

**Initial mechanical stability of cementless highly-porous titanium tibial components:
*Biomechanical comparison of micromotion and vibration analysis.***

Introduction & Background

Cementless fixation in total knee replacement has enjoyed limited success in the past; however, a renewed interest in cementless fixation is being heralded due to a number of factors. Recent development of porous metal technology has provided improved biomechanical and biological properties which theoretically allow improved stability and ultimate osseointegration. In addition, it is commonly understood that cement represents a weak interface and if successfully eliminated, would likely result in improved knee replacement implant survivorship via long-term osseointegration. Finally, an additional impetus results from the increased efficiency and decreased operative times that would result from elimination of the cementation process and the time required for curing. It has been clearly elucidated that minimizing surgical duration decreases the incidence of infection which is clearly in the best interest of patient and surgeon alike.

The initial mechanical stability of cementless implants is critical to minimizing micromotion between the bone and porous-coated surface, subsequently providing the necessary conditions for successful osseointegration of the implant. Numerous studies demonstrate micromotion greater than 150 μ m leads to fibrous tissue formation at the interface between the implant and the host bone, whereas micromotion of 40 μ m or less provides sufficient stability for reliable osseous integration.[1-4] Osseointegration of the porous metal implant surface is necessary for maintaining the interface and integrity of the fixation of the implant over an extended time period. Therefore, minimizing micromotion through optimal initial mechanical fixation is critical to the long-term success of cementless knee replacement implants.

A critical component to any total knee replacement system is a durable and well-functioning tibial component. Cementless tibial components have experienced limited use since reports of early failure emerged in the late 80s and early 90s.[5-9] In addition, biomechanical studies have demonstrated superior mechanical stability of cementless tibial components augmented with supplemental screw fixation.[10, 11] The clinical implication of supplemental screw fixation is the additional technical steps required and

potential for error, as well the potential for the deleterious screw track osteolysis long-term.[9, 12, 13] However, with success of certain cementless tibial component designs[14-17] and the emergence of improved biomaterials, particularly porous titanium and tantalum[18-24], there is a renewed interest in developing a cementless tibial component to enhance long-term survivorship.

Purpose

The purpose of this biomechanical study is to twofold. First, other than in vivo RSA techniques, the traditional method used to assess initial mechanical stability of cementless implant designs has been via measuring micromotion at the implant-bone interface during simulated in vitro mechanical loading.[25-28] This methodology, although well established in the orthopaedic literature, has significant limitations inherent in using linear variable differential transducers (LVDT) of varying specifications and quality, as well as the frequently challenging task of constructing a test apparatus and configuration that allows accurate and reliable placement of LVDTs in multiple planes of motions to be measured. Therefore, the first purpose of this study is to assess whether vibration analysis techniques can be used to evaluate and characterize initial mechanical stability of cementless implants more accurately than the traditional method of micromotion analysis.

The second purpose of this study is to evaluate and determine the comparative mechanical stability of various designs of cementless tibial components under mechanical loading designed to simulate in vivo forces. The various designs will include a control group of a traditional cemented design compared with four different newly-developed cementless, highly-porous titanium implants of two different fixation-peg designs and two-different surface frictional coefficients. A key question is whether the increased surface provides substantial resistance to micromotion over the inherent stability of the geometrical interference fit of the fixation-pegs in the highly-porous tibial components.

Investigation Hypotheses

1. Vibration analysis will represent a more specific and consistent methodology to assess initial mechanical stability of cementless tibial components as

compared with traditional micromotion measurements under simulated in vivo mechanical loading.

