

Implant Summary Report for:

Implantcast GmbH

EcoFit Hip Stem Highly Polished

Comprising PRIMARY hips implanted up to:
NJR Database extract:

08 March 2019
07 May 2019

Produced on:
Licenced for use until:

15 May 2019
15 September 2019

Contents

Recorded Usage in NJR	2
Patient and Procedure Details	3
Revision and Survivorship	4
Patient Reported Outcomes	12
APPENDIX A – Component List	15

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 Hip Stem Highly Polished 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:

Femoral components **EcoFit Hip Stem Highly Polished**

Acetabular Components **Any Acetabular Components from all manufacturers**

Appendix A lists details of all EcoFit Hip Stem Highly Polished components included in this report. This report is made available to Implantcast GmbH under licence. Under this licence, Implantcast GmbH is free to distribute this document, subject to the restrictions specified in the National Joint Registry Supplier Feedback Data Access and Use Code of Practice.

NJR Recorded Usage

Implant Usage

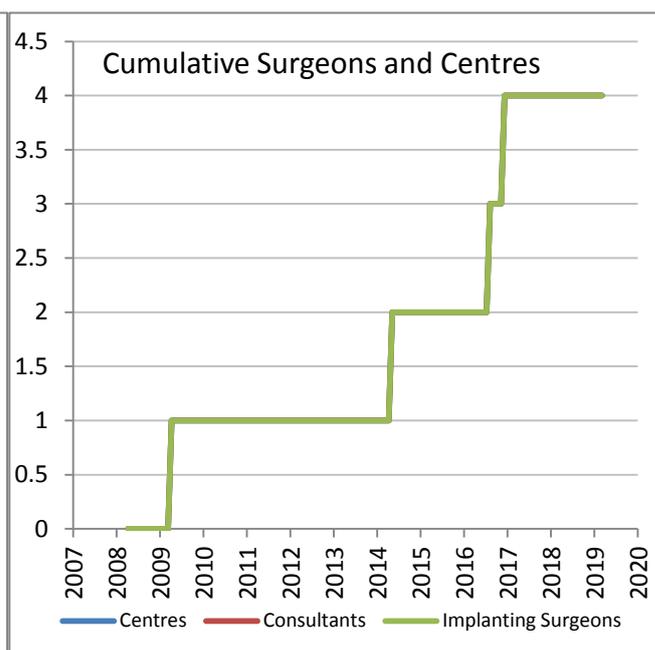
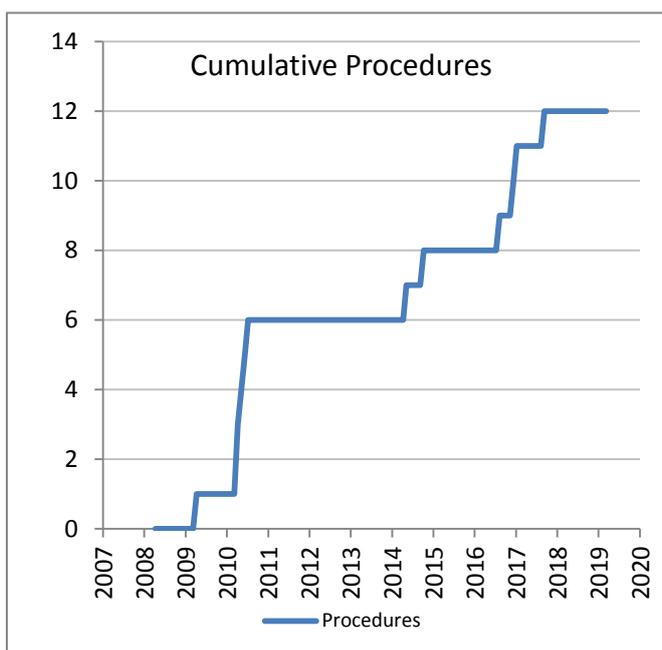
Date of first recorded usage in the NJR: **17 March 2009**

Date of last recorded usage in this dataset: **17 August 2017**

Maximum implantation time: **8.8 years**

Mean implantation time: **3.7 years**

Totals Recorded in NJR	Cumulative Total
Procedures	12
Patients	12
Centres	4
Consultants	4
Implanting Surgeons	4



Current Outcome	Year of implantation														Total	%
	Pre-2008	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019			
Death	0	0	1	3	0	0	0	0	0	0	1	0	0	5	41.7%	
Revised	0	0	0	1	0	0	0	0	0	0	0	0	0	1	8.3%	
Unrevised	0	0	0	1	0	0	0	2	0	3	0	0	0	6	50.0%	
Total	0	0	1	5	0	0	0	2	0	3	1	0	0	12	100%	

