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Biomechanical evaluation of kyphoplasty and vertebroplasty with calcium phosphate cement in a simulated osteoporotic compression fracture

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Abstract Kyphoplasty and vertebroplasty with polymethylmethacrylate (PMMA) have been used for the treatment of osteoporotic vertebral compression fractures. We performed kyphoplasty and vertebroplasty with α-tricalcium phosphate cement (CPC) and PMMA to compare the biomechanical properties. Thirty osteoporotic vertebrae were harvested from nine embalmed cadavers. We randomized the vertebrae into four treatment groups: (1) kyphoplasty with CPC; (2) kyphoplasty with PMMA; (3) vertebroplasty with CPC; and (4) vertebroplasty with PMMA. Prior to injecting the cement, all vertebrae were compressed to determine their initial strength and stiffness. They were then recompressed to determine their augmented strength and stiffness. Although the augmented strength was greater than the initial strength in all groups, there was no significant difference between the two bone cements for either kyphoplasty or vertebroplasty. The augmented stiffness was significantly less than the initial stiffness in the kyphoplasty groups, but the difference between the two cements did not reach significance. In the vertebroplasty groups, the augmented stiffness was not significantly different from the initial stiffness. There was no significant difference between the two bone cements for either procedure when cement volume and restoration of anterior height were assessed. We concluded that kyphoplasty and vertebroplasty with CPC were viable treatment alternatives to PMMA for osteoporotic vertebral compression fractures.

Key words Kyphoplasty · Vertebroplasty · α-Tricalcium phosphate cement · Polymethylmethacrylate · Osteoporotic compression fracture

Introduction

Osteoporotic vertebral compression fractures have traditionally been treated conservatively, but these fractures are sometimes responsible for persistent pain with impaired quality of life. Vertebroplasty[11] with polymethylmethacrylate (PMMA) has been accepted as a viable treatment option for osteoporotic vertebral compression fractures.[2,7,13,17,19] Recently, kyphoplasty[12,18] with PMMA has been developed as a new technique for osteoporotic vertebral compression fractures. It strengthens the vertebrae and reportedly restores the anterior height.[5] Kyphoplasty and vertebroplasty can give highly effective pain relief and strengthen weakened vertebrae. Long-term bed rest, prolonged external fixation, and pressure sores can all be avoided. Kyphoplasty and vertebroplasty with PMMA form the mainstay of treatment for osteoporotic vertebral compression fractures. Despite these advantages, there are a number of reservations about using PMMA. It is not bioactive and there are theoretical thermal effects[10] both inside and outside the vertebral body during polymerization. α-Tricalcium phosphate cement (CPC) was developed in Japan[15] and has been used for vertebroplasty.[23] It is bioactive and is gradually transformed to hydroxyapatite with little heat emission.

Limited information exists to compare the biomechanical properties of CPC and PMMA for kyphoplasty or vertebroplasty. The purpose of the current study was to compare the biomechanical properties of these two cements for either procedure.

Materials and methods

Forty-five vertebrae (T10-L2) from nine spines were harvested from female embalmed cadavers in formalin (average age at death 83 ± 9 years; range 74–97 years). Anteroposterior and lateral radiographs of all vertebrae were obtained. Fifteen vertebrae (T11, 3; T12, 4; L1, 4; L2, 4) that had already sustained a compression fracture were excluded, and the remaining 30 vertebrae (T10, 9; T11, 6; T12, 5; L1, 5; L2, 5) were used in this study. The

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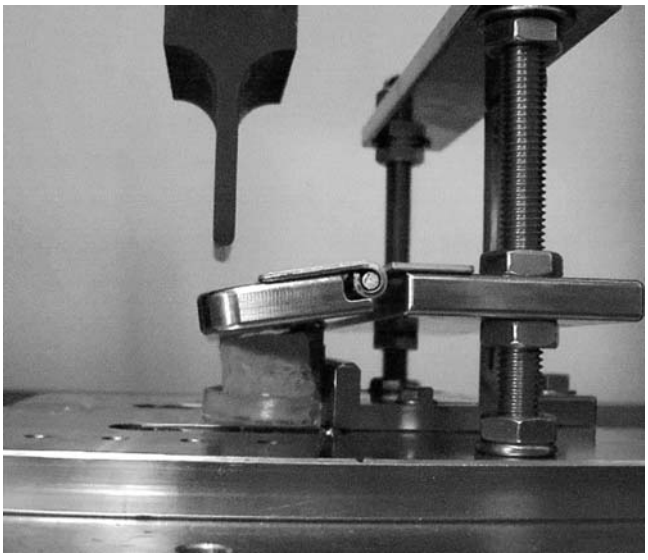

