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ORIGINAL ARTICLE

Biomechanical comparison of vertebral augmentation with silicone and PMMA cement and two filling grades

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Abstract
Purpose Vertebral augmentation with PMMA is a widely applied treatment of vertebral osteoporotic compression fractures. Subsequent fractures are a common complication, possibly due to the relatively high stiffness of PMMA in comparison with bone. Silicone as an augmentation material has biomechanical properties closer to those of bone and might, therefore, be an alternative. The study aimed to investigate the biomechanical differences, especially stiffness, of vertebral bodies with two augmentation materials and two filling grades.
Methods Forty intact human osteoporotic vertebrae (T10–L5) were studied. Wedge fractures were produced in a standardized manner. For treatment, PMMA and silicone at two filling grades (16 and 35 % vertebral body fill) were assigned to four groups. Each specimen received 5,000 load cycles with a high load range of 20–65 % of fracture force, and stiffness was measured. Additional low-load stiffness measurements (100–500 N) were performed for intact and augmented vertebrae and after cyclic loading.
Results Low-load stiffness testing after cyclic loading normalized to intact vertebrae showed increased stiffness with 35 and 16 % PMMA (115 and 110 %) and reduced stiffness with 35 and 16 % silicone (87 and 82 %). After cyclic loading (high load range), the stiffness normalized to the untreated vertebrae was 361 and 304 % with 35 and 16 % PMMA, and 243 and 222 % with 35 and 16 % silicone augmentation. For both high and low load ranges, the augmentation material had a significant effect on the stiffness of the augmented vertebra, while the filling grade did not significantly affect stiffness.
Conclusions This study for the first time directly compared the stiffness of silicone-augmented and PMMA-augmented vertebral bodies. Silicone may be a viable option in the treatment of osteoporotic fractures and it has the biomechanical potential to reduce the risk of secondary fractures.

Keywords Silicone · PMMA · Vertebral augmentation · Elastoplasty · Vertebroplasty · Osteoporosis · Compression fracture · Stiffness

Introduction

Vertebroplasty (VP) using polymethylmethacrylate (PMMA) cement is a widely used form of treatment for vertebral osteoporotic compression fractures. However, there is still a lack of consensus regarding the clinical long-term efficacy and superiority of this technique in comparison with conservative treatment [1–9]. Reported complications, possibly due to the addition of a material that is stiffer than the surrounding bone, include fractures of the augmented and adjacent vertebrae. New osteoporotic vertebral compression fractures, in the months after VP, are reported in 7–63 % of VP patients, up to 82 % of these occur at the adjacent levels, with adjacent fractures occurring sooner than nonadjacent fractures; rates of recurrent fracture of the augmented vertebra itself range up to 63 % in the literature [1, 10–26]. It is still under debate whether new vertebral fractures appear more often in patients who received cement augmentation than in

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conservatively treated patients; some studies support this hypothesis [1, 6, 7, 27–29], while others question it [2, 3, 26, 30]. Reducing the augmentation volume [31], using low-modulus PMMA [32] and prophylactic augmentation of adjacent vertebrae [13, 25, 33] have been proposed as ways of minimizing the risk of subsequent fractures. In particular, a need for materials with less stiffness has been identified to prevent this adverse effect of VP [34].

VK100 (BONWRX, Phoenix, AZ, USA), a two-component injectable, self-curing elastomeric material ("silicone"), is a new alternative material available for vertebral augmentation. VK100 was engineered to be less stiff than PMMA and to have a stiffness in the same range as cancellous bone. It is hypothesized that an augmentation material with mechanical properties similar to those of cancellous bone may reduce the rates of adjacent fractures and vertebral sintering [32].

The aim of the present biomechanical in vitro cadaver study was to compare the stiffness of vertebrae augmented with VK100 and PMMA using two different filling grades.

Materials and methods

Forty human intact vertebrae (T10–L5, mean age 75.3 ± 13.9 years) were evenly distributed in four groups, each consisting of ten vertebrae with identical levels and comparable bone mineral density (BMD). To exclude vertebrae with previous fractures, a qCT was conducted (GE Lightspeed 16, GE Medical Systems, Waukesha, WI, USA), and trabecular BMD was measured. Mean trabecular BMD was 74.4 ± 22.5 mg/cm^3, osteoporosis was, therefore, present [35].

