A Novel Planning Paradigm for Augmentation of Osteoporotic Femora

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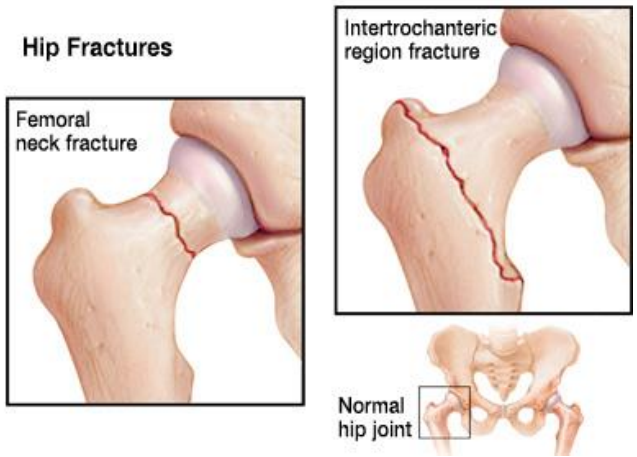
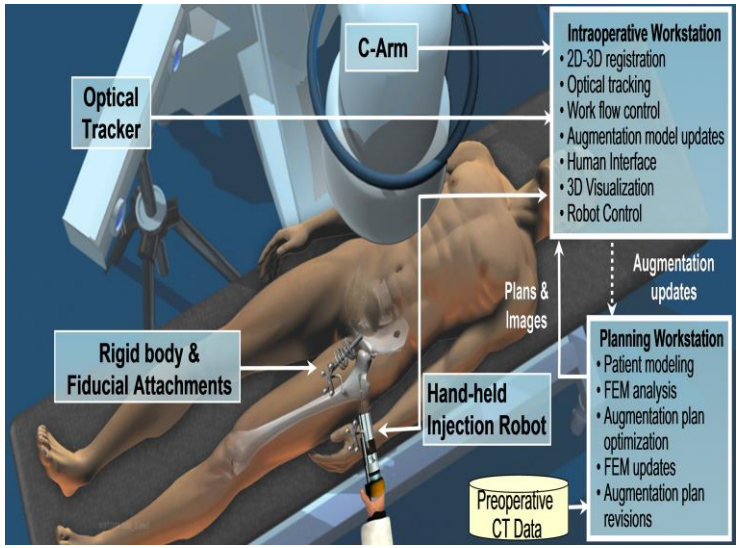
Motivation and Background

- One of the common problems for elderly with osteoporotic are **bone fractures**
- Osteoporotic fractures are responsible for thousands of deaths and billions of dollars of treatment
- **Short term Approach:** Inject bone cement to an osteoporotic femur to reduce the risk of fracture



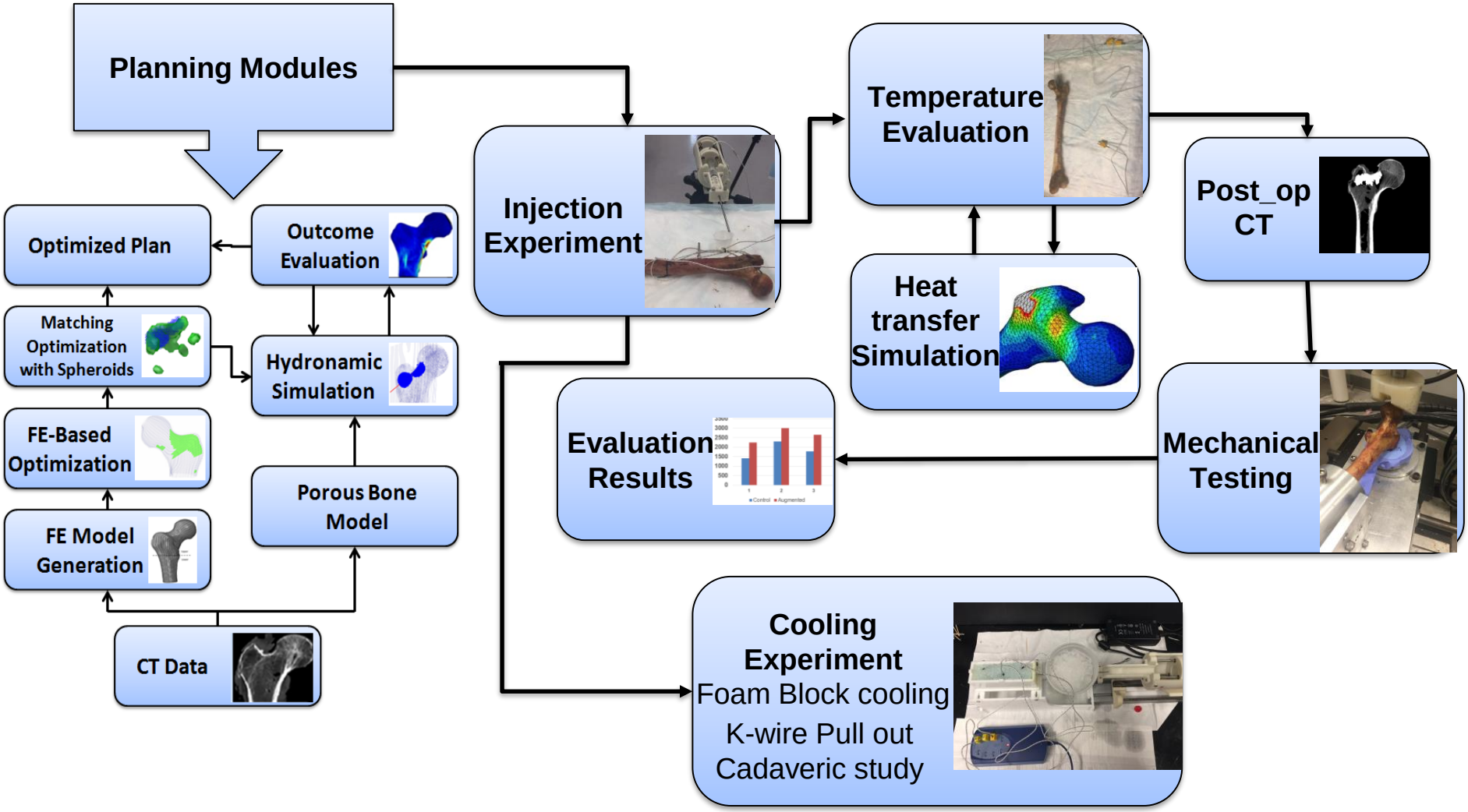


Overview of Goals

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

Work Flow


Planning Modules
Optimized Plan
Outcome Evaluation
Matching Optimization with Spheroids
Hydronamic Simulation
FE-Based Optimization
Porous Bone Model
FE Model Generation
CT Data
Injection Experiment
Temperature Evaluation
Post_op CT
Heat transfer Simulation
Evaluation Results
Mechanical Testing
Cooling Experiment
Foam Block cooling
K-wire Pull out
Cadaveric study

