Project Proposal

A Novel Planning Paradigm for Augmentation of Osteoporotic Femora

Project Proposal: Group 9

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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].

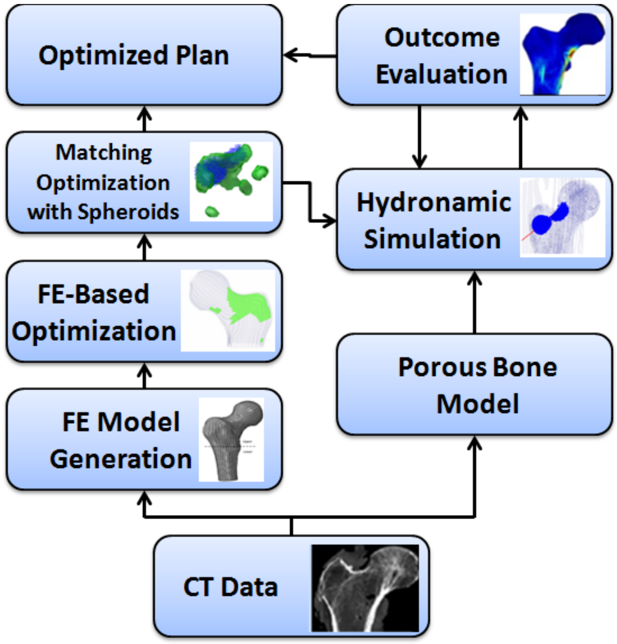

Figure 1 Preoperative Planning architecture

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).

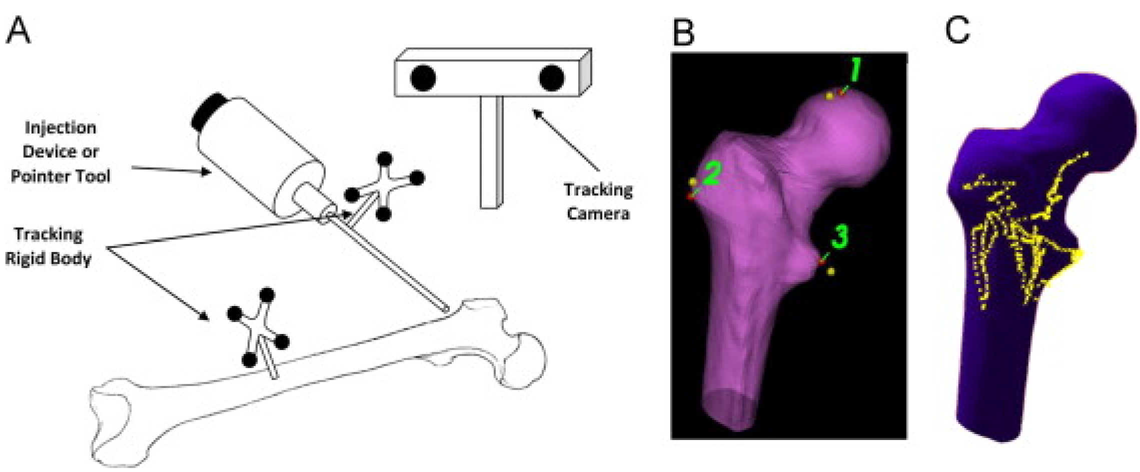

Figure 2- A) Injection setup B) Initial registration C) ICP Registration and surface points [3]

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.

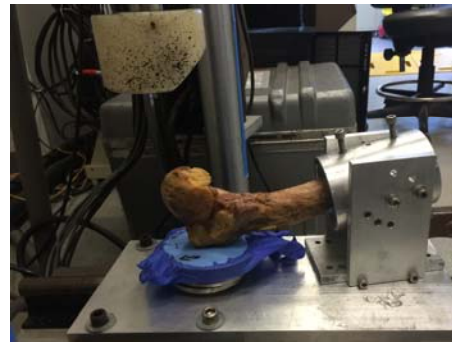

Figure 3- Mechanical Testing Setup

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.

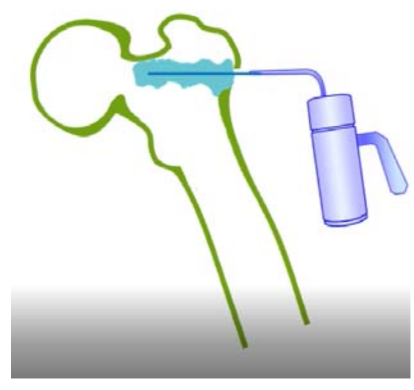

Figure 4- Initial design of the cooling system

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:

Minimum		Expected		Maximum	
Task	Date	Task	Date	Task	Date
Conduct the Planning Approach for 2 Osteoporotic Femora	Feb 16	Measure and evaluate the temperature-rise of bone in cadaveric studies	March 23	Conduct few experiments for the cooling system proposed	April 28
Evaluate the post-operative results of 2 femora	March 8	Create COMSOL FE heat transfer Model	April 26	Evaluate the cooling system	May 5
Conduct the Planning Approach for 2 Osteoporotic Femora	March 17	Compare the simulation results with experimental data	April 28		
Evaluate the post-operative results of 2 femora	March 27				
Evaluate the new planning approach	March 31				