Patient / Procedure Details

Patient Details

	EcoFit Hip Stem Highly Polished	All NJR Cemented Stems	All NJR hip replacement
Total Procedures	12	610,209	1,124,650
Total Patients	12	536,883	954,645
Demographics			
Mean age	78.3	71.9	68.6
< 50	0.0%	2.8%	6.0%
50 – 59	0.0%	8.0%	13.8%
60 – 69	25.0%	25.0%	29.1%
70 – 79	8.3%	41.3%	34.6%
≥ 80	66.7%	23.0%	16.5%
Median BMI	29	28	28
% BMI information available	58.3%	60.9%	60.6%
Underweight (BMI < 18.5)	0.0%	1.1%	0.9%
Normal (18.5 ≤ BMI < 25)	14.3%	22.2%	20.8%
Overweight (25 ≤ BMI < 30)	57.1%	39.8%	39.7%
Obese I (30 ≤ BMI < 35)	14.3%	24.9%	25.7%
Obese II (35 ≤ BMI < 40)	14.3%	9.0%	9.7%
Obese III (BMI ≥ 40)	0.0%	3.0%	3.3%
% Male	25.0%	35.1%	40.2%
ASA Grades			
P1 - Fit and healthy	0.0%	12.1%	16.1%
P2 - Mild disease not incapacitating	50.0%	68.1%	67.6%
P3 - Incapacitating systemic disease	50.0%	19.1%	15.7%
P4 / P5	0.0%	0.7%	0.6%
Indications			
Osteoarthritis	75.00%	90.44%	91.62%
Rheumatoid Arthritis	0.00%	1.44%	1.32%
Avascular Necrosis	8.33%	2.50%	2.50%
Fractured Neck of Femur	0.00%	4.64%	3.31%
CDH/DDH	0.00%	1.11%	1.56%
Other	25.00%	2.25%	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 [†]	Expected Revisions [*]	p value
Unexplained Pain	0	0.01	1
Dislocation / Subluxation	0	0.05	1
Adverse Soft Tissue Reaction	0	0.00	1
Infection	0	0.04	1
Aseptic Loosening - Stem	0	0.01	1
Aseptic Loosening - Socket	1	0.02	0.018
Periprosthetic Fracture Stem	0	0.03	1
Periprosthetic Fracture Socket	0	0.00	1
Malalignment Stem	0	0.00	1
Malalignment Socket	0	0.01	1
Wear Of Acetabular Component	0	0.00	1
Lysis Stem	0	0.00	1
Lysis Socket	0	0.00	1
Implant Fracture Stem	0	0.00	1
Implant Fracture Socket	0	0.00	1
Implant Fracture Head	0	0.00	1
Dissociation of Liner	0	0.00	1
Other / reason not recorded	0	0.01	1
Total Revised	1	0.16	0.145

* Based on All NJR Cemented Stems adjusted for agegroup, gender, and indications

† 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 Hip Stem Highly Polished	All other Cemented Stems in NJR
Femoral only	0	0%	21%
Acetabular only	1	100%	24%
Both femoral and acetabular	0	0%	47%
Neither femoral nor acetabular revision recorded *	0	0%	8%

* includes isolated head and/or liner exchange

Revision and Survivorship

Reasons for Revision - excluding Metal on Metal

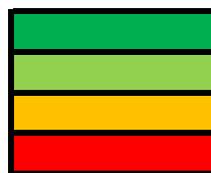
Reasons for revision of non-MoM primary procedures in which the implant was used.

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Unexplained Pain	0	0.01	1
Dislocation / Subluxation	0	0.03	1
Adverse Soft Tissue Reaction	0	0.00	1
Infection	0	0.02	1
Aseptic Loosening - Stem	0	0.01	1
Aseptic Loosening - Socket	0	0.01	1
Periprosthetic Fracture Stem	0	0.02	1
Periprosthetic Fracture Socket	0	0.00	1
Malalignment Stem	0	0.00	1
Malalignment Socket	0	0.01	1
Wear Of Acetabular Component	0	0.00	1
Lysis Stem	0	0.00	1
Lysis Socket	0	0.00	1
Implant Fracture Stem	0	0.00	1
Implant Fracture Socket	0	0.00	1
Implant Fracture Head	0	0.00	1
Dissociation of Liner	0	0.00	1
Other / reason not recorded	0	0.00	1
Total Revised	0	0.10	1

