Clinical Biomechanics 28 (2013) 725–730

Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech

Height restoration and maintenance after treating unstable osteoporotic vertebral compression fractures by cement augmentation is dependent on the cement volume used

Antonio Krüger [a,*], Gamal Baroud [b], David Noriega [c], Jens Figiel [d], Christine Dorschel [a], Steffen Ruchholtz [a], Ludwig Oberkircher [a]

[a] Department of Trauma, Hand and Reconstructive Surgery, Philipps University, Marburg, Germany
[b] Laboratory of Biomechanics, Department of Mechanical Engineering, Université de Sherbrooke, Sherbrooke, Quebec, Canada
[c] Spine-Unit, University Hospital Valladolid, Royal Academy of Medicine and Surgery, Spain
[d] Department of Diagnostic Radiology, Philipps University, Marburg, Germany

ARTICLE INFO

Article history:
Received 1 February 2013
Accepted 11 June 2013

Keywords:
Vertebral compression fractures
Kyphoplasty
Height restoration
Height maintenance
Cement volume

ABSTRACT

Background: Two different procedures, used for percutaneous augmentation of vertebral compression fractures were compared, with respect to height restoration and maintenance after cyclic loading. Additionally the impact of the cement volume used was investigated.
Methods: Wedge compression fractures were created in 36 human cadavaric vertebrae (T10-L3). Twenty-seven vertebrae were treated with the SpineJack® with different cement volumes (maximum, intermediate, and no cement), and 9 vertebrae were treated with Balloon Kyphoplasty. Vertebral heights were measured pre- and postfracture as well as after treatment and loading. Cyclic loading was performed with 10,000 cycles (1 Hz, 100–600 N).
Findings: The average anterior height after restoration was 85.56% for Kyphoplasty; 96.20% for SpineJack® no cement; 93.44% for SpineJack® maximum and 96% for the SpineJack® intermediate group. The average central height after restoration was 93.89% for Kyphoplasty; 100.20% for SpineJack® no cement; 99.56% for SpineJack® maximum and 101.13% for the SpineJack® intermediate group. The average anterior height after cyclic loading was 85.33 % for Kyphoplasty; 87.30% in the SpineJack® no cement, 92% in the SpineJack® maximum and 87% in the SpineJack® intermediate group. The average central height after cyclic loading was 92% for Kyphoplasty; 93.80% in the SpineJack® no cement; 98.56% in the SpineJack® maximum and 94.25% in the SpineJack® intermediate group.
Interpretation: Height restoration was significantly better for the SpineJack® group compared to Kyphoplasty. Height maintenance was dependent on the cement volume used. The group with the SpineJack® without cement nevertheless showed better results in height maintenance, yet the statistical significance could not be demonstrated.

1. Introduction

According to the literature the age adjusted annual incidence of vertebral compression fractures (VCF) in Europe is 10.7/1000 in women and 5.7/1000 in men and furthermore is markedly increasing with age (Felsenberg et al., 2002). The treatment of osteoporotic vertebral compression fractures using transpedicular cement augmentation has grown significantly over the last two decades. Balloon kyphoplasty was developed to offer the opportunity to restore the vertebral height and to improve the sagittal alignment. Percutaneous vertebroplasty (VP) and Balloon kyphoplasty (BKP) have been well established procedures to address painful osteoporotic vertebral compression fractures. BKP has become a popular technique leading to improved pain reduction and lower complication rates (e.g. cement leakage) compared to standard vertebroplasty (Kim et al., 2012; Lee et al., 2009; Wardlaw et al., 2009). Several systematic reviews have reported efficacy with regard to significant pain reduction in 87% of the patients undergoing vertebroplasty and in 92% of the patients undergoing Kyphoplasty (Hulme et al., 2006). Overall, the complication rate of both procedures is considered to be low (Taylor et al., 2006).

According to the criteria of evidence-based medicine, there are only two level Ib evidence studies (Boonen et al., 2011; Wardlaw et al., 2009) that show the benefits of Balloon kyphoplasty compared to conservative treatment especially in the early stage after osteoporotic fractures. The level Ia studies comparing vertebroplasty and conservative

* Corresponding author at: Department of Trauma, Hand and Reconstructive Surgery, Philipps University, Baldingerstraße, D-35033 Marburg, Germany.
E-mail address: akrueger@med.uni-marburg.de (A. Krüger).