To create fractures, the vertebral bodies were compressed by 30 % of their intact anterior height (loading rate 5 mm/min) using a servohydraulic biaxial material testing machine (858 Mini Bionix II; MTS, Eden Prairie, Minnesota, USA). The wedge fracture was created in a specially designed adjustable jig, allowing a standardized load application in the ventral third of the vertebral bodies for fracture creation and subsequent cyclic loading (Fig. 1) [36]. The ventral third of each vertebral body was determined using axial fluoroscopy images of each single vertebrae.

The intact vertebral body volume (excluding pedicles) was determined prior to fracture using the Archimedes principle. For fracture treatment, two different filling materials, PMMA (CementoFixx, Optimed, Ettlingen, Germany) and VK100 (BONWRX, Phoenix, AZ, USA), and two different filling grades (16 and 35 % of intact vertebral body volume filling) were assigned to the four groups. These filling grades resulted in an average augmentation volume of 5.4 ml for the 16 % filling groups and 11.8 ml for the 35 % augmentation groups. According to

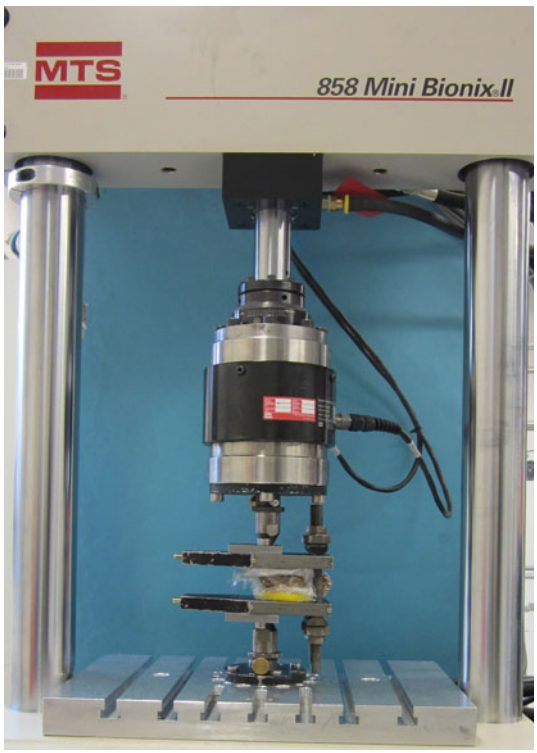

Fig. 1 The test setup in the material testing machine, with adjustable load application via ball-and-socket joints and a hinge joint at the dorsal side used to provoke a vertebral wedge fracture and for cyclic loading

the literature, 16 % filling is required to restore the biomechanical properties and 35 % filling is equivalent to endplate-to-endplate filling [32, 37, 38]. An experienced senior spine surgeon performed a bipedicular VP in each vertebra under fluoroscopic guidance.

Each augmented specimen was subjected to 5,000 load cycles (0.5 Hz) using the same jig, load application point (ventral third), and material testing machine as for fracture creation. To standardize the cyclic load magnitude, each vertebral body was sinusoidally loaded between 20 and 65 % of the compressive force initially required to fracture the corresponding vertebra (high load range).

The stiffness of the vertebra being treated was calculated for cyclic loading and normalized to the corresponding stiffness of the intact vertebrae determined during fracture creation (high load range 20–65 % of fracture force). Additional low load magnitude stiffness measurements in the load range between 100 and 500 N (loading rate 50 N/s) were carried out for the intact vertebra, after augmentation and at the end of the cyclic loading (low load range). Height loss of the augmented vertebrae and the elastic per cycle motion in the course of cyclic loading were determined from the displacement of the load application point. For height loss measurements, the initial ten cycles were taken as preconditioning of the augmented specimens.

Statistical analysis was carried out using SPSS version 20 and included a one way ANOVA with repeated measurements of the tested conditions in the course of the experiment and a two way ANOVA with Bonferroni post-hoc test to evaluate the effect of the material and the filling grade. The level of significance was set to 0.05.

Results

Fracture loads of the four groups were comparable ($p = 0.67$): 3,667 ± 1,062 N (35 % PMMA), 3,409 ± 683 N (35 % VK100), 3,208 ± 856 N (16 % VK100) and 3,009 ± 863 N (16 % PMMA). Wedge type fractures with intact posterior walls could be created in all specimens.