Fig. 1. Biomechanical testing. Each vertebra was compressed at a rate of 5 mm/min until the anterior height was decreased by 25%

vertebrae were disarticulated, their discs were excised, and the posterior elements were removed to facilitate mechanical testing. Then the vertebrae were placed in a waterbath to provide 15 cm of soft tissue surrogate. The bone mineral density (BMD) of the vertebral bodies was measured in the posteroanterior projection using dual energy X-ray absorptiometry (DEXA) (Lunar DPX-L; Lunar, Madison, WI, USA).

Classification

The vertebrae were divided into four treatment groups: kyphoplasty with CPC (KC, $n = 7$: T10, 2; T11, 1; T12, 2; L1, 1; L2, 1); kyphoplasty with PMMA (KP, $n = 7$: T10, 2; T11, 1; T12, 1; L1, 1; L2, 2); vertebroplasty with CPC (VC, $n = 8$: T10, 3; T11, 2; T12, 1; L1, 1; L2, 1), and vertebroplasty with PMMA (VP, $n = 8$: T10, 2; T11, 2; T12, 1; L1, 2; L2, 1).

Compression test

The vertebrae were wrapped in formalin-soaked gauze and sealed in plastic bags at room temperature. An impression of the endplates of each vertebra was made using a common epoxy resin. The anterior and posterior heights were measured using digital calipers accurate to 0.1 mm. Each vertebra was seated in a loading fixture (Fig. 1) and compressed at a rate of 5 mm/min using a materials compression machine (Autograph AG-5000B; Shimadzu, Kyoto, Japan) until the anterior height of the vertebra was decreased by 25%. All vertebrae, irrespective of level, were compressed in the same manner. Initial strength and stiffness of each vertebra were measured. Strength was defined as the peak load, and stiffness was defined as the slope of the force versus the deformation curve.

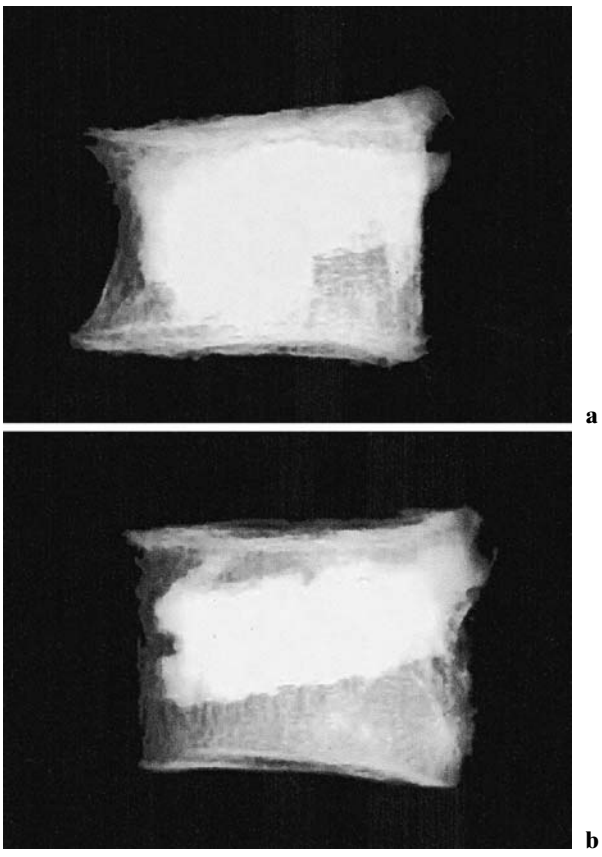

Fig. 2. Lateral radiographs of vertebral bodies following **a** kyphoplasty with α-tricalcium phosphate cement (CPC) or **b** vertebroplasty with CPC. Note the better distribution of cement (column of cement) with kyphoplasty than with vertebroplasty

Procedures

After the simulated compression fractures were created, two cannulas (provided by the manufacturer of CPC: Mitsubishi Materials, Tokyo, Japan) were inserted into each vertebra, one through each pedicle. In the kyphoplasty groups, the vertebrae were curetted and the endplates were elevated through each pedicle *as* much as possible. The void was then filled with either CPC or PMMA. In the vertebroplasty groups, either of the two cements was injected into the vertebrae without prior creation of a void (Fig. 2). The cement was poured into a 5-ml syringe and injected until the cement leaked from the vertebral body or it could not be injected any more by hand because of the high injection pressure (in either procedure). The cement volume was recorded.

Table 1. Average data for each group before the procedure

Group	BMD (g/cm^2)	Initial strength (N)	Initial stiffness (N/mm)
KC	0.297 ± 0.083	883.8 ± 523.5	393.3 ± 274.6
KP	0.293 ± 0.097	736.8 ± 447.8	403.6 ± 201.3
VC	0.287 ± 0.105	700.2 ± 310.4	306.5 ± 178.7
VP	0.294 ± 0.135	745.1 ± 602.3	395.9 ± 336.0

KC, kyphoplasty with CPC; KP, kyphoplasty with polymethylmethacrylate (PMMA); VC, vertebroplasty with CPC; VP, vertebroplasty with PMMA; BMD, bone mineral density
Values are means ± SD
No significant differences were observed in BMD, initial strength, or initial stiffness of the vertebrae between the four groups

Bone cements

The CPC was mixed with a powder/liquid ratio of 3.0 g/ml. For PMMA (Stryker Howmedica Osteonics, Carrigtwohill, Co. Cork, Ireland), 5 g of $BaSO_4$ was mixed by hand into the standard 20 g dose of cement powder to increase radiopacity. The two cements were chilled to 4°C before mixing to prolong their working time.

Recompression test

After injection, each vertebra was wrapped in saline-soaked gauze, sealed in a plastic bag, and placed in a waterbath maintained at 37°C for 24 h to simulate physiological conditions and allow complete polymerization for the PMMA groups. The CPC groups were left in the bath for 7 days to reach its peak compressive force.[15] Before performing the postinjection tests, the anterior height of each vertebra was measured, and the restoration of anterior height was calculated as follows.

$$\frac{\text{Posttreatment height} - \text{postcompression height}}{\text{initial anterior height}} \times 100\,(\%)$$

Vertebrae were recompressed according to the initial crush protocol. The augmented strength and stiffness were measured as previously described.

Evaluation and statistical analysis

One-factor analysis of variance (ANOVA) was used to compare the BMD, initial strength, and initial stiffness of vertebrae of the four groups. We assessed the effects of kyphoplasty and vertebroplasty using both PMMA and CPC on vertebral strength and stiffness with a paired *t*-test. Cement volume and restoration of anterior height were analyzed using Student's *t*-test. Significance was set at $P < 0.05$ unless otherwise specified.

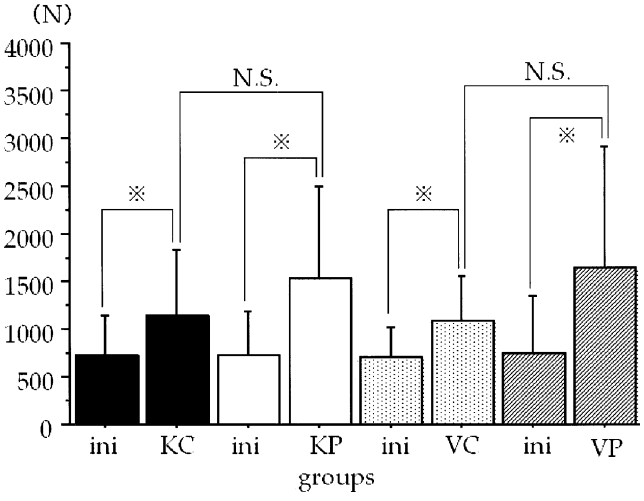

Fig. 3. Initial and augmented strength in each group: *ini*, initial; *KC*, kyphoplasty with CPC; *KP*, kyphoplasty with polymethylmethacrylate (PMMA); *VC*, vertebroplasty with CPC; *VP*, vertebroplasty with PMMA. ※$P < 0.05$; *N.S.*, no significant difference. Strength after treatment increased significantly in all groups. There were no significant differences in augmented strength between the CPC and PMMA groups for the two procedures

