

ANALYSIS OF TOTAL HIP REPLACEMENT USING BI-MENTUM™ DUAL MOBILITY SYSTEM IN THE NATIONAL JOINT REGISTRY OF ENGLAND, WALES, NORTHERN IRELAND AND THE ISLE OF MAN

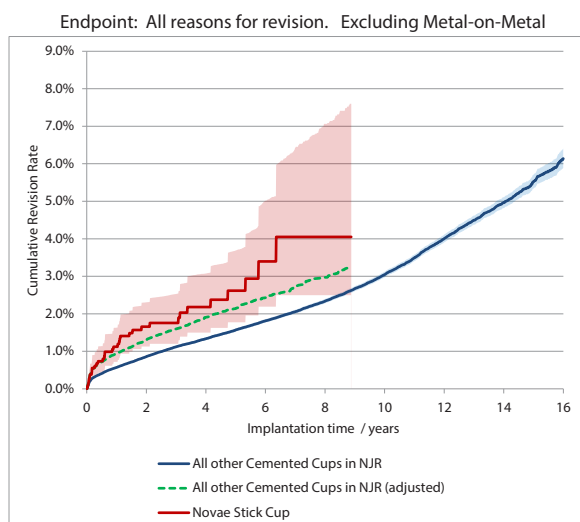
National Joint Registries provide valuable information on the revision rates and survivorship of orthopaedic implants. Typically they include large cohorts with data from all surgeons and from all centres, irrespective of surgeon experience level. The National Joint Registry for England, Wales, Northern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

Following a commercial agreement between DePuy Synthes and SERF, BI-MENTUM™ Dual Mobility System is an updated brand-name for the Novae dual mobility system manufactured by SERF. BI-MENTUM Dual Mobility System is available in both cemented and cementless variants. The NJR has produced a new report analyzing the performance of the cemented Novae system, which, following the re-branding, will be referred to as the cemented BI-MENTUM Dual Mobility System throughout this document.² This analysis was commissioned by DePuy Synthes, but conducted and validated by the NJR. The reports details 1,855 cemented BI-MENTUM Dual Mobility System Implantations. In order to better understand the performance of the cemented BI-MENTUM Dual Mobility System the reports provide comparison to all other Cemented Cups on the NJR (n=420,759).

Demographics		Novae cemented	All other Cemented Cups on the NJR
Mean Age		76.0	73.3
ASA Grade	P1 / P2 / P3 / P4&P5 (%)	3.2 / 46.8 / 44.8 / 5.2	10.8 / 68.1 / 20.3 / 0.8
Indication	Osteoarthritis	46.15%	91.34%
	Rheumatoid Arthritis	2.53%	1.39%
	Avascular Necrosis	6.58%	2.20%
	Fractured Neck of Femur	30.24%	4.27%
	CDH/DDH	1.46%	0.62%
	Other	19.03%	2.14%

Table 1 - Demographics

In comparing to all other Cemented Cups, the BI-MENTUM Dual Mobility System cohort is slightly older, has a higher rate of systemic disease and has a much higher proportion of patients with fracture neck of femur as the primary surgical indication. The cumulative revision rates (CRR) are presented on the chart below and include a hazard ratio and an adjusted KM curve (age, gender, diagnosis and year of implantation). The report also includes PROMs at pre-op and 6 months follow up using the Oxford Hip Score (OHS), EQ-5D and EQ-VAS. All Metal-on-Metal articulations were excluded. All reports can be accessed at <http://www.corailpinnacle.net/supporting-evidence/overview>.



Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	1.84 (1.33 - 2.56)	<0.001
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.29 (0.93 - 1.80)	0.129

Oxford Hip Score (0 - 48)	Novae cemented	All other Cemented Cups in NJR	All THR in NJR
Paired Records	207	102,771	291,079
PreOp score	12.6 (11.5 - 13.7)	17.3 (17.3 - 17.4)	18.0 (18.0 - 18.0)
6 month score	35.0 (33.7 - 36.2)	38.2 (38.2 - 38.3)	39.3 (39.3 - 39.4)
6 month score (adjusted)	39.2 (38.0 - 40.5)	38.8 (38.8 - 38.9)	39.3 (39.3 - 39.4)
Health gain	22.3 (20.9 - 23.8)	20.9 (20.8 - 21.0)	21.3 (21.3 - 21.4)
Health gain (adjusted)	21.2 (20.0 - 22.5)	20.8 (20.8 - 20.9)	21.3 (21.3 - 21.4)
p value (adjusted health gain)	0.25		
Score Improved	96.6%	97.0%	97.2%

EQ-5D Index (-0.59 - 1.00)	Novae cemented	All other Cemented Cups in NJR	All THR in NJR
Paired Records	189	93,796	267,686
PreOp score	0.184 (0.137 - 0.230)	0.331 (0.329 - 0.333)	0.355 (0.354 - 0.356)
6 month score	0.638 (0.595 - 0.680)	0.770 (0.768 - 0.771)	0.792 (0.791 - 0.792)
6 month score (adjusted)	0.728 (0.689 - 0.766)	0.781 (0.779 - 0.782)	0.792 (0.791 - 0.792)
Health gain	0.454 (0.406 - 0.503)	0.438 (0.436 - 0.441)	0.437 (0.435 - 0.438)
Health gain (adjusted)	0.373 (0.334 - 0.411)	0.426 (0.424 - 0.427)	0.437 (0.436 - 0.437)
p value (adjusted health gain)	0.019		
Score Improved	87.8%	88.8%	89.4%

