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

- **Temperature elevation caused by bone cement polymerization during vertebroplasty**
  Authors: Deramond, H., N. T. Wright, and Stephen M. Belkoff
  *Journal of Bone* (1999)

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

- **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.

- **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 16-gauge 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**

- **Vitro**: T3 thermocouple embedded in cement
- **Vivo**: Thermocouples T2 and T5 embedded in cement while T1, T3, T4 at bone-cement interface
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.

<table>
<thead>
<tr>
<th>Bone Cement/Thermocouple</th>
<th>Peak Temperature</th>
<th>Temperature over 50°C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1</td>
<td>T2</td>
</tr>
<tr>
<td>Orthocomp</td>
<td>40.1±0.8°C</td>
<td>51.2±6.2°C</td>
</tr>
<tr>
<td>Simplex P</td>
<td>38.5±1.4°C</td>
<td>61.8±12.7°C</td>
</tr>
</tbody>
</table>
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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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

\[ \frac{\partial T(x, t)}{\partial t} = a_i \nabla^2 T(x, t) + q_v(x, t) \quad \text{in } \Omega_i, \]

\[ q_v(x, t) = \eta(x, t) \frac{Q}{\rho_1 c_1} \frac{\partial w(x, t)}{\partial t} \]

\[ \eta(x) = \begin{cases} 1 & \text{if } x \in \Omega_1, \\ 0 & \text{otherwise}. \end{cases} \]

Kinetic equation for the polymerization fraction \( w \)

\[ \frac{\partial w(x, t)}{\partial t} = a \exp \left( - \frac{E_a}{RT(x, t)} \right) P(T(x, t), w(x, t)) \]

\[ P(T, w) = \begin{cases} \frac{w}{w^*(T)} w^{1-1/x} \left(w^*(T) - w \right)^{1+1/x} & \text{if } w < w^*(T), \\ 0 & \text{if } w \geq w^*(T). \end{cases} \]

\[ w^* = \begin{cases} \frac{T}{T_g} & \text{if } T \leq T_g, \\ 1 & \text{if } T > T_g, \end{cases} \quad T_g = 378 \text{ K} \]
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Initial Condition
\[ T_{|t=0}(x) = 300 \text{ K}, \quad w_{|t=0}(x) = 0.01. \]

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