

## Implant Summary Report for:

Implantcast GmbH

### EcoFit Cup HA

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 HA 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:

**Acetabular components**

**EcoFit Cup HA**

**Femoral Component**

**Any Femoral Components manufactured by Implantcast GmbH**

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

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**NJR Recorded Usage**

**Implant Usage**

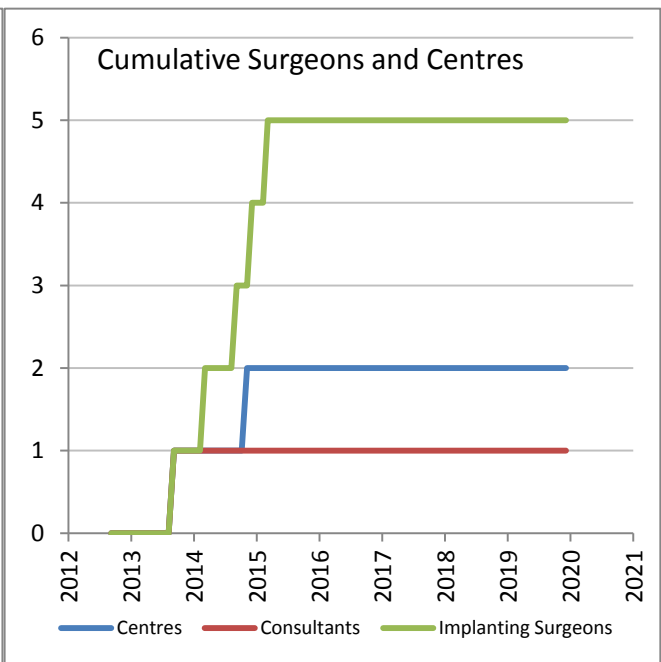
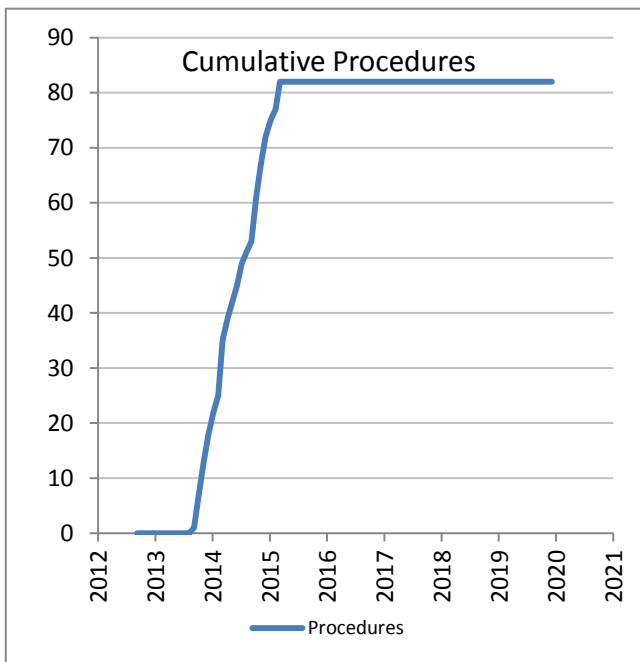
Date of first recorded usage in the NJR: **05 September 2013**

Date of last recorded usage in this dataset: **04 March 2015**

Maximum implantation time: 6.3 years

Mean implantation time: 5.2 years

Totals Recorded in NJR	Cumulative Total
Procedures	82
Patients	82
Centres	2
Consultants	1
Implanting Surgeons	5



Current Outcome	Year of implantation														Total	%
	Pre-2008	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019			
<b>Death</b>	0	0	0	0	0	0	2	8	0	0	0	0	0	10	12.2%	
<b>Revised</b>	0	0	0	0	0	0	1	0	1	0	0	0	0	2	2.4%	
<b>Unrevised</b>	0	0	0	0	0	0	19	45	6	0	0	0	0	70	85.4%	
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>22</b>	<b>53</b>	<b>7</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>82</b>	<b>100%</b>	

