Vertebroplasty with self-locking hexagonal metal implants shows comparable primary and secondary stiffness to PMMA cement augmentation techniques in a biomechanical vertebral compression fracture model

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Abstract With the growing incidence of vertebral compression fractures in elderly patients having a fair overall health condition, minimal-invasive treatment techniques are getting in focus of surgical therapy. Cement augmentation is widely performed and its complications and mechanical limitations are well described. Implants avoiding the side effects of cement augmentation while reaching the same level of stability would be desirable. The primary and secondary stability of a new augmentation method with self-locking hexagonal metal implants were investigated and compared with the performance of established augmentation options. 18 fresh-frozen human spinal specimens (Th12–L2/L3–L5) were tested with pure moments of 7.5 Nm in a six-degree-of-freedom spine simulator to investigate primary and secondary stability of three augmentation techniques: (1) vertebroplasty, (2) PMMA filled cavity and (3) hexagonal metal implants. An increasing three-step cyclic loading model was included. Elastic displacement and height loss under loading did not show significant differences between the three test groups. Investigation of primary and secondary stability evenly demonstrated comparable results for all techniques

indicating an insufficiency to stabilise the fracture with higher load cycles. The newly introduced method for augmentation with the metal implant Spine Pearls achieved comparable results to bone cement based techniques in a biomechanical in vitro study. Midterm and longterm reduction preservation and ingrowth of the implants have to be proven in further studies.

Keywords Thoracolumbar spine · Vertebral compression fracture · Vertebroplasty · Kyphoplasty · Three-dimensional stability

Introduction

In a constantly growing and aging population, the number of pathologic vertebral compression fractures (VCF) is also increasing. Therefore, adequate surgical strategies are getting in focus because of the burden of the disease comprising pain, impaired mobility and reduced quality of life [5, 19, 28, 37]. Different implants and techniques for fixation and/or stabilisation of the fractured vertebral body are being investigated with clinical and ex vivo studies [6, 10, 17, 23, 27, 33]. All of these studies have the restoration of function and if possible also the restoration of morphology of the altered vertebral body in common. Cement augmentation with PMMA for pathological VCF was the first method described and successfully applied for the treatment of selected cases [4, 11, 28]. After the first success of vertebroplasty techniques for cement application and height restoration, new techniques such as kyphoplasty [9, 13] or lordoplasty [11] were introduced to improve clinical outcome, safety and benefits of surgical procedures. As minimal-invasive treatment options all of this procedures show fast pain relief, as well as a partial

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reduction and stability to a certain extent combined with a short rehabilitation period [7, 11, 28].

Nevertheless, placement of bone cement into vertebral bodies has well-described limitations and complications as leakage and embolism. The leakage of the cement into the neighbouring structures can affect the spinal canal, venous vessels and intervertebral discs. Bone cement thrombosis in paraspinal vessels and lung embolism are also known risks. However, open questions such as the vascular situation in the treated vertebral body after cement filling remain. Furthermore, the ideal mechanical behaviour of the bone cement at the interface and the large difference of structural stiffness between the PMMA cement filling and the fractured bone are still under investigation. Different filling materials [24] and implants [17] were introduced to overcome these limitations. These arguments were the reason to develop a new PMMA-free technique based on small metal implants implanted through a transpedicular cannula. They are designed to interlock each to another and by forming a “cloud” they are able to stabilise the vertebral body.

In this biomechanical in vitro study different augmentation techniques were investigated in an established VCF model. Primary and secondary stability of this new augmentation technique were compared with vertebroplasty and a PMMA-filled cavity. These techniques were evaluated using a six-degree-of-freedom spine simulator and a cyclic loading protocol with a stepwise increasing load magnitude.

Materials and methods

Specimens

For testing purposes, 18 fresh-frozen human thoracolumbar spine specimens of the levels Th12–L2 (9×) and L3–L5 (9×) were used to assess biomechanical stability following fracturing and subsequent stabilisation of the middle vertebra. Specimens were harvested from male ($n = 14$) and female ($n = 4$) donors with an average age at death of 68.8 (standard deviations, SD 13.6) years. Bone mineral density (BMD) of the specimens was measured using a preoperative quantitative CT scan (GE Lightspeed 16, GE Medical Systems, Waukesha, WI, USA) including European Forearm Phantom calibration (EFP; QRM GmbH, Möhrendorf, Germany). Specimens showing pathologic changes were excluded from this study. Mean trabecular BMD was 85.2 mg/cm^3 (SD 20.0). Reference values for QCT BMD are reported in the literature with 96.6 and 68.6 mg/cm^3 for the age groups of 60–69 and 70–79 years, respectively [2]. Specimens were evenly distributed among three groups according to age, spinal level and BMD.

