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Biomechanical Evaluation of the Vertebral Jack Tool and the Inflatable Bone Tamp for Reduction of Osteoporotic Spine Fractures

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Study Design. Controlled *in vitro* study.

Objective. To compare two kyphoplasty techniques in cadaveric fractured vertebrae: an experimental vertebral jack tool (VJT) and an inflatable bone tamp (IBT).

Summary of Background Data. A previous biomechanical study showed restored strength and stiffness after height restoration in cadaveric-fractured osteoporotic vertebrae using a new device for reduction of osteoporotic vertebral fractures.

Methods. Anterior wedge fractures (AO type A1.2) were created in 8 (4 lumbar, 4 thoracic) vertebrae by displacement eccentric external forces. In all vertebrae the amount of height reduction was 35%. After compression, 4 vertebrae were restored in height using the VJT procedure. Four vertebrae were restored in height using the IBT procedure. Posttreatment strength and stiffness of the vertebrae were determined by a compression test identical to the pretreatment compression protocol.

Results. In the VJT group the postrestoration strength was 81% ± 13% of the original strength and in the IBT group it was 96% ± 32%. The postrestoration stiffness in the VJT group was 61% ± 42% of the original stiffness and in the IBT group 76% ± 62% of the original stiffness. The vertebrae in the VJT group were restored to 101% ± 2% of their original height whereas this was 104% ± 14% in the IBT group. In this study, no cases of cement leakage were found. No cases of damaging of the end plates, new fractures or perforations were seen in both groups. The mean amount of cement inserted for the VJT group was 3.6 ± 0.9 cm^3 and for the IBT group 5.9 ± 0.8 cm^3.

Conclusion. Both kyphoplasty procedures were able to restore height in this *in vitro* study, while strength and stiffness were partially restored, with no significant differences. In this study on average significant less cement was used in the VJT procedure. No complications were noted in both groups. This new end plate-to-end plate laminar augmentation technique may be of clinical advantage.

Key words: vertebroplasty, vertebral fractures, kyphoplasty, inflatable bone tamp, osteoporosis. **Spine 2009;34: E640–E644**

Percutaneous vertebroplasty seems to be effective in pain reduction in osteoporotic vertebral fractures, and is nowadays widely accepted. However, devastating clinical adverse effects have been reported, mainly due to cement leakage.[1,2] Kyphoplasty is a variation on this technique, in which a void is created in the fractured body, reducing the pressure needed to inject cement into the vertebral body (VB). This controlled cementing technique is reported to lead to a smaller incidence of complications due to cement leakage.[3]

Kyphoplasty was mainly developed with the intention of restoring height of the collapsed VB.[4–6] Several studies show an association of severe vertebral deformity with clinical signs and symptoms, including chronic back pain, decreased activity, changes in mood, reduced pulmonary function, increased risk of further vertebral fractures, and impairment of quality of life.[7–15] However, clinical studies have shown that kyphoplasty can only partially maintain the initially achieved height restoration (66.3%–91.5% restoration of initial height).[16–20] The reason for this failure probably lies in the fact that the mechanism used to create a void is balloon expansion. This technique leaves a layer of compressed trabecular bone of unknown strength between the void and the upper and lower end plates. Failure of these zones will lead to secondary loss of height restoration.[21] To avoid this failure mechanism, we developed a new device called the vertebral jack tool (VJT). This new device creates a vertical slit from end plate-to-end plate, which is filled with cement thus creating a laminar strut maintaining complete height restoration. Because the orientation of the vertical strut is mainly in the AP direction with a lateral width of 4.7 mm., less cement is necessary to achieve post procedural increase in strength and height restoration of the VB. In the current study, we compare both techniques of percutaneous vertebral fracture reduction in clinically relevant wedge fractures (AO1.2) with a height reduction of 35%. A previously study showed that a clinical relevant AO1.2 wedge fracture only can be created in compressing the vertebra with 35% height reduction.[22] Our first study aim was to compare the biomechanical properties of treated VBs in terms of stiffness and strength. Our second study aim was

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Table 1. Preoperative Vertebral Characteristics

	VJT (n = 4) Mean ± SD	IBT (n = 4) Mean ± SD
Geometrical characteristic		
Estimated VB volume (mL)	39.3 ± 7.4	38.4 ± 10.7
DEXA characteristics		
t value	−4.6 ± 0.8	−4.6 ± 0.7
Bone mineral density (g/cm²)	0.52 ± 0.04	0.47 ± 0.1

to compare the results of height restoration. Our final study aim was to compare the incidence of complications in terms of cement leakage or newly created lesions such as fractures or cortical perforations.

