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Augmentation of mechanical properties in osteoporotic vertebral bones – a biomechanical investigation of vertebroplasty efficacy with different bone cements

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Abstract Recent clinical trials have reported favorable early results for transpedicular vertebral cement reinforcement of osteoporotic vertebral insufficiencies. There is, however, a lack of basic data on the application, safety and biomechanical efficacy of materials such as polymethylmethacrylate (PMMA) and calciumphosphate (CaP) cements. The present study analyzed 33 vertebral pairs from five human cadaver spines. Thirty-nine vertebrae were osteoporotic (bone mineral density $<0.75 \text{ g/cm}^2$), 27 showed nearly normal values. The cranial vertebra of each pair was augmented with either PMMA (Palacos E-Flow) or experimental brushite cement (EBC), with the caudal vertebra as a control. PMMA and EBC were easy to inject, and vertebral fillings of 20–50% were achieved. The maximal possible filling was inversely correlated to the bone mineral density (BMD) values. Cement extrusion into the spinal canal was observed in 12% of cases.

All specimens were subjected to axial compression tests in a displacement-controlled mode. From load-displacement curves, the stiffness, S , and the maximal force before failure, F_{\max} , were determined. Compared with the native control vertebrae, a statistically significant increase in vertebral stiffness and F_{\max} was observed by the augmentation. With PMMA the stiffness increased by 174% ($P=0.018$) and F_{\max} by 195% ($P=0.001$); the corresponding augmentation with EBC was 120% ($P=0.03$) and 113% ($P=0.002$). The lower the initial BMD, the more pronounced was the augmentation effect. Both PMMA and EBC augmentation reliably and significantly raised the stiffness and maximal tolerable force until failure in osteoporotic vertebral bodies. In non-osteoporotic specimens, no significant increase was achieved.

Keywords Spine · Osteoporosis · Vertebroplasty · Biomechanics

Introduction

Osteoporosis is a disease characterized by low bone mass, which leads to increased susceptibility to fractures. It is a common condition in the elderly, affecting predominantly women over the age of 65 [2]. The spine is the most common site of fracture in patients with osteoporosis. In the United States, 25% of women over the age of 70 and 50% of women over the age of 80 show evidence of vertebral fractures, the majority of which occur in the midthoracic

region and the thoracolumbar junction [16,20]. The potential sequelae include disabling pain, vertebral collapse, and progressive loss of physiologic spinal alignment [22]. Declines in physical function and changes in appearance contribute to social isolation and loss of self-esteem, thus impairing quality of life. Significant neurological compromise due to spontaneous fracture of osteoporotic vertebrae has been described [12,19]. The morbidity associated with osteoporosis and vertebral fractures represents an enormous socio-economic cost [2].

Over the last years, strenuous attempts have been made to treat osteoporosis by increasing bone mass and decreasing fracture incidence. Despite encouraging results, there remains a certain percentage of non-responding patients, whatever the medical treatment may be. Furthermore, many patients are referred to specific treatments at a very late stage of the disease, i.e. after several fractures have already occurred or are imminent. In these late-stage cases, a mechanical reinforcement of the vertebral body by means of percutaneous cement injection (vertebroplasty) could provide a solution to the challenge of preventing progressive deformity or collapse and alleviating disabling pain.

Polymethylmethacrylate (PMMA) in spine surgery has been described as a spacer and reinforcement material in metastatic diseases. Promising clinical results with percutaneous injections of bone cement in the treatment of selected cases with osteolytic metastases or vertebral myeloma have been achieved [4,25]. More recently, vertebral PMMA augmentation has been reported to be also useful in cases of osteoporosis-related spinal pain [5,6]. Despite successful clinical applications, there are very few basic data on the mechanical effect of augmentation in such vertebrae, nor do we have precise information about the potential risks of these procedures, such as the risk of extravasation or heat generation.

Calciumphosphate (CaP) cements are used in several orthopedic applications [15,18], and are under consideration for vertebral column reinforcement [1,23]. Again, there are only few data available on their applicability and mechanical effect.

The aim of the present study was to compare the mechanical efficacy of cement injection into vertebral bodies during vertebroplasty, using a CaP cement and PMMA. The feasibility, safety and potential hazards of the procedure were also assessed *in vitro*.