## Patient / Procedure Details

## Patient Details

	EcoFit Cup HA	All other Cementless Cups in NJR	All NJR hip replacement
<b>Total Procedures</b>	82	772,646	1,204,099
<b>Total Patients</b>	82	658,598	1,017,482
<b>Demographics</b>			
Mean age	<b>71.1</b>	<b>66.1</b>	<b>68.6</b>
< 50	1.2%	8.3%	5.9%
50 – 59	4.9%	18.1%	13.8%
60 – 69	39.0%	32.4%	29.0%
70 – 79	35.4%	29.7%	34.7%
≥ 80	19.5%	11.5%	16.6%
Median BMI	<b>27</b>	<b>28</b>	<b>28</b>
% BMI information available	32.9%	64.1%	62.0%
Underweight ( BMI < 18.5)	3.7%	0.8%	0.9%
Normal (18.5 ≤ BMI < 25)	25.9%	19.9%	20.7%
Overweight (25 ≤ BMI < 30)	44.4%	39.4%	39.6%
Obese I (30 ≤ BMI < 35)	18.5%	26.2%	25.8%
Obese II (35 ≤ BMI < 40)	3.7%	10.2%	9.7%
Obese III (BMI ≥ 40)	3.7%	3.5%	3.3%
% Male	51.2%	43.7%	40.2%
<b>ASA Grades</b>			
P1 - Fit and healthy	6.1%	18.4%	15.7%
P2 - Mild disease not incapacitating	69.5%	67.5%	67.6%
P3 - Incapacitating systemic disease	24.4%	13.7%	16.1%
P4 / P5	0.0%	0.4%	0.6%
<b>Indications</b>			
Osteoarthritis	89.02%	91.81%	91.50%
Rheumatoid Arthritis	0.00%	1.28%	1.32%
Avascular Necrosis	9.76%	2.64%	2.50%
Fractured Neck of Femur	2.44%	2.94%	3.45%
CDH/DDH	3.66%	2.08%	1.57%
Other	1.22%	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	0.09	1
Dislocation / Subluxation	0	0.34	1
Adverse Soft Tissue Reaction	0	0.04	1
Infection	0	0.32	1
Aseptic Loosening - Stem	0	0.19	1
Aseptic Loosening - Socket	0	0.06	1
Periprosthetic Fracture Stem	1	0.32	0.276
Periprosthetic Fracture Socket	0	0.04	1
Malalignment Stem	0	0.05	1
Malalignment Socket	0	0.07	1
Wear Of Acetabular Component	0	0.05	1
Lysis Stem	0	0.02	1
Lysis Socket	0	0.01	1
Implant Fracture Stem	0	0.01	1
Implant Fracture Socket	0	0.02	1
Implant Fracture Head	0	0.00	1
Dissociation of Liner	1	0.04	0.035
Other / reason not recorded	0	0.07	1
<b>Total Revised</b>	<b>2</b>	<b>1.49</b>	<b>0.665</b>

† multiple reasons may be listed for one revision procedure

\* Based on All NJR Cementless Cups, 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	EcoFit Cup HA	All other Cementless Cups in NJR
Femoral only	0	0%	22%
Acetabular only	0	0%	25%
Both femoral and acetabular	1	50%	43%
Neither femoral nor acetabular revision recorded *	1	50%	10%

\* 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	0.09	1
Dislocation / Subluxation	0	0.34	1
Adverse Soft Tissue Reaction	0	0.03	1
Infection	0	0.32	1
Aseptic Loosening - Stem	0	0.19	1
Aseptic Loosening - Socket	0	0.06	1
Periprosthetic Fracture Stem	1	0.32	0.276
Periprosthetic Fracture Socket	0	0.04	1
Malalignment Stem	0	0.05	1
Malalignment Socket	0	0.07	1
Wear Of Acetabular Component	0	0.05	1
Lysis Stem	0	0.02	1
Lysis Socket	0	0.01	1
Implant Fracture Stem	0	0.01	1
Implant Fracture Socket	0	0.02	1
Implant Fracture Head	0	0.00	1
Dissociation of Liner	1	0.04	0.035
Other / reason not recorded	0	0.07	1
<b>Total Revised</b>	<b>2</b>	<b>1.49</b>	<b>0.664</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  $p < 0.001$



