

ANALYSIS OF COLLARED AND COLLARLESS TOTAL HIP REPLACEMENT USING THE CORAIL® FEMORAL UNCEMENTED 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 890,000 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 Companies biostatistician on data made available from the NJR Supplier Feedback system, downloaded on 10th August 2017.⁴ The details of the cohorts can be found in Table 1.

Results

In total, the dataset records 58,658 CORAIL STD Collared Stem implantations and 56,462 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

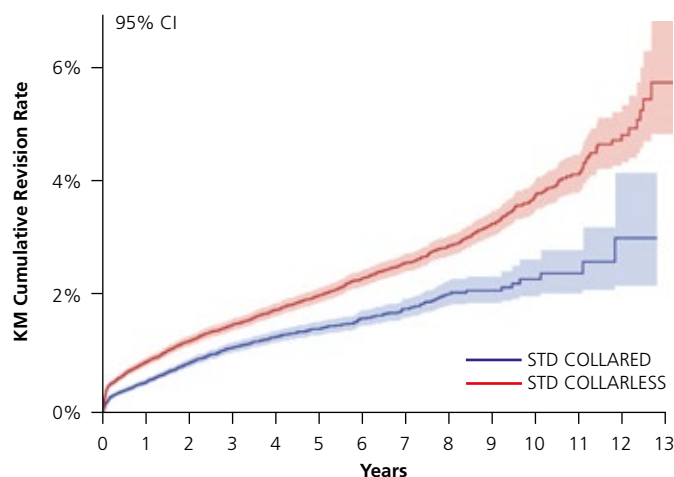


Table 1. CORAIL STD Primary THR: Cumulative Revision Rate Estimates split by use of a collar (2017 NJR).

Group	N	Males	Females	Age - Mean and Range
STD Collared	58,658	19,918	38,740	67.83 (11-101)
STD Collarless	56,462	20,253	36,209	65.45 (14-98)

Table 1. CORAIL STD Primary THR: Cohort demographics split by use of a collar (2017 NJR).

Group	1 yr	3 yrs	5 yrs	10 yrs	12 yrs
CORAIL STD Collared N=58658	0.55% (0.49, 0.62%) n=49129	1.15% (1.06, 1.25%) n=30782	1.47% (1.36, 1.60%) n=16702	2.34% (2.04, 2.68%) n=1020	3.05% (2.22, 4.19%) n=167
CORAIL STD Collarless N=56462	0.90% (0.82, 0.98%) n=52014	1.55% (1.45, 1.66%) n=41712	2.06% (1.93, 2.19%) n=30107	3.83% (3.56, 4.12%) n=4637	4.84% (4.36, 5.36%) n=969

Table 2. CORAIL STD Primary THR: Cumulative Revision Rate Estimates split by use of a collar (2017 NJR) (95% CI), n with Later Follow-up.

The 10 year cumulative revision rate (CRR) estimate for the CORAIL STD Collared Stem cohort is 2.34% (95% CI 2.04, 2.68%), and for CORAIL STD Collarless Stem is 3.83% (3.56, 4.12%). 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 4.18% (95% CI 3.97, 4.39%).⁶ Based on analysis of the point estimates and confidence intervals, the 10 year CRR of the CORAIL STD Collared appears to be lower than the class rate, while the 10 year CRR of the CORAIL STD Collarless appears to be equivalent to the class.

The risk of revision has been compared, and, after controlling for age, gender, head size and bearing, the CORAIL STD Collared Stem demonstrates a statistically significant lower risk of revision than the CORAIL STD Collarless stem (HR=1.368, p=<0.0001). In order to understand this difference 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 stems for revisions attributed to peri-prosthetic fracture. This reason is cited for 7.5% of the collared revisions, and 17.2% 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.

Reason	Collared		Collarless	
	N	% of revisions	N	% of revisions
Adverse Soft Tissue Reaction to Particulate Debris	17	2.5	36	2.8
Aseptic Loosening – Socket	60	8.7	84	6.5
Aseptic Loosening – Stem	117	16.9	268	20.8
Dislocation/Subluxation	171	24.7	252	19.6
Dissociation of Liner	25	3.6	44	3.4
Head/Socket Mismatch – Head	2	0.3	9	0.7
Head/Socket Mismatch – Socket	3	0.4	5	0.4
Head/Socket Mismatch MDS2	1	0.1	1	0.1
Implant Fracture – Head	3	0.4	4	0.3
Implant Fracture – Socket	27	3.9	50	3.9
Implant Fracture – Stem	7	1.0	15	1.2
Infection	131	18.9	184	14.3
Lysis – Socket	12	1.7	25	1.9
Lysis – Stem	9	1.3	36	2.8
Malalignment – Socket	51	7.4	71	5.5
Malalignment – Stem	31	4.5	48	3.7
Other	59	8.5	119	9.2
Pain	67	9.7	154	12.0
Peri-Prosthetic Fracture – Socket	8	1.2	15	1.2
Peri-Prosthetic Fracture – Stem	52	7.5	221	17.2
Wear of the Acetabular Component	40	5.8	64	5.0

Table 3. CORAIL STD Primary THR: Reasons for Revision split by use of a collar (2017 NJR).

Summary

The National Joint Registry results detailed for the CORAIL STD Collarless and Collared Femoral Stems demonstrate low cumulative revision rates out to 12 years that compare favorably to the class of uncemented THR using a Metal-on-Poly bearing.

The overall risk of revision for the CORAIL STD Collared Stem is lower, with a CORAIL STD Collarless stem 37% more likely to be revised ($p < 0.0001$). 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.

References

1. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 14th Annual Report, 2017. Table 3.3. Available from: www.njrreports.org.uk
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3. Does a Collar Improve the Immediate Stability of Uncemented Femoral Hip Stems in Total Hip Arthroplasty? A Bilateral Comparative Cadaver Study. Demey G, Fary C, Lustig S, Neyret P, Ait si Selmi T. *J Arthroplasty* 26 (2011), No.8, p. 1549
4. NJR-NJR data from 1st April 2003-10th August 2017 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2017. Note: NJR-NJR PMS data do not include Hospital Episode Statistics (HES) data linkage. Revisions may therefore be underreported.
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6. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 14th Annual Report, 2017. Table 3.6. Available from: www.njrreports.org.uk

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