THE HIGH PERFORMANCE MODULAR HIP: *WHAT A SURGEON SHOULD KNOW*

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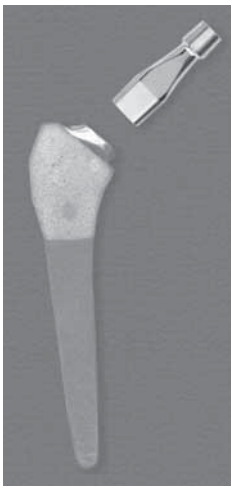
INTRODUCTION

Modularity in total hip arthroplasty design has received increased citation in the clinical literature. The advantages of these systems include off-the-shelf flexibility for customizing proximal and distal canal filling, preservation of soft tissue structures, biomechanical restoration of offset, version and leg length, as well as accommodating difficult situations of femoral deformity and bone loss.

Example of mid-stem modularity (Link MP)

Both mid-stem and distal neck modular femoral systems have been successfully employed for a variety of patient skeletal pathology.[1,3,4,11-13] However, they are not without clinical concerns. The maintenance of anatomical stability within the femoral canal, structural compromise at metal-metal interconnections due to cyclic microdisplacements defined as fretting, decoupling of components *in vivo*, and increased potential for metallic wear debris generation and corrosion have all been reported.[2,5,6,10,14,15]

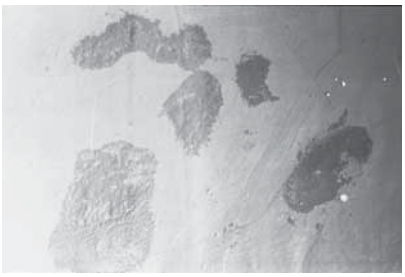
This exhibit describes a laboratory basis for the evaluation of modular femoral stem designs and suggests a thought process when considering their employ.



Example of distal neck modularity (ProFemur Z)

METAL-METAL MODULARITY

The nature of modular hip systems is manifest through a series of interconnected metal-metal junctions involving the use of tapers. These are seen to be a structural weak link in comparison to their nonmodular counterparts due to surface damage resulting from microdisplacements at these interfaces under dynamic *in vivo* loading. This is referred to as fretting, which creates foci for crack initiation and is a first step in the sequela leading to component fracture. Component weakening can be further catalyzed through *in vivo* corrosion processes at these locations.



Scanning Electron Microscopy (SEM) displaying material loss on a metal-metal taper interface resulting from cyclic microdisplacements (x15 magnification)

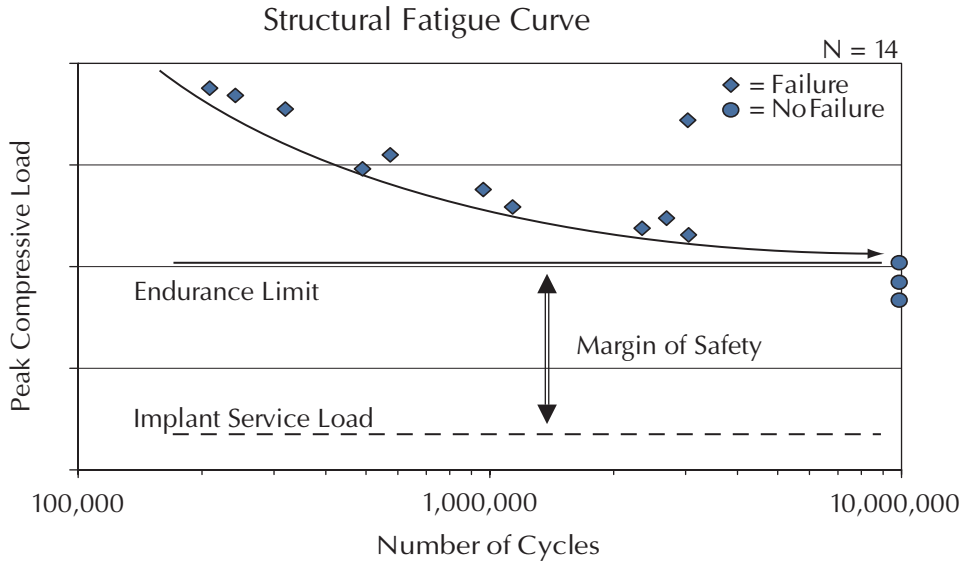
LABORATORY EVALUATION

In the laboratory setting, components are mounted to evaluate the strength of taper connections under cyclic loading in a physiologic orientation and environment.[7-9] Multiple femoral stems of the particular design are evaluated under sinusoidal load profiles at decreasing amplitude until fracture or 10 million cycles. The number of cycles and peak load are then plotted to create a structural fatigue curve particular to each implant design.

In the below idealized graph for a given design, the **endurance limit** defines the maximum cyclic load an implant system can support and theoretically never fail. For these studies, it is the largest load at which 10 million, uninterrupted cycles occur without device failure.

The **implant service load** is the maximum *in vivo* dynamic load on the hip during walking gait. Its value is dependent on the variables of patient weight, walking speed and stride length.

For this particular example of the Link MP, the level of potting approximates the distal end of the taper to appreciate its structural integrity



The **margin of safety** is the difference between the endurance limit and the implant service load. When presented as a ratio and referred to as the safety factor, it serves as a predictor of implant structural integrity. Increasing patient body weight (BW) and activity level serve to increase the implant service load while the impact of fretting and corrosion is seen to decrease the endurance limit at modular connections.

