Biomechanical Evaluation of Augmentation of Osteoporotic Cancellous Bone with an Injectable Nano-hydroxyapatite/ Polyamide 66 Composite Cement

Wei Huang 1), Hong An 1), Dianming Jiang 1), Yubao Li 2), Jie Wei 2), and Tingwu Qin 3)

1) Dept. of Orthopaedics, First Affiliated Hospital, Chongqing University of Medical Sciences, Chongqing 400016, China
2) Research Center for Nano-Biomaterials, Sichuan University, Chengdu 610064, China
3) Division of Stem Cell and Tissue Engineering, State Key Laboratory of Biotherapy, West China Hospital, Sichuan University, Chengdu Sichuan, 610041, China

Abstract: A new injectable biomimetic composite cement composed of nano-hydroxyapatite (n-HA) and polyamide 66 (polyhexamethylene adipamide, PA66) has been developed. This study investigated that in vitro biomechanical performances of three n-HA/PA composite cements in the augmentation of osteoporotic cancellous bone were different in various n-HA content to evaluate the clinical applicability. The thoracic vertebrae and femoral condyles of five osteoporotic and one normal cadaver were utilized to divide into five groups: 60wt%, 70wt%, 80wt%, the osteoporotic and the normal groups. The thoracic vertebrae and femoral condyles performed by vertebroplasty were loaded in compression until 75 percent of vertebral height. The cancellous bone specimens made of femoral condyles were applied to torsional testing. Biomechanical testing showed the compressive and torsional performances in the groups injected with 60%, 70% and 80% n-HA/PA composite cement increased markedly than that in osteoporosis. Some of the mechanical parameters were close to normal cancellous bone, in particular, 70% group in compressive properties and 60% group in torsional properties. This study demonstrated that the injectable n-HA/PA composite cement was capable of strengthening the compressive and torsional properties of osteoporotic cancellous bone and suggested that 60% and 70% cement might be competent materials in the treatment and prophylaxis of osteoporotic fracture.

Key words: Nano-hydroxyapatite, Polyamide 66, Injectable.

Introduction
Calcium phosphates such as synthetic bone substitutes have proved beneficial in orthopaedics in recent years. With the development of non-invasive approaches such as percutaneous surgery, directly injectable biomaterials will be needed. Percutaneous vertebroplasty – cement augmentation of vertebral bodies – is an efficient procedure for the treatment of painful vertebral fractures in osteoporosis.

A new injectable biomimetic composite cement composed of nano-hydroxyapatite (n-HA) and polyamide 66 (polyhexamethylene adipamide, PA66) has been developed, in which n-HA crystals are similar to bone apatite and PA66 has carboxyl and amide group like collagen. Therefore, this composite is provided with the bioactivity of HA and the mechanical property of PA66. Powders of n-HA/PA66 composite are incorporated at metallic alcohol solution so that the material was easily injectable. The material should set in about 20 minutes without temperature change. According to our previous study, the compressive strength of n-HA/PA66 composite with a n-HA content of 48 wt%, 64 wt% and 70 wt% were 40MPa, 53MPa and 40MPa respectively. This study investigated in vitro the biomechanical performances of three n-HA/PA composite cements in the augmentation of osteoporotic cancellous bone were different in various n-HA content to evaluate the clinical applicability.

Materials and Methods
The thoracic vertebrae and femoral condyles of five osteoporotic and one normal cadaver were utilized to divide into five groups: 60wt%, 70wt%, 80wt%, the osteoporotic and the normal groups. Compression Testing. The thoracic vertebrae performed by vertebroplasty were loaded in compression until 75 percent of vertebral height. These tests were conducted using an Instron 8874 universal testing machine provided at a cross-head speed of 5 mm/min (Figure 1).

Torsional Testing. The condyles of the femur were injected compressively with n-HA/PA66 cement, then were placed at room temperature until the cement got setting about 12 hours. The condyles injected cement were cut into about 10mmx10mmx30mm bars in size. The both ends of bars were embedded with polymethylmethacrylate for a stable fixation in a standardized fixture. The specimens were mounted in an Instron Testing Machine and a 35° external angular displacement was applied for one cycles at 0.3 deg/sec (Figure 2).

