Project Proposal

A Novel Planning Paradigm for Augmentation of Osteoporotic Femora

Project Proposal: Group 9
Team members: Amirhossein Farvardin, Mahsan Bakhtiarinejad
Mentors: Dr. Mehran Armand, Dr. Ryan Murphy

Goal

A modified planning paradigm has been created to reduce the injection volume for osteoporotic bone augmentation. The goal of this project is to validate this new planning approach through cadaveric experiments. In addition, we aim to create and validate a COMSOL Finite Element (FE) model to estimate the bone temperature after cement injection. Finally, we intend to introduce a methodology to reduce the cement’s curing temperature inside the bone.

Relevance/Importance

The one-year mortality rate after osteoporotic hip fracture in elderly is 23% [1]. Current preventive measures commonly do not have a short-term (less than one year) effect. Moreover, the risk of a second hip fracture increases 6-10 times in elderly with osteoporosis [2]. Osteoporotic hip augmentation (femoroplasty) is a possible preventive approach for patients at the highest risk of fracture and who cannot tolerate other treatment modalities. Recent computational work and cadaveric studies have shown that osteoporotic hip augmentation with Polymethylmethacrylate (PMMA) can significantly improve yield load and fracture energy [3]. However, higher volumes of PMMA injection may introduce the risk of thermal necrosis. In this project, we validate a modified planning approach to lower the injection volume as compared to the previous work [3]. This will likely reduce the risk of thermal necrosis caused by exothermic polymerization of PMMA.

Background

1. Planning workstation

The modified planning paradigm involves three steps: 1) finite element (FE) optimization of the PMMA distribution, 2) geometric optimization for approximating the FE-optimized model geometry with spheroids, and 3) hydrodynamic simulation to predict the resulting PMMA distribution in the bone (Fig. 1). FE models of the femora were created using CT scans obtained from the specimens following the procedure described earlier in [4]. The boundary conditions simulated a fall to the side. For the first step of planning, three injection patterns were optimized utilizing the Bi-directional Evolutionary Optimization (BESO) method [5].
2. Surgical Execution and Tracking System

The surgical execution and tracking system has been described in detail in [3]. Briefly, we remove the soft tissue from the femora that has been selected for augmentation. We then attach a tracking rigid body with reflective markers (NDI, Waterloo, ON, Canada) to the femur. We then utilize an in-house navigation system [6] to register the bone to its CT volume. For this purpose, we first identify three landmarks on the femur utilizing a tracking digitizer and perform a rigid transformation from the camera coordinates to the CT. We then digitize several surface points and perform a point cloud-to-surface registration utilizing the iterative closest point (ICP) method. In this setup, we use a hand drill (DeWalt Inc., Baltimore, MD) with a custom attachment for a tracking rigid body to drill the desired injection path (Fig.1).

Figure 2- A) Injection setup B) Initial registration C) ICP Registration and surface points [3]
Technical Summery of the Approach

1. Cadaveric studies

For the first part of our project, we will obtain 4-5 pairs of osteoporotic femora from the Maryland State Anatomy Board. We then take computed tomography (CT) scan of each pair and keep them frozen at -20°C. We select one femur from each pair randomly for augmentation and plan the injection per the architecture described above. One day prior to testing, femora will be taken out of the freezer and left at the room temperature (25 °C). After execution of the injection plans, we will perform a mechanical testing simulating a fall to the side on the greater trochanter. Effectiveness of the augmentation will be assessed by performing paired t-tests on the mean differences in the fracture load and fracture energy between control and augmentation sets.

2. COMSOL Simulation Model

In the second part of this project, we will create a COMSOL heat transfer model capable of bone temperature estimation prior to augmentation. This model will assume a homogenous material property inside the bone and a uniform heat flow from the bone-cement-interface towards the bone surface. The model will be validated by direct temperature measurements of the bone surface during the cadaveric studies described above. For this purpose, K-type thermocouples will be attached to the bone surface at several selected landmarks and compared to the temperature profiles of the model.

3. Bone Augmentation Cooling system

In the third part of this project, we aim to introduce and validate a methodology to reduce the PMMA’s curing temperature after cement injection. For this purpose, we will conduct controlled sawbone experiments via a k-wire that is inserted through the injected cement. The metallic k-wire will be attached to an Ice-water bath to lower the curing temperature (Fig. 4). This model will be tested in at least one cadaver experiment to validate its feasibility.
**Deliverables**

The minimum, expected and maximum deliverables of the project are listed as below:

**Minimum**
- Pre-operative planning models for 4-5 osteoporotic femora
- Experimental post-operative results of osteoporotic femora
- Efficacy and statistical analysis of the new planning approach for femoroplasty

**Expected**
- Temperature-rise measurements of the bone surface after the injection
- Heat transfer FE COMSOL model to predict the curing temperature of PMMA inside the bone
- Comparison of the experimental results with FE model

**Maximum**
- A Methodology to reduce the curing temperature
- Experimental results and validation of the cooling system

**List of dependencies & plan for resolving:**

We have few dependencies for the project that are listed as below:

1. Access to osteoporotic femora: The project depends on acquisition of 4-5 pairs of osteoporotic femora for experimental verification studies. This dependency has already been resolved by coordinating with Dr. Armand and Demetries Boston of Bayview Alpha Center.
   **Resolution Status: Resolved**

2. Access to add-on slicer modules for cadaveric experiment: For experimental studies, we need to use add-on slicer modules for navigation, ICP registration and Injection. In order to resolve aforementioned dependency, we coordinated with Dr. Murphy who had previously developed these modules to become more familiar with the usage of them.
   **Resolution Status: Resolved**

3. Bayview lab availability for cadaveric and sawbone experiments: As discussed before, this project involves the conduct of many experiments that will carry out in the Bayview Alpha Center. When we are prepared for each experiment, we need to coordinate with Demetries to make sure the lab is available and schedule the experiment accordingly.
   **Resolution Status: In progress**

4. Access to the MTS machine for mechanical testing: As mentioned before, after we inject each femur with PMMA, we need to conduct the mechanical testing in a configuration simulating a fall to the side on the greater trochanter. For this purpose, it is required to have access to the MTS machine in the Bayview lab and we need to coordinate with Dr. Belkoff
who is in charge of the machine and schedule the mechanical testing according to his availability.

**Resolution Status: In progress**

5. **Access to tools:** We need to have access to several tools such as PMMA, syringe, k-wire, thermocouple, Polaris, etc. for the experimental studies. Bayview lab is equipped with most of the tools needed for this project; however, in case we run out of any of the items, we will place orders through Dr. Armand.

**Resolution Status: In progress**

6. **Access to simulation software:** We are depending on acquisition of the following software products to assist us in the overall planning and thermal simulation of the project.
   a. **ABAQUS:** It will be used for finite element simulation of the cadaveric femora to predict stiffness and yield load before and after injection.
   b. **COMSOL:** It will be used for heat transfer simulation of the cadaveric femora to estimate the bone temperature after the injection.

We have already installed the software on our machines.

**Resolution Status: resolved**

**Management Plan and assigned responsibilities:**

We include 4 important management plan: File management, Time/Resource management, Schedule management and project closeout and lessons learned.

- **File Management**
  We will share all the files related to the project in Dropbox to ensure that we both stay updated on the project and the changes made. We both also have access to the BIGSS Lab source that includes required femoroplasty codes for the planning phase.

- **Time/Resource management**
  As far as time management, we will have weekly meeting with our mentors to discuss the schedule and progress of the project. We need to coordinate with each other to arrange a time for the experiments at Bayview based on individual schedules; furthermore, we’ve set Fridays to go to the Bayview for any necessary preparation of the experiments.