Normalized to the intact vertebra the low-load stiffness tests (100–500 N) showed an initial stiffness reduction after augmentation (Fig. 2) for both filling materials and grades ($p < 0.05$). In comparison with the augmented stiffness, the low-load stiffness increased significantly ($p < 0.05$) after the cyclic loading period in all of the test groups. In comparison with the intact vertebra, the stiffness after cyclic loading increased in the 16 and 35 % PMMA augmented vertebra (110 and 115 %) and decreased in the 16 and 35 % VK100 augmented vertebra (82 and 87 %). When the materials for the two filling grades were pooled at the end of cyclic loading, significant differences in stiffness were noted between PMMA and VK100 ($p = 0.01$), whereas the difference between the filling grades (16 or 35 %) was not significantly independent of the filling material ($p = 0.591$).

Normalized to the intact vertebra, the high-load range stiffness (20–65 % of fracture load) at the end of the cyclic loading was 361 and 304 % for the 35 and 16 % PMMA augmentation, and 243 and 222 % for the 35 and 16 % VK100 augmentation (Fig. 3). The stiffness increased in all of the test groups during cyclic loading ($p < 0.05$). At the end of cyclic loading, the VK100 groups showed a lower stiffness in high load ranges than the PMMA groups. When the two filling grades for the two materials were pooled, no significant differences in the stiffness between 16 and 35 % filling were found for the high load range at the end of cyclic loading ($p = 0.202$). Independent of the filling grade, the PMMA groups showed a significantly greater stiffness ($p = 0.001$) for the high load range than the VK100 groups.

During cyclic loading, the height loss at the load application point for the VK100 augmented groups was significantly higher than the PMMA-augmented groups ($p = 0.001$) with magnitudes of 3.0 and 2.7 mm for the 35 and 16 % VK100 groups and 1.2 and 1.1 mm for the 35 and 16 % PMMA groups after 5,000 load cycles (Fig. 4).

The elastic per cycle motion at the end of the cyclic loading was significantly higher than the PMMA-augmented groups than for the VK100-augmented groups ($p = 0.04$) with a magnitude of 0.26 mm for both VK100 and 0.22 mm for both PMMA groups (Fig. 5).

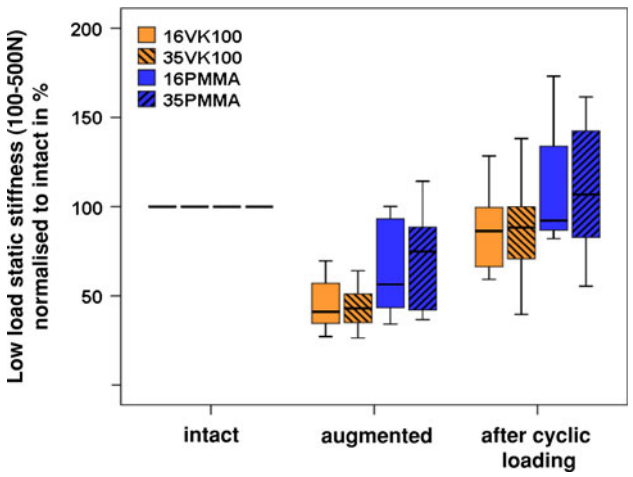

Fig. 2 *Box plot* of the stiffness normalized to the intact state for low load magnitude (100–500 N) for augmented and postcycling states

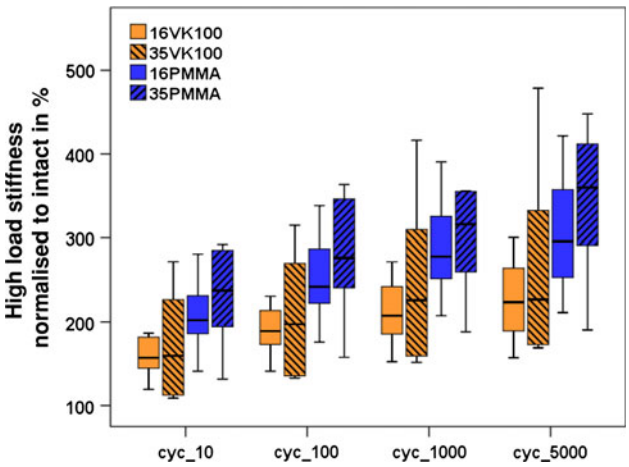

Fig. 3 *Box plot* of the stiffness normalized to the intact state for high load magnitude (20–65 % of fracture load) after 10 (cyc_10), 100 (cyc_100), 1,000 (cyc_1000) and 5,000 (cyc_5000) load cycles

Discussion

Vertebroplasty, first developed to treat vertebral angioma [39] and first described in 1989 to treat vertebral osteoporotic fractures [40], is the current gold standard for surgical treatment of osteoporotic compression fractures. The development of kyphoplasty [41] modified the surgical technique, but the augmentation material—PMMA—remained the same.