Status of Deliverables

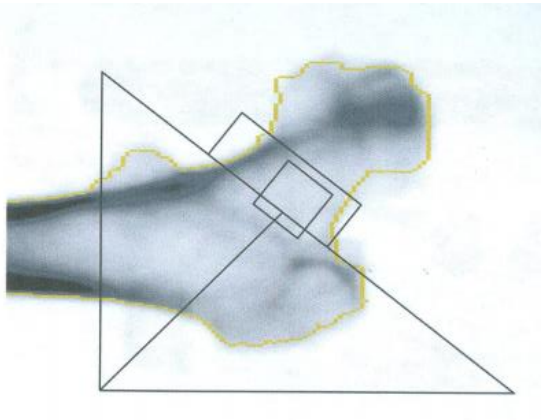
Deliverables		Status
Minimum	• Pre-operative planning models of 4 osteoporotic femora	✓
	• Experimental post-operative results of osteoporotic femora	✓
	• Efficacy analysis of the new planning approach for femoroplasty	In Progress
Expected	• Temperature rise measurement of the bone surface after the injection	✓
	• Heat transfer FE COMSOL model	In Progress
	• Comparison of the experimental results with FE model	Not Started
Maximum	• A Methodology to reduce the curing temperature	✓
	• Experimental results and validation of the cooling system	In Progress

Pre-Operative Simulations: Yield Load estimation

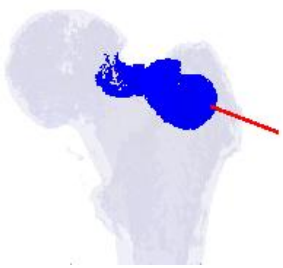
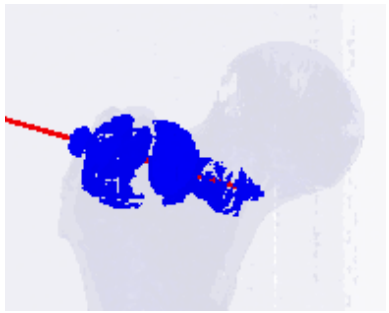
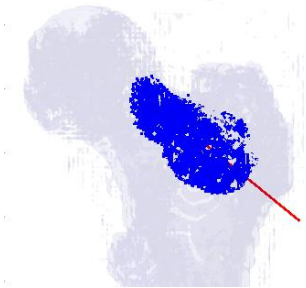
	Specimen #1 (Female, W, 92 YO)	Specimen #2 (Male, W, 85 YO)	Specimen #3 (Female, W, 91.8 YO)	Specimen #4 (Female, W, 59.4 YO)
Right	**1350 N** Neck t-score: -3.8	**1825 N** Neck t-score: -3.2	**1815 N** Neck t-score: - 3.6	**2620 N** Neck t-score: - 2.2
Left	**1500 N** Neck t-score: -2.0	**1745 N** Neck t-score: -3.4	**1890 N** Neck t-score: - 4.0	**In progress** Neck t-score: - 2.0

Neck t-score range for Osteoporotic femurs < -2.5

Average T-score of our samples = -3.03 , SD = 0.83



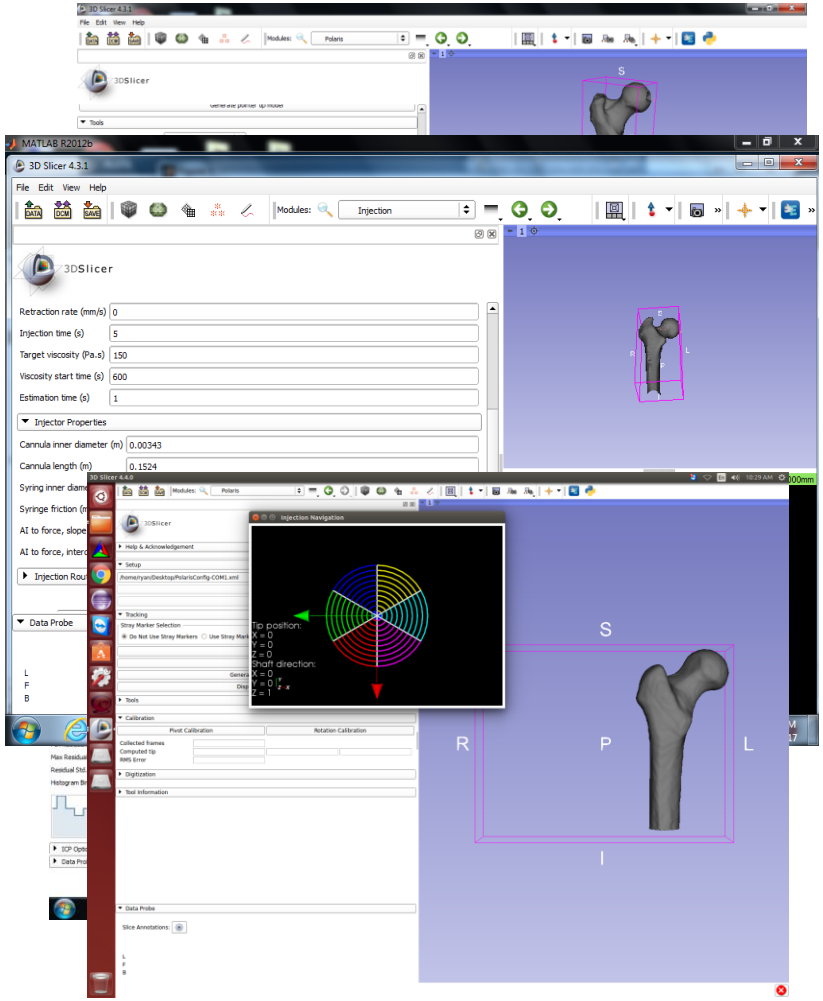
Pre-Operative Simulations: BESO & SPH

	Specimen #1 (Right)	Specimen #2 (Left)	Specimen #3 (Left)	Specimen #4 (Right)
BESO				
SPH Result				