* Based on All NJR Cemented Stems (excluding metal on metal), adjusted for agegroup, gender, and indications

† 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

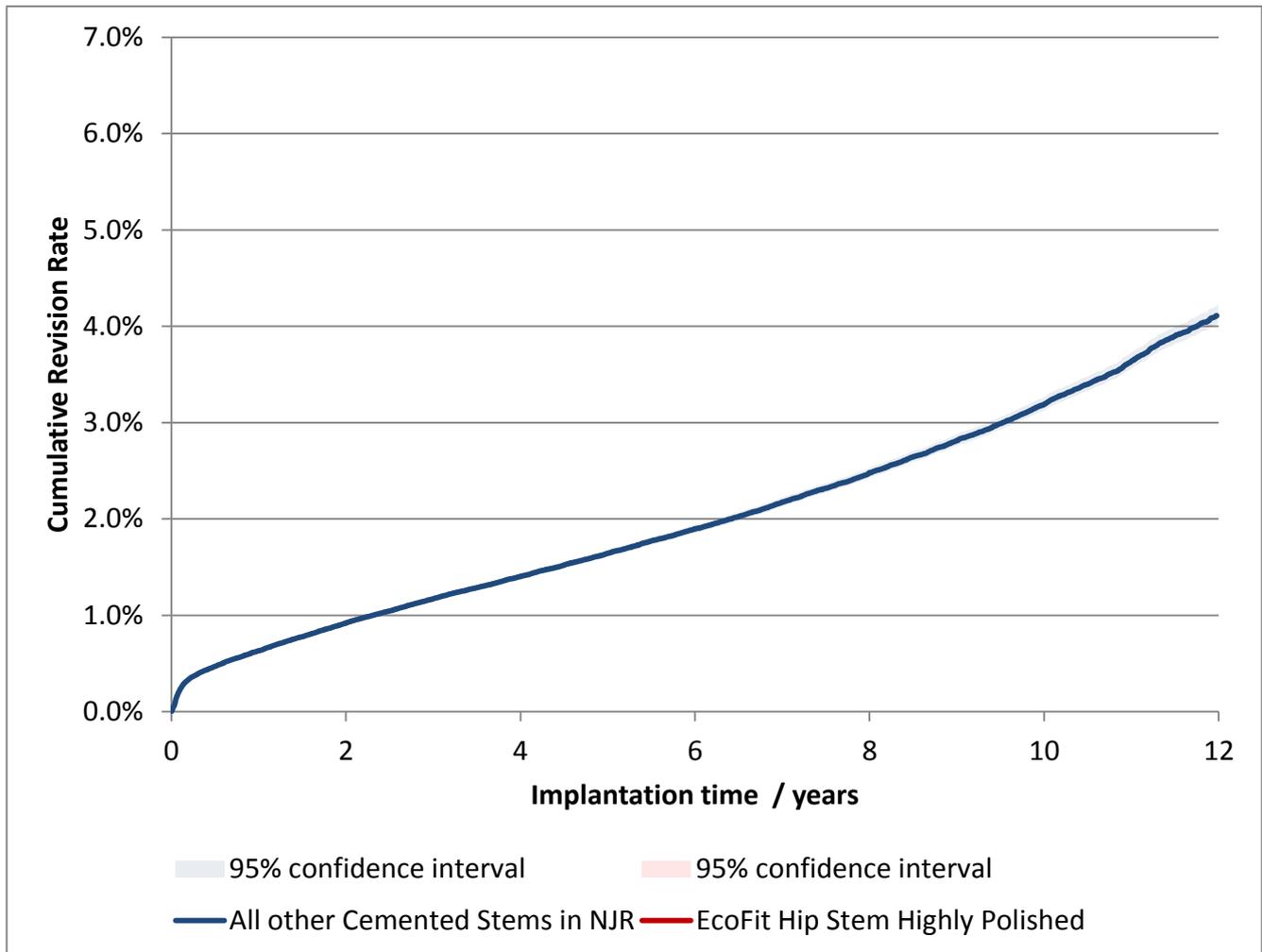


Components Revised	Number of procedures	EcoFit Hip Stem Highly Polished	All other Cemented Stems in NJR
Femoral only	0	NaN	21%
Acetabular only	0	NaN	24%
Both femoral and acetabular	0	NaN	46%
Neither femoral nor acetabular revision recorded *	0	NaN	9%

