A Novel Planning Paradigm for Augmentation of Osteoporotic Femora

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Mentors:

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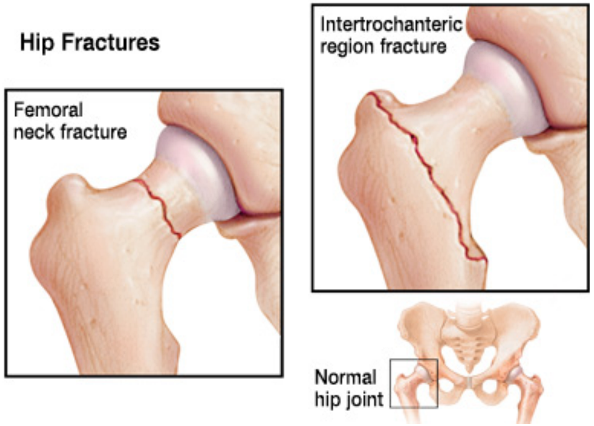
Motivation

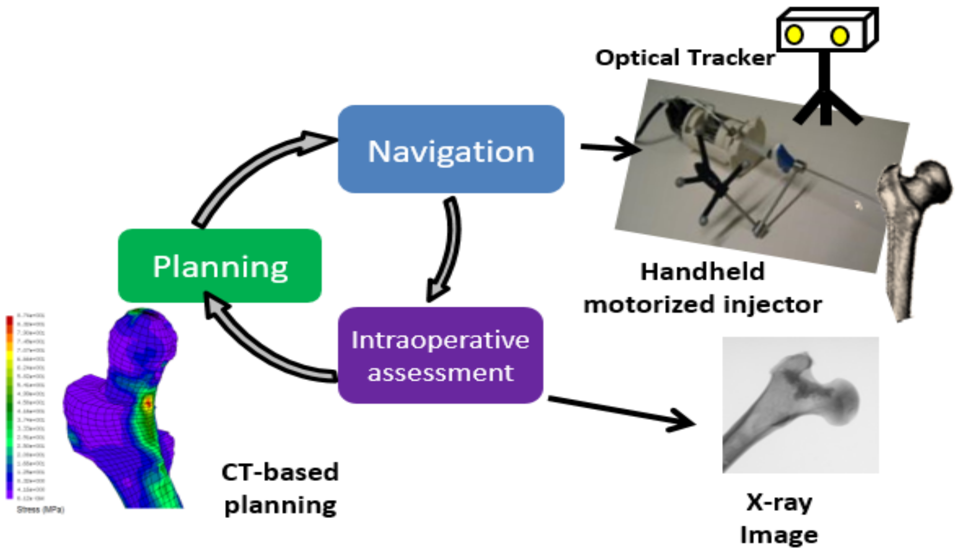
- Osteoporotic fractures are responsible for thousands of deaths and billions of dollars of treatment
- The risk of a second hip fracture increases 6-10 times in elderly with osteoporosis
- The one-year mortality rate after osteoporotic hip fracture in elderly is 23%.