Materials and methods

Specimens

Five fresh human cadaver spines from a geriatric population were retrieved within 24 h after death, wrapped in saline-soaked tissue, frozen at -20°C , and thawed prior to testing. Each specimen was retrieved as a whole from T2 to L3 (spine 2 and 4), from T3 to L4 (spine 1 and 3), and from T4 to L1 (spine 5). Bone mineral density (BMD) was determined in the postero-anterior and lateral projections on each vertebra, using Dual-energy X-ray absorptiometry technique (DXA, Hologic QDR 2000, Hologic Inc., Waltham, Mass.). The specimens were placed into a plastic container and embedded in granular semolina to simulate the soft tissue envelope surrounding the spine, allowing the comparison of *in vivo* and *in vitro* normal values [21]. The determination of the degree of porosis was based on the values obtained at the lumbar levels (L4–L1), as no reference exists for vertebrae above the level of L1. Osteoporosis was defined according to the WHO, as a BMD of more than 2.5 standard deviations below the mean of a young healthy reference population of the same gender ("T-score"). Using our local reference database, osteoporosis of the lumbar spine (L2–L4) corresponded to a BMD of less than 0.75 g/cm^2 , and the cutoff for

osteopenia (i.e. T-score <-1.0 SD according to WHO criteria) was at 0.95 g/cm^2 at that skeletal site.

The spines were dissected into 66 single vertebrae, with all soft tissues removed. Radiographs in two planes were used to exclude specimens with lytic lesions or other bony abnormality apart from osteopenia. Overall, 33 pairs of adjacent vertebrae were tested. The cranial vertebra of each pair was augmented with cement, the caudal one served as a control.

Bone cements

Two types of augmentation material were investigated.

1. Copolymer of methylmethacrylate/ethylacrylate (PMMA) Palacos E-Flow (Essex Chemie AG, Luzern, Switzerland), low viscosity
2. Experimental brushite cement (EBC; École polytechnique fédérale de Lausanne, Département des matériaux): mixture of β -tricalcium-phosphate (β -TCP) and monocalciumphosphate monohydrate (MCPM) powder, with a $0.1\text{ mol H}_2\text{SO}_4$ solution containing 0.45 wt% Xanthan. A small amount of $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ was added to control the setting time. β -TCP was synthesized in the laboratory. MCPM was purchased from Albright & Wilson

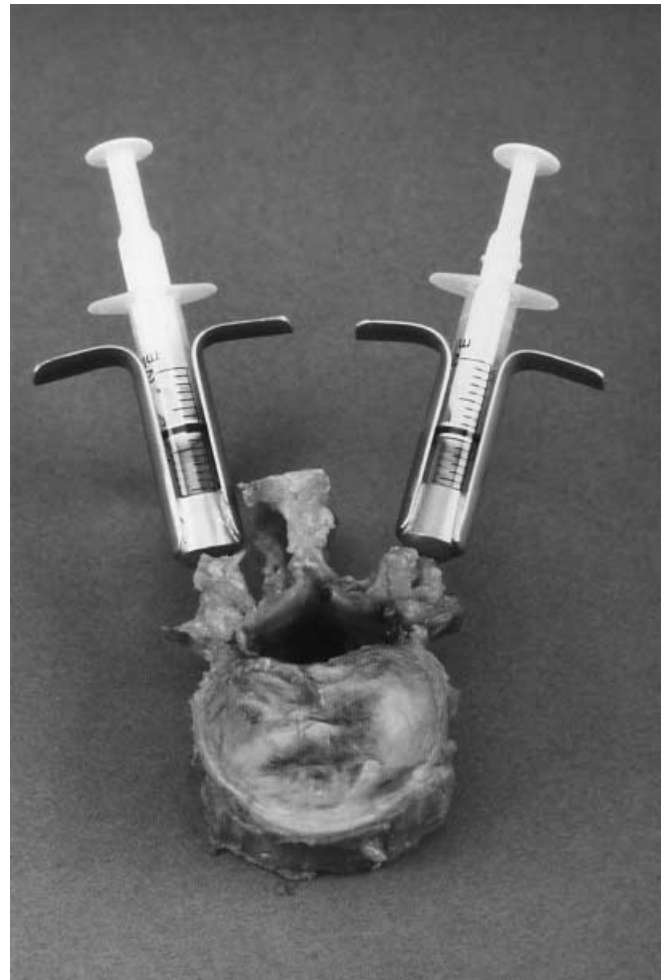


Fig. 1 Vertebral specimen with syringe adapter for bipedicular cement application

