

Profemur® Gladiator

CLINICAL DATA



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Profemur® Gladiator Plasma Femoral Stem



All data on file with MicroPort

Introduction

As of 04 February 2020, there have been 111 hips implanted with the Profemur® Gladiator Plasma femoral stem (80 modular, 31 fixed-neck) in a company-sponsored study located in Germany and included for analysis. Demographic information is provided below.

There has been 1 revision reported resulting in a survivorship of 99.1% at 5 years postoperatively, with any reason requiring removal of the femoral component as the endpoint. There were no confirmed cases of femoral component loosening.

Patient-reported outcome measures (PROMs) have been collected at two postoperative time windows: 2-5 years (early) and 5-7 years (midterm). The PROMs scores presented indicate satisfactory function, quality of life, and pain levels at the early postoperative visit and have been maintained through the latest midterm visit.

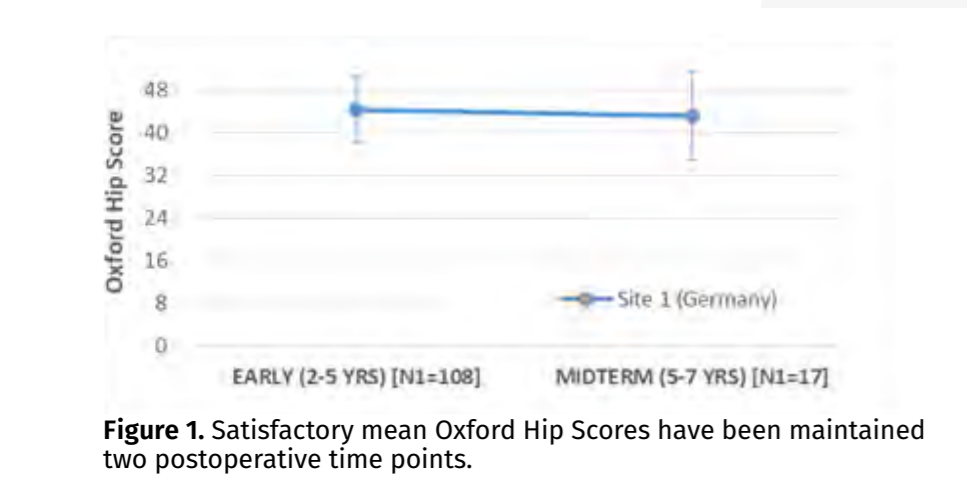


Figure 1. Satisfactory mean Oxford Hip Scores have been maintained two postoperative time points.

Hips 111

Age (years)
69.34 ± 6.72
(range, 36.4-78.6)

BMI (kg/m²)
28.32 ± 4.88
(range, 17.9-40.22)

Germany



Satisfaction
No confirmed cases of femoral component loosening out to 5 years

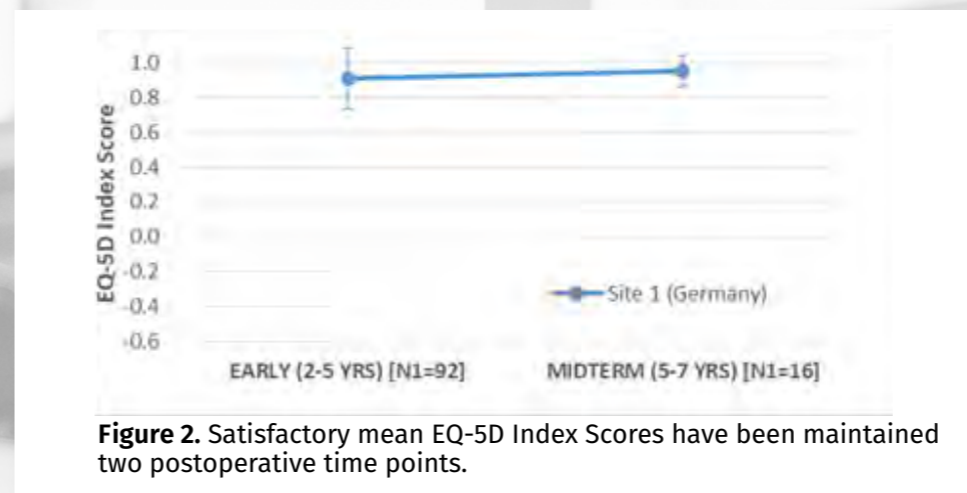


Figure 2. Satisfactory mean EQ-5D Index Scores have been maintained two postoperative time points.

