**Interactions of Bone Cement Viscosity and Vertebral Fracture on Cement Leakage during Vertebroplasty**

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**INTRODUCTION:**

The percutaneous vertebroplasty (PVP) is a minimally invasive method in treating the compression fractured osteoporotic vertebrae (CFOV). The treatment is effective and the outcome is well recognized. The effectiveness of PVP is contributed by the PMMA bone cement enhancement of the mechanical strength of CFOV. However, the complication of the cement leakage is frequently observed during the PVP surgery. The leakage into spinal canal may induce the neurological deterioration, and the leakage through foraman may produce nerve root compression. The leakage may be the consequences of posterior wall defect, and it is also reasonably assumed that the increased risk of leakage is associated with lower viscosity of the injected substance. The purpose of this study is to find the effect vertebral fracture and cement viscosity on the cement leakage during vertebroplasty.

**METHODS:**

Specimen. Twenty fresh human cadaveric vertebrae from 5 human spines were used with an average age of 68 (range: 52-87 years). All spines were examined with CT and DEXA. CT examination of specimens showed normal degenerative changes. The magnitude of BMD is 0.548 (0.176) (ranged from 0.296 to 0.805 g/cm²), and the magnitude of T-score is -3.9 (1.3) (ranged from -2.3 to -5.5). The posterior process was removed, and only vertebral body was used for the experiment. Compression Fracture. The compression fracture of vertebral body was made using a home made compressive testing machine. The specimens were compressed to the loss of 30% (Low Level Fracture) and 60% (High Level Fracture) of original body height. A 5-degree anterior wedge was applied on top of the specimen to mimic the compression fracture due to flexion compression. Injection Apparatus. The bone cement was delivered using an automatic cement injection apparatus. The injection apparatus is able to measure the injected cement volume and the developed force during injection. In order to monitor the cement injection, a flexible pressure tubing (ID= 1.4 mm, OD= 2.8 mm) was used instead of steel bone needle. A bone needle drilled a hole into the vertebra through pedicle, and the flexible tubing was then inserted into the center of vertebra. A radiantocent fixture held the specimen for scanning alignment. All devices including specimens were put on top of the CT table. Three consecutive 1 ml bone cement injection was conducted at the rate of 1 ml/min. The viscosity of injected bone cement is controlled by the powder-liquid ratio. The 1.3 ratio represents “Low Viscosity”, while the 1.6 ratio represents “High Viscosity”. Cine-CT scanning. In order to use cine CT-scans to monitor the progression of bone cement during injection, a remote access of injection apparatus was designed to prevent the risk of radiation exposure. The CT scans the specimen at 32 slices each time. The thickness of each slide is 0.625 mm. The total thickness of each scanning is 2 cm. The scanning frequency is 1 stack (32 slides) per second. One minute scanning was conducted for each injection, which means 60 stacks of images were collected for each injection. The field of view of CT scanning was 96 mm. The 3-dimensional structure of bone cement infiltration and the infiltration volume was constructed and calculated using a home-made software. A cine movie of bone cement infiltration within the vertebrae can be acquired to find the infiltration of cement leakage. Data Analysis. The independent variables of this study include levels of fracture and cement viscosity. A full-factorial experiment was designed, which yields 4 groups of experiment (Table 1). The dependent variables include the maximum force during injection, volume of infiltration, and numbers of specimens which leaked during injection.

**RESULTS:**

Two peak forces were found during the injection. With the help of the synchronization of cine-CT images and force history, the first peaked was found to be at the period that the cement flowed out the tubing. The injection force dropped dramatically after the cement pushed out the tubing, but gradually increased as the cement injected (Figure 1). The 3D cine-CT images showed the infiltration and leakage of bone cement (Figure 2). The injection force ranged at 100 N for using low viscosity cement, while ranged at 200 N for using high viscosity cement. The level of fracture reached less affect on the injection force. The infiltration volume was larger at low level fracture and low level viscosity, but was smaller at high level fracture and high level viscosity. Three out 10 specimens leaked in low fracture level group, and total specimens leaked in high fracture level group. Effect of viscosity on leakage seems to be minimal.

![Figure 1: The force history during injection. Two peaks were found during injection. The first peak occurred when the cement was pushed out the tubing.](image1)

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**Table 1: Summary of experimental results**

<table>
<thead>
<tr>
<th>Fracture Level</th>
<th>Cement Viscosity</th>
<th>Force (N)</th>
<th>Infiltration Volume (ml)</th>
<th>Leakage (#/total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td></td>
<td>Low</td>
<td>Low</td>
<td>1.29(0.15)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High</td>
<td>215(45)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Low</td>
<td>134(36)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High</td>
<td>200(36)</td>
</tr>
</tbody>
</table>

*The low fracture level is defined 30% compression fracture, the high fracture level is defined as 60% compression fracture.
**The low cement viscosity level is defined as 1.3 power-liquid ratio, while the high cement viscosity level is defined as 1.6 power-liquid ratio.
***The infiltration volume is calculated at the end of first injection. Since the first injection has to fill out the tubing, only 0.75 ml cement was delivered into vertebral body.

**DISCUSSION:**

1. This study found the bone viscosity plays an important role in injection force. The 100 N force is a durable force for manual operation, but the 200 N force is too high for surgeon to apply without help of instrument. 2. The calculated infiltration volume is always larger than 1 ml at the end of 1 ml injection. It is because of the infiltration volume is the summation of bone cement and cancellous bone. 3. The risk of leakage depends on the levels of fracture. It is advised that the integrity of bony structure should be examined before the operation of vertebroplasty.