Results and Discussion
Biomechanical testing showed the compressive and torsional performances in the groups injected with 60%, 70% and 80% n-HA/PA composite cement increased markedly than that in osteoporosis. Some of the mechanical parameters were close to normal cancellous bone, in particular, 70% group in compressive properties and 60% group in torsional properties (Table 1-2, Figure 3-4).

A desirable biomaterial for repairing osteoporotic fractures should be able to bear the weight in the early stage after fracture, as well as conducing to osseointegration and improving the quality of bone microstructure in the late. Nanoscale HA has a higher solubility, surface energy, ion exchange capability and polarization, differs greatly from micron HA in chemical and physical properties. Bai et al. found that common PMMA and CPC were able to augment the vertebral strength and could be
used prophylactically to prevent fracture of the osteoporotic vertebral bodies. Some research shows that a smaller size of hydroxyapatite will result in a higher mechanical strength.

In present study, the compressive yield strength and ultimate strength for cement-injected vertebrae significantly increased as compared with the osteoporotic vertebrae (1591.00N and 1591.00N). Especially, the yield strength and ultimate strength of 70% group were up to 2080.14N and 3927.07N, respectively 81.33% and 88.4% as compared with normal group. This proved this cement could increase the stiffness of osteoporotic vertebrae to prevent collapse of vertebral bodies. In the torsional testing, torsional strength in the groups injected with 60%, 70% and 80% n-HA/PA composite cement and osteoporotic group for femoral condyles were 85.24%, 62.52%, 28.43% and 26.74% respectively as compared with normal group. This result showed the cement might improve the capability of cancellous bone in torsional properties, especially the 60% group whose polyamide 66 content was the highest of the cement groups.

This study demonstrated that the injectable n-HA/PA composite cement was capable of strengthening the compressive and torsional properties of osteoporotic cancellous bone and suggested that 60% and 70% cement might be competent materials in the treatment and prophylaxis of osteoporotic fracture.

**References**


---

Table 1. Compressive mechanical properties in various vertebral groups**

<table>
<thead>
<tr>
<th>Group</th>
<th>Yield strength (N)</th>
<th>Ultimate compressive strength (N)</th>
<th>Compressive stiffness (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OP</td>
<td>1591±278.39</td>
<td>2509.19±418.67</td>
<td>579.78±103.55</td>
</tr>
<tr>
<td>HP1</td>
<td>1942±430.07</td>
<td>3456.92±232.31</td>
<td>800.94±198.37</td>
</tr>
<tr>
<td>HP2</td>
<td>2080±427.71</td>
<td>3927.07±223.40</td>
<td>875.60±117.18</td>
</tr>
<tr>
<td>HP3</td>
<td>772.57±396.67</td>
<td>3003.54±39.49</td>
<td>623.84±54.63</td>
</tr>
<tr>
<td>N</td>
<td>2537.67±249.07</td>
<td>4421.16±271.73</td>
<td>1009.36±214.93</td>
</tr>
</tbody>
</table>

**The values was expressed as mean ± SD (x ± s) of each group.
*The groups with cement injection showed significant difference compared with OP group (p<0.05).
1*The groups with cement injection showed significant difference compared with N group (p<0.05).

Table 2 Torsional mechanical properties in various vertebral groups**

<table>
<thead>
<tr>
<th>Group</th>
<th>Torsional strength (Kpa)</th>
<th>Torsional stiffness (N:Degree)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OP</td>
<td>29.54±5.77</td>
<td>0.046±0.011</td>
</tr>
<tr>
<td>HP1</td>
<td>94.17±15.01</td>
<td>0.028±0.015</td>
</tr>
<tr>
<td>HP2</td>
<td>69.07±4.26</td>
<td>0.079±0.013</td>
</tr>
<tr>
<td>HP3</td>
<td>31.41±8.59</td>
<td>0.054±0.017</td>
</tr>
<tr>
<td>N</td>
<td>110.47±19.81</td>
<td>0.024±0.017</td>
</tr>
</tbody>
</table>

**The values was expressed as mean ± SD (x ± s) of each group.
*The groups with cement injection showed significant difference compared with OP group (p<0.05).
1*The groups with cement injection showed significant difference compared with N group (p<0.05).