



FEMORAL STEM FATIGUE CHARACTERISTICS OF MODULAR HIP DESIGNS - SERIES II

Orthopaedic Research Laboratories
The Mt. Sinai Medical Center
Cleveland, Ohio 44106

Christine S. Heim, B.Sc.
Paul D. Postak, B.Sc.
A. Seth Greenwald, D.Phil.(Oxon)

INTRODUCTION

Modularity in total hip arthroplasty design is an evolving concept that is receiving increased citation in the clinical literature. The advantages of these systems include off the shelf flexibility for customizing proximal and distal canal filling as well as accommodating difficult situations of femoral deformity and bone loss.

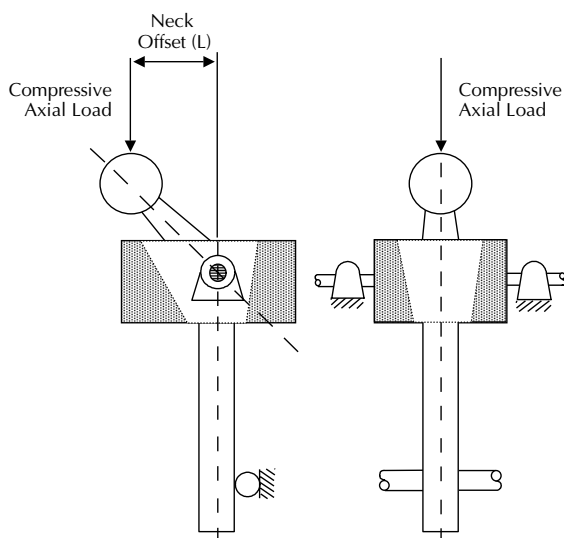
Clinical concerns in the application of modular hip designs include the maintenance of anatomical stability within the femoral canal, structural compromise at metal-metal interconnections due to cyclic microdisplacements (fretting) and increased potential for metallic wear debris generation.

This study determines the structural integrity of four contemporary modular hip designs in terms of their fatigue behavior.

MATERIALS AND TESTING METHODOLOGY

The designs studied include the **IMPACT** which allows for femoral neck retention, the **INFINITY** and the **S-ROM** which require femoral neck sacrifice and the **RMHS** which provides proximal and distal augmentation components.

These designs rely on *in vivo* proximal support to achieve clinical longevity. The fatigue evaluation required the use of a closed loop servo hydraulic Materials Testing System and a customized test assembly which provided proximal support under dynamic loading conditions.



TEST ASSEMBLY

The proximal portion of each stem was rigidly fixed in acrylic across all porous coated surfaces to simulate optimal anticipated bone contact. All mounts were circumferential with **INFINITY** and **RMHS** utilizing a relief material to exclude non-porous coated surfaces.

The components were mounted with an A-P rotational axis that passed through the intersection of the neck and stem axes in neutral anteversion. A sinusoidal loading sequence was applied parallel to the stem through the femoral head. A simple distal support counters the loading moment about the A-P axis, allowing maximum bending stresses to occur on the lateral side of the component.

Multiple femoral stem systems of each design were evaluated at decreasing sinusoidal load profiles, one profile per stem, until failure or 10 million cycles. The number of cycles and peak load were plotted on a semi-log scale to create a structural fatigue curve particular to each implant design.



Pre-Op

IMPACT Modular Hip System

The **IMPACT** Modular Hip System offers modularity with femoral neck retention through a variety of metaphyseal and diaphyseal components. The outer geometry of the metaphyseal section provides proximal anatomic stability and allows variable stem anteversion through a Morse taper. Distal cutting flutes assist rotatory stability with diaphyseal fit achieved through a coronal slot configuration.

The system's versatility is appreciated in this primary total hip arthroplasty performed on a 41 year old, female patient with CDH. A complex reconstruction requiring both shortening and correction of a severe proximal rotational deformity was facilitated through a transverse osteotomy. The **IMPACT** stem permits the distal femur to maintain normal alignment while the metaphyseal component allows independent rotation of the proximal femur correcting the deformity and restoring more normal hip mechanics. The true acetabulum has been reestablished and appreciation of Shenton's arc is observed. Modularity in this instance has permitted the uncoupling of a complex skeletal deformity.

