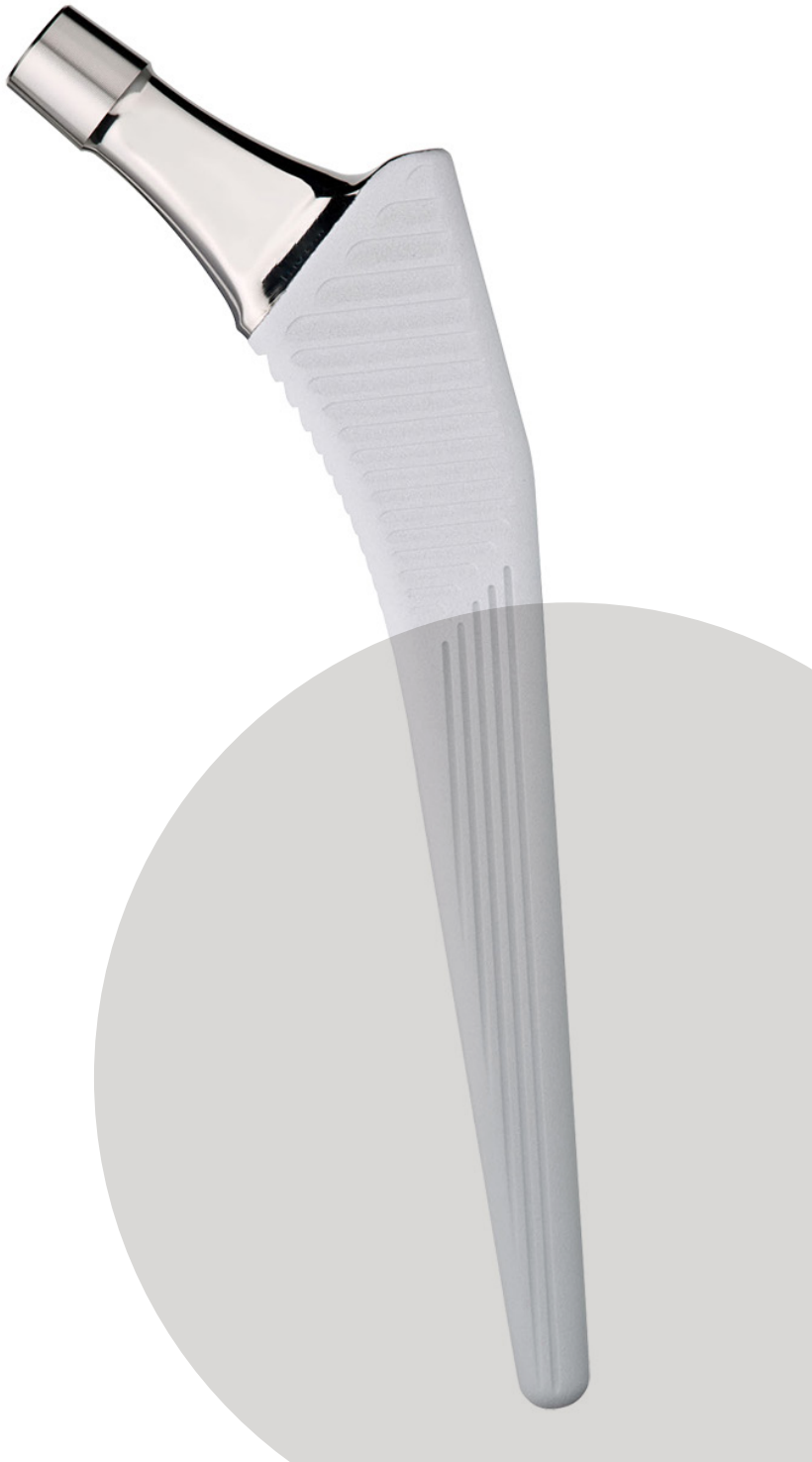
Profemur® L

CLINICAL DATA



MicroPort Orthopedics

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Registry Data

ODEP
Orthopaedic Data Evaluation Panel

The Orthopedic Data Evaluation Panel (ODEP) reviews clinical data submissions of hip products to apply globally recognized benchmarks signifying product performance.

