

Bespoke Report for:**MicroPort Orthopedics**
Profemur Z StemProduced on: **07 October 2018****Introduction**

This report summarises the outcome of the MicroPort Profemur Z stem in total hip replacement in patients registered in the National Joint Registry. It consists of two parts:

Part 1

The first part summarises the usage and survival associated with the Profemur Z stem, based upon all data recorded in the NJR for this product up to 9 July 2018. This is restricted to primary usage, since there were only 4 Profemur Z stems implanted in traceable consented revision cases. This includes analyses including and excluding metal on metal articulations, and specific analysis of the use of this stem in Ceramic on Ceramic articulations. The report includes Kaplan Meier survival analysis and Cox Regression analysis, comparing the product with all other cementless hip stems in the NJR. The Cox Regression includes calculation of a Hazard Ratio adjusted for age, gender, year cohort and indications.

Part 2

The second part summarises the outcomes of an additional Patient Reported Outcome Measures (PROMs) study requested by MicroPort Orthopedics on the Profemur Z stem, using Oxford Hip scores and EQ-5D-3L scores, at a range of time intervals following surgery.

This report is subject to the National Joint Registry Supplier Feedback Terms and Conditions of Use. In particular, this analysis must not be released to any third party, unless directly employed by the Supplier, without written permission of the Healthcare Quality Improvement Partnership, with the exception of submissions to UK Regulatory Authorities and Notified Bodies.

PART 1: All-NJR Survival Analysis

Bespoke Report for:

Profemur Z Stem

Comprising PRIMARY hips implanted up to:
NJR Database extract:

09 July 2018
07 September 2018

This report section summarises usage and outcomes associated with the Profemur Z Stem, based on data collected by the NJR up to the specified date, for the following femoral stem components used in primary hip arthroplasty, in combination with any acetabular component:

Part Number	Description
PHA00232	PROFEMUR® Z Modular Stem, Size 1
PHA00234	PROFEMUR® Z Modular Stem, Size 2
PHA00236	PROFEMUR® Z Modular Stem, Size 3
PHA00238	PROFEMUR® Z Modular Stem, Size 4
PHA00240	PROFEMUR® Z Modular Stem, Size 5
PHA00242	PROFEMUR® Z Modular Stem, Size 6
PHA00244	PROFEMUR® Z Modular Stem, Size 7
PHA00246	PROFEMUR® Z Modular Stem, Size 8
PHA00248	PROFEMUR® Z Modular Stem, Size 9

Appendix A lists numbers of all Profemur Z Stem components included in this part of the report.

NJR Recorded Usage

Implant Usage

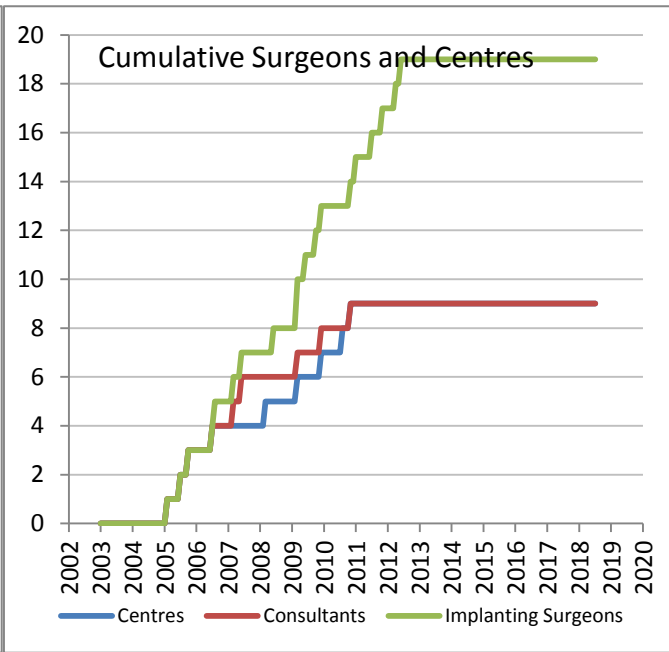
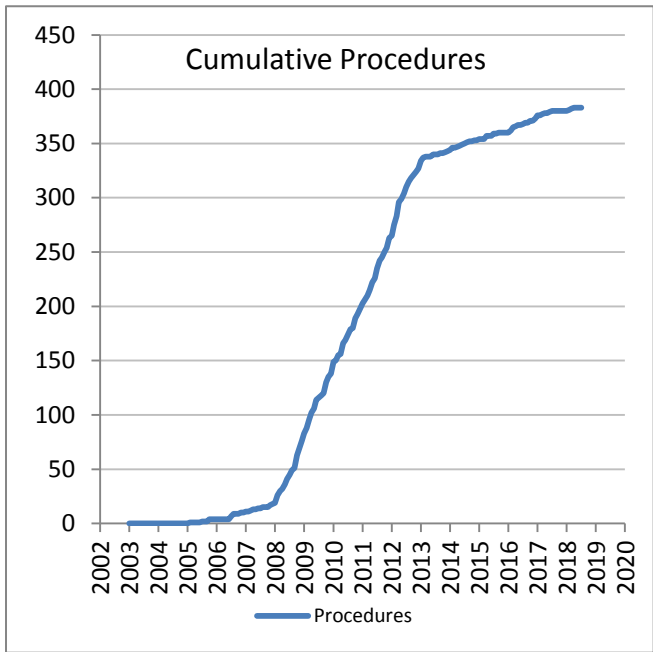
Date of first recorded usage in the NJR: **07 January 2005**

Date of last recorded usage in this dataset: **14 March 2018**

Maximum implantation time: 13.0 years

Mean implantation time: 6.9 years

Totals Recorded in NJR	Cumulative Total
Procedures	383
Patients	344
Centres	9
Consultants	9
Implanting Surgeons	19



	Year of implantation														Total	%
	Current Outcome	Pre-2007	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018		
Death	3	1	9	11	1	5	4	1	1	0	1	0	0	37	9.7%	
Revised	3	3	12	2	1	1	2	0	0	0	0	0	0	24	6.3%	
Unrevised	5	4	43	53	52	56	63	9	9	6	15	4	3	322	84.1%	
Total	11	8	64	66	54	62	69	10	10	6	16	4	3	383	100%	

Patient / Procedure Details

Patient Details

	Profemur Z Stem	All NJR Cementless Stems	All NJR hip replacement
Total Procedures	383	429,591	1,054,087
Total Patients	344	373,516	899,157
Demographics			
Mean age	64.0	65.4	68.6
< 50	11.0%	8.4%	6.0%
50 – 59	17.2%	18.8%	13.7%
60 – 69	38.9%	35.0%	29.3%
70 – 79	26.9%	28.5%	34.5%
≥ 80	6.0%	9.2%	16.4%
Median BMI	28	28	28
% BMI information available	80.7%	61.9%	59.4%
Underweight (BMI < 18.5)	0.6%	0.7%	0.9%
Normal (18.5 ≤ BMI < 25)	19.4%	18.9%	20.7%
Overweight (25 ≤ BMI < 30)	38.5%	39.3%	39.7%
Obese I (30 ≤ BMI < 35)	26.9%	26.7%	25.7%
Obese II (35 ≤ BMI < 40)	10.0%	10.7%	9.6%
Obese III (BMI ≥ 40)	4.5%	3.7%	3.3%
% Male	41.3%	44.1%	40.2%
ASA Grades			
P1 - Fit and healthy	18.3%	18.6%	16.4%
P2 - Mild disease not incapacitating	68.9%	68.6%	67.6%
P3 - Incapacitating systemic disease	12.5%	12.3%	15.5%
P4 / P5	0.3%	0.4%	0.6%
Indications			
Osteoarthritis	91.64%	93.05%	91.75%
Rheumatoid Arthritis	3.39%	1.22%	1.32%
Avascular Necrosis	3.39%	2.59%	2.51%
Fractured Neck of Femur	1.04%	1.81%	3.16%
CDH/DDH	2.35%	2.02%	1.55%
Other	0.52%	1.82%	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 - all bearing types

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

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Pain	2	2.75	1
Dislocation / Subluxation	2	2.12	1
Adverse Soft Tissue Reaction	10	3.99	0.008
Infection	2	1.95	0.722
Aseptic Loosening - Stem	2	2.74	1
Aseptic Loosening - Socket	0	1.50	0.414
Periprosthetic Fracture Stem	2	1.34	0.389
Periprosthetic Fracture Socket	1	0.20	0.182
Malalignment Stem	0	0.46	1
Malalignment Socket	2	0.90	0.227
Wear Of Acetabular Component	0	0.75	1
Lysis Stem	4	0.53	0.002
Lysis Socket	3	0.49	0.013
Implant Fracture Stem	0	0.19	1
Implant Fracture Socket	0	0.27	1
Implant Fracture Head	0	0.10	1
Dissociation of Liner	0	0.29	1
Other / reason not recorded	2	0.97	0.253
Total Revised	24	16.19	0.061

[†] multiple reasons may be listed for one revision procedure^{*} Based on All NJR Cementless Stems, adjusted for agegroup, gender, and indicationsSignificantly better, $p < 0.001$ Significantly better, $p < 0.05$ Significantly worse $p < 0.05$ Significantly worse $p < 0.001$ 

Components Revised	Number of procedures	Profemur Z Stem	All other Cementless Stems in NJR
Femoral only	3	13%	22%
Acetabular only	4	17%	34%
Both femoral and acetabular	16	67%	32%
Neither femoral nor acetabular revision recorded [*]	1	4%	11%

^{*} 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
Pain	0	1.15	0.636
Dislocation / Subluxation	1	1.68	1
Adverse Soft Tissue Reaction	0	0.39	1
Infection	2	1.29	0.368
Aseptic Loosening - Stem	0	1.76	0.43
Aseptic Loosening - Socket	0	0.79	1
Periprosthetic Fracture Stem	1	1.10	1
Periprosthetic Fracture Socket	1	0.17	0.153
Malalignment Stem	0	0.34	1
Malalignment Socket	0	0.60	1
Wear Of Acetabular Component	0	0.46	1
Lysis Stem	1	0.22	0.195
Lysis Socket	1	0.16	0.147
Implant Fracture Stem	0	0.13	1
Implant Fracture Socket	0	0.22	1
Implant Fracture Head	0	0.07	1
Dissociation of Liner	0	0.22	1
Other / reason not recorded	1	0.45	0.364
Total Revised	7	8.61	0.733

* Based on All NJR Cementless 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	Profemur Z Stem	All other Cementless Stems in NJR
Femoral only	1	14%	30%
Acetabular only	2	29%	26%
Both femoral and acetabular	4	57%	32%
Neither femoral nor acetabular revision recorded *	0	0%	11%

* includes isolated head and/or liner exchange

Revision and Survivorship

Reasons for Revision - Ceramic on Ceramic Articulations

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

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Pain	0	0.98	1
Dislocation / Subluxation	1	1.34	1
Adverse Soft Tissue Reaction	0	0.33	1
Infection	2	1.06	0.286
Aseptic Loosening - Stem	0	1.48	0.414
Aseptic Loosening - Socket	0	0.66	1
Periprosthetic Fracture Stem	0	0.79	1
Periprosthetic Fracture Socket	1	0.13	0.121
Malalignment Stem	0	0.28	1
Malalignment Socket	0	0.50	1
Wear Of Acetabular Component	0	0.39	1
Lysis Stem	0	0.18	1
Lysis Socket	0	0.14	1
Implant Fracture Stem	0	0.11	1
Implant Fracture Socket	0	0.19	1
Implant Fracture Head	0	0.07	1
Dissociation of Liner	0	0.18	1
Other / reason not recorded	0	0.38	1
Total Revised	4	7.06	0.343

* Based on All NJR Cementless 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	Profemur Z Stem	All other Cementless Stems in NJR
Femoral only	0	0%	30%
Acetabular only	1	25%	26%
Both femoral and acetabular	3	75%	32%
Neither femoral nor acetabular revision recorded *	0	0%	11%

Revision and Survivorship

Analysis by Implant Combination

Articulation	Implanted	PTIR	Group PTIR	p.PTIR	Revised	Expected Revisions	p Log-rank
Metal on Polyethylene	39	1.02	0.61	0.337	2	1.0	0.258
Ceramic on Ceramic	252	0.23		0.043	4	8.9	0.128
Ceramic on Metal	0						
Ceramic on Polyethylene	13	0.00		1.000	0	0.3	1.000
Metal on Ceramic	0						
Metal on Metal	65	3.13		<0.001	17	5.8	<0.001
Metal on Polyurethane	0						
Unknown	14	0.87		0.504	1	0.8	0.547

Significantly better, p < 0.001



Significantly better, p < 0.05

Significantly worse p < 0.05



Significantly worse p < 0.001

Patient Time Incidence Rate (PTIR) is calculated as revisions per 100 patient years.

The Group PTIR corresponds to all other cementless stems in the NJR.

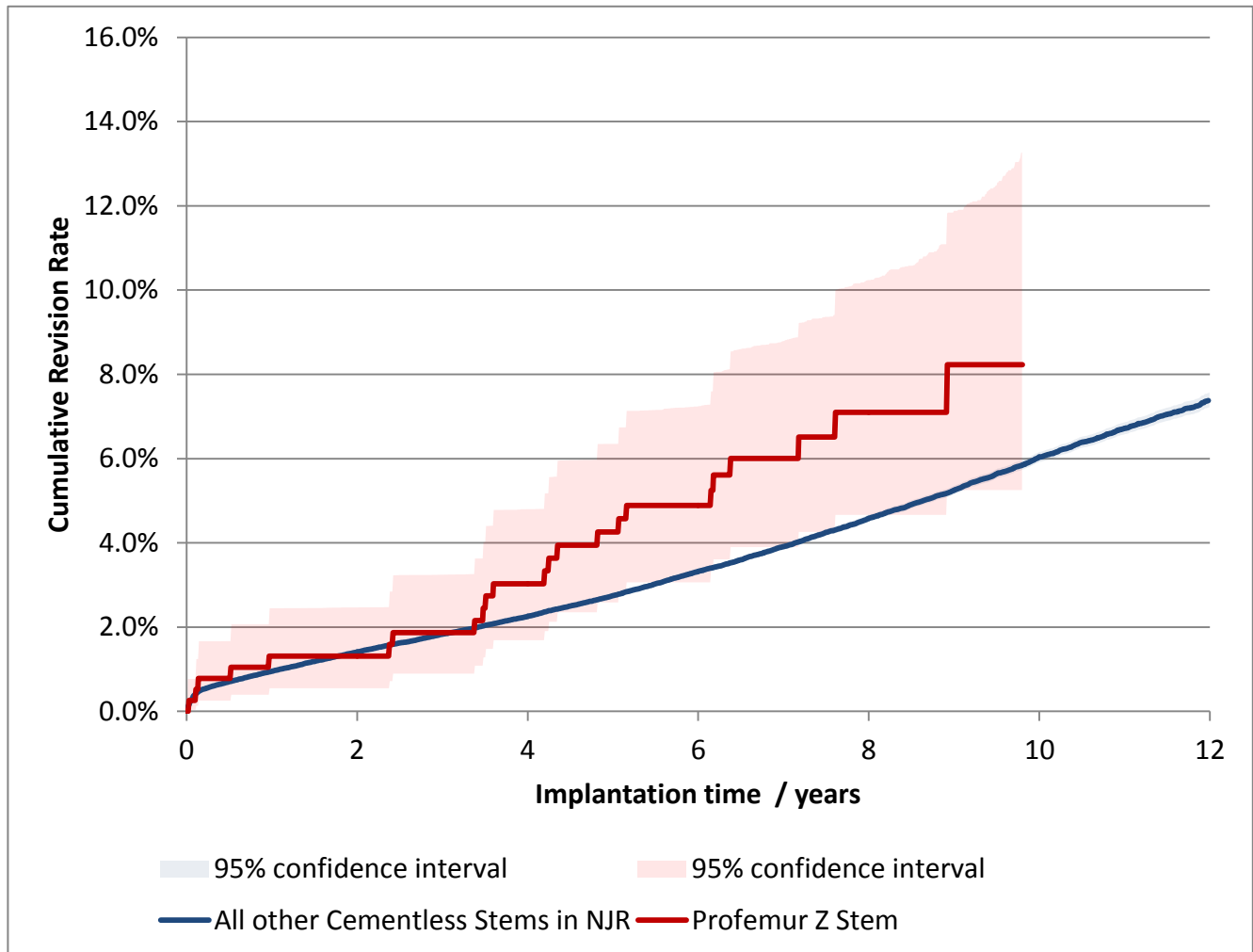
The p value for the PTIR comparison is calculated using a Poisson exact test

The expected number of revisions is calculated using the logrank method, and is adjusted for year cohort, age group, gender, and indications.