Results

There were no significant differences in BMD, initial strength, or stiffness of vertebrae when the preinjection groups were analyzed (Table 1). The augmented strength increased significantly in all four groups (P_{KC} = 0.04, P_{KP} = 0.02, P_{VC} = 0.01, P_{VP} = 0.03) (Fig. 3). Although the augmented strength with PMMA [KP: 1532.6 ± 966.2 N (502.3–3087.0 N); VP: 1643.6 ± 1280.8 N (490.0–3528.0 N)] was greater than that with CPC [KC: 1147.5 ± 692.2 N (465.5–2365.1 N); VC: 1083.4 ± 470.0 N (647.0–2070.3 N)] in each procedure, the difference was not significant ($P_{kyphoplasty}$ = 0.41, $P_{vertebroplasty}$ = 0.27).

The augmented stiffness was significantly less than the initial stiffness in both kyphoplasty groups (P_{KC} = 0.048, P_{KP} = 0.01), whereas the augmented stiffness in

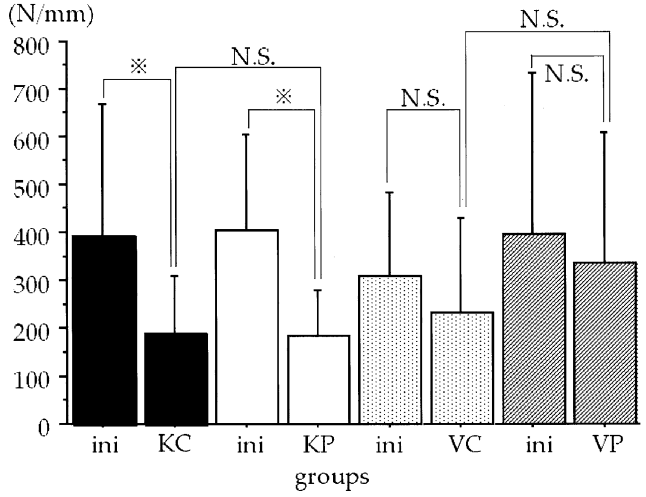

Fig. 4. Initial and augmented stiffness in each group. ※$P <$ 0.05. Stiffness after treatment decreased significantly in the kyphoplasty groups. There were no significant differences in augmented stiffness between the CPC and PMMA groups for the two procedures

the two vertebroplasty groups was not significantly different from the initial stiffness (Fig. 4). There was no significant difference in augmented stiffness between the CPC groups [KC: 189.1 ± 118.0 N/mm (30.6–408.3 N/mm); VC: 231.5 ± 198.9 N/mm (94.2–612.5 N/mm)] and the PMMA groups [KP: 184.8 ± 96.1 N/mm (64.9–306.3 N/mm); VP: 339.1 ± 269.1 N/mm (90.9–816.7 N/mm)] for each procedure.

Cement volumes for the CPC and PMMA groups were 4.5 ± 1.0 ml (3.2–6.0 ml) and 4.5 ± 0.8 ml (3.2–5.6 ml) in the kyphoplasty groups and 3.9 ± 0.6 ml (3.1–4.8 ml) and 4.4 ± 0.6 ml (3.5–5.2 ml) in the vertebroplasty groups, respectively. The difference in cement volume between the CPC and PMMA groups in each procedure was not statistically significant. Restoration of anterior height for the CPC and PMMA groups were 7.7% ± 6.5% (0%–20.0%) and 13.1% ± 7.5% (0%–22.7%) in the kyphoplasty groups, and 6.1% ± 5.3% (0%–11.4%) and 6.5% ± 4.7% (0%–11.5%) in the vertebroplasty groups, respectively. The difference in restoration of anterior height between the CPC and PMMA groups with each procedure was not statistically significant.

Discussion

Vertebroplasty with PMMA is now an established technique for stabilizing osteoporotic vertebral compression fractures, but there are still a number of problems associated with this treatment. Extravasation[7–9,17,20] is the most common complication of vertebroplasty, although it is usually asymptomatic. High injection pressures during vertebroplasty can cause extravasation of cement and pulmonary embolization.[20] Kyphoplasty[12,18] has been developed in an attempt to decrease the injection pressure, but no reports have described how much difference there is in injection pressure between kyphoplasty and vertebroplasty.

