

Implant Summary Report for:

Implantcast GmbH

EcoFit Hip Stem cpTI + 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 Hip Stem cpTI + 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:

Femoral components **EcoFit Hip Stem cpTI + HA**

Acetabular Component **Any Acetabular Components manufactured by Implantcast GmbH**

Appendix A lists details of all EcoFit Hip Stem cpTI + HA components included in this report.

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NJR Recorded Usage

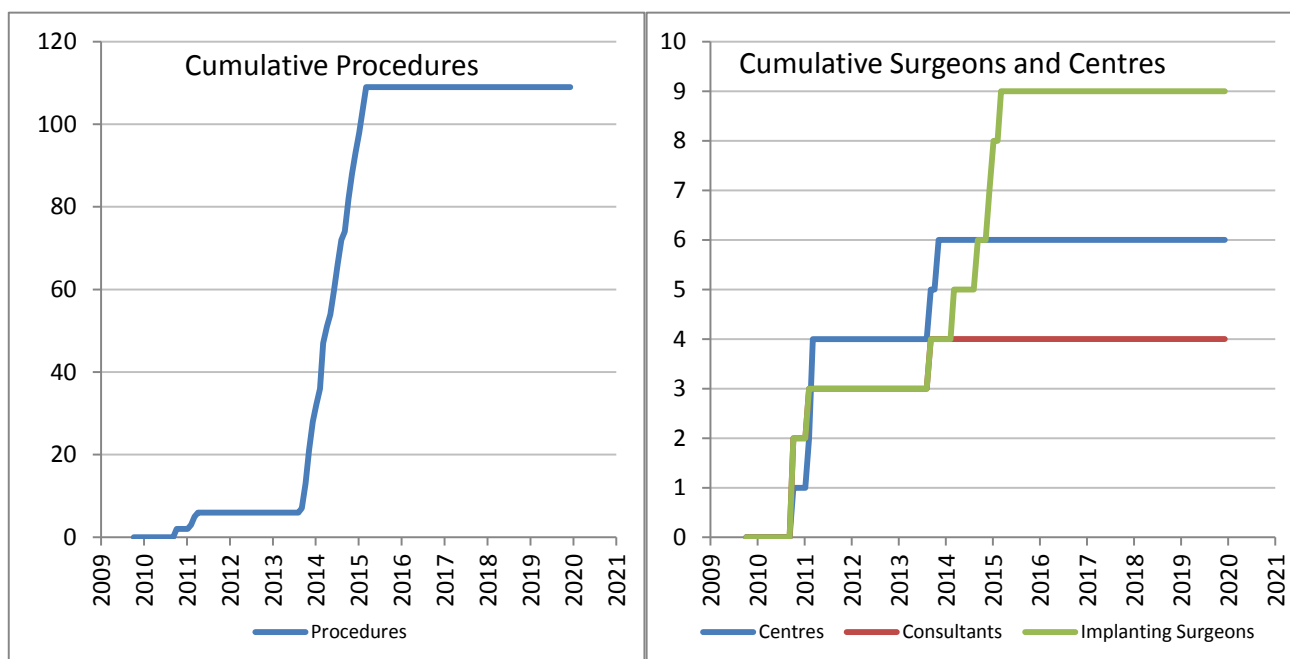
Implant Usage

Date of first recorded usage in the NJR: **08 September 2010**Date of last recorded usage in this dataset: **04 March 2015**

Maximum implantation time: 9.2 years

Mean implantation time: 5.4 years

Totals Recorded in NJR	Cumulative Total
Procedures	109
Patients	109
Centres	6
Consultants	4
Implanting Surgeons	9



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	2	0	3	8	0	0	0	0	0	13	11.9%	
Revised	0	0	0	0	0	0	1	0	1	0	0	0	0	2	1.8%	
Unrevised	0	0	0	2	2	0	22	58	10	0	0	0	0	94	86.2%	
Total	0	0	0	2	4	0	26	66	11	0	0	0	0	109	100%	

Patient / Procedure Details

Patient Details

	EcoFit Hip Stem cpTI + HA	All other Cementless Stems in NJR	All NJR hip replacement
Total Procedures	109	486,799	1,204,099
Total Patients	109	419,966	1,017,482
Demographics			
Mean age	70.6	65.3	68.6
< 50	0.9%	8.4%	5.9%
50 – 59	8.3%	19.1%	13.8%
60 – 69	40.4%	34.8%	29.0%
70 – 79	32.1%	28.4%	34.7%
≥ 80	18.3%	9.2%	16.6%
Median BMI	27	28	28
% BMI information available	34.9%	64.0%	62.0%
Underweight (BMI < 18.5)	2.6%	0.7%	0.9%
Normal (18.5 ≤ BMI < 25)	23.7%	18.8%	20.7%
Overweight (25 ≤ BMI < 30)	42.1%	39.1%	39.6%
Obese I (30 ≤ BMI < 35)	23.7%	26.9%	25.8%
Obese II (35 ≤ BMI < 40)	5.3%	10.8%	9.7%
Obese III (BMI ≥ 40)	2.6%	3.7%	3.3%
% Male	50.5%	44.3%	40.2%
ASA Grades			
P1 - Fit and healthy	12.8%	18.1%	15.7%
P2 - Mild disease not incapacitating	66.1%	68.9%	67.6%
P3 - Incapacitating systemic disease	21.1%	12.6%	16.1%
P4 / P5	0.0%	0.4%	0.6%
Indications			
Osteoarthritis	89.91%	93.05%	91.50%
Rheumatoid Arthritis	0.92%	1.22%	1.32%
Avascular Necrosis	11.01%	2.56%	2.50%
Fractured Neck of Femur	1.83%	1.85%	3.45%
CDH/DDH	3.67%	2.07%	1.57%
Other	0.92%	1.79%	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	0.18	1
Dislocation / Subluxation	0	0.43	1
Adverse Soft Tissue Reaction	0	0.08	1
Infection	0	0.37	1
Aseptic Loosening - Stem	0	0.39	1
Aseptic Loosening - Socket	0	0.12	1
Periprosthetic Fracture Stem	1	0.37	0.309
Periprosthetic Fracture Socket	0	0.07	1
Malalignment Stem	0	0.08	1
Malalignment Socket	0	0.10	1
Wear Of Acetabular Component	0	0.10	1
Lysis Stem	0	0.03	1
Lysis Socket	0	0.02	1
Implant Fracture Stem	0	0.02	1
Implant Fracture Socket	0	0.04	1
Implant Fracture Head	0	0.00	1
Dissociation of Liner	1	0.05	0.045
Other / reason not recorded	0	0.11	1
Total Revised	2	2.14	1