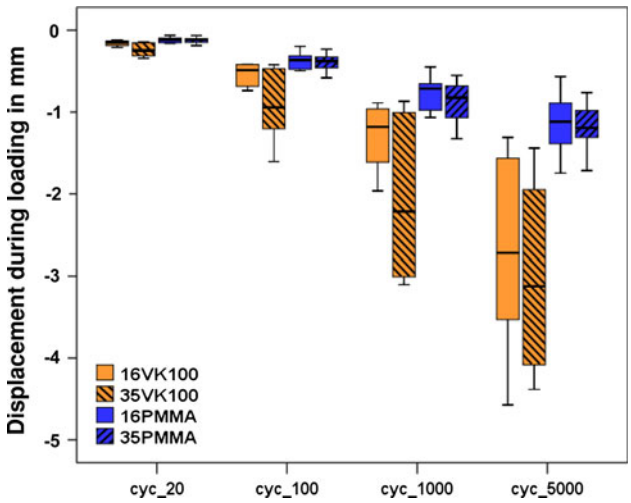

Fig. 4 Displacement at the lower load point after 20 (cyc_20), 100 (cyc_100), 1,000 (cyc_1000) and 5,000 (cyc_5000) load cycles

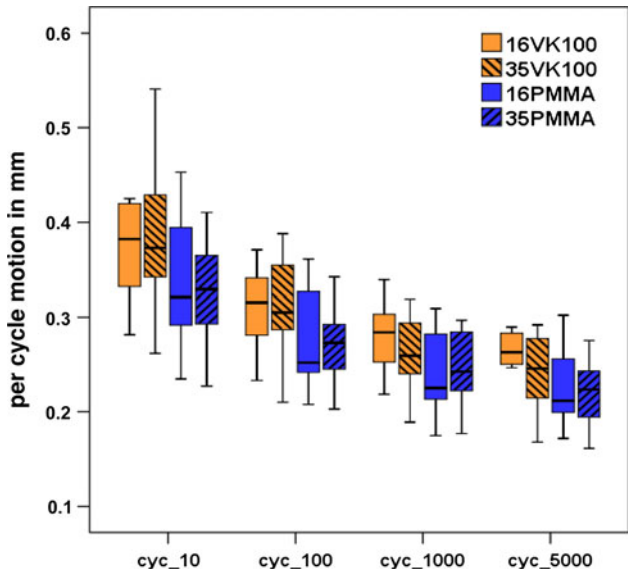

Fig. 5 Per cycle elastic displacement after 10 (cyc_10), 100 (cyc_100), 1,000 (cyc_1000) and 5,000 (cyc_5000) load cycles

Placing a relatively stiff material such as PMMA in a fragile and soft osteoporotic vertebra carries a risk of interface failure at the cement–trabecular bone boundary and subsequent sintering of the cement within the augmented vertebra due to high interface stresses. Reducing the difference in stiffness between the augmentation material used and the surrounding bone reduces interface stresses and may reduce the risk of sintering. Aiming for endplate-to-endplate filling to prevent cement sintering in an augmented vertebral body may shift the fracture risk resulting from the increased stiffness further toward the adjacent segments.

