

ANALYSIS OF TOTAL HIP REPLACEMENT USING THE PINNACLE® GRIPTION™ ACETABULAR SHELL 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 PINNACLE® Acetabular Cup System has been in clinical use since 2001 and initially comprised a cementless modular shell which utilised POROCOAT™ porous coating, also available as a DUOFIX™ shell with a thin layer of hydroxyapatite coating oversprayed on the porous coating. The GRIPTION™ coating was introduced in 2007 and in this design the spherical titanium beads that comprise the POROCOAT porous coating are supplemented with additional multiple coats of irregularly shaped titanium particles, added to provide a high porosity, high friction surface. The intent of this analysis is to examine the data made available via the NJR Supplier Feedback system on the use of the PINNACLE GRIPTION shell in both primary and revision THR and compare to the well-established POROCOAT and DUOFIX variants.

Results

Primary THR

In total the dataset records 9,888 cases in which a PINNACLE GRIPTION shell had been used in primary THR (excluding metal liners). The mean age of this cohort was 65.7 years (range 13-99) and there were 5972 females and 3916 males. In 87% of cases the primary diagnosis was osteoarthritis, with dysplasia (5%) and Avascular Necrosis (4%) the next most prevalent diagnoses. The equivalent data points for POROCOAT and DUOFIX shells are provided in table 1.²

The overall PINNACLE GRIPTION cohort extends to 9,888 cases and the longest follow up is 7.5 years. There have been 136 revisions procedures and this calculates to a crude revision rate of 1.38%. Within the GRIPTION cohort there are 7 revision procedures recorded in which aseptic loosening of the acetabular component was listed as a reason for revision. This calculates to a crude aseptic cup loosening rate of 0.07%. The equivalent rate is 0.1% for POROCOAT (58/60758) and 0.06% for DUOFIX (55/92775).

An unadjusted Kaplan-Meier survival analysis was undertaken with an end point of revision of any component for any cause and the annual cumulative revision rate estimates for all variants are provided in Table 2 and Figure 1.

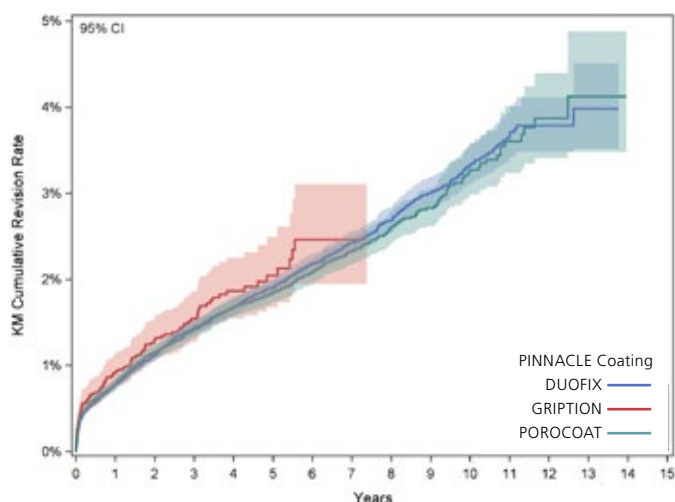


Figure 1. PINNACLE Acetabular Cups Primary THR: Cumulative Revision Rate Estimates split by Fixation Surface. (2018 NJR).²

Group	Cohort	Age (mean and range)	Male	Female	Diagnoses		
					OA	CDH/DDH	AVN
GRIPTION	9888	65.7 (13-99)	39.6%	60.4%	87%	5%	4%
POROCOAT	60758	66.3 (11-117)	42.6%	57.4%	93%	2%	2%
DUOFIX	92775	66.1 (12-99)	43.5%	56.5%	93%	2%	2%

Table 1. PINNACLE Acetabular Cups Primary THR: Demographic Details, Split by Fixation Surface (2018 NJR).²

