Comparative Stability of Cementless Tibial Components of Different Designs in Normal and Osteoporotic Bone Models

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INTRODUCTION:
Cementless tibial components have experienced limited use since reports of early failure emerged in the late 80’s and early 90’s. However, with the success of certain cementless tibial component designs and the emergence of improved biomaterials, particularly porous titanium and tantalum, there is a renewed interest in developing a cementless tibial component to enhance long-term survivorship.

The initial mechanical stability of press-fit implants as measured by micro-motion at the implant-bone interface is critical to facilitate osseointegration. Laboratory test models that measure micromotion utilizing bone analogs are helpful to compare designs; however, a single bone analog may not address performance within the variable bone densities seen within patients, such as those with osteoporosis. This study evaluated the ability of a new test model to differentiate micromotion as a function of both design and bone density.

MATERIALS AND METHODS:
The experiment consisted of two cementless modular tibial components. The two peg cementless test group had a highly porous (60-65% porosity) Ti ingrowth surface proximally and on the full length of the pegs. The keeled cementless test group had a CoCr beaded surface proximally and a solid Co-Cr keel.

Bone replicates were used to simulate the in vivo tibial structure while minimizing the variability often seen in cadaver studies. The bone replicates were made of 12.5 PCF and 20 PCF Cellular Rigid foam by Pacific Research (Sawbones, Pacific Research Laboratories Inc. Vashon, WA) and were chosen because they most closely resembled osteoporotic and “normal” bone respectively as determined by subjective surgeon assessment. The test bone specimens were shaped to replicate the anatomical geometry of the resected proximal tibia during a TKA. A 40 PCF Solid Rigid foam cortex provided additional rigidity to both the “normal” and osteoporotic specimens with the “normal” cortex at .125” and the osteoporotic cortex at .100”. (Figure 1.)

Rapid prototype bone preparation guides were utilized to ensure alignment standardization. Preparation of bone replicates and impaction of the tibial components were performed by an experienced arthroplasty surgeon. Each test component was implanted in 10 tibial bone replicates, with 5 in each of the two different densities, for a total of 20 test articles.

All components were tested utilizing a 9-mm thick modular posterior stabilized tibial insert. The tibial components were individually loaded through a mating femoral component, fixed at 60° of flexion and 6° of fixed external rotation. A constant compressive load of 700 N was applied using an air cylinder while anterior and posterior displacement of the tibia was controlled by a servo-hydraulic load frame (MTS Eden Prairie, MN) (Figure 2). Cyclic AP motion was applied for 30 cycles at a rate of 0.1 Hz. Components were positioned such that cam post engagement resulted in shear forces of up to 350 N.

Six LVDTs were mounted on a rigid frame attached to the tibial specimen and the LVDT plungers contacted a flat surface of cubes attached to the loaded tibial component. Micromotion was calculated at the specimen-implant interface in five peripheral locations via the LVDT displacement data. Maximum cyclic displacement was calculated as the difference in minimum and maximum for the last 5 cycles of the LVDT data. ANOVA testing and individual t-tests were used for statistical comparison between test groups.

RESULTS:
The ANOVA showed a significant effect of both design and bone density on mean micromotion at all locations. (p<0.0014) Data is presented for the mean micromotion at the posterior medial edge of the tibial component. This location exhibited the greatest micromotion in all the test specimens. In the “normal” bone replicate, average motion of the two-pegged highly porous Ti Cementless group was 3.1 times higher than the CoCr cementless keel group (214±69 µm, and 69±26 µm respectively) (See Figure 3.) In the osteoporotic bone replicate, average motion in the posterior medial edge of the two pegged highly porous Ti Cementless group was 1.2 times greater than the CoCr cementless keel group (371±86 µm and 310±142 µm respectively.) Individual t-tests showed significant increases in micromotion of both designs as a result of decreased density of the tibial bone replicates (p<0.018). Micromotion of the keeled design was lower than the 2-pegged design in both bone densities but this difference was only statistically significant in the “normal” bone density (per t-test results: Osteoporotic p=0.219 and “normal” p<0.003.)

CONCLUSION:
This method was able to distinguish significant differences in micromotion as a result of differences in design as well as variations in bone density. This model can be utilized to optimize the fixation features of cementless tibial components and insure that they perform favorably in various bone densities. This study demonstrates the importance of evaluating press-fit designs under both normal and osteoporotic bone conditions. Designs that may perform in a similar manner under one condition may be substantially different under the other.

It should be noted that micromotion displacements measured in this study represent a combination of elastic deformation of the test samples as well as motion at the implant bone interface. Motion at the implant bone interface consists of subsidence, lift-off, and shear. Future efforts should be directed towards discerning the actual motion at the implant bone interface in terms of subsidence, lift-off, and shear as well as evaluating motion for other loading conditions.