

ANALYSIS OF COLLARED AND COLLARLESS TOTAL HIP REPLACEMENT USING THE CORAIL® FEMORAL COMPONENT IN THE NATIONAL JOINT REGISTRY FOR ENGLAND, WALES, NORTHERN IRELAND AND THE ISLE OF MAN

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Introduction

National joint registries provide valuable information on the revision rates and survivorship of orthopaedic implants. Typically they include large cohorts with data from all surgeons and from all centres, irrespective of surgeon experience level. The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) has been in operation since 2003 and in that time has collected data on over 708,000 primary total hip replacements (THR).¹

The standard CORAIL® femoral stem is available both with and without a collar. Proponents of the use of a collared prosthesis claim that it provides advantages in the early stability of the implant, allowing for earlier post-operative weight bearing, protection against subsidence, and a positive dispersion of the vertical forces via the collar into the medial calcar.²⁻³

The purpose of this analysis is to examine the results of the collared and collarless versions of the standard offset CORAIL uncemented femoral stem. Analysis was conducted by a DePuy Synthes biostatistician on data made available from the NJR Supplier Feedback system, downloaded on 14th May 2015.⁴ The details of the cohorts can be found in Table 1.

Results

In total the dataset records 37,351 CORAIL STD collared stem implantations and 46,865 CORAIL STD collarless stem implantations.⁴ All usage was in primary THR and the analysis excludes the use of metal liners. An unadjusted Kaplan-Meier survival analysis was undertaken with an end point of revision of any component for any cause and the annual estimates are provided in Figure 1 and Table 2 with results truncated when fewer than 40 implants remained at risk.⁵ The 10 year

cumulative revision rate estimate for the CORAIL STD collared cohort is 3.13% (95% CI 2.16, 4.53%), and for CORAIL STD collarless is 4.13% (3.63, 4.69%). The closest class comparison from the UK NJR is uncemented THR with a Metal-on-Poly bearing. The 10 year cumulative revision rate estimate for this class is 4.40% (95% CI 4.09, 4.72%).⁶ Based on analysis of the point estimates and confidence intervals both the CORAIL STD collarless and collared have similar 10 year cumulative revision rates and are performing in line with the class.

The risk of revision has been compared and, after controlling for age and gender, the CORAIL STD collared stem demonstrates a lower risk of revision within the first year post-op (HR=0.154, p<0.0001), and then the CORAIL STD collarless has a lower risk of revision from one year post-op

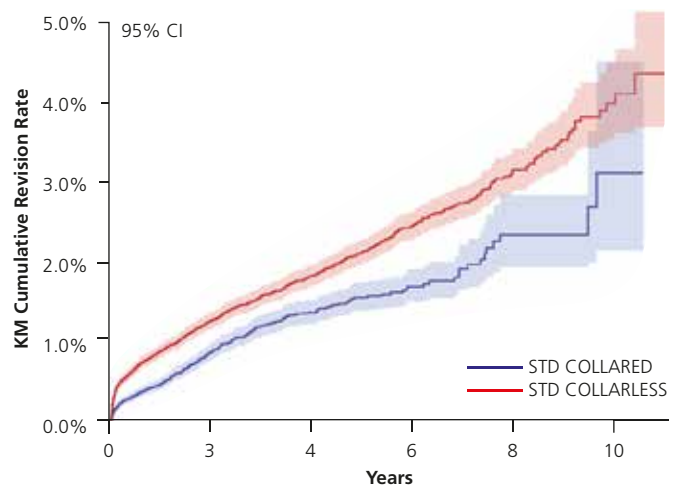


Figure 1. CORAIL STD Primary THR: Cumulative Revision Rate Estimates split by use of a collar. (2015 NJR)

Group	N	Males	Females	Age - Mean and Range
STD Collared	37351	12588	24762	67.89 (11 - 101)
STD Collarless	46865	16647	30218	65.61 (14 - 98)

Table 1. CORAIL STD Primary THR: Cohort demographics split by use of a collar. (2015 NJR)