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



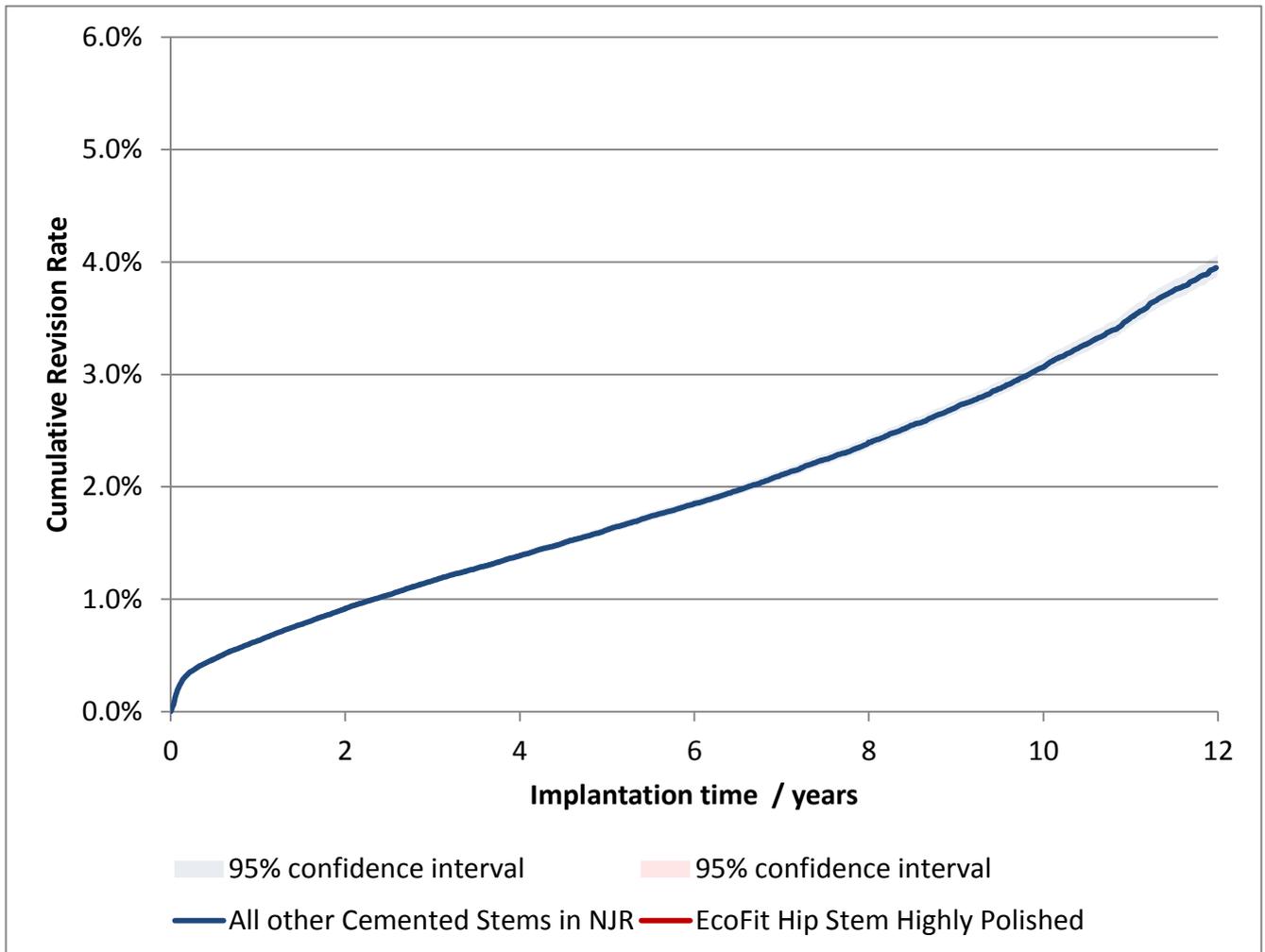
Cox Proportional Hazards model for revision risk ratio of EcoFit Hip Stem Highly Polished / All other Cemented Stems in NJR, with endpoint as any revision.

