INTRODUCTION
Using minimally invasive techniques to inject bone cement for treating fractured or osteoporotic vertebral body has significant clinical potential. According to orthopaedic surgeons, bone cement used in spinal fracture surgery should have the following characteristics:

1. An injectable nature, fast-setting and adequate stiffness, leading to immediate load bearing strength and stiffness resembling to natural bone.
2. Bioactivity and low setting temperature, allowing integration with bone at the interface.
3. Radiopacity, providing accurate control of cement location and depth due to easy radiographic imaging.

The purposes of this study were:

i. To develop new injectable bioactive bone cement designed specifically for spinal surgery (consisting of strontium-containing hydroxyapatite powder and Bisphenol A Diglycidylether Dimethacrylate (D-GMA) resin) and

ii. To conduct in vitro biomechanical and radiographical tests of this bone cement after being injected into burst fractured spine.

MATERIALS AND METHODS
Strontium-containing hydroxyapatite (Sr-HA) powder was made through the wet method. The chemical formula for the process is as follows:

\[ 10 \text{SrO} + 21 \text{H} \rightarrow 2 \text{Sr} + 21 \text{H}_2 \text{O} \]

The theoretical value of \((\text{Ca} + \text{Sr})/\text{P}\) in strontium-containing hydroxyapatite is 1.67.

Fourier transform Infrared spectra were obtained using KBr tablets. The spectra were recorded from 4000-400cm-1. XRD spectra were obtained.

D-GMA resin was prepared from equal weights of D-GMA and Triethylene-glycol dimethacrylate. N,N-Dihydroxypropyl-p-toluidine, instead of N,N-Dimethyl-p-toluidine, was produced by the authors and was dissolved into the mixture at 0.25% by weight of resin.

L929 cells were used for cytotoxicity testing (RGR method). Powder and liquid cement components were mixed, shaped and set into a cylinder specimen of 5 mm diameter and 1 mm height. Each sterilized specimen was extracted in the culture medium. 1ml of 5x10^4cells/ml suspension was added into individual test tubes. Cultures were maintained at 37°C and collected after 2, 4 and 7 days, respectively. Cytotoxicity rate of the tested biomaterial was classified according to standard methods.

20 fresh porcine spine specimens (T10-L1) were divided into three groups: pilot (3 pieces), intact (7 pcs), and cemented (10 pcs). For the intact group, the superior and inferior vertebrae were mounted before testing in the jigs with fast dry Epoxy resin and the center of the vertebral body was vertically aligned to the loading axis. Stiffness and failure strength of the intact specimens were recorded.

In the cemented group, a pre-injury was created in each specimen, and then were mounted to the MTS 858 bionix testing machine with spinal fixture used to control spine flexion. Stiffness was recorded. Bio-active bone cement was then injected into the fractured site. After one hour, the same mechanical testing was applied. Instant stiffness after bone cement injection was recorded, and a fatigue cyclic loading (~100 to ~1000N) was then conducted at 1Hz for up to 3,000 cycles. Spinal stiffness was recorded again under the same loading conditions and failure strength was recorded when applying compressive failure load to the spine.

All specimens were radiographed before and after injury, as well as after bone cement injection. All collected data was pooled for statistical analysis.

RESULTS
FT-IR test results and XRD spectra are shown in Figure 1. Comparing with the standard infrared spectra of apatites indicate that Sr-HA was typically made through wet method. Spectra of the Sr-HA powder and that of standard HA were found to be similar. Powder X-ray diffraction patterns of Sr-HA powder have two strong characteristic peaks of HA.


discussion

This study is the first to use only bone cement to stabilize a fractured spine and to show augmentation of fractured vertebral bodies with bioactive bone cement has similar stiffness to natural bone. Results demonstrated that using only bioactive bone cement could support burst fractured spine with cyclic loading. Instant and post-fatigue bonding were also satisfactory. The possible extrusion of bone cement into the spinal canal that may likely create canals.

Relative growth rate test results indicated that RGR in days 2, 4 and 7 was 87.8%, 93.4% and 91.8% respectively. Overall cytotoxicity of the new bone cement was Class 1 or no cytotoxicity.

The bone cement had an average setting time of 15-20 minutes with a peak curing temperature of less than 55°C. Mean stiffness of the spine conditions are listed in Table 1. Stiffness of the spine dropped significantly after fracture (53.3% of intact condition, p < 0.001). After injection, instant stiffness of the spine recovered to 112% of the intact condition (p < 0.01). Average failure strength of the spine after injection and after 3000 cyclic loads was 5056 N, which was 86% of the intact situation.

Radiographs displayed a near-complete restoration of the vertebral body’s dimensions. Cement-bone bonding quality was satisfactory. However, two out of ten cemented specimens had bioactive cement retroplution into the canals.

Table 1. Stiffness and strength of intact and cemented spines

<table>
<thead>
<tr>
<th></th>
<th>Intact</th>
<th>Fractured</th>
<th>Cemented</th>
<th>Fatigued</th>
<th>Strength</th>
<th>Cement</th>
</tr>
</thead>
<tbody>
<tr>
<td>(N/mm)</td>
<td>1304.3</td>
<td>694.6</td>
<td>1462.4</td>
<td>1247.3</td>
<td>5855</td>
<td>5055.8</td>
</tr>
<tr>
<td>(SD)</td>
<td>(145.8)</td>
<td>(90.2)</td>
<td>(154)</td>
<td>(130)</td>
<td>(502)</td>
<td>(682)</td>
</tr>
<tr>
<td>% intact</td>
<td>100%</td>
<td>55.3%</td>
<td>112.1%</td>
<td>95.6%</td>
<td>100%</td>
<td>86.4%</td>
</tr>
<tr>
<td>P</td>
<td>N/A</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>0.05</td>
<td>N/A</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

*p-value was determined by comparison to intact condition.

REFERENCES

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