Investigation Protocol & Budget

Initial mechanical stability of cementless porous titanium patellar components: *A biomechanical study comparing micromotion and vibration analysis.*

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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 clearly understood that cement represents a weak interface that if successfully eliminated, would result in improved knee replacement implant survivorship via long-term osseointegration. Finally, an additional impetus results from the increased operative 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, 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 150μm leads to fibrous tissue formation at the interface between the implant and the host bone, whereas micromotion of 40μm 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 patellar component. As with tibial and femoral components, cementless metal-backed patellar components have experienced limited use since reports of early failure emerged in the late 80s and early 90s.[5-20] However, with success of certain cementless, metal-backed patellar component designs[21-25] and the emergence of improved biomaterials, particularly porous titanium and tantalum[26-32], there is a renewed interest in developing a cementless patellar 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.[33-39] 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 patella components under mechanical loading designed to simulate in vivo forces. The various designs will include a control group of a cemented patella design, a "cementless control" of a currently accepted cementless design and compare three different newly-developed cementless, porous-titanium designs.

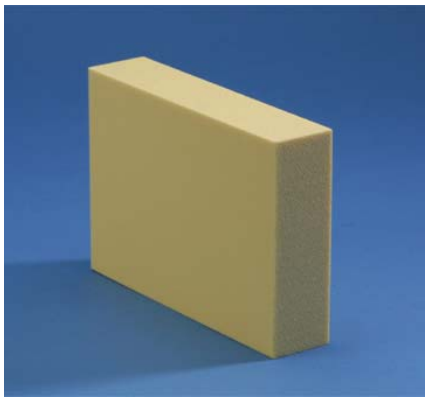
Investigation Hypotheses

1. Vibration analysis will represent a more specific and consistent methodology to assess initial mechanical stability of cementless patella components as compared with traditional micromotion measurements under simulated *in vivo* mechanical loading.
2. New porous-titanium metal backed patellar components will compare favorable with the control group (cemented all-polyethylene patella) and demonstrate superior mechanical stability over the currently accepted porous metal cementless patella when subjected to identical *in vivo* forces via mechanical testing.

Methods

Different patella component designs will be subjected to mechanical testing designed to simulate *in vivo* loads seen in the native patellofemoral joint and in the patella after total knee arthroplasty.[40-50] It is proposed to test 5 specimens of each of the 6 groups listed below in order to provide sufficient power for statistical comparison between groups. The five patella designs (six test scenarios including 2a) will be:

1. Cemented all-polyethylene patellar component (control group)
2. Cementless porous-coated, metal-backed patellar component of established 3-cylindrical-peg design ("cementless control")
    a. Simulated patellar component "aseptic loosening" via over-drilled peg holes. This additional test group should enhance the comparison of vibration and micromotion techniques to assess implant stability.
3. Cementless porous titanium patellar component with three <u>cylindrical</u> pegs similar in geometry to #2
4. Cementless porous titanium patellar component with three <u>hex</u> pegs designed for enhanced interference fit of the peg within prepared bone peg hole
5. Cementless porous titanium patellar component with three cylindrical pegs (identical in geometry to #3) with the added design feature of a 1mm thick layer of porous titanium on the anterior baseplate that is "inset" into the patellar bone to minimize shear stress at the peg/baseplate interface



Each patellar 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 in rigid polyurethane Foam Block specimens (Sawbones, Pacific Research Laboratories Inc, Vashon, WA). The ASTM F-1839 "Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments" states that; "The uniformity and consistent properties of rigid polyurethane foam make it an ideal material for comparative testing of bones screws and other medical devices and instruments." The polyurethane blocks 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. A control group of a five cemented all-polyethylene patellar component will be prepared using Simplex-P polymethylmethacrylate cement and the remaining patellar component design groups (containing 5 specimens in each design group) will be inserted without cement.

Once implanted into the polyurethane foam blocks, the patellar implant will be attached to a servohydraulic MTS testing machine. The specimen construct will be rigidly aligned so that the MTS load cell impacts the patella eccentrically and in a direction that has been determined to represent the direction of the maximum force vector. The magnitude and direction of the maximum force vector was determined by a comprehensive review of the available patellofemoral biomechanical studies in the current literature.[40-50] The maximum anteroposterior compressive force magnitude reported is 800 N and occurred at 85 degrees of the flexion cycle.[44] The maximum mediolateral and superoinferior shear force reported is 200 N.[44] Numerous other in vitro patellar force studies report similar magnitudes of compressive and shear force measurements that occur from 70 to 110 degrees in the knee flexion cycle. Therefore the load cell of the MTS machine will be applied to create a resultant force equal to that

which creates a maximum 800 N anteroposterior compressive force and a 200 N mediolateral and superoinferior shear force as the maximum values in the loading cycle. In addition, the load cell will contact the patella approximately 5mm superior and 1 mm medial to the center of the patella, where the resultant force center of pressure has been determined to be located in vitro.[47]

Loading Cycle

The loading cycle has been determined based on established and reported micromotion studies involving tibial components in total knee arthroplasty[33-39, 51, 52] and adapted to reach the maximum forces from the applicable *in vitro* patellofemoral studies discussed previously[40, 41, 43-48, 50, 53]. The patella will be preloaded with 50 N 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 load from 50 N to 850 N at 0.1 Hz for 60 cycles.

