

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

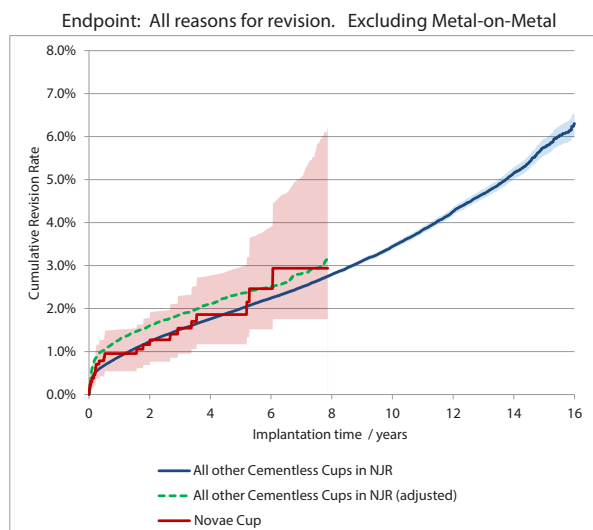
National Joint Registries provide valuable information on the revision rates and survivorship of orthopaedic implants. Typically they include large cohorts with data from all surgeons and from all centres, irrespective of surgeon experience level. The National Joint Registry for England, Wales, Northern 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 the updated brand-name for the existing 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 cementless Novae system, which, following the re-branding, will be referred to as the cementless BI-MENTUM Dual Mobility System throughout this document. This analysis was commissioned by DePuy Synthes, but conducted and validated by the NJR. The reports details 1,311 cementless BI-MENTUM Dual Mobility System Implantations. In order to better understand the performance of the cementless BI-MENTUM Dual Mobility System the reports provide comparison to all other Cementless Cups on the NJR (n=784,688).²

Demographics		Novae cementless	All other Cementless Cups on the NJR
Mean Age		73.8	66.1
ASA Grade	P1 / P2 / P3 / P4&P5 (%)	5.4 / 54.3 / 38.2 / 2.1	18.3 / 67.6 / 13.7 / 0.4
Indication	Osteoarthritis	36.23%	91.87%
	Rheumatoid Arthritis	1.22%	1.28%
	Avascular Necrosis	2.97%	2.64%
	Fractured Neck of Femur	52.63%	2.88%
	CDH/DDH	0.61%	2.09%
	Other	8.01%	1.95%

Table 1 - Demographics²

In comparing to all other Cementless Cups, the BI-MENTUM Dual Mobility System cohort is older, has a greater proportion of serious 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.	1.06 (0.70 - 1.61)	0.783
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.87 (0.57 - 1.33)	0.518

Oxford Hip Score (0 - 48)	Novae Cup	All other Cementless Cups in NJR	All THR in NJR
Paired Records	157	185,310	291,079
PreOp score	12.8 (11.6 - 14.0)	18.4 (18.4 - 18.4)	18.0 (18.0 - 18.0)
6 month score	35.9 (34.4 - 37.5)	40.0 (39.9 - 40.0)	39.3 (39.3 - 39.4)
6 month score (adjusted)	39.4 (37.9 - 40.8)	39.6 (39.6 - 39.7)	39.3 (39.3 - 39.4)
Health gain	23.1 (21.5 - 24.7)	21.6 (21.5 - 21.6)	21.3 (21.3 - 21.4)
Health gain (adjusted)	21.3 (19.9 - 22.8)	21.6 (21.6 - 21.7)	21.3 (21.3 - 21.4)
p value (adjusted health gain)	0.85		
Score Improved	98.1%	97.3%	97.2%

EQ-5D Index (-0.59 - 1.00)	Novae Cup	All other Cementless Cups in NJR	All THR in NJR
Paired Records	143	171,132	267,686
PreOp score	0.190 (0.138 - 0.242)	0.368 (0.367 - 0.370)	0.355 (0.354 - 0.356)
6 month score	0.699 (0.652 - 0.747)	0.804 (0.803 - 0.805)	0.792 (0.791 - 0.792)
6 month score (adjusted)	0.771 (0.727 - 0.814)	0.798 (0.797 - 0.799)	0.792 (0.791 - 0.792)
Health gain	0.509 (0.454 - 0.565)	0.436 (0.434 - 0.437)	0.437 (0.435 - 0.438)
Health gain (adjusted)	0.416 (0.372 - 0.460)	0.443 (0.442 - 0.444)	0.437 (0.436 - 0.437)
p value (adjusted health gain)	0.31		
Score Improved	92.3%	89.8%	89.4%