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



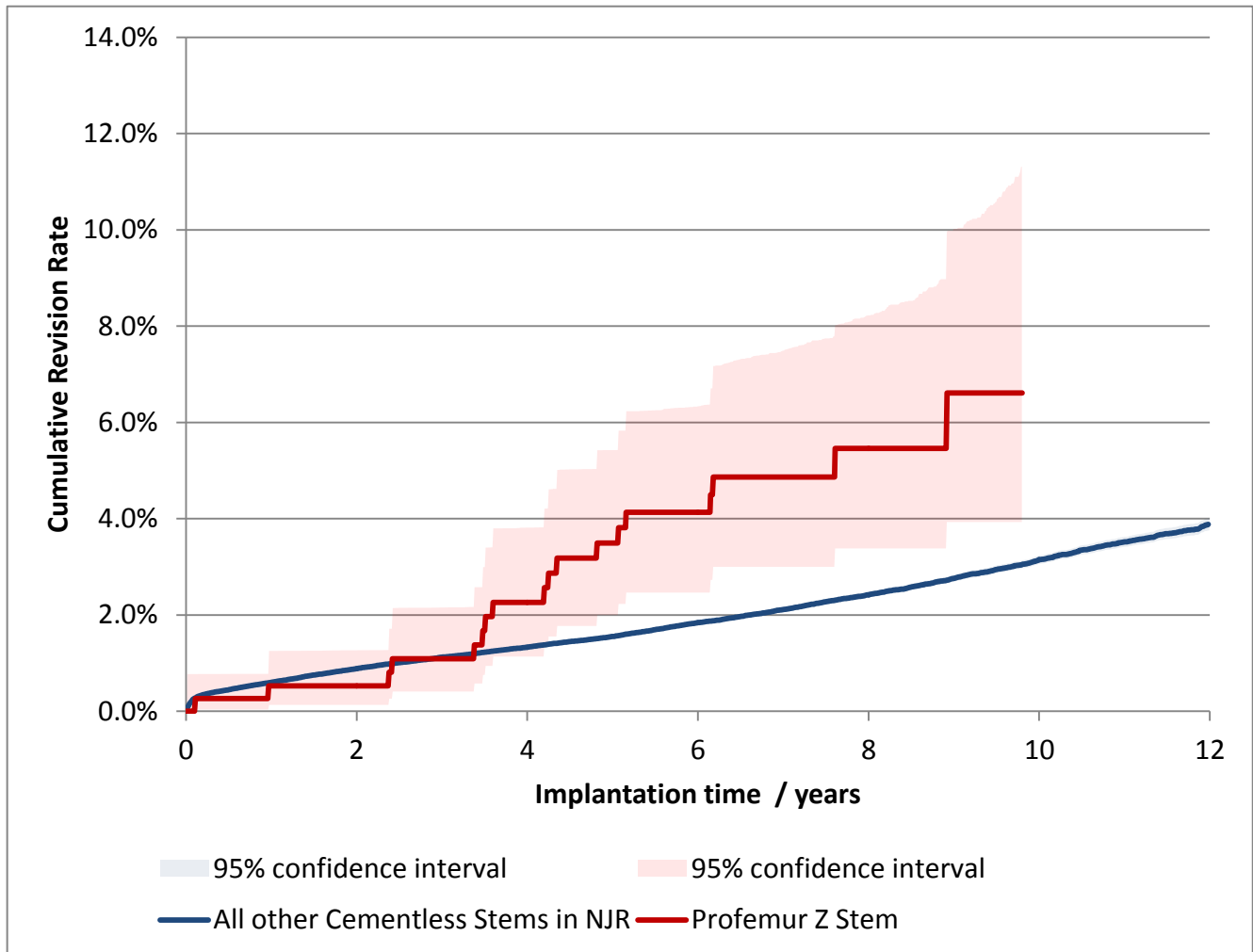
Cox Proportional Hazards model for revision risk ratio of Profemur Z Stem / All other Cementless Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	1.54 (1.03 - 2.30)	0.034
All bearings. Adjusted for age, gender, year cohort and indications.	1.44 (0.96 - 2.14)	0.077

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision. All Bearing types



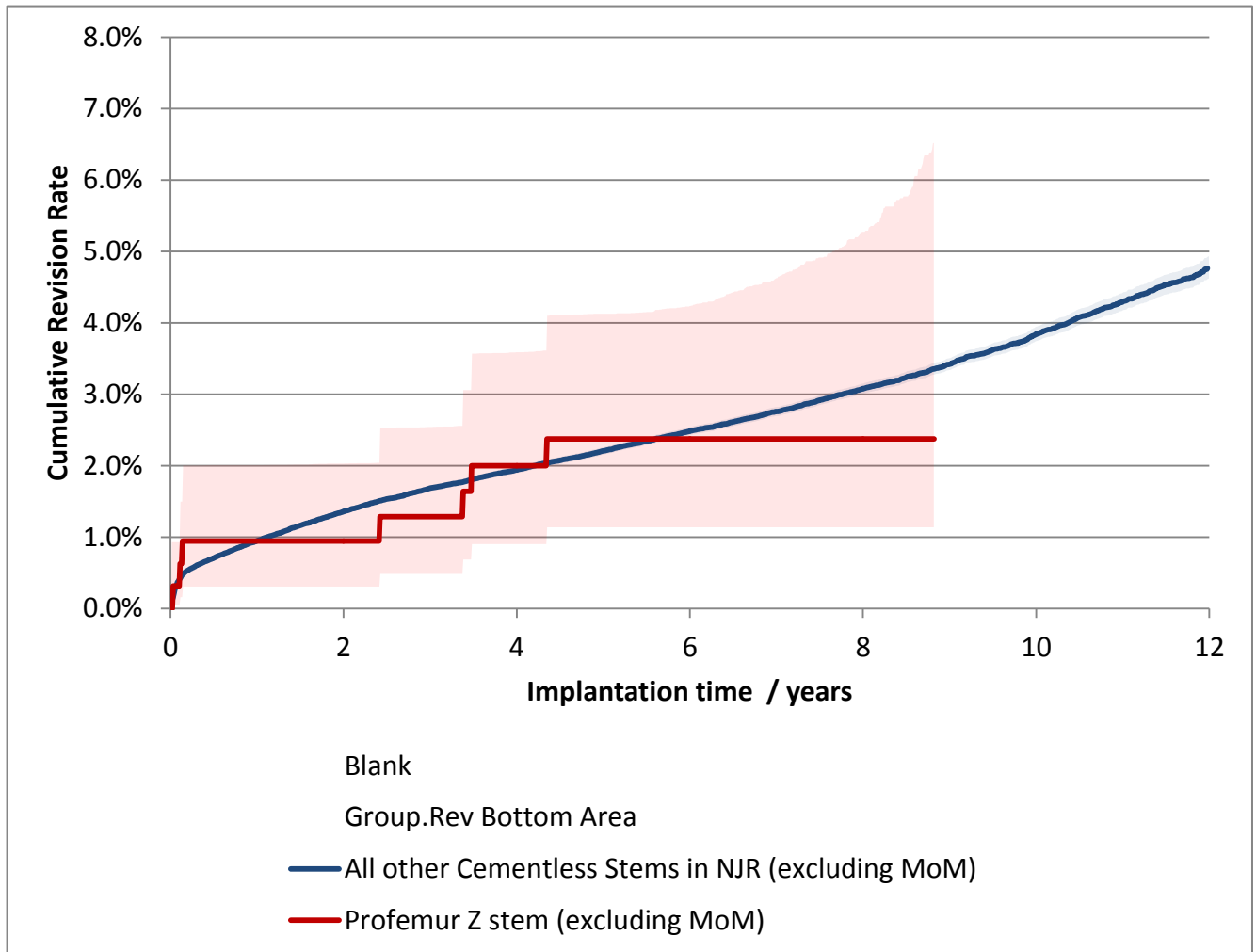
Cox Proportional Hazards model for revision risk ratio of Profemur Z Stem / all other All other Cementless Stems in NJR, with endpoint as Femoral revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	2.29 (1.46 - 3.59)	<0.001
All bearings. Adjusted for age, gender, year cohort and indications.	2.16 (1.37 - 3.39)	<0.001