PMMA itself presents several problems. The cement may lead to thermal damage[10] owing to its highly exothermic polymerization, and it lacks osteoconductivity and bioactivity. In recent years, several nonexothermic and bioactive cements, especially calcium phosphate, have been studied in regard to its use for vertebroplasty[1,14,21] to resolve these problems. In Japan, CPC is one such cement.[16,22] In contrast to PMMA, which attains a temperature of 50°C during polymerization,[10] CPC is gradually transformed to hydroxyapatite with little heat emission. Moreover, Shibata et al.[22] reported that CPC diffused well in osteoporotic vertebral bodies, bonded directly and progressively to newly formed bone, and increased the strength of the cancellous bone in dogs with experimentally induced osteoporosis. Information about the biomechanical properties for kyphoplasty or vertebroplasty with CPC is limited. In the current study, we compared the biomechanical properties of CPC and PMMA for the two procedures.

Belkoff et al.[3] reported that restoration of stiffness and increasing strength of the vertebrae were likely desirable goals of vertebroplasty. They also concluded that restoration of vertebral stiffness was the most important factor but cautioned against attaining a stiffness that was significantly greater than the initial value. Their concern was that a stress riser may be produced above and below the augmented vertebra.

The strength of CPC itself is less than that of normal cortical bone and greater than that of cancellous bone.[16] Therefore, the weaker the strength of the original vertebrae, the greater was the relative resultant strengthening effect from kyphoplasty or vertebroplasty. Because osteoporotic vertebrae were used in the current study, as in previous studies, the augmented strength was significantly greater than the initial strength. This finding corroborated the results of other previous studies.[1,5,6,14]

As reported previously,[6] the augmented stiffness after vertebroplasty in the VC and VP groups tended to be less than the initial stiffness, although the difference was not statistically significant ($P_{VC} = 0.38$, $P_{VP} = 0.46$). However, some authors[1,14] have found that the augmented stiffness is comparable to its initial stiffness. In another study,[5] stiffness and anterior height were restored by kyphoplasty with PMMA. In contrast, the current study indicated that the augmented stiffness was

significantly less than the initial stiffness in the KC and KP groups. This disparity between our study and previous studies may be because of the cement volume and the sort of cement used. Cement volumes utilized in previous studies were greater than the volumes used in the current study. A previous study[4] using a similar volume of hydroxyapatite cement did not restore stiffness. Moreover, bone cement might not have been injected sufficiently to fill the void in vertebrae because we curetted the vertebral bodies and injected bone cement blindly.

The strength of vertebrae after augmentation with bone cement typically increases, whereas the stiffness decreases. The reason for the decrease in stiffness is probably disruption in the cortical shell. This phenomenon — that the strength of vertebrae increased and their stiffness decreased after kyphoplasty or vertebroplasty — might mean that the cancellous bone between the endplate and the bone cement was crushed first followed by crushing of the bone cement. To restore stiffness, the bone cement should be injected sufficiently between the endplates. Little information exists whether complete restoration of stiffness is required for successful fracture healing. Further clinical studies are necessary.

No significant difference was observed between the volume of CPC and that of PMMA during the two procedures. In accordance with the previous study,[5] all vertebrae had some elastic recovery after compression, thereby tending to restore the anterior height. A similar recovery phenomenon might occur less in vivo than ex vivo because there are muscle forces and body weight. In the current study, we calculated restoration of anterior height as follows.

(Posttreatment height − postcompression height after the recovery phenomenon)/initial anterior height × 100 (%)

There was no significant difference between the two cements with each procedure.

Conclusions

The augmented strength after injection of PMMA or CPC was significantly greater than the initial strength with either kyphoplasty or vertebroplasty. However, it was difficult to restore stiffness when performing kyphoplasty and vertebroplasty with either CPC or PMMA. Further studies of bioactive cements with material properties similar to those of bone, the appropriate method, and the appropriate cement volume of bone cement injected between the endplates are necessary to establish its use for kyphoplasty and vertebroplasty.

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