2. New porous-titanium cementless tibial components will exhibit adequate mechanical stability versus the cemented control group when subjected to identical in vivo forces via mechanical testing.
3. There will be a difference in initial stability between the two-peg and more peripherally-placed four peg cementless tibial baseplate design.
4. Both the two-peg and four peg designs with high surface coefficient of friction via the highly-porous titanium structure will demonstrate greater stability via less inducible micromotion over implants with less frictional coefficient.
5. *Additional hypotheses involving stability in suboptimal bone preparation and in poor quality (osteoporotic bone) are planned to be carried out in future studies at the New England Musculoskeletal Institute at University of Connecticut Health Center.*

Methods & Materials

Test Samples

Five tibial baseplate component designs will be subjected to mechanical testing. Five samples will be tested from each test group. A 9mm Posterior Stabilizing tibial insert will be inserted in every tibial baseplate. The purposed test groups are as follows.

1. A cemented control group consisting of a Triathlon keeled tibial baseplate. The control group is expected to have minimal micromotion as compared to the cementless samples.
2. A high coefficient of friction 2 peg cementless tibial baseplate component.
3. A low coefficient of friction 2 peg cementless tibial baseplate component.
4. A high coefficient of friction 4 peg cementless tibial baseplate component.
5. A low coefficient of friction 4 peg cementless tibial baseplate component.

Bone model

Each tibial prosthesis will be implanted by a surgeon who specializes in knee replacement surgery utilizing prosthesis-specific instrumentation which will be standardized to be similar for all specimens. The implants will be inserted into rigid polyurethane foam tibial sawbones specimens (Sawbones, Pacific Research Laboratories Inc, Vashon, WA), either polyurethane foam blocks or tibial replicate specimens, depending on specimen availability. The mechanical testing replicate tibial specimens are designed to minimize the inter-specimen variability that exists in cadaveric specimens. This will provide a more accurate assessment of the comparative biomechanical stability of the various implant designs by minimizing the confounding variable of specimen variability. The control group of five cemented tibial baseplate components will be prepared using Simplex-P PMMA cement and the remaining tibial baseplate component design groups will be inserted without cement.



Load Application

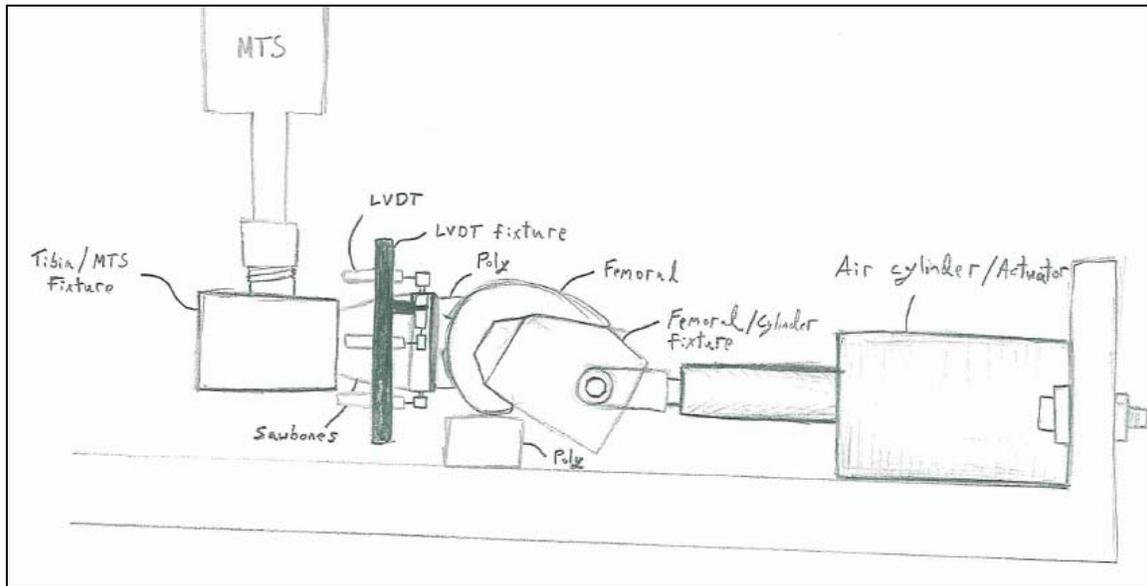
Tibial baseplate component designs will be subjected to mechanical testing designed to simulate in vivo loads seen in the native tibiofemoral joint and in the tibia after total knee arthroplasty. The loading cycle has been determined based on established and reported micromotion studies involving tibial components in total knee arthroplasty[10, 11, 25-28] and adapted to incorporate the associated axial compressive, shear and rotational forces to induce detrimental micromotion. In addition, this test methodology is based on an established ASTM testing protocol for biomechanically-induced loosening of glenoid components in total shoulder replacement (ASTM F-2028-08).