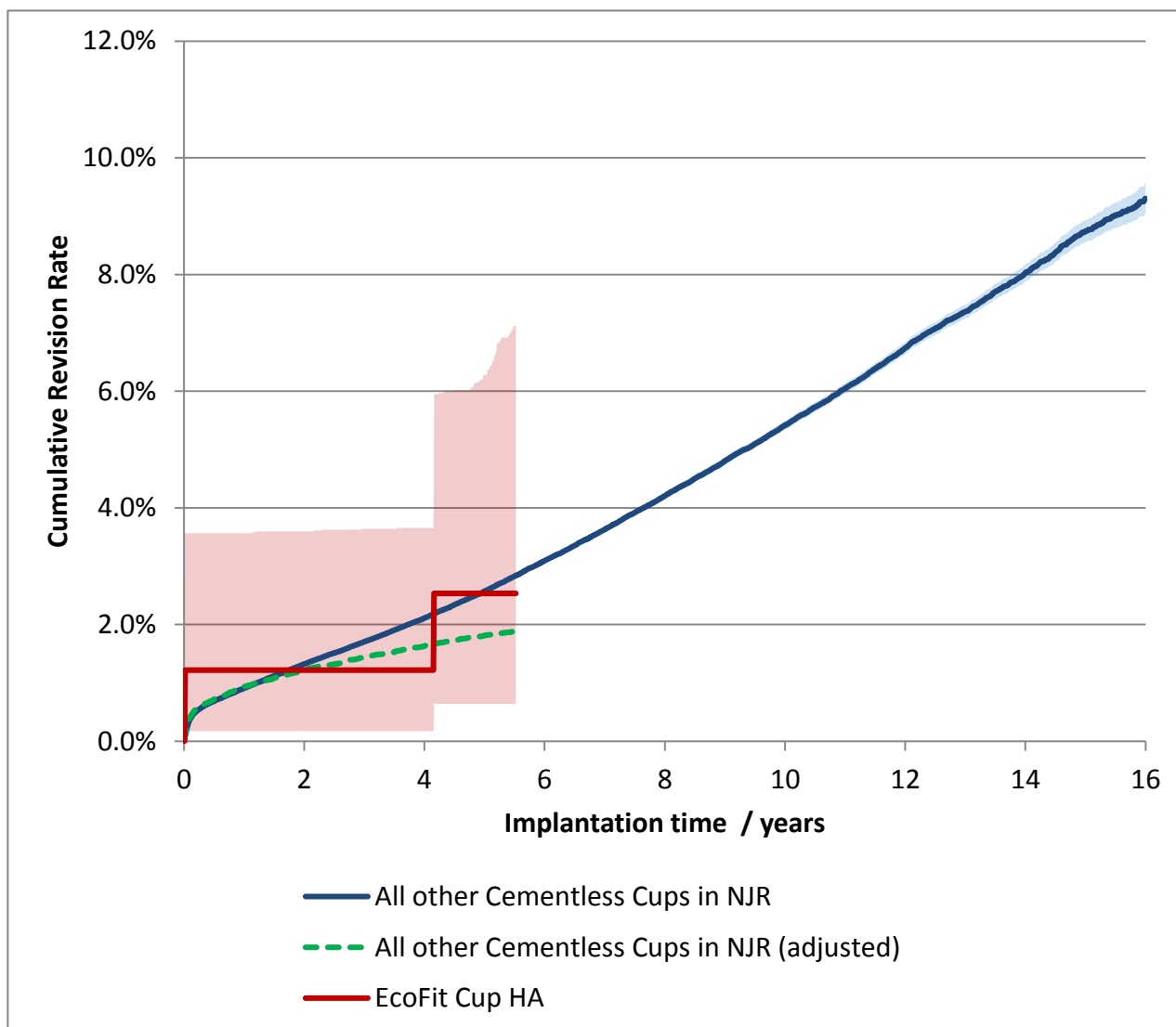
Components Revised	Number of procedures	EcoFit Cup HA	All other Cementless Cups in NJR
Femoral only	0	0%	31%
Acetabular only	0	0%	24%
Both femoral and acetabular	1	50%	33%
Neither femoral nor acetabular revision recorded *	1	50%	13%