Injection Experiment

1. Bone Cement Injection

- 3-points Initial Registration
- ICP Registration
- Pivot and Rotation Calibration for drill
- Drill Navigation
- Cement Injection

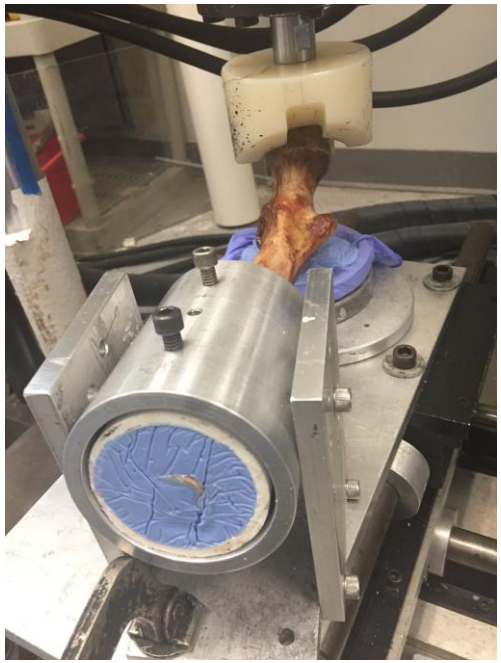


Mechanical Testing

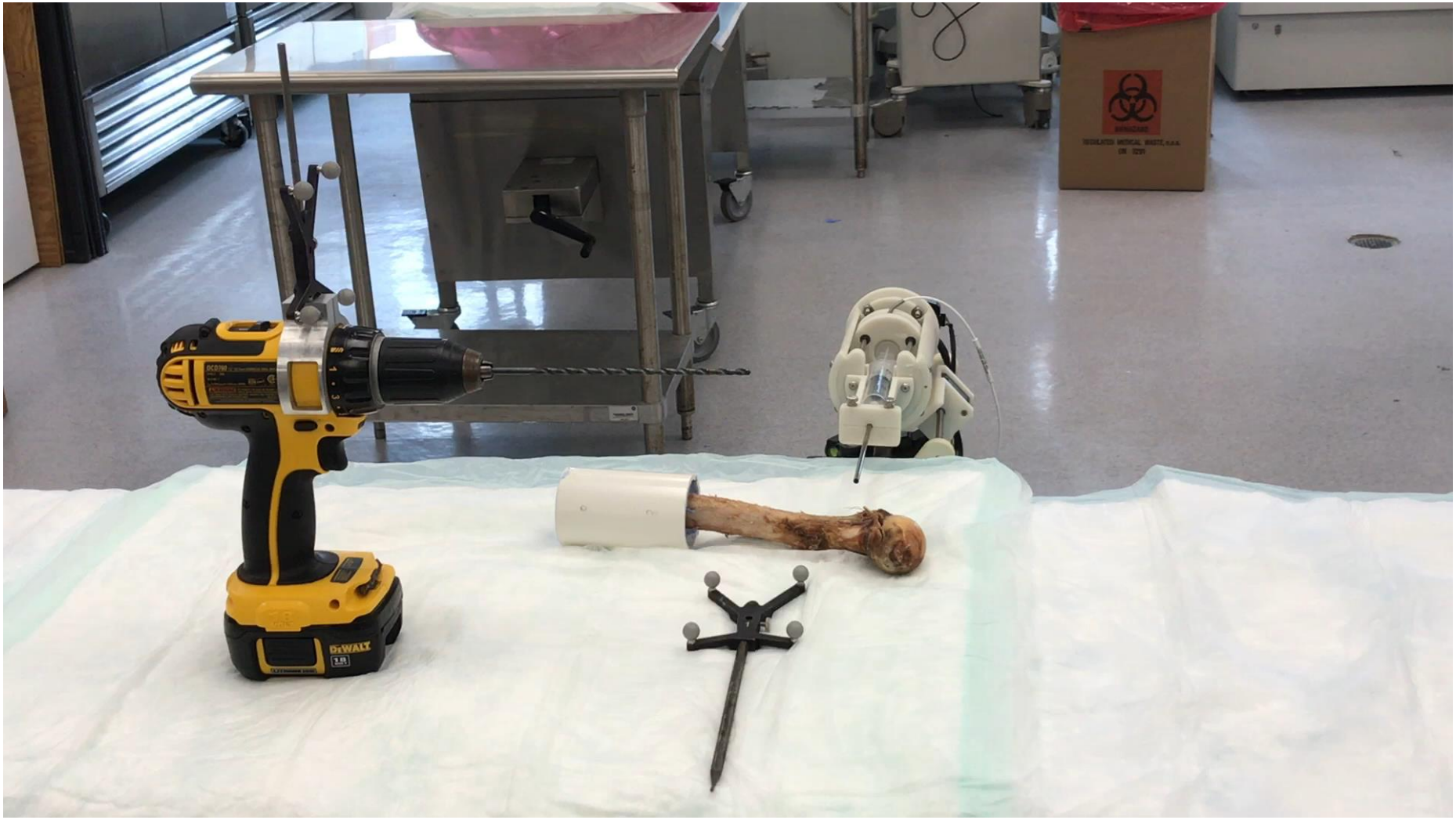
2. Mechanical Testing

Mechanical testing simulating a fall to the side on the greater trochanter

Total Displacement =25 mm
rate =100 mm/s