Group	1 yr	3 yrs	5 yrs	7 yrs	10 yrs
CORAIL STD Collared N=37351	0.49% (0.42, 0.56%) n=29772	1.21% (1.08, 1.35%) n=16005	1.57% (1.41, 1.76%) n=6100	1.93% (1.66, 2.23%) n=1782	3.13% (2.16, 4.53%) n=154
CORAIL STD Collarless N=46865	0.90% (0.81, 0.99%) n=41496	1.59% (1.48, 1.72%) n=29841	2.15% (2.00, 2.31%) n=17399	2.77% (2.57, 2.98%) n=7698	4.13% (3.63, 4.69%) n=775

Table 2. CORAIL STD Primary THR: Cumulative Revision Rate Estimates split by use of a collar. (2015 NJR)

onwards (HR=0.208, p<0.0001). In order to understand these differences further, the reasons for revision have been examined. The NJR database allows for multiple reasons for revision to be entered and these are provided in Table 3. There appears to be a difference in the incidence rates between CORAIL STD collarless and collared for revisions attributed to peri-prosthetic fracture. This reason is cited for 6.5% of the collared revisions, and 16.3% of the collarless. It is possible that this difference is the result of minor undiagnosed intra-operative femoral cracks. The calcar mill instrument can be used to prepare the resected femur prior to stem insertion. This surgical step is recommended when using a collared stem, and would potentially increase the likelihood of noticing minor femoral cracks. Additionally, if a minor crack were to occur during femoral preparation and go untreated by the surgeon, a collared stem may potentially provide some protection against the crack progressing to a full fracture in the early post-operative period prior to bone on-growth.

Summary

The National Joint Registry results detailed for the CORAIL STD collarless and collared femoral stems demonstrate low cumulative revision rates out to 10 years that compares favourably to the class of uncemented THR using a Metal-on-Poly bearing. The overall risk of revision for the CORAIL STD collared is lower in the first year, and then higher between 1 and 10 years. At ten years both femoral stem designs demonstrate a cumulative revision rate of lower than 5%, which is in line with the NICE guidance issued in 2014, and there is no statistical difference in cumulative revision rates between the two designs.

Reason	Collared		Collarless	
	N	% of revisions	N	% of revisions
Adverse Soft Tissue Reaction to Particulate Debris	8	2.0	30	3.3
Aseptic Loosening – Socket	37	9.3	66	7.2
Aseptic Loosening – Stem	67	16.8	169	18.3
Dislocation/Subluxation	95	23.9	198	21.5
Dissociation of Liner	11	2.8	27	2.9
Head/Socket Mismatch – Head	1	0.3	8	0.9
Head/Socket Mismatch – Socket	3	0.8	3	0.3
Head/Socket Mismatch MDS2	1	0.3	1	0.1
Implant Fracture – Head	3	0.8	4	0.4
Implant Fracture – Socket	23	5.8	34	3.7
Implant Fracture – Stem	3	0.8	12	1.3
Infection	77	19.3	135	14.6
Lysis – Socket	7	1.8	19	2.1
Lysis – Stem	4	1.0	24	2.6
Malalignment – Socket	31	7.8	55	6.0
Malalignment – Stem	17	4.3	36	3.9
Other	46	11.6	88	9.5
Pain	49	12.3	137	14.9
Peri-Prosthetic Fracture – Socket	5	1.3	9	1.0
Peri-Prosthetic Fracture – Stem	26	6.5	150	16.3
Wear of the Acetabular Component	19	4.8	42	4.6

Table 3. CORAIL STD Primary THR: Reasons for Revision split by use of a collar. (2015 NJR)

References

1. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 12th Annual Report, 2015. Table 3.2. Available from: www.njrreports.org.uk
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4. NJR-NJR data from 1st April 2003 - 14th May 2015 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2015. Note: NJR-NJR PMS data do not include Hospital Episode Statistics (HES) data linkage. Revisions may therefore be underreported.
5. Lettin AWF, Ware HS, Morris RW. Survival analysis and Confidence Intervals. An assessment with reference to the Stanmore total knee replacement. *J Bone Joint Surg Br*. 1991;73B(5):729-31.
6. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 12th Annual Report, 2015. Table 3.7. Available from: www.njrreports.org.uk

All analysis was carried out by DePuy Synthes, the NJR do not vouch for the accuracy of the interpretation.

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