Revision and Survivorship

Cumulative Revision Rate

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



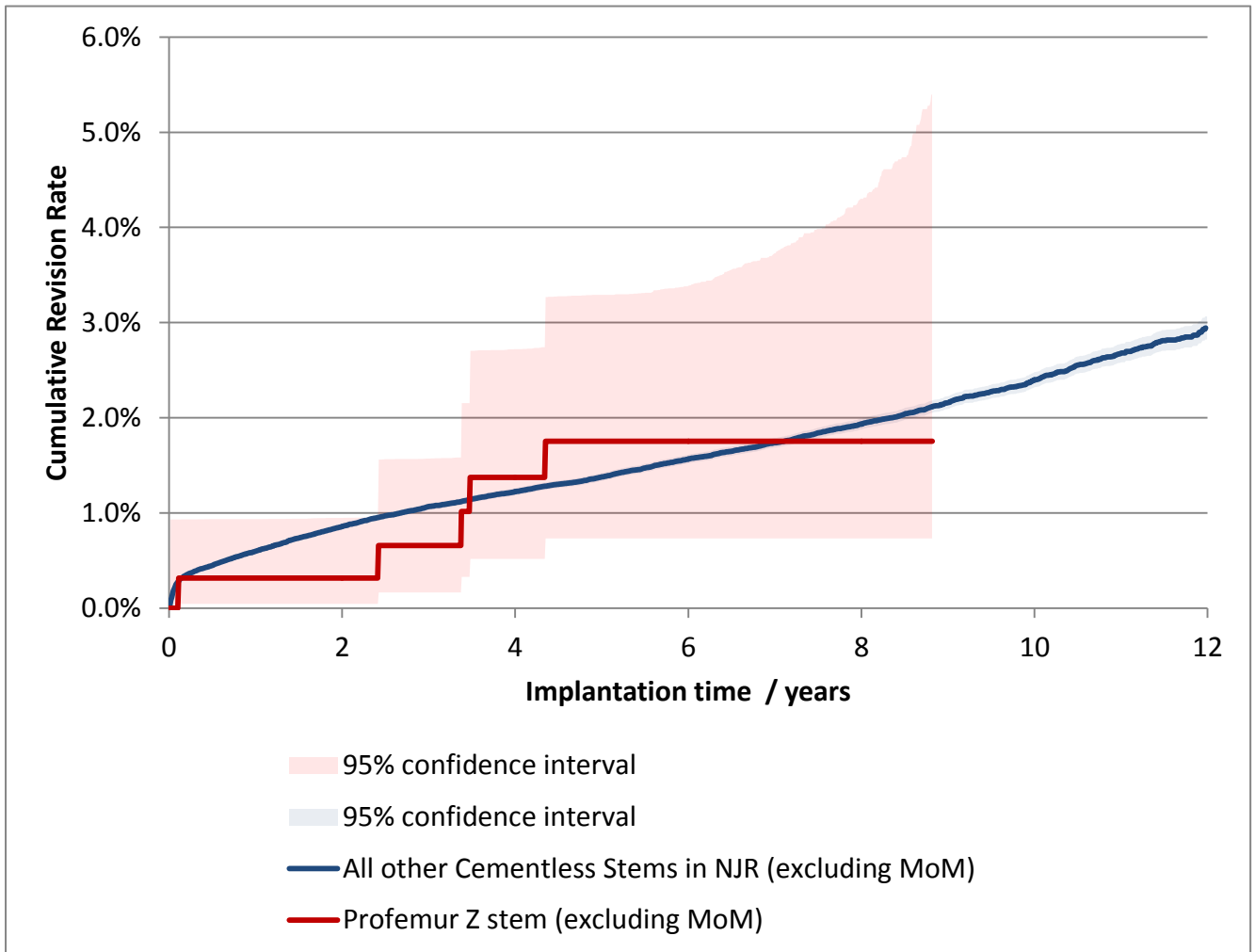
Cox Proportional Hazards model for revision risk ratio of Profemur Z Stem (excluding MoM) / All other Cementless Stems in NJR (excluding MoM), with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	0.81 (0.39 - 1.71)	0.586
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.80 (0.38 - 1.67)	0.549

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision. Excluding Metal-on-Metal



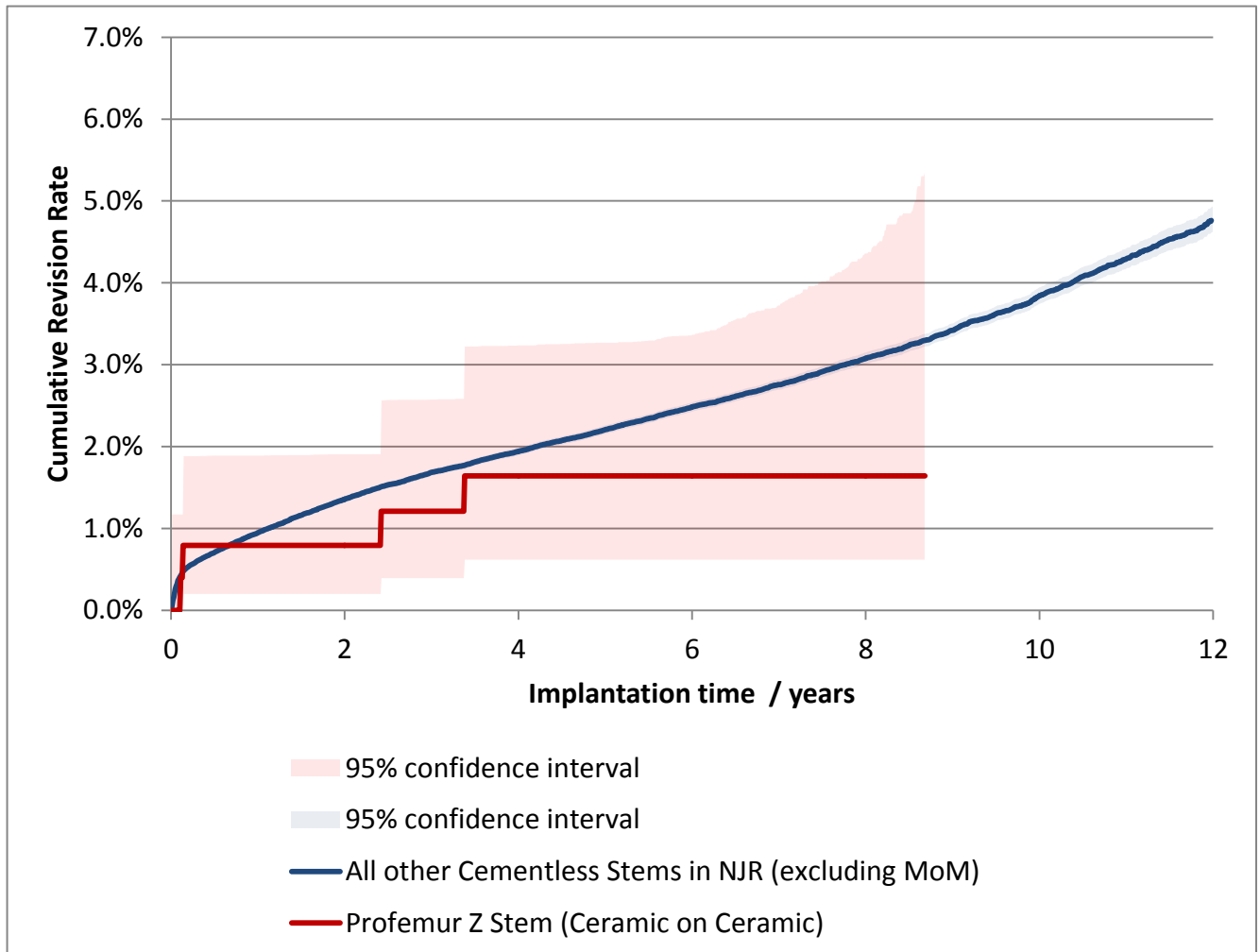
Cox Proportional Hazards model for revision risk ratio of Profemur Z Stem (excluding MoM) / All other Cementless Stems in NJR (excluding MoM), with endpoint as Femoral revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted	0.93 (0.39 - 2.23)	0.867
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.91 (0.38 - 2.19)	0.831

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. Profemur Z Ceramic on Ceramic