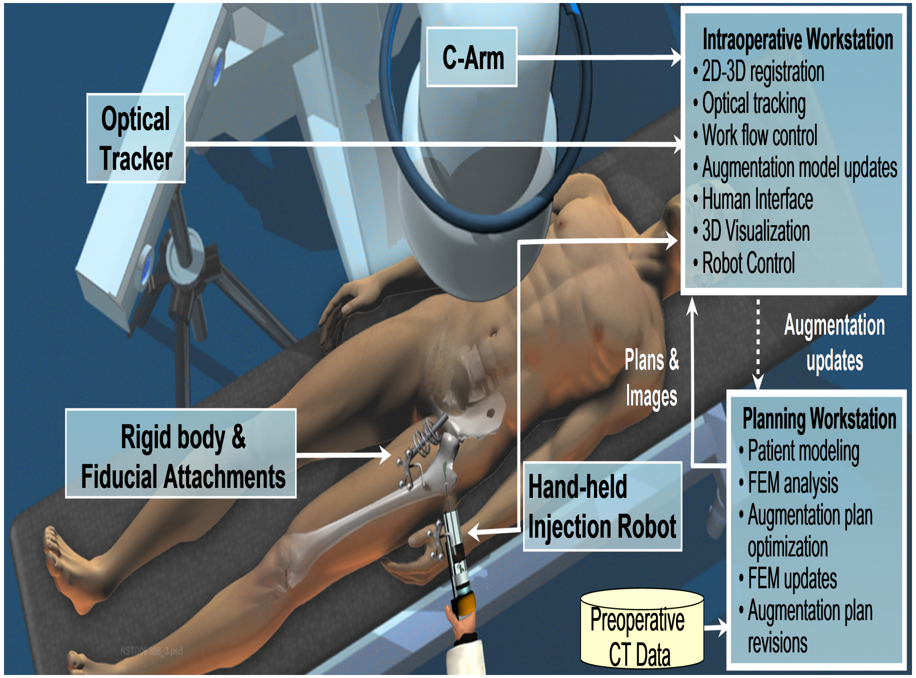


NY injury case weblog

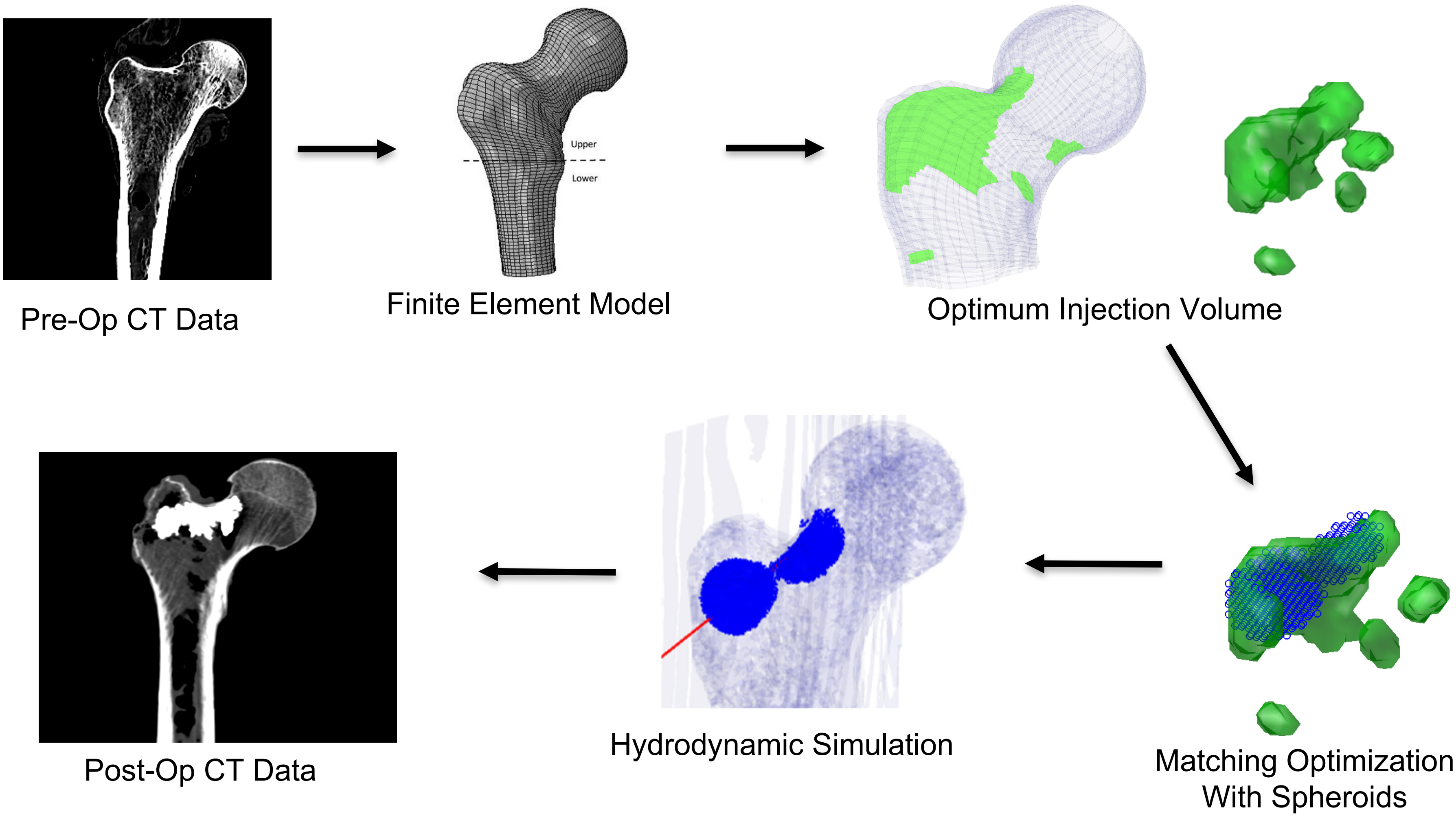
Background: Approach

Short term Approach: Inject bone cement to an osteoporotic femur to reduce the risk of fracture





Background: Overview of the Planning Module



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Background: Overview of the Planning Module

Step 1:

Finite element optimization of the PMMA Distribution

Project Goals

