A Novel Planning Paradigm for Augmentation of Osteoporotic Femora

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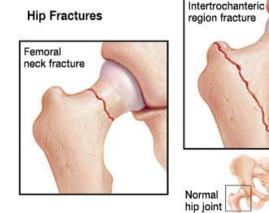
Overview of Project Goal

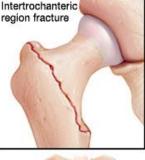
Common Problem for elderly:

Osteoporotic bone fractures

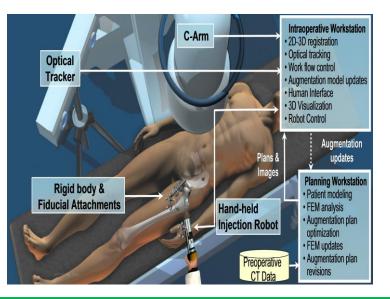
Goals:

- Address the potential risk of thermal necrosis associated with femoroplasty
- Thermal necrosis in tissues exposed to temperatures above 50° C for more than 1 min
- Measure and evaluate temperature rise of the bone surface after the injection
- Create a thermal Finite Element (FE) model simulating temperature distribution during femoroplasty















Paper Selection

<u>Temperature elevation caused by bone cement polymerization during</u> <u>vertebroplasty</u>

Authors: Deramond, H., N. T. Wright, and Stephen M. Belkoff *Journal of Bone* (1999)

<u>Temperature measurement during polymerization of bone cement in percutaneous vertebroplasty: an in vivo study in humans</u>
 Authors: Anselmetti, Giovanni Carlo, et al.
 Journal of *Cardiovascular and interventional radiology* (2009)

 \checkmark Experimental Studies to measure in vitro and vivo temperatures

Thermal analysis of bone cement polymerisation at the cement-bone interface

Authors: Stańczyk, M., and B. Van Rietbergen.

Journal of biomechanics (2004)

✓ Thermal Finite Element Simulation study to evaluate temperature distribution







Vertebroplasty

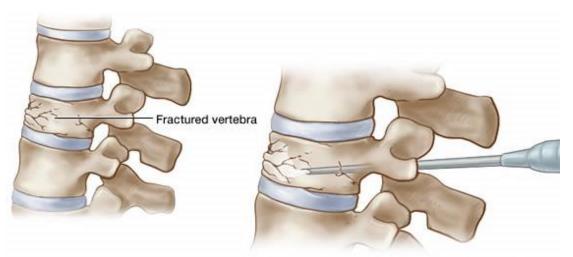
Percutaneous vertebroplasty (PV) treat osteoporotic vertebral compression fracture

Procedure:

- Cement injected in cancellous bone
- Cannula inserted through each pedicle

Complication:

• Thermal necrosis of neural tissue by the heat generated during exothermic polymerization









Significance and Key Results

□ Experimental Studies to measure in vitro and vivo temperatures:

- ✓ Thermal necrosis of neural tissue→ Studying thermal effects associated with PVP plays an important role in clinical development of PVP
- ✓ No thermal damage to spinal cord and nerve roots
- ✓ Longer dwell time for the medial and anterior parts of vertebral body
- ✓ Critical items:
 - Injected volume of cement
 - Concentration of the cement

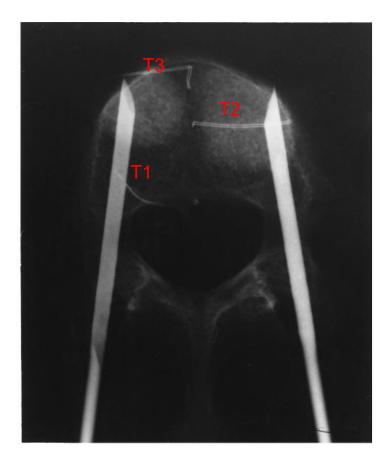






Experiment Setup → In Vitro

- Three spines from elderly females cadavers with vertebral levels T11-T12 and L1-L2
- Two different bone cements injected in each pair
- Temperatures measured in a bath of saline (37° C), for 15 minutes after the injection
- Two 10-gauge needles with three 30-gauge, butt welded, T-type thermocouples along midline of the vertebral bodies
- 10cc of bone cement total, 5cc through each needle