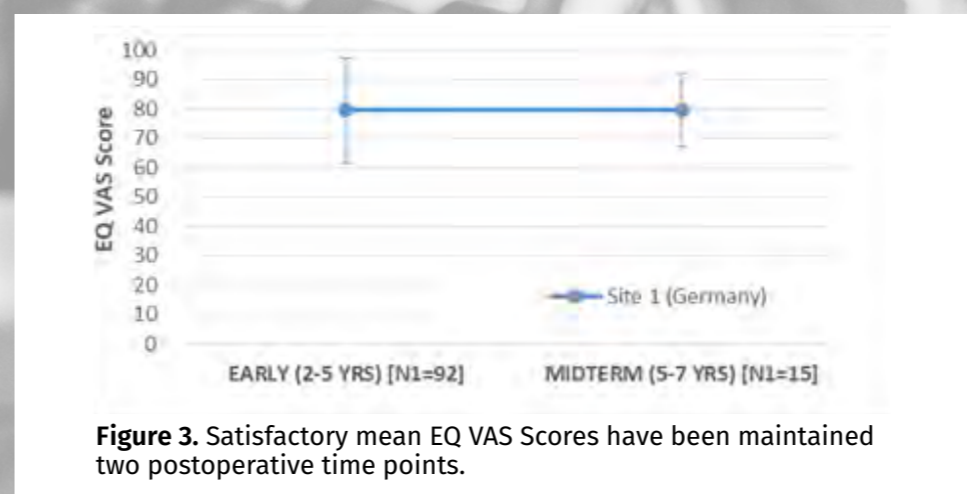


Figure 3. Satisfactory mean EQ VAS Scores have been maintained two postoperative time points.



Survivorship
99.1% survivorship at 5 years



Satisfaction
Satisfactory patient-reported function, quality of life, return to functional activities, and pain levels at all postoperative visits out to midterm follow-up

Profemur® Gladiator Plasma Femoral Stem

Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)¹

There have been 305 hips (164 male, 141 female) with an average age of 69.3 years (range, 30-90 years) implanted with the Profemur® Gladiator Plasma Classic femoral stem in the AOANJRR between July 2012 and August 2020. These patients have been implanted by 8 different surgeons in 6 hospitals.

In total, 11 hips have been revised for any reason; however, only 3 of these have required removal of the femoral component. The cumulative percent revision of the Profemur® Gladiator Plasma Classic stem is 1.9% at 6 years (95% CI: 0.5-7.0%) with the endpoint of femoral stem removal. Based on point estimates and confidence intervals, the incidence of femoral stem revisions is in line with the class of all other Total Conventional Hip at 6 years follow-up. Expressed as survivorship, the Profemur® Gladiator Plasma Classic has a 98.1% (95% CI: 93.0-99.5%) survivorship at six years with the endpoint of femoral stem removal.

Table 17: Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Model (All Diagnoses, Femoral Stem Revisions)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
Profemur Gladiator	0.7 (0.2, 2.8)	0.7 (0.2, 2.8)	0.7 (0.2, 2.8)	0.7 (0.2, 2.8)	1.9 (0.5, 7.0)	1.9 (0.5, 7.0)
Other Total Conventional Hip	0.7 (0.6, 0.7)	0.9 (0.8, 0.9)	1.1 (1.0, 1.1)	1.2 (1.2, 1.3)	1.4 (1.4, 1.4)	1.6 (1.6, 1.6)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs
Profemur Gladiator						
Other Total Conventional Hip	1.8 (1.8, 1.8)	2.0 (2.0, 2.1)	2.2 (2.2, 2.3)	2.5 (2.4, 2.5)	2.7 (2.6, 2.8)	3.0 (2.9, 3.1)

CPR	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs
Profemur Gladiator							
Other Total Conventional Hip	3.3 (3.2, 3.4)	3.6 (3.5, 3.7)	3.9 (3.8, 4.0)	4.2 (4.0, 4.3)	4.4 (4.3, 4.6)	4.7 (4.6, 4.9)	5.1 (4.9, 5.3)

Note: Excludes procedures using metal/metal prostheses with head size larger than 32mm
 Note: Femoral Stem Revisions include both THR (femoral/acetabular) and stem only revisions



Survivorship

The survivorship is 99.6% (95% CI: 97.4-99.9%) at 6 years with the endpoint of femoral stem revisions for loosening

The survivorship is 98.1% (95% CI: 93.0-99.5%) at 6 years with the endpoint of femoral stem revisions

The cumulative percent revision of the Profemur® Gladiator Plasma Classic stem is 0.4% at 6 years (95% CI: 0.1-2.6%) with the endpoint of femoral stem removal for loosening. Based on point estimates and confidence intervals, the incidence of femoral stem revisions for loosening is in line with the class of all other Total Conventional Hip at 6 years follow-up. Expressed as survivorship, the Profemur® Gladiator Plasma Classic has a 99.6% (95% CI: 97.4-99.9%) survivorship at 6 years with the endpoint of femoral stem removal for loosening.

