INTRODUCTION:
Compressive vertebral fractures caused by low-energy trauma are very common in osteoporotic patients. Based on recent epidemiologic estimations this injury will become even more frequent in the future. Conventional treatment includes analgesic, bed rest and bracing. Unfortunately such treatment does not effectively prevent severe pain during the period of healing. Furthermore, the reduced mobility will enhance the bone loss even more. Over the last decade, vertebroplasty, has developed into an established method of treatment for compressed vertebral fractures in osteoporotic patients. Irrespective of operation technique used a large number of studies have shown that this treatment provides a very good pain relief and improved mobility. The improvement is almost instant following cement injection and with a lasting effect for several years.

Unfortunately, so far there is no cement that meets all necessary criteria for this kind of treatment. Due to lack of specifically designed cement types, clinicians are still using conventional bone cement, polymethylmethacrylate (PMMA), for vertebroplasty. PMMA was originally designed for fixation of artificial joints and not for use in the spine. When PMMA is used in vertebroplasty, it is associated with drawbacks such as extensive exothermal reaction during curing, foreign body response and inadequate radio-opacity. It is therefore a need for specifically designed cement types that are optimized for use in the treatment of osteoporotic spinal fractures.

The aim must be to develop injectable biocompatible cement types that provide optimised injection characteristics, high X-ray opacity, favourable bone integration and immediate stability, hardening without extensive exothermal reaction and strength enough to allow early and active rehabilitation. Such cement will allow the elderly patients who suffer an osteoporotic spinal fracture to regain their pre-fracture level of mobility safely and more rapidly. To achieve the target material for vertebroplasty different formulation routes are presently pursued by industry and academia, mainly resins, e.g. PMMA or calcium phosphate cements (CPC). A novel route is to use another cement system based on calcium aluminate.

Calcium aluminates originate from the same chemical family as the calcium phosphates, i.e. the chemically bonded ceramics. Calcium aluminate is delivered in the form of powder and liquid. Upon mixing the two components an injectable paste is formed. The setting reaction is described as a dissolution precipitation process, where the calcium aluminate powder is first dissolved in water and precipitates as hydrates, i.e. under the bonding of water. The system has several unique features, such as, high water bonding ability and chemical inertness after hardening. The high water bonding capacity allows the design of materials with high strength even when high amounts of inert fillers are added to the formulation. This means that compared to the CPC, a high radio opacity combined with a high strength can be achieved.

The objective with the investigation is to describe the most important physical properties of a novel injectable bioceramic material designed for vertebroplasty in comparison to the properties of PMMA and CPC.

MATERIALS AND METHODS:
A material based on the calcium aluminate chemistry, Xeraspine™, was compared to a PMMA material with barium sulfate as radiopaque additive and to a CPC material. Xeraspine contains calcium aluminate and zirconium dioxide powder that is machine mixed with a liquid. The zirconium dioxide is added to achieve extra radio opacity. The liquid contains mainly water and small amounts of additives to control rheology during injection and setting time. The working time was determined by measuring the extrusion time through 11 gauge needles at room temperature. The working time was defined as the time from completion of mixing until the cement no longer could be expressed out of the syringe. The setting time was determined using the Gillmore needle method [3]. Compressive strength and flexural strength were measured following [4, 5]. The setting temperature was determined following [6]. Before measurements of strength, the samples were stored in phosphate buffered saline for 24 hours.

RESULTS:
In comparison Xeraspine showed about the same characteristics as the PMMA material, except for the curing temperature that was much lower, see Table 1. In general the strength characteristics were more than twice the values for the CPC material. Due to a too liquid consistence directly after mixing, the working time for PMMA started 4 minutes after mixing and ended after 8 minutes.

Table 1. Selected physical properties for Xeraspine compared to those of conventional injectable material systems

<table>
<thead>
<tr>
<th></th>
<th>Xeraspine™</th>
<th>PMMA</th>
<th>CPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working time (minutes) 23 °C</td>
<td>5</td>
<td>4-8</td>
<td>5</td>
</tr>
<tr>
<td>Setting time (minutes) 37 °C</td>
<td>10</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Flexural strength - MPa 24h</td>
<td>55</td>
<td>60</td>
<td>20</td>
</tr>
<tr>
<td>Compressive strength MPa 24 h</td>
<td>90</td>
<td>92</td>
<td>40</td>
</tr>
<tr>
<td>Setting temperature °C</td>
<td>55</td>
<td>100</td>
<td>&lt;40</td>
</tr>
</tbody>
</table>

DISCUSSION:
For the chemically bonded ceramics, such as CPC, the ability to bond water is very important to achieve a material of high strength. The added water should be consumed during setting to achieve a low porosity end product. The calcium aluminate bonds much more water than the conventional CPC does, and this is reflected in the high strength values. The hydrophilic nature of the material also gives a low setting temperature and possibly also improved adherence to the vertebrae compared to the hydrophobic resin materials such as PMMA. The adherence is also favoured by the precipitation of nano-size hydrates in the general curing reaction.

Compared to the PMMA the chemically bonded materials can be injected directly after mixing and do not require a waiting time until the correct viscosity has been reached. It should be noted that the working time values are dependent on the exact room temperature. Higher room temperature gives a shorter working time.

In conclusion, Xeraspine show promising features and is the first bioceramic implant to receive CE certification for VCF therapy.

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