FEMORAL NECK MODULARITY IN THA: NOT A BRIDGE TOO FAR?

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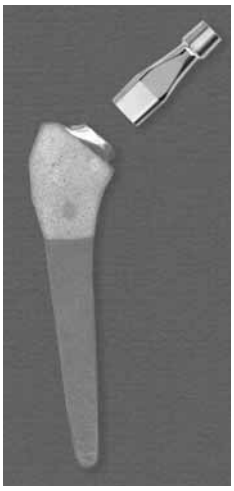
INTRODUCTION

Femoral neck modularity in total hip arthroplasty design is receiving increased citation in the clinical literature. The advantages of these systems include a potential reduction in the occurrence of femoro-acetabular impingement and its consequences as well as an ability to optimize leg length, version and offset.[1,3,13,14,15]

While modular femoral neck systems have been successfully employed for a variety of patient skeletal pathology, they are not without clinical concerns. Their structural compromise at metal-metal interconnections due to cyclic microdisplacements, component disassociation *in vivo*, and increased potential for metallic wear debris generation and corrosion have all been reported along with tissue reactivity surrounding the tapers.[2,4-8,12,16-22] Whether the cited benefits of deformity and biomechanical correction, tissue preservation and revision options outweigh these risks is a consideration in their selection.

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



Example of a modular femoral neck (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 may be further catalyzed through *in vivo* corrosion processes at these locations.

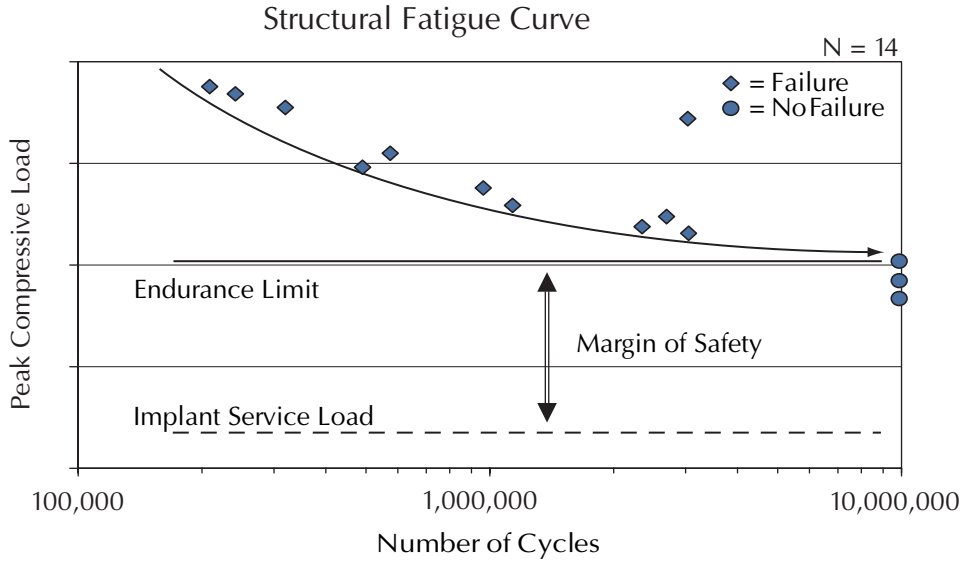
Scanning Electron Microscopy (SEM) displaying material loss on a metal-metal taper interface resulting from cyclic microdisplacements (x15 magnification)

LABORATORY EVALUATION

In the laboratory setting, components are mounted to evaluate the durability of taper connections under cyclic loading in a physiologic orientation and environment.[9-11] Multiple femoral necks 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 modular neck design.

In the below idealized graph for a given design, the **endurance limit** defines the maximum cyclic load a modular femoral neck 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 variables of patient weight, walking speed and stride length.



The **margin of safety** is the difference between the endurance limit and the implant service load. When presented as a ratio, it represents a **safety factor** for a particular implant and 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 decreases 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

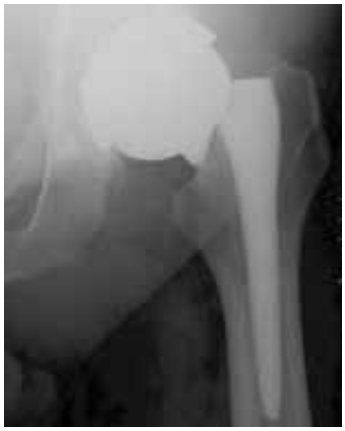
Failure modes for modular femoral neck designs being subjected to dynamic loading conditions may be characterized as either **mechanical** or **functional**. The former describes component damage within the modular connections (i.e. fretting) that does not influence the device's ability to continue supporting the implant service load. When the device no longer allows patient function, requiring revision, it is termed 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.

A close-up view of a laboratory-induced fretting failure for the ProFemur

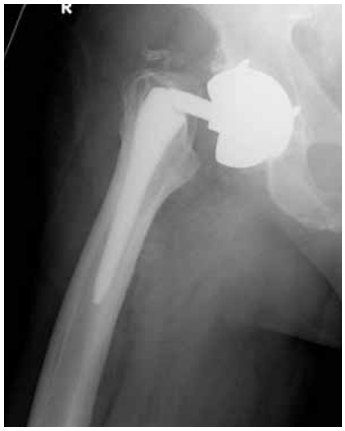
CLINICAL REALITIES

While patented modular femoral neck designs have been utilized successfully since the early 1990s, contemporary design variants offered by medical device manufacturers have reported clinical failure rates that have resulted in international device recalls and regulatory agency monitoring. With the increased use of modular femoral necks, several design and patient factors have been identified as contributing to their *in vivo* fracture including the aspect ratio of the neck width in relation to its length, the use of mixed or same metal taper connections, patient activity level as well as device offset and version required to restore hip joint biomechanics.[4,8,12,19,21,22] In addition, the observation of adverse local tissue responses (ALTR) in patients with metal-metal interconnections further compromised by corrosion, raises concerns about their continued employ by hip arthroplasty surgeons.

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



CASE 1 - A clinical example of a modular femoral neck, 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.[22]



CASE 2 – A clinical example of a modular femoral neck, 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.

The above situations are clearly **functional** failures of the modular femoral neck implant chosen, subsequently requiring revision.

WHAT A SURGEON SHOULD KNOW

The clinical advantages of modular femoral neck designs permit their use as a solution option for difficult reconstructive problems where anatomic variability exists. But coincident with their advantages, concerns relative to design structural integrity, *in situ* corrosion, stability and debris generation have been continuously cited since their introduction.

Pre-clinical laboratory evaluations, although meeting the standards set by regulatory bodies at the time of device approval, require the tincture of *in vivo* clinical time to fully appreciate unknown or unanticipated responses. This coupled with the extremes of patient factors, particularly BMI, activity level and anatomy, encountered by the reconstructive orthopaedic surgeon results in laboratory evaluative and clinical algorithms which help to determine device selection. The ultimate *in vivo* success of modular femoral neck employ relies on the surgeon's contemporary appreciation of the above as well as the 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 neck is chosen, what is the optimal design configuration?

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 neck 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 neck devices are evaluated and to assist the thought process when considering their use.

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