\* includes isolated head and/or liner exchange

## Revision and Survivorship

### Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



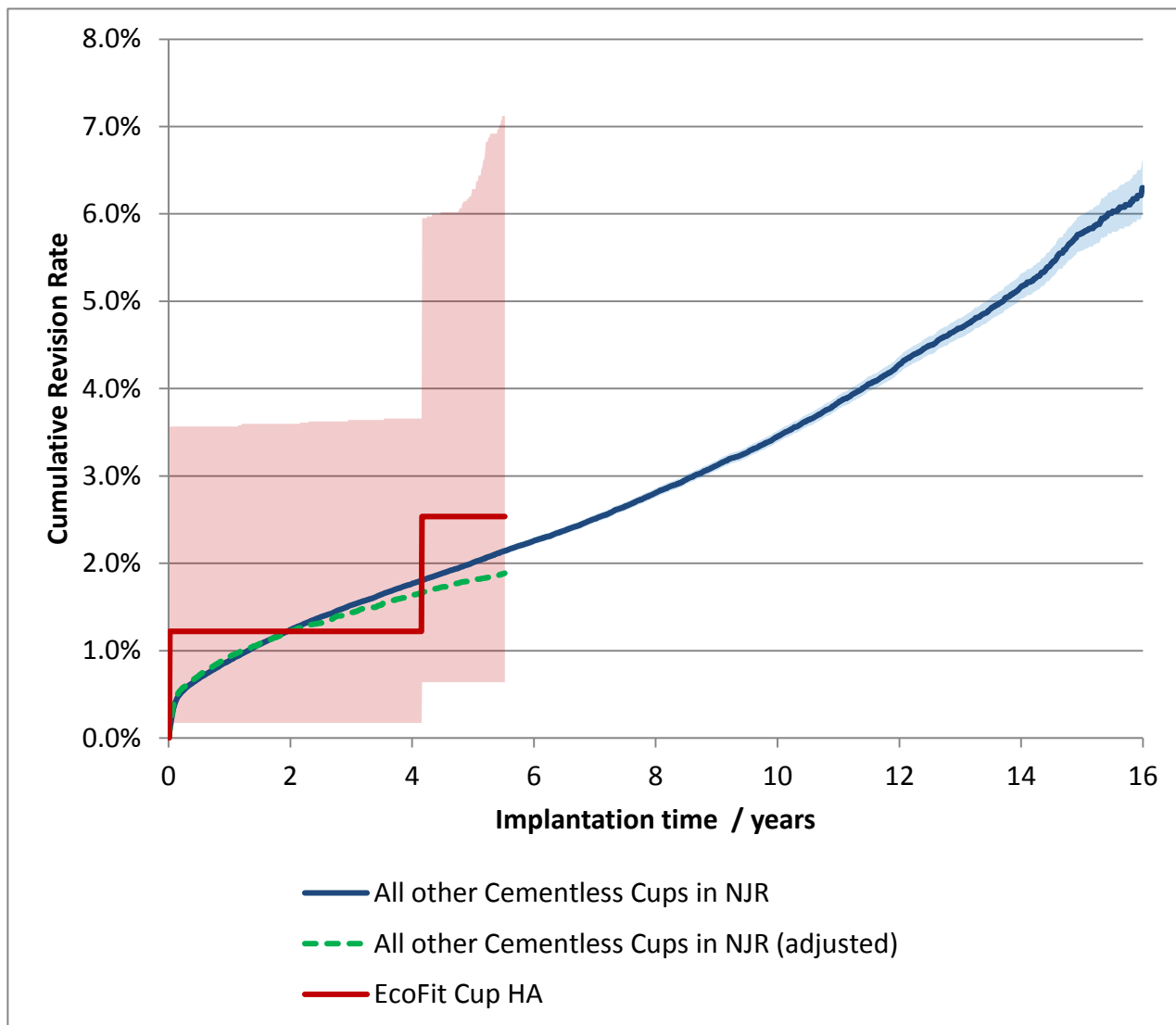
Cox Proportional Hazards model for revision risk ratio of EcoFit Cup HA / All other Cementless Cups in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.89 (0.22 - 3.58)	0.875
All bearings. Adjusted for age, gender, year cohort and indications.	1.34 (0.33 - 5.37)	0.679

