

PATIENT REPORTED OUTCOME MEASURES OF THE CORAIL[®]/PINNACLE[®] HIP CONSTRUCT

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INTRODUCTION

The CORAIL[®] Hip System was designed to accommodate a metal or ceramic femoral head, and the PINNACLE[®] Modular Acetabular Cup System was designed to accommodate a polyethylene, or ceramic liner. The combination of a CORAIL Hip System and a PINNACLE Acetabular Cup System together with the various head and liner options comprises a modular system which has been commercially available for 15 years. The modularity of this system provides surgeons with options in primary total hip arthroplasty (THA), which may potentially reduce the need to revise an otherwise well positioned, well-fixed stem or cup in a revision procedure.

The purpose of this clinical brief is to present Patient Reported Outcome Measures (PROMs) from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) for primary THA with the CORAIL/PINNACLE Hip construct and cementless fixation in articulation constructs which are currently available (CoC*, CoP, and MoP).

METHODS

The NJR is a large national joint replacement registry which has been established for the purpose of tracking the outcomes of total joint replacement procedures. Historically, survivorship of the implant was the only outcome tracked by the NJR. However, in recent years PROMs have become increasingly important in the monitoring of an implanted device by measuring the improvement in quality of life. As such, PROMS have been routinely collected by all providers of publically-funded care in England since April 2009. The PROMs questionnaire is administered twice; an initial questionnaire prior to surgery and then again approximately six months following the operation. PROMs collected include the Oxford score for Hips and Knees, the EQ-5D Index and VAS scores, and Success and Satisfaction questions. The Oxford Hip Score¹ is an

established hip focused quality of life score, while the EQ-5D2 is a standardized instrument used to measure general health outcomes, applicable to a wide range of health conditions and treatments. All EQ-5D Index scores are calculated using UK specific coefficients.

The NJR has published class-level PROMs results in their 2013 annual report.³ Additionally, the NJR provides companies with data on their own products,⁴ with which product-level analyses can be conducted. An analysis of NJR CORAIL/PINNACLE Hip construct data was performed by DePuy Synthes and compared with the class-level published results.

Results from the analysis of NJR data include primary THA procedures with the CORAIL/PINNACLE Hip construct and cementless fixation in articulation constructs which are currently available (CoC, CoP, and MoP) for which both the preoperative and 6 month Oxford and EQ-5D scores were completed. Similar search criteria were used for the published class-level results, with details available in the 2013 Annual Report. Median and interquartile ranges (IQR) for continuous scores and frequency counts for categorical questions are presented and compared to all primary hips due to the availability of published summaries for all PROMs.

RESULTS

There were a total of 11,576 CORAIL/PINNACLE Hip constructs for which pre-operative and 6 month PROMs were complete. These were on surgeries done from September 2008 through October 2012. The median pre-operative Oxford hip score was 18, the median 6 month score was 43 with a median improvement of 22 points for CORAIL/PINNACLE Hip constructs. The median pre-operative score was identical to the class of all primary hips, with CORAIL/PINNACLE Hip constructs having a 1 point greater median improvement.⁴

*THE CORAIL TOTAL HIP SYSTEM IS not approved for use with a ceramic-on-ceramic system in the United States.