EQ-VAS (0 - 100)	Novae cemented	All other Cemented Cups in NJR	All THR in NJR
Paired Records	185	89,362	256,680
PreOp score	55.1 (51.3 - 58.8)	64.4 (64.2 - 64.5)	65.0 (64.9 - 65.1)
6 month score	66.9 (63.9 - 69.9)	75.2 (75.1 - 75.3)	76.8 (76.7 - 76.9)
6 month score (adjusted)	74.2 (71.3 - 77.0)	76.2 (76.1 - 76.3)	76.8 (76.7 - 76.8)
Health gain	11.8 (7.6 - 16.0)	10.8 (10.7 - 11.0)	11.8 (11.7 - 11.9)
Health gain (adjusted)	9.1 (6.3 - 12.0)	11.2 (11.1 - 11.3)	11.8 (11.7 - 11.8)
p value (adjusted health gain)	0.21		
Score Improved	62.2%	63.6%	65.6%

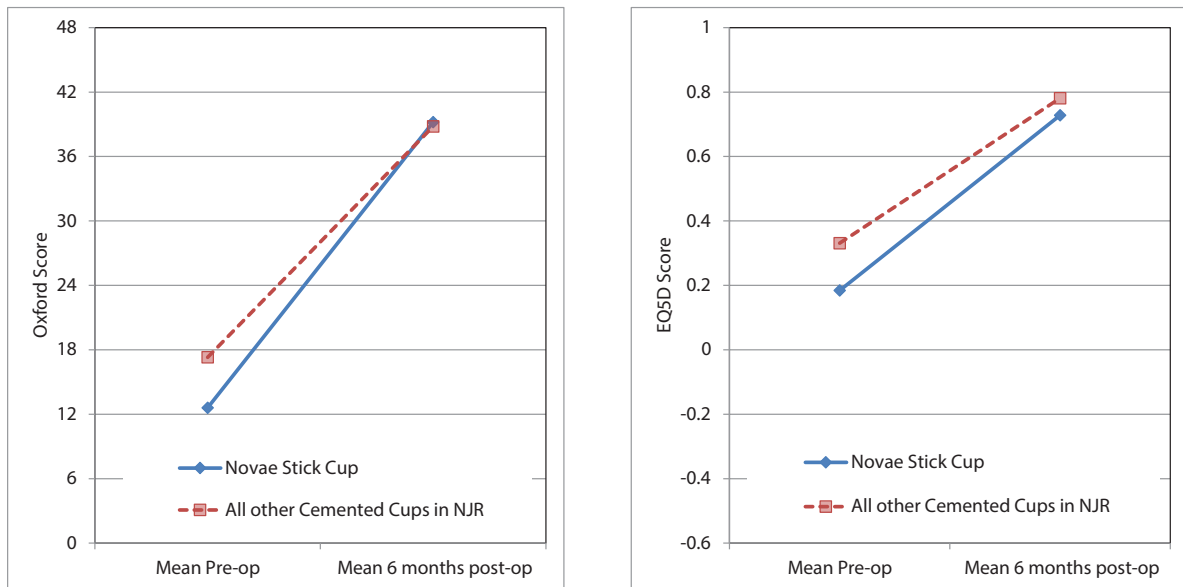


Figure 1 - Pre-op and six months PROMs. NJR 2020²

The cemented BI-MENTUM Dual Mobility System is typically used in a slightly older patient cohort, with a greater proportion of serious systemic disease and for a surgical indication that is known for a poor outcome versus routine elective procedures. The CRR for the cemented BI-MENTUM Dual Mobility System is 2.7% (1.4-5.6%) at 8 years. This appears to be equivalent to the CRR for all other Cemented Cups on the NJR of 1.7% (1.7-1.8%). The adjusted HR is 1.29 (0.93-1.80) $p=0.129$, indicating no statistical difference in risk of revision when compared to all other cemented cups on the NJR. The PROMs for the cemented BI-MENTUM Dual Mobility System show comparable adjusted health gains in the OHS ($p=0.25$), EQ-5D ($p=0.019$) and EQ-VAS ($p=0.21$). The much lower pre-operative baseline values (Figure 1) may suggest the patients receiving the cemented BI-MENTUM Dual Mobility System made greater clinical improvements - although it should be acknowledged that pre-operative scores are not adjusted for patient and surgical factors.

The cemented BI-MENTUM Dual Mobility System

- Is used in a challenging patient population.
- Demonstrates a low revision rate out to 8 years that is equivalent to all other cemented cups on the NJR.
- Shows PROMs scores that improve out to six months and are in line with all other cemented cups on the NJR.

References

1. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 16th Annual Report, 2019. Table 3.3. Available from: www.njrreports.org.uk
2. Bespoke Implant report Novae Cup. NJR. Report can be accessed at <http://www.corailpinnacle.net/resources>

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