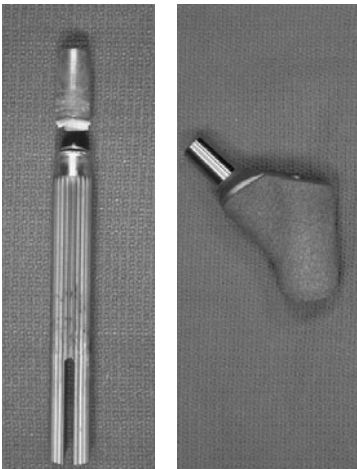
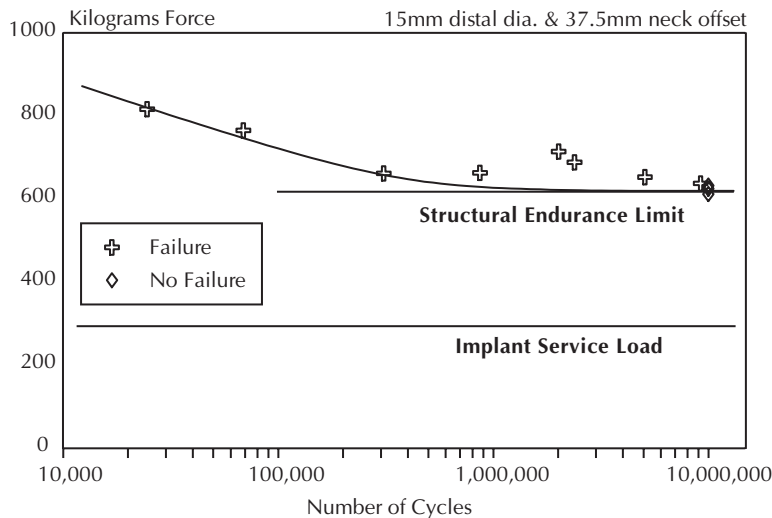


Post-Op

IMPACT Modular Hip System

Structural Fatigue Curve

In Vitro Fatigue Evaluation

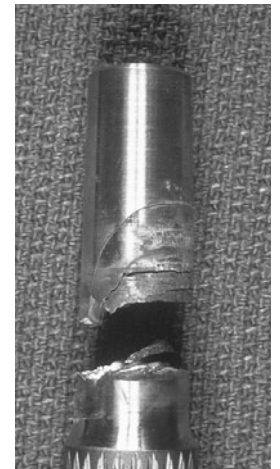


M-L view of a failed diaphyseal component. A proximal component is also shown.

The structural fatigue curve for the **IMPACT** system evaluated indicates an endurance limit 2.1 times the implant service load.

In the majority of cases, stem failure occurred slightly proximal to the distal end of the metaphyseal component, within the Morse taper and initiated across a lateral fretting surface.

In this study, the **IMPACT'S** margin of safety suggests that the fretting induced failure should not influence the device's longevity during *in vivo* service loading for a 74 kg_p (163 lb_p) patient. As the weight of the patient increases the margin of safety will be reduced for this size implant.



A close-up antero-lateral view of the fracture site.



Post-Op

INFINITY Modular Hip System

The **INFINITY** Modular Hip System provides modularity through a variety of trochanteric and distal stem modules. Femoral stem assembly is achieved through a Morse taper angled at 27 degrees which approximates a resultant hip joint force vector. Variable anteversion and A-P proximal canal fill is assisted by rotational displacement of the trochanteric component. Distal grooves assist rotatory stability in the diaphysis.

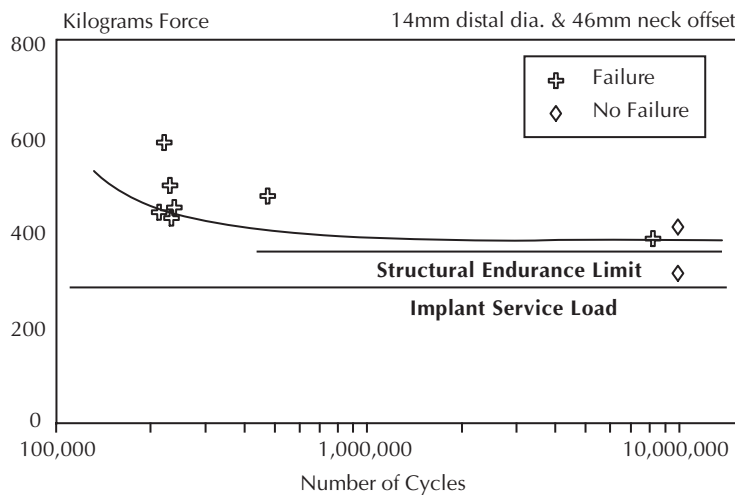
The system's versatility is appreciated in this primary total hip arthroplasty in a 65 year old, male patient with severe DJD. An **INFINITY** hip system was utilized to achieve independent endosteal canal fit in the metaphysis and diaphysis. At two years, DEXA scans revealed minimal bone loss in the calcar regions which is indicative of good proximal stress transfer. The absence of radiolucent lines and distal pedestal ledges suggest device stability.