(ref. IBEX). Xanthan gum is a filtered food grade product from Scheller (FNCJ 1740107.01, E415 food grade). $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ powder was purchased from Fluka (ref. 71501). One milliliter of cement was prepared by mixing 1.2 g β -TCP, 0.8 g MCPM and 0.015 g $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$. The solid/liquid ratio was adjusted to 2.8 g/ml, in order to obtain a viscosity of 2 Pa.s, to approach PMMA cement viscosity. It is a biocompatible and resorbable cement that has a shear-thinning behavior, which is favorable for injection.

Injection technique

In each vertebra, bilateral pedicle canals of 4.5 mm diameter were drilled. The vertebrae were sealed in plastic bags and warmed to body temperature in a water bath. Cement injections were performed using a custom made adapter long enough to ensure cement application to the center of the vertebral body (Fig. 1).

The augmentation materials were prepared according to the manufacturer's recommendations. Cement application was performed bilaterally, under continuous monitoring for potential leakage. A temperature recorder measured bony surface temperature until 15 min after injection.

PMMA was injected into three spines. In spine 1 it was injected into seven vertebrae with normal BMD; in spines 2 and 3 it was injected into seven vertebrae each, all severely osteoporotic. The vertebrae of spines 1 and 2 were filled to a maximum possible, until cement started to appear at the surface of the bone. Any leakage of cement terminated the filling. The injected volume of cement was documented. After injection, the vertebral body was stripped of the posterior elements, and its volume was assessed. From the amount of injected cement, the degree of filling was determined. Based on this information, spine 3 was injected deliberately with limited cement filling of about 20–30%.

EBC was injected into two spines – in spine 4, into seven severely porotic vertebrae, and in spine 5, into five vertebrae with osteopenia – again until leakage at the surface was observed.

Following cement injection, all specimens were further inspected for cement leakages into the spinal canal. For semiquantitative assessment of the degree of filling, biplanar radiographs of the vertebrae were obtained (Faxitron X-Ray Systems, Hewlett Packard, McMinnville, Ore.).

Mechanical testing

Both vertebral endplates were embedded in molding material (Bercryl, Fuhlenbach, Switzerland), ensuring parallel orientation of both outer molding surfaces as well as perpendicular orientation of the specimen with respect to the loading axis. These layers were 1–3 mm thick, which represents less than 10% of the vertebral body height. All specimens were subjected to axial compression in a displacement-controlled mode at a rate of 2 mm/min in a universal testing machine (Zwick 1475, Zwick GmbH, Germany) (Fig. 2). Load-displacement curves were automatically recorded. From these curves the stiffness (N/mm) (S) and maximal load (N) before failure (F_{\max}) were determined. The data of both vertebrae of each pair were compared, and the relative difference calculated (ΔS and ΔF_{\max}). The results of each spine were analyzed separately and pooled to a group of 14 pairs of osteoporotic vertebrae filled with PMMA, 7 pairs of non-porotic vertebrae filled with PMMA, and 12 pairs of osteoporotic vertebrae filled with EBC.

Statistical testing was performed using Wilcoxon signed rank test. Intra-individual pairs of vertebrae were compared only, as this ensured a minimal BMD difference. Also, the presumably weaker cranial vertebra of each pair was always cement augmented. P -values of <0.05 were accepted as significant.

