

ECONOMIC EVALUATION OF TOTAL HIP ARTHROPLASTY REVISION PROCEDURES IN PATIENTS RECEIVING A CORAIL® PINNACLE® CONSTRUCT OR OTHER CEMENTLESS HIP IMPLANTS

Abstract

Objective: The objective of this analysis is to evaluate the direct medical costs associated with total hip arthroplasty (THA) revision procedures in patients receiving a CORAIL® PINNACLE® Construct, a CORAIL Collared PINNACLE Construct or other cementless hip constructs based on implant survivorship data from a National Joint Registry.

Methods: National Joint Registries provide valuable information on the revision rates and survivorship of orthopaedic implants. Cumulative THA revision rates over a 12-year period for 134,000 patients receiving CORAIL PINNACLE Hip Implants (mean age 66, 56% female), 74,000 patients receiving CORAIL Collared PINNACLE Hip Implants (mean age 67, 60% female) and 350,000 patients receiving other cementless hip implants (mean age 65, 56% female) were obtained from a report by the UK National Joint Registry.^{1,2} The THA revision survival curves from this report were used to quantify the expected medical costs for hypothetical cohorts of patients receiving a CORAIL PINNACLE Construct (n=500) or patients receiving other cementless hip implants (n=500) in an economic model over a 12-year period. Direct costs of THA revision procedures were estimated from the literature² and costing algorithms. An annual discount rate of 3% was applied to future years.

Results: Cumulative THA revision rates at 12 years were 4.0%, 3.4% and 4.5% for the CORAIL PINNACLE Construct, CORAIL Collared PINNACLE Construct and other cementless implants. Patients receiving the CORAIL PINNACLE Cementless Hip Construct were 14% less likely to be revised when compared to all other uncemented hip constructs on the NJR.¹ The patients receiving the CORAIL Collared PINNACLE cementless Hip Construct were 28% less likely to be revised when compared to all other cementless hip constructs on the NJR.² For a hypothetical cohort of 500 patients, cumulative revision costs over 12 years totaled £185,270 in the CORAIL PINNACLE group, £152,254 in the CORAIL Collared PINNACLE group and £219,080 in the other cementless hip implant group. Costs were £33,810 (CORAIL PINNACLE) and £66,825 (CORAIL Collared PINNACLE) lower due to less revision procedures over the 12-year period. Results were most sensitive to the cost of revision and least sensitive to changes in the discount rate.

Conclusion: The results of this analysis demonstrate that hip implants with better survivorship over a 12-year period have lower cumulative costs of approximately 15% (CORAIL PINNACLE) and 30% (CORAIL Collared PINNACLE) compared to hip implants with lower survivorship over the same period due to the costs attributable to revision procedures. On a per implant basis this results in £67 lower cost for CORAIL PINNACLE and £134 lower cost for CORAIL Collared PINNACLE both compared to other cementless hip constructs.

Introduction

Total hip arthroplasty (THA) is one of the most successful orthopaedic surgical procedures for the surgical treatment of advanced degenerative hip disease.^{3,4} Patients undergoing THA experience increased mobility, improved function, sustained pain relief, and improved quality of life from previously incapacitating joint disease. There are a number of different fixation options available to orthopaedic surgeons including cemented and cementless hip constructs. Although cementing has been used for decades for THA implant fixation, and demonstrates good implant survival rates, cemented fixation may be associated with potential morbidity in the form of bone cement implantation syndrome.⁵ The risk of bone cement implantation syndrome has led some surgeons towards using uncemented implant fixation for THA procedures.⁵ One of the most widely used cementless hip implant systems is the CORAIL® Hip Stem with the PINNACLE® Acetabular Cup System (CORAIL PINNACLE Construct) from DePuy Synthes.⁶

National Joint Registries provide valuable information on the revision rates and survivorship of hip implants, including cemented and cementless hip constructs. These registries include large cohorts with data from all surgeons from all centers, 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 has collected data on over 1,000,000 primary THAs.⁷ Recently, the NJR produced a bespoke report (August 2019) analyzing

the survival of the CORAIL PINNACLE cementless Hip Construct compared to all other cementless hip constructs.¹ The results of this analysis showed that patients receiving the CORAIL PINNACLE cementless Hip Construct were 14% less likely to be revised when compared to all other cementless hip constructs on the NJR [adjusted HR 0.86 (0.82-0.90), p<0.001].¹ The patients receiving the CORAIL Collared PINNACLE cementless Hip Construct were 28% less likely to be revised when compared to all other cementless hip constructs on the NJR [adjusted HR 0.72 (0.68-0.77), p<0.001].² The long-term economic impact of cementless hip implants with better survivorship data has yet to be examined.

