AN ANALYTICAL APPROACH TO EVALUATING UNCEMENTED TOTAL HIP REPLACEMENT INTRAOPERATIVE PROXIMAL FEMUR FRACTURE RISK

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INTRODUCTION

Intraoperative proximal femoral fracture during uncemented femoral stem insertion is a recognized complication during primary total hip arthroplasty, with published fracture rates reported as high as 20% [1] in clinical studies.

Uncemented, proximally filling, porous-coated femoral components, along with associated reamers and broaches, must be designed with both an optimized level of press-fit and with sufficient manufacturing precision. An optimized press-fit level ensures adequate stem support for short-term stability, promotes bone in-growth in the short to medium term, and minimizes stem subsidence in the long term. Manufacturing tolerances which are overly generous can lead to an inconsistent stem seating depth. If the stem appears proud under a typical stem insertion sequence, there may be a temptation to drive the stem deeper into the bone with additional mallet blows risking femoral fracture. If too little force is exerted in driving the stem to its ideal seating depth, it may be an indicator of a lack of press-fit and stem subsidence in the long term.

In this study, an analytical approach to assess intraoperative femoral fracture risk of uncemented THR design concepts (prior to implant approval and use) is proposed.

METHODS

Finite element models of a predicate device and three design concepts, used in conjunction with a numerically identical proximal femur model, were generated using the following protocol:

Femoral Stem Modeling: 3D CAD models of a predicate device (Secur-Fit™ Plus HA Cementless Hip Stem, Stryker Orthopaedics) and 3 design concepts (referred to hereafter as design concepts A, B, and C) were developed. A consistent, midrange stem size was selected for all design evaluations.

Proximal Femoral Bone Modeling: An individual CT scan was selected from a CT scan database whose left proximal femur accommodated the femoral stem size being investigated. The CT scan was generated using a 1.0mm slice thickness. Both outer cortical and cortical-to-cancellous bone boundaries were segmented out of the CT scan, exported as STL files, and converted to IGES files. Next, a CAD assembly model containing component models of the cortical and cancellous bone, surgical reamer and broach was prepared. Virtual surgery was then performed to prepare the bone as per surgical protocol. The assembly model generation and virtual surgery steps are repeated for each design concept utilizing mathematical duplicates of the bone model. A reference FEM model of the intact, proximal third of the proximal femur was also exported. Each finite element within the cancellous bone of the reference model was mapped with unique elastic modulus properties [2], while the cortical bone was mapped with a uniform elastic modulus of 12GPa [3]. Refer to Figure 1.

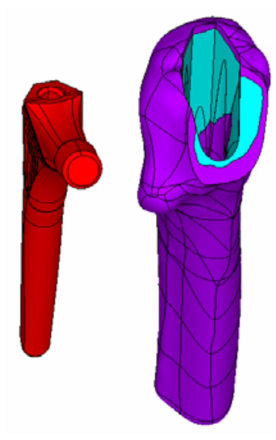

Figure 1:
Predicate CAD Model

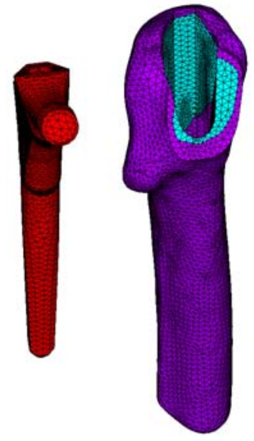

Figure 2:
Predicate FEA Model

Femoral Stem Finite Element Model Generation: A finite element model of each femoral stem was generated within ANSYS v11 (ANSYS Inc, Canonsburg, PA) with a variable mesh size varying from 0.5 to 2.5mm. Material properties pertaining to each stem was supplied.

Resected Proximal Femur Finite Element Model Generation: A finite element model for the resected, proximal third of four numerically identical femura, each prepared per the surgical protocol of each associated stem, was also generated within ANSYS v11. A variable mesh size from 1 to 5mm was utilized. Bone material properties, using the material properties from the intact reference model, were mapped onto the resected bone model. Refer to Figure 2.

Analysis Sequence: Each stem was seated into the bone from a 1mm proud to 1mm recessed position in 0.5mm displacement increments.

RESULTS

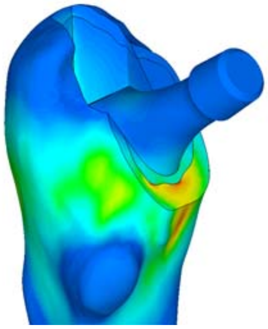

Figure 3: Predicate Model Hoop Strain

The cortical bone maximum circumferential (hoop) strains (Figures 3 & 4) and insertion force necessary to generate the imposed displacement (Figure 4) were extracted and plotted for each insertion step.

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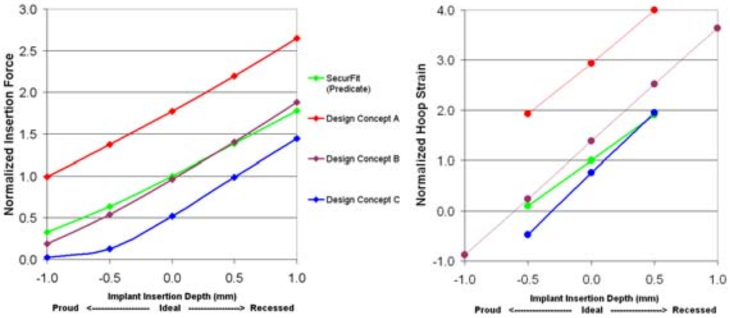

Figure 4: Normalized Insertion Force & Hoop Strain as a Function of Insertion Depth

A qualitative ranking of the design concepts and predicate device was generated and subsequently validated by independent evaluations using physical sawbones [4] and cadaveric testing [5], preparing the bone test/cadaveric samples per the equivalent surgical protocol.

DISCUSSION

An analytical method for comparing cortical bone hoop strains and implant insertion forces between proposed uncemented femoral stem designs to a predicate device has been developed.

In this study, design concept B was the best match to the predicate from an insertion force perspective, while design concept C was the best match from a hoop strain perspective. The slope of the insertion force and hoop strain versus insertion depth curves provides additional insight as to the "level of forgiveness" of the design to over or under reaming.

This method is currently limited to providing a qualitative ranking due to the use of elastic material properties for the bone. As a result, this method tended to overestimate the ultimate strain and insertion force values, but from a qualitative perspective, predicted comparative behavior accurately, as validated by sawbones and cadaveric testing [4,5]. The addition of nonlinear bone material properties for a better quantitative evaluation represents the basis for future work.

Although this study was performed using nominal tolerances, it is recommended to perform additional comparative evaluations using MMC (maximum material condition) and LMC (least material condition) tolerance conditions.

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