EQ-VAS (0 - 100)	Novae Cup	All other Cementless Cups in NJR	All THR in NJR
Paired Records	136	164,662	256,680
PreOp score	57.1 (53.1 - 61.1)	65.4 (65.3 - 65.5)	65.0 (64.9 - 65.1)
6 month score	69.0 (65.4 - 72.6)	77.7 (77.6 - 77.8)	76.8 (76.7 - 76.9)
6 month score (adjusted)	74.6 (71.2 - 78.0)	77.1 (77.0 - 77.2)	76.8 (76.7 - 76.8)
Health gain	11.9 (7.4 - 16.4)	12.3 (12.2 - 12.4)	11.8 (11.7 - 11.9)
Health gain (adjusted)	9.6 (6.2 - 13.0)	12.1 (12.0 - 12.2)	11.8 (11.7 - 11.8)
p value (adjusted health gain)	0.31		
Score Improved	65.4%	66.8%	65.6%

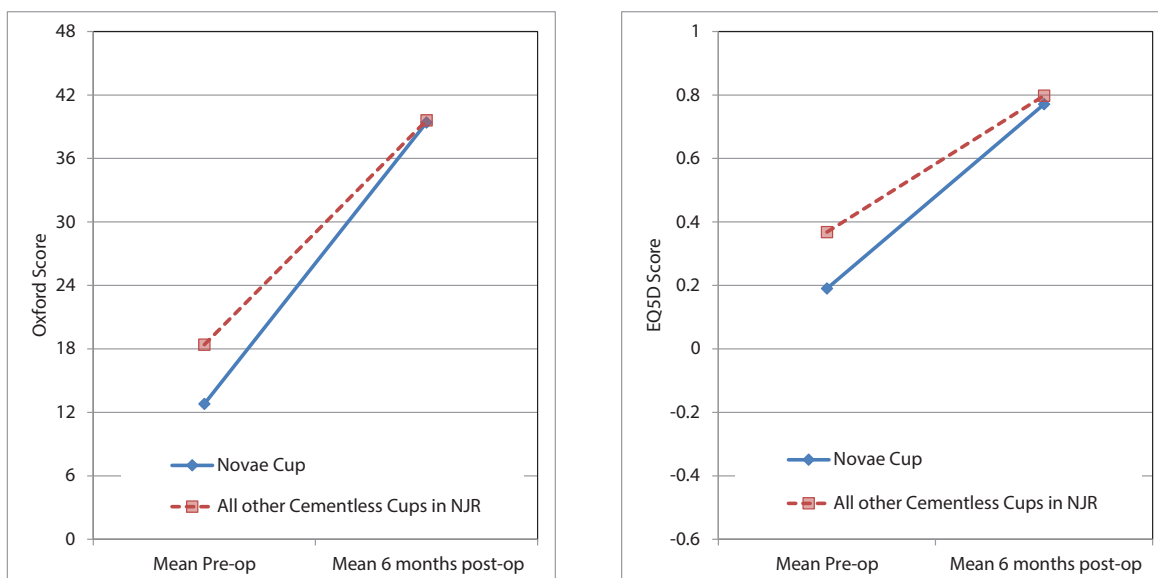


Figure 1 - Pre-op and six months PROMs. NJR 2020²

The cementless BI-MENTUM Dual Mobility System is typically used in an 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 cementless BI-MENTUM Dual Mobility System is 2.9% (1.8, 5.1%) at 7 years. This compares favorably with the CRR for all other Cementless Cups on the NJR of 2.5% (2.5, 2.5%). The adjusted HR is 0.87 (0.57-1.33) $p=0.518$, indicating no statistical difference in risk of revision when compared to all other cementless cups on the NJR. The PROMs for cementless BI-MENTUM Dual Mobility System show comparable adjusted health gains in the OHS ($p=0.85$), EQ-5D ($p=0.31$) and EQ-VAS ($p=0.31$). The much lower pre-operative baseline values (Figure 1) may suggest the patients receiving the cementless 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 cementless BI-MENTUM Dual Mobility System

- Is used in an older and more complex patient population
- Demonstrates a low revision rate out to 7 years that is equivalent to all other cementless cups on the NJR.
- Shows PROMs scores that improve out to six months and are in line with all other cementless 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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Johnson & Johnson Medical Limited PO BOX 1988, Simpson Parkway, Livingston, West Lothian, EH54 0AB, United Kingdom.
Incorporated and registered in Scotland under company number SC132162.

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46582
USA
Tel: +1 (800) 366 8143
Fax: +1 (800) 669 2530

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (0)113 270 0461

DePuy (Ireland)
Loughbeg
Ringaskiddy
Co. Cork
Ireland
Tel: +353 21 4914 000
Fax: +353 21 4914 199

SERF
85 avenue des Bruyères
69150 Décines-Charpieu
FRANCE

www.jnjmedicaldevices.com