The objective of this analysis is to evaluate the direct medical costs associated with THA revision procedures in patients potentially receiving CORAIL PINNACLE Implants or CORAIL Collared PINNACLE Implants or other cementless hip constructs based on implant survivorship data from a National Registry.

Methods

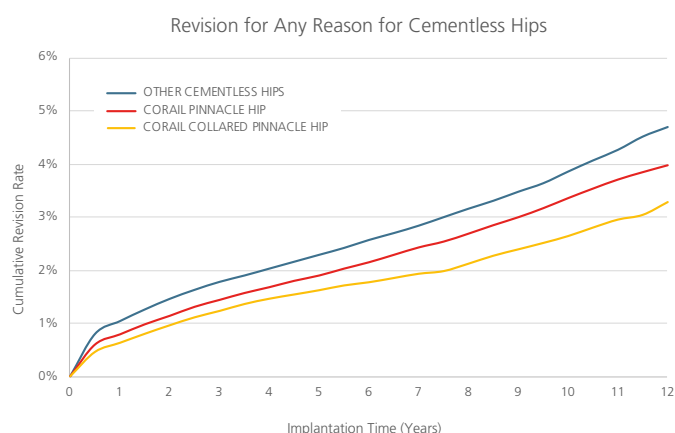
Cumulative THA revision rates over a 12-year period for 134,000 patients receiving CORAIL PINNACLE Hip Implants, 74,000 patients receiving CORAIL Collared PINNACLE Hip Implants and 350,000 patients receiving other cementless hip implants were obtained from a bespoke report by the NJR.^{1,2}

Patient and Procedure Details for NJR Analysis of CORAIL PINNACLE vs CORAIL Collared PINNACLE vs All Other Cementless Hips

| Characteristics | CORAIL PINNACLE | CORAIL Collared PINNACLE | All Other Cementless Implants |
|-------------------------|-----------------|--------------------------|-------------------------------|
| Total Patients (n) | 134,036 | 73,867 | 350,193 |
| Total Hips (n) | 150,465 | 81,685 | 402,309 |
| Mean Age | 65.8 years | 66.7 years | 65.2 years |
| Median BMI | 28 | 28 | 28 |
| % Female | 56% | 60% | 56% |
| Indications | | | |
| Osteoarthritis | 94.2% | 94.2% | 93.3% |
| Rheumatoid Arthritis | 1.1% | 1.0% | 1.2% |
| Avascular Necrosis | 2.1% | 1.9% | 2.5% |
| Fractured Neck of Femur | 1.9% | 2.3% | 1.8% |
| CDH/DDH | 1.5% | 1.3% | 2.1% |
| Other | 1.1% | 1.0% | 1.6% |

Source: NJR. Bespoke Implant Report for DePuy CORAIL PINNACLE vs. All Other Cementless Hips. Figure entitled "Patient/Procedure Details." August 30 2019. NJR. Bespoke Implant Report for DePuy CORAIL Collared PINNACLE vs. All Other Cementless Hips. Figure entitled "Patient/Procedure Details." August 30 2019. NJR Analysis of Cumulative Revision Rate for CORAIL PINNACLE vs CORAIL Collared PINNACLE vs All Other Cementless Hips

NJR Analysis of Cumulative Revision Rate for CORAIL PINNACLE vs CORAIL Collared PINNACLE vs All Other Cementless Hips



Cumulative revision rates are depicted as time to event data using Kaplan Meier curves. Cumulative revision rates were extracted from these Kaplan Meier curves, from graphical images using the Digitizeit (<http://www.digitizeit.de/>) software application as recommended in Wei 2017.³

Source: NJR. Bespoke Implant Report for DePuy CORAIL PINNACLE vs. All Other Cementless Hips. Figure entitled "Endpoint for Any Revision." August 30 2019. Note: All reasons for revision were included in analysis. NJR. Bespoke Implant Report for DePuy CORAIL COLLARED PINNACLE vs. All Other Cementless Hips. Figure entitled "Endpoint for Any Revision." August 30 2019. Note: All reasons for revision were included in analysis.

The results of this analysis showed that cumulative THA revision rates at 12 years were 4.0%, 3.4% and 4.5% for the CORAIL PINNACLE, CORAIL Collared PINNACLE and other cementless implants, respectively. Patients receiving the CORAIL PINNACLE cementless Hip Construct were 14% less likely to be revised when compared to all other uncemented hip constructs on the NJR.¹ The patients receiving the CORAIL Collared PINNACLE cementless Hip Construct were 28% less likely to be revised when compared to all other cementless hip constructs on the NJR.²

Revision Risk Ratio of CORAIL PINNACLE vs All Other Cementless Hip Constructs

| Adjustment | Hazard Ratio, (95% CI) | p-Value |
|------------|------------------------|---------|
| Unadjusted | 0.83 (0.80-0.87) | P<0.001 |
| Adjusted | 0.86 (0.82-0.90) | P<0.001 |

Source: NJR. Bespoke Implant Report for DePuy CORAIL PINNACLE vs. All Other Cementless Hips. Figure entitled

"Endpoint for Any Revision." August 30 2019. Note: All reasons for revision were included in analysis; "Adjusted" includes patient gender, age group, year of implantation and indications.