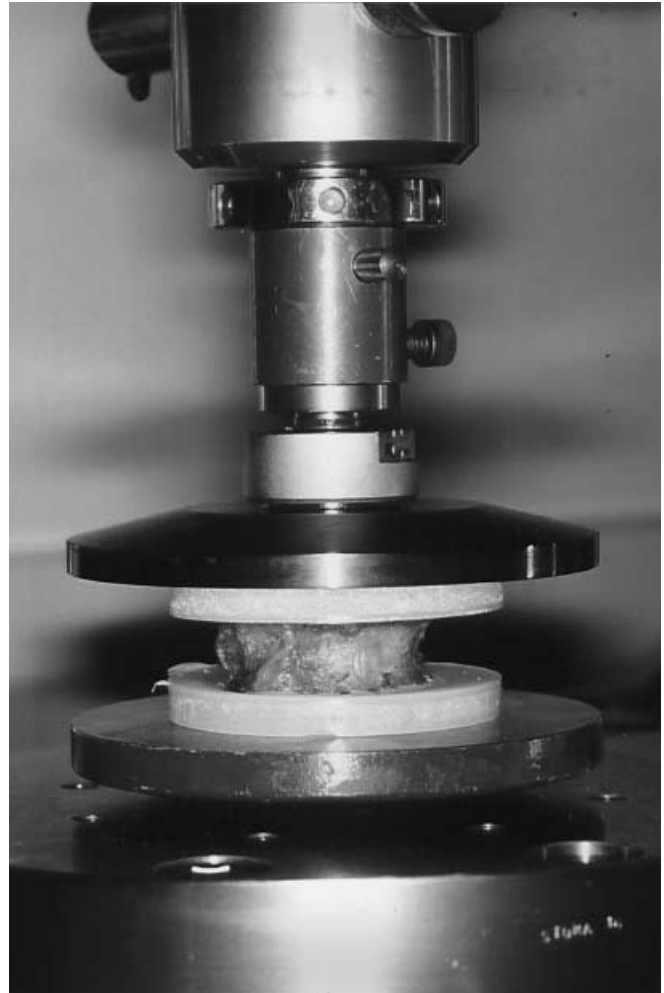


Fig. 2 Set-up of specimen in the universal testing machine for axial compression testing. The specimen is embedded in a thin layer of bone cement in order to achieve parallel surfaces

Results

Bone mineral density

The BMD determined at L1–L4 showed for spines 1 and 5 normal values; the remaining three spines were found to be osteoporotic (spines 2, 3, 4) (Table 1). The results of individual vertebrae within each spine showed a tendency towards a decrease in BMD from caudal to cranial (Table 2).

Cement application

PMMA and EBC cements were easy to inject, and volumes between 5 and 20 ml could be applied, representing a degree of filling between 20 and 50% (Table 1).

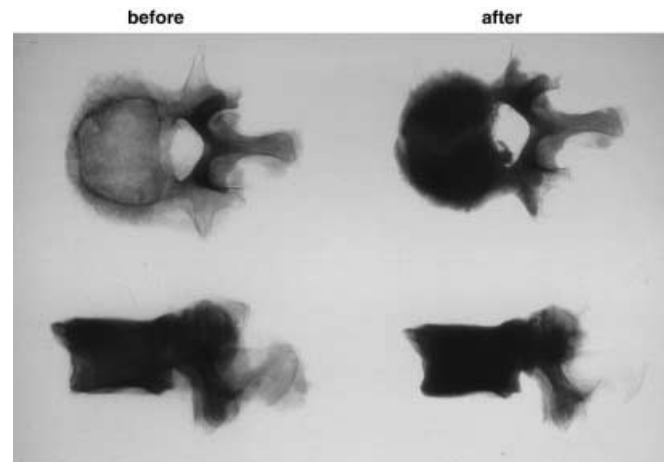
In 12% of cases, a cement leakage through the basivertebral veins towards the spinal canal was observed (Fig. 3).

Table 1 Data on all tested spines (BMD bone mineral density, F_{max} maximal load before failure, PMMA polymethylmethacrylate, EBD experimental brushite cement)