Micromotion Measurements

Implant motion relative to the polyurethane foam specimen block 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 and then contact the patellar implant collinear to the direction of motion resulting in six degrees of freedom. Three LVDTs will be required and positioned to measure micromotion in the superoinferior, mediolateral and anteroposterior direction. LVDT data will be sampled at a rate of 10 Hz for the 60 cycles. 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 1 Test Setup Front View

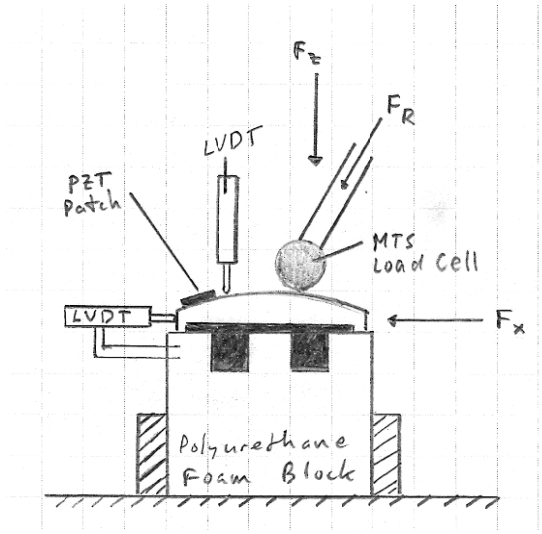
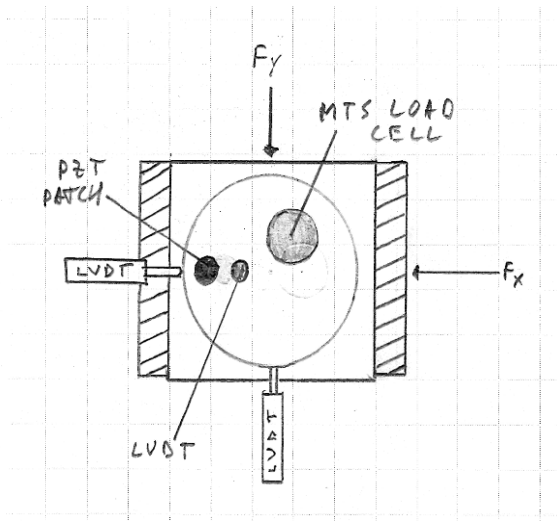


Figure 2 Test Setup View from Above



Vibration Analysis

Vibration analysis will be utilized to assess the integrity of the mechanical fixation between the prosthesis and underlying polyurethane foam specimen. Accelerometers and a piezoelectric (PZT) patch will be attached to the experimental construct and configured to record acceleration and impedance data, respectively, 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 patella 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.

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 implant types and six 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 Rose-Hulman Institute of Technology/Los Alamos National Laboratory:

- 35 polyurethane foam testing blocks
- MTS machines, MTS testing jigs and experimental setup
- Laboratory technician, assistance and support

Supplied by Stryker, Inc:

- 3 linear variable differential transducers
- Patellar Implants
    - 5 all-polyethylene
    - 5 traditional porous coated cementless
    - 5 porous-titanium cylindrical peg
    - 5 porous titanium hex peg
    - 5 porous titanium cylindrical peg, 1 mm inset baseplate
- Patella Implant specific instrumentation (power, drills, drill guides, inset reamer, impactor)
- 22m femoral head (attach to MTS load cell for contact with patellar implant)
- 5 batches PMMA cement

Principle Investigator (R. Michael Meneghini, MD):

- Project inception, discussion with Rose-Hulman and Stryker engineers for additional insight & support
- Literature review of existing mechanical studies regarding
- Development of project methods and mechanical testing protocol
- Travel to Rose-Hulman (Terre Haute, IN) and Stryker (Mahwah, NJ) for project development and implementation
- Specimen preparation and implant insertion.
- Abstract submission to various orthopaedic meetings if appropriate.
- Manuscript preparation for peer-reviewed orthopaedic journal if appropriate.

Timeline

January 2007

- Project Inception and initial presentation to Stryker (RMM & ADH)

January – May 2007

- 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 and budget
- Meetings between Drs. Meneghini, Cornwell, Hanssen and Stryker engineers to fine-tune study protocol, testing methods and implant and testing material acquisition.
- Stryker implant manufacture and delivery (with remaining materials) to Los Alamos National Laboratory by last week of May.

June 2007

- Summer "Vibrations School" commences at Los Alamos National Lab, with project team under the direction of Phil Cornwell, PhD.

August 2007

- Data analysis and completed manuscript.
- Project team presentation at IMAC conference.

April 2008

- If appropriate, submit "Assessment of cementless implant stability using micromotion vs. vibration analysis" abstract to AAHKS 2008 Annual Meeting (RMM & ADH)

June 2008

- If appropriate, submit "Assessment of cementless implant stability using micromotion vs. vibration analysis" abstract to ORS 2009 Annual Meeting (RMM, PC & ADH)