[†] multiple reasons may be listed for one revision procedure^{*} Based on All NJR Cementless Stems, 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 Hip Stem cpTI + HA	All other Cementless Stems in NJR
Femoral only	0	0%	23%
Acetabular only	0	0%	33%
Both femoral and acetabular	1	50%	32%
Neither femoral nor acetabular revision recorded [*]	1	50%	12%

^{*} 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	0.14	1
Dislocation / Subluxation	0	0.41	1
Adverse Soft Tissue Reaction	0	0.06	1
Infection	0	0.34	1
Aseptic Loosening - Stem	0	0.34	1
Aseptic Loosening - Socket	0	0.10	1
Periprosthetic Fracture Stem	1	0.35	0.297
Periprosthetic Fracture Socket	0	0.07	1
Malalignment Stem	0	0.07	1
Malalignment Socket	0	0.08	1
Wear Of Acetabular Component	0	0.09	1
Lysis Stem	0	0.02	1
Lysis Socket	0	0.01	1
Implant Fracture Stem	0	0.02	1
Implant Fracture Socket	0	0.04	1
Implant Fracture Head	0	0.00	1
Dissociation of Liner	1	0.04	0.042
Other / reason not recorded	0	0.10	1
Total Revised	2	1.93	0.721

^{*} Based on All NJR Cementless Stems (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 $p < 0.001$



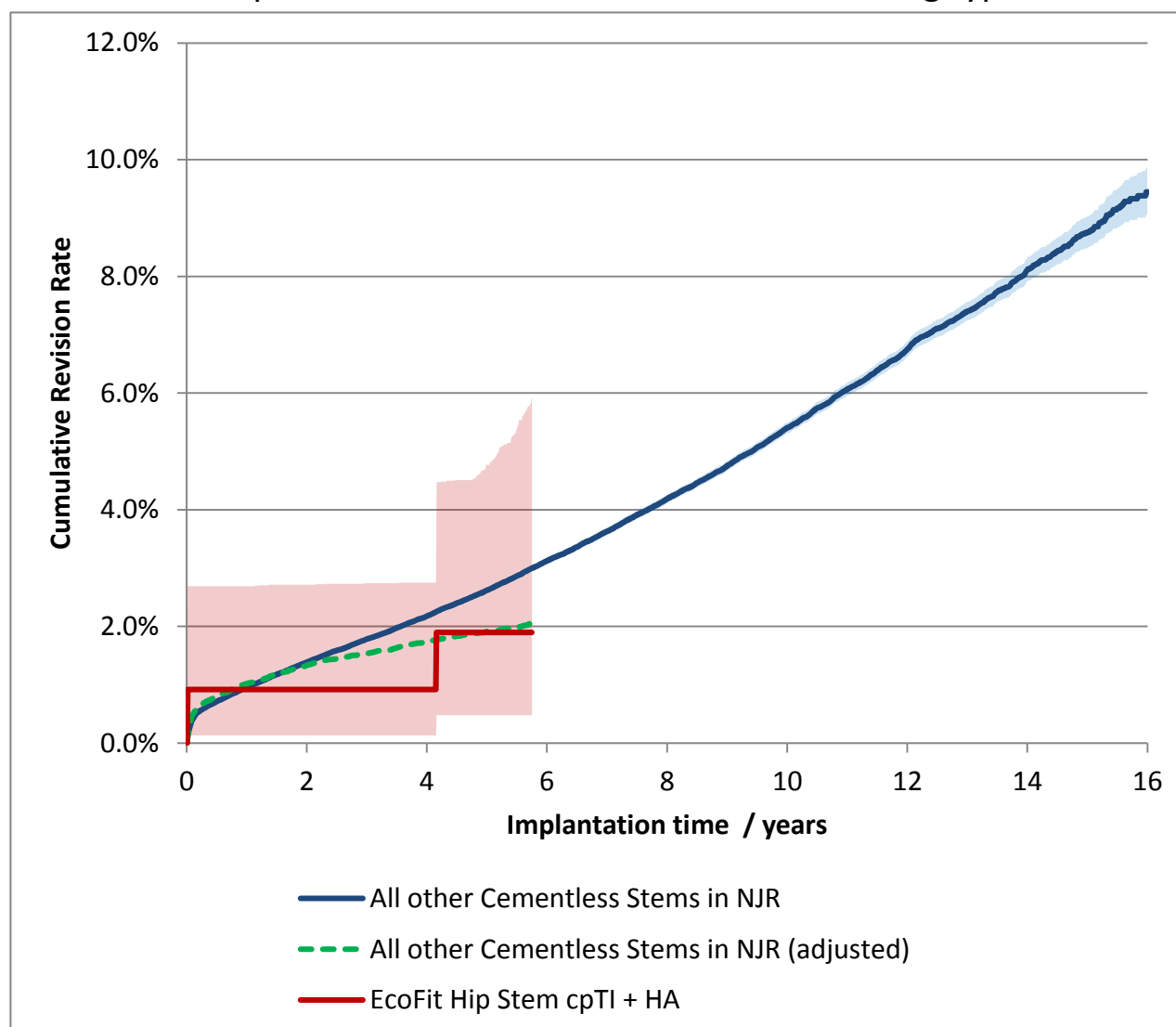
Components Revised	Number of procedures	EcoFit Hip Stem cpTI + HA	All other Cementless Stems in NJR
Femoral only	0	0%	31%
Acetabular only	0	0%	26%
Both femoral and acetabular	1	50%	31%
Neither femoral nor acetabular revision recorded [*]	1	50%	12%