Preparation of specimens

The vacuum-sealed specimens were kept frozen at -20°C in double plastic bags until the definite testing date. Specimens were thawed overnight at 6°C and prepared at room temperature right before testing [30]. Leaving supporting structures intact (e.g. discs, ligaments, capsules) all muscular tissue was removed. After preparation the middle vertebral body (L1 or L4) of the test specimen was aligned horizontally in a fixation device. The upper part of the cranial (Th12/L3) and the lower part of the caudal (L2/L5) ends of the specimens were embedded in PMMA cement (polymethylmethacrylate, Technovit 3040, Heraeus Kulzer, Wehrheim, Germany) leaving the facet joints and discs intact. Cranial and caudal flanges were mounted to the PMMA blocks of the specimens. The flanges were rigidly fixed to the frame of the spine tester. Fixation screws for the 3D Motion analysis system (Winbiomechanics, Zebris, Isny, Germany) were mounted to the anterior side of the cranial and caudal PMMA block.

For standardised anterior–posterior (a.p.) and lateral X-rays (BV 25, Philips, Eindhoven, The Netherlands) specimens were fixed in a custom-made X-ray jig. The radiolucent jig allowed the application of a defined axial preload of 20 N.

Fracture creation

Prior to the reduction and stabilisation procedures the middle vertebra of each prepared specimen was fractured in a standardised set-up. In order to ensure that only the middle vertebra was fractured, the cranial and caudal vertebrae were protectively filled with 8–10 ml PMMA cement. A predetermined fracture line was created by a saw notch at the middle vertebra (L1 or L4) in the transversal plane. The saw notch reached from the mid third of the vertebral body ventrally leaving the anterior wall intact, similar to the technique described by Kettler et al. [17]. The fracture was created using a specifically designed device in a servohydraulic material testing machine (858 MiniBionix II, MTS), which allowed the creation of a reproducible wedge fracture with an intact posterior vertebral wall. Vertebral bodies were fractured with an eccentric, displacement-controlled loading rate (10 mm/min) up to 50% of the intact vertebral body height (20–25 mm).

Fracture treatment with augmentation techniques

To simulate the surgical procedures implantations were carried out fixing the specimens in an X-ray jig and applying an axial preload of 20 N allowing a partial passive reduction in the X-ray jig.

Vertebroplasty

Bipedicular vertebroplasty was performed according to a previously described technique [11] under fluoroscopy control. Through each pedicle PMMA cement (Vertebroplastic, DePuy, Blackpool, UK) was injected to stabilise the fracture (mean 4 ml, SD 0.46). The specimens were left fixed to the X-ray jig until the PMMA cement was polymerised.

PMMA filled cavity

Through transpedicular guide bushings a bone expander device (Sky Bone Expander, Discotech, Israel) was inserted bipedicularly. By expansion of the device a cavity was created and the fracture was reduced. Following reduction each of the two cavities was filled with 3.4 ml (SD 0.4) of PMMA bone cement (Vertebroplastic, DePuy, Blackpool, UK). Specimens were left fixed in the X-ray jig until the PMMA cement was polymerised.

Hexagonal metal implants (Spine Pearls)

Spine Pearls are small implants designed to be inserted transpedicular through a cannula into vertebral body. The implants fill up the fractured segment and are intended to aggregate to a load bearing cloud of implants within the vertebral body. Structural stiffness of the cloud can probably be explained by the “self-locking” effect of the Spine Pearls. In preliminary experiments this self-locking effect of different sizes and shapes of Spine Pearls (Fig. 1) was investigated. Large hexagonal Spine Pearls showed the best stiffness of the cloud and interlocking effect of the tested geometrical shapes and were therefore selected for further in vitro experiments and comparison with clinically established augmentation techniques.