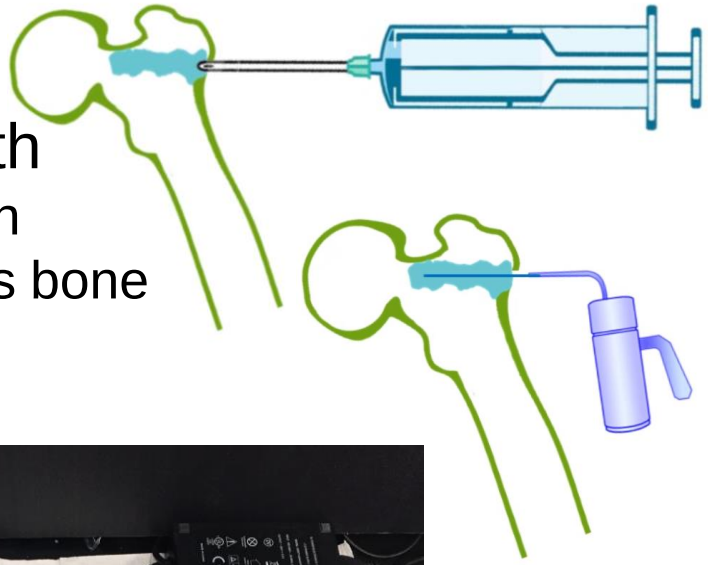
Experiment Flow (Video)

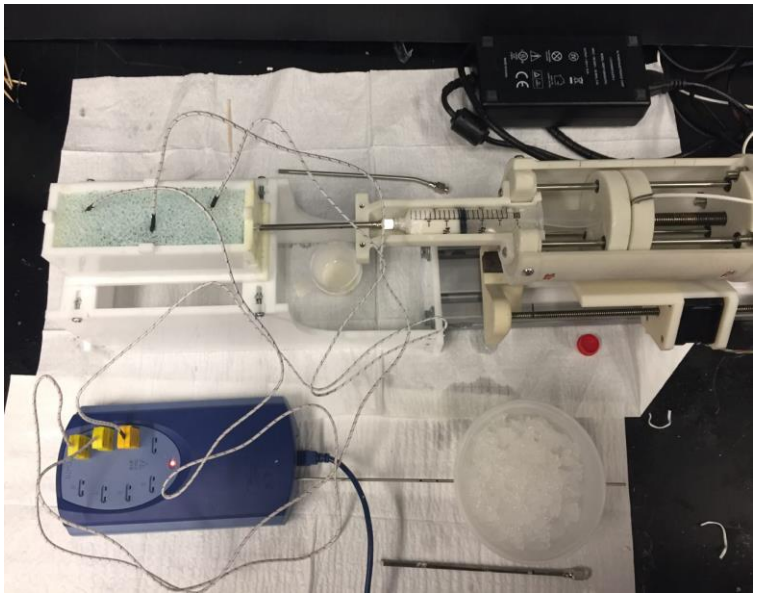


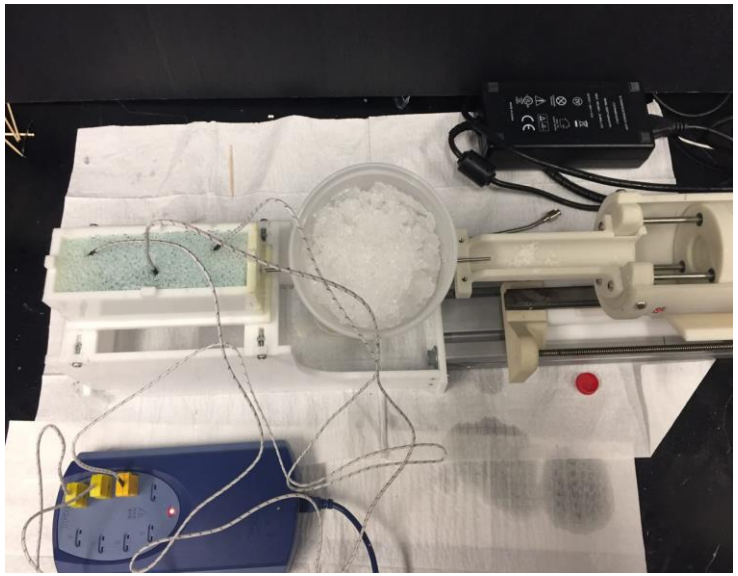
Cooling System

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

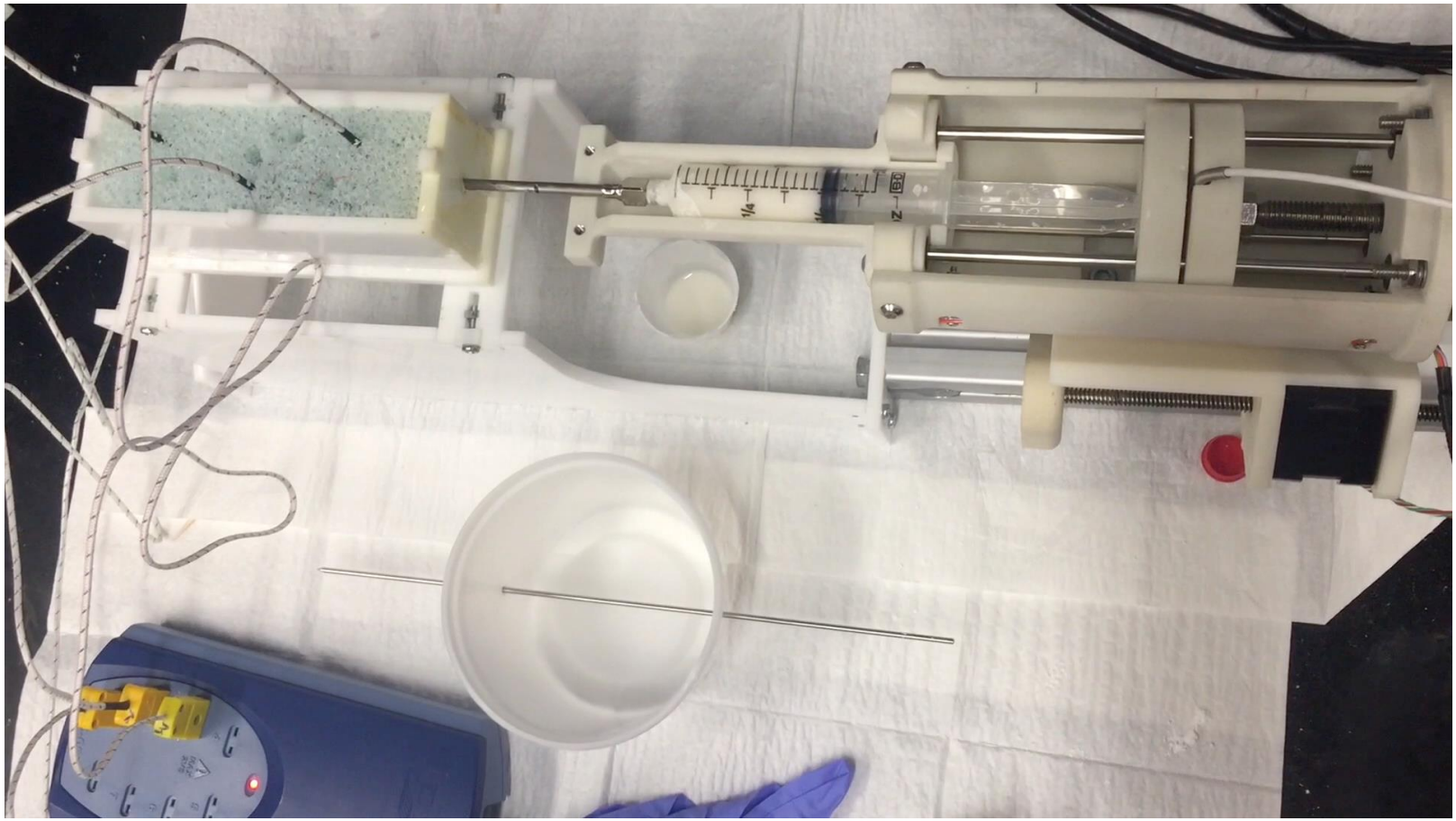
- 2 Experiments injecting 15 mL cement into an open cell block resembling human cancellous bone with canola oil bone mimicking bone marrow with and without cooling