Various reasons and risk factors for fractures that occur following VP have been discussed: increased stiffness in the vertebra treated [34, 42], cement formation of a solid mass rather than interdigitation [43], changes in load transfer [44, 45], an altered loading direction [46], cement leakage into the disc (pro: [12, 14, 21, 47–49], contra: [50]), use of too much cement [15, 49], the degree of vertebral height restoration [12, 15] and persistent local kyphosis [20], deflection of the endplate and the intervertebral disc into adjacent vertebra [34], fracture shape [51], pre-existing fracture [12, 23], advanced patient age [23], ongoing osteoporosis [16, 20, 24], and low BMD [12, 16, 19, 21, 23], and a high number of VPs at baseline [16, 26]. In addition, patients with high parathyroid hormone concentrations, low body mass index, no use of back brace, no anti-osteoporosis therapy, history of metabolic disease, and use of drugs which influence bone metabolism tend to have a greater risk of recurrent fractures [16, 17, 47]. Studies on refractures of augmented vertebrae focused on the influence of vertebral height restoration, distribution patterns of cement in the augmented vertebra and intravertebral clefts [52], pre-operative osteonecrosis [18, 53], fracture shape, loading case and elastic modulus of fracture region and cement [51]. The initiation of fissures along the cement-bone interface due to uneven deformation of the vertebra is attributed to refractures claiming for a VP technique that ensures even deformation of the augmented vertebra [54].

Ahn et al. [47] described the "direct pillar effect (that is, the difference in strength caused by cement augmentation)" as being responsible for subsequent vertebral fractures.

The problem of potentially detrimental differences in stiffness between the augmentation material and the surrounding cancellous bone led to the innovative introduction of silicone as an augmentation material. Silicones have been used increasingly in the medical field since the 1960s with well-documented biocompatibility and biodurability [55–57]. The innovative technique investigated in the present study—i.e., augmentation of a vertebral body with silicone—thus represents only a further application of a well-known material in a new field of medicine.

The idea to use augmentation materials with less stiffness than regular PMMA is not new. In an in vitro biomechanical study, Boger et al. [32] observed biomechanical advantages with a low-modulus PMMA in comparison with regular PMMA. Other types of cement in addition to PMMA have also been developed for augmentation. In comparison with PMMA, calcium phosphate cement, for example, leads to fewer adjacent fractures in biomechanical studies, although, the rate of recurrent fractures in the augmented vertebrae themselves is still very high [58]. The use of completely different augmentation materials, such as silicone, instead of cement to achieve better stiffness parameters is new, however.

The present study is the first to directly compare the biomechanical stiffness of PMMA-augmented and silicone-augmented vertebrae in an in vitro setting. The results show that fractured vertebrae undergoing VP have a significantly lower stiffness with VK100 in comparison with PMMA. Both materials have greater stiffness values with 35 % augmentation in comparison with 16 %. The difference was not significant, but was more pronounced with PMMA. However, the overall height loss during cyclic loading was significantly higher for VK100 augmented vertebrae than the PMMA augmented vertebrae. Further experiments to investigate this overall height loss of the VK augmented vertebrae are planned.

The question of the ideal amount of vertebral filling with augmentation material has been investigated for PMMA with controversial results. Liebschner et al. [37] found that only a small amount of bone cement (about 15 % of the vertebral body volume) was needed to restore stiffness to predamage levels, while greater filling can result in a substantial increase in stiffness well beyond the intact level. Molloy et al. [38] reported that restoration of strength required filling of approximately 16 % of the vertebral body volume and that restoration of stiffness required filling of approximately 29 % of the vertebral body volume.

Luo et al. [59] compared the PMMA augmentation of 3.5 cm^3 (about 13 % of the vertebral body volume) and 7 cm^3 (about 25 % of the vertebral body volume) and reported that a 13 % filling largely restored the distribution of compressive stress acting on the fractured and adjacent vertebral bodies. An additional 3.5 cm^3 of PMMA had no further effect on these stress distributions, but was required to restore spinal stiffness and to normalize load sharing between the vertebral body and neural arch. Vertebral augmentation using too much PMMA has been discussed as one of the reasons for subsequent fractures [15, 49].

In typical everyday activities, loads acting on the spine are higher than those applied in the low load protocol. For greater load magnitudes, VK100 augmented vertebrae show stiffness results that are much closer to that of the intact vertebrae when compared to PMMA augmented vertebrae. Given that, it is desirable to achieve a stiffness close to the intact vertebra under all loading conditions of the spinal column, these results support the use of 16 % VK100 augmentation.

Further clinical and radiographic studies are now necessary to investigate the clinical and radiological results and to focus on correlations with these biomechanical findings. In particular, the rates of recurrent fracture of augmented vertebrae and of fractures in adjacent vertebrae require detailed investigation, in addition to possible side effects such as osteonecrosis, infection, and embolism.

Conflict of interest None.

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