

Profemur[®] Preserve

CLINICAL DATA

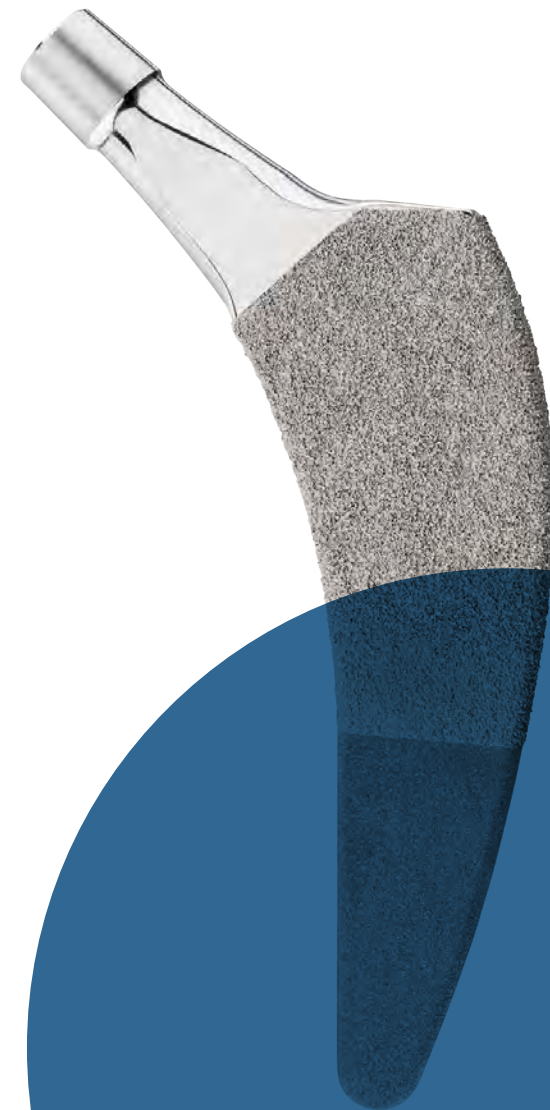


Table of contents

CLINICAL STUDIES **4** Mid-term results of total hip arthroplasty using a novel uncemented short femoral stem with metaphyso-diaphyseal fixation

5 A new triconical greater throcanter sparing short stems. Results at four years

COMPANY SPONSORED STUDIES **6**

REFERENCES **9**





Mid-term results of total hip arthroplasty using a novel uncemented short femoral stem with metaphyso-diaphyseal fixation.

Blakeney WG, Lavigne M, Beaulieu Y, Puliero B, Vendittoli PA.

[published online, 2020 Jan 30]. Hip Int. 2020;1120700020903451. doi:10.1177/1120700020903451¹

Purpose

Short stems were developed with the promise of providing easier implantation, facilitating revision, reducing thigh pain and proximal stress shielding. The aim of this study is to present the mid-term clinical results of a titanium short stem with modular neck.

Methods

This is a prospective case series of 144 THAs performed on a series of 131 patients using the PROFEMUR Preserve Femoral Stem (MicroPort Orthopedics, Arlington, TN, USA). 2 surgeons operated on the patients using a mini-posterior approach. The primary outcomes evaluated were stem revision for aseptic loosening and all-cause stem revision. Clinical and radiographic outcomes were also assessed.

Conclusions: This short modular stem produced satisfactory clinical and radiological results at mid-term, with 98.5% implant survival for any cause of stem revision and no revisions for aseptic loosening. Long-term results are required to further evaluate the stem's promising early results.

Results

Of the 144 THAs, there were 43 males and 101 females, with an average age of 61 (range 22-92) years at surgery. After a mean of 78 (range 53-87) months follow-up, there were 2 (1.5%) femoral implant revisions; 1 for early femoral periprosthetic fracture and 1 for fatigue failure of the modular femoral neck. There were no cases of stem aseptic loosening and radiographic analysis demonstrated no cases of stem migration. The mean UCLA activity, WOMAC and Forgotten Joint scores were respectively 6.1, 10.7 and 86.6. 70% of prosthetic hips were observed as having no restriction and 99.2% of patients were satisfied with their THA.



Survivorship

Kaplan-Meier survivorship is 98.5% at 6.5 years, with the any reason for removal of the stem as the endpoint



Revision rate

There were no cases of stem aseptic loosening and radiographic analysis demonstrated no cases of stem migration at a mean follow-up of 6.5 years



Satisfaction

70% of prosthetic hips were observed as having no restriction.

99.2% of patients were satisfied with their THA.



A new triconical greater trochanter sparing short stems. Results at four years.

Ribas FM, Cardenas N, Bellotti V, Astarita E, Moya E, Ramirez L.

026-497 – EHS congress, 20-22 September 2018, The Hague, the Netherlands²

Introduction

In the last decade, different short stems have appeared on the market, but not all are equal in design, femoral cut level, biomechanical properties or host bone response. A new non-cemented titanium alloy porous coated triconical short stem with calcar resection was introduced. The aim of this study is to analyze clinical-functional results as well as data related to stem behavior.