Materials and Methods

Eight intact vertebral bodies were obtained (4 lumbar, 4 thoracic) from 3 human cadaveric vertebral columns. The specimens were radiographically screened to ensure that there were no previous fractures. Bone mineral density was assed using Lunar DPX-L (Lunar Radiation Corp., Madison, WI) (Table 1). The paravertebral muscles, the ligaments, and the discs were dissected and the VB disarticulated, while keeping the posterior bony structures intact. Geometrical measurements were made using digital calipers accurate to 0.05 mm. The relevant geometrical specifications are summarized in Table 1. The vertebrae were wrapped in saline-soaked gauze, sealed in plastic bags, and stored frozen at −20°C until the day before testing. All specimens were thawed at room temperature (20°C) 24 hours before testing.

Preoperative Crush Sequence

Anterior wedge fractures (AO type A1.2) were created by displacement controlled eccentric external force in each VB, with a preset height reduction of 35%. A displacement controlled device (MTS) was used with a range of 30 mm, accuracy ±0.1 mm, force range 0 to 1500 N, accuracy ±5 N. A 35% compression fracture was created using a MTS as previously described (Figure 1).

Measurements Strength and Stiffness

The deformation of the silicon (1–3 mm depending on the size of the silicon pad) is taken into account when the VB is deformed. The following definitions were used: failure is defined as a fracture of the anterior cortical wall. This point is defined in the measurements as the moment where the force decreases with continuing deformation. Maximum force is defined as the maximum measured value of axial force before a fracture/failure occurs. Displacement is defined as the deformation of the anterior cortical wall after applying a preload of 100 N. Stiffness is defined as the amount of axial force needed to deform the anterior cortical wall by 1 mm. The value is obtained from the curve by drawing a straight line from the max force to half of the maximum force. The resulting $\delta F/\delta x$ is a measure for the stiffness of the VB.

Vertebral Jack Tool

The vertebral jack tool VJTmkIII (BAAT, The Netherlands) is a new device which can be used, through a bilateral transpedicular approach, to reduce compressed VBs (Figure 2). The essence of the VJT is an expanding mechanism which can restore the height of the vertebra by reducing the end plates. At the same time a vertical slit is created to direct the cement flow to both

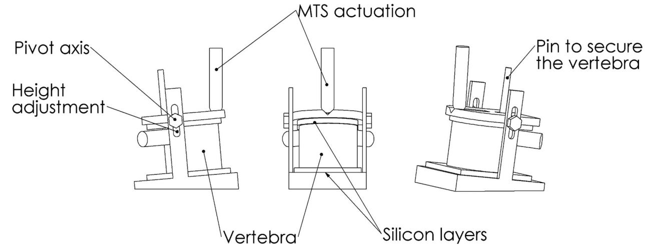

Figure 1. Fracture test set-up.

end plates. In this way a laminar cement strut supports the forces on the end plates. Each VJT has a force indicator at the tip of the device that shows the compression load on the tip. During surgery, the indicator will show the current load on the tip and visualizes changes in force. The force indicator includes a red zone, which indicates that the force applied has reached a level which is known to increase the risk of end plate fractures. Two sizes were used to accommodate the variation in vertebral geometry: large (TC expanded: 20 mm[height] × 13.5 mm [length] × 4.7 mm[width]) and small (TA expanded: 13 mm[height] × 13.5 mm[length] × 4.7 mm[width]).

Inflatable Bone Tamp

The inflatable bone tamp (IBT) first described by M. Reiley 1997 is a balloon device, which is positioned percutaneously in the VB to reduce fractures.[6,24] The balloon device is connected with a manometer system so the pressure can be read out during the reduction procedure. After removing the balloon tamp bone cement can be inserted under low pressure in the created void.