Post-Op

In Vitro Fatigue Evaluation

INFINITY Modular Hip System Structural Fatigue Curve



The structural fatigue curve for the **INFINITY** system evaluated indicates an endurance limit 1.3 times the implant service load.

All cases of stem failure initiated across a lateral fretting surface at the mid-height of the Morse taper.

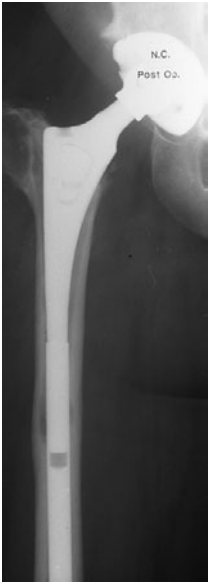
In this study, the **INFINITY'S** margin of safety suggests that the fretting induced failure should not influence the device's longevity during *in vivo* service loading for a 74 kg_f (163 lb_f) patient. As the weight of the patient increases the margin of safety will be reduced for this size implant.



A-P view showing a failed device.



A close-up antero-medial view of the fracture site.



Post-Op

RMHS Modular Hip System

The **RMHS** Modular Hip System provides femoral canal stability through utilization of a series of proximal, anterior and posterior augmentation pads used in conjunction with a range of distal sleeves.

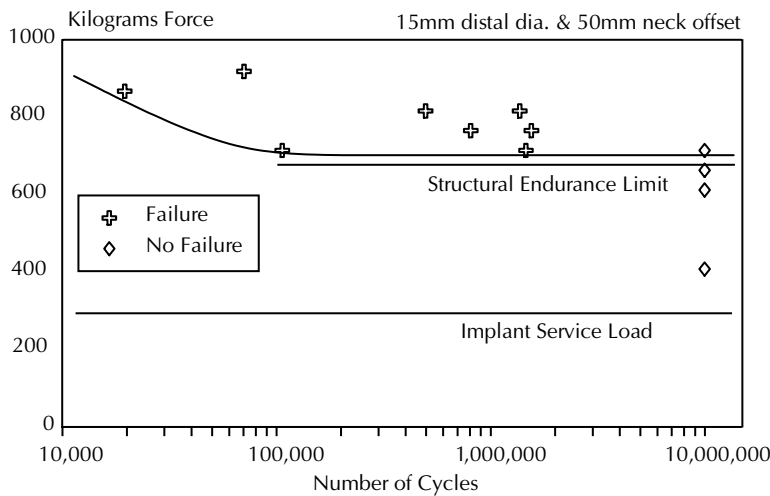
The system's versatility is appreciated in this hip revision performed on a 38 year old, female patient with osteoarthritis resulting from CDH. At four years, cemented stem loosening with proximal and distal osteolysis was observed requiring revision within a small distal canal. A **RMHS** curved, narrow, distal stem and large, proximal pads were selected. The post-operative films illustrate the customization of both proximal and distal geometries to achieve canal filling and stability.



Post-Op

In Vitro Fatigue Evaluation

RMHS Modular Hip System Structural Fatigue Curve



The structural fatigue curve for the **RMHS** system evaluated indicates an endurance limit 2.3 times the implant service load.

In this study, stem failure location was not consistent. Fracture initiated on the lateral aspect of the stem through the distal end of the sintered porous pad. This crack propagated through the pad attachment sites. While fretting was observed on the anterior pad/stem interface, it was not felt to be a contributory factor to failure. Other locations included failure through the femoral neck and across the mid-stem where a change of curvature occurs. Because these failures did not initiate at metal-metal interfaces, fretting was not implicated as a contributor.

In this study, the **RMHS'S** margin of safety and fracture sites suggest that fretting should not influence the device's longevity during *in vivo* service loading for a 74 kg_r (163 lb_r) patient. As the weight of the patient increases the margin of safety will be reduced for this size implant.



A-P view showing a failed device.



A close-up antero-lateral view of the fracture site.



Pre-Op

S-ROM Modular Hip System

The **S-ROM** Modular Hip System offers modularity using a femoral neck sacrificing sleeve/stem configuration. The outer geometry of the sleeve provides proximal anatomic stability and allows variable stem anteversion through a Morse taper. Distal cutting flutes assist rotatory stability with diaphyseal fit achieved through a coronal slot configuration.

