Impact Load Test Model for Femoral Press-Fit Design Optimization in Uncemented THA

INTRODUCTION:
Uncemented proximally filling porous-coated femoral components must be designed with an optimal level of press-fit. An optimized press-fit 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. However, this optimization requires the delicate balance of femoral stress. Excessive stress can result in periprosthetic femoral fracture (PPFs). The incidence of femoral fracture reported in the literature ranges widely from 3-17% [1, 2] in primary procedures to 27.8% [3] in revision procedures. Insufficient femoral stress can lead to a lack of initial mechanical stability which “is necessary to achieve bone ingrowth into the porous surface” [4] of the implant.

An optimal press-fit design should also provide an accurate and repeatable femoral stem seating height in all patients throughout the stem’s manufacturing tolerance band. If the stem is proud after a normal impaction sequence, there may be a tendency to continue to impact it, risking fracture. If too little force is required to seat the stem, it may not have sufficient initial mechanical stability.

A battery of cadaveric tests [5], physical “bench-top” tests, and finite-element analyses (FEA) [6] should be used in order to both quantitatively and qualitatively optimize a press-fit design prior to surgical use. In this study, a method is proposed to quantitatively evaluate fracture risk and stem seating height through a controlled “bench-top” impact loading model.

METHODS:
This test model quantitatively ranks different press-fit designs based on stem seating height and fracture risk. This is achieved by recreating the impact loading applied during surgery with a drop tower. Three press-fit designs (A, B & C) utilizing different amounts of broach press-fit were compared to two predicate stems, Secur-Fit Max and Meridian TMZF (Stryker Orthopaedics, Mahwah, NJ). Since this “bench-top” test is free of much of the variability occurring in live surgery, the following acceptance criteria were set: the stem must be stable and within the desired range of stem seating height (+3 to -1mm of the medial resection point) without causing fracture and, after stability is obtained, the stem must able to be forced past -1mm countersunk without causing fracture. Standard cortical bone foam Sawbones® femurs (Pacific Research Laboratories, Inc., Vashon, WA) were prepared following the respective surgical protocols. One operator utilizing uniform impactions prepared all femurs in order to keep the broaching technique consistent; all broaches were impacted to flush (0mm). The prepared femurs were then mounted in a custom made drop tower and a custom universal stem impactor was threaded into the insertion features of the stems (Figure 1). The stem was impacted into the prepared Sawbones® femur until stable and within +3mm proud or -1mm countersunk of the medial resection point. A stable stem is defined as when the axial displacement of the stem component is less than 0.5mm over 3 impactions. One half millimeter is a clinically relevant resolution in which the surgeon might determine the stem seating height with a ruler or by feel. The stems were then step loaded until femoral fracture occurred (Figure 2). The height above/below the medial resection plane (seating height) was measured after each impaction.

RESULTS:
Initially five prepared Sawbones® femur samples and one stem sample for each press-fit design were run based on the standard deviation of the results in a pilot study. A Paired T-Test was used to evaluate if there was a statistical difference between the samples; five additional femur samples were run for three of the designs to generate a statistical differences in the T-values. Two identical Meridian TMZF samples were rejected with 95% confidence using a Q-test. Microsoft Excel 2003 (Redmond, WA) was used for all statistical analysis.

All stems had an initial stable seating height between +3mm proud and -1mm countersunk from the medial resection point. Design C was the most accurate at -0.02mm countersunk. Design A was the most repeatable with a stem seating height standard deviation of .09mm. The Secur-fit Max stem countersunk more than the other designs prior to fracture. Meridian TMZF and Design A had samples which fractured the femurs prior to countersinking -1mm.

DISCUSSION:
All press-fit designs yielded stable stems within +3mm proud to -1mm countersunk without causing fracture. Design C had the best overall results, combining accurate and repeatable femoral stem seating height. The Secur-Fit Max has the lowest fracture risk followed by Design C, as they could be pushed the furthest past -1mm countersunk before causing fracture. In order to determine the optimal design, each press-fit design was ranked with equal weight given to seating height and fracture risk. Design C ranked first as the optimal combination of seating height accuracy and consistency with a low risk of calcar fracture.

A limitation of this impaction model is that it does not directly predict fracture rate, it only quantifies risk of fracture. Another limitation is that this model it does not simulate all of the variability that is inherent to real bone. This test is just one step in a battery of tests, including cadaveric evaluation [4] and FEA [5], which should be used in order to optimize a press-fit design prior to surgical use.

REFERENCES: