Clinical observations of osteoporotic vertebral compression fractures by using mineralized collagen modified polymethylmethacrylate bone cement

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Abstract

To investigate the clinical outcomes of the treatment of osteoporotic vertebral compression fractures (OVCFs) by using mineralized collagen (MC) modified polymethylmethacrylate (PMMA) bone cement. 52 cases (52 vertebras) who sustained OVCF treated with MC modified PMMA bone cement from July 2014 to December 2015 were reviewed retrospectively. All the cases (52 patients, 52 vertebras) included 8 males and 44 females with an average age of 74.83 (ranging from 57- to 90-years old). The visual analogue scale (VAS), vertebral body height, Cobb angle, CT values pre- and post-operation as well as incidence of complications were used to be observed. All the patients underwent the surgery were successfully followed-up with an average period of 13.54 months (ranging from 6 to 23 months). The patients can ambulate at the second day after the operation. The VAS scores 2 days after the operation and during the last follow-up were significantly decreased compared with that before the operation (\(P < 0.05\)); the average vertebral height and local Cobb angle had significant recovery (\(P < 0.05\)); the CT value of the treated vertebra significantly increased compared with that before the operation (\(P < 0.05\)). MC with good osteogenic activity and degradation properties can effectively improve the mechanical properties and biocompatibility of the PMMA bone cement, thus obtain better clinical results.

Keywords: mineralized collagen; PMMA bone cement; osteoporosis; vertebral compression fractures

Introduction

Percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) have been becoming commonly used surgeries for the treatment of osteoporotic vertebral compression fractures (OVCF) [1–4]. An idea bone filling material with good operating performance, biomechanical properties and biological characteristics (biocompatibility, osteointegration ability, osteoconductivity etc.) is expected by those surgeons performing PVP and PKP [5, 6]. Nowadays, polymethylmethacrylate (PMMA) bone cements with good injectability and high contrast effect have been widely applied in PVP and PKP [7–9].

However, many disadvantages influenced clinical performance of these PMMA bone cements. The compressive modulus is relative higher than that of the natural vertebral bone, the suddenly increased intensity of the treated vertebral body may induce secondary fracture on adjacent ones, especially for those osteoporotic bodies [10–13]. On the other hand, PMMA is a bioinert material that
cannot form osteointegration with the host bone at the implant site [14]. The implanted PMMA bone cement may loosen or even dislodge inside the vertebral body [15, 16]. Such complications need further surgeries, which increase illness and economic burden for the patients.

Many efforts were tried to modify existing PMMA bone cements in terms of biomechanical and biological properties. In a general way, biomaterials were added into the PMMA bone cements to improve their performance [17–19]. Such biomaterials include calcium phosphate, chitosan, sodium hyaluronate and so on. However, there were no reports indicate that both biomechanical properties and osteointegration ability could be improved by using a single component.

In recent years, a biomimetic mineralized collagen (MC) material ‘Bongold’ with similar chemical components and microstructures of the natural bone tissue was developed by Tsinghua University, China and has been commercialized by Beijing Allgens Medical Science and Technology Co., Ltd., China [20–23]. With good biocompatibility, biodegradability and osteoconductivity, this biomaterial could be used to repair bone defects at various body sites [24–30]. Such MC products been approved by both Chinese Food and Drug Administration and US food and drug administration as implantable medical devices [31]. In this clinical observation, in order to improve the properties of the commercially available PMMA bone cement, we used the MC ‘Bongold’ for the modification of the PMMA bone cement. On the basis of previous studies, such modification could effectively reduce the hardness and improve its biocompatibility, so as to reduce the occurrence of either secondary fracture at the adjacent vertebrae or dislodgement of the implanted bone cement for the treatment of patients with OVCF.

Clinical date and methods

Clinical data

The patients with OVCF treated with vertebroplasty with MC modified PMMA bone cement between July 2014 and December 2015 in our department were screened. Patients’ clinical data is listed in Table 1. Pre-operative vertebral X-ray, MRI and CT examinations were performed for each patient, except those with vertebral lesions, disc disease, spinal stenosis caused by dural sac and nerve root compression caused by pain. CT examinations confirmed the integrity of the vertebral posterior wall with fractures, whether unilateral or bilateral pedicle is intact, and the lower part of the vertebral body and the lower endplate did not burst (Table 1).

Surgical techniques

Patients were treated at prone position with abdomen hung. Local or general anesthesia was selected according to the general condition of the patient. The surface projection of the pedicle was positioned and marked under a C-arm X-ray machine, followed by disinfecting the skin.

A working channel was first established through the pedicle at the puncture side. The working channel was-established percutaneously at the right side outside the top right side of the vertebral pedicle at 2 o'clock direction with a sagittal angle of about 15°. The needle was punctured through the pedicle, and reached one-third position in front of the vertebral body. Then the needle core was removed after the needle position was confirmed. The MC modified bone cement was prepared by mixing the MC with the PMMA bone cement follow the instructions (Fig. 1a and b). When the cement became a viscous state, it was injected under the C-arm X-ray to monitor its distribution. C-arm X-ray showed the bone cement infiltrated along the bone trabecular and dispersed evenly over the centre line, and the edge of butt-like cortical bone stopped excess of the bone cement (Fig. 2a and b). After the bone cement was completely cured, the needle was pulled out. The patient was then observed for 10 min. Normal feeling, activities of the lower limbs, and stable vital signs indicated the end of the surgery.

Observation data

Pre-operative, 2 days post-operative, and last follow-up visual analogue scale (VAS) scores were performed to assess pain relief of the patients. Lateral X-ray was used to measure vertebral height and local Cobb angle before and after the surgery to evaluate clinical effects. Average length of the centre line of the anterior vertebral body before and after the surgery was used as the average height of the vertebral body for statistical analysis, according to Phillips’s method [32]. Cobb angle was measured before and after the surgery according to CT images. A plane at 1 cm higher than the mid-point of the lower edge of the treated vertebral body was selected for CT value measurement (Fig. 3a). In order to ensure balance of the measurement, the measured plane was divided into nine regions (Fig. 3b). CT value of the centre points of each region were tested, and the average value was used as the CT value of the treated vertebral body for further analysis.

Statistical analysis

Data are expressed with x ± S, the application SPSS 16.0 software for statistical analysis, pre- and post-operative data 2d and last follow-up data comparisons are using paired t-test, P < 0.05 was considered statistically significant.

Results

All 52 patients were followed up for 6–18 months, with an average follow-up of 12.19 months. Mean operative time was (32 ± 13) minutes. One case occurred vertebral bone cement leakage, two cases occurred vertebral paraspinal soft tissue leakage. No bone cement was injected into the vertebral body from the trailing edge of the neural canal, and there were no clinical symptoms caused by leakage of bone cement. Intraoperative lateral X-ray films showed vertebral height of the central part of the vertebral body recovered, without bone cement leakage. Surgery slander anteroposterior X-ray showed vertebral bone cement distributed well (Fig. 2a and b). For the post-operative follow-ups, VAS scores, vertebral height, Cobb angle and T value of CT were significantly improved compared with those pre-operative values (P < 0.05). One-year follow-up showed the MC modified PMMA bone cement was stable within the treated vertebral body without loosening or dislodgement. Although after

Table 1. Patients’ clinical data

| Parameters             | Data                  |
|------------------------|-----------------------|
| Number of patients     | 52                    |
| Mean age (years)       | 74.83 ± 7.85 (from 57 to 90) |
| Gender (male/female)   | 8/44                  |
| Treated vertebral body | T7: 1, T8: 2, T10: 1, T11: 5, T12: 17, L1: 11, L2: 10, L3: 5 |
| Operation time (min)   | 32 ± 13               |
| Follow-up period (months) | 12.19 ± 3.75 (from 6 to 18) |
the first 2 days, all the values still improved, there were no significant differences between the 2 days post-operation and the last follow-up ($P > 0.05$), (Table 2).

**Discussion**

The stiffness of the vertebral body treated with traditional PMMA bone cement becomes significantly higher than the adjacent ones, thus resulting stress concentration and may cause new fracture on those adjacent vertebral bodies [10, 11]. It was reported that the occurrence of the new fracture on the adjacent vertebral bodies after PVP and PKP was 7–20% [12]. The bioinert PMMA cannot form osteointegration with the bone tissue within the vertebral body [14]. Apparent interface will exist between the bone cement and the host bone, and the combination strength will be very weak. Micro motion between the bone cement and the bone is inevitable, osteolysis and further aseptic loosening or even dislodgement of the bone cement inside the vertebral body may be produced [14, 15].

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**Figure 1.** Modulation of the MC modified PMMA bone cement (a) MC, liquid component and powder component of the PMMA bone cement from left to right; (b) The three components were mixed uniformly during the surgery

**Figure 2.** Intraoperative and follow-up plain radiographs of a treated vertebral body (intraoperative plain radiographs showed good dispersion of the modified cement in coronal plane (a) and sagittal plane (b); sagittal (c) and coronal (d) plain radiographs of 1-year follow-up of the treated vertebral body)

**Figure 3.** CT value measurement method of the treated vertebral body (a) Sagittal CT of the spine, the black line indicated 1 cm higher than the lower edge of the treated vertebral body; (b) The measured plane divided into nine regions
We use MC good osteogenic activity and degradation in vivo ab-
sorption characteristics of the conventional PMMA bone cement
composite, can effectively control the mechanical properties and
biocompatibility [33–35], MC will also enable the degradation of
bone cement and autogenous bone to form a good osteointegration,
better clinical results. Herein were followed up by the discovery of
bone cement MC modified after vertebral, fractures can effectively
improve the pain caused to the patient by injecting PVP, while the
vertebrae play a good role in supporting and securing the postopera-
tive follow-up, the vertebral front height and Cobb angle compared
with that obtained significant recovery was not found in the verte-
bral bone cement loose and fall off. There are an average follow-up
time after the end of the CT values of vertebral significantly im-
proved compared with the pre-operative, the difference was statisti-
cally significant, indicating that the ability to promote local bone
fracture healing by MC modified cement thereby increasing bone
density. In summary, we believe that after MC modified bone ce-
ment has good mechanical properties and biocompatibility of the or-
ganization, worthy of clinical patients choose to use.

Conclusion

By adding biomimetic MC, PMMA bone cement was improved to have better mechanical properties and biocompatibility than traditional PMMA bone cements. In this clinical observation, by using MC modified PMMA bone cement, all the patients obtained good clinical effects. VAS scores of the patients were significantly improved, as well as vertebral height and Cobb angle recovered well.

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Conflict of interest statement. None declared.

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Table 2. The average VAS score, the average height of the vertebral, Cobb angle and the T value of CT before and after surgery (x ± S)

| Evaluation time | VAS score | Average height of the vertebral (mm) | Cobb angle (°) | T value of CT (HU) |
|----------------|-----------|--------------------------------------|---------------|------------------|
| Pre-operation  | 8.6 ± 2.4 | 10.7 ± 4.8                           | 32.7 ± 12.3   | 76.3 ± 11.5      |
| After 2 days   | 2.8 ± 2.2a| 12.5 ± 5.1a                          | 21.6 ± 9.7a   | 93.2 ± 12.9a     |
| Last follow-up | 2.9 ± 2.6a| 12.4 ± 5.3a                          | 22.5 ± 11.5a  | 98.7 ± 10.3a     |

*When compared with the pre-operative values, P < 0.05.
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