Cooling System (Video)



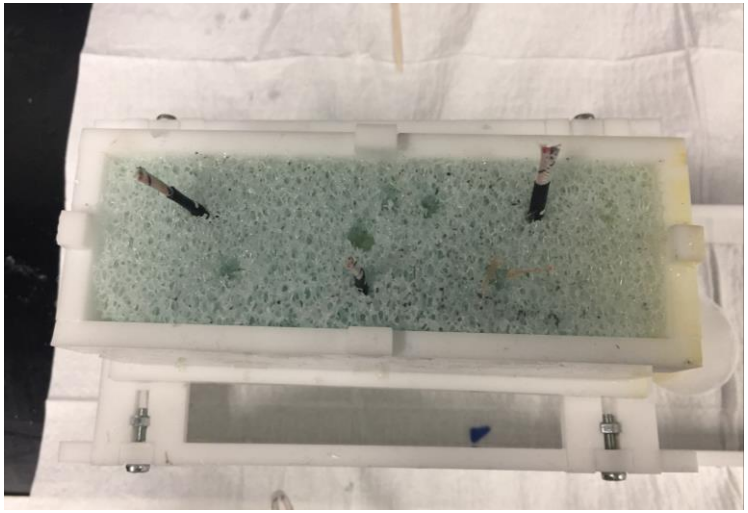
Cooling System

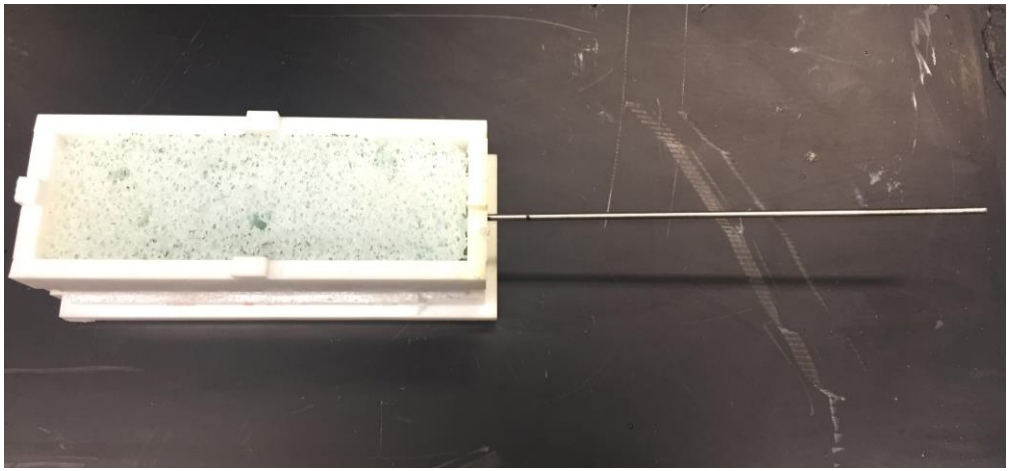
What is next plan?

K-Wire got stuck into foam block after injection

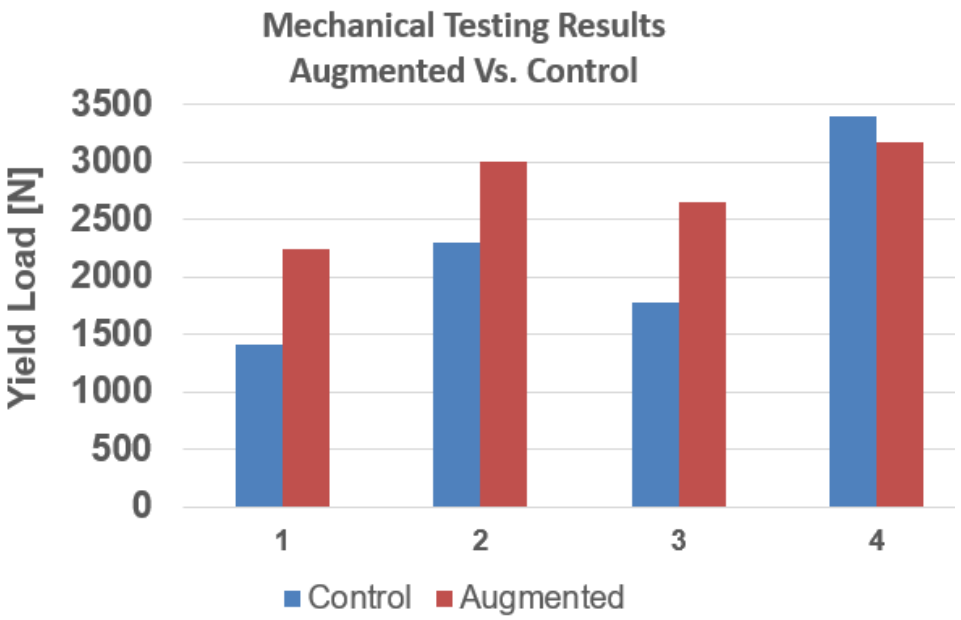
- K-Wire Pull out Test:
- Rotating K-Wire with drill while inserting
- Take it out sooner after reaching curing temperature