^{*} includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



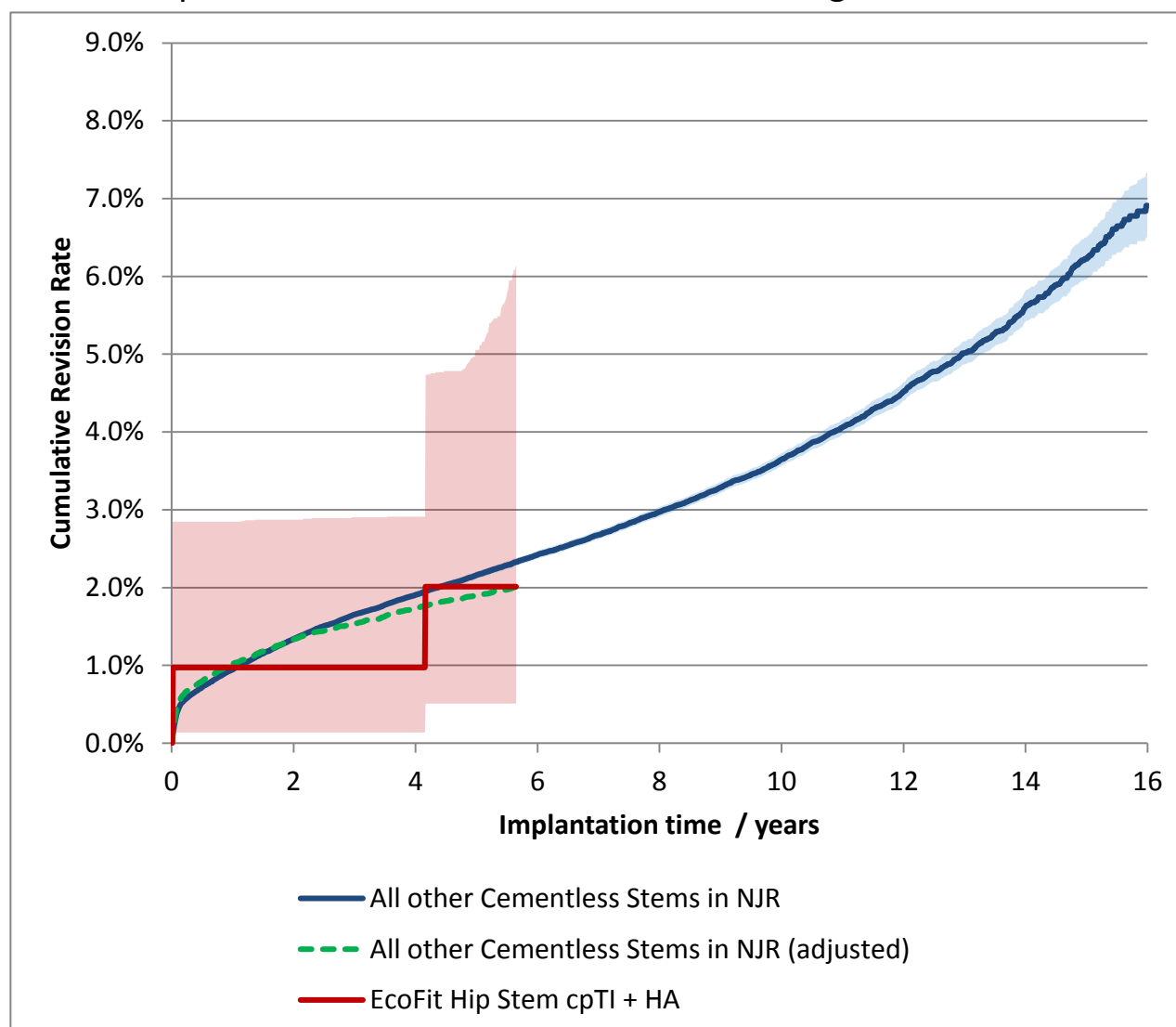
Cox Proportional Hazards model for revision risk ratio of EcoFit Hip Stem cpTI + HA / All other Cementless Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.64 (0.16 - 2.56)	0.529
All bearings. Adjusted for age, gender, year cohort and indications.	0.94 (0.23 - 3.75)	0.925