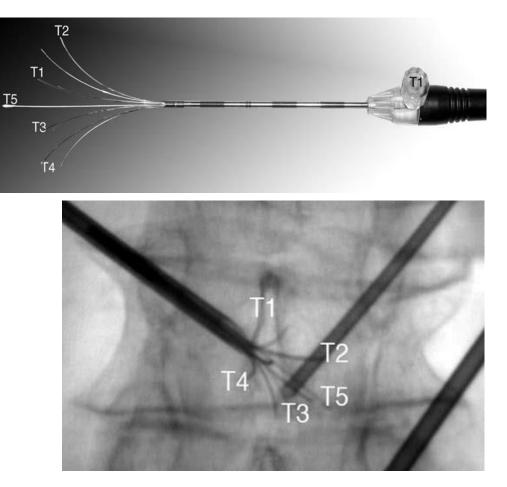






Experiment Setup → In Vivo

- 22 women with mean age of 75 years suffering from osteoporotic vertebral collapse
- 11 different bone cements, each injected into two patients
- Two 10-gauge needles with 16gauge radiofrequency (RFA) needle with five thermocouples
- 3 ml of bone cement injected in each vertebral levels L1, L2, L3, L4
- Temperatures recorded every 30 seconds until dropped below 45° C

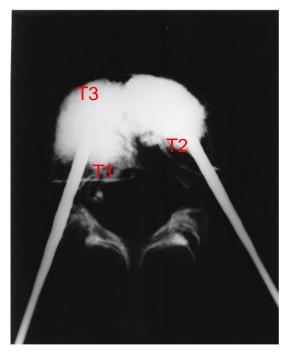


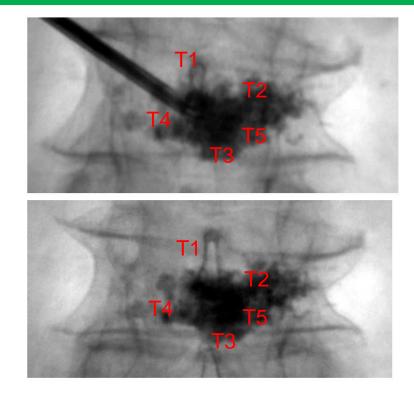






Experiment Results









- In vitro: T3 thermocouple embedded in cement
- In vivo: Thermocouples T2 and T5 embedded in cement while T1, T3, T4 at bone-cement interface







Experiment Results → In Vitro

	Peak Temperature			Temperature over 50° C		
Bone	T1	T2	T3	T1	T2	T3
Cement/Thermocouple						
Orthocomp	40.1±0.8°C	51.2 <u>±</u> 6.2°C	45.2±4.9°C	-	1.3 <u>±</u> 1.4	0.2 ± 0.6
					min	min
Simplex P	38.5±1.4°C	61.8±12.7°C	50.3±9.8°C	-	3.6±2.1	1.2 ± 1.6
					min	min

On average temperature histories for Simplex greater and longer in duration than Orthocomp

- > At T1, no substantial difference in peak temperatures between two cements
- At T2 and T3 the peak temperature was greater and longer for temperature above 50°C with Simplex cement than Orthocomp
- Overall temperatures liberated at thermocouples T2 and T3 might be significantly high and long in duration, potential of causing thermal necrosis of bone tissue







Experiment Results → In Vivo

	Thermocouple T2					
Bone Cement Group	Group A mean peak temperature >60°C	Group B 50°C < mean peak temperature < 60°C	Group C mean peak temper <50°C			
Peak temperature	86.7±10.7°C	60.5±3.7°C	44.8 <u>±</u> 2.6°C			
Temperature over 50°C	Average of all : 2 min 2 Longer in Osteopal-V :	42s±1 min 33s Osteofirm				

- Peak temperature for vertebrae injected with Group A were significantly higher than those injected with Group B and C.
- In Group C temperatures did not reach 50°C and the average dwell time was less than 1 min
- Using Group C cements can significantly reduce or eliminate the possibility of thermal necrosis.