Reading List

1. **Bone Augmentation Planning**
    - Basafa, E., Murphy, R. J., Otake, Y., Kutzer, M. D., Belkoff, S. M., Mears, S. C., & Armand, M. (2015). Subject-specific planning of femoroplasty: An experimental verification study. Journal of biomechanics, 48(1), 59-64
    - Basafa, E., Armiger, R. S., Kutzer, M. D., Belkoff, S. M., Mears, S. C., & Armand, M. (2013). Patient-specific finite element modeling for femoral bone augmentation. Medical engineering & physics, 35(6), 860-865
    - Basafa, E., & Armand, M. (2014). Subject-specific planning of femoroplasty: A combined evolutionary optimization and particle diffusion model approach. Journal of biomechanics, 47(10), 2237-2243.
    - Basafa, E., Murphy, R. J., Kutzer, M. D., Otake, Y., & Armand, M. (2013). A particle model for prediction of cement infiltration of cancellous bone in osteoporotic bone augmentation. PloS one, 8(6), e67958.
    - Basafa, E., & Armand, M. (2013, August). Cement placement optimization in femoral augmentation using an evolutionary algorithm. In ASME 2013 International Design Engineering Technical Conferences and Computers and Information in Engineering Conference (pp. V004T08A009-V004T08A009). American Society of Mechanical Engineers.
    - Kutzer, M. D., Basafa, E., Otake, Y., & Armand, M. (2011, January). An automatic injection device for precise cement delivery during osteoporotic bone augmentation. In ASME 2011 International Design Engineering Technical Conferences and Computers and Information in Engineering Conference (pp. 821-827). American Society of Mechanical Engineers.

2. **Bone Temperature Evaluation**
    - Anselmetti, Giovanni Carlo, Antonio Manca, Khanna Kanika, Kieran Murphy, Haris Eminefendic, Salvatore Masala, and Daniele Regge. "Temperature measurement during polymerization of bone cement in percutaneous vertebroplasty: an in vivo study in humans." *Cardiovascular and interventional radiology* 32, no. 3 (2009): 491-498.
    - Deramond, H., N. T. Wright, and Stephen M. Belkoff. "Temperature elevation caused by bone cement polymerization during vertebroplasty." *Bone* 25, no. 2 (1999): 17S-21S.
    - Stańczyk, M., and B. Van Rietbergen. "Thermal analysis of bone cement polymerisation at the cement–bone interface." *Journal of biomechanics* 37, no. 12 (2004): 1803-1810.

3. **Osteonecrosis**
    - Augustin, Goran, Slavko Davila, Kristijan Mihoci, Toma Udiljak, Denis Stjepan Vedrina, and Anko Antabak. "Thermal osteonecrosis and bone drilling parameters revisited." *Archives of Orthopaedic and Trauma Surgery* 128, no. 1 (2008): 71-77.

- Augustin, Goran, Tomislav Zigman, Slavko Davila, Toma Udilljak, Tomislav Staroveski, Danko Brezak, and Slaven Babic. "Cortical bone drilling and thermal osteonecrosis." *Clinical biomechanics* 27, no. 4 (2012): 313-325.

References:

[1] Cummings, Steven R., Susan M. Rubin, and Dennis Black. "The future of hip fractures in the United States: numbers, costs, and potential effects of postmenopausal estrogen." *Clinical orthopaedics and related research* 252 (1990): 163-166.

[2] Dinah, A. F. "Sequential hip fractures in elderly patients." *Injury* 33, no. 5 (2002): 393-394.

[3] Basafa, Ehsan, Ryan J. Murphy, Yoshito Otake, Michael D. Kutzer, Stephen M. Belkoff, Simon C. Mears, and Mehran Armand. "Subject-specific planning of femoroplasty: An experimental verification study." *Journal of biomechanics* 48, no. 1 (2015): 59-64.

[4] Basafa, Ehsan, Robert S. Armiger, Michael D. Kutzer, Stephen M. Belkoff, Simon C. Mears, and Mehran Armand. "Patient-specific finite element modeling for femoral bone augmentation." *Medical engineering & physics* 35, no. 6 (2013): 860-865.

[5] Basafa, Ehsan, and Mehran Armand. "Subject-specific planning of femoroplasty: A combined evolutionary optimization and particle diffusion model approach." *Journal of biomechanics* 47, no. 10 (2014): 2237-2243.

[6] Otake, Y., M. Armand, O. Sadowsky, M. Kutzer, R. Armiger, E. Basafa, P. Kazanzides, and R. Taylor. "Development of a navigation system for femoral augmentation using an intraoperative C-arm reconstruction." *Proc CAOS-International* (2009): 177-180.

ID	Task Name
1	**Minimum Deliverable**
2	Conduct the Planning Approach for 2 Femora
3	Carryout the Cadaveric Experiment
4	Conduct Post-Operative CT
5	Perform Mechanical Testing
6	Evaluate Post-Operative Results
7	Conduct the Planning Approach for 2 Femora
8	Carryout the Cadaveric Experiment
9	Conduct Post-Operative CT
10	Perform Mechanical Testing
11	Evaluate Post-Operative Results
12	Minimum Deliverable Met: Validation of the new planning approach for
13	**Expected Deliverable**
14	Measure and evaluate the temperature-rise of bone in cadaveric studies
15	Create COMSOL FE heat transfer model
16	Compare the simulation results with exprimental
17	Expected Deliverable Met:temperature rise evaluation and FEA
18	**Maximum Deliverable**
19	Conduct the cooling expriment with Foam block
20	Conduct the K-Wire Pullout Test
21	Conduct the cooling Experiment with a cadaveric femur
22	Evaluate the cooling system
23	Maximum Deliverable Met: Method for reducing the temperature rise
24	**Closeout**
25	Prepare Cloesout Document
26	Poster Session