Revision and Survivorship

Cumulative Revision Rate

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



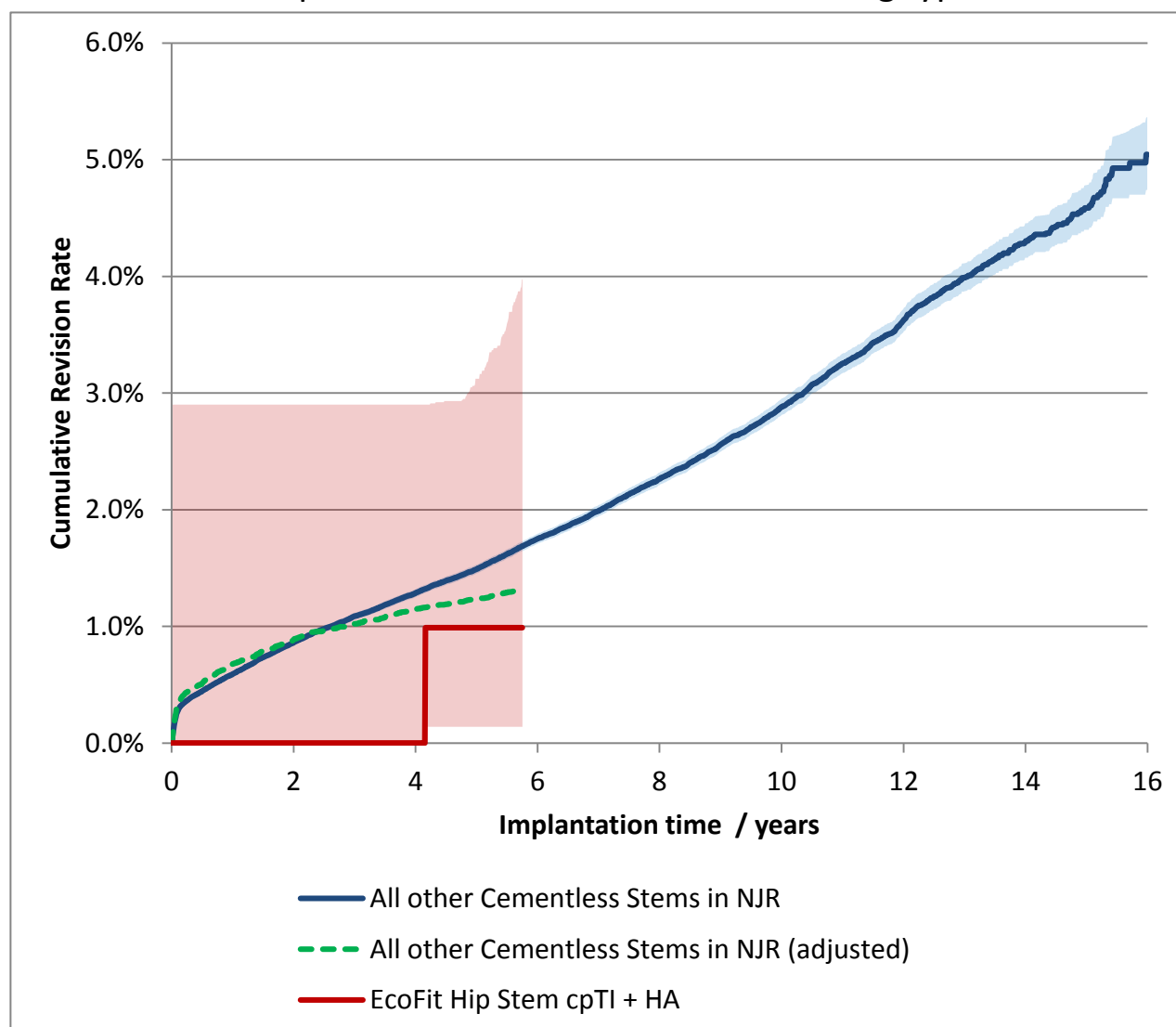
Cox Proportional Hazards model for revision risk ratio of EcoFit Hip Stem cpTI + HA / All other Cementless Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	0.87 (0.22 - 3.50)	0.849
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.03 (0.26 - 4.14)	0.963

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision. All Bearing types



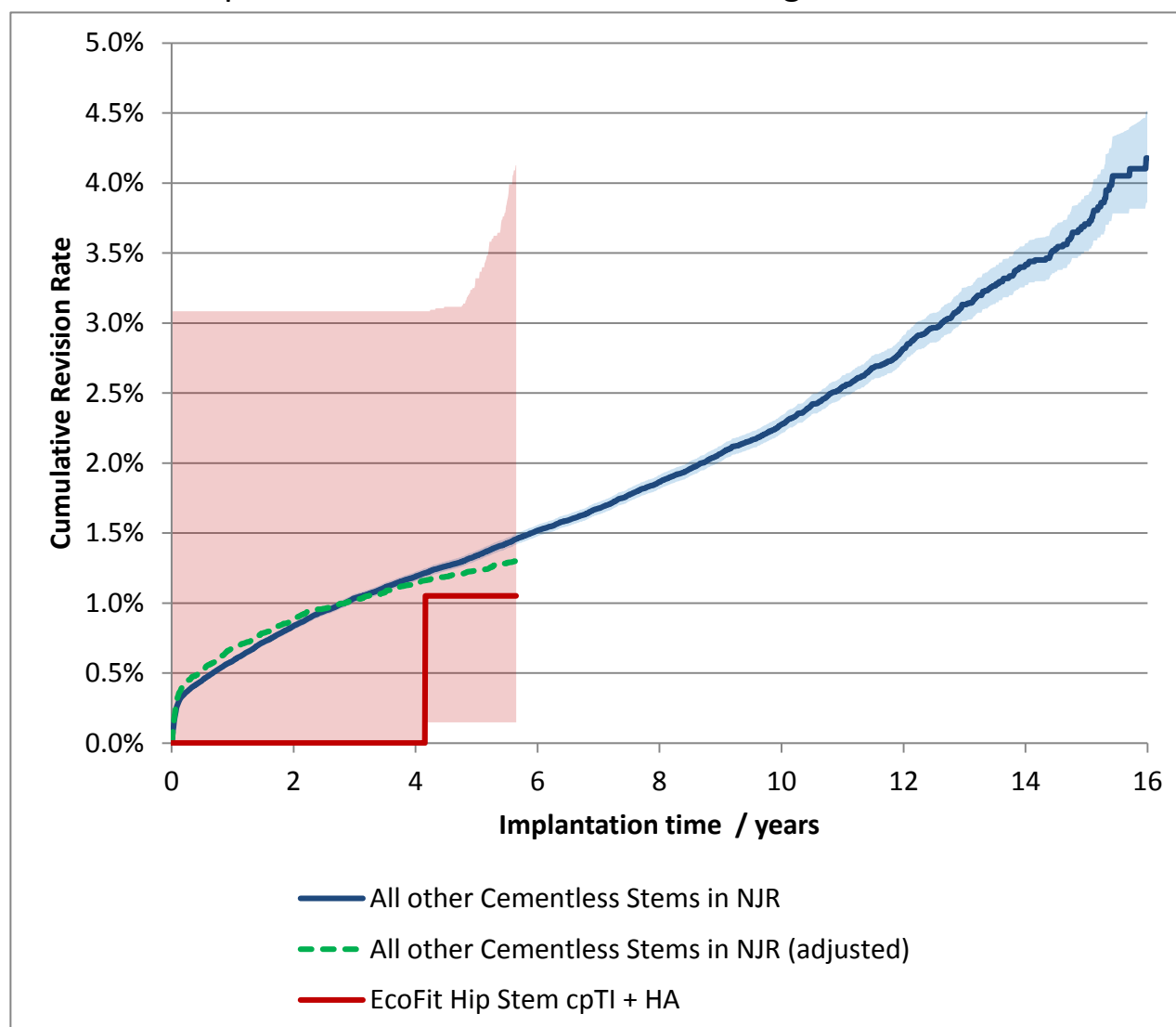
Cox Proportional Hazards model for revision risk ratio of EcoFit Hip Stem cpTI + HA / All other Cementless Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.57 (0.08 - 4.05)	0.575
All bearings. Adjusted for age, gender, year cohort and indications.	0.73 (0.10 - 5.18)	0.752