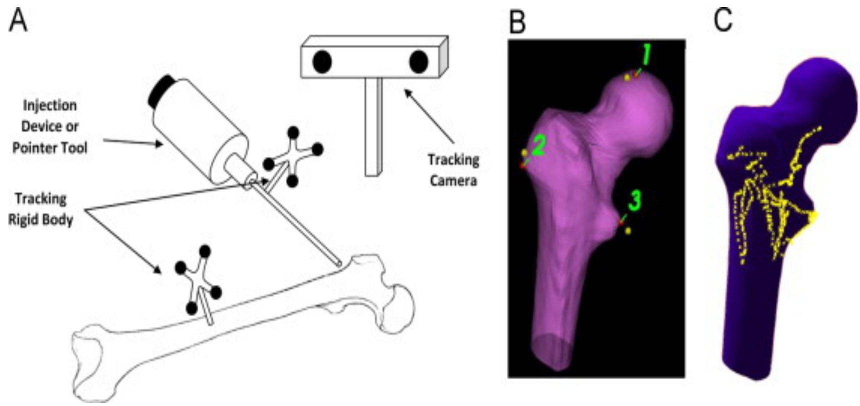
Address the potential risk of thermal-necrosis associated with femoroplasty in the following ways:

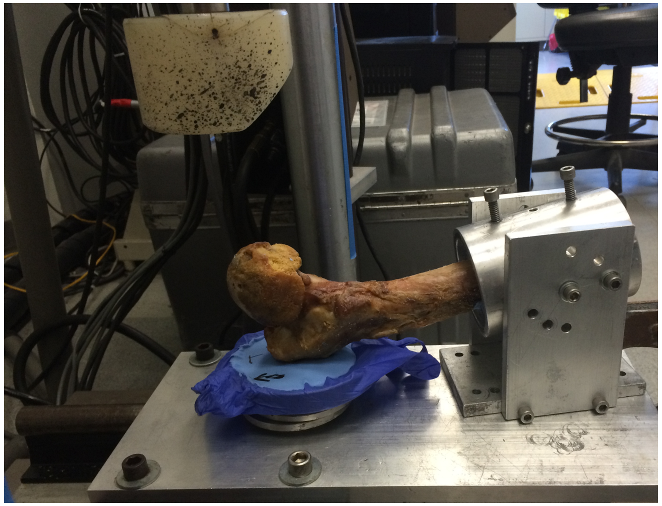
- Validate the new planning (Reduced Injection Volume) approach through cadaveric experiments
- Create and validate a COMSOL Finite Element (FE) model to estimate the bone temperature after cement injection
- Introduce a methodology to reduce the curing temperature of the cement inside the bone