Table 21: Yearly Cumulative Percent Revision of Primary Total Conventional Hip Replacement by Model (All Diagnoses, Femoral Stem Revisions for Loosening)

CPR	1 Yr	2 Yrs	3 Yrs	4 Yrs	5 Yrs	6 Yrs
Profemur Gladiator	0.4 (0.1, 2.6)	0.4 (0.1, 2.6)	0.4 (0.1, 2.6)	0.4 (0.1, 2.6)	0.4 (0.1, 2.6)	0.4 (0.1, 2.6)
Other Total Conventional Hip	0.1 (0.1, 0.1)	0.2 (0.2, 0.2)	0.3 (0.3, 0.3)	0.4 (0.3, 0.4)	0.4 (0.4, 0.5)	0.5 (0.5, 0.5)

CPR	7 Yrs	8 Yrs	9 Yrs	10 Yrs	11 Yrs	12 Yrs
Profemur Gladiator						
Other Total Conventional Hip	0.6 (0.5, 0.6)	0.6 (0.6, 0.7)	0.7 (0.7, 0.8)	0.8 (0.8, 0.9)	0.9 (0.9, 1.0)	1.0 (1.0, 1.0)

CPR	13 Yrs	14 Yrs	15 Yrs	16 Yrs	17 Yrs	18 Yrs	19 Yrs
Profemur Gladiator							
Other Total Conventional Hip	1.1 (1.1, 1.2)	1.2 (1.1, 1.3)	1.3 (1.2, 1.4)	1.4 (1.3, 1.4)	1.5 (1.4, 1.5)	1.5 (1.4, 1.6)	1.6 (1.5, 1.7)

Note: Excludes procedures using metal/metal prostheses with head size larger than 32mm
 Note: Femoral Stem Revisions include both THR (femoral/acetabular) and stem only revisions

Disclaimer – AOANJRR is confident in the accuracy of the data included in this report, at the time it was provided. However, it was generated using an automated reporting system and has not been reviewed by the AOANJRR personnel.

Profemur® Gladiator HA Femoral Stem

All data on file with MicroPort

Introduction

As of 04 February 2020, there have been 152 hips implanted with the Profemur® Gladiator HA modular femoral stem in a company-sponsored study located in Belgium. Demographic information is provided below.

There have been no revisions reported resulting in a survivorship of 100% at 8 years postoperatively with any reason as the endpoint. There were no confirmed cases of femoral component loosening.

Patient-reported outcome measures (PROMs) have been collected at 5 months, 1 year, 2 years, 5 years, and 7 years postoperatively. The PROMs scores presented indicate satisfactory function, quality of life, return to functional activities, and pain levels at the 5 month postoperative visit and have been maintained through the 7 year visit.