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



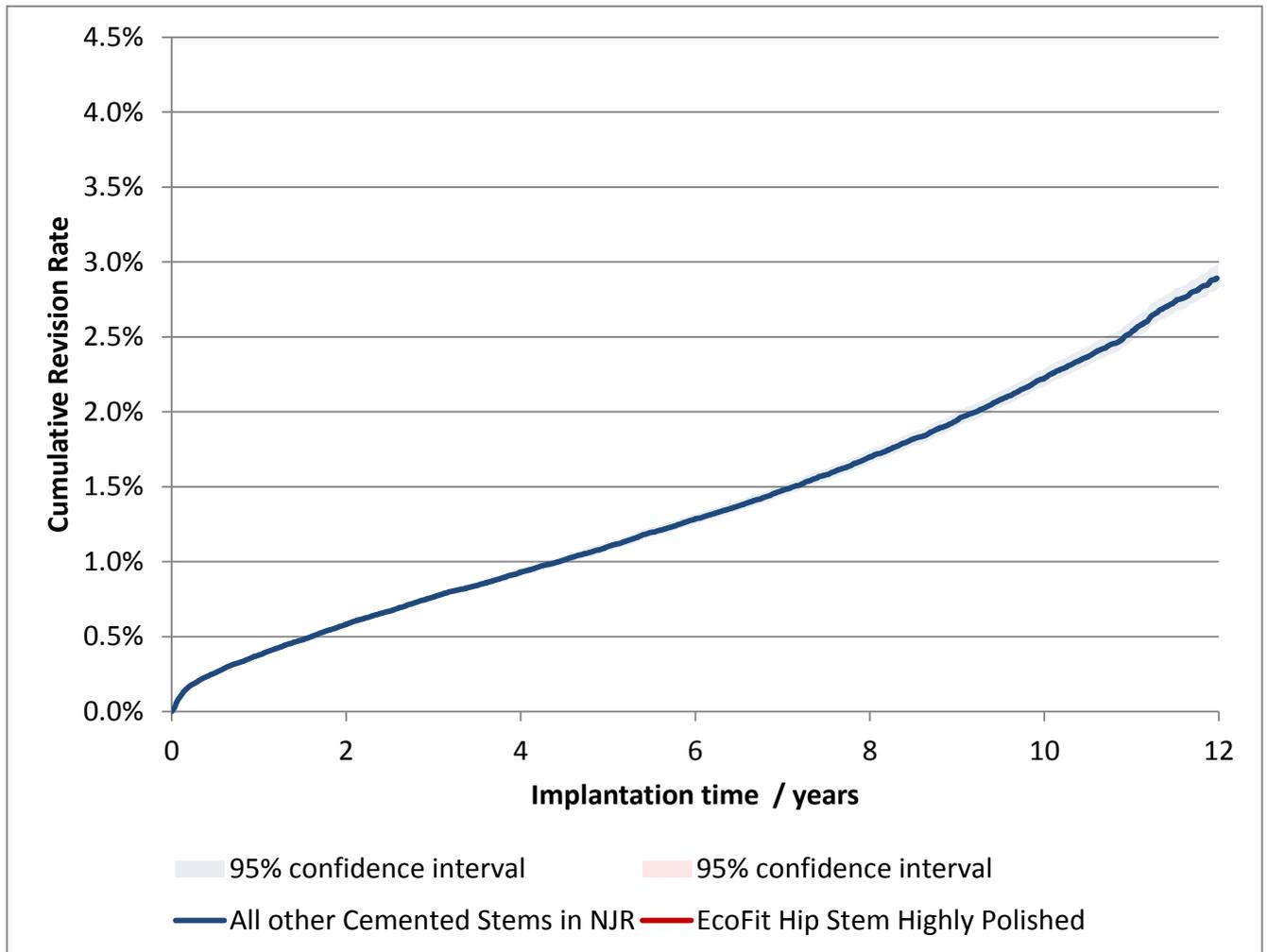
Cox Proportional Hazards model for revision risk ratio of EcoFit Hip Stem Highly Polished / All other Cemented Stems in NJR, with endpoint as any revision.

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: Femoral Revision. All Bearing types