Assessment

Pros

- Well written workflow describing the experiment
- Providing an informative insight to temperature measurement of bone cement polymerization
- Vitro: Simulating physiologic conditions by placing VB in a saline bath at body temperature
- Vivo: Premier in vivo temperature measurement
- Vivo: Utilizing RFA needle with five thermocouples

Cons

- In vitro measurements may not be completely accurate since 10cc cement is not injected at the same time
- Vitro: Experiment setup is not clearly depicted
- Vivo: Temperature were not matched by histologic findings
- Vivo: It would be beneficial to include more details of the patients who underwent PV







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- ✓ Experimental Studies to measure in vitro and vivo temperatures
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Significance and Key Results

- Thermal Finite Element Simulation study to evaluate temperature distribution
- ✓ Major complications of cementation:

Thermal necrosis due to high heat generation during polymerization Chemical necrosis due to unreacted monomer release

- ✓ Finite element (FE) modeling scheme for distribution of temperature and monomer leftover after cementation
- ✓ Temperatures in the cement embedded trabeculae regions were much higher than those in the bone-marrow region adjacent to the bone-cement interface
- ✓ Bone tissue with highest temperature also subjected to high leftover monomer concentration

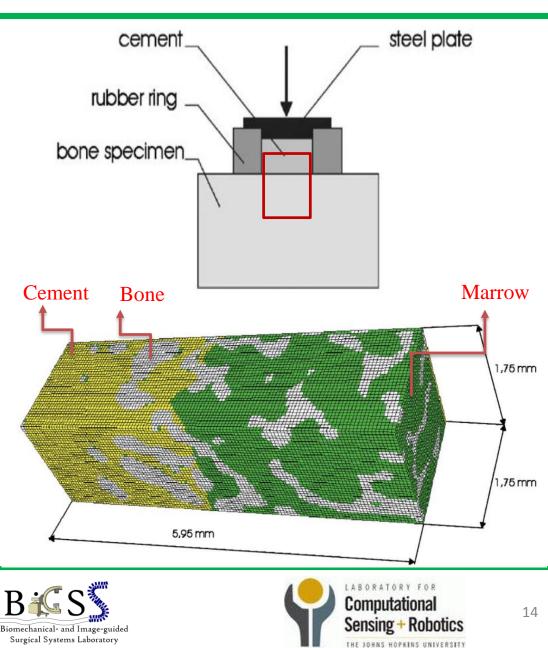






Technical Approach

- Cube of bovine trabecular bone
- Cement mixed and placed directly on the bone surface within a rubber ring
- Micro CT scan of the specimen
- Sub-Volume:
 1.75mm×1.75mm×5.95mm
- Identification of domains of marrow, cement and bone using two level threshold
- 3-D computer model of bovine cancellous bone created





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Temperature field equations $\frac{\partial T(\mathbf{x}, t)}{\partial t} = a_i \nabla^2 T(\mathbf{x}, t) + q_v(\mathbf{x}, t) \quad \text{in } \Omega_i,$ $q_v(\mathbf{x}, t) = \eta(\mathbf{x}, t) \frac{Q}{\rho_1 c_1} \frac{\partial w(\mathbf{x}, t)}{\partial t}$ $\eta(\mathbf{x}) = \begin{cases} 1 & \text{if } \mathbf{x} \in \Omega_1, \\ 0 & \text{otherwise.} \end{cases}$

Kinetic equation for the polymerization fraction *w*

$$\begin{aligned} \frac{\partial w(\mathbf{x}, t)}{\partial t} &= a \exp\left(-\frac{E_{a}}{RT(\mathbf{x}, t)}\right) P(T(\mathbf{x}, t), w(\mathbf{x}, t)),\\ P(T, w) &= \begin{cases} \frac{\alpha}{w^{*}(T)} w^{1-1/\alpha} \left(w^{*}(T) - w\right)^{1+1/\alpha} & \text{if } w < w^{*}(T),\\ 0 & \text{if } w \ge w^{*}(T). \end{cases}\\ w^{*} &= \begin{cases} \frac{T}{T_{g}} & \text{if } T \le T_{g},\\ 1 & \text{if } T > T_{g}, \end{cases} T_{g} = 378 \text{ K} \end{aligned}$$