- **Schedule management**
  We used Microsoft Project for the **schedule management** section of the project. All the project deliverables were broken down to tasks and work packages with assigned duration. Afterwards, the relationship between the tasks was defined and the complete project schedule was then generated using this information. At this step, the slack of each task is calculated by MS Project and the critical path is located. Throughout the project, we will monitor the tasks on the critical path more closely to ensure that we meet the specified milestones, and in case of any delays, the project schedule will be modified accordingly.

The timeline of the project is documented at the end of the proposal.
• **Project closeout and lessons learned**
  In the final phase of the project, we will carry out a formal project closeout procedure to ensure that all the project objectives have been met. The list of deliverables, project progress and the final lessons learned will be the main items in our final report and the final poster presentation will be the deliverable of the project closeout phase.

**Assigned responsibilities:**
Even though each team member will be included in all the phases of the project, the chart below shows the responsibility distribution for each part of the project. All the experiments will be done by both group members.

- Preparing the planning models of 2 femora  
  Mahsan
- Preparing the planning models of 2 femora  
  Amir
- COMSOL model simulation  
  Mahsan
- Post-operative and statistical evaluation  
  Amir
- Cadaveric, mechanical testing and thermal experiments  
  Mahsan & Amir

**Key Dates**
Below are the key dates listed for minimum, expected and maximum deliverables of the project:

<table>
<thead>
<tr>
<th>Task</th>
<th>Minimum Date</th>
<th>Expected Date</th>
<th>Maximum Date</th>
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</thead>
<tbody>
<tr>
<td>Conduct the Planning Approach for 2 Femora</td>
<td>Feb 16</td>
<td>March 23</td>
<td>April 28</td>
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<tr>
<td>Measure and evaluate the temperature-rise of bone in cadaveric studies</td>
<td>March 23</td>
<td>April 28</td>
<td>May 5</td>
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<td>Conduct few experiments for the cooling system proposed</td>
<td>April 28</td>
<td>May 5</td>
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<tr>
<td>Evaluate the post-operative results of 2 femora</td>
<td>March 8</td>
<td>April 26</td>
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1. Bone Augmentation Planning

2. Bone Temperature Evaluation

3. Osteonecrosis

References:


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<th>ID</th>
<th>Task Name</th>
<th>February 2017</th>
<th>March 2017</th>
<th>April 2017</th>
<th>May 2017</th>
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<tbody>
<tr>
<td>1</td>
<td>Minimum Deliverable</td>
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<tr>
<td>2</td>
<td>Conduct the Planning Approach for 2 Femora</td>
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<td>3</td>
<td>Carry out the Cadaveric Experiment</td>
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<td>4</td>
<td>Conduct Post-Operative CT</td>
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<td>5</td>
<td>Perform Mechanical Testing</td>
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<td>6</td>
<td>Evaluate Post-Operative Results</td>
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<td>7</td>
<td>Conduct the Planning Approach for 2 Femora</td>
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<td>Carry out the Cadaveric Experiment</td>
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<td>Conduct Post-Operative CT</td>
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<td>Perform Mechanical Testing</td>
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<td>Evaluate Post-Operative Results</td>
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<td>Minimum Deliverable Met: Validation of the new planning approach for</td>
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<td>Measure and evaluate the temperature-rise of bone in cadaveric studies</td>
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<td>15</td>
<td>Create COMSOL FE heat transfer model</td>
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<td>16</td>
<td>Compare the simulation results with experimental</td>
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<td>Conduct the cooling experiment with Foam block</td>
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<td>Conduct the K-Wire Pullout Test</td>
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<td>Conduct the cooling Experiment with a cadaveric femur</td>
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<td>Evaluate the cooling system</td>
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<td>Maximum Deliverable Met: Method for reducing the temperature rise</td>
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<td>Closeout</td>
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<td>25</td>
<td>Prepare Closeout Document</td>
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<td>26</td>
<td>Poster Session</td>
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