ODEP rates the strength of the presented clinical data based upon the number of centres and surgeons outside of development centre(s), minimum total cohort, minimum at risk at the benchmark time, and revision rate.

ODEP 5A — The Profemur® L Classic stem was awarded a 5A ODEP Rating during the Fall 2019 meeting.

ODEP 5A* — The Profemur® L Modular stem in combination with a CoCr modular neck was awarded a 5A* ODEP Rating during the Spring 2019 meeting.

ODEP 10A* — The Profemur® L Modular stem in combination with a Titanium modular neck was awarded a 10A* ODEP Rating during the Spring 2019 meeting.

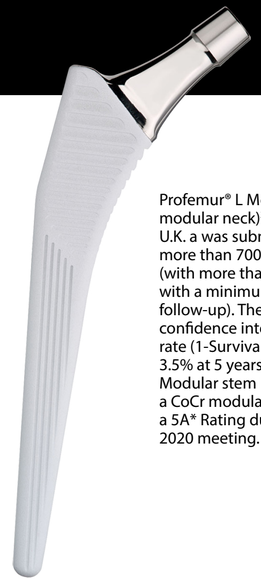
The number represents the number of years for which the product's performance has been evidenced, the letter represents the strength of evidence (data) presented by the manufacturer.

5 or 10 Years of evidence: full compliance with NICE benchmark;

A Strong evidence: generally higher numbers of patients (giving greater confidence in the results presented), with all patients being subject to follow-up (their outcomes recorded);

***** The star has been added to the rating system following revised guidelines from NICE in February 2014, in which a benchmark replacement rate of less than 1 in 20 (5%) at 10 years was defined. The star is awarded where products are evidenced to comply with this benchmark. A* represents very strong evidence above A and B.

Profemur® L Classic[1]: Data from Australia was submitted containing more than 2000 total implants (with approximately 200 implants with a minimum of five years follow-up). The upper 95% confidence interval for KM revision rate (1-Survival) was lower than 3.5% at 5 years. The Profemur® L Classic stem was awarded a 5A Rating during the Fall 2019 meeting. A 5A* rating was not applied for because the requirement for minimum cohort with 5 years of follow-up (225 implants) was not available at the time of data extraction.



Profemur® L Modular (CoCr modular neck)[2]: Data from the U.K. a was submitted containing more than 700 total implants (with more than 250 implants with a minimum of five years follow-up). The upper 95% confidence interval for KM revision rate (1-Survival) was lower than 3.5% at 5 years. The Profemur® L Modular stem in combination with a CoCr modular neck was awarded a 5A* Rating during the Spring 2020 meeting.

Profemur® L Modular (Ti modular neck)[3]: Data from the U.K. a was submitted containing more than 3000 total implants (with more than 500 implants with a minimum of ten years follow-up). The upper 95% confidence interval for KM revision rate (1-Survival) was lower than 5.0% at 10 years. The Profemur® L Modular stem in combination with a Ti modular neck was awarded a 10A* Rating during the Spring 2020 meeting.

NJR BeSpoke Report

National Joint Registry
www.njrcentre.org.uk

As part of the NJR (UK National Joint Registry) services, suppliers can request BeSpoke Reports and, under certain conditions, are allowed to publish on their websites such reports. At the moment, a report is available and can be found at the link below, providing clinical data on survivorship and PROMs.[4]
This report summarizes the outcome of the MicroPort Profemur® L Classic in total hip replacement in patients registered in the National Joint Registry.