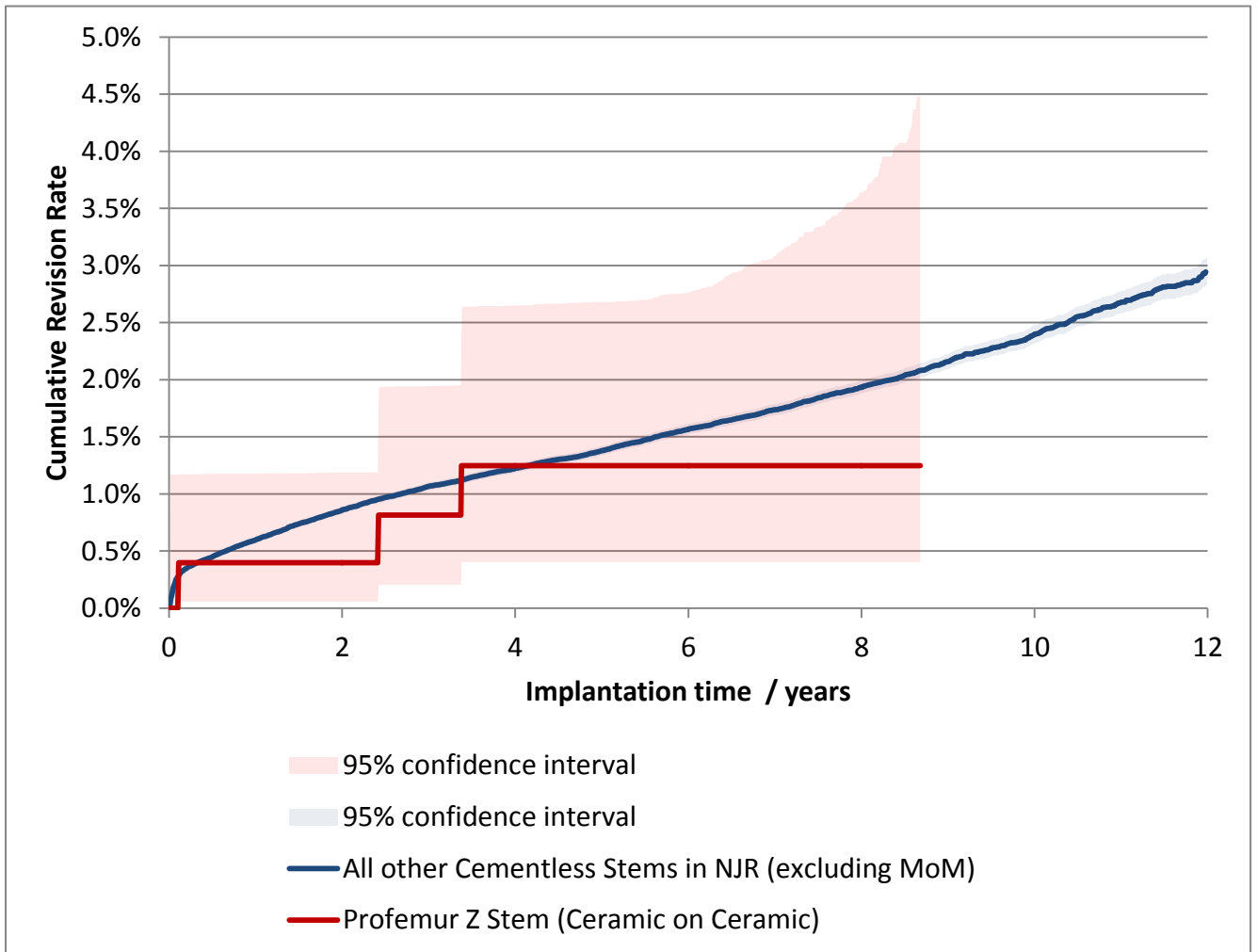
Cox Proportional Hazards model for revision risk ratio of Profemur Z Stem Ceramic on Ceramic / All other Cementless Stems in NJR (excluding MoM), with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	0.57 (0.22 - 1.53)	0.266
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.56 (0.21 - 1.49)	0.243

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision. Profemur Z Ceramic on Ceramic



Cox Proportional Hazards model for revision risk ratio of Profemur Z Stem Ceramic on Ceramic / All other Cementless Stems in NJR (excluding MoM), with endpoint as Femoral revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted	0.69 (0.22 - 2.13)	0.514
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.67 (0.22 - 2.08)	0.489

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Profemur Z Stem	All NJR Cementless Stems	All THR	At Risk	Profemur Z Stem	All NJR Cementless Stems	All THR
0	383	-	-	-	318	-	-	-
1	374	1.3% (0.5% - 2.4%)	1.0% (0.9% - 1.0%)	0.8% (0.8% - 0.8%)	311	0.9% (0.3% - 2.0%)	0.9% (0.9% - 1.0%)	0.8% (0.7% - 0.8%)
2	361	1.3% (0.5% - 2.5%)	1.4% (1.4% - 1.4%)	1.2% (1.1% - 1.2%)	299	0.9% (0.3% - 2.0%)	1.4% (1.3% - 1.4%)	1.1% (1.1% - 1.1%)
3	345	1.9% (0.9% - 3.2%)	1.8% (1.8% - 1.9%)	1.5% (1.5% - 1.5%)	284	1.3% (0.5% - 2.5%)	1.7% (1.6% - 1.7%)	1.4% (1.4% - 1.4%)
4	325	3.0% (1.7% - 4.8%)	2.3% (2.2% - 2.3%)	1.9% (1.9% - 1.9%)	268	2.0% (0.9% - 3.6%)	1.9% (1.9% - 2.0%)	1.6% (1.6% - 1.6%)
5	304	4.3% (2.6% - 6.4%)	2.7% (2.7% - 2.8%)	2.3% (2.3% - 2.3%)	251	2.4% (1.1% - 4.1%)	2.2% (2.2% - 2.3%)	1.9% (1.8% - 1.9%)
6	273	4.9% (3.1% - 7.2%)	3.3% (3.3% - 3.4%)	2.8% (2.7% - 2.8%)	222	2.4% (1.1% - 4.2%)	2.5% (2.4% - 2.5%)	2.1% (2.1% - 2.2%)
7	199	6.0% (3.9% - 8.8%)	3.9% (3.8% - 4.0%)	3.2% (3.2% - 3.3%)	151	2.4% (1.1% - 4.6%)	2.8% (2.7% - 2.8%)	2.4% (2.3% - 2.4%)
8	136	7.1% (4.7% - 10.2%)	4.6% (4.5% - 4.7%)	3.8% (3.7% - 3.8%)	90	2.4% (1.1% - 5.3%)	3.1% (3.0% - 3.1%)	2.7% (2.7% - 2.7%)
9	78	8.2% (5.3% - 11.9%)	5.3% (5.2% - 5.4%)	4.3% (4.3% - 4.4%)		(-)	3.4% (3.3% - 3.5%)	3.0% (3.0% - 3.1%)
10		(-)	6.0% (5.9% - 6.2%)	4.9% (4.8% - 4.9%)		(-)	3.8% (3.7% - 3.9%)	3.4% (3.3% - 3.5%)
11		(-)	6.7% (6.6% - 6.9%)	5.5% (5.4% - 5.5%)		(-)	4.3% (4.2% - 4.4%)	3.8% (3.8% - 3.9%)
12		(-)	7.4% (7.2% - 7.6%)	6.0% (6.0% - 6.1%)		(-)	4.8% (4.6% - 4.9%)	4.3% (4.2% - 4.4%)
13		(-)	8.0% (7.8% - 8.3%)	6.6% (6.5% - 6.7%)		(-)	5.3% (5.1% - 5.5%)	4.8% (4.7% - 4.9%)
14		(-)	8.7% (8.4% - 9.1%)	7.2% (7.1% - 7.3%)		(-)	6.0% (5.7% - 6.3%)	5.3% (5.1% - 5.4%)
15		(-)	(-)	7.9% (7.6% - 8.1%)		(-)	(-)	(-)