**Revision and Survivorship**

**Cumulative Revision Rate**

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



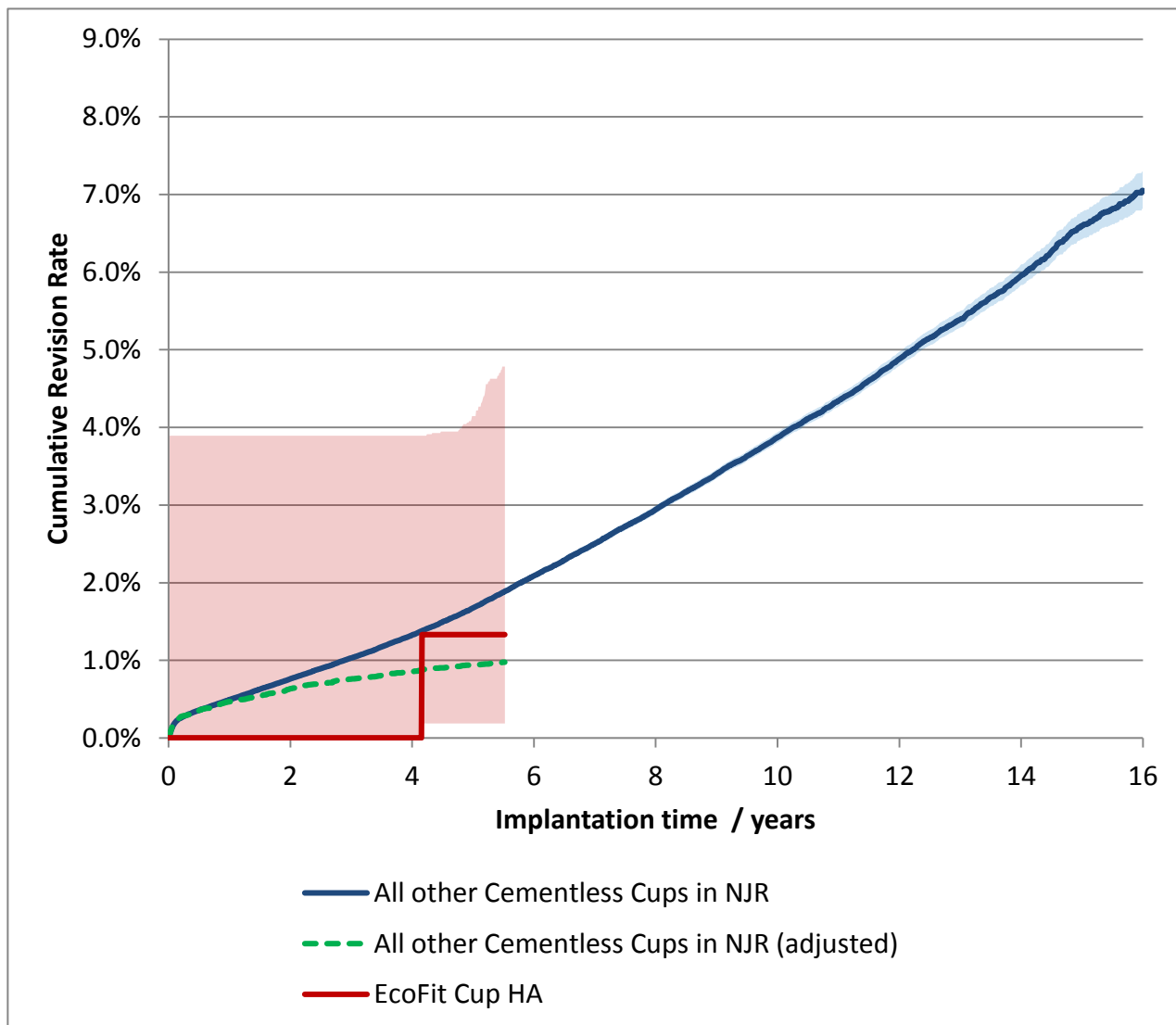
Cox Proportional Hazards model for revision risk ratio of EcoFit Cup HA / All other Cementless Cups in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	1.18 (0.30 - 4.73)	0.813
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.34 (0.34 - 5.38)	0.677

