

Economic Evidence for CORAIL[®] Collared Stem and PINNACLE[®] Cup



Burden of Disease

Total Hip Arthroplasty (THA) is an effective treatment to relieve pain and restore mobility for patients.

Alongside the growing volume of THA procedures, there have been changes to the patient demographic. Average body mass index, age profile, and post-operative activity levels have all evolved over time. Increased volume in younger patients with high activity levels, elderly patients, and patients with higher BMI could all potentially increase the rates of periprosthetic fracture.^{2,7,16}

The frequency of THA in the United States has been rising over recent years; it is projected to grow by 174% to reach an annual volume of 572,000 by 2030.¹

Retrospective cohort study found a 216% increase in the number of patients presenting with a periprosthetic hip fracture between 2002 and 2006.³

Periprosthetic hip fractures can be categorized as either intra-operative and post-operative fractures. Intra-operative fractures occur within the THA procedure and the incidence rate is reported to range from 0.1% to 27.8% in cementless THA.⁴⁻⁵ This review will focus on post-operative periprosthetic fracture which tend to occur within the early post-operative period. The reported incidence rate ranges from 0.07% to 18%.⁴⁻⁵

The mortality rate after a periprosthetic femoral fracture was found to be significantly higher when compared to matched THA patients without periprosthetic fracture (16.5% vs 2.9%, $p < 0.0001$).³ Recent literature suggests a 17.7% 1-year mortality rate after periprosthetic femur fractures, identifies age as a key risk factor and found 80% of the deaths occurred within the first three months.¹⁵

Risk Factors Associated with Periprosthetic Hip Fractures



Cementless THA

Strong compression forces must be applied to achieve initial stability, increasing the risk for fractures.⁶



Age

The elderly often have fragile bones that are more susceptible to fracture.⁷



Gender

Women appear to have a higher incidence of fracture due to the greater risk of osteoporosis compared to men.⁸

Financial Burden of Periprosthetic Hip Fractures

Research has been conducted in multiple healthcare systems to examine the economic burden associated with periprosthetic fracture following THA. Shields et al. found the mean cost to be \$24,831 with an average hospital length of stay (LOS) of 6.3 days (\pm 8.8).¹⁵ Lyons et al. retrospectively reviewed 48 patients with postoperative periprosthetic fractures; for patients requiring revision (stem + plates/cables), the mean LOS was 26 days and the mean cost was over €27,000.¹⁶ Patients requiring revision of the stem alone had a slightly lower mean LOS of 21 days and the mean cost was €21,945.¹⁶ In a UK context Phillips et al. reviewed 146 periprosthetic fractures and found a mean LOS of 41 days and the mean cost of revision £23,756 per patient. The majority of revision costs are derived from hospital LOS (80.3%), followed by investigations (7.3%), implant costs (6.7%), and theatre costs (5.7%).¹⁷

Chitnis et al. conducted research on the Medicare population that showed a significant ($p < 0.0001$) increase in cost and resource utilization (at 90-days and 1-year) for patients suffering with postoperative peri-prosthetic hip fractures compared to a matched cohort of patients with no fractures. Postoperative periprosthetic fracture is associated with mean incremental cost of \$33,882 in the 90-day window and of \$39,853 at one year.⁸

Medicare claim payments and length of stay associated with treating postoperative periprosthetic hip fracture patients and control patients over a 90-day period after discharge from hospitalization for THA.⁸

	Patients WITH post-operative periprosthetic fractures	Control Cohort Patients WITHOUT post-operative periprosthetic fractures
Readmission	LOS 5.95 \pm 5.74 days \$21,885	LOS 0.43 \pm 1.86 days \$1,071
Index Hospitalization	LOS 2.79 \pm 1.60 days \$13,059	LOS 2.56 \pm 1.28 days \$12,545
Skilled Nursing Facilities	LOS 21.03 \pm 23.10 days \$10,444	LOS 5.26 \pm 11.49 days \$2,665
Inpatient Rehabilitation Facility	LOS 3.16 \pm 6.82 days \$4,598	LOS 0.77 \pm 2.99 days \$1,069
Home Health Agency	LOS 12.75 \pm 12.71 days \$2,471	LOS 8.60 \pm 10.29 days \$1880
Outpatient	LOS 2.90 \pm 3.37 days \$815	LOS 2.35 \pm 2.74 days \$543
Long-Term Care	LOS 0.34 \pm 3.10 days \$388	LOS 0.04 \pm 0.97 days \$45
Hospice	LOS 0.05 \pm 1.32 days \$9	LOS 0.00 \pm 0.00 days \$0
Total Mean 90-Day Adjusted All-Cause Payments	\$53,699	\$19,817

Note: Costs in the table above were derived from US Medicare database. These values may not equally apply to EMEA healthcare markets

LOS = Length of Stay



CORAIL® Collared Stem Reduces Risk of Periprosthetic Hip Fractures

Proponents of the use of a collared prosthesis claim that it provides advantages in the early stability of the implant, allowing for earlier post-operative weight bearing, protection against subsidence, and a positive dispersion of the vertical forces via the collar in the medial calcar.⁹ This could potentially lower the risk of periprosthetic hip fractures.