It has been determined through various studies that the tibiofemoral joint is subject to compression between 700 to 2200 N (1-3 times body weight), shear forces of 350 to 980 N, and torsion of 5 to 10 N-m. Previous micromotion testing has shown that

as joint compressive forces increased, micromotion due to shear forces is subsequently decreased due to the high compressive loads that preclude shear-induced translational motion.[26] For this reason, testing will be conducted at 700 N compressive (1 x body weight) to allow shear loads of up to 1000 N to induce micromotion. Torsion will not be applied actively as it adds increased complexity to the test setup. Torsion will be induced through a fixed external rotation of the femoral component of 6 degrees and induced via the articulating geometry of the tibial polyethylene and femoral component through the induced translation in the presence of the compressive force. The induced torsion will be calculated as part of this test effort.

A constant joint compressive force will be applied by a pressure cylinder attached directly to the femoral component. Shear forces will be induced on the tibial component by an MTS machine controlling cyclic Anterior/Posterior motion of the tibial baseplate relative to the femoral component. Initial testing will determine the displacement needed anteriorly and posteriorly to result in shear forces of 350-1000 N. The tibial component will be preloaded with a compressive force from the hydraulic actuator for 10 seconds in order to determine the initial conditions of each experimental construct and measure the background noise inherent in the system. The prosthesis will then be subjected to a sinusoidal AP translational motion via the MTS load cell at 0.1 Hz for 30 cycles to enact the required translation for shear force up to 1000N. If available, this will be performed via displacement-control mode with a load stop of 1000 N.

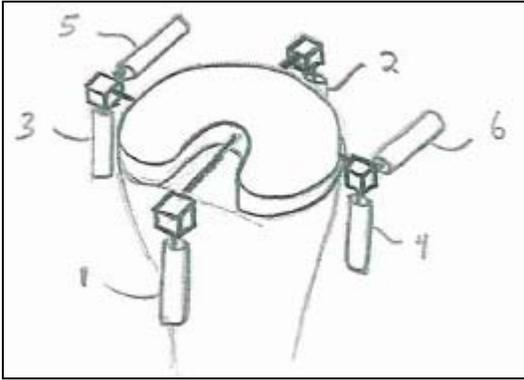
Figure 1: Test Setup



Micromotion Detection

Implant motion relative to the polyurethane foam specimen will be measured by linear variable differential transducers (LVDT) with a manufacturer reported resolution of 2 μm . The LVDTs will be attached rigidly to the polyurethane foam block or the replicate tibial specimen via an LVDT mount located approximately 5 mm from the implant bone junction and then contact the tibial baseplate implant collinear to the direction of motion resulting in six degrees of freedom. Six LVDTs will be required and positioned to measure linear micromotion in the superior/inferior and anterior/posterior planes and rotational (internal/external and varus/valgus) micromotion. Figure 2 shows the approximate locations of the LVDT's on the specimen. LVDT data will be sampled at a rate of 10 Hz. Micromotion is considered the maximum recoverable motion during each cycle, whereas non-recoverable motion is termed migration or subsidence. These values will be determined for each plane of motion, in each cycle, for each of the tested specimens via the data acquisition system.