**Revision and Survivorship**

**Cumulative Revision Rate**

Endpoint: Acetabular Revision. All Bearing types



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

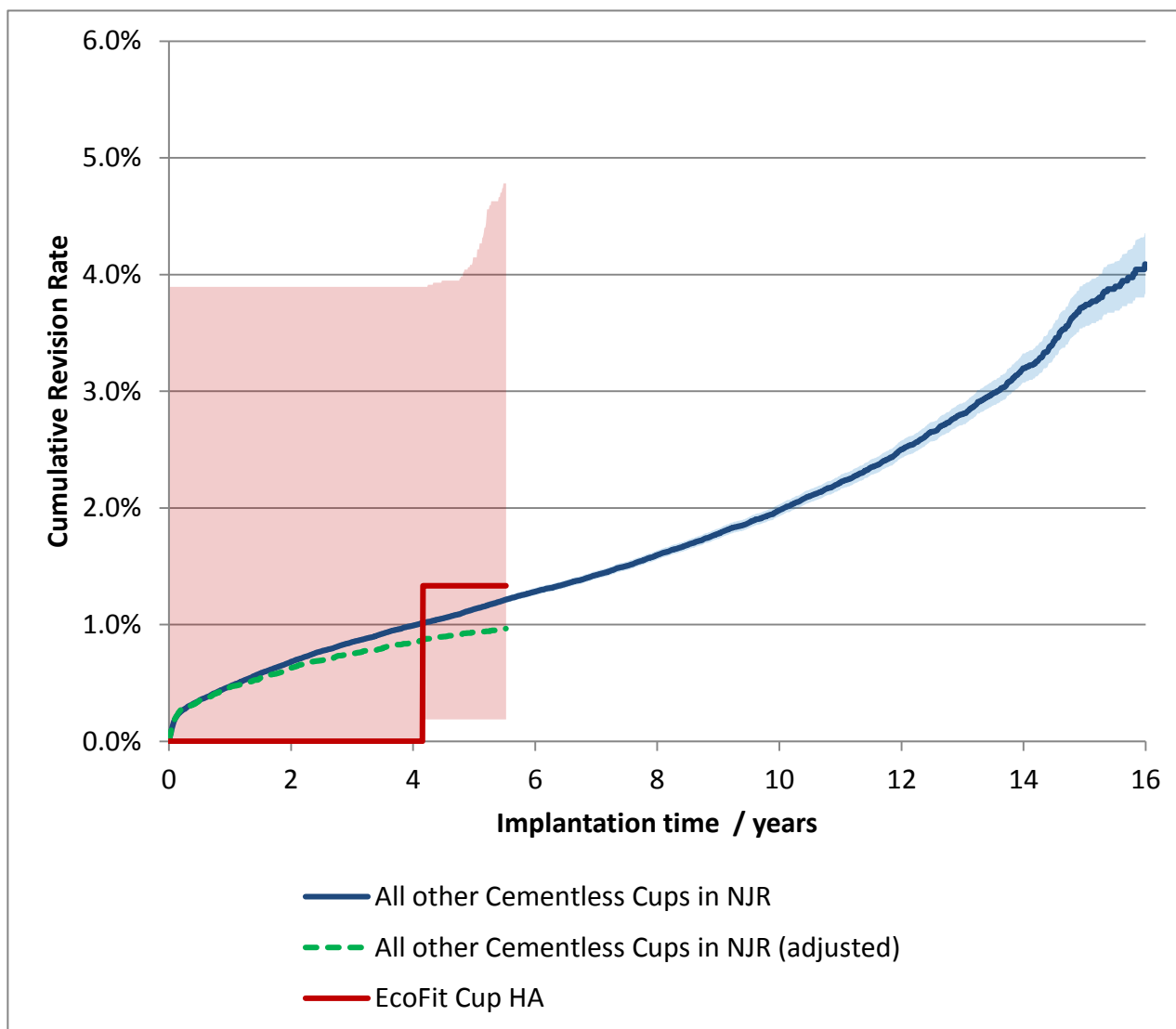
Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.68 (0.10 - 4.83)	0.699
All bearings. Adjusted for age, gender, year cohort and indications.	1.31 (0.18 - 9.32)	0.787



**Revision and Survivorship**

**Cumulative Revision Rate**

Endpoint: Acetabular Revision. Excluding Metal-on-Metal



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

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	1.05 (0.15 - 7.45)	0.962
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.32 (0.19 - 9.41)	0.780

**Revision and Survivorship**

**Cumulative Revision Rate**

Endpoint: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	EcoFit Cup HA	All other Cementless Cups in NJR	All THR	At Risk	EcoFit Cup HA	All other Cementless Cups in NJR	All THR
0	82	-	-	-	82	-	-	-
1	81	1.2% (0.2% - 3.6%)	0.9% (0.9% - 0.9%)	0.8% (0.8% - 0.8%)	81	1.2% (0.2% - 3.6%)	0.9% (0.9% - 0.9%)	0.8% (0.8% - 0.8%)
2	79	1.2% (0.2% - 3.6%)	1.3% (1.3% - 1.4%)	1.2% (1.1% - 1.2%)	79	1.2% (0.2% - 3.6%)	1.2% (1.2% - 1.3%)	1.1% (1.1% - 1.1%)
3	76	1.2% (0.2% - 3.6%)	1.7% (1.7% - 1.7%)	1.5% (1.5% - 1.5%)	76	1.2% (0.2% - 3.6%)	1.5% (1.5% - 1.6%)	1.4% (1.4% - 1.4%)
4	75	1.2% (0.2% - 3.7%)	2.1% (2.1% - 2.1%)	1.8% (1.8% - 1.9%)	75	1.2% (0.2% - 3.7%)	1.8% (1.7% - 1.8%)	1.6% (1.6% - 1.6%)
5	61	2.5% (0.6% - 6.3%)	2.6% (2.5% - 2.6%)	2.2% (2.2% - 2.3%)	61	2.5% (0.6% - 6.3%)	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 HA	All other Cementless Cups	All THR	At Risk	EcoFit Cup HA	All other Cementless Cups	All THR
0	82	-	-	-	82	-	-	-
1	81	0.0% (0.0% - 4.1%)	0.5% (0.5% - 0.5%)	0.4% (0.4% - 0.5%)	81	0.0% (0.0% - 4.1%)	0.5% (0.5% - 0.5%)	0.4% (0.4% - 0.4%)
2	79	0.0% (0.0% - 4.1%)	0.8% (0.7% - 0.8%)	0.7% (0.7% - 0.7%)	79	0.0% (0.0% - 4.1%)	0.7% (0.7% - 0.7%)	0.6% (0.6% - 0.7%)
3	76	0.0% (0.0% - 4.1%)	1.0% (1.0% - 1.1%)	0.9% (0.9% - 1.0%)	76	0.0% (0.0% - 4.1%)	0.9% (0.8% - 0.9%)	0.8% (0.8% - 0.9%)
4	75	0.0% (0.0% - 4.1%)	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)	75	0.0% (0.0% - 4.1%)	1.0% (1.0% - 1.0%)	1.0% (1.0% - 1.0%)
5	61	1.3% (0.2% - 4.1%)	1.7% (1.6% - 1.7%)	1.5% (1.5% - 1.5%)	61	1.3% (0.2% - 4.1%)	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%)