Spine levels	Mean (SD) BMD (g/cm ²)	Min/max BMD (g/cm ²)	Cement	Mean (SD) filling (ml)	Mean (SD) filling (vol.%)	Min/max filling (vol.%)	Mean (SD) ΔF_{max} (%)	Min/max ΔF_{max} (%)	Mean (SD) Δ stiffness (%)	Min/max Δ stiffness (%)	Native/reinforced displacement (mm)
Spine 1 (T3-L4)	1.160 (0.100)	1.041/1.354	PMMA	6.4 (2.129)	24.7 (5.1)	20.0/33.0	25.8 (34.0)	-8.6/88.3	-10.1 (24.3)	-54.5/27.8	1.47/2.46
Spine 2 (T2-L3)	0.659 (0.061)	0.598/0.779	PMMA	12.9 (6.875)	47.0 (4.1)	40.0/50.0	253.9 (287.2)	67.0/887.4	188.6 (173.0)	28.1/587.4	1.14/1.17
Spine 3 (T3-L4)	0.596 (0.054)	0.534/0.721	PMMA	6.1 (2.416)	26.4 (4.2)	18.0/31.0	136.0 (117.5)	34.9/348.2	159.3 (137.0)	13.9/400.1	1.34/1.10
Spine 4 (T2-L3)	0.653 (0.078)	0.575/0.848	EBC	8.4 (3.812)	41.4 (8.5)	25.0/50.0	104.0 (105.8)	13.5/256.7	107.8 (103.0)	-5.2/269.5	1.33/1.34
Spine 5 (T4-L1)	0.987 (0.085)	0.857/1.166	EBC	11.8 (3.60)	48.4 (5.5)	40.0/53.0	125.7 (41.3)	81.5/186.8	130.8 (82.3)	18.5/275.3	1.19/1.10

Table 2 Individual BMD values of the vertebrae of each spine (g/cm²)

Level	Specimen no. (no. of vertebral bodies)				
	1 (n=14)	2 (n=14)	3 (n=14)	4 (n=14)	5 (n=10)
T2		0.631		0.588	
T3	1.066	0.598	0.543	0.606	
T4	1.051	0.603	0.575	0.586	0.857
T5	1.047	0.624	0.580	0.575	0.993
T6	1.157	0.632	0.590	0.583	0.989
T7	1.061	0.612	0.569	0.599	0.957
T8	1.087	0.603	0.569	0.632	0.907
T9	1.241	0.704	0.597	0.690	1.003
T10	1.288	0.671	0.582	0.704	1.032
T11	1.224	0.687	0.570	0.611	0.998
T12	1.159	0.631	0.566	0.714	1.019
L1	1.194	0.734	0.597	0.848	1.060
L2	1.268	0.764	0.650	0.677	
L3	1.354	0.779	0.701	0.726	
L4	1.162		0.721		

**Fig. 3** Bipedicular filling of specimens with polymethylmethacrylate (PMMA). Note the cement leakage towards the spinal canal in the axial view

The likelihood of leakage was related to the degree of cement filling.

The degree of filling that was achievable was related to the BMD (Fig. 4). Radiographic analysis showed a homogeneous cement distribution in all cases, usually with a radiographic lucency remaining in the vertebral midline (Fig. 3).

With PMMA filling rates of more than 40%, the temperature at the posterior cortical bone was elevated, in one case to a maximum of 48°C; when the degree of filling was up to 30%, the temperature increased maximally to 39°C. With EBC, no temperature change was detected.

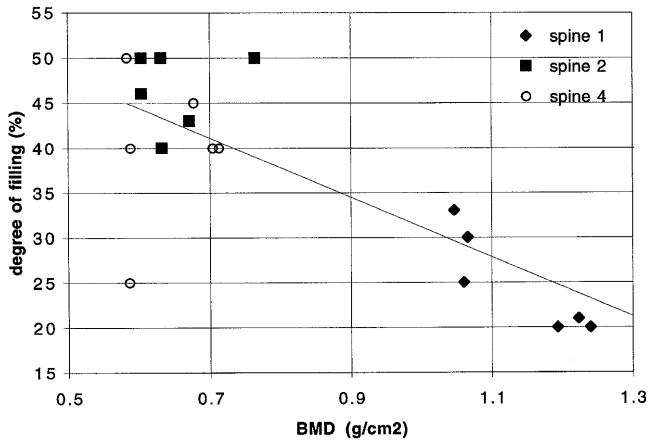


Fig. 4 The degree of filling depends on the bone mineral density (BMD). In non-porotic vertebrae the amount of injectable bone cement is small in contrast to porotic vertebrae

Mechanical effect

Qualitative behavior

The load-displacement record for a non-porotic specimen in comparison to a severely porotic vertebra is given

in Fig. 5 a. Injection of bone cement into a normal vertebra led to a small change in the mechanical properties (Fig. 5b), whereas in a porotic situation they were changed considerably (Fig. 5c,d).