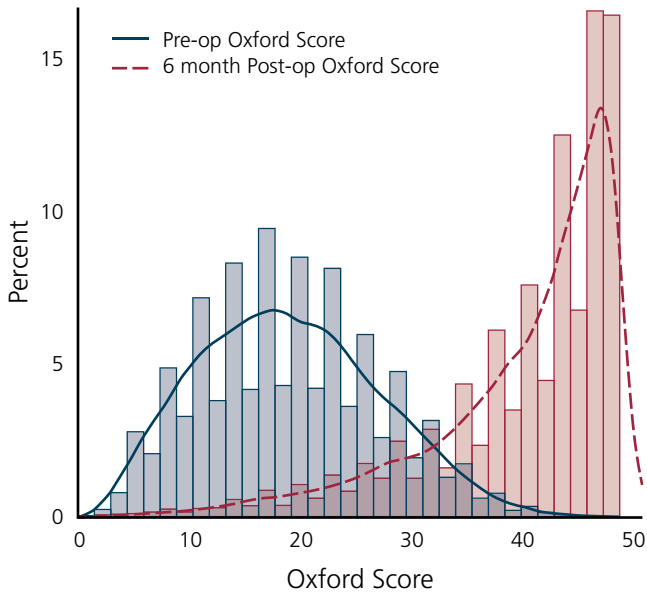


Figure 1. Pre-Op and 6 Month Oxford Hip Scores for CORAIL/PINNACLE subjects

General health improvement, as measured by the EQ-5D Index and VAS scores, was similar for both the CORAIL/PINNACLE Hip construct and All Primary Hips. (Table 1)⁴

The PROMs also include questions regarding the overall success and satisfaction of the operation from the patient’s perspective. Six months following hip replacement 88.6% of CORAIL/PINNACLE Hip construct patients reported that their problems with their hip joint were much better, indicating a very successful procedure. An excellent or very good result of the operation was also reported by 79.1% of CORAIL/PINNACLE Hip construct patients. Success and satisfaction both compare favorably to All Primary Hips. (Table 2; Figures 2 and 3)⁴

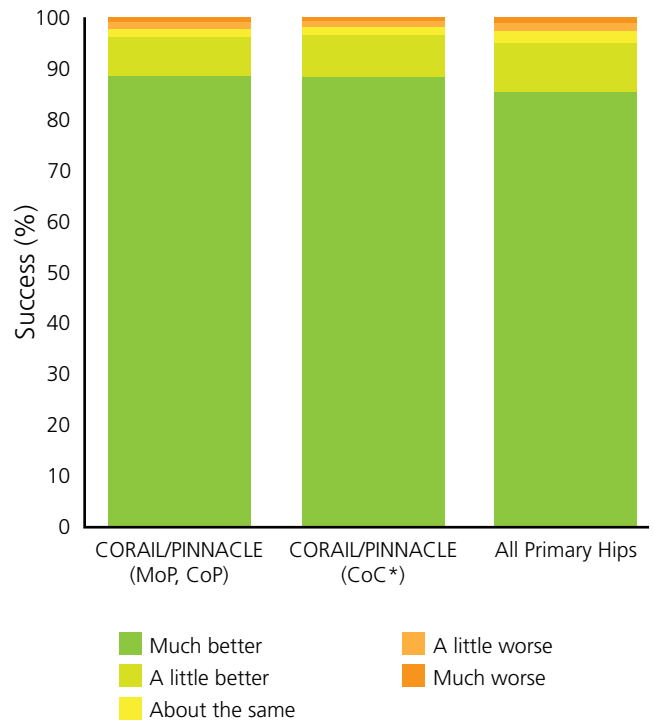


Figure 2. Overall, how are your problems now, compared to before your operation?