For this test large hexagonal Spine Pearls (Akross AG, Schaffhausen, Switzerland) were inserted through transpedicular cannulas. Spine Pearls were manufactured of titanium alloy used for medical implants (Ti6Al4V) and were implanted in groups of five pieces alternating on each side and impacted using elastic shockwaves (Orthoclast, EMS,

Switzerland). The plunger used for impaction has an angulated tip allowing to place the Spine Pearls in the desired region and to aggregate them to a cloud in the vertebral body. The number of Spine Pearls varied according to the filling degree of the fractured vertebra (approximately 50–70 Spine Pearls per pedicle, (mean 58.8, SD 8.3). Implantation was controlled under biplanar fluoroscopy.

Flexibility testing

Biomechanical testing of the specimens was performed in a six-degree-of-freedom spine tester in accordance with the recommendations for testing of spinal implants [29, 31, 38]. The spine simulator was constructed as previously described by Knop et al. [20]. The flexibility tests were performed in flexion/extension. Moments and forces induced at the cranial end of the specimen were recorded by a six-component load cell (Schunk FT Delta SI 660-60, Lauffen/Neckar, Germany) and intersegmental rotation was measured by an ultrasound-based motion analysis system (Winbiomechanics, Zebris, Isny, Germany). The measurement of the range of motion (RoM) during loading included the fractured vertebral body as well as the two adjacent discs. The hysteresis curves of the moment/angle graphs were used to determine the RoM and neutral zone (NZ). To allow a preconditioning of the specimens and minimise the viscoelastic effect only the third load cycle was evaluated and used for further analysis and comparison.

Cyclic loading

All cyclic loading was carried out in a servo-hydraulic material testing machine (858 Minibionix II, MTS, MN, USA). Specimens were loaded in a custom-made loading jig, which allowed an eccentric loading of the specimens in flexion and was already used for fracture creation (Fig. 2). Specimens were loaded three times for 1,000 sinusoidal cycles with 0.5 Hz with the following load magnitudes:

1. 50–250 N, cyc_1
2. 50–450 N, cyc_2
3. 50–650 N, cyc_3

While cyclically loading, the eccentric force and the displacement of the actuator at the point of load application were recorded continuously. The elastic displacement of a treated specimen was calculated from the displacement measured with the actuator at the lower and upper turning point in intervals of 200 cycles. The elastic displacement during cyclic loading yields an indication of the stiffness of the treated specimens. The height loss of a specimen was also calculated for every 200 cycles. In order to obtain a constant loading, all height measurements were taken at the lower turning point of 50 N during all cyclic loading

Fig. 1 Different geometrical shapes and sizes of Spine Pearls investigated in the preliminary experiments: small round (a), large round (b), small hexagonal (c) and large hexagonal (d)

Fig. 2 Test setup in the servohydraulic material testing machine used for fracture creation and cyclic loading of the specimens. Arrows indicate the eccentric load application resulting a bending moment in flexion

periods. The measurements of elastic displacement and height loss include the treated vertebral body and the two adjacent discs.

Test sequences

1. Flexibility test in the spine simulator of the intact specimen (INT)
2. Fracture creation of the middle vertebra
3. Flexibility test in spine simulator (FRAC)
4. Treatment of the fracture according to the three test groups
5. Flexibility test in the spine simulator (TREAT)
6. Eccentric sinusoidal cyclic loading of the specimens in the material testing machine (force controlled 50–250 N for 1,000 load cycles)
7. Flexibility test in spine simulator (CYC_1)
8. Eccentric sinusoidal cyclic loading of the specimens in the material testing machine (force controlled 50–450 N for 1,000 load cycles)
9. Flexibility test in spine simulator (CYC_2)
10. Eccentric sinusoidal cyclic loading of the specimens in the material testing machine (force controlled 50–650 N for 1,000 load cycles)
11. Flexibility test in spine simulator (CYC_3)

Statistical analysis

Statistical analysis was performed using the SPSS software package (Microsoft Windows release 17.0; SPSS Inc. Chicago, IL, USA). Data and results of the RoM, specimen height and mean elastic displacement per cycle are presented as means and SD. An analysis of variance (ANOVA) followed by a post hoc test according to Bonferroni was carried out to analyse for differences in per cycle displacement, height loss and flexibility data. Significance was determined at a p value lower than 0.05 for all statistical test methods.

Results

The entire testing series could be completed for all specimens without observing any implant failures. Fluoroscopic control at the end of the load cycles revealed that the implanted Spine Pearls stayed aggregated to an intact cloud in the vertebral body throughout the experiment and cement fracture or displacement was not observed in the vertebroplasty and PMMA-cavity filled group. Radiographic analysis of the fractured specimens according to the AO classification showed the fracture pattern of A1-2 fractures (wedge compression fracture) in all specimens (see Fig. 3).