Height Restoration and Cementing Technique

A spine surgeon trained in both kyphoplastic techniques performed all the VJT and IBT insertion and height restoration interventions. A bilateral transpedicular approach was used for both techniques. Based on the effective VB depth, which was measured fluoroscopically, the size of the VJT was chosen. The pedicles were reamed over a guide wire. After sleeves were inserted the VJTs were inserted. Height was restored under a compressive load of 100 N to simulate the intraoperative forces

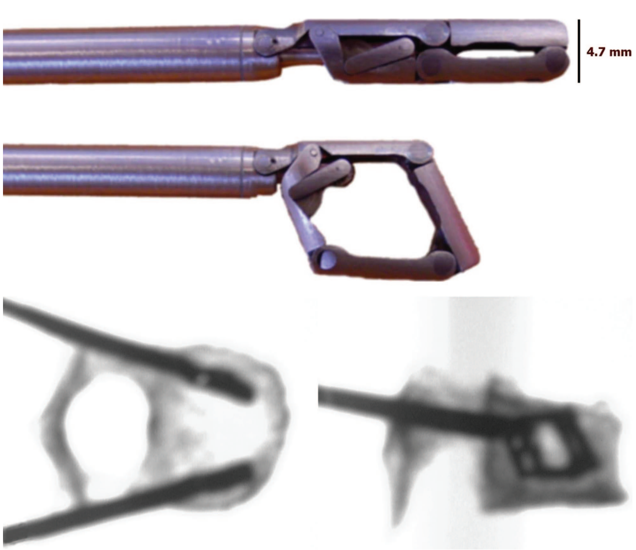

Figure 2. VJT in collapsed and maximal expanded state. VJT after reduction in thoracic vertebra.

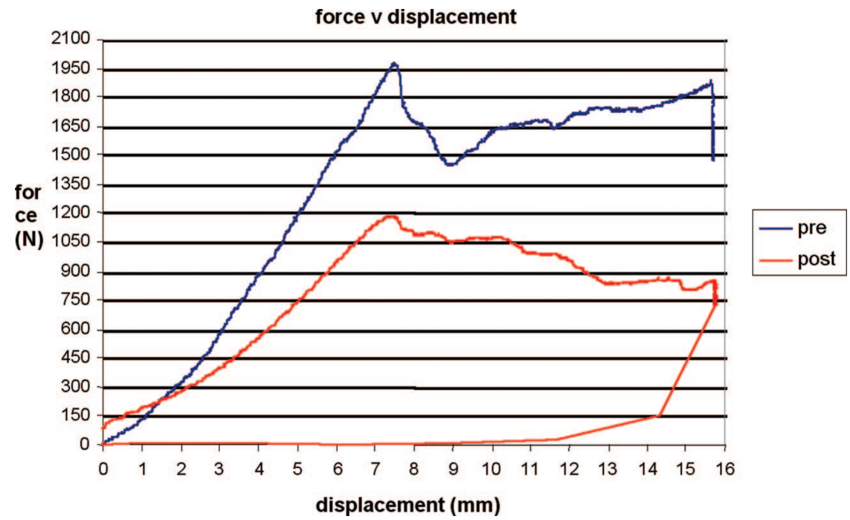

Figure 3. Force *versus* displacement graph showing a fracture of a cortical wall as a sudden drop after reaching peak force illustrated in the blue graph.

on the spine while the patient is lying prone.[25–27] During the procedure, the feedback on height restoration was verified using the force indicator on the VJT device and visually by radiograph. The restored height was then confirmed by measuring the anterior height. In each case, with the height fully restored, a force indicator showed a safe force between the VJT tip and the VB end plate. After height restoration, bone cement was inserted. When using the large VJT a preset amount of 3.0 mL of PMMA was inserted in each cavity, whereas 1.3 mL was used in each cavity after using the small VJT. In this way 4 VBs were treated. The remaining 4 VBs were treated with IBT procedure as previously described.[28] In both pedicles drill channels were created to give entrance for the IBT (Kyphon, Inc., Santa Clara, CA). Two sizes bone tamps (15/3;20/3) were used, to accommodate the variation in vertebral geometry. The IBTs were inflated with radiopaque contrast, so continuous monitoring with fluoroscopy was possible, during the reduction of the vertebral deformity. Reduction of the fracture was performed under an axial load of 100 N. After reduction of the fracture, the IBT was deflated and removed. The created void was filled with bone cement. A maximum 4 mL of PMMA cement was injected when using bone tamp size 15/3 per side. A maximum 6 mL of PMMA cement was injected when using bone tamp size 20/3 per side. The cement selected for the trials was the Parallax cementing system. The system consists of Secour PMMA cement plus a tracer (TCR-105, Arthrocare Europe AB, Stockholm, Sweden). The cement was mixed and delivered in accordance to manufacturers instructions.