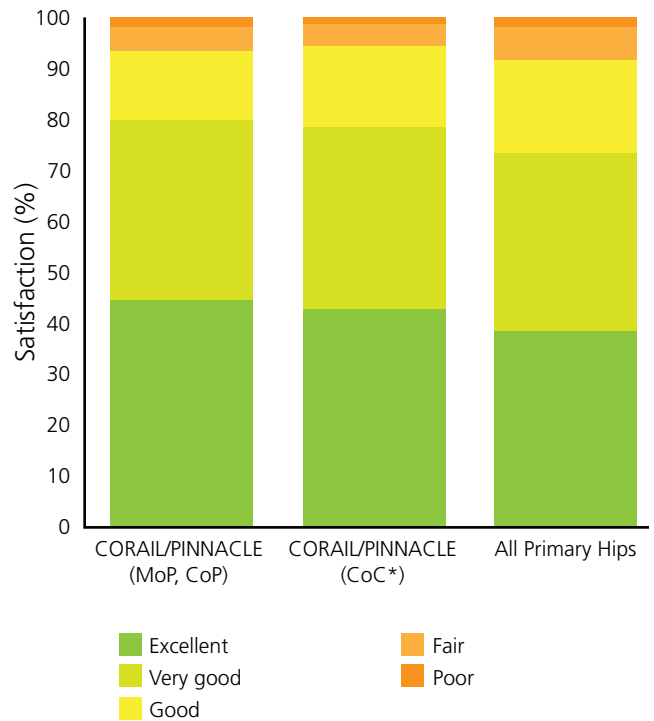


Figure 3. How would you describe the results of your operation?

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Measure (Score Range)	Group	N	Pre-Op	6 Month	Heath Gain	P-value
Oxford Hip (0 – 48)	CORAIL/PINNACLE Hip Construct	11,576	18 (13, 24)	43 (37, 47)	22 (15, 28)	<0.001
	All Primary Hips	92,133	18 (12, 24)	41 (34, 46)	21 (14, 28)	<0.001
EQ-5D Index (-0.59 – 1.00)	CORAIL/PINNACLE Hip Construct	11,576	0.516 (0.055, 0.691)	0.848 (0.691, 1.00)	0.380 (0.193, 0.700)	<0.001
	All Primary Hips	83,202	0.516 (0.055, 0.656)	0.796 (0.691, 1.00)	0.380 (0.175, 0.694)	<0.001
EQ-5D VAS (0 – 100)	CORAIL/PINNACLE Hip Construct	11,576	70 (50, 80)	80 (70, 90)	10 (0, 24)	<0.001
	All Primary Hips	80,394	70 (50, 80)	80 (69, 90)	9 (-2, 20)	<0.001

Table 1. Median (IQR) PROMs for subjects with pre-operative and 6 month scores.

Success (Overall, how are your problems now, compared to before your operation?)	CORAIL/PINNACLE Hip Construct Frequency (%)	All Primary Hips Frequency (%)
Much Better	10,251 (88.6%)	78,617 (85.6%)
Satisfaction (How would you describe the results of your operation?)	CORAIL/PINNACLE Hip Construct Frequency (%)	All Primary Hips Frequency (%)
Excellent	5,061 (43.7%)	35,313 (38.5%)
Very Good	4,102 (35.4%)	32,147 (35.0%)
Good	1,723 (14.9%)	16,826 (18.3%)
Fair	519 (4.5%)	5,739 (6.3%)
Poor	171 (1.5%)	1,735 (1.9%)

Table 2. Success and Satisfaction Distributions

CONCLUSIONS

Based on these data patients are generally happy and satisfied with their CORAIL/PINNACLE Hip Construct. Subjects who received a CORAIL/PINNACLE Hip Construct had a statistically significant median increase of 22 points on the Oxford hip score. Global health, as measured by the EQ-5D, also significantly increased. The 6 month Oxford hip and EQ-5D scores were generally higher than the class of all primary hip replacements in the UK, although not likely to be statistically significant.

Six months after surgery 88.6% of CORAIL/PINNACLE Hip Construct patients self-reported problems with their hip to be much better. This was 3 percentage points higher than all primary hips.

Six months after surgery 79.1% of CORAIL/PINNACLE Hip Construct patients reported excellent or very good levels of satisfaction with their hip replacement compared to 73.5% of all primary hips.⁴

References

1. Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of subjects about total hip replacement. J Bone Joint Surg March 1996; 78-B, No 2: 185-190.
2. The EuroQol Group. EuroQol – a new facility for the measurement of health-related quality of life Health Policy (1990;16(3):199-208).
3. National Joint Registry for England, Wales and Northern Ireland, 10th Annual Report, 2013. Available from www.njrreports.org.uk.
4. NJR-NJR data from 1st April 2003 -10th July 2015 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2015.



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