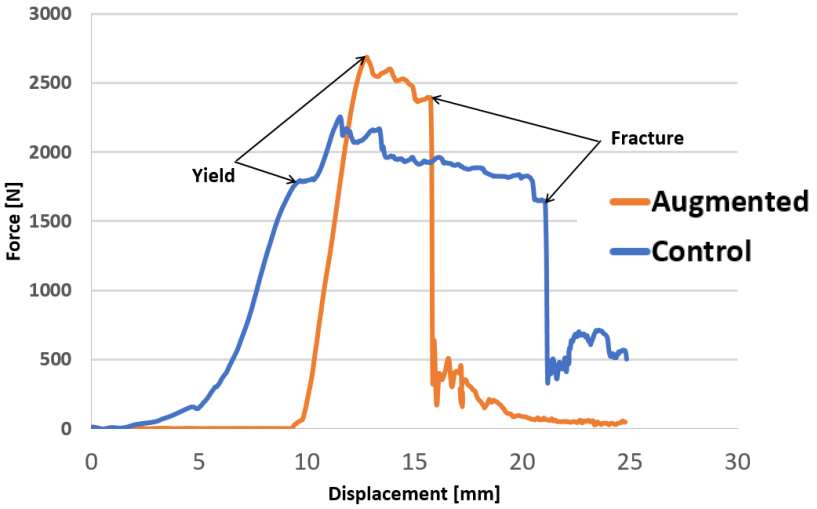
- Cooling Experiment with Cadaveric Femur if available





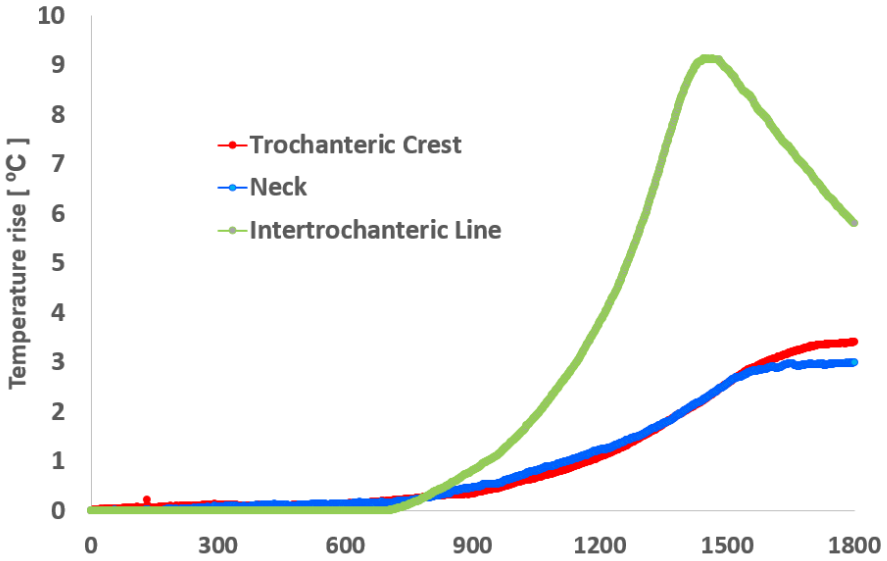
Mechanical Testing Results

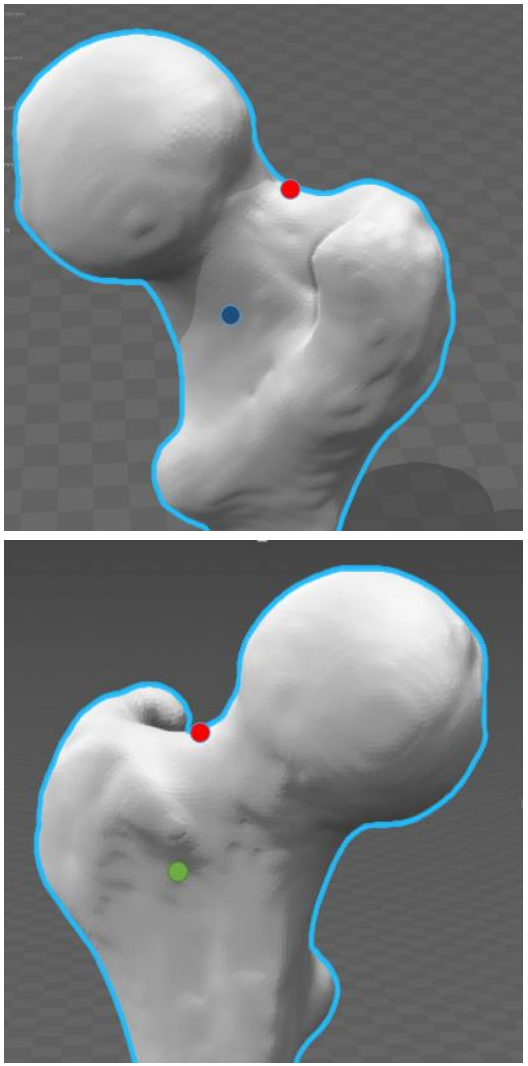




- Yield Load for Augmented pair of Osteoporotic femurs is 43.5% higher than that of the control pair
- Average Injection Volume = 8.83 mL
- Augmentation did not improve osteopenic femur