The 7-year cumulative revision rate estimate for the PINNACLE GRIPTION cohort in primary THR is 2.46% (95% CI 1.95, 3.11). No significant differences were found in the risk of revision between GRIPTION, POROCOAT or DUOFIX coatings, after adjusting for age and gender (p=0.4991). Survival analysis was also run on different head size categories and bearing articulations within the PINNACLE GRIPTION cohort. The risk of revision has been compared and, after controlling for age, gender and articulation, 36mm and greater head sizes had a non-significant different risk of revision in the first 60 days (HR=0.816, p=0.5338) and from 60 days to one year (HR=1.162, 0.6969), but had a significantly higher risk of revision from 1 to 2 years (HR=3.524, p=0.0037). No differences were observed between head sizes after 2 years (HR=0.673, p=0.3809), or between PINNACLE GRIPTION used with Ceramic-on-Ceramic, Metal-on-Poly or Ceramic-on-Poly bearings (p=0.0872). Despite these trends observed by head size, the revision rate estimates for all head sizes and bearings were consistent with NICE guidelines.²

Group	1 Year	3 Years	4 Years	5 Years	7 Years	10 Years
GRIPTION N=9888	0.91% (0.74, 1.13%) n=7475	1.54% (1.28, 1.86%) n=3468	1.86% (1.54, 2.25%) n=2260	2.04% (1.67, 2.49%) n=1272	2.46% (1.95, 3.11%) n=86	N/A
POROCOAT N=60758	0.78% (0.71, 0.86%) n=53290	1.42% (1.32, 1.52%) n=37539	1.67% (1.56, 1.78%) n=30082	1.85% (1.73, 1.98%) n=24029	2.33% (2.17, 2.49%) n=13254	3.27% (2.98, 3.59%) n= 2984
DUOFIX N=92775	0.78% (0.72, 0.84%) n=81744	1.43% (1.35, 1.52%) n=58516	1.68% (1.59, 1.77%) n=48019	1.90% (1.80, 2.01%) n=38440	2.42% (2.29, 2.56%) n=21550	3.33% (3.11, 3.56%) n=5277

Table 2. PINNACLE Acetabular Cups Primary THR: Cumulative Revision Rate Estimates split by Fixation Surface. (2018 NJR) (95% CI), n with Later Follow-up.²

Revision THR

In total the dataset records 3708 cases in which a Pinnacle Gription shell had been used in first revision THR (excluding metal liners). The mean age of this cohort was 69 years (range 16-101) and there were 2013 females and 1695 males. The most prevalent indication for first revision was aseptic loosening of the socket or stem (55%), followed by adverse soft tissue reaction (25%).² From the overall cohort of 3708 cases there have been 220 revisions procedures and this calculates to a crude re-revision rate of 6.01%. An unadjusted Kaplan-Meier survival analysis was undertaken with an end point of revision of any component for any cause and the annual cumulative re-revision rate estimates are provided in Table 3 and Figure 2.

The 5 year cumulative second revision rate estimate for the PINNACLE GRIPTION cohort in first revision THR is 7.55% (95% CI 6.57, 8.67%). In order to provide a valid comparison to a class re-revision rate, the survivorship analysis was also run excluding those cases with infection as the indication for first revision, see table 4. The resultant 5 year cumulative second revision rate estimate is 7.62% (95% CI 6.61, 8.77%).²

The AOANJRR provides cumulative second revision rates for conventional THR (primary diagnosis OA, excluding infection indications) in a supplement to the main 2017 Annual Report.³ The 5 year estimate for major total revision is 11.8% (95% CI 10.0, 14.0%). Based on analysis of the point estimate and confidence intervals, the cumulative percent re-revision rate for PINNACLE GRIPTION compares favorably.

Survivorship analysis was also run on different head size categories and bearing articulations within the PINNACLE GRIPTION cohort used in first revision THR.