Revision Risk Ratio of CORAIL Collared PINNACLE vs All Other Cementless Hip Constructs

| Adjustment | Hazard Ratio, (95% CI) | p-Value |
|------------|------------------------|---------|
| Unadjusted | 0.68 (0.64-0.73) | P<0.001 |
| Adjusted | 0.72 (0.68-0.77) | P<0.001 |

Source: NJR. Bespoke Implant Report for DePuy CORAIL Collared PINNACLE vs. All Other Cementless Hips. Figure entitled

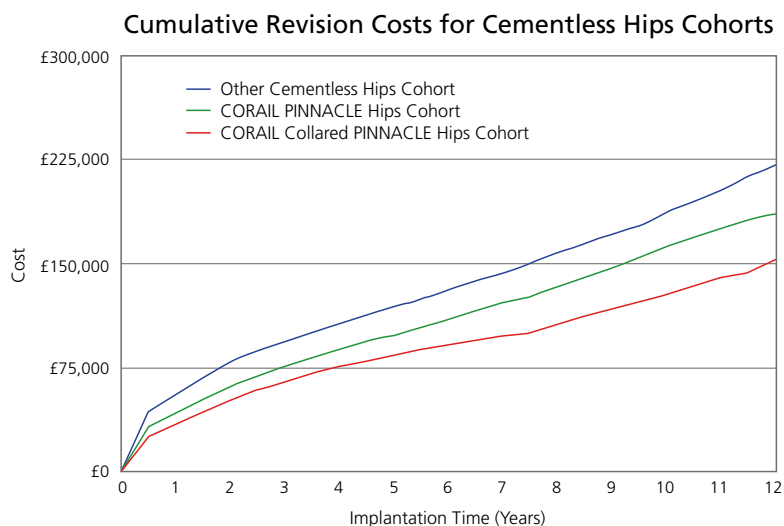
"Endpoint for Any Revision." August 30 2019. Note: All reasons for revision were included in analysis; "Adjusted" includes patient gender, age group, year of implantation and indications.

The THA survival curves from this report were used to quantify the expected medical costs for hypothetical cohorts of patients receiving CORAIL Collared PINNACLE Implants (n=500), CORAIL PINNACLE Implants (n=500) or other Cementless Hip Constructs (n=500) in an economic model over a 12-year period. To conduct an economic analysis at various timepoints over the 12-year period, the THA survival curves from the NJR report were digitized and imported into an Excel model. Direct costs of THA revision procedures were estimated from the medical literature and costing algorithms. More specifically, a mean cost of £10,902 was used as the default estimate for revision THA procedures for both the CORAIL PINNACLE patients and other cementless hip patients. The mean revision cost was estimated based on Hospital Episode Statistics data, 2019-2020 fiscal year. HES data covers all inpatient admissions in England. Hospitalizations for revision were identified based on procedure codes (OPCS) as defined by the UK National Joint Registry.⁹ An annual discount rate of 3% was applied to future years.

Results

The results of this economic evaluation for a hypothetical cohort of 500 patients showed that cumulative revision costs over 12 years totaled £185,270 in the CORAIL PINNACLE group, £152,254 in the CORAIL Collared PINNACLE group and £219,080 in the other cementless hip implant group.

12-Year Cumulative Revision Costs for Cementless Hip Cohort (n=500 for each cohort)



Costs were £33,810 lower in the CORAIL PINNACLE cohort and £66,825 lower in the CORAIL Collared PINNACLE cohort due to less revision procedures over the 12-year period both compared to other cementless hip cohort. On a per implant basis this results in £67 lower cost for CORAIL PINNACLE and £134 lower cost for CORAIL Collared PINNACLE both compared to other cementless hip constructs. Results were most sensitive to the cost of revision and least sensitive to changes in the discount rate.