Flexibility testing (RoM)

For comparison of the treatment all RoM results were normalised to the fractured state (Fig. 4). Fracture creation had a similar effect on all specimens, with the intact RoM of the two measured motion segments in all groups being 0.68 (SD 0.08) of the fractured state. After treatment, the RoM was reduced to 0.91 (SD 0.05) of the fractured state for all groups independent of the treatment and did not reach the state of the intact specimens. During cyclic loading the measured RoM in all three treatment groups increased steadily and was in the range of the fractured specimens (1.01, SD 0.06) after the third period of cyclic loading. The differences between the treatment groups were very small for all tested states and statistically non-significant (ANOVA, $p = 0.53$ – 0.96).

Elastic displacement during cyclic loading

The elastic displacement of the specimens showed small but non-significant differences (ANOVA, $p = 0.21$ – 0.30) between the three treatment groups throughout the three periods of cyclic loading (Fig. 5). After the first period of cyclic loading (50–250 N) all groups showed a comparable elastic displacement with 0.91 mm (SD 0.22), 0.94 mm

Fig. 3 Anterior–posterior and lateral view of the three investigated augmentation techniques

Fig. 4 Range of motion of the three test groups normalised to the fractured state of each specimen

(SD 0.23) and 1.13 mm (SD 0.31) for the vertebroplasty, PMMA-filled cavity and Spine pearls group, respectively. At the end of the third cyclic loading period the elastic displacement was highest for the Spine Pearls group (2.72 mm, SD 0.78), followed by the PMMA-filled cavity group (2.45 mm, SD 0.50) and the vertebroplasty (2.06 mm, SD 0.49).

Height loss during cyclic loading

After the first period of cyclic loading, all three groups showed comparable height loss (ANOVA, $p = 0.99$) of approximately 2.1 mm (Fig. 6) at the lower turning point (50 N). During the second period of cyclic loading, the

Fig. 5 Elastic per cycle displacement of the three test groups during the eccentric cyclic loading in the material testing machine

Spine Pearls group showed the largest height loss with 4.15 mm (SD 0.45) at the end of the second loading period (ANOVA $p = 0.29$). The vertebroplasty and PMMA-filled cavity group had a height loss of 3.66 mm (SD 0.84) and 3.61 mm (SD 0.51), respectively. In the third period of cyclic loading, the PMMA-filled cavity showed the largest increase in height loss and at the end of cyclic loading the Spine Pearls, vertebroplasty and PMMA-filled cavity group showed 5.93 mm (SD 0.74), 5.20 mm (SD 1.0) and 6.0 mm (SD 1.03), respectively. However, none of the differences in the height loss measured for the three groups was statistically significant (ANOVA, $p = 0.29$).

Discussion

The increasing average age of the population in western countries elevates the incidence and co-morbidities of reduced low bone marrow density [5, 19, 28, 40]. Osteoporosis as the most common cause for low BMD values and VCF as one of its signs of mechanical insufficiency is still a problem in the surgical treatment of the elderly and has a major impact on the socio-economical costs. Therefore, the need for situation-adaptable treatment strategies is high. Introduction of PMMA-based augmentation initially demonstrated stabilisation and pain relief with persistent height loss and later, with the development of techniques, an advance of reduction ability. Although routinely performed today, these surgeries have shown some limitations [8, 11, 14, 21, 22, 40] resulting in a continuous development of alternative products [17]. The aim of this study was to show whether an augmentation method with hexagonal metal implants is capable of restoring the stability in an in vitro model of VCF comparable to known methods of treatment (vertebroplasty and PMMA cavity).

Biomechanically, the experiments demonstrated comparable results for all three stabilisation techniques. With