Temperature Results



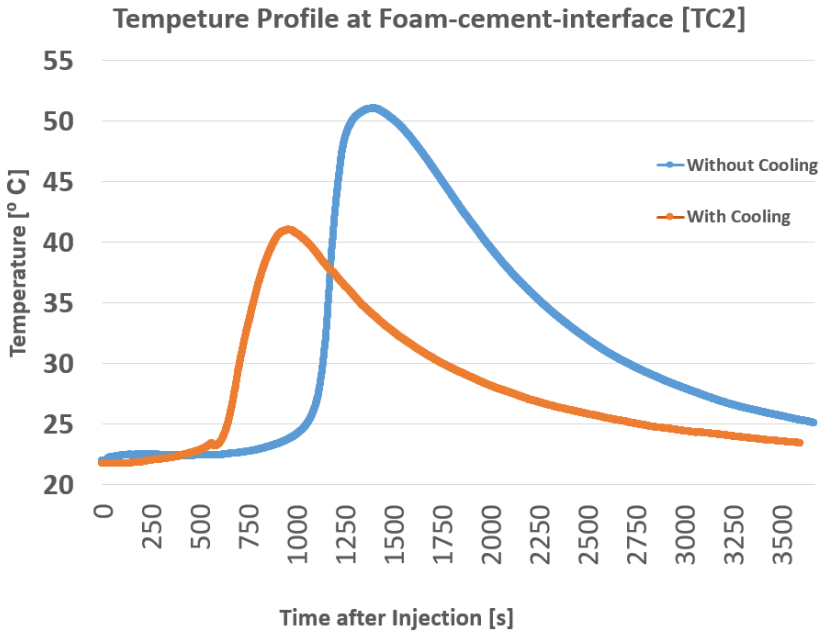


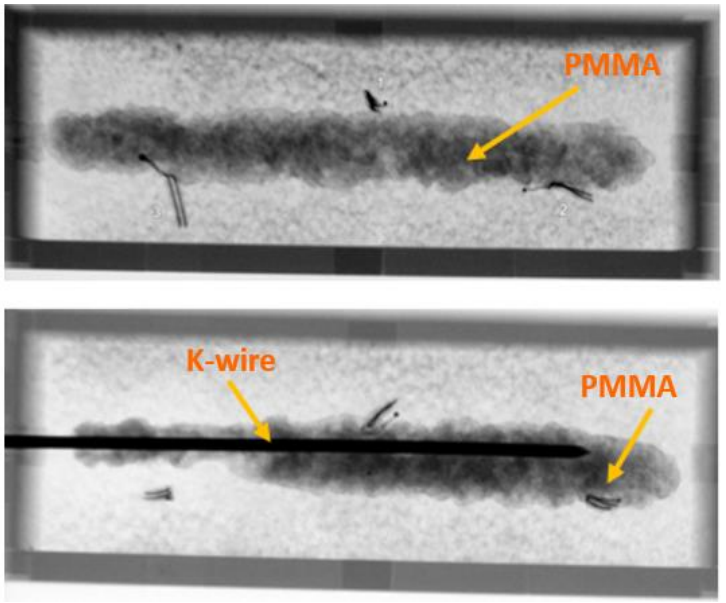
Next Step:

- Create a Comsol model to estimate the temperature Prior to injection
- Validate the model utilizing the thermocouple readings in cadaver experiments

Cooling System Results

Comparison of thermocouple measurement of the injection with the cooling system with measurement of the control experiment without cooling





Challenges and Problems

- BESO and SPH simulations are time-consuming
  - average run time on BIGSS lab PC is 12.4 hours for BESO

- Biological Variations
  - Osteopenic Vs. osteoporotic
  - Left femur Vs. right Femur

- Experimental Challenges:
  - Losing field of view during drilling
  - Bone slippage during Mechanical testing

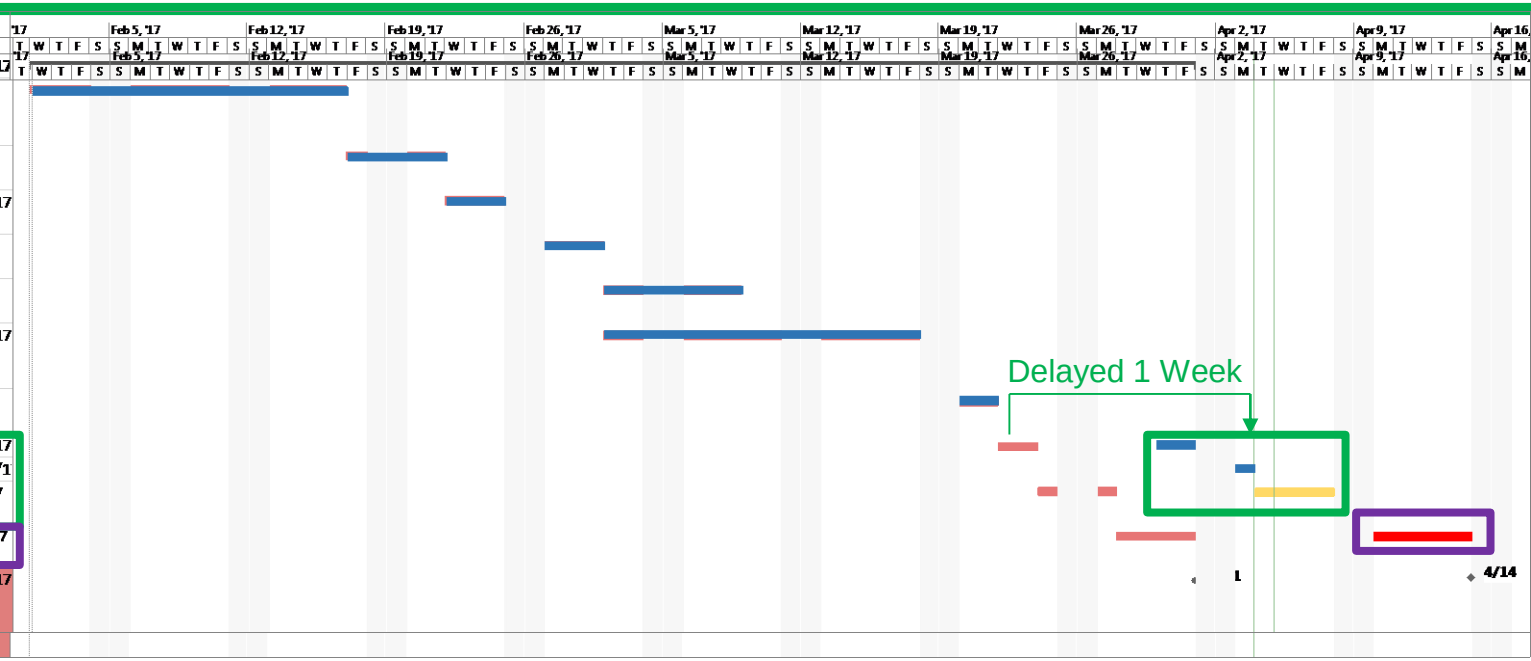
- Dr. Belkoff's availability for Mechanical testing

