



FEMORAL STEM MODULARITY: DO THE TESTING STANDARDS ADDRESS THE CLINICAL CONCERNS?

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INTRODUCTION

Femoral head modularity in total hip arthroplasty (THA) design emerged in the 1970's as an alternative to monolithic stem designs to overcome the disadvantages of limited head size and offset availability. Through the use of tapers, modularity has evolved and includes the femoral neck and stem to provide 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.^{1,4,5,7,23-25}

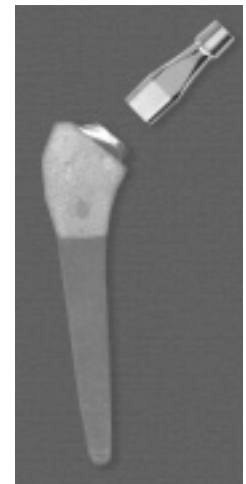


Example of mid-stem modularity (Link MP)

While modular femoral stem designs have been successfully employed for a variety of patient skeletal pathology, they are not without clinical concerns. The maintenance of anatomical stability within the femoral canal, structural compromise at taper interconnections due to cyclic microdisplacements, and component disassociation have all been reported along with pain and tissue reactivity surrounding the tapers.^{2,3,8-14,20,22,27-30,32-34}

With the increasing citations in the peer-reviewed literature regarding adverse local tissue reactions (ALTR) and taper degradation for modular femoral stems, junction design parameters and bioinert materials including ceramics, titanium nitride/aluminum nitride (TiN/AlN) coatings and oxidized zirconium are being investigated as potential solutions.^{18,19,21,26}

This exhibit describes a set of test parameters, based on clinical and scientific evidence, to produce a clinically relevant and laboratory-based evaluation for modular femoral stem designs.

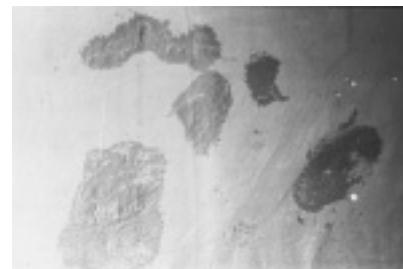


Example of distal neck modularity (ProFemur Z)

THE QUESTION

“Do the pre-clinical testing standards utilized by regulatory agencies to determine whether devices are safe and effective address the clinical realities?”

The taper interconnections utilized in modular femoral stem designs are seen to be a structural weak link in comparison to their monolithic counterparts due to surface damage resulting from microdisplacements at these interfaces under dynamic loading. The definitions on the following page assist appreciation of the subsequent commentary and the complexity involved in evaluating modular femoral stem designs in a laboratory setting.



SEM displaying material loss on a metal-metal taper interface resulting from fretting (x15 magnification)

Wear	<i>damage to a solid surface, generally involving progressive loss of material, due to relative motion between two contacting surfaces.</i>
Fretting	<i>small amplitude oscillatory motion between two solid surfaces in contact.</i>
Fretting Wear	<i>wear arising as a result of fretting.</i>
Corrosive Wear	<i>wear in which chemical or electrochemical reaction with the environment is significant.</i>
Fretting Corrosion	<i>the deterioration at the interface between contacting surfaces as the result of corrosion and slight oscillatory slip between the two surfaces.</i>
Crevice Corrosion	<i>localized corrosion of a metal surface at, or immediately adjacent to, an area that is shielded from full exposure to the environment because of close proximity between the metal and the surface of another material.</i>
Passive (Oxide) Layer	<i>a thin layer of oxide alloy which is extremely durable, inert and corrosion resistant.</i>
Repassivation	<i>regeneration of the oxide layer that was destroyed through abrasion and fretting corrosion.</i>



A clinical example where fretting and corrosion are visible on the stem/neck junction.

PRE-CLINICAL TESTING STANDARDS

The American Society of Testing and Materials (ASTM) and the International Organization for Standardization (ISO) continually develop testing standards that evaluate parameters that will potentially influence the durability of medical devices *in vivo*. Particular to femoral stem designs, these standards include the structural endurance of the entire construct (*ISO 7206-4:2010 - Implants for surgery -- Partial and total hip joint prostheses -- Part 4: Determination of endurance properties and performance of stemmed femoral components*) and the fretting corrosion testing of taper junctions (*ASTM F1875:2009 - Standard practice for fretting corrosion testing of modular implant interfaces: Hip femoral head-bore and cone taper interface*).

With regards to ASTM F1875:2009, two methods are described to evaluate the resistance of a modular femoral hip stem design to wear associated with fretting and corrosion:

1. Short-term *in vitro* testing that is useful to assess the potential of wear due to changes in taper fit, not materials, during device development.
2. Long-term *in vitro* testing to produce damage to and debris from a taper interconnection.

The following discussion focuses on the below test parameters associated with the long-term testing.