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 cpTI + HA / All other Cementless Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	0.70 (0.10 - 4.99)	0.725
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.80 (0.11 - 5.71)	0.826

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	EcoFit Hip Stem cpTI + HA	All other Cementless Stems in NJR	All THR	At Risk	EcoFit Hip Stem cpTI + HA	All other Cementless Stems in NJR	All THR
0	109	-	-	-	103	-	-	-
1	108	0.9% (0.1% - 2.7%)	1.0% (0.9% - 1.0%)	0.8% (0.8% - 0.8%)	102	1.0% (0.1% - 2.8%)	0.9% (0.9% - 1.0%)	0.8% (0.8% - 0.8%)
2	105	0.9% (0.1% - 2.7%)	1.4% (1.4% - 1.4%)	1.2% (1.1% - 1.2%)	99	1.0% (0.1% - 2.9%)	1.3% (1.3% - 1.4%)	1.1% (1.1% - 1.1%)
3	102	0.9% (0.1% - 2.7%)	1.8% (1.7% - 1.8%)	1.5% (1.5% - 1.5%)	96	1.0% (0.1% - 2.9%)	1.7% (1.6% - 1.7%)	1.4% (1.4% - 1.4%)
4	101	0.9% (0.1% - 2.8%)	2.2% (2.1% - 2.2%)	1.8% (1.8% - 1.9%)	95	1.0% (0.1% - 2.9%)	1.9% (1.9% - 1.9%)	1.6% (1.6% - 1.6%)
5	80	1.9% (0.5% - 4.8%)	2.6% (2.6% - 2.7%)	2.2% (2.2% - 2.3%)	75	2.0% (0.5% - 5.1%)	2.2% (2.1% - 2.2%)	1.9% (1.8% - 1.9%)
6		(-)	3.1% (3.1% - 3.2%)	2.6% (2.6% - 2.7%)		(-)	2.4% (2.4% - 2.5%)	2.1% (2.1% - 2.1%)
7		(-)	3.6% (3.6% - 3.7%)	3.1% (3.0% - 3.1%)		(-)	2.7% (2.6% - 2.7%)	2.4% (2.3% - 2.4%)
8		(-)	4.2% (4.1% - 4.3%)	3.5% (3.5% - 3.6%)		(-)	3.0% (2.9% - 3.0%)	2.7% (2.6% - 2.7%)
9		(-)	4.8% (4.7% - 4.8%)	4.0% (4.0% - 4.1%)		(-)	3.3% (3.2% - 3.4%)	3.0% (2.9% - 3.0%)
10		(-)	5.4% (5.3% - 5.5%)	4.6% (4.5% - 4.6%)		(-)	3.6% (3.6% - 3.7%)	3.3% (3.3% - 3.4%)
11		(-)	6.1% (6.0% - 6.2%)	5.1% (5.1% - 5.2%)		(-)	4.1% (4.0% - 4.2%)	3.7% (3.7% - 3.8%)
12		(-)	6.8% (6.6% - 6.9%)	5.7% (5.7% - 5.8%)		(-)	4.5% (4.4% - 4.6%)	4.2% (4.1% - 4.3%)
13		(-)	7.4% (7.2% - 7.6%)	6.3% (6.2% - 6.4%)		(-)	5.0% (4.9% - 5.2%)	4.7% (4.6% - 4.8%)
14		(-)	8.1% (7.9% - 8.3%)	6.9% (6.8% - 7.0%)		(-)	5.6% (5.4% - 5.8%)	5.1% (5.0% - 5.3%)
15		(-)	8.7% (8.5% - 9.0%)	7.6% (7.4% - 7.7%)		(-)	6.2% (6.0% - 6.5%)	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