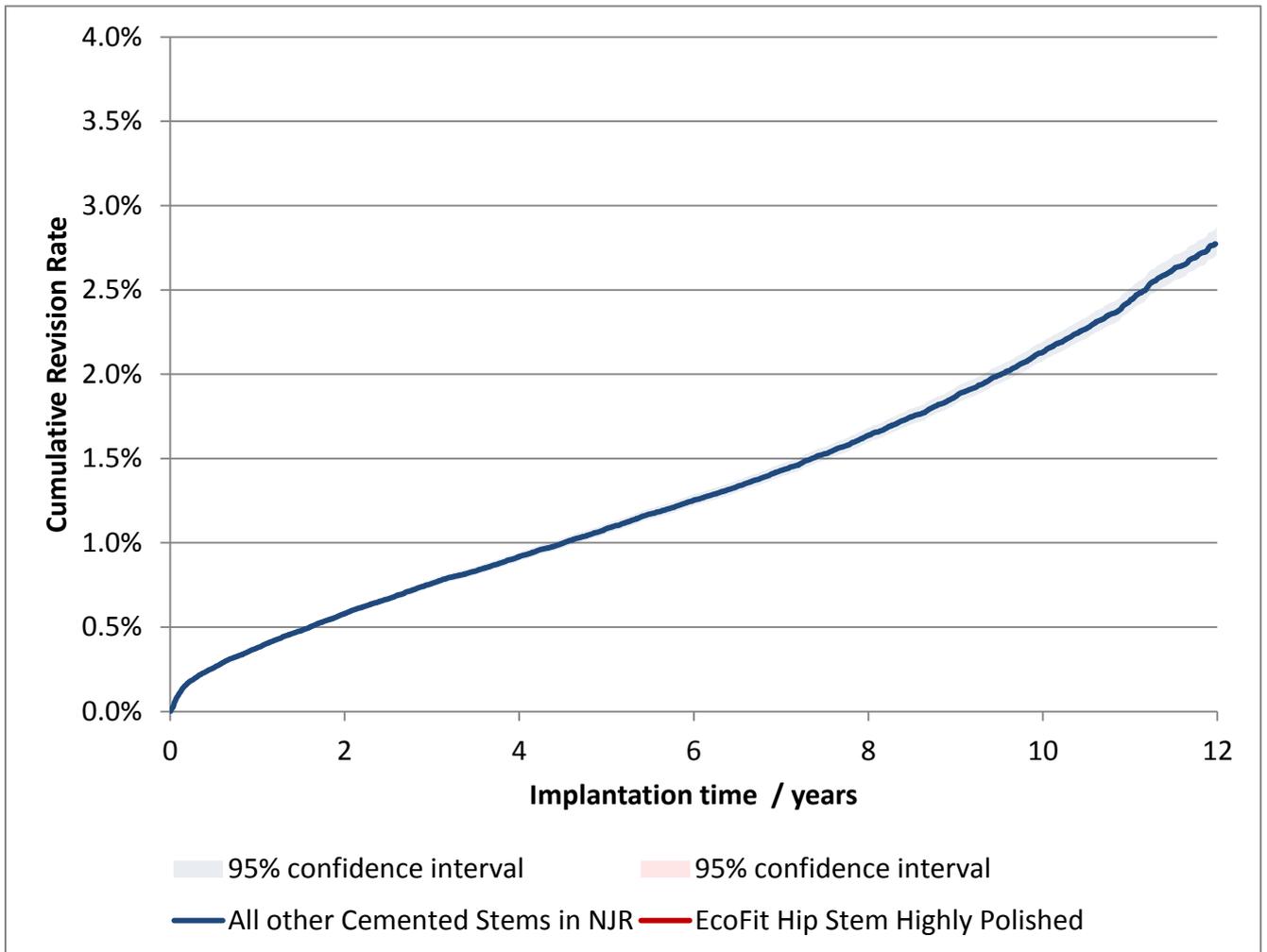
Cox Proportional Hazards model for revision risk ratio of EcoFit Hip Stem Highly Polished / all other All other Cemented Stems in NJR, with endpoint as Femoral revision.