Stiffness

PMMA injection increased the stiffness in osteoporotic vertebrae only. With normal BMD values, the stiffness averaged 9667 N/mm, and no change was noted after cement augmentation (Table 1). In the osteoporotic spines the stiffness in a native state was about 2000 N/mm; with PMMA an increase of 174% was noted, to 5430 N/mm ($P=0.0018$).

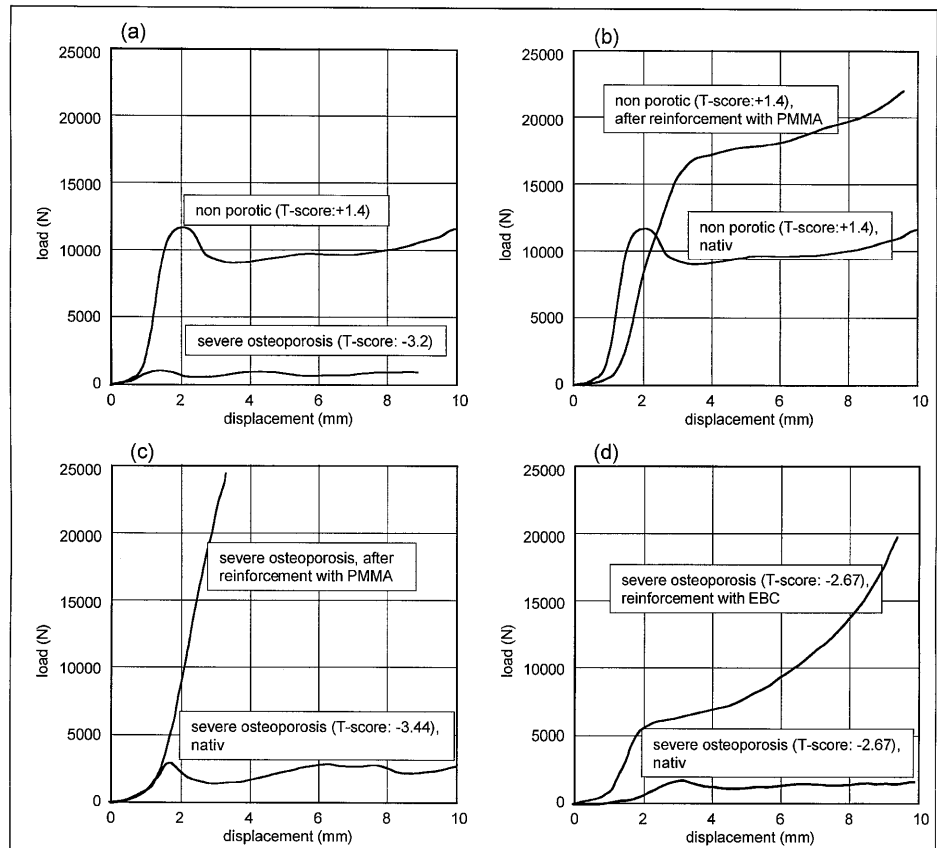
With EBC augmentation the stiffness was increased on average by 120%, ($P=0.03$).

The augmentation effect was inversely related to BMD and proportional to the degree of filling.

Maximal force until vertebral failure (F_{max})

With PMMA, the maximal force until vertebral failure was 6407 N on average (SD 6336 N), compared to 2019 N in the corresponding controls (SD 979 N). This

Fig. 5 Qualitative load-displacement curves representing **a** native porotic and non-porotic vertebral bodies, **b,c** the reinforcement effect of PMMA on **b** a non-porotic pair of vertebrae and **c** a severely porotic pair of vertebrae with a maximal degree of filling, and **d** the reinforcement effect of experimental brushite cement (EBC) on a severely porotic pair of vertebrae with a maximal degree of filling