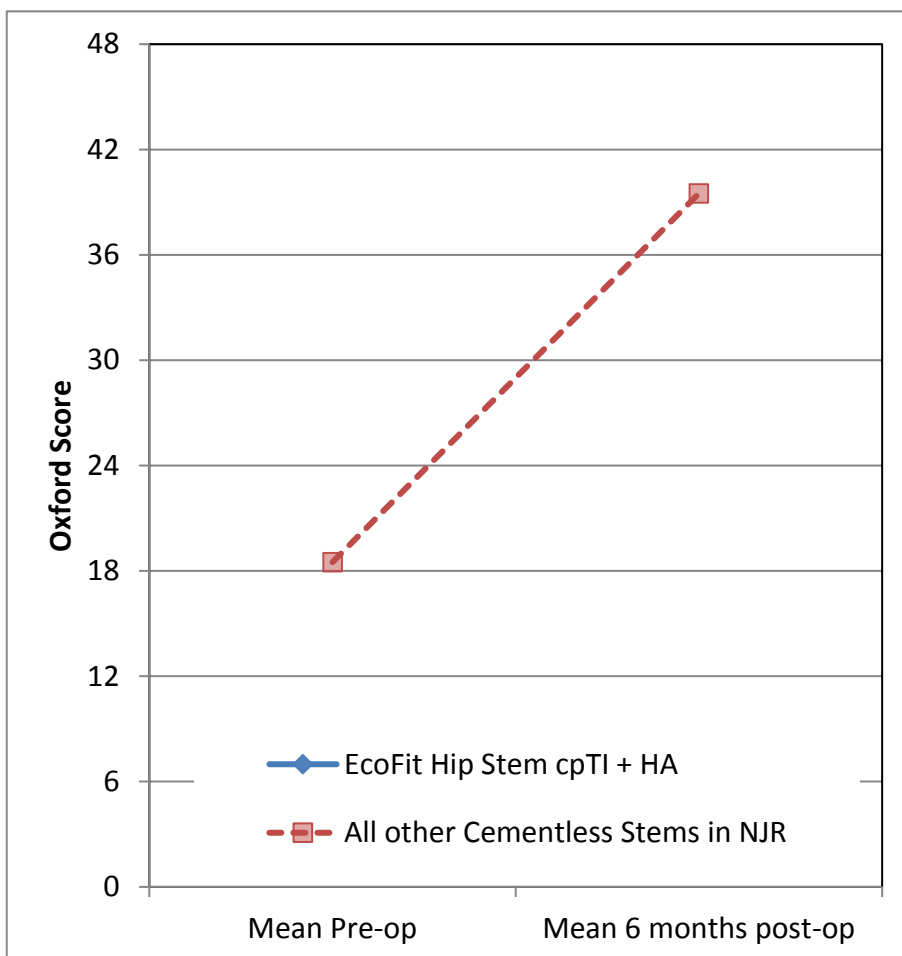
Endpoint: Femoral Revision

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	EcoFit Hip Stem cpTI + HA	All other Cementless	All THR	At Risk	EcoFit Hip Stem cpTI + HA	All other Cementless	All THR
0	109	-	-	-	103	-	-	-
1	108	0.0% (0.0% - 3.1%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)	102	0.0% (0.0% - 3.3%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)
2	105	0.0% (0.0% - 3.1%)	0.9% (0.8% - 0.9%)	0.8% (0.7% - 0.8%)	99	0.0% (0.0% - 3.3%)	0.8% (0.8% - 0.9%)	0.7% (0.7% - 0.7%)
3	102	0.0% (0.0% - 3.1%)	1.1% (1.1% - 1.1%)	1.0% (1.0% - 1.0%)	96	0.0% (0.0% - 3.3%)	1.0% (1.0% - 1.1%)	0.9% (0.9% - 0.9%)
4	101	0.0% (0.0% - 3.1%)	1.3% (1.3% - 1.3%)	1.2% (1.2% - 1.2%)	95	0.0% (0.0% - 3.3%)	1.2% (1.2% - 1.2%)	1.0% (1.0% - 1.1%)
5	80	1.0% (0.1% - 3.1%)	1.5% (1.5% - 1.5%)	1.4% (1.4% - 1.5%)	75	1.1% (0.1% - 3.3%)	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)
6		(-)	1.8% (1.7% - 1.8%)	1.7% (1.7% - 1.8%)		(-)	1.5% (1.5% - 1.6%)	1.4% (1.4% - 1.4%)
7		(-)	2.0% (1.9% - 2.0%)	2.0% (2.0% - 2.0%)		(-)	1.7% (1.6% - 1.7%)	1.5% (1.5% - 1.6%)
8		(-)	2.3% (2.2% - 2.3%)	2.3% (2.3% - 2.3%)		(-)	1.9% (1.8% - 1.9%)	1.7% (1.7% - 1.8%)
9		(-)	2.6% (2.5% - 2.6%)	2.7% (2.6% - 2.7%)		(-)	2.1% (2.0% - 2.1%)	2.0% (1.9% - 2.0%)
10		(-)	2.9% (2.8% - 3.0%)	3.0% (3.0% - 3.0%)		(-)	2.3% (2.2% - 2.3%)	2.2% (2.2% - 2.2%)
11		(-)	3.3% (3.2% - 3.3%)	3.4% (3.3% - 3.4%)		(-)	2.5% (2.5% - 2.6%)	2.5% (2.4% - 2.5%)
12		(-)	3.6% (3.5% - 3.7%)	3.8% (3.8% - 3.9%)		(-)	2.8% (2.7% - 2.9%)	2.8% (2.8% - 2.9%)
13		(-)	4.0% (3.9% - 4.1%)	4.2% (4.2% - 4.3%)		(-)	3.1% (3.0% - 3.3%)	3.1% (3.1% - 3.2%)
14		(-)	4.3% (4.2% - 4.5%)	4.6% (4.5% - 4.7%)		(-)	3.4% (3.3% - 3.6%)	3.4% (3.3% - 3.5%)
15		(-)	4.6% (4.4% - 4.8%)	5.1% (5.0% - 5.2%)		(-)	3.7% (3.5% - 3.9%)	3.8% (3.7% - 3.9%)