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	Profemur Z Stem	All NJR Cementless Stems	All THR	At Risk	Profemur Z Stem	All NJR Cementless Stems	All THR
0	383	-	-	-	318	-	-	-
1	374	0.5% (0.1% - 1.3%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)	311	0.3% (0.0% - 0.9%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)
2	361	0.5% (0.1% - 1.3%)	0.9% (0.9% - 0.9%)	0.8% (0.8% - 0.8%)	299	0.3% (0.0% - 0.9%)	0.9% (0.8% - 0.9%)	0.7% (0.7% - 0.7%)
3	345	1.1% (0.4% - 2.2%)	1.1% (1.1% - 1.2%)	1.0% (1.0% - 1.0%)	284	0.7% (0.2% - 1.6%)	1.1% (1.0% - 1.1%)	0.9% (0.9% - 0.9%)
4	325	2.3% (1.1% - 3.8%)	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.3%)	268	1.4% (0.5% - 2.7%)	1.2% (1.2% - 1.3%)	1.1% (1.0% - 1.1%)
5	304	3.5% (2.0% - 5.4%)	1.6% (1.5% - 1.6%)	1.5% (1.5% - 1.5%)	251	1.8% (0.7% - 3.3%)	1.4% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)
6	273	4.1% (2.5% - 6.3%)	1.8% (1.8% - 1.9%)	1.8% (1.8% - 1.8%)	222	1.8% (0.7% - 3.4%)	1.6% (1.5% - 1.6%)	1.4% (1.4% - 1.4%)
7	199	4.9% (3.0% - 7.5%)	2.1% (2.1% - 2.2%)	2.1% (2.1% - 2.2%)	151	1.8% (0.7% - 3.7%)	1.7% (1.7% - 1.8%)	1.6% (1.5% - 1.6%)
8	136	5.5% (3.4% - 8.2%)	2.4% (2.4% - 2.5%)	2.5% (2.4% - 2.5%)	90	1.8% (0.7% - 4.3%)	1.9% (1.9% - 2.0%)	1.8% (1.8% - 1.8%)
9	78	6.6% (3.9% - 10.0%)	2.8% (2.7% - 2.8%)	2.8% (2.8% - 2.9%)		(-)	2.2% (2.1% - 2.2%)	2.0% (2.0% - 2.1%)
10		(-)	3.2% (3.1% - 3.2%)	3.2% (3.2% - 3.3%)		(-)	2.4% (2.3% - 2.5%)	2.3% (2.2% - 2.3%)
11		(-)	3.5% (3.4% - 3.6%)	3.6% (3.6% - 3.7%)		(-)	2.7% (2.6% - 2.8%)	2.6% (2.5% - 2.6%)
12		(-)	3.9% (3.8% - 4.0%)	4.1% (4.0% - 4.2%)		(-)	2.9% (2.8% - 3.1%)	2.9% (2.8% - 3.0%)
13		(-)	4.3% (4.1% - 4.5%)	4.5% (4.4% - 4.6%)		(-)	3.3% (3.1% - 3.5%)	3.2% (3.1% - 3.3%)
14		(-)	4.5% (4.3% - 4.7%)	4.9% (4.8% - 5.0%)		(-)	3.5% (3.3% - 3.7%)	3.5% (3.4% - 3.7%)
15		(-)	(-)	5.4% (5.2% - 5.6%)		(-)	(-)	(-)

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: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Profemur Z Stem (Ceramic on Ceramic)	All NJR Cementless Stems	All THR	At Risk	Profemur Z Stem (Ceramic on Ceramic)	All NJR Cementless Stems	All THR
0	252	-	-	-	252	-	-	-
1	247	0.8% (0.2% - 1.9%)	1.0% (0.9% - 1.0%)	0.8% (0.8% - 0.8%)	247	0.8% (0.2% - 1.9%)	0.9% (0.9% - 1.0%)	0.8% (0.7% - 0.8%)
2	240	0.8% (0.2% - 1.9%)	1.4% (1.4% - 1.4%)	1.2% (1.1% - 1.2%)	240	0.8% (0.2% - 1.9%)	1.4% (1.3% - 1.4%)	1.1% (1.1% - 1.1%)
3	233	1.2% (0.4% - 2.6%)	1.8% (1.8% - 1.9%)	1.5% (1.5% - 1.5%)	233	1.2% (0.4% - 2.6%)	1.7% (1.6% - 1.7%)	1.4% (1.4% - 1.4%)
4	225	1.6% (0.6% - 3.2%)	2.3% (2.2% - 2.3%)	1.9% (1.9% - 1.9%)	225	1.6% (0.6% - 3.2%)	1.9% (1.9% - 2.0%)	1.6% (1.6% - 1.6%)
5	216	1.6% (0.6% - 3.3%)	2.7% (2.7% - 2.8%)	2.3% (2.3% - 2.3%)	216	1.6% (0.6% - 3.3%)	2.2% (2.2% - 2.3%)	1.9% (1.8% - 1.9%)
6	192	1.6% (0.6% - 3.4%)	3.3% (3.3% - 3.4%)	2.8% (2.7% - 2.8%)	192	1.6% (0.6% - 3.4%)	2.5% (2.4% - 2.5%)	2.1% (2.1% - 2.2%)
7	131	1.6% (0.6% - 3.7%)	3.9% (3.8% - 4.0%)	3.2% (3.2% - 3.3%)	131	1.6% (0.6% - 3.7%)	2.8% (2.7% - 2.8%)	2.4% (2.3% - 2.4%)
8	76	1.6% (0.6% - 4.4%)	4.6% (4.5% - 4.7%)	3.8% (3.7% - 3.8%)	76	1.6% (0.6% - 4.4%)	3.1% (3.0% - 3.1%)	2.7% (2.7% - 2.7%)
9		(-)	5.3% (5.2% - 5.4%)	4.3% (4.3% - 4.4%)		(-)	3.4% (3.3% - 3.5%)	3.0% (3.0% - 3.1%)
10		(-)	6.0% (5.9% - 6.2%)	4.9% (4.8% - 4.9%)		(-)	3.8% (3.7% - 3.9%)	3.4% (3.3% - 3.5%)
11		(-)	6.7% (6.6% - 6.9%)	5.5% (5.4% - 5.5%)		(-)	4.3% (4.2% - 4.4%)	3.8% (3.8% - 3.9%)
12		(-)	7.4% (7.2% - 7.6%)	6.0% (6.0% - 6.1%)		(-)	4.8% (4.6% - 4.9%)	4.3% (4.2% - 4.4%)
13		(-)	8.0% (7.8% - 8.3%)	6.6% (6.5% - 6.7%)		(-)	5.3% (5.1% - 5.5%)	4.8% (4.7% - 4.9%)
14		(-)	8.7% (8.4% - 9.1%)	7.2% (7.1% - 7.3%)		(-)	6.0% (5.7% - 6.3%)	5.3% (5.1% - 5.4%)
15		(-)	(-)	7.9% (7.6% - 8.1%)		(-)	(-)	(-)

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	Profemur Z Stem (Ceramic on Ceramic)	All NJR Cementless Stems	All THR	At Risk	Profemur Z Stem (Ceramic on Ceramic)	All NJR Cementless Stems	All THR
0	252	-	-	-	252	-	-	-
1	247	0.4% (0.1% - 1.2%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)	247	0.4% (0.1% - 1.2%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)
2	240	0.4% (0.1% - 1.2%)	0.9% (0.9% - 0.9%)	0.8% (0.8% - 0.8%)	240	0.4% (0.1% - 1.2%)	0.9% (0.8% - 0.9%)	0.7% (0.7% - 0.7%)
3	233	0.8% (0.2% - 1.9%)	1.1% (1.1% - 1.2%)	1.0% (1.0% - 1.0%)	233	0.8% (0.2% - 1.9%)	1.1% (1.0% - 1.1%)	0.9% (0.9% - 0.9%)
4	225	1.2% (0.4% - 2.7%)	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.3%)	225	1.2% (0.4% - 2.7%)	1.2% (1.2% - 1.3%)	1.1% (1.0% - 1.1%)
5	216	1.2% (0.4% - 2.7%)	1.6% (1.5% - 1.6%)	1.5% (1.5% - 1.5%)	216	1.2% (0.4% - 2.7%)	1.4% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)
6	192	1.2% (0.4% - 2.8%)	1.8% (1.8% - 1.9%)	1.8% (1.8% - 1.8%)	192	1.2% (0.4% - 2.8%)	1.6% (1.5% - 1.6%)	1.4% (1.4% - 1.4%)
7	131	1.2% (0.4% - 3.1%)	2.1% (2.1% - 2.2%)	2.1% (2.1% - 2.2%)	131	1.2% (0.4% - 3.1%)	1.7% (1.7% - 1.8%)	1.6% (1.5% - 1.6%)
8	76	1.2% (0.4% - 3.6%)	2.4% (2.4% - 2.5%)	2.5% (2.4% - 2.5%)	76	1.2% (0.4% - 3.6%)	1.9% (1.9% - 2.0%)	1.8% (1.8% - 1.8%)
9		(-)	2.8% (2.7% - 2.8%)	2.8% (2.8% - 2.9%)		(-)	2.2% (2.1% - 2.2%)	2.0% (2.0% - 2.1%)
10		(-)	3.2% (3.1% - 3.2%)	3.2% (3.2% - 3.3%)		(-)	2.4% (2.3% - 2.5%)	2.3% (2.2% - 2.3%)
11		(-)	3.5% (3.4% - 3.6%)	3.6% (3.6% - 3.7%)		(-)	2.7% (2.6% - 2.8%)	2.6% (2.5% - 2.6%)
12		(-)	3.9% (3.8% - 4.0%)	4.1% (4.0% - 4.2%)		(-)	2.9% (2.8% - 3.1%)	2.9% (2.8% - 3.0%)
13		(-)	4.3% (4.1% - 4.5%)	4.5% (4.4% - 4.6%)		(-)	3.3% (3.1% - 3.5%)	3.2% (3.1% - 3.3%)
14		(-)	4.5% (4.3% - 4.7%)	4.9% (4.8% - 5.0%)		(-)	3.5% (3.3% - 3.7%)	3.5% (3.4% - 3.7%)
15		(-)	(-)	5.4% (5.2% - 5.6%)		(-)	(-)	(-)