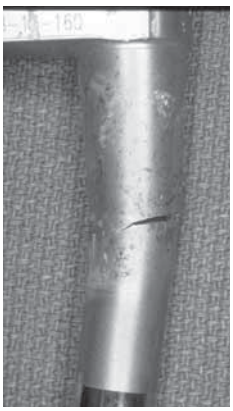
$$\text{Safety Factor} = \frac{\text{Endurance Limit}}{\text{Implant Service Load}}$$

↑ BW & Activity Level = ↑ Implant Service Load

↑ Fretting & Corrosion = ↓ Endurance Limit

Failure modes for modular femoral stem designs being subjected to dynamic loading conditions may be characterized as either **mechanical** or **functional**. The former describes component damage within the modular connections (i.e. fretting) that does not detract from the device's ability to continue supporting the implant service load. When the device no longer allows patient function and requires revision, this is referred to as a functional failure. Mechanical failures observed in the laboratory setting are usually predictive of locations for potential functional failure within the *in vivo* loading environment.

These are examples of laboratory induced fretting failures for contemporary, mid-stem and distal neck modular femoral stem designs.



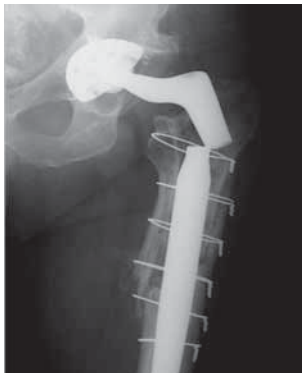
A close-up view of a fretting-induced fracture site for the S-ROM

A close-up view of a fretting surface for the Link MP

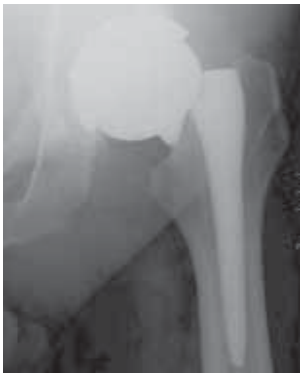
A close-up view of a fretting-induced fracture site for the ProFemur

CLINICAL REALITIES

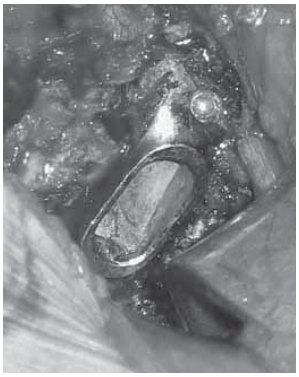
The following examples depict *in vivo* scenarios where mid-stem and distal neck modular interconnections have structurally failed. They can be traced to variables of design and material, patient habitus, and technical proficiency.

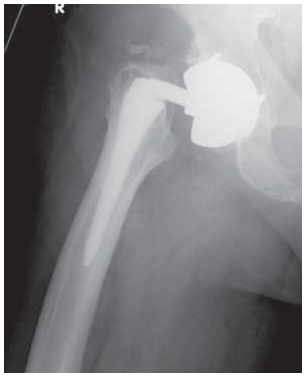


CASE 1 - A clinical example of a distally fixed, mid-stem modular, titanium alloy, revision system. Device fracture is observed at the taper junction. Cerclage wiring and strut allografts failed to achieve bone containment in the taper area and provide the needed anatomic support. A large patient BMI and femoral offset coupled with activity compounded the issue.



CASE 2 - A clinical example of a distal neck, modular, titanium alloy, primary system. Device fracture is observed at the neck/stem junction two months after a fall. This device survived in situ in this 340 lb patient 4 years before the trauma. The view of the stem/neck junction describes fretting and corrosion at the interface.[15]





CASE 3 – A clinical example of a distal neck modular, titanium alloy, primary system. Device fracture is observed at the neck/stem junction. A long varus neck coupled with a BMI of 34.2 and moderate activity contributed to device failure at 29 months in situ.

These above situations are clearly **functional** failures of the modular implant system chosen and subsequently required revision.

WHAT A SURGEON SHOULD KNOW

The clinical advantages of modular hip designs permit their use for the solution of difficult reconstructive problems where canal dimensional abnormalities, bone loss and deformity exist. But coincident with their advantages, concerns relative to design structural integrity, stability and debris generation have been continuously cited since their introduction.

Pre-clinical laboratory evaluations, although meeting the standards set by regulatory bodies, do not always appreciate the extremes of patient factors, particularly BMI, activity level and anatomy, encountered by the orthopaedic surgeon. The ultimate *in vivo* success of their employ relies on the surgeon's appreciation of the limitations of a particular modular device and its required technical proficiency.

The following six propositions describe a thought process informed clinicians should consider when choosing a total hip system for a particular patient.

1. Does the presenting pathological anatomy preclude the use of a nonmodular femoral stem?

2. If a modular femoral stem is chosen, what is the optimal design configuration: mid-stem, distal neck or both?

3. What information has the medical device manufacturer provided in addition to the peer-reviewed literature that indicates device longevity and failure scenarios? How do these match with your particular patient characteristics?

4. Has the device been mechanically evaluated in the prescribed configuration (i.e., stem size, neck length, version)? Is the anticipated *in vivo* environment likely to supersede the safety factor of the device?

5. Are there labeling restrictions for the device? Have there been any regulatory warnings or recalls issued due to premature *in vivo* failures? If so, have the design and/or materials been altered?

6. In today's healthcare climate where cost-effective medicine is the theme, it is important to weigh not just the cost of the implant, but the effectiveness of the femoral stem to correct the presenting pathology, restore stable joint biomechanics, and avoid the prospect of revision surgery.

The above remarks are intended to increase surgeon awareness of how modular femoral stem devices are evaluated and to assist the thought process when considering their use.

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