

ANALYSIS OF TOTAL HIP REPLACEMENT USING THE C-STEM® AMT FEMORAL COMPONENT IN THE NATIONAL JOINT REGISTRY FOR ENGLAND, WALES, NORTHERN IRELAND AND THE ISLE OF MAN

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National joint registries provide valuable and generalizable information on the revision rates / survivorship of newer and older implants alike. Typically they include large cohorts with contributions from all surgeons, irrespective of 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.¹

C-STEM® AMT is a triple tapered, polished cemented stem that can be used with both metal and ceramic heads. C-STEM AMT can be used in a fully cemented total hip replacement (THR) with a range of all polyethylene cemented cups. It can also be used in hybrid THR and is compatible with the PINNACLE® Cup System which comprises a cementless modular shell and offers a range of bearing articulations including metal-on-polyethylene, ceramic-on-ceramic and ceramic-on-polyethylene.

The NJR 14th Annual report details the combination of the C-STEM AMT stem with a non-cross-linked all-poly cemented cup (ELITE PLUS™ OGEE Cemented Cup). The cumulative revision rate (CRR) at 10 years for this combination is 1.73% (95% CI 1.14, 2.64).² This compares favourably with the cumulative revision rate for the class of cemented THR at 10 years, which is reported to be 3.05% (95% CI 2.95, 3.14).³ The statistical significance of this comparison was not assessed in the annual report, but given that the confidence intervals do not overlap, this difference may be statistically significant.

In addition to the published NJR reports, data is also made available for post-marketing surveillance from the NJR Supplier Feedback system.

The purpose of this analysis is to examine the cumulative revision rate estimates of the C-STEM AMT cemented stem in the various configurations described above.

A dataset was downloaded by DePuy Synthes on 10th April 2018. This comprises detailed data on all C-STEM AMT implantations included on the registry.

Results

In total the dataset records 28,997 cases in which a C-STEM AMT stem had been used (excluding combination with a resurfacing cup or metal liner). The mean age of this cohort was 73.13 years (range 18-102) and there were 19,035 (66%) females and 9,962 (34%) males. In 90% of cases osteoarthritis was listed as at least one of the primary diagnoses. In 57% of cases the intervention was a fully cemented THR.⁴

The follow-up for the cohort extends to 12 years and the patient time incidence rate (PTIR) is 0.31 (95% CI 0.27, 0.34) revisions per 100 observed component years. A Kaplan-Meier analysis was undertaken to estimate the cumulative revision rate with an end point of revision of any component for any cause and the annual cumulative revision rate estimates are provided in Table 1.⁵

Time	CRR (95% CI)	Cumulative Revised	Number at Risk
1 Years	0.49 (0.42, 0.58%)	136	23615
2 Years	0.78 (0.67, 0.89%)	196	18572
3 Years	1.06 (0.93, 1.21%)	242	13942
4 Years	1.25 (1.10, 1.42%)	265	10116
5 Years	1.41 (1.24, 1.60%)	279	7351
6 Years	1.53 (1.35, 1.75%)	287	5426
7 Years	1.88 (1.63, 2.15%)	303	3751
8 Years	2.09 (1.81, 2.41%)	310	2636
9 Years	2.18 (1.88, 2.54%)	312	1863
10 Years	2.42 (2.05, 2.85%)	316	1179
11 Years	2.51 (2.11, 3.00%)	317	494
12 Years	2.51 (2.11, 3.00%)	317	76

Table 1: C-STEM AMT Primary THR: Cumulative Revision Rate Estimates. (2018 NJR)

Group	N	Revised	Revisions/100 Obs. Years	Cumulative Revision Rate	Closest Comparative Class ³	
					Rate	Description
ALL C-STEM AMT	28997	316	0.31 (0.27, 0.34)	10yr – 2.42% (2.05, 2.85%)	10yr - 3.05% (2.95, 3.14%)	All Cemented
C-STEM AMT + ELITE PLUS Cemented Cups	7526	101	0.26 (0.21, 0.31)	10yr – 2.34% (1.85, 2.96%)	10yr - 3.05% (2.95, 3.14%)	All Cemented
C-STEM AMT + MARATHON XLPE Cemented Cups	8496	66	0.30 (0.23, 0.37)	7yr – 1.41% (1.03, 1.93%)	7yr- 2.05% (1.98, 2.11%)	All Cemented
C-STEM AMT + PINNACLE (≠metal liners)	10233	116	0.37 (0.30, 0.43)	10yr – 2.84% (2.04, 3.93%)	10yr - 3.62% (3.46, 3.79%)	All Hybrids
C-STEM AMT + PINNACLE Ceramic on Ceramic	1366	19	0.27 (0.17, 0.41)	10yr – 2.86% (1.66, 4.90%)	10yr - 2.78% (2.47, 3.11%)	Hybrids + (CoC)
C-STEM AMT + PINNACLE Metal on Standard Poly	417	9	0.32 (0.15, 0.55)	10yr – 3.05% (1.49, 6.18%)	10yr - 3.40% (3.20, 3.62%)	Hybrids + (MoP)
With PINNACLE Metal on X-Linked Poly	5176	58	0.40 (0.30, 0.51)	7 yr – 1.92% (1.36, 2.72%)	7yr - 2.29% (2.17, 2.41%)	Hybrids + (MoP)

Table 2: C-STEM AMT Primary THR: Cumulative Revision Rate Estimates and Patient Time Incidence rates by bearing option. (2018 NJR).⁴ Most applicable class rates selected from 2017 NJR.³

Survivorship analysis was also run on the different acetabular options, as detailed in Table 2. These cumulative revision rate estimates have been compared and, after controlling for age and gender, no significant differences were found between C-STEM AMT with either a MARATHON[®] ELITE PLUS or PINNACLE acetabular component ($p = 0.1805$).

Similarly, no significant differences were found between any of the different articulations used within the C-STEM AMT/PINNACLE combination ($p = 0.9958$).

Summary

The National Joint Registry results detailed for the combination of C-STEM AMT with various acetabular cup designs and bearing articulations are generally similar to the class results published by the NJR. Analysis of the estimates and confidence intervals suggests that there are no statistically significant differences.

Conclusion

The C-STEM AMT cemented femoral stem presents a 2.42% (2.05, 2.85%) estimated cumulative revision rate at 10 years on the NJR. This is in line with the 3.05% (2.95, 3.14%) 10 year revision rate detailed for the class of cemented THR,³ despite the fact that in nearly 40% of cases the C-STEM AMT stem was used with a cementless acetabular component. Similar analysis was completed on the range of cup designs and bearing articulations used with C-STEM AMT, and all cumulative revision rate estimates were found to be similar to the relevant class data. C-STEM AMT demonstrates reliable performance regardless of the acetabular design and bearing materials selected.

References

1. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 14th Annual Report, 2017, Table 3.5. Available from: www.njrreports.org.uk
2. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 14th Annual Report, 2017, Table 3.8. Available from: www.njrreports.org.uk
3. 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
4. NJR-NJR data from 1st April 2003 - 10th April 2018 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2017. Note: NJR-NJR Supplier Feedback 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.

The data used for this analysis was obtained from the NJR Supplier Feedback System. All analyses of NJR data were undertaken by DePuy Synthes. The Healthcare Quality Improvement Partnership ('HQIP') and the National Joint Registry ('NJR') take no responsibility for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation.

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