Materials & Methods

128 hips in 119 patients were included in this study with a mean follow-up of 45.4 months (range: 37-61 months). 75 patients were male and 83 implantations occurred with a ceramic on ceramic bearing, while the rest was ceramic on XL-UHMWPE bearing. Average patients age at the time of implantation was 58.7 years. 119 cases were primary surgeries, while 4 cases were revisions of two resurfacing prostheses and two malpositioned traditional stems in young patients. All patients were implanted with a Profemur® Preserve stem (modular and classic) and either a mini posterior or a supracapsular portal assisted approaches were used.

Conclusions: The evaluation over 4 years of this new implant offers promising results in terms of clinical, functional, radiological, although more long-term results are needed.



Survivorship

Kaplan-Meier survivorship is 99.21% at 6 years

Patients were followed at 6 months, 12 months and annually. WOMAC, Merle D'Aubigne, Harris Hip Scores and the UCLA activity scale were recorded in the preoperative and postoperative clinical records. Selection criteria for the implantation of this stem were a value of femoral T-score above -1, Dorr femur type A and B, age less than 75 years and BMI <30.

Results

The mean WOMAC score improved from 42.2 points (29 -51) to 96.7 (66 - 100, p <0.001), Merle D'Aubigne from 11.8 (10 - 14) to 17.1 (16 - 18, p <0.01), HHS of 37.4 points (range 26 - 66) to 93.8 (61 - 100, p <0.001). The UCLA Scale was 7.1 (R +/- 1.1, 95% CI). Radiolucencies <1 mm were observed in zone 4 in 13 cases without further changes later. Neoformation of trabecular pattern was observed in zones 2, 3, 5 and 6 without peripheral widening. Two revisions occurred in this series: one recurrent dislocation in an alcoholic patient was treated with an acetabular ex-changed (dual mobility system) and one Profemur® Preserve stem was revised with a 2 stages procedure for infection. The Kaplan-Meier projected survivorship at 6 years for the series is 99.21%.



Revision rate

No hips were revised due to femoral component loosening at a mean follow-up of 45.4 months.



Satisfaction

WOMAC scores, Merle D'Aubigne scores, and Harris Hip Score improved significantly between preoperative and a mean follow-up of 45.4 months.

Company Sponsored Studies

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

Overview

As of 07 May 2020, there have been 49 hips (33 males, 16 females) implanted with the PROFEMUR® Preserve Modular femoral stem for primary indications and included for analysis in a company-sponsored study in Spain³.

The study design is a prospective follow-up of previously implanted subjects who were consecutively enrolled. Mean age at the time of operation was 59.9 years (range, 23.0 – 78.6) and mean body mass index was 26.4 kg/m² (range, 19.5 – 36.9).

There have been no revisions reported resulting in a survivorship of 100% at a mean follow-up of 5.4 years postoperatively. There have been no confirmed cases of femoral component loosening and no radiolucencies have been observed.



Satisfaction

No confirmed cases of femoral component loosening and no radiolucencies observed at a mean follow-up of 5.4 years postoperatively.

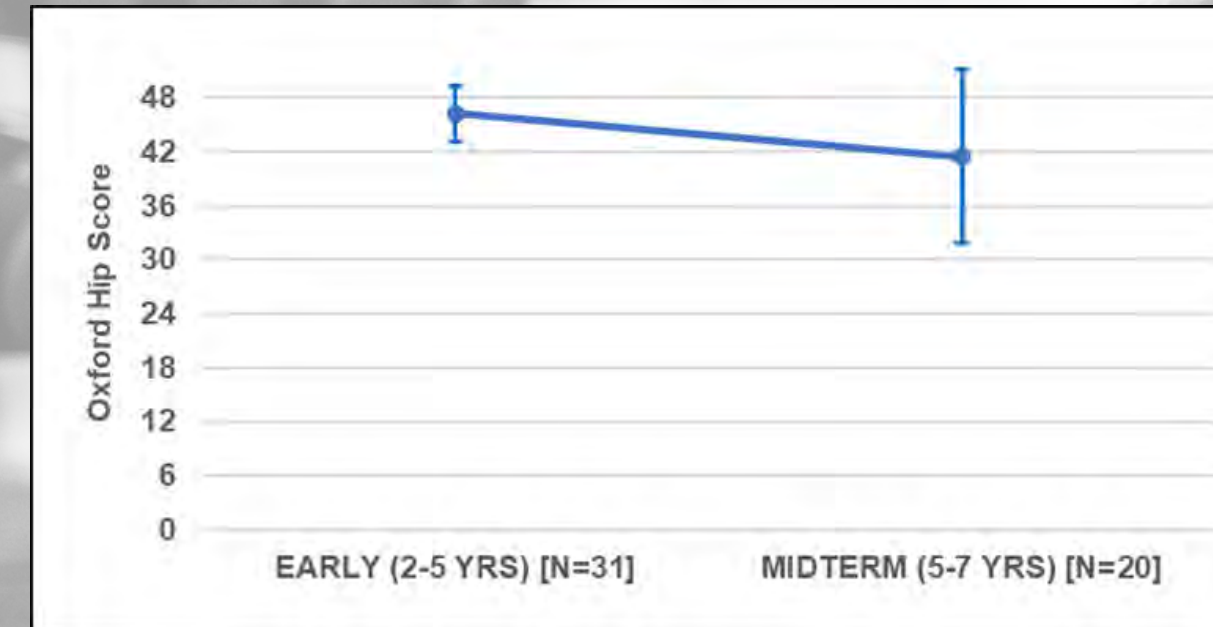


Survivorship

Survivorship is 100% at a mean follow-up of 5.4 years postoperatively.