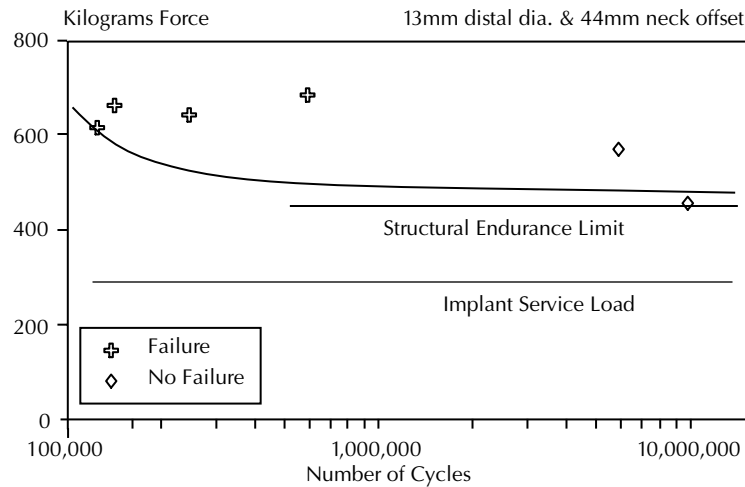
The system's versatility is appreciated in this multiply operated septic hip in a 65 year old, male patient. Two years prior to his revision, a hip implant was removed, the site debrided and closed. At exploration, minimal abductor musculature was observed. A lateralized **S-ROM** stem was chosen in conjunction with an oblong cup, avoiding the use of structural allograft. The lateralization compensates for the loss of abductor muscle group function and assists stability of the hip.



Post-Op

S-ROM Modular Hip System Structural Fatigue Curve

In Vitro Fatigue Evaluation



A-P view showing a failed device.

The structural fatigue curve for the **S-ROM** system evaluated indicates an endurance limit 1.5 times the implant service load.

All cases of stem failure occurred slightly proximal to the distal end of the sleeve, within the Morse taper and initiated across a lateral fretting surface.

In this study, the **S-ROM'S** margin of safety suggests that the fretting induced failure should not influence the device's longevity during in vivo service loading for a 74 kg_r (163 lb_r) patient. As the weight of the patient increases the margin of safety will be reduced for this size implant.



A close-up A-P view of the fracture site.

STRUCTURAL FATIGUE METHODOLOGY

Structural Fatigue Curve

The characteristics of structural fatigue curve are visualized in the graph.

The **endurance limit** defines the maximum dynamic load an implant system can support and theoretically, never fail. It is the largest load at which 10 million, uninterrupted cycles occur without device failure.

The **implant service load** is defined as the maximum *in vivo* dynamic load on the hip during walking gait. Its value is dependent on patient weight and gait parameters including walking speed and stride length. For this study, a 74 kg_f (163 lb)_f¹ person was assumed with a maximum joint force of 4 x body weight (296 kg)_f².

The **margin of safety** is the difference between the endurance limit and the implant service load and serves as an indicator of implant structural integrity. Margins of safety are important in predicting implant longevity as population weight varies and unknown factors increase the implant service load (i.e., high activity level) or decrease the endurance limit (i.e., corrosion).

The structural fatigue curve is influenced by several parameters including stem geometry, neck length, material properties and surface preparation. Neck length is important as it determines the system's moment arm. Larger moment arms produce larger tensile bending stresses on the lateral side of the stem. When analyzing a structural fatigue curve, the moment arm (L) or neck offset coupled with the applied load determines the severity of the loading environment.

Implant Fracture

Fracture occurs where the highest stress acts on a structure. Sites of fretting, notches due to porous coating and surface defects serve as stress concentrators and are foci for crack initiation. Crack propagation is most commonly associated with oscillating tensile stress. In the case of the hip, this translates into a crack that initiates on the lateral side and propagated medially.

Implant fatigue and fracture occur when the implant service load exceeds the endurance limit suggesting weight limitations for particular devices. Clinically, this is accommodated by general association between increasing patient weight and larger femoral canals requiring increased stem diameters.

DISCUSSION

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.

It was observed, in this study, that fretting plays a clear and relatively uniform role in the failure patterns observed for the **IMPACT**, **INFINITY** and **S-ROM** designs. The failure locations for the **RMHS** design suggest that factors, other than fretting, initiated crack propagation.

However, all failures occurred at peak loads above the anticipated implant service load, suggesting that their *in vivo* longevity should not be compromised by the presence of metal-metal interconnections.

These ongoing laboratory evaluations assist an understanding of the anticipated performance of contemporary hip implant designs. The results are intended to aid the surgeon in device selection when considering patient factors. Further, they provide the manufacturer with design criteria and assist regulatory agencies in determining the safety and efficacy of specific hip designs.

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2. Crowninshield, R.D., Johnston, R.C., Andrews, J.G., and Brand, R.A.: A Biomechanical Investigation of the Human Hip, Journal of Biomechanics, Vol. 11, No. 1/2: 75-85, 1978.