increasing load magnitude during cyclic loading a progressive height loss and an increase in elastic displacement were evidenced in all augmentation techniques, finally showing an increase of ROM to the level of the fractured specimens. However, it must be considered that the height loss and elastic displacement reported in the present study are not measured of the isolated treated vertebral body but also encompasses the two adjacent discs. McCann et al. [27] compared vertebroplasty, osteoplasty, a cavity-creating system and kyphoplasty. Analogous to our results they did not find a difference in strength and height restoration among all four bone cement based techniques. Kim et al. [18] biomechanically investigated vertebroplasty and kyphoplasty. They reported higher compression stiffness and reduced reduction capabilities for the vertebroplasty technique. While restoring initial vertebral body height, kyphoplasty was not able to maintain the height during cyclic loading with a final vertebral body height smaller than vertebroplasty. Although these studies showed comparable results for the different bone cement augmentation techniques they point to factors which are able to influence the achieved results. One important factor is the type of bone cement and the associated material properties used for augmentation. Aside from PMMA—that was used in the two cement based techniques in this study—different cements were developed and introduced to the market. These cements differ in polymerisation temperatures, viscosity and mechanical stiffness [1, 3]. In the clinical and in vitro situation a further variable influencing the outcome is the amount of bone cement injected. The volume that has to be injected to gain secure stability and height restoration without resulting in an over-stiffening of the treated vertebra is yet not clear and might vary due to the reason that different cements have different material properties. Regarding the filling of the vertebrae, some authors recommend a volume of 15–20% of the vertebral body [16, 25] while lately others recommended an endplate-to-endplate filling having an increased strength compared with incomplete filling [36]. To avoid this possible source of failures in the presented study, following pre-testing procedures, standard volumes of one bone cement were injected in the investigated vertebrae. Similarly, a standardised number of Spine Pearls were implanted bipedicularly. Standardisation in all groups was attempted by the use of homogenous specimens of the thoracolumbar spine evenly distributed to the three test groups by BMD and segmental level.

With the induced loads a parallel increase in elastic displacement and height loss of the tested specimens was demonstrated for all three techniques. The behaviour for all the treatment groups showed small but no significant differences. Due to the viscoelastic effect of the two adjacent discs included in the measurement setup due to technical

Fig. 6 Specimen height loss during the course of cyclic loading for the three test groups at the lower load magnitude (50 N) in the course of cyclic loading

reasons, elevated displacement and height loss are being expected under repetitive cyclic loading for an intact control group without a fracture treatment, too. Even with a progressive elastic displacement and parallel height loss the cloud of metal implants stayed intact until the end of testing without a structural breakdown of the conglomerate or of the vertebra. In the bone cement groups no structural breakdown was seen as well. The height loss, of up to 6 mm during cyclic loading in the present study, is comparable to findings of the study by Kettler et al. [17] using a similar test setup. Therefore, the results of this study are interindividually and intraindividually comparable and allow drawing transferable conclusions.

A stepwise increase of the flexibility (RoM) to the range of the fractured state after the highest cyclic loading period (up to 650 N) was observed in all three treatment groups. This is in part due to the fact that in this VCF model two motion segments were included in RoM measurement in the spine tester. With progressive loading the loss of fluid in the intervertebral discs and the repetitive straining of ligamentous structures would contribute to the increased RoM. However, with progression of loading none of the used techniques were able to sufficiently stabilise the affected vertebrae. Despite the advanced primary binding capacity of PMMA to bone the gapping motion in extension could not effectively be limited for vertebroplasty and PMMA cavity compared with metal implants. In turn it could be speculated that secondary healing capacities and ingrowth of the metal implant could exceed abilities of bone cement as already discussed intensively on cemented and uncemented arthroplasties [15, 35, 39]. While secondary ingrowth of Spine Pearls has to be proven in future animal and clinical studies, the cement alternative with conventional bioresorbable cements have shown incoherent results. Although in vitro experiments demonstrated comparable strength of bioresorbable cements to PMMA augmentation [26, 32, 34], clinical trials evidenced reduced radiopacity, handling problems [12] and a higher failure rate following injection [14]. However, in this in vitro study the introduced new implant demonstrated comparable results in biomechanical primary and secondary stability to the clinically well-established techniques of vertebroplasty and PMMA cavity. Future studies have to prove the abilities of the implant in terms of surgical feasibility, possible complications and their management, preserving reduction, healing capabilities and ingrowth.

Conclusions

The newly introduced metal implant Spine Pearls achieved comparable results to bone cement based techniques in a

biomechanical in vitro study of VCF. While loaded, elastic displacement, height loss and RoM in a spine tester differed non-significantly for all investigated groups. Nevertheless, with increasing cyclic loading all techniques progressively failed to stabilise the fracture. From a biomechanical point of view Spine Pearls could be an alternative to well-established techniques in terms of primary and secondary stability. Midterm and longterm reduction preservation and ingrowth of the implants have to be proven in further studies.

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