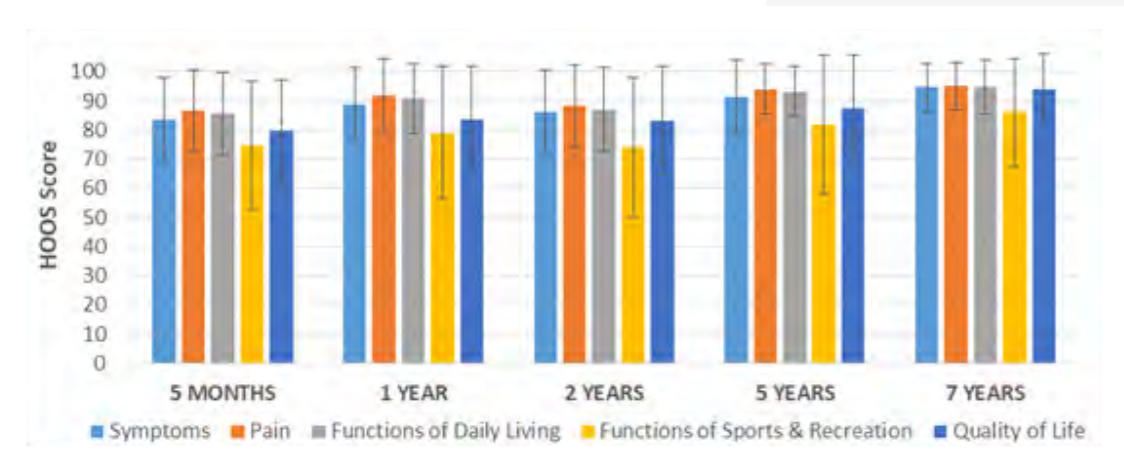


Figure 4. Satisfactory mean HOOS Scores have been maintained at five postoperative time



Hips 152

Age (years)
65 ± 9.29,
range (37.25-83.42)

BMI (kg/m²)
27.3 ± 4.08,
range (16.01-40.39)

Belgium



Satisfaction

No confirmed cases of femoral component loosening out to 8 years

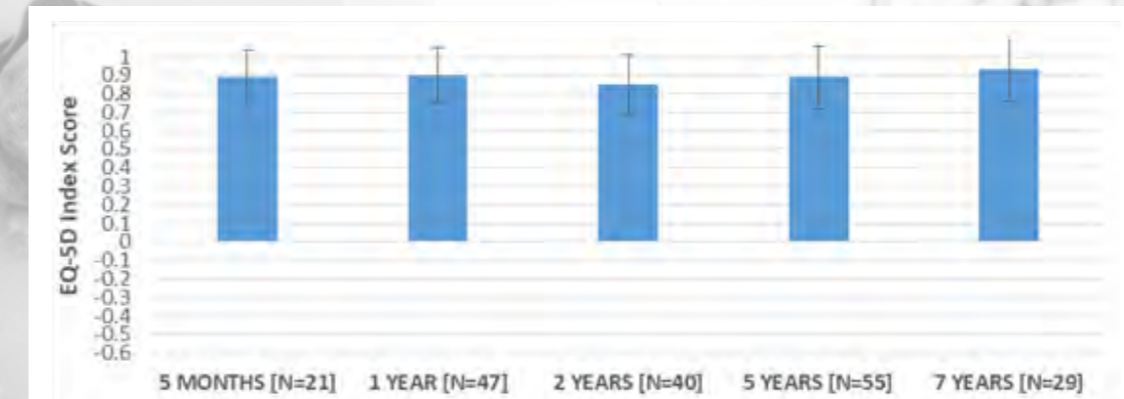


Figure 5. Satisfactory mean EQ-5D Index Scores have been maintained at five postoperative

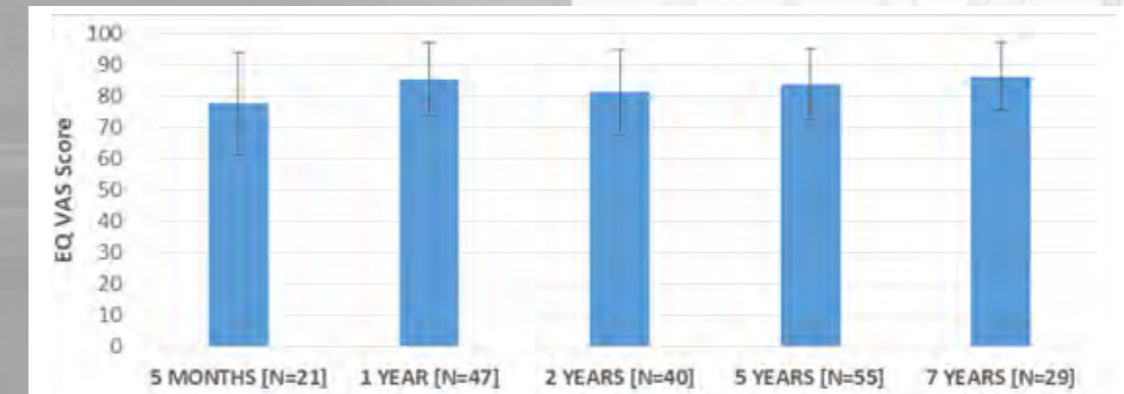


Figure 6. Satisfactory mean EQ VAS Scores have been maintained at five postoperative time



Survivorship

100% survivorship at 8 years



Satisfaction

Satisfactory patient-reported function, quality of life, return to functional activities, and pain levels at midterm follow-up

Profemur® Gladiator Cemented Femoral Stem

All data on file with MicroPort

Introduction

As of 04 February 2020, there have been 95 hips implanted with the Profemur® Gladiator cemented femoral stem in company-sponsored studies located in the United States (Site 1) and Germany (Site 2) and included for analysis. As shown below, there are 75 hips from Site 1 and 20 hips from Site 2 included in the analysis.

