Profemur® Xm

Clinical Data

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Introduction

The Profemur® X^{m} and Exeter® (Styker™) stems both feature dual-tapered, collarless, force-closed geometries. Both stems are highly polished and are implanted with a complete circumferential cement mantle. The Profemur® X^{m} and Stryker™ Exeter® stems feature equivalent design features (Table1) and equivalent RSA and FEA outcomes[4-5]. It can therefore be expected that the Profemur® X^{m} will demonstrate a similar long term clinical performance as the Exeter®.

Table 1:
Comparison of design features of Profemur® X^{m} and Stryker™ Exeter® femoral stems[3]

	Profemur® X^{m}	Exeter®
Geometry	Dual Tapered, trapezoidal cross section proximally, force-closed design, collarless	Double tapered, rectangular cross section, force-closed design, collarless
Surface Finish	Highly Polished	Highly Polished
Material	CoCrMo alloy (ASTM-F1537/ISO-5832-12)	Stainless Steel (REX 734, Orthinox®)
Fixation Method	Cemented (2mm circumferential cement mantle)	Cemented, uniform cement mantle distribution
Dimensions / Size	5 sizes: (size 0 to size 4) ranging from 133mm to 149mm in length and from 29.3mm to 51.1mm in offset*	**9 'Central Range' options:** 2 CDH stems, 3 with 37.5mm offset, 4 with 44mm offset **14 'Extension To Central Range' options:** 1 with 30mm offset, 1 with 33mm offset, 1 with 37.5mm offset, 2 with 44mm offset, 4 with 50mm offset, 5 long stems
Modularity	Yes	No

The Stryker™ Exeter® has an extensive record of long-term (>10 years) survivorship. In a study from the hospital where the Exeter® stem originated, the survivorship of this stem was found to be 93.5% at an average follow-up of 30.6 years[1] . Further, national joint registries have reported good clinical outcomes of the Exeter® stem out to 13 years. The 2009 Danish registry[2] reported a 13 year survival of over 11,000 patients with this stem between 91.5% and 94.2%.

ODEP is the Orthopedic Data Evaluation Panel which reviews hip products clinical submissions.
ODEP rates the strength of the presented clinical data resulting in a rate. The Profemur® X^{m} has been awarded a 3A score. 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.

3
3 years of evidence: product is on-track to achieve the 10 year benchmark, but has not yet got sufficient data to evidence performance at 10 years.

A
strong evidence: generally higher numbers of patients (giving greater confidence in the results presented), with all patients being subject to follow-up .

150 implants have a minimum of three years follow up and show actual revision rates of less than 3%.

** Offset calculation excluding Long Varus 8° neck.*

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The design features of cemented femoral hip implants.

Scheerlink T., Casteleyn P.,
Journal Bone & Joint Surgery 2006; 88-B; 1409-18.

Summary

Cemented femoral implants have been developed to function either as loaded-tapers (force-closed fixation) or composite-beams (shape closed fixation).
A force-closed fixation design may act as a taper within the cement, where fixation is achieved through the forces across the interface and bonding between stem and cement is not necessary.
A shape- closed design is one in which the stem achieves fixation at the stem-cement interface through a match in the shapes of the surfaces of the stem and the cement with the cement gripping the surface of the stem.
Although in vivo both concepts of stem fixation proved to be effective, they cannot work together.
It is important to understand on which principle a particular stem relies.

Loaded-taper stems become lodged as a wedge in the cement mantle during axial loading. The stem is allowed to subside until compressive forces are created in the cement and transferred to the bone.
In the composite-beam philosophy, the stem needs to be rigidly bound to the cement and subsidence needs to be avoided not to damage the cement mantle.

Loaded-taper stems (as the Profemur® X^{m}) feature tapered design, no collar, thick circumferential cement mantle, highly polished surface finish to promote stepwise subsidence within the cement and reduce metal and cement debris generated at the cement-stem interface.
For the composite-beam designs, stability is optimized by features such as medial collar, thin cement mantle, rectangular cross-section and rough surface to increase the cement-stem bonding.

Authors conclude that both design principles are capable of producing successful long-term results, providing that the specific requirements of stem metallurgy, shape and surface finish, bone preparation and cement-handling are observed.

Effect of modular neck variation on bone and cement mantle mechanics around a total hip arthroplasty stem.

Simpson DJ, Little JP, Gray H, Murray DW, Gill HS.,
Clinic Biomech 2009 Mar;24(3):274-85.