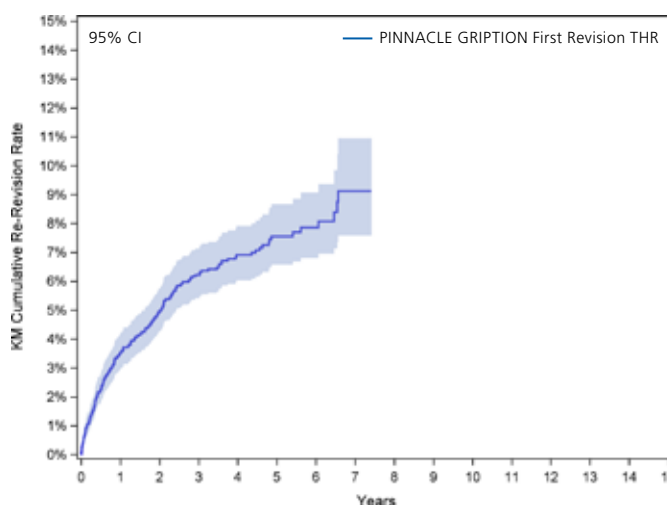


Figure 2. PINNACLE GRIPTION Acetabular Cups: Cumulative Second Revision Rate Estimates for Use in First Revision THR (2018 NJR).²

These survivorship estimates have been compared and, after controlling for age and gender, no significant differences were found between PINNACLE GRIPTION used in first revision THR with head size categories of up to 28mm, 32mm, or 36mm and greater (p=0.3561), or between PINNACLE GRIPTION used in first revision THR with Ceramic-on-Ceramic, Metal-on-Poly or Ceramic-on-Poly bearings (p=0.1235).²

Group	1 Year	2 Years	3 Years	4 Years	5 Years	6 Years	7 Years
GRIPTION (Revision) N=3,708	3.53% (2.96, 4.19%) n=3074	4.95% (4.26, 5.75%) n=2464	6.21% (5.41, 7.13%) n=1867	6.91% (6.03, 7.91%) n=1344	7.55% (6.57, 8.67%) n=816	7.86% (6.80, 9.07%) n=446	9.12% (7.58, 10.95%) n=117
GRIPTION (Revision, excluding infection indications) N=3,475	3.49% (2.91, 4.18%) n=2888	4.97% (4.26, 5.80%) n=2322	6.31% (5.47, 7.27%) n=1765	7.04% (6.12, 8.09%) n=1275	7.62% (6.61, 8.77%) n=774	7.94% (6.85, 9.19%) n=424	9.27% (7.67, 11.18%) n=111

Table 3. PINNACLE GRIPTION Acetabular Cups: Cumulative Revision Rate Estimates for use in First Revision THR (2018 NJR) (95% CI), n with Later Follow-up²

Summary

The National Joint Registry results detailed for the PINNACLE GRIPTION shell demonstrate cumulative revision estimates equivalent to those demonstrated by the clinically established POROCOAT and DUOFIX variants out to 7 years follow up in primary THR. The cumulative re-revision rate estimates for the use of the PINNACLE GRIPTION shell in first revision THR have been compared to a class rate from the AOANJRR, and the PINNACLE GRIPTION shell compares favorably.

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. NJR-NJR data from 1st April 2003 - 10th April 2018 on DePuy products supplied for post-marketing surveillance, NJR Centre, 2018.
Note: NJR-NJR Supplier Feedback data do not include Hospital Episode Statistics (HES) Data Linkage. Revisions may therefore be underreported.
3. Australian Orthopaedic Association National Joint Replacement Registry. Supplement to the Annual Report, Adelaide; AOA 2017. Revision Hip and Knee Arthroplasty Table R3.

Table R3: Cumulative Percent Revision of 1st Revision of Known Primary Total Conventional Hip Replacement by Class of 1st Revision (Primary Diagnosis OA, excluding 1st Revision for Infection)³

Class of 1st Revision	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	16 Yrs
Minor	505	2712	10.5 (9.4, 11.8)	16.6 (15.2, 18.2)	20.5 (18.8, 22.3)	26.7 (24.3, 29.3)		
Major Partial	1015	8082	7.1 (6.5, 7.7)	11.0 (10.3, 11.8)	13.3 (12.5, 14.2)	19.7 (18.3, 21.3)		
Major Total	136	1319	6.1 (4.9, 7.6)	9.6 (8.0, 11.5)	11.8 (10.0, 14.0)	15.4 (12.4, 19.1)		
TOTAL	1656	12113						

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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