Cumulative revision rate with 95% confidence intervals

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

PART 2: PROMs Analysis

Bespoke Report for:

MicroPort Orthopedics

Profemur Z Stem

Questionnaires and Responses

A total of 317 PROMs questionnaires were mailed out to patients implanted with a Profemur Z stem. These consisted of Oxford Hip Score and EQ5D-3L questionnaires. The forms sent to patients are attached as Appendix B. Patients were randomly selected from those with NJR consent and tracing information, and who were known to be alive with the index procedure unrevised.

Oxford Hip Scores were calculated by adding the scores from the 12 questions and subtracting the total from 60. This gives a score range of 0 to 48, where 0 is worst and 48 is best.

EQ5D scores were calculated using the time trade-off (TTO) valuation technique with the value set for the UK. This is the same technique as used with the NHS national PROMs. This gives a range -0.59 to 1.00, where 1 corresponds to 'Best imaginable health state' and -0.59 corresponds to 'Worst imaginable health state'. Negative numbers correspond to a self-assessed health state worse than being dead.

For the purpose of analysis, results were grouped by time from the index procedure to completion of the PROMs forms, as follows:

- o Early (<5yrs post op)
- o Midterm (≥5yrs – <8yrs Post Op)
- o Long-term (≥8yrs Post Op)

Procedures were also grouped by articulation type, which was calculated from the composition of the articulating components (femoral heads and monoblock cup / modular liner). Where one or more articulating component was not recorded in the NJR record, the articulation was marked as unknown.

The PROMs data only included 2 revision cases, out of a total of only 4 traceable revision cases in the NJR in which a Profemur Z stem was used. The analysis was therefore restricted to primary cases only. In one case, multiple femoral stem components were found in the NJR record. This case was excluded. There were 3 cases of simultaneous bilaterals with Profemur stems. In those cases the PROMs score and articulation details for the right hip were used. Totals and a breakdown by bearing are as follows:

Surveys issued	317
Responses by 3 October 2018	199
Primary cases using Profemur Z	196

Primary Bearing	Responses	OHS Complete	EQ5D Complete	EQ VAS Complete
Ceramic on Ceramic	140	121	125	123
Ceramic on Polyethylene	7	4	4	4
Metal on Metal	27	18	22	22
Metal on Polyethylene	14	13	13	13
Unknown	8	6	6	6
Total	196	162	170	168

Analyses were conducted for all bearings grouped together, and for all bearings except metal on metal.

PROMs responses also were compared with the corresponding measures for primary hips taken from the NHS PROMs programme.

Oxford Hip Score

Group	Responses	Complete Scores	Time post-operation (years)			Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
			Mean	Min	Max				
All Profemur Z	196	162	7.02	0.42	12.78	39.75	9.86	38.10	41.15
Early (< 5 yrs)	28	23	2.86	0.42	4.73	41.65	8.59	37.39	44.48
Midterm (5 - 8 yrs)	100	85	6.64	5.03	7.99	39.89	9.70	37.59	41.73
Long-term (> 8 yrs)	68	54	9.39	8.02	12.78	38.70	10.61	35.46	41.17
NJR Primary Hips	NA	252093	0.60	0.44	1.18	39.22	8.88	39.18	39.25

Oxford Hip Score (excluding MoM)

Group	Responses	Complete Scores	Time post-operation (years)			Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
			Mean	Min	Max				
All Profemur Z (excl. MoM)	169	144	6.63	0.42	12.78	40.02	9.71	38.30	41.46
Early (< 5 yrs)	28	23	2.86	0.42	4.73	41.65	8.59	37.43	44.52
Midterm (5 - 8 yrs)	100	85	6.64	5.03	7.99	39.89	9.70	37.56	41.73
Long-term (> 8 yrs)	41	36	9.03	8.02	12.78	39.28	10.53	35.06	42.08
NJR Primary Hips (excl. MoM)	NA	247215	0.60	0.44	1.18	39.19	8.88	39.16	39.23

Oxford Hip scores lie in the range of 0 to 48, where 0 is worst and 48 is best.

95% confidence intervals for the mean Oxford Hip Score for the Profemur Z were calculated using the bias-corrected and accelerated (BCa) bootstrap interval.

The maximum and minimum post-operative times for the "All NJR PROMs" scores were taken as the 0.5% and 99.5% quantiles, to eliminate data-entry outliers.

EQ5D Score

Group	Responses	Complete Scores	Time post-operation (years)			Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
			Mean	Min	Max				
All Profemur Z	196	170	7.05	0.42	12.78	0.806	0.238	0.767	0.839
Early (< 5 yrs)	28	25	2.87	0.42	4.73	0.893	0.145	0.829	0.942
Midterm (5 - 8 yrs)	100	88	6.64	5.03	7.99	0.824	0.233	0.766	0.865
Long-term (> 8 yrs)	68	57	9.50	8.02	12.78	0.740	0.262	0.665	0.802
NJR Primary Hips	NA	241927	0.60	0.44	1.18	0.789	0.245	0.788	0.789

EQ5D Score (excluding MoM)

Group	Responses	Complete Scores	Time post-operation (years)			Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
			Mean	Min	Max				
All Profemur Z (excl. MoM)	169	148	6.57	0.42	12.78	0.827	0.217	0.788	0.859
Early (< 5 yrs)	28	25	2.87	0.42	4.73	0.893	0.145	0.829	0.942
Midterm (5 - 8 yrs)	100	88	6.64	5.03	7.99	0.824	0.233	0.766	0.865
Long-term (> 8 yrs)	41	35	9.06	8.02	12.78	0.789	0.212	0.713	0.852
NJR Primary Hips (excl. MoM)	NA	237238	0.60	0.44	1.18	0.788	0.245	0.787	0.789

EQ5D-3L scores lie in the range -0.59 to 1.00, where 1 corresponds to ‘Best imaginable health state’ and -0.59 corresponds to ‘Worst imaginable health state’.

95% confidence intervals for the mean EQ5D Score for the Profemur Z were calculated using the bias-corrected and accelerated (BCa) bootstrap interval.

The maximum and minimum post-operative times for the "All NJR PROMs" scores were taken as the 0.5% and 99.5% quantiles, to eliminate data-entry outliers.

EQ VAS

Group	Responses	Complete Scores	Time post-operation (years)			Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
			Mean	Min	Max				
All Profemur Z	196	168	7.04	0.42	12.78	75.2	20.6	71.9	78.1
Early (< 5 yrs)	28	25	2.87	0.42	4.73	83.9	13.6	77.6	88.3
Midterm (5 - 8 yrs)	100	86	6.64	5.03	7.99	76.2	21.1	71.0	80.1
Long-term (> 8 yrs)	68	57	9.49	8.02	12.78	70.0	21.0	64.2	75.0
NJR Primary Hips	NA	240621	0.60	0.44	1.18	76.6	18.1	76.5	76.6

EQ VAS (excluding MoM)

Group	Responses	Complete Scores	Time post-operation (years)			Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
			Mean	Min	Max				
All Profemur Z (excl. MoM)	169	146	6.56	0.42	12.78	75.9	20.9	72.2	79.0
Early (< 5 yrs)	28	25	2.87	0.42	4.73	83.9	13.6	77.6	88.3
Midterm (5 - 8 yrs)	100	86	6.64	5.03	7.99	76.2	21.1	71.1	80.1
Long-term (> 8 yrs)	41	35	9.03	8.02	12.78	69.5	23.0	61.4	76.4
NJR Primary Hips (excl. MoM)	NA	235918	0.60	0.44	1.18	76.5	18.1	76.5	76.6

EQ-VAS scores lie in the range 0 to 100, where patients are asked to mark how good or bad their health is today on a visual scale, with "the best state you can imagine" corresponding to 100 and "the worst state you can imagine" corresponding to 0.