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: Femoral Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of EcoFit Hip Stem Highly Polished / All other Cemented Stems in NJR, with endpoint as Femoral 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 Hip Stem Highly Polished	All NJR Cemented Stems	All THR	At Risk	EcoFit Hip Stem Highly Polished	All NJR Cemented Stems	All THR
0	12	-	-	-	9	-	-	-
1		(-)	0.6% (0.6% - 0.7%)	0.8% (0.8% - 0.8%)		(-)	0.6% (0.6% - 0.7%)	0.8% (0.8% - 0.8%)
2		(-)	0.9% (0.9% - 0.9%)	1.2% (1.1% - 1.2%)		(-)	0.9% (0.9% - 0.9%)	1.1% (1.1% - 1.1%)
3		(-)	1.2% (1.1% - 1.2%)	1.5% (1.5% - 1.5%)		(-)	1.2% (1.1% - 1.2%)	1.4% (1.4% - 1.4%)
4		(-)	1.4% (1.4% - 1.4%)	1.9% (1.8% - 1.9%)		(-)	1.4% (1.4% - 1.4%)	1.6% (1.6% - 1.6%)
5		(-)	1.6% (1.6% - 1.7%)	2.3% (2.2% - 2.3%)		(-)	1.6% (1.6% - 1.7%)	1.9% (1.8% - 1.9%)
6		(-)	1.9% (1.9% - 1.9%)	2.7% (2.7% - 2.7%)		(-)	1.9% (1.8% - 1.9%)	2.1% (2.1% - 2.2%)
7		(-)	2.2% (2.1% - 2.2%)	3.2% (3.1% - 3.2%)		(-)	2.1% (2.1% - 2.2%)	2.4% (2.3% - 2.4%)
8		(-)	2.5% (2.4% - 2.5%)	3.7% (3.6% - 3.7%)		(-)	2.4% (2.3% - 2.4%)	2.7% (2.6% - 2.7%)
9		(-)	2.8% (2.8% - 2.9%)	4.2% (4.1% - 4.2%)		(-)	2.7% (2.7% - 2.8%)	3.0% (3.0% - 3.1%)
10		(-)	3.2% (3.1% - 3.3%)	4.7% (4.7% - 4.8%)		(-)	3.1% (3.0% - 3.1%)	3.4% (3.3% - 3.4%)
11		(-)	3.6% (3.6% - 3.7%)	5.3% (5.2% - 5.4%)		(-)	3.5% (3.4% - 3.6%)	3.8% (3.7% - 3.9%)
12		(-)	4.1% (4.0% - 4.2%)	5.9% (5.8% - 6.0%)		(-)	4.0% (3.9% - 4.1%)	4.3% (4.2% - 4.3%)
13		(-)	4.6% (4.5% - 4.7%)	6.5% (6.4% - 6.6%)		(-)	4.4% (4.3% - 4.5%)	4.7% (4.6% - 4.8%)
14		(-)	5.0% (4.9% - 5.2%)	7.1% (7.0% - 7.2%)		(-)	4.9% (4.7% - 5.0%)	5.2% (5.1% - 5.3%)
15		(-)	5.7% (5.5% - 5.9%)	7.8% (7.6% - 7.9%)		(-)	5.5% (5.3% - 5.7%)	5.9% (5.7% - 6.1%)

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: Femoral Revision

Period /years	All Bearing types			Excluding Metal on Metal Bearings				
	At Risk	EcoFit Hip Stem Highly Polished	All NJR Cemented Stems	All THR	At Risk	EcoFit Hip Stem Highly Polished	All NJR Cemented Stems	All THR
0	12	-	-	-	9	-	-	-
1		(-)	0.4% (0.4% - 0.4%)	0.5% (0.5% - 0.5%)		(-)	0.4% (0.4% - 0.4%)	0.5% (0.5% - 0.5%)
2		(-)	0.6% (0.6% - 0.6%)	0.8% (0.7% - 0.8%)		(-)	0.6% (0.6% - 0.6%)	0.7% (0.7% - 0.7%)
3		(-)	0.8% (0.7% - 0.8%)	1.0% (1.0% - 1.0%)		(-)	0.8% (0.7% - 0.8%)	0.9% (0.9% - 0.9%)
4		(-)	0.9% (0.9% - 1.0%)	1.2% (1.2% - 1.2%)		(-)	0.9% (0.9% - 0.9%)	1.0% (1.0% - 1.1%)
5		(-)	1.1% (1.1% - 1.1%)	1.5% (1.4% - 1.5%)		(-)	1.1% (1.1% - 1.1%)	1.2% (1.2% - 1.2%)
6		(-)	1.3% (1.3% - 1.3%)	1.8% (1.7% - 1.8%)		(-)	1.3% (1.2% - 1.3%)	1.4% (1.4% - 1.4%)
7		(-)	1.5% (1.4% - 1.5%)	2.1% (2.0% - 2.1%)		(-)	1.4% (1.4% - 1.5%)	1.6% (1.5% - 1.6%)
8		(-)	1.7% (1.7% - 1.7%)	2.4% (2.4% - 2.4%)		(-)	1.6% (1.6% - 1.7%)	1.8% (1.7% - 1.8%)
9		(-)	1.9% (1.9% - 2.0%)	2.7% (2.7% - 2.8%)		(-)	1.9% (1.8% - 1.9%)	2.0% (2.0% - 2.0%)
10		(-)	2.2% (2.2% - 2.3%)	3.1% (3.1% - 3.2%)		(-)	2.1% (2.1% - 2.2%)	2.2% (2.2% - 2.3%)
11		(-)	2.5% (2.5% - 2.6%)	3.5% (3.5% - 3.6%)		(-)	2.4% (2.4% - 2.5%)	2.5% (2.5% - 2.6%)
12		(-)	2.9% (2.8% - 3.0%)	4.0% (3.9% - 4.0%)		(-)	2.8% (2.7% - 2.9%)	2.9% (2.8% - 2.9%)
13		(-)	3.2% (3.1% - 3.3%)	4.4% (4.3% - 4.5%)		(-)	3.1% (3.0% - 3.2%)	3.2% (3.1% - 3.3%)
14		(-)	3.5% (3.4% - 3.7%)	4.8% (4.7% - 4.9%)		(-)	3.4% (3.3% - 3.5%)	3.5% (3.4% - 3.6%)
15		(-)	4.0% (3.8% - 4.2%)	5.3% (5.1% - 5.4%)		(-)	3.9% (3.7% - 4.0%)	3.9% (3.8% - 4.1%)