Postoperative Crush Sequence

The strength and stiffness of the VB after height restoration and cement augmentation was determined by compressing the VB again in a postoperative compression sequence identical to the pretreatment compression sequence. Postprocedural strength and stiffness were compared with the original preoperative values. Cement leakage and any fractures caused by the procedure were assessed by direct visual and radiologic inspection before postprocedure testing (Figure 4).

Statistical Analysis

Results are presented as mean and standard deviations. For comparison between groups unpaired t tests were used. All calculations and tests were performed using SPSS 14.0 (SPSS Inc., Chicago, IL).

Results

The 2 different groups were homogeneous in estimated VB volume and in *t*-values for osteoporosis (Table 1). Figure 3 shows the force/displacement graph as typically obtained. The fracturing of the vertebral cortical wall is clearly visible as a sudden drop in force after reaching peak force. In the VJT group, the postrestoration strength was 81% ± 13% of the original strength and in the IBT group it was 96% ± 32% (Table 2). The postrestoration stiffness in the VJT group was 61% ± 42% of the original stiffness and in the IBT group 76% ± 62% of the original stiffness (Table 2). The VBs in the VJT group were restored to 101% ± 2% of their original height whereas this was 104% ± 14% in the IBT group (Table 2). In all VBs of the VJT group, we succeeded to achieve end plate-to-end plate filling. In this study, no cases of cement leakage were found. No cases of damaging of the end plates, new fractures, or perforations were seen in either group.

The mean amount of cement inserted for the VJT group was 3.6 ± 0.9 cm^3 and for the IBT group 5.9 ± 0.8 cm^3. The postrestoration strength per mL inserted PMMA cement in the VJT group was 385 ± 117 N/mL and in the IBT group 208 ± 115 N/mL (Table 2).

Discussion

Both IBT and VJT procedures were equally able to restore height in this *in vitro* study. Strength and stiffness

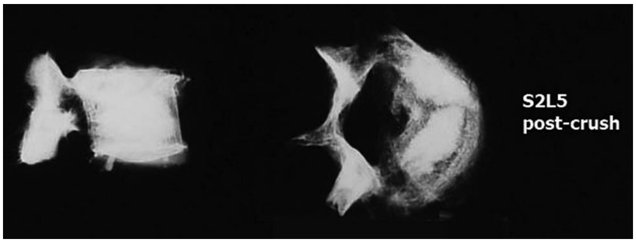

Figure 4. Lateral and transverse views after VJT-reduction and cement filling of a vertebra.

Table 2. Data of the 35% Anterior Wedge Model: VJT *Versus* IBT Independent Sample *t*-Test

	VJT (n = 4) Mean ± SD	IBT (n = 4) Mean ± SD	*P*
Reconstruction height (%)	101 ± 2	104 ± 14	0.765
Maximum strength			
Preoperative	1683 ± 445	1263 ± 392	0.207
Postoperative	1348 ± 299	1167 ± 492	0.552
Stiffness			
Preoperative	311 ± 180	206 ± 52	0.304
Postoperative	138 ± 51	134 ± 65	0.913
Postoperative *vs.* preoperative max. strength ratio (%)	81 ± 13	96 ± 32	0.450
Postoperative *vs.* preoperative stiffness ratio (%)	61 ± 42	76 ± 62	0.709
Volume inserted PMMA (mL)	3.6 ± 0.9	5.9 ± 0.8	0.012*
Postoperative strength per mL inserted cement	385 ± 117	208 ± 115	0.075
Percentage fill with cement (%) (volume inserted cement/VB volume)	9.5 ± 2.7	16.3 ± 5.0	0.054

*$P < 0.05$.

of an osteoporotic vertebral wedge fracture (AO1.2) were partially restored. In this study, we did not see iatrogenic damage of the end plates, new fractures or perforations, and no leakage of cement. In our opinion, both procedures can be considered to be safe. Although there were no significant differences in values of strength, stiffness, and height restoration of VBs between the VJT and IBT procedures, we noticed some differences. First, the intraoperative time taken for the VJT procedure was approximately half that of the IBT procedure, and consequently, the fluoroscopy time was less for the VJT procedure. Second, more strength (mean: 177 N) was gained per mL inserted cement in the VJT procedure compared with the IBT procedure (Table 2). But more important is the fact that in this study on average significant less cement was used in the VJT treated VBs compared with the IBT treated VBs. *In vivo* injection of high volumes of cement can lead to cement leakage and induce iatrogenic complications.[9,17] "Safe volumes" varying from 2 mL to 8 mL are recommended in the literature.[29] During *in vitro* studies extravasation of cement has been observed after injection of volume larger than 6 mL.[29] A smaller amount of cement is therefore desirable.