Part 1
The first part summarizes the usage and survival associated with the Profemur® L Classic stem, based upon all data recorded in the NJR for this product up to 8 February 2020. None of these were used with a metal-on-metal bearing. The report includes Kaplan Meier survival analysis and Cox Regression analysis, comparing the product with all other cementless hip stems in the NJR, excluding metal on metal. The Cox Regression includes calculation of a Hazard Ratio adjusted for age, gender, year cohort and indications. The Kaplan-Meier revision rate of the Profemur® L Classic stem was 0.8% (0.3%-3.1%) at 4 years follow-up with femoral revision as the endpoint.

Part 2
The second part summarizes the outcomes of an additional Patient Reported Outcome Measures (PROMs) study requested by MicroPort Orthopedics on the Profemur® L Classic stem, using Oxford Hip scores and EQ-5D-5L scores at a range of time intervals following surgery.

Reasons for revision

No difference in any reasons for revision compared to class average for all cemented NJR primary hips ($p>0.05$)

Survivorship

99.2% stem survivorship at 4 years

Satisfaction

Similar Oxford Hip Score and EQ-5D Score compared to the class average for all NJR Primary hips

*Report can be accessed at: https://www.microportortho.com/products/hips/femoral-stems/primary/Profemur-l-hip-stem
**Disclaimer: The data used for this analysis was obtained from the NJR Supplier Feedback System. The Healthcare Quality Improvement Partnership ("HQIP") and/or 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.

Company Sponsored Studies

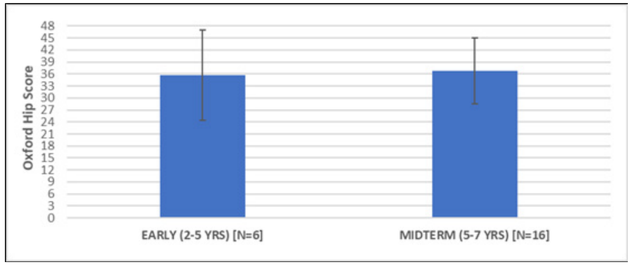
Preliminary Analysis of MicroPort Orthopedics Company-Sponsored Study for the Profemur® L Revision Stem

Overview

As of 12 May 2020, there have been 27 hips (17 males, 9 females, and 1 unknown) implanted with either the Profemur® L Revision stem (n=12) or the Profemur® L Modular stem (n=15) used in revision indication included for analysis in a company-sponsored study in the U.K. [5].

Mean age at the time of operation was 62.1 years (range, 41.2 – 78.1) and mean body mass index was 31.3 ± 5.1 years (range, 23.4 – 40.7). There have been no re-revisions reported resulting in a survivorship of 100% at a mean follow-up of 8.2 years postoperatively.

Patient-reported outcome measures (PROMs) have been collected for subjects at 2-5 years and 5-7 years postoperatively. As shown, mean PROMs scores have been maintained over time out to mid-term follow-up.

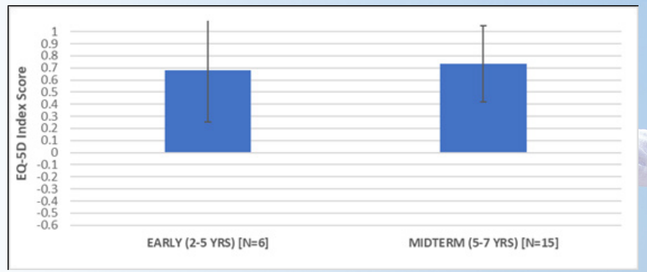


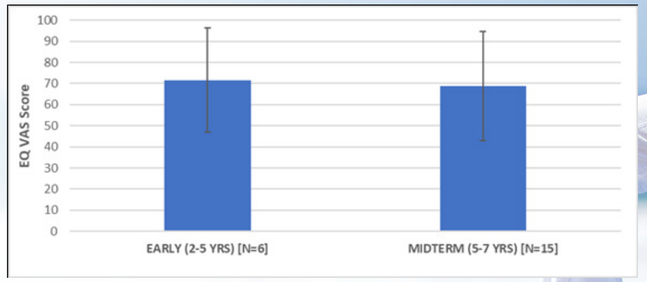
Satisfaction

Function and quality of life scores have been maintained over time out to mid-term follow-up

Survivorship

100% survivorship ;
No re-revisions at a mean follow-up of 8.2 years follow-up





Clinical Studies

Minimally Invasive Total Hip Arthroplasty - An Australian Experience.