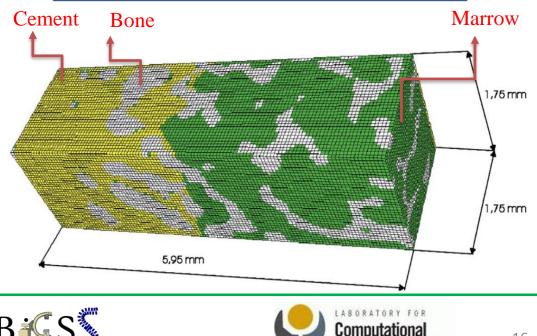
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Initial Condition $T|_{t=0}(\mathbf{x}) = 300 \text{ K}, \quad w|_{t=0}(\mathbf{x}) = 0.01.$

Boundary Condition

- Adiabatic Condition on all walls perpendicular to interface and leftmost wall
- Free convection on the rightmost wall





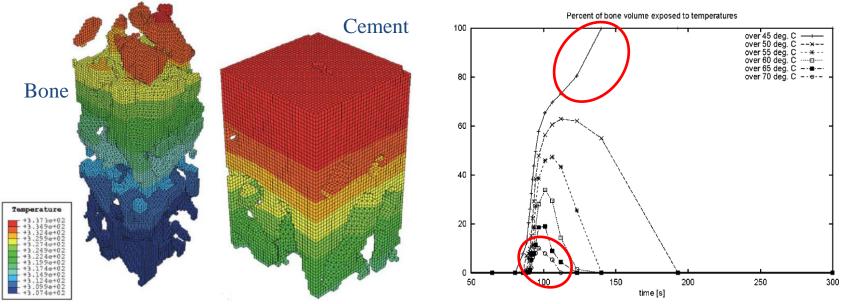


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Simulation Results

Distribution of temperature for possibility of thermal necrosis during polymerization



- Maximum temperature in the bone or cement (337 K) is much higher than temperature in the bone/marrow region (307 K)
- All the bone is exposed to a temperature higher than 45°C from t=140 s until the end of analysis
- Only 10% of the bone were subjected to temperatures higher than 70° C with dwell time of 50s

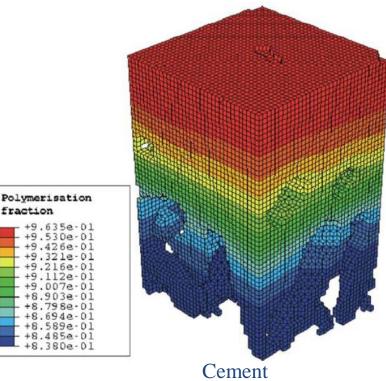






Simulation Results

- Distribution of monomer leftover for possibility of chemical necrosis during polymerization
- Cement polymerization fraction at the Centre is higher than in the region near the bone
- Polymerization at the Centre of the cement is more complete than that near the bone interface.
- Polymerization at the Centre of the cement occurs earlier









Assessment

Pros

- Well written workflow describing the development of simulation
- Providing a good insight to thermal finite element modeling of cement polymerization
- Developing a realistic microstructure bone-cement architecture and realistic temperature-dependent polymerization FE model
- Using more accurate material properties by separating bone and marrow

Cons

- Homogenous material instead of inhomogeneous
- Thermal conditions were not described and depicted clearly
- It is not clear that the bone-cement interface model can be relied for cemented implant or after vertebroplasty
- Cement penetration found is expected to be higher than that in clinical practice

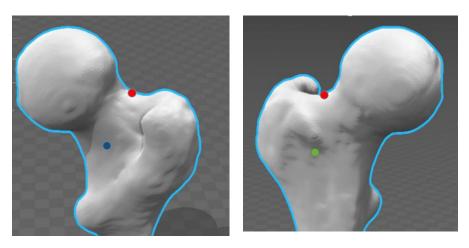






Relevance and Takeaways

Recorded surface temperature of the bone using three k-type thermocouples placed at neck, trochanteric crest and intertrochanteric line for femur





- Similar workflow to segment bone and cement as homogeneous continuum materials and simulate the heat transfer model using temperature field equations
- Femoroplasty, utilizes a larger volume of PMMA, the effects of bone cement injection causing risk of thermal necrosis must be taken into consideration







Questions?

Thank you







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