Technical Summary of Approach

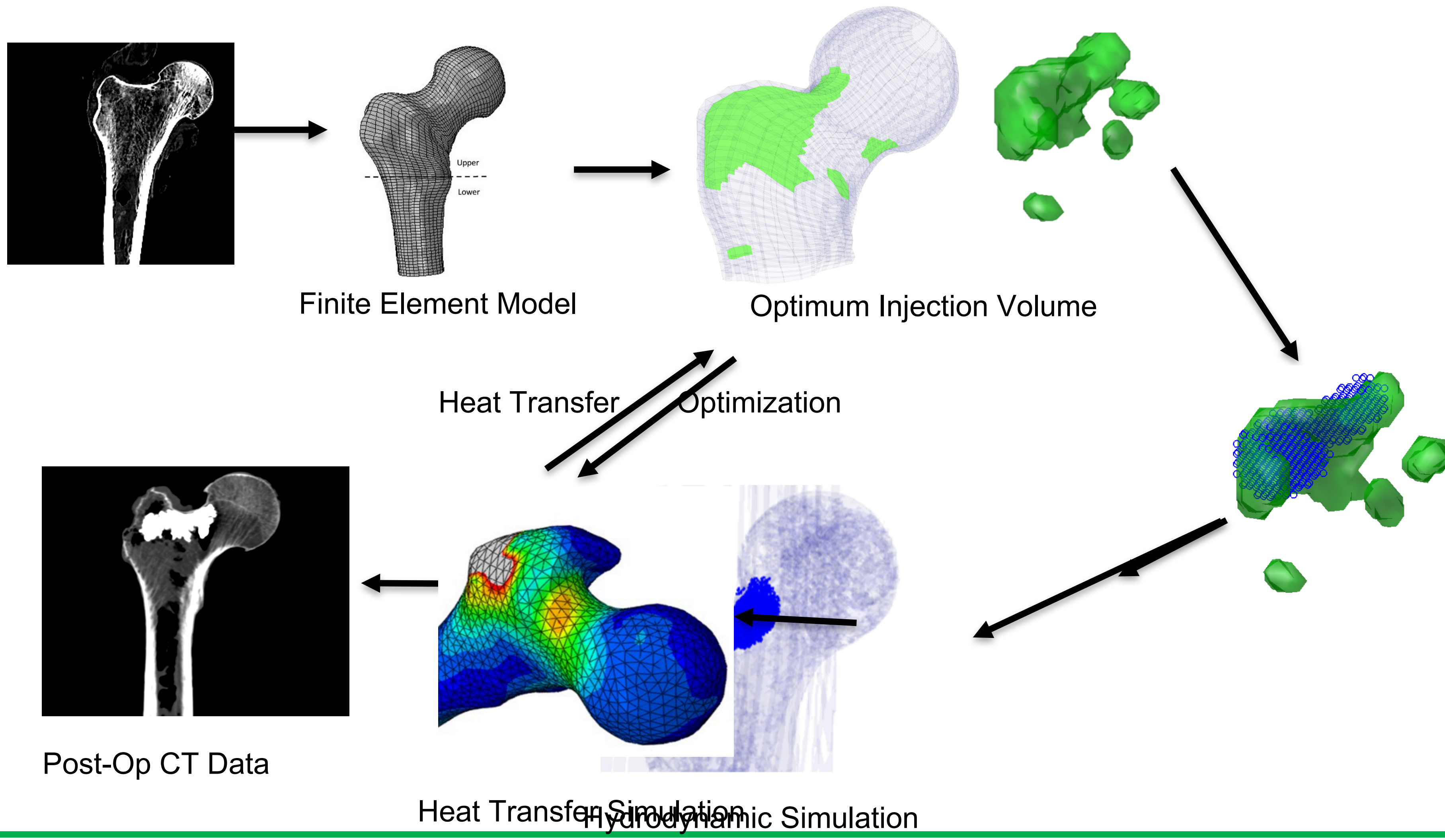
Cadaveric Studies

- New Planning approach constrains the injection volume of cement to 10cc
- Plan will be tested through cadaveric experiments on 4-5 pairs of femora
- Effectiveness of the plan will be verified via mechanical testing simulating a fall to the side