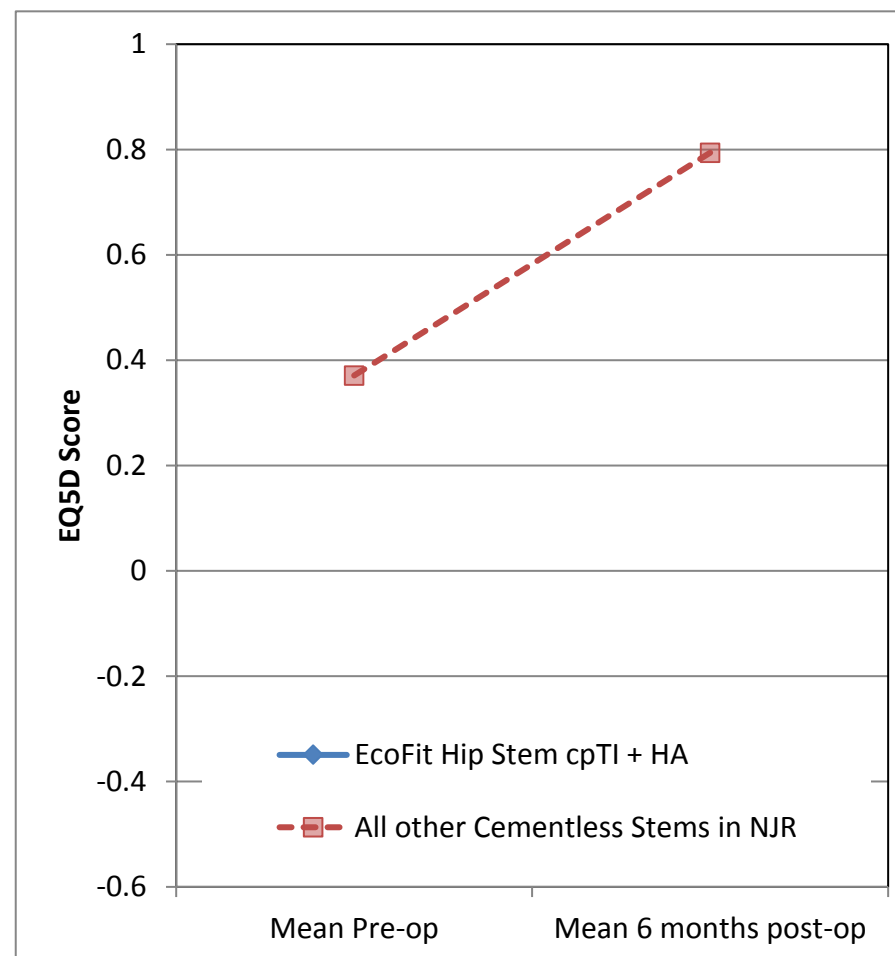
Cumulative revision rate with 95% confidence intervals

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

PROMs Analysis



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 Hip Stem cpTI + HA	All other Cementless Stems in NJR	All THR in NJR
Paired Records	1	128,745	291,075
PreOp score		18.5 (18.4 - 18.5)	18.0 (18.0 - 18.0)
6 month score		39.9 (39.8 - 39.9)	39.3 (39.3 - 39.4)
6 month score (adjusted)		39.5 (39.4 - 39.5)	39.3 (39.3 - 39.4)
Health gain		21.4 (21.3 - 21.4)	21.3 (21.3 - 21.4)
Health gain (adjusted)		21.4 (21.4 - 21.5)	21.3 (21.3 - 21.4)
p value (adjusted health gain)			
Score Improved	0.0%	97.1%	97.2%

EQ-5D Index (-0.59 - 1.00)	EcoFit Hip Stem cpTI + HA	All other Cementless Stems in NJR	All THR in NJR
Paired Records	1	118,954	267,683
PreOp score		0.371 (0.369 - 0.372)	0.355 (0.354 - 0.356)
6 month score		0.801 (0.800 - 0.802)	0.792 (0.791 - 0.792)
6 month score (adjusted)		0.794 (0.793 - 0.795)	0.792 (0.791 - 0.792)
Health gain		0.430 (0.428 - 0.432)	0.437 (0.435 - 0.438)
Health gain (adjusted)		0.439 (0.438 - 0.440)	0.437 (0.436 - 0.437)
p value (adjusted health gain)			
Score Improved	0.0%	89.4%	89.4%

EQ-VAS (0 - 100)	EcoFit Hip Stem cpTI + HA	All other Cementless Stems in NJR	All THR in NJR
Paired Records	0	114,409	256,675
PreOp score		65.4 (65.3 - 65.6)	65.0 (64.9 - 65.1)
6 month score		77.6 (77.5 - 77.7)	76.8 (76.7 - 76.9)
6 month score (adjusted)		76.9 (76.8 - 77.0)	76.8 (76.7 - 76.8)
Health gain		12.2 (12.0 - 12.3)	11.8 (11.7 - 11.9)
Health gain (adjusted)		11.9 (11.8 - 12.0)	11.8 (11.7 - 11.8)
p value (adjusted health gain)			
Score Improved	0.0%	66.7%	65.6%