Sensitivity Analysis Results

| Parameter | 12-Year Cumulative Costs | | | | |
|---|--------------------------|--------------------------------------|---|--|--|
| | CORAIL PINNACLE n=500 | CORAIL Collared PINNACLE n=500 | Other Cementless Constructs n=500 | Difference CORAIL PINNACLE /Other Cementless Constructs | Difference CORAIL Collared PINNACLE /Other Cementless Constructs |
| Base Case Analysis Sensitivity Analysis | £185,270 | £152,254 | £219,080 | £33,810 | £66,825 |
| 30% Higher Cost of Revision Procedure | £240,851 | £197,930 | £284,803 | £43,952 | £86,873 |
| 30% Lower Cost of Revision Procedure | £129,689 | £106,578 | £153,356 | £23,666 | £46,777 |
| Discount Rate Set at 0% | £216,960 | £178,801 | £256,209 | £39,249 | £77,408 |
| Discount Rate Set at 6% | £160,943 | £132,035 | £190,732 | £29,789 | £58,697 |

Validation of Economic Analysis Methodology

The methodology for this economic evaluation was validated using two approaches. In the first approach, an alternative estimate for the cost of THA revision procedures was identified from a study by Vanhegan et al (2012) on the economic burden of revision hip arthroplasty in the UK.¹⁰

In this study, the mean total costs for revision surgery in aseptic cases were £11,897, for septic revision £21,937, for peri-prosthetic fracture £18,185, and for dislocation £10,893. On average the cost for revision surgery amounted to £15,728 (in 2012 pounds) and then inflated to £18,716 (to the year 2019) for the validation analysis.

The results of this validation analysis were as follows:

Validation Analysis Results Using Alternative Estimate for Cost of THA Revision Procedures

| Parameter | 12-Year Cumulative Costs | | | | |
|---|--------------------------|--------------------------------------|---|--|--|
| | CORAIL PINNACLE n=500 | CORAIL Collared PINNACLE n=500 | Other Cementless Constructs n=500 | Difference CORAIL PINNACLE /Other Cementless Constructs | Difference CORAIL Collared PINNACLE /Other Cementless Constructs |
| Base Case Analysis | £185,270 | £152,254 | £219,080 | £33,810 | £66,825 |
| Validation Using Alternative Costs for THA Revision Procedures | £318,047 | £261,369 | £376,086 | £58,039 | £114,717 |

The validation analysis showed that results using the alternative value for cost of THA revisions were similar to the results using the base case cost of THA revisions (cost savings of £58,039 vs. £33,810 for CORAIL PINNACLE/Other Cementless Constructs and £114,717 vs. £66,825 for CORAIL Collared PINNACLE/Other Cementless Constructs).

For the second approach, the digitized values (used in the base-case analysis) for the THA survival curves were compared with the actual annual THA survival estimates from the NJR report. The results of this validation analysis were as follows:

Validation Analysis Results Using Actual Annual THA Revision Survival Estimates

| Years | Cumulative THA Revision Rates | | | | | |
|-------|-------------------------------|---------------------|--------------------------|---------------------|-----------------------------|---------------------|
| | CORAIL PINNACLE | | CORAIL Collared PINNACLE | | Other Cementless Constructs | |
| | Digitized Estimates(%) | Report Estimates(%) | Digitized Estimates(%) | Report Estimates(%) | Digitized Estimates(%) | Report Estimates(%) |
| 1 | 0,79 | 0,8 | 0,63 | 0,6 | 1,04 | 1,0 |
| 2 | 1,14 | 1,1 | 0,69 | 1,0 | 1,46 | 1,4 |
| 3 | 1,44 | 1,4 | 1,23 | 1,2 | 1,78 | 1,7 |
| 4 | 1,68 | 1,7 | 1,46 | 1,5 | 2,03 | 1,9 |
| 5 | 1,90 | 1,9 | 1,62 | 1,6 | 2,29 | 2,2 |
| 6 | 2,15 | 2,2 | 1,77 | 1,8 | 2,57 | 2,4 |
| 7 | 2,43 | 2,4 | 1,93 | 1,9 | 2,84 | 2,7 |
| 8 | 2,69 | 2,7 | 2,12 | 2,1 | 3,16 | 3,0 |
| 9 | 3,00 | 3,0 | 2,39 | 2,4 | 3,48 | 3,3 |
| 10 | 3,36 | 3,3 | 2,64 | 2,6 | 3,86 | 3,7 |
| 11 | 3,71 | 3,7 | 2,95 | 2,9 | 4,27 | 4,1 |
| 12 | 3,98 | 4,0 | 3,28 | 3,4 | 4,70 | 4,5 |

This validation analysis showed that the results using the actual annual THA survival estimates were similar to the base case analysis results using the digitized estimates. Overall, these validation analyses demonstrate that the methodological assumptions chosen for this economic evaluation were appropriate.

Conclusion

In summary, the results of this analysis demonstrate that hip implants with better survivorship over a 12-year period with 500 implants respectively have lower cumulative costs of approximately 15% with £33,810 (CORAIL PINNACLE) and 30% with £66,825 (CORAIL Collared PINNACLE) compared to hip implants with lower survivorship over the same period due to the costs attributable to revision procedures. On a per implant basis this results in £67 lower cost for CORAIL PINNACLE and £134 lower cost for CORAIL Collared PINNACLE both compared to other cementless hip constructs.

References

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