The **CORAIL Collared Stem** has been shown to demonstrate a significant reduced risk of revision when compared to all other cementless hips on the UK National Joint Registry (NJR) (28% reduced risk of revision – Adjusted HR 0.72 (0.68, 0.77) $p < 0.001$). Further, this analysis shows that CORAIL Collared Stem presents significantly fewer than expected revisions due to post-operative periprosthetic fracture.¹⁰ This analysis includes 81,685 procedures using CORAIL Collared with the PINNACLE Cup. Based on the performance of all other cementless hips on the NJR, the expected number of revisions due to post-operative periprosthetic fracture for a cohort of this size is 245.34, or 0.3%. The actual number of revisions recorded for CORAIL Collared Stem with PINNACLE Cup is 76, or 0.09%, which is a statistically significant reduction ($p < 0.001$). CORAIL Collared Stem with PINNACLE Cup was able to reduce revision rates by 69% when compared to expected performance of all other cementless hips on the NJR for a cohort of the size.

CORAIL STD Collared Femoral Stem – Reasons for Revision Compared to Expected Rates on NJR¹⁰

Implant Characteristics	Reason for Revision	Revisions	Total Procedures	Revision Rate
CORAIL Collared with PINNACLE Cup	Periprosthetic Fracture Stem	76	81,685	0.09%
Expected Revision Rate*	Periprosthetic Fracture Stem	245.34	81,685	0.30%

*Based on performance of all NJR Cementless Stems (excluding Metal-on-Metal), adjusted for age, gender, and other indications

The frequency of THA in the United States has been rising over recent years. It is projected to grow by 174% to reach an annual volume of 572,000 by 2030.¹ Using the projected 2030 volume of 572,000, an expected rate of revision due to periprosthetic fracture of 0.30% would result in approximately 1,716 revision cases. Projecting the revision rate of 0.09% exhibited by the CORAIL Collared with the PINNACLE Cup reduces this to an estimated 514 revision cases. Use of CORAIL Collared with PINNACLE Cup could potentially reduce the number of revisions due to periprosthetic hip fractures by 1,202 cases in 2030.

Implant Characteristics	Estimated Revision Cases ¹⁰ (Based on 2030 procedure projections)	Estimated Revision Cost (Cost inflated 2% per year to projected 2030 cost)	Total Projected Cost
Expected Revision Rate*	1,716	\$68,103	\$116,864,748
CORAIL Collared with PINNACLE Cup	514	\$68,103	\$35,004,942

At an estimated cost of \$68,103/revision* and with a potential 1,202 revision cases avoided, CORAIL Collared with PINNACLE Cup could reduce the economic burden to the US Healthcare System in 2030 by over

\$81,850,000

*Mean revision cost of \$53,699⁸ has been inflated at 2% per year across 11 years (2019-2030)
<https://knoema.com/kyawwad/us-inflation-forecast-2020-2021-and-long-term-to-2060-data-and-charts>

Literature suggests that one of the key risk factors for periprosthetic hip fracture is age.^{7,10} Rates of osteoporosis and osteopenia are increased in elderly patients making them more susceptible to fracture, especially with the use of cementless implants where strong compression forces must be applied to achieve the initial stability.^{7,10} In patients aged 70+ at the time of operation, CORAIL Collared with PINNACLE Cup has also demonstrated a significant reduction in risk of revision when compared to all other cementless hips (42% reduced risk of revision – HR 0.58 (0.52, 0.65) P<0.001), as well as significantly fewer than expected revisions due to periprosthetic fracture (50 vs 145.44 p<0.001).¹¹

There is a growing body of independent research in this area.¹²⁻¹⁴ Lamb et al provide an analysis of NJR data examining cementless femoral designs, finding that the collarless design is associated with an almost five-fold increase in the risk of early revision for periprosthetic fracture - HR 4.7 (3.5, 6.3) P<0.001.¹² Kahn et al also analysed NJR data and established that collared cementless stems have a significantly reduced risk of revision for periprosthetic fracture, (Adjusted HR 0.45 (95% CI 0.36-0.55) and suggest that a collar is an independently protective feature against periprosthetic fracture.¹³ Teeter et al looked at the use of the Direct Anterior Approach (DAA) in THR using collared and collarless designs. This study found that patients receiving the collared design demonstrated significantly lower levels of implant subsidence in the early post-operative period, which could potentially reduce the risk of periprosthetic hip fracture.¹⁴

Key Takeaways

Periprosthetic hip fractures are costly complications that are increasing in frequency due to the growing THA volume and changes in the demographics of the patient population.^{2,7,10,16}

Patients with post-operative periprosthetic hip fractures had significantly higher resource utilization (p<0.001) and mean 90-day all-cause adjusted payments (\$53,699) when compared to patients without fractures (\$19,817) (p<0.001).⁸

The CORAIL Collared Implant has been demonstrated by the NJR to significantly reduce the risk of periprosthetic hip fracture as compared to all other cementless hips, even in older patients (aged 70+).^{10,11}

The reduced rates of periprosthetic fracture, evidenced by the CORAIL Collared Implant, could potentially lead to healthcare savings of over \$81,850,000 in 2030.

Independent literature corroborates these findings and confirms that the use of a collared cementless implant significantly reduces the risk of periprosthetic fracture when compared to collarless cementless implants.¹²⁻¹⁴

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