Mounting position	<i>ISO 7206-4:2010</i>
Cyclic Load	<i>1800N ± 1500N (Sinusoidal; R=10)</i>
Testing Frequency	<i>5 Hz</i>
Duration	<i>10 Million Cycles</i>
Testing Medium	<i>Proteinaceous solution consisting of 10% solution of calf serum in 0.9% NaCl in distilled water at room temperature.</i>
Visual analysis	<i>Optical microscopy and scanning electron microscopy (SEM).</i>
Gravimetric analysis	<i>In cases where the weight of the specimen(s) is small enough, weight loss may be evaluated by microbalance.</i>
Lubricant analysis	<i>The total amount of metal release can be calculated by multiplying the concentration of measured species by the total fluid volume.</i>

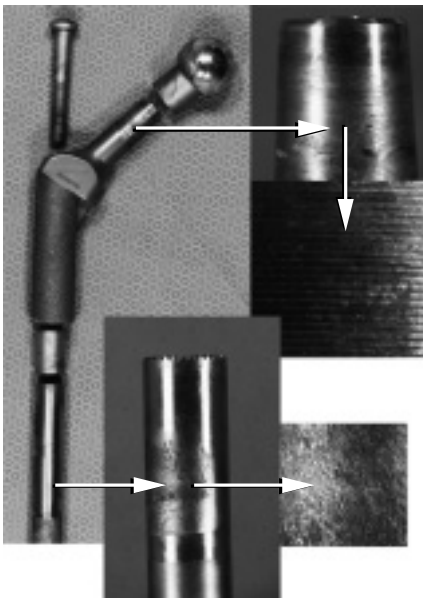
THE SHORTFALLS

In reviewing the test parameters stated in the table and recognizing that standards are developed through consensus while ensuring that multiple testing laboratories can perform the evaluation, basic science studies should continue to strive to align pre-clinical testing standards with clinical outcomes.

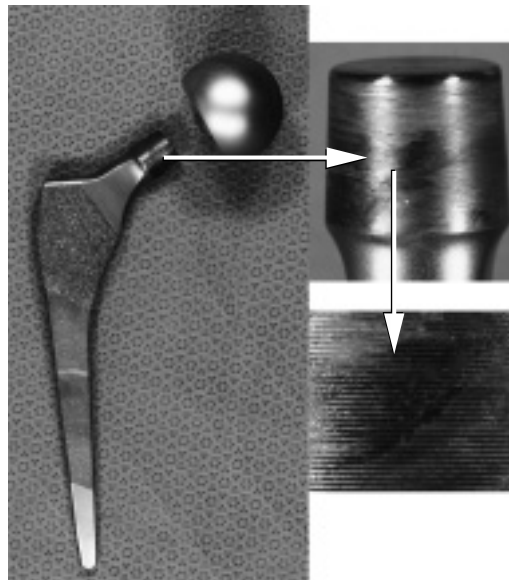
Researchers have determined that (a) the load required to initiate the fretting and (b) proper assembly of the taper interconnections in conjunction with (c) a relevant number of testing cycles are all important testing variables when studying corrosion.³¹ ASTM F1875:2009 addresses the latter two parameters (b and c), but does not address variable loading magnitudes which should be considered to appreciate differences between the “initial loading” conditions up to 1 million cycles and the subsequent cycles where particulate debris has now become trapped in the crevices, changing the fretting and corrosion properties of the taper.¹⁷

The repassivation time for both Ti-alloy and CoCr-alloy materials have been studied^{15,18} and balancing testing frequencies to simulate anticipated *in vivo* loading while optimizing evaluation duration to not create anomalies is challenging.^{6,31} Beyond that, what is not addressed within the testing standard is the inclusion of dwell periods. For any given patient, periods of rest or unloading exist on a daily basis and have been shown to influence crevice corrosion in these materials.¹⁷

Examples of high frequency, laboratory-induced fretting evaluations performed at 10 Hz and 15 Hz, respectively, in distilled water at 37 degrees Celsius for 10 million cycles, clearly demonstrate the occurrence of surface damage on the taper connections. While these evaluations were not specifically performed for corrosion, surface phenomena that align with clinical findings are apparent.¹⁶



Close-up views of laboratory-induced fretting on modular femoral stem taper connections after 10 million cycles at 10 Hz.



Close-up views of laboratory-induced fretting on a femoral neck-stem taper connection after 10 million cycles at 15 Hz.

These findings along with those of other researchers indicate that a balance between a testing frequency above 5 Hz and the implementation of dwell periods could be adopted without an increase in cost or time to medical device manufacturers and provide more clinically relevant data to predict long-term *in vivo* device durability.

Overall, ASTM F1875:2009 serves as a basis for fretting corrosion determination for taper connections, no matter their location for a given femoral stem design or materials utilized. However, the parties involved in determining the safety and effectiveness of these devices need to realize that testing parameters should be flexible to best address a given situation while continually reviewing the basic science and clinical literature for relevance.

CONCLUSION

The clinical advantages of modular femoral stem 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, debris generation and ALTR have been continuously cited since their introduction.

Pre-clinical laboratory evaluations, although meeting the standards utilized by regulatory bodies to determine safety and effectiveness, do not always align with the observations encountered by the orthopaedic surgeon in the clinical setting. Researchers should continue to analyze device retrieval data with the goal of optimizing the testing standards to more accurately predict long-term, *in vivo* device durability.

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