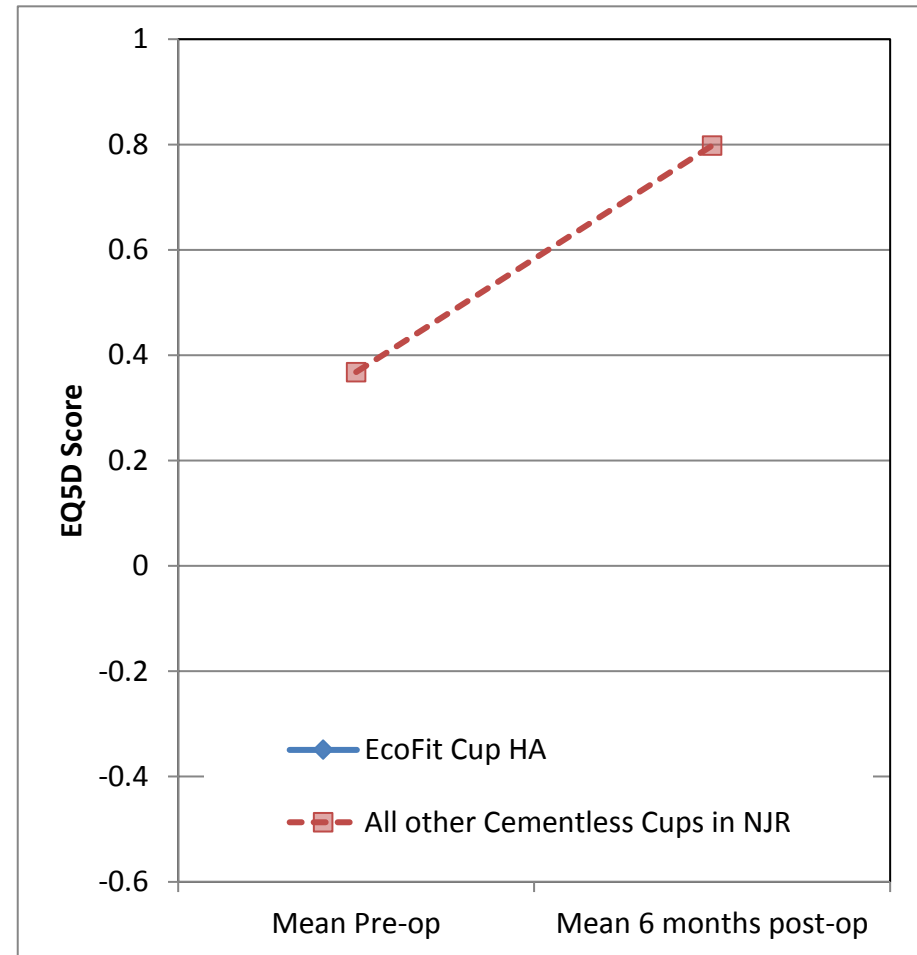
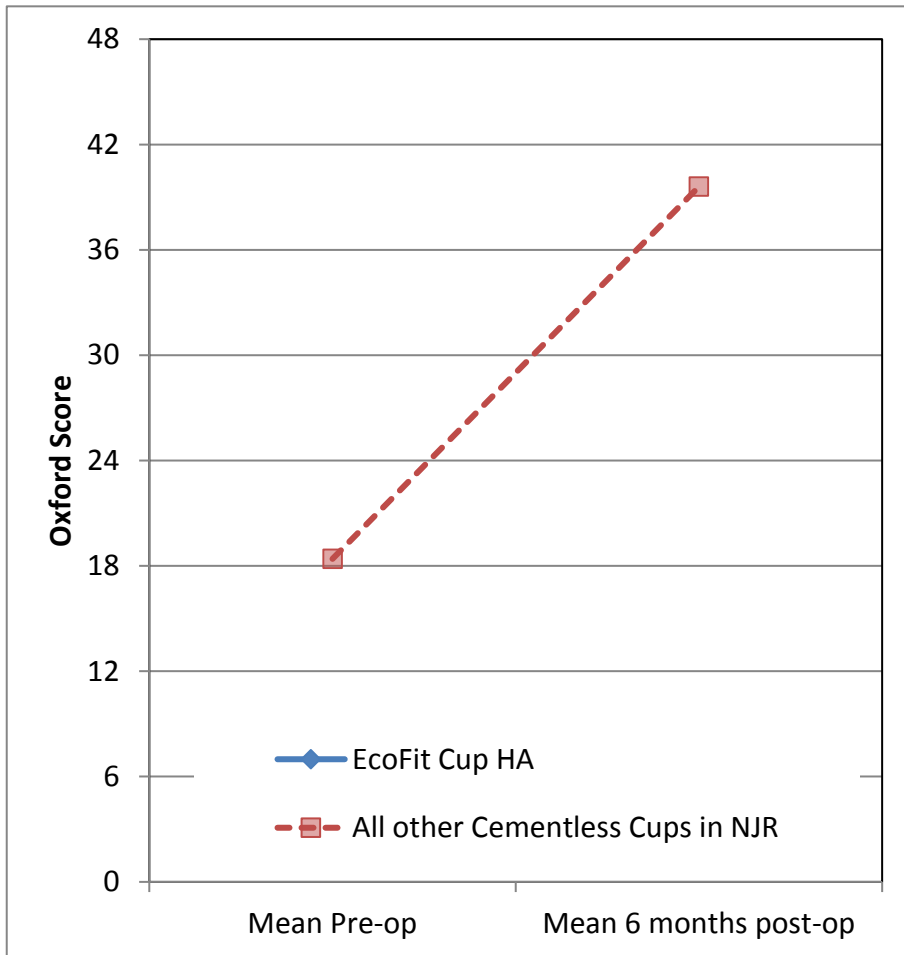
Cumulative revision rate with 95% confidence intervals

