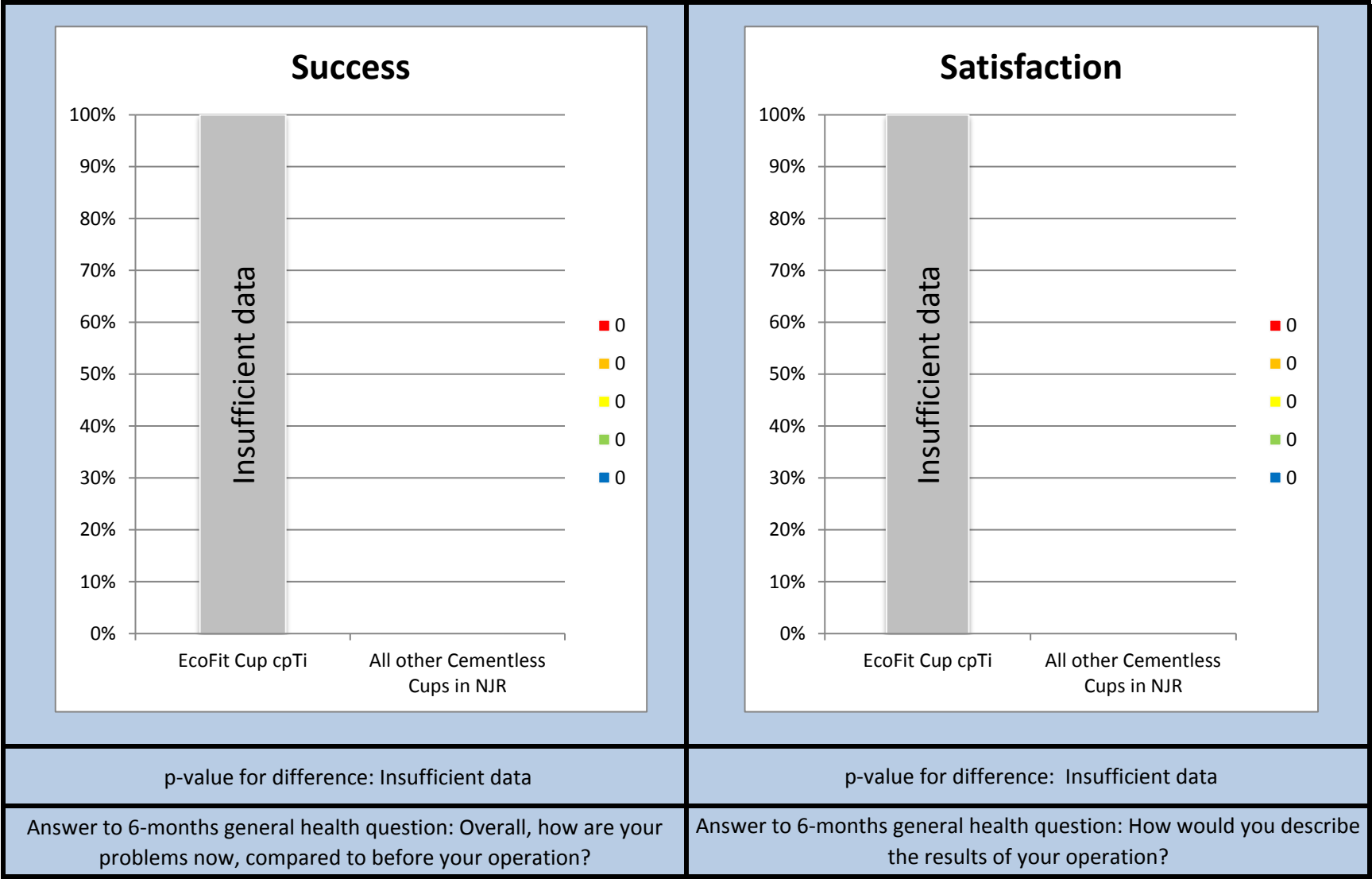
Adjusted scores correspond to the NHS Digital version 3 casemix-adjustment model. This includes patient variables from PROMs, HES, and IMD data.

Summary Report for:

EcoFit Cup cpTi

Responses are not case mix adjusted

Patient Reported Outcomes



## Patient Reported Outcomes

### Success

Response	EcoFit Cup cpTi	All other Cementless Cups in NJR

Answer to 6-months general health question:

"Overall, how are your problems now, compared to before your operation?"

### Satisfaction

Response	EcoFit Cup cpTi	All other Cementless Cups in NJR

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
02200048	EcoFit® cup cementless size Ø 48mm incl. central hole cover	4
02200050	EcoFit® cup cementless size Ø 50mm incl. central hole cover	4
02200052	EcoFit® cup cementless size Ø 52mm incl. central hole cover	7
02200054	EcoFit® cup cementless size Ø 54mm incl. central hole cover	2
02200056	EcoFit® cup cementless size Ø 56mm incl. central hole cover	3
02200058	EcoFit® cup cementless size Ø 58mm incl. central hole cover	1

## Appendix A: Component List

Catalogue Number	Description	Number Implanted
02203239	BIOLOX® delta-cup insert size Ø 32/39mm	3
02203644	BIOLOX® delta cup insert size Ø 36/44mm	5
02203648	BIOLOX® delta cup insert size Ø 36/48mm	1
02802139	PE-cup insert 10° size Ø 28/39mm	1
02802144	PE-cup insert 10° size Ø 28/44mm	6
02802148	PE-cup insert 10° size Ø 28/48mm	3
02803144	PE-cup insert 10° size Ø 32/44mm	1
02803444	PE-cup insert 0° size Ø 32/44mm	1