Mean Oxford Hip Scores indicate good function out to mid-term follow-up.

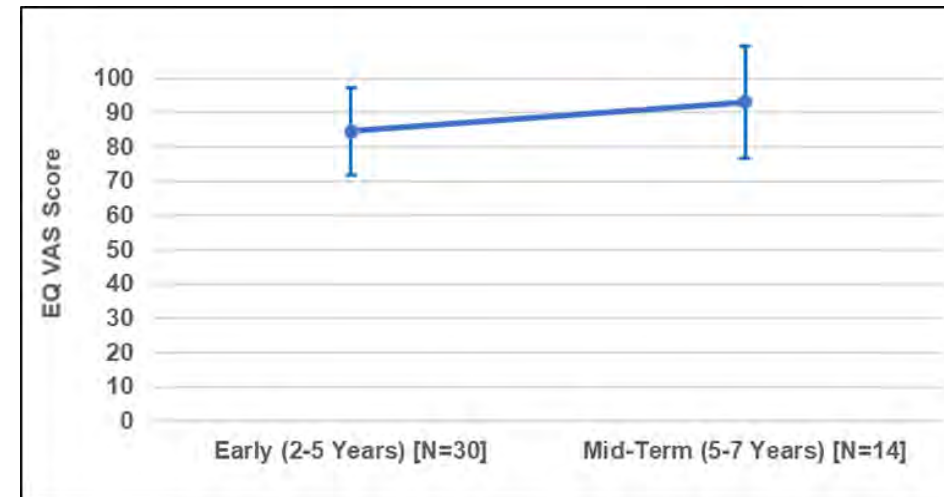
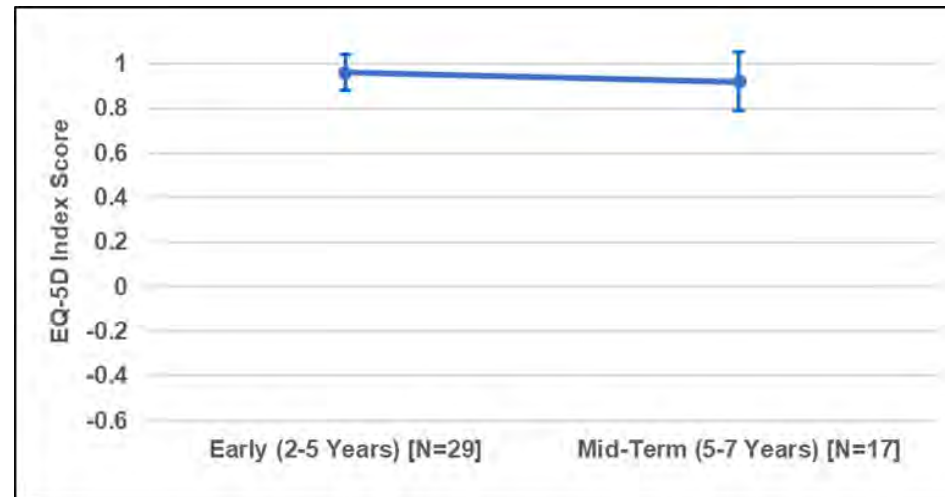
Oxford Hip Scores have been collected for subjects at the early (2-5 years) and mid-term (5-7 years) postoperative visits. Mean Oxford Hip Scores indicate good function out to mid-term follow-up.



References

Mean EQ-5D-3L scores have been maintained at the early (2-5 years) and mid-term visits (5-7 years)

EQ-5D-3L scores have been collected for subjects at the early (2-5 years) and mid-term (5-7 years) postoperative visits. The mean EQ-5D-3L scores have been maintained at the early visit (2-5 years) and at the mid-term visit (5-7 years).



Disclaimer:

Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level. There are risks and recovery times associated with surgery and there are certain individuals who should not undergo surgery

1. Blakeney WG, Lavigne M, Beaulieu Y, Puliero B, Vendittoli PA. Mid-term results of total hip arthroplasty using a novel uncemented short femoral stem with metaphyso-diaphyseal fixation [published online, 2020 Jan 30]. Hip Int. 2020;1120700020903451. doi:10.1177/1120700020903451.
2. Ribas FM, Cardenas N, Bellotti V, Astarita E, Moya E, Ramirez L. A new triconical greater trochanter sparing short stems. Results at four years. O26-497 – EHS congress, 20-22 September 2018, The Hague, the Netherlands.
3. Preliminary Analysis of MicroPort Orthopedics Company-Sponsored Study for the Profemur® Preserve Modular Femoral Stem, as of 07 May 2020. Data on File.