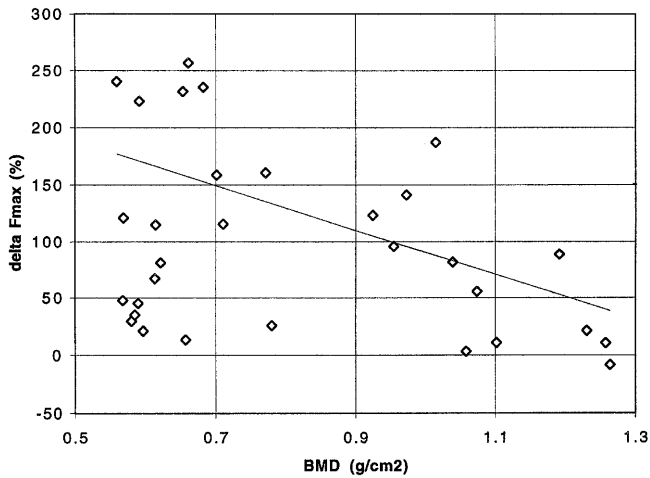


Fig. 6 Effect of augmentation on the peak load (F_{\max}) in relation to the BMD. Each point represents the average BMD of a pair of vertebrae and the resulting increase of F_{\max} as a percentage

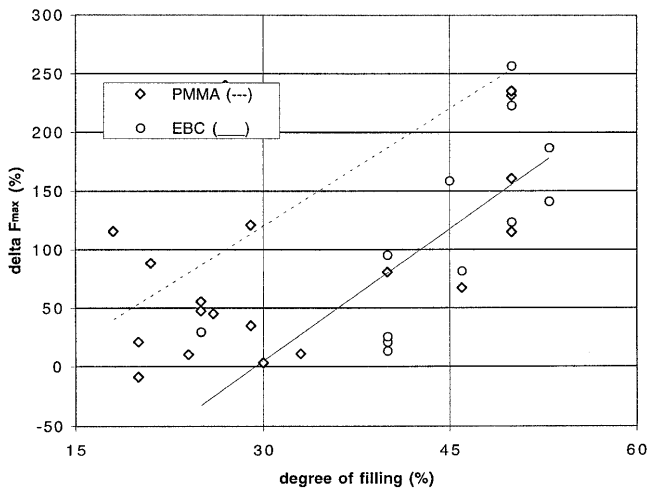


Fig. 7 Relation between amount of filling and increase in peak load (F_{\max}) for PMMA and EBC. For a given degree of filling, PMMA increases the peak load nearly twice as much as EBC

represents a statistically significant increase of 195% ($P=0.001$).

ΔF_{\max} ranged from 26% in spine 1 with normal BMD values ($P=0.063$), through 136% in spine 3 with decreased BMD values but deliberately limited cement volume ($P=0.018$), to 254% in spine 2 with decreased BMD values and maximal possible filling ($P=0.018$) (Table 1, Fig. 8)

EBC augmentation increased F_{\max} by 113% ($P=0.002$). In the two EBC augmented spines, ΔF_{\max} was comparable. For PMMA and EBC the increase was again inversely related to the BMD and positively related to the degree of filling (Fig. 6, Fig. 7).

Direct comparison of PMMA and EBC reinforced spines showed a higher ΔF_{\max} and ΔS with PMMA for the

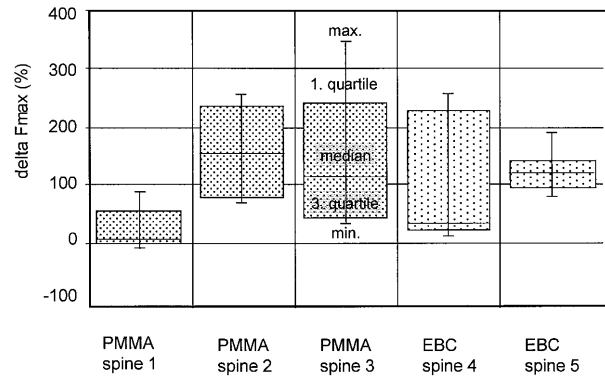


Fig. 8 Box plot representing a summary of the obtained values for change in peak load (F_{\max}) for PMMA and EBC augmentation. Except for the non-porotic specimen (spine 1), in all cases an increase of more than 100% could be observed

same degree of filling than with EBC, and vice versa; for the same degree of reinforcement less filling was necessary with PMMA than with EBC (Fig. 8).