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

**Patient Reported Outcomes**

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

**PROMs Analysis**



## Patient Reported Outcomes

### PROMs Analysis

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

Oxford Hip Score (0 - 48)	EcoFit Cup HA	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 HA	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 HA	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.

Responses are not case mix adjusted

**Patient Reported Outcomes**



**Patient Reported Outcomes**

**Success**

Response	EcoFit Cup HA	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 HA	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
02200346	EcoFit® cup HA cementless size Ø 46mm incl. central hole cover	1
02200348	EcoFit® cup HA cementless size Ø 48mm incl. central hole cover	7
02200350	EcoFit® cup HA cementless size Ø 50mm incl. central hole cover	17
02200352	EcoFit® cup HA cementless size Ø 52mm incl. central hole cover	16
02200354	EcoFit® cup HA cementless size Ø 54mm incl. central hole cover	14
02200356	EcoFit® cup HA cementless size Ø 56mm incl. central hole cover	10
02200358	EcoFit® cup HA cementless size Ø 58mm incl. central hole cover	11
02200360	EcoFit® cup HA cementless size Ø 60mm incl. central hole cover	6

## Appendix A: Component List

Catalogue Number	Description	Number Implanted
02203239	BIOLOX® delta-cup insert size Ø 32/39mm	4
02203244	BIOLOX® delta cup insert size Ø 32/44mm	10
02203248	BIOLOX® delta cup insert size Ø 32/48mm	1
02203644	BIOLOX® delta cup insert size Ø 36/44mm	4
02802044	PE-cup insert 0° size Ø 28/44mm	2
02802048	PE-cup insert 0° size Ø 28/48mm	3
02802139	PE-cup insert 10° size Ø 28/39mm	4
02802144	PE-cup insert 10° size Ø 28/44mm	29
02802148	PE-cup insert 10° size Ø 28/48mm	15
02802152	PE-cup insert 10° size Ø 28/52mm	5
02803144	PE-cup insert 10° size Ø 32/44mm	1
02803148	PE-cup insert 10° size Ø 32/48mm	1
02803152	PE-cup insert 10° size Ø 32/52mm	1
02803444	PE-cup insert 0° size Ø 32/44mm	1