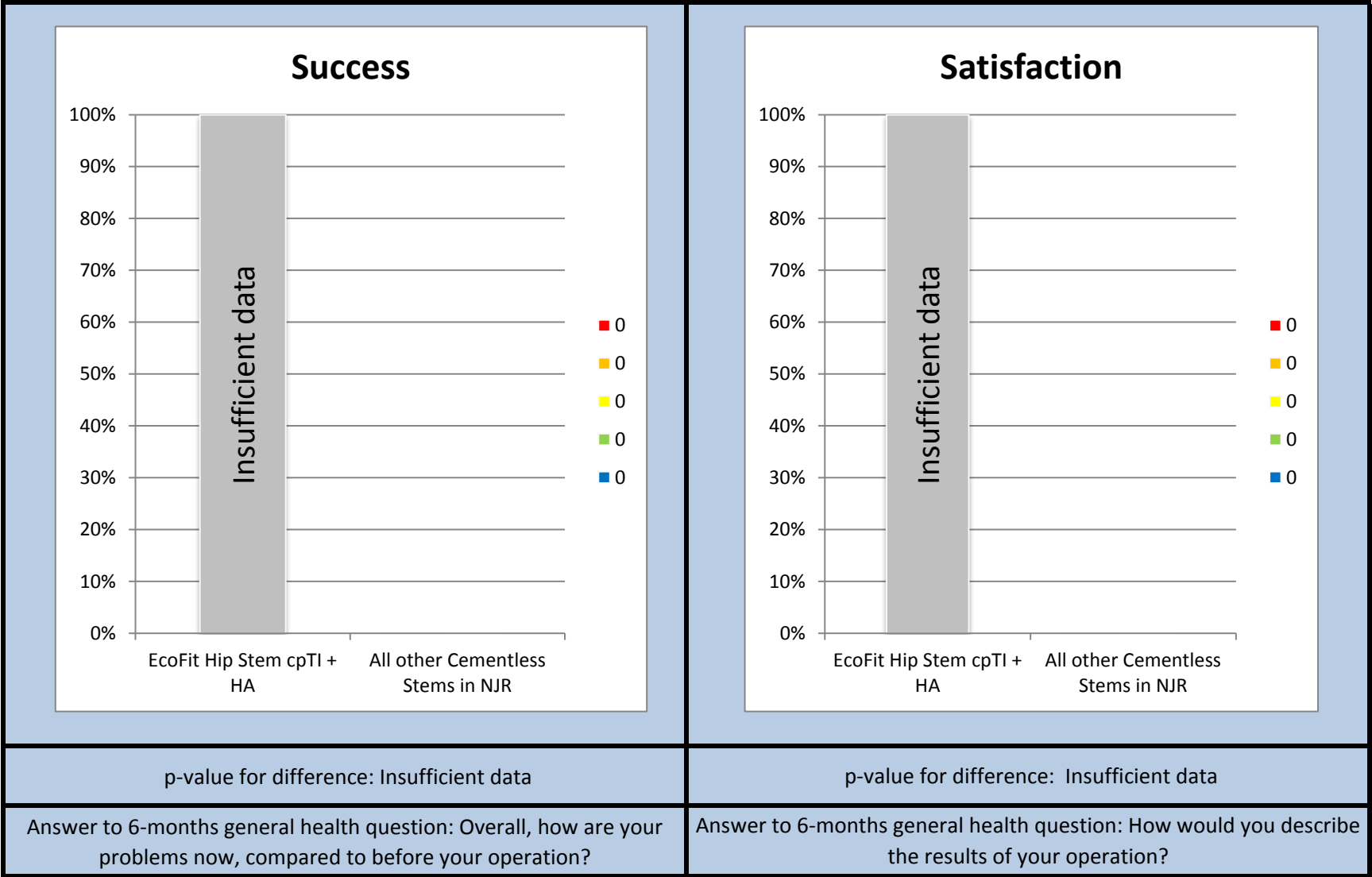
Adjusted scores correspond to the NHS Digital version 3 casemix-adjustment model. This includes patient variables from PROMs, HES, and IMD data.

Summary Report for:

EcoFit Hip Stem cpTI + HA

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	EcoFit Hip Stem cpTI + HA	All other Cementless Stems in NJR

Answer to 6-months general health question:

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

Satisfaction

Response	EcoFit Hip Stem cpTI + HA	All other Cementless Stems 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
30383062	EcoFit® hip stem cementless HA standard size 6.25mm	2
30383075	EcoFit® hip stem cementless HA standard size 7.5mm	2
30383087	EcoFit® hip stem cementless HA standard size 8.75mm	5
30383100	EcoFit® hip stem cementless HA standard size 10mm	8
30383112	EcoFit® hip stem cementless HA standard size 11.25mm	4
30383125	EcoFit® hip stem cementless HA standard size 12.5mm	1
30383137	EcoFit® hip stem cementless HA standard size 13.75mm	3
30383150	EcoFit® hip stem cementless HA standard size 15mm	1
30384062	EcoFit® hip stem cementless HA lateralized size 6.25mm	4
30384075	EcoFit® hip stem cementless HA lateralized size 7.5mm	8
30384087	EcoFit® hip stem cementless HA lateralized size 8.75mm	14
30384100	EcoFit® hip stem cementless HA lateralized size 10mm	16
30384112	EcoFit® hip stem cementless HA lateralized size 11.25mm	10
30384125	EcoFit® hip stem cementless HA lateralized size 12.5mm	8
30384137	EcoFit® hip stem cementless HA lateralized size 13.75mm	8
30384150	EcoFit® hip stem cementless HA lateralized size 15mm	11
30384175	EcoFit® hip stem cementless HA lateralized size 17.5mm	4

Appendix A: Component List

Catalogue Number	Description	Number Implanted
23872800	ic- head CoCrMo taper 12/14mm size Ø 28mm S	10
23872805	ic- head CoCrMo taper 12/14mm size Ø 28mm M	12
23872810	ic- head CoCrMo taper 12/14mm size Ø 28mm L	4
23872815	ic- head CoCrMo taper 12/14mm size Ø 28mm XL	2
23873200	ic- head CoCrMo taper 12/14mm size Ø 32mm S	1
25862800	ic- head BioloX® delta taper 12/14mm size Ø 28mm S	17
25862805	ic- head BioloX® delta taper 12/14mm size Ø 28mm M	17
25862810	ic- head BioloX® delta taper 12/14mm size Ø 28mm L	5
25863200	ic- head BioloX® delta taper 12/14mm size Ø 32mm S	8
25863205	ic- head BioloX® delta taper 12/14mm size Ø 32mm M	13
25863210	ic- head BioloX® delta taper 12/14mm size Ø 32mm L	3
25863600	ic- head BioloX® delta taper 12/14mm size Ø 36mm S	3
25863605	ic- head BioloX® delta taper 12/14mm size Ø 36mm M	6
25863610	ic- head BioloX® delta taper 12/14mm size Ø 36mm L	1
25872805	ic- head BioloX® forte taper 12/14mm size Ø 28mm M	1
29020042	ACCIS® head modular size Ø 42mm	1
29020044	ACCIS® head modular size Ø 44mm	1
29020046	ACCIS® head modular size Ø 46mm	1
29020050	ACCIS® head modular size Ø 50mm	2
29020054	ACCIS® head modular size Ø 54mm	1