95% confidence intervals for the mean EQ VAS Score for the Profemur Z were calculated using the bias-corrected and accelerated (BCa) bootstrap interval.

The maximum and minimum post-operative times for the "All NJR PROMs" scores were taken as the 0.5% and 99.5% quantiles, to eliminate data-entry outliers.

Disclaimer

Disclaimer

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
PHA00232	PROFEMUR® Z FEMORAL STEM SIZE 1 CEMENTLESS	19
PHA00234	PROFEMUR® Z FEMORAL STEM SIZE 2 CEMENTLESS	25
PHA00236	PROFEMUR® Z FEMORAL STEM SIZE 3 CEMENTLESS	94
PHA00238	PROFEMUR® Z FEMORAL STEM SIZE 4 CEMENTLESS	110
PHA00240	PROFEMUR® Z FEMORAL STEM SIZE 5 CEMENTLESS	75
PHA00242	PROFEMUR® Z FEMORAL STEM SIZE 6 CEMENTLESS	45
PHA00244	PROFEMUR® Z FEMORAL STEM SIZE 7 CEMENTLESS	14
PHA00246	PROFEMUR® Z FEMORAL STEM SIZE 8 CEMENTLESS	1

Appendix B

Questionnaires



Unique Ref No:

Patient Name

Address 1

Address 2

Address 3

Town

County

Postcode

Dear {Patient Name}

‘After Your Operation’ Questionnaire

A number of years ago you had a hip replacement operation and we are interested to know how you have been doing after your surgery and would be grateful if you could complete the questionnaire that is enclosed with this letter.

What is this questionnaire for?

The purpose of collecting information in this questionnaire is to find out about your experience after surgery. The information that you provide will help us understand the factors that influence how well people do after their operation.

Implant manufacturers are also required to monitor the performance of their implants and by collecting this type of data, they are able to improve the information that they have available to undertake that monitoring. We are sending this questionnaire to you at the request of Microport Orthopaedics, Inc who manufactured the implant that you have had fitted. There is no need to be alarmed by this request: the manufacturer simply wants more complete information about how its implants are performing, and regards the patient’s assessment of the outcome of their hip replacement operation as essential information.

Do I have to take part?

Your help would be greatly appreciated, but it is not compulsory. If you do not want to take part in the survey, or to answer some of the questions, you do not need to give a reason. Your decision not to take part in this survey or not to answer some of the questions in the survey will not have any negative impact on your further medical care or the relationship with your doctor.

What do I have to do?

If you decide to take part, please complete the questionnaire and return it in the envelope provided. No stamp is needed. The questionnaire should take around 10 minutes to complete.

If you do not wish to take part, please promptly return the blank questionnaire in the postage paid envelope. Otherwise an automatic reminder will be sent to you in 2 or 3 weeks’ time.

How is the data stored?

More details about how data will be processed and stored securely are available from the NJR Website at www.njrcentre.org.uk or from the NJR Helpline.

Can I change my mind after I have returned the questionnaire?

Yes, up to the point where the data is analysed and personal details removed. Withdrawing your information will not affect your medical or legal rights in any way. You can do so by contacting the NJR Helpline on: 0845 345 9991

How will my taking part be kept confidential?

Your personal details will be held confidentially in accordance with the Data Protection Act and the General Data Protection Regulation (GDPR). Your personal details will only be used for the purpose of helping Microport Orthopaedics Inc, gather information from patients about the outcomes of hip replacement surgery where its products have been used.

Whilst your responses to the questions will be passed to Microport Orthopaedics Inc, your personal information (such as name, address, and contact details) will not be passed to them. They will not be able to contact you directly. Additionally, any published reports will not contain any personal details of any individual patient and without disclosing your identity. Your information will be kept confidential and protected from unauthorised access. The handling and storage of personal information will be undertaken to the very highest standards and more details about how data is processed and stored securely are available from the NJR Website at www.njrcentre.org.uk or from the NJR Helpline.

Contact for further information

If you would like more information about the questionnaire, or how to complete it, you can call the NJR Helpline on 0845 345 9991, and the survey team will do their best to help. The line is open between 9am and 5pm, Monday to Friday and there is an answer-phone at all other times where you can leave a message.

Thank you for your help.

Hip Surgery Questionnaire

After your operation

A number of years ago you had a Hip Replacement Operation. You may remember that you were asked to complete two follow up questionnaires: one about six months after the operation and the other about one year after your operation. We are still very interested to know how you have been doing after your surgery and would be grateful if you could now fill in this additional questionnaire and return it using the provided pre-paid envelope. Thank you for your help.

Prior to completing the questionnaire, please complete the following:

Today's Date

--	--

D D

--	--

M M

2	0		
---	---	--	--

Y Y Y Y

On which side of your body is the affected hip **for which you are receiving treatment?**

Left

Right

Both

If you said 'Both' please complete the first questionnaire thinking about the right side. A second questionnaire, for the left side, will follow.

We are interested in the hip on which you had surgery.

Please mark the boxes below with a tick or numbers where appropriate. If you are unsure about how to answer a question, please give the best answer you can.

Tick (✓) one box for every question.

Q1. During the past 4 weeks...

How would you describe the pain you usually had from your hip?

None Very mild Mild Moderate Severe
₁ ₂ ₃ ₄ ₅

Q2. During the past 4 weeks...

Have you had any trouble with washing and drying yourself (all over) because of your hip?

No trouble Very little Moderate Extreme Impossible
at all trouble trouble difficulty to do so
₁ ₂ ₃ ₄ ₅

Q3. During the past 4 weeks...

Have you had any trouble getting in and out of a car or using public transport because of your hip? (whichever you tend to use)

No trouble Very little Moderate Extreme Impossible
at all trouble trouble difficulty to do so
₁ ₂ ₃ ₄ ₅

Q4. During the past 4 weeks...

Have you been able to put on a pair of socks, stockings or tights?

Yes, easily With little With moderate With extreme No,
₁ difficulty difficulty difficulty impossible
₂ ₃ ₄ ₅

Q5. During the past 4 weeks...
Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Q6. During the past 4 weeks...
For how long have you been able to walk before pain from your hip becomes severe? (with or without a stick)

No pain/More than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all – pain severe on walking
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Q7. During the past 4 weeks...
Have you been able to climb a flight of stairs?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Q8. During the past 4 weeks...

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Q9. During the past 4 weeks...
Have you been limping when walking, because of your hip?

Rarely/ Never	Sometimes or just at first	Often, not just at first	Most of the time	All of the time
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Q10. During the past 4 weeks...

Have you had any sudden, severe pain – ‘shooting’, ‘stabbing’, or ‘spasms’ – from the affected hip?

No days	Only 1 or 2 days	Some days	Most days	Every day
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Q11. During the past 4 weeks...

How much has pain from your hip interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Q12. During the past 4 weeks...

Have you been troubled by pain from your hip in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

By placing a tick in one box in each group (Questions 13-17) below, please indicate which statements best describe your own health state today.

Q13. Mobility

- I have no problems in walking about ₁
- I have some problems in walking about ₂
- I am confined to bed ₃

Q14. Self-Care

- I have no problems with self-care ₁
- I have some problems with self-care ₂
- I am unable to wash or dress myself ₃

Q15. Usual Activities

(e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities ₁
- I have some problems with performing my usual activities ₂
- I am unable to perform my usual activities ₃

Q16. Pain/Discomfort

- I have no pain or discomfort ₁
- I have moderate pain or discomfort ₂
- I have extreme pain or discomfort ₃

Q17. Anxiety/Depression

- I am not anxious or depressed ₁
- I am moderately anxious or depressed ₂
- I am extremely anxious or depressed ₃

Q18. To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicated how good or bad your health state is today.

**Your own
health state
today**

Best
imaginable
health state



Worst
imaginable
health state

Contact us for further details:

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