Cumulative revision rate with 95% confidence intervals

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

Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/12/2016

Oxford Hip Score (0 - 48)	EcoFit Hip Stem Highly Polished	All NJR Cemented Stems	All THR in NJR
Paired Records	0	130,132	247,201
PreOp score		17.6 (17.6 - 17.7)	18.1 (18.1 - 18.1)
6 month score		38.8 (38.7 - 38.8)	39.2 (39.2 - 39.3)
6 month score (adjusted)		39.1 (39.1 - 39.2)	39.2 (39.2 - 39.3)
Health gain		21.1 (21.1 - 21.2)	21.1 (21.1 - 21.2)
Health gain (adjusted)		21.0 (21.0 - 21.1)	21.1 (21.1 - 21.2)
p value (adjusted health gain)			
Score Improved	0.0%	97.1%	97.1%

EQ-5D Index (-0.59 - 1.00)	EcoFit Hip Stem Highly Polished	All NJR Cemented Stems	All THR in NJR
Paired Records	0	118,970	226,961
PreOp score		0.342 (0.340 - 0.344)	0.357 (0.356 - 0.359)
6 month score		0.780 (0.779 - 0.782)	0.789 (0.788 - 0.790)
6 month score (adjusted)		0.787 (0.786 - 0.788)	0.789 (0.788 - 0.790)
Health gain		0.439 (0.437 - 0.440)	0.432 (0.431 - 0.433)
Health gain (adjusted)		0.430 (0.429 - 0.431)	0.432 (0.431 - 0.433)
p value (adjusted health gain)			
Score Improved	0.0%	89.2%	89.2%

EQ-VAS (0 - 100)	EcoFit Hip Stem Highly Polished	All NJR Cemented Stems	All THR in NJR
Paired Records	0	113,755	217,777
PreOp score		65.0 (64.8 - 65.1)	65.3 (65.2 - 65.4)
6 month score		75.9 (75.8 - 76.0)	76.6 (76.6 - 76.7)
6 month score (adjusted)		76.5 (76.5 - 76.6)	76.6 (76.6 - 76.7)
Health gain		11.0 (10.8 - 11.1)	11.3 (11.2 - 11.4)
Health gain (adjusted)		11.2 (11.1 - 11.3)	11.3 (11.3 - 11.4)
p value (adjusted health gain)			
Score Improved	0.0%	64.1%	65.0%

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



Disclaimer

Disclaimer

The National Joint Registry (NJR) produces this report through its contractor, Northgate Public Services (UK) Limited (NPS) using data collected, collated and provided by third parties. As a result, neither NJR or NPS takes any responsibility for the accuracy, currency, reliability and correctness of any data used or referred to in this report, and disclaims all warranties in relation to such data, in each case to the maximum extent permitted by legislation.

To the maximum extent permitted by law, neither the NJR or NPS shall have any liability (including but not limited to liability by reason of negligence) for any loss, damage, cost or expense incurred or arising by reason of any person using or relying on the data within this report and whether caused by reason of any error, omission or misrepresentation in the report or otherwise. This report is not to be taken as advice. Third parties using or relying on the data in this report do so at their own risk and will be responsible for making their own assessment and should verify all relevant representations, statements and information with their own professional advisers.

Appendix A: Component List

Catalogue Number	Description	Number Implanted
30380100	EcoFit® hip stem cemented highly polished standard size 10mm	1
30381062	EcoFit® hip stem cemented highly polished lateralized size 6.25mm	1
30381075	EcoFit® hip stem cemented highly polished lateralized size 7.5mm	6
#####	EcoFit® hip stem cemented highly polished lateralized size 10mm	2
#####	EcoFit® hip stem cemented highly polished lateralized size 12.5mm	2