Qurashi, S. Reconstructive Review, 2016.[6]

Summary

The aim of this study was to measure surgical and functional outcomes in the short term of a single surgeon series using the SuperPath® technique in Australia. The first 100 patients received the Profemur® L Classic femoral component in combination with a Dynasty® acetabular component.

There was one revision reported due to motor vehicle trauma requiring removal of the Profemur® L Classic femoral stem. At 4 weeks postoperatively, 81% of patients were driving. Of patients who were working full-time prior to surgery, 33% of them were back to work or functional baseline within 1 week postoperatively and 52% by 2 weeks.

Patient function and satisfaction was measured by a questionnaire administered 6 weeks postoperatively. 100% of patients were extremely satisfied with the operation.

The study concluded that SuperPath® is a safe technique of hip arthroplasty with excellent functional recovery and patient satisfaction.

Revision rate

No revisions of the Profemur® L Classic femoral component due to loosening at 1 year

Satisfaction

100% patient satisfaction at 6 weeks postoperatively

Comparative cohort study of the SuperPath® approach and the conventional posterior approach in primary cementless hip replacement surgery.

Más Martínez J. Journal of Orthopaedic Surgery and Traumatology: 2019 [7]

Revision rate

The revision rate of the Profemur® L femoral component is low at 12 months

Satisfaction

Hip functional scores significantly improved from preoperative values to 12 month values

Summary

The purpose of this study was to compare the SuperPath® surgical approach (n=30) and a traditional posterior approach (n=60). All patients in the SuperPath® group received the Profemur® L femoral component in combination with a Procotyl® L acetabular component.

There was one revision requiring removal of the Profemur® L femoral component reported at 6 months follow-up.

Patient-reported outcome measures (PROMs), including IHOT-12, SF-12 mental and physical scores, WOMAC pain and function scores, Merle d'Aubigné, and Harris Hip Scores, were collected preoperatively as well as at 3 months, 6 months, and 12 months postoperatively. Hip function surveys significantly improved from preoperative values to 12 month values for both groups. The SuperPath® cohort showed better results for IHOT-12 at 3 months and for SF-12 scores at 12 months.

The study concluded that the learning curve for the SuperPath® approach provides similar outcomes to the conventional posterior approach within the first year after surgery.

References

1. ODEP – Orthopedic Data Evaluation Panel Website, http://www.odep.org.uk/product.aspx?pid=296
2. ODEP – Orthopedic Data Evaluation Panel Website, http://www.odep.org.uk/product.aspx?pid=186
3. ODEP – Orthopedic Data Evaluation Panel Website, http://www.odep.org.uk/product.aspx?pid=9597
4. NJR BeSpoke Report for the Profemur® L Classic Femoral Stem. Report can be accessed at: https://www.microportortho.com/products/hips/femoral-stems/primary/profemur-l-hip-stem
5. Preliminary Analysis of MicroPort Orthopedics Company-Sponsored Study for the Profemur® L Revision Femoral Stem, as of 12 May 2020. Data on File.
6. Qurashi, S., SuperPATH(R) Minimially Invasive Total Hip Arthroplasty - An Australian Experience. Reconstructive Review, 2016. 6(2): p. 43-48.
7. Más Martínez J, et al. Comparative cohort study of the SuperPath approach and the conventional posterior approach in primary cementless hip replacement surgery. Journal of Orthopaedic Surgery and Traumatology. 2019. https://doi.org/10.1016/j.recote.2019.07.002

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