There have been 5 revisions reported at Site 1 resulting in a survivorship of 96.8% at 5.5 years postoperatively, with any reason requiring removal of the stem or neck as the endpoint. There were no confirmed cases of femoral component loosening.

At Site 1 (United States), patient-reported outcome measures (PROMs) have been collected at two postoperative time windows: 2-5 years (early) and 5-7 years (midterm). At Site 2 (Germany), PROMs have been collected at 2-5 years postoperatively (early visit). The PROMs scores presented indicate satisfactory function, quality of life, and pain levels at the early postoperative visit. At Site 1 (United States), PROMs scores have been maintained through the latest midterm visit.



Figure 7. Satisfactory mean Oxford Hip Scores for Site 1 (United States) and Site 2 (Germany) were obtained at the early postoperative visit. These scores have been maintained at Site 1 (United States) at the midterm visit.

Hips 75
Age (years)
 71.75 ± 7.46
 (range, 55.8-92.5)
BMI (kg/m²)
 30.58 ± 7.44
 (range, 20.84-55.72)

Site 1 United

Hips 20
Age (years)
 74.53 ± 4.23
 (range, 66.6-85.5)
BMI (kg/m²)
 26.31 ± 3.88
 (range, 20.08-32.42)

Site 2 Germany

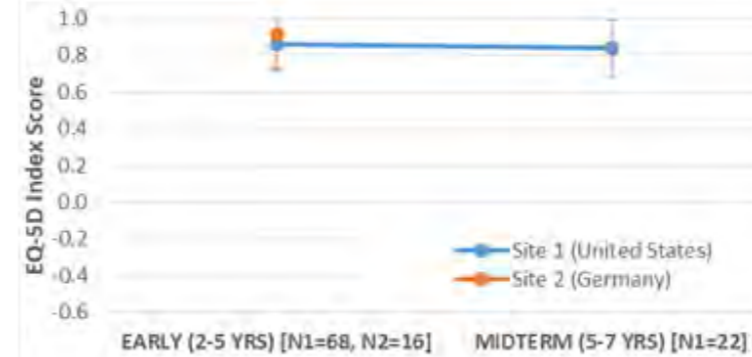


Figure 8. Satisfactory mean EQ-5D Index Scores for Site 1 (United States) and Site 2 (Germany) were obtained at the early postoperative visit. These scores have been maintained at Site 1 (United States) at the midterm visit.

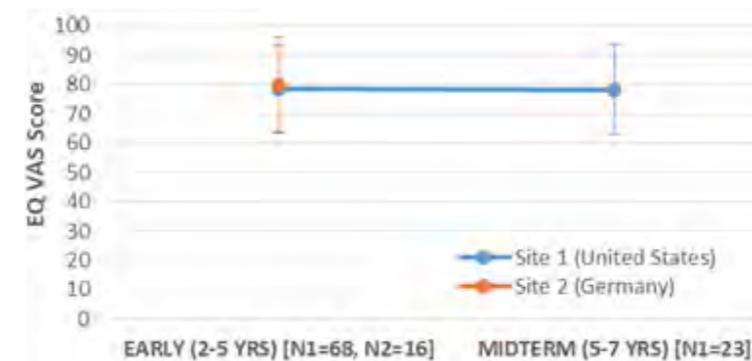


Figure 9. Satisfactory mean EQ VAS Scores for Site 1 (United States) and Site 2 (Germany) were obtained at the early postoperative visit. These scores have been maintained at Site 1 (United States) at the midterm visit.



Satisfaction

No confirmed cases of femoral component loosening out to 5 years



Satisfaction

Satisfactory patient-reported function, quality of life, return to functional activities, and pain levels at midterm follow-up

References

1. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Automated Industry Report System (AIRS), ID No. 3178 for MicroPort Orthopedics, Profemur Gladiator Total Conventional Hip, (Procedures from 27 July 2012 – 26 August 2020), Accessed 13 October 2020, AOA, Adelaide: 1-19.



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