Updated Dependencies

Dependency	Plan for resolving	Status
Access to 4-5 pairs of osteoporotic femora	Coordinate with Dr. Armand and Demetries	We need one femur for cadaveric cooling experiment
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	Resolved
Access to tools (PMMA, k-wire , syringe, thermocouple, Polaris, …)	Coordinate with Dr. Armand	Resolved
Access to simulation software	_	Resolved

Updated Project Timeline

ID	Task Name	Start	Finish
1	Minimum Deliverable	Wed 2/1/17	Fri 3/31/17
2	Conduct the Planning Approach for 2 Osteporotic Femora	Wed 2/1/17	Thu 2/16/17
3	Carryout the Cadaveric Experiment	Fri 2/17/17	Tue 2/21/17
4	Conduct Post-Operative CT	Wed 2/22/17	Fri 2/24/17
5	Perform Mechanical Testing	Mon 2/27/17	Wed 3/1/17
6	Evaluate Post-Operative Results	Thu 3/2/17	Wed 3/8/17
7	Conduct the Planning Approach for 2 Osteporotic Femora	Thu 3/2/17	Fri 3/17/17
8	Carryout the Cadaveric Experiment	Mon 3/20/17	Tue 3/21/17
9	Conduct Post-Operative C	Thu 3/30/1	Fri 3/31/17
10	Perform Mechanical Test	Mon 4/3/1	Mon 4/3/1
10	Evaluate Post-Operative Results	Tue 4/4/17	Fri 4/7/17
12	Evaluate New planning versus Old	Mon 4/10/17	Fri 4/14/17
13	Minimum Deliverable Met: Validation of the new planning approach for femoroplasty	Fri 4/14/17	Fri 4/14/17



Completed

In Progress

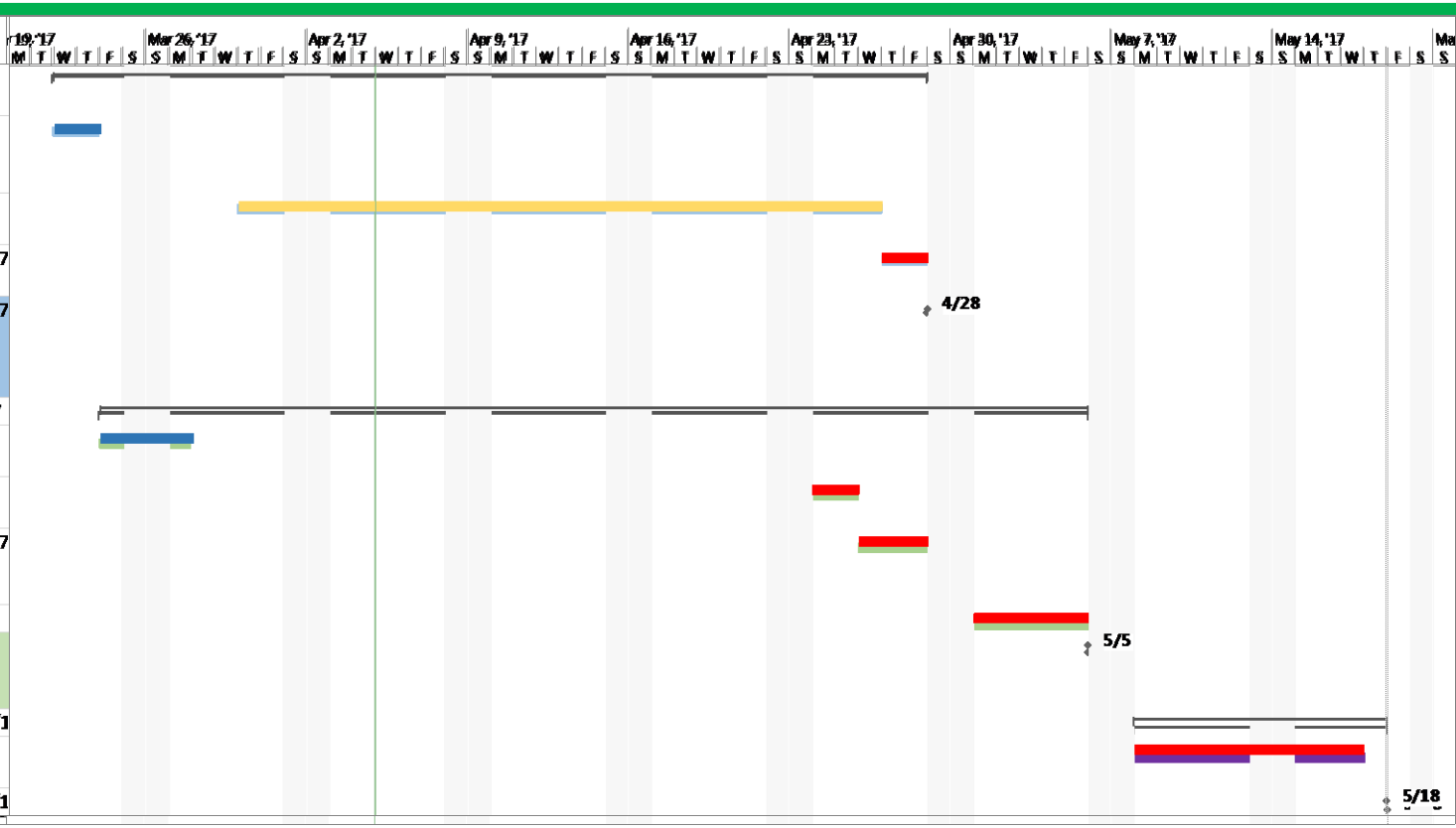
Not Yet Started

Delayed Tasks

New Added Task

Project Timeline

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



Completed

In Progress

Not Yet Started

Questions?

Thank you