Figure 2: LVDT Locations



Vibrations Methods

Vibration analysis will be utilized to assess the integrity of the mechanical fixation between the prosthesis and underlying polyurethane foam sawbone specimen. Piezoelectric (PZT) patches will be attached to the experimental construct and configured to record acceleration and impedance data during the loading cycles. Various metrics will then be analyzed and compared to the micromotion data obtained to assess for accuracy within test specimen groups and between the various tibial baseplate design groups. In particular, the vibration data collection and analysis techniques will be analyzed to assess whether these methods are comparable, or even superior, to the micromotion measurement methods for assessing initial implant mechanical stability and subsequent loosening under cyclic loading. This portion of the study design and methods will be developed by the summer student team at Los Alamos National Laboratory under the direction of Phil Cornwell, PhD.

Test Setup

Figure 2 shows the typical test setup. The femoral component will be flexed at 45 degrees. Polyurethane will be used to set 6 degrees of external rotation into the femoral component and will prevent rotation of the femoral component during testing to induce the rotational loads. A fixture will hold the polyurethane block or replicate tibial sawbone specimen and allow the MTS machine to apply load to it. A rapid-prototyped plastic ring will hold the LVDT's in place on the proximal tibia during testing. PZT

patch locations will be determined through an optimization effort conducted by the Los Alamos student group conducting the experiment.

Statistical Analysis

One-way analysis of variance will be used to determine whether there is a statistically significant difference between the micromotion measurements of the 5 different test groups. A significance level of less than 0.05 was considered statistically significant.

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Project Resources and Material

Supplied by Los Alamos National Laboratory:

- Student protocol development, data collection and analysis, statistical analysis
- MTS machine, Data acquisition software and experimental setup
- Laboratory technician, assistance and support
- Vibration analysis PZT patches, data acquisition materials and software

Supplied by Stryker, Inc:

- 30 sawbone testing specimens
- Specimen mounting material and MTS load cell attachment
- 6 linear variable differential transducers and mounting device
- Tibial Implants
 - 5 cemented Triathlon keeled controls
 - 5 two-pegged highly-porous cementless (high frictional coefficient)
 - 5 two-pegged highly-porous cementless (lower frictional coefficient)
 - 5 four-pegged highly-porous cementless (high frictional coefficient)
 - 5 four-pegged highly-porous cementless (lower frictional coefficient)
- Tibial Implant specific instrumentation (power, tibial template, peg hole reamer guides, tibial impactor)
- Femoral component, attached actuator/external component rotation apparatus
- 5 batches PMMA cement (tibial component control specimens to be prepared ahead of time at Stryker and shipped to Los Alamos ahead of time for student orientation and familiarization)

Principle Investigator (R. Michael Meneghini, MD):

- Project inception, discussion with Los Alamos and Stryker engineers for additional insight & support
- Literature review of existing mechanical studies regarding
- Development of project methods and mechanical testing protocol with engineers
- Travel to Los Alamos National Lab and Stryker (Mahwah, NJ) for project development and implementation

- Cementless tibial specimen preparation and implant insertion.
- Abstract submission to various orthopaedic meetings if appropriate.
- Manuscript preparation for peer-reviewed orthopaedic journal if appropriate.

Timeline

April – May 2008

- Identification of existing literature and biomechanical studies
- Review of existing protocols and identification of study hypothesis
- Establish methods and mechanical testing protocol
- Create draft of protocol
- Stryker implant manufacture and delivery (with remaining materials) to Los Alamos National Laboratory in early June.

June 2008

- Student group studying vibrations technology commences at Los Alamos National Lab, with project team under the direction of Phil Cornwell, PhD.
- June 25-27th: Mohamed Soliman and Dr. Meneghini to attend initial testing at Los Alamos Laboratory with student group/Phil Cornwell

August 2008

- Data analysis and completed manuscript.
- Project team presentation at IMAC conference.
- Transition phase 2 and 3 (bone preparation and bone quality variations) of study to New England Musculoskeletal Institute at University of Connecticut

June 2008

- If appropriate, submit “Assessment of cementless tibial implant stability using micromotion vs. vibration analysis” abstract to ORS 2009 Annual Meeting