Peri-Prosthetic Fracture Vibration Testing Protocol

Mentor: Phil Cornwell

Project Overview

The goal of this project is to evaluate the potential of vibratory mechanisms to aid in the prediction/ prevention of peri-prosthetic proximal femur fractures due to press-fit stem insertion. Efforts will be built on previous studies completed at LADSS and University of Connecticut.

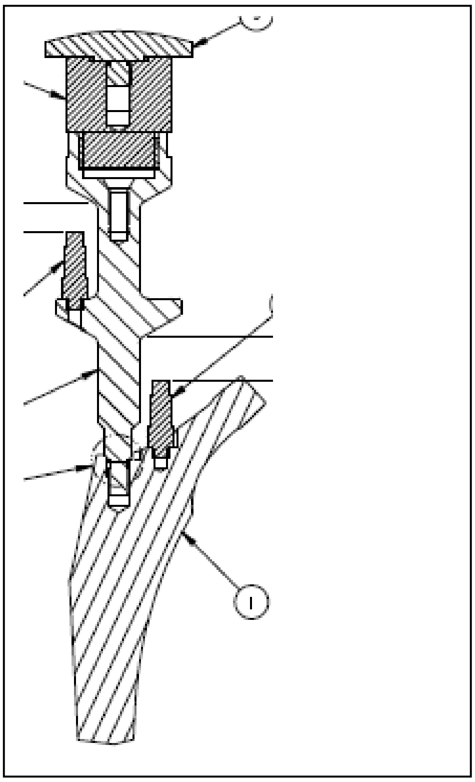
Deliverables from this study include:

1) Relative ranking on usefulness of various signals ability to predict device seating and sawbone fracture. Signals include hard mounted accelerometer, inserter mounted accelerometer and bolt-on accelerometer.
2) Comparison of device analog, Secur Fit and Accolade stem seating characteristics.
3) Integrated portable data acquisition system capable of being used in a cadaver lab environment with:
    a. Enhanced data acquisition parameters as needed for successful evaluation of signals of interest.
    b. Enhanced signal conditioning metrics used to assess device seating
    c. Visual output parameter used to provide real time seating limit feedback.

Test Equipment

Testing will require the following components:

1) Drop tower capable of delivering constant energy impacts (supplied from UConn).
2) Drop tower load impactor head, Impactor with load cell (Fig 1 Accolade, Fig 2 Secur Fit Max), Impactor with clamp on accelerometer (Figure 3). Kistler pizeoletric force transducers Type 9176 will be integrated into the impactor at the point of impact. Kistler accelerometers, Type 8742A10 will be mounted to the stem and the impactor. Vise with bone clamp.



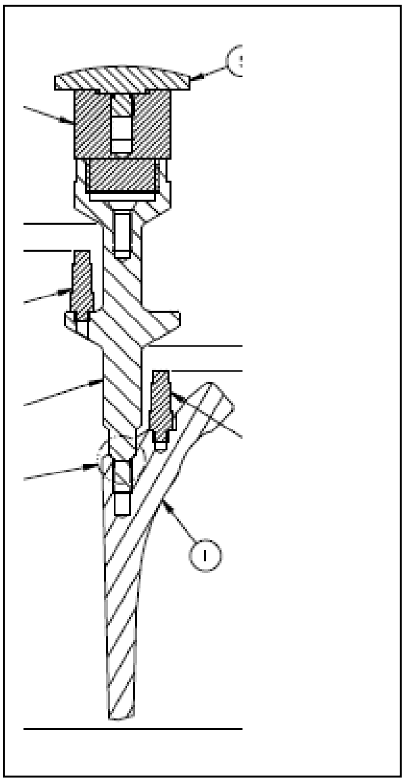


Figure 1: Accolade Inserter With load Cell

Figure 2: Secur Fit Max Inserter With Load cell

3) Visual device insertion tracking system will be considered as a nice to have, not required for effort to go forward. Marks will be provided on the impactors to gage stem seating vs impaction.

4) Data acquisition system capable of recording outputs from each device will be supplied along with all charge amplifiers. System will interface with any computer USB 2.0.