Technical Summary of Approach:
Heat Transfer Simulation Prior to Injection



Technical Summary of Approach:
Bone Augmentation Cooling system

Controlled sawbone experiment via a metallic K-wire attached to ice-water bath

Deliverables

Minimum	• Pre-operative planning models of 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 measurement of the bone surface after the injection • Heat transfer FE COMSOL model • Comparison of the experimental results with FE model
Maximum	• A Methodology to reduce the curing temperature • Experimental results and validation of the cooling system

Dependencies

Dependency	Plan for resolving	Status
Access to 4-5 pairs of osteoporotic femora	Coordinate with Dr. Armand and Demetries	Resolved
Access to add-on slicer modules for cadaveric experiment	Coordinate with Dr. Murphy	Resolved
Bayview lab availability for cadaveric and sawbone experiments	Coordinate with Bayview lab technician	In progress
Access to the MTS machine for mechanical testing	Coordinate with Dr. Belkoff	In progress
Access to tools (PMMA, k-wire , syringe, thermocouple, Polaris, …)	Coordinate with Dr. Armand	In progress
Access to simulation software	_	Resolved

Management Plan

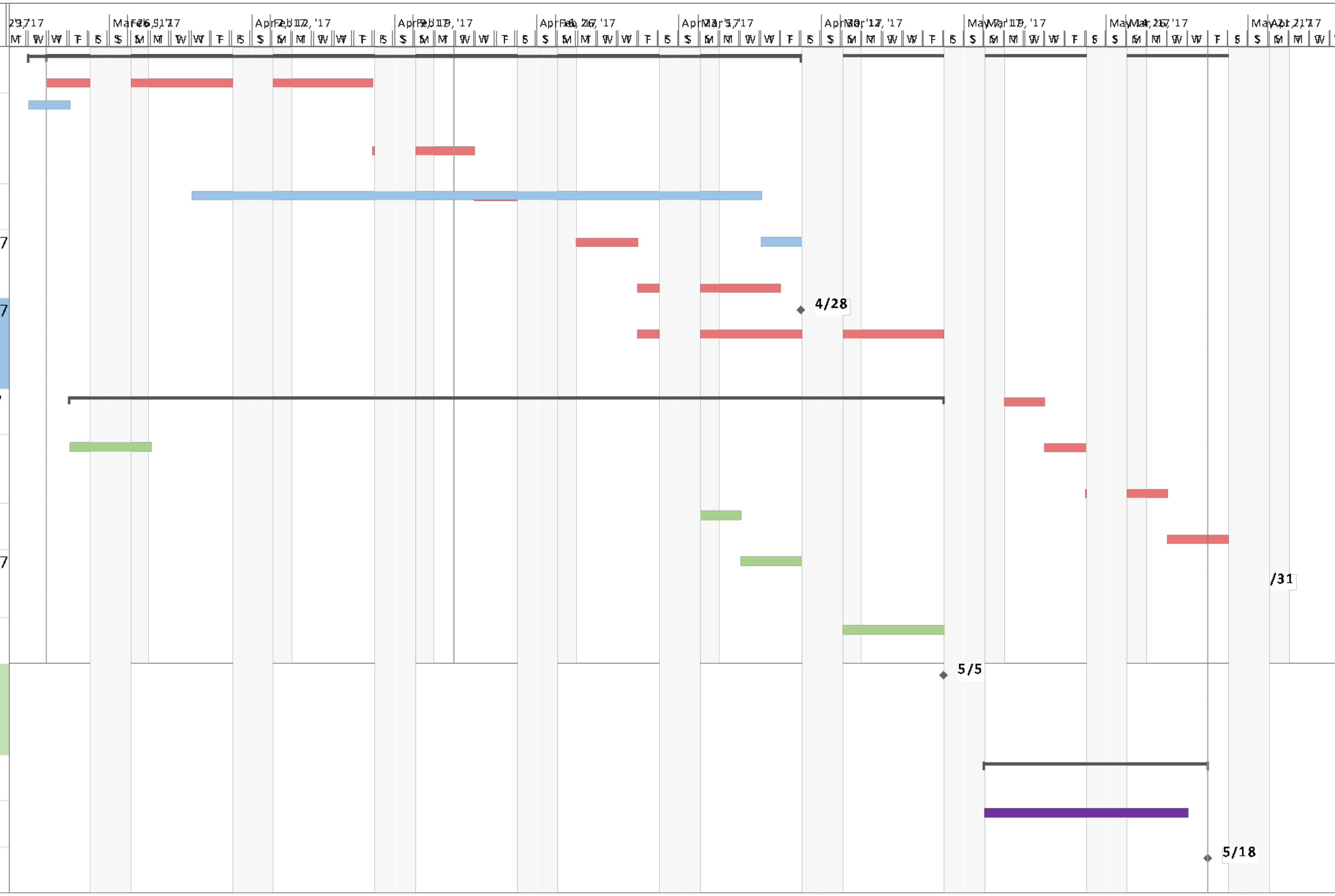
- **Time Management**
  - Weekly Meeting with mentors
- **Primary Responsibility**