Discussion

Osteoporosis is characterized by a decrease in amount of normal quality bone, increasing the susceptibility to fracture, which may in severe cases even occur with normal physical activity. Vertebral fractures are the most common complication of osteoporosis [16]. The loss of horizontal bone trabeculae and the increase in intertrabecular space significantly compromises the vertebral body's compressive strength, which is highly correlated to the bone mineral content and density [7,11]. In contrast, the elastic properties of bone are almost exclusively a function of collagen, and largely independent of bone mineral content [3]. The comparative analysis of pairs of vertebrae, where the upper and smaller vertebra was reinforced, allowed the minimization of intra- and interindividual differences regarding BMD and dimension of the spines. The resulting effect of reinforcement is rather underestimated, as the caudal lower neighbor served as reference.

Our data clearly show that cement augmentation increases vertebral stiffness and compressive force. The maximal tolerable force until irreversible deformation was reliably and significantly raised by the cement injections; however, this was true in cases of osteoporotic bone only. With normal BMD values, no significant changes were noted. In osteoporotic vertebrae, a significant effect was observed even with cement volumes of 6–7 ml, representing a filling of about one-quarter of the vertebral body volume. In our own and also others' in vivo experience, this degree of filling is achievable either by a uni- or a bipedicular approach [14,24]. However, it remains unclear what degree of local stiffness and force augmentation would be desirable. It is conceivable that large differ-

ences in stiffness from one vertebra to another could result in later damage to the „weaker“ vertebra. Therefore, the optimum levels of augmentation, taking into account the effects on neighboring segments, remains to be investigated. It is interesting to note that, with augmentation, significant increases in stiffness only occur in osteoporotic vertebrae.

Vertebroplasty as a percutaneous technique was first described by Galibert et al. in 1987, and was initially applied for the reinforcement of hemangiomas, myelomas and metastatic tumors [9]. Cement is injected through a transpedicular approach under fluoroscopic control. More recently, this technique has been used for the augmentation of severely osteoporotic vertebral bodies. Although clinical experience is fairly limited, initial studies and also our own experience show good pain relief and prevention of further collapse [10,13, 14]. The clinical application of PMMA augmentation is, however, not without hazards. In a series of 40 percutaneous vertebroplasties performed for metastatic disease and myeloma, PMMA leaks into adjacent paravertebral tissue were the most frequent complication, albeit mostly without clinical consequences [4]. Cement extrusion into the spinal canal may potentially lead to neurological compromise due to mechanical compression or heat induction generated by polymerization of the cement [17]. In the present study this posterior leakage through the basivertebral veins was observed in 12%, with the risk of leakage being related to the injected volume.

Even in the „contained“ cases, temperature elevations up to 48°C were recorded after injection of PMMA at the posterior vertebral cortex, albeit only in vertebrae with maximal cement filling. It has been hypothesized that this exothermic reaction of the PMMA in combination with the neurotoxic effect of the cement contributes to the marked pain relief of the patients, especially as the clinical improvement is not necessarily related to the injected volume of cement [4].

A biologically more inert material for augmentation would nevertheless be desirable [1]. The present study evaluated one CaP cement, which shows less exothermic reaction. Schildhauer et al. used a special pressure-suction device to augment lumbar vertebrae with an earlier version of Norian [23]. Under axial compression it was shown that augmentation resulted in a significant increase in energy absorption capabilities, albeit after initial collapse of about 25%. However, in order to prevent vertebral collapse, it seems important to augment the vertebral body at its maximal possible height. Other experimental studies have shown that CaP cements can have a favorable effect over time. Frankenburg et al. used Norian for filling proximal tibial and distal femoral metaphyseal defects in dogs [8]. Histological follow-up confirmed that the cement was osteoconductive, and that gradual remodeling resulted in almost normal cortical and cancellous bone. Whether human osteoporotic bone reacts in a similar pattern remains an open question.

Conclusion

Cement augmentation of vertebral bodies reliably enhances their biomechanical properties, i.e. stiffness and maximal load to failure. The higher the degree of osteoporosis, the more pronounced is the observed effect. The transpedicular application of cement may be hazardous due to potential cement leakages, and a continuous fluoroscopic control in vivo is recommended.

EBC showed very good properties regarding applicability and mechanical effect. The material is at present being tested in animal studies.

At the present stage, however, PMMA seems the material most favorable for the percutaneous vertebroplasty technique, as significant effects were achieved with easy application and relatively small volumes.

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