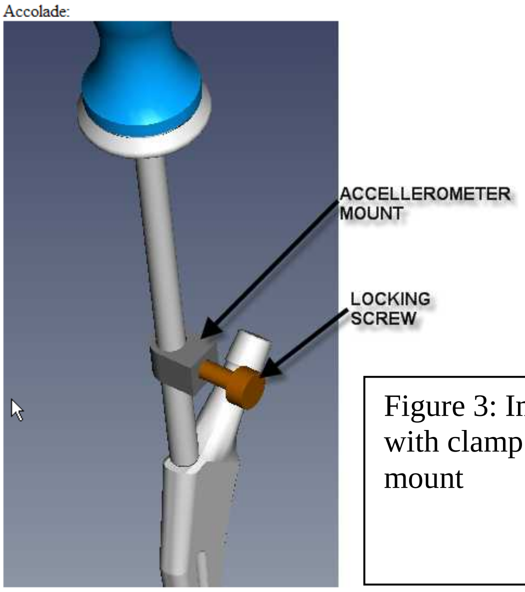


Figure 3: Impactor with clamp an accel mount

5) Labview expertise necessary to:
    a. Modify and further develop the data acquisition and user interface
    b. Develop the force and accelerometer data conditioning in support of metrics which will assess device seating.
6) Test Environment

All tests to be run in air at room ambient

Test Samples

<u>Bone Analog</u>

Testing will be conducted with foam cortical shell sawbones

Foam cortical shell models are made of a rigid foam shell with inner cancellous material. These models cut and drill easier than the plastic cortical shell models.

Most commonly used for:

- Total joint replacement
- Internal fixation
- Fracture and pathology models
- General orthopaedics (where a medium cost bone is desirable)

Testing will be carried out using sawbones type large left femur, sawbones part number 1130.

A total of 40 femurs will be prepared for testing which involves a) cutting to a consistent length, 2) resecting the proximal bone and 3) preparing the canal to accept the appropriate stem. 20 Femurs will be prepped in a consistent manner for each stem type. A vise will be used to clamp the distal portion of the stem while impaction testing is ongoing.

<u>Hip Stems</u>

A total of 2 Types of hip stems will be supplied

- Secur Fit Max 132 deg neck, size 10, cat # 6051-1035S
- Accolade TMZF Cementless Femoral Stem 132 deg neck, size 4.5, cat # 6020-4535

Program Outline:

Phase 1: Goal: Setup and baseline supplied system performance using Secur Fit Max stem and up to 4 sawbones.

Setup:

1) Assemble drop tower.
2) Assemble impactor head to drop tower cross head.
3) Assemble sawbone to vise
4) Assemble kistler accelerometer to secure fit stem (hard mount)
5) Assemble kistler load cell and kistler accelerometer to impactor with load cell.

6) Assemble impactor with load cell to secure fit stem
7) Insert secure fit stem into sawbone.
8) Align load point on cross-head to impactor head.
9) Determine drop height necessary to fully seat and fracture sawbone. Record this drop height.
10) Assemble electrical hook up and set up computer data acquisition (I will have detailed instructions for this effort in a few weeks)
11) Replace sawbone and conduct initial impaction test to set up data acquisition parameters
12) Implement data acquisition

Phase 2: Goal: Take baselined system and implement on sawbones models with actual femoral components. Modify and further develop the data acquisition, user interface and force in support of metrics which will assess device seating.

Accelerometer Mount Comparison Test

Outputs from this section include:

1) Relative ranking on usefulness of various signals ability to predict device seating and sawbone fracture. Signals include a)hard mounted accelerometer on stem, b)inserter mounted accelerometer and c)bolt on accelerometer.
2) Comparison of device analog, Secur Fit and Accolade stem seating characteristics.

Procedure

1) Test a total of 4 Secur Fit stems to fracture with the Impactor with load cell
2) Test a total of 4 Secur Fit stems to fracture with the Impactor with clamp on accelerometer mount.
3) Test a total of 4 Accolade stems to fracture with the Impactor with load cell
4) Test a total of 4 Accolade stems to fracture with the Impactor with clamp on accelerometer mount.
5) Evaluate data files generated for each test. (Note: Detailed, step by step, test procedure will be developed when system is up and functioning at Stryker prior to shipment to Los Alamos. Procedure will allow for the generation of output data for each of the force/ accelerometer sensors)

Vibration Algorithm Prediction Effort

Outputs from this section include:

1) Integrated portable data acquisition system capable of being used in a cadaver lab environment with:
    d. Enhanced data acquisition parameters as needed for successful evaluation of signals of interest.
    e. Enhanced signal conditioning metrics used to assess device seating
    f. Visual output parameter used to provide real time seating limit feedback.