Summary

Finite element models of a whole femur implanted with either the Exeter® or with a cemented modular-neck total hip stem (Profemur® X^{m}) were developed. The changes in bone and cement mantle stress/strain were assessed for varying amounts of neck offset and version angle for the modular-neck device for two simulated physiological load cases: walking and stair climbing.

The average cement stress at the calcar and implant tip showed minimal variation between the modular neck models and the Exeter® for the two physiological conditions, and were well below the fatigue strength of the cement mantle.

The authors found no differences between the Profemur® X^{m} and Stryker™ Exeter® femoral stems with regards to any variable tested.

These results suggest that the Profemur® X^{m} transmits stress/strains to the surrounding cement mantle and bone in a similar manner to the Exeter®, a well-established cemented polished THA stem.
The Profemur® X^{m} could be expected to have a similar clinical performance to the Exeter®, while providing the additional advantage of increased modularity.

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A prospective clinical RSA study to evaluate fixation of the Profemur® Xm Modular Femoral Stem. One Year results.

Gross, M. et al
40th Annual Meeting of the Eastern Orthopaedic Association. 2009

Summary

In 2009, early (1 year minimum) results of a radio-stereometric analysis (RSA) of 25 patients that received a Profemur® Xm femoral stem were presented and compared to historical data of the Stryker™ Exeter® femoral stem.

Primary outcome measure was stem micro-motion measured using Model-based RSA. Stereo supine X-rays were taken 2 days and 3, 6, and 12 months after surgery.

At 1 year the femoral stems had subsided 0.7mm (SD=0.7mm), migrated posteriorly 1.0mm (SD=1.5mm), and migrated laterally 0.1mm (SD=0.33mm).

The authors found that the initial stability of the Profemur® Xm femoral stems (stem subsidence, posterior migration, and medial migration) was not significantly different from published findings of the Stryker™ Exeter®.

Metal Ion levels in ceramic-on-ceramic THR with modular necks: analysis of cobalt and chromium levels in 30 healthy hip patients.

Somers J, Hip Int. 2015 Sep-Oct;25(5):484-7

Summary

Serum ion levels were measured in healthy volunteers with well-functioning ceramic-on- ceramic THR.
The patients (32 hips) had an hybrid THR with Profemur® Xm (CoCr modular stem), Procotyl® L with ceramic on ceramic bearing (max head diameter 36mm) and Titanium Profemur® modular necks.
The cohort of patients consisted of 20 females and 10 males, with an average UCLA activity score of 7/10 and a minimum follow up of 12 months after implantation.

The average metal ion values were:

1. Cobalt:	1.20 µg/l (0.8-2) in the short neck group (10 THRs)
	1.26 µg/l (<0.5-2) in the long neck group (22 THRs)
	1.21 µg/l overall average for unilateral THR
	Two bilateral THRs (all with Long necks): 2.0 and 2.4 µg/l
2. Chromium:	None of the samples had quantifiable levels of chromium (<0.5 µg/l)

No safe limits for Cobalt and Chromium levels have been published on THR.
For hip resurfacing, safe limits have been established to be <4 µg/l for Cobalt and <4.6 µg/l for Chromium.
In a randomly selected group of patients with well-functioning THAs (hybrid THR Profemur® Xm and Procotyl® L with Titanium modular necks) excellent short-term clinical outcomes were observed with no evidence of abnormal serum Cobalt or Chromium levels.

Referemces:
1. Ling, R.S., et al., The long-term results of the original Exeter polished cemented femoral component: a follow-up report. J Arthroplasty, 2009. 24(4): p. 511-7.
2. Danish Hip Arthroplasty Register 1995-2008. 2009; Available from: http://www.dhr.dk/.
3. Stryker_Corporation. Stryker Exeter Total Hip System. Available from: http://www.stryker.com/en-us/products/Orthopaedics/HipReplacement/Primary/Cemented/ExeterCemented/index.htm.
4. Simpson DJ1, Little JP, Gray H, Murray DW, Gill HS., Effect of modular neck variation on bone and cement mantle mechanics around a total hip arthroplasty stem. Clinic Biomech 2009 Mar;24(3):274-85.
5. Gross, M. et al;A prospective clinical RSA study to evaluate fixation of the Profemur® Xm Modular Femoral Stem. One Year results.
6. Scheerlink T., Casteleyn P.,Journal Bone & Joint Surgery 2006; 88-B; 1409-18.
7. Somers J, Hip Int. 2015 Sep-Oct;25(5):484-7.

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