We think that these advantages are obtained because of the advanced augmentation technique that was used in the VJT group, creating a vertical slit from posterior to anterior directed end plate-to-end plate. Using this technique, the cement flow is directional and lower volumes of cement are therefore needed. The configuration of the strut, created by the VJT, has been designed based on the size of the contact area of commercial intervertebral cages. The optimal size of contact area has been determined in *in vitro* studies. The combination of the use of less cement and optimal cement strut configuration, results in a greater efficacy.

This end plate-to-end plate laminar augmentation technique may be of clinical advantage, but first both other experimental and clinical studies must confirm these results. A point of attention in these studies should be the strength and elasticity modulus of PMMA. The rigid PMMA column may theoretically run the risk of fatigue fracture of the PMMA or PMMA end plate junction.

In this study, we have used VBs with a height reduction of 35% instead of 25% height reduction, which is more common in the literature.[5,29–33] Compression of a VB to a deformation of 25% of its initial height leads to a dysplastic deformation rather than creating a fracture.[22] The amount of injected cement has therefore less influence on the post restored strength and stiffness.

We used the anterior wedge fracture model instead of the compressive fracture model used by Belkoff *et al*, because we believe that the anterior fracture model is of greater clinical relevance.[8,10,13,34–36] In contrast to our study, the study by Steens *et al* showed increased postoperative strength of the vertebra compared with the original VB and comparable postoperative stiffness.[22] This might be related to the greater percentage fill of cement in relation to the VB volume that was used in his study. Applying high volume of cement into a VB eventually leads to full restoration of strength and stiffness but at the same time increases the risk of cement leakage. Although strength and stiffness are weakly correlated with the percentage fill volume of cement injected,[32] Molloy *et al*[31] found in their study that restoration of strength on average required filling of 16.2% and that restoration of the stiffness required filling of 29.8% of the VB volume. We found a filling percentage of 9.4% of the VB volume in the VJT group and 16.2% percentage in the IBT group. In the study by Steens *et al*, the filling percentage of cement was higher, that is 19.5%.

A limitation of our study is the fact that it is an *in vitro* study and does not exactly replicate the clinical situation. For example, we do not exactly know the amount of load exerted on the crushed VB, while the patient is lying in the prone position. We attempted to simulate these intraoperative forces by applying a preload of 100 N during reduction of the VB.[24,25] During the cementing phase of the procedure the preload was removed from the VB. The human body behaves as a viscous system and, the amount of height gained during the reduction will not immediately fall back (in a test situation we performed, approximately 2 mm height reduction was lost over the first 2 minutes.).The exact amount of muscle force that are exerted in the clinical setting, especially in patients who are in pain, is not known. The finding in this study that kyphoplasty was able to achieve full height restoration might be an indication that such as yet unquantified additional forces may need to be taken into account. In addition, we do not know the influence of the force reaction of both adjacent disci during reduction.

Another limitation of the study was the assessment of post restoration radiographs. It was not always easy to determine exactly if cement reached the end plate on the lateral and AP radiographs. This limitation can be addressed by making postprocedure CT scans of the VBs.

In conclusion, both IBT and VJT procedures were able to restore height in this *in vitro* study, while strength and stiffness were partially restored. There were no significant differences in height restoration, strength, and stiffness found between the 2 techniques. On average, significantly less cement was used in the VJT-treated VBs. The combination of the use of less cement and optimal cement strut configuration, results in a greater efficacy.

This end plate-to-end plate laminar augmentation technique may be of clinical advantage, but future research needed focused to further validate this new end plate-to-end plate laminar augmentation technique. Second, further improvement of new cadaveric models must be conducted. Variables of biomechanical relevance which, up until now, have never been implemented in cadaveric studies, such as variation in muscle forces and the influence of the force reaction of both adjacent disci, still have to be investigated.

Key Points

- Both kyphoplasty procedures were able to restore height in clinically relevant osteoporotic wedge fractures, while postoperative vertebral strength and stiffness were partially restored.
- In both kyphoplasty procedures no damage of the end plates, new fractures or perforations, and no leakage of cement were found.
- In this study, on average significant less cement was used in the vertebral jack tool treated vertebrae compared with the inflatable bone tamp treated vertebrae, while comparable postoperative strength and stiffness values were gained among both groups.

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