Amir	Mahsan
Planning 2 femora	Planning 2 femora
Post-operative and statistical evaluation	COMSOL model simulation
Cadaveric, mechanical testing and thermal experiments	Cadaveric, mechanical testing and thermal experiments

- **Project close-out**
  - Deliverable submission and evaluation
  - Final poster presentation

Project Timeline

ID	Task Name	Start	Finish
13 2	**Expected Deliverable**	**Wed 3/22/17**	**Fri 4/28/17**
14 3	Measure and evaluate the temperature-rise of bone in cadaveric studies	Wed 3/22/17	Thu 3/23/17
15	Create COMSOL FE heat transfer model	Thu 3/30/17	Wed 4/26/17
16 6	Compare the simulation results with exprimental data	Thu 4/27/17	Fri 4/28/17
17 7	Expected Deliverable Met:temperature rise evaluation and FEA simulation	Fri 4/28/17	Fri 4/28/17
18	**Maximum Deliverable**	**Fri 3/24/17**	**Fri 5/5/17**
19 10	Conduct the cooling expriment with Foam block	Fri 3/24/17	Mon 3/27/17
20 11	Conduct the K-Wire Pullout Test	Mon 4/24/17	Tue 4/25/17
21 12	Conduct the cooling Experiment with a cadaveric femur	Wed 4/26/17	Fri 4/28/17
22	Evaluate the cooling system	Mon 5/1/17	Fri 5/5/17
23	Maximum Deliverable Met: Method for reducing the temperature rise	Fri 5/5/17	Fri 5/5/17
24	**Closeout**	**Mon 5/8/17**	**Thu 5/18/17**
25	Prepare Cloesout Documents	Mon 5/8/17	Wed 5/17/17
26	Poster Session	Thu 5/18/17	Thu 5/18/17



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Key dates

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				

What if…

	Deliverables	Contingency Plan
Minimum	We don't succeed to conduct all the experiments for 5 femora successfully	We will do the analysis with less femora
Expected	COMSOL finite element simulation doesn't converge successfully	We try to simplify the model
Maximum	We don't succeed in the pulling the K-Wire out of the cement in the final phase	We will evaluate the consequences of leaving the K-Wire inside the bone

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.

Reading List

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.

Questions?