0268-0033/$ – see front matter © 2013 Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.clinbiomech.2013.06.007

treatment show inconsistent results and have been discussed in detail elsewhere (Buchbinder et al., 2008; Kallmes et al., 2009).

Most scientist and clinicians agree that the pain control, which is still the main treatment goal in vertebroplasty and Kyphoplasty, is independent from the cement volume used. In some fractures, especially in fresh fractures, burst fractures or traumatic fractures in patients with osteoporosis, the cement has an important stabilizing function. Controversy still exists over how much cement should be used. Some authors believe in complete filling of the vertebral body (as much as possible), some authors believe that a lot of cement has a negative influence on bone healing or might even increase the rate of adjacent fractures since the elastic modulus of the treated vertebral body is increased.

The discussion about which kind and how much cement should be used in younger patients is even more controversial (Lewis, 2011; Maestretti et al., 2007). There is consensus that as few cement as possible should be injected.

Balloon kyphoplasty was designed to improve patients' safety. Especially the cement leakage that occurred in percutaneous vertebroplasty was addressed by this technique. By inflation of the Balloon the surrounding trabecular bone is compressed. A void is created in which the cement, which is of higher viscosity than in vertebroplasty can be injected.

The aim of the present study was to evaluate two different procedures, used for percutaneous augmentation of vertebral compression fractures, with respect to height restoration and height maintenance after cyclic loading. Additionally the impact of the cement volume used was investigated.

2. Methods

2.1. Specimens

To analyze the performance of the Balloon kyphoplasty and SpineJack® procedures it was necessary to create similar conditions for both devices. 36 vertebral bodies (T10–L3) of six intact fresh human cadaveric spines of Caucasian females with a mean donor age of 84.5 years (range 79–93 years) and a mean Body Mass Index (BMI) of 23.1 (range 14–32.9 kg/m^2) were used. Specimens were stored at −20 °C. Prior to surgery a CT-scan of the spine was performed to identify any pathology, especially preexistent vertebral fractures or deformities. In addition, bone density was measured for all vertebral bodies separately, which showed substantial osteoporosis Bone Mineral Density (BMD 0.38 g/cm^2, range = 0.196–0.531, SD = 0.08). The spines were dissected into single vertebral bodies and the surrounding soft tissues were completely removed. The laminae and spinal processes were kept in place. Altogether 36 undamaged vertebral bodies were prepared. The vertebral bodies were assigned to four groups, with homogeneous distributions of vertebral levels and donors. The four groups were randomized to the four different treatments Afterwards the endplates were embedded in Technovit 3040, Heraeus Kulzer, Wehrheim, Germany (cold-curing resin for surface testing and impressions, Kulzer, Germany (Fig. 1)).

Twenty seven vertebral bodies were treated with the SpineJack® (SJ, Vexim, France). This group was subdivided into three groups. In 9 vertebral bodies the maximum amount of cement was used (cementing was stopped, when leakage was observed), in 10 vertebral bodies no cement was used at all. In 8 vertebral bodies only a little amount of cement (just around the SpineJack®) was injected. Nine vertebral bodies were treated with Balloon Kyphoplasty, Kyphon Medtronic, Sunnyvale, USA (BKP, Kyphon, Medtronic) (Fig. 4).

2.2. Fracture generation and experimental groups

Vertebral heights were measured at the anterior wall as well as in the center of the vertebral bodies in the medial sagittal plane after multiplanar reconstruction of the CT-scans. Vertebral wedge compression fractures were created by a material testing machine (Universal Testing Machine, Instron 5566, Instron, Pfungstadt, Germany). The endplates of the vertebral bodies were embedded in Technovit and placed in a plastic device. The load was transferred by a pivot mounted pressure plate that was placed on the plastic holding device on the superior vertebral endplate (Fig. 1). The main vector of the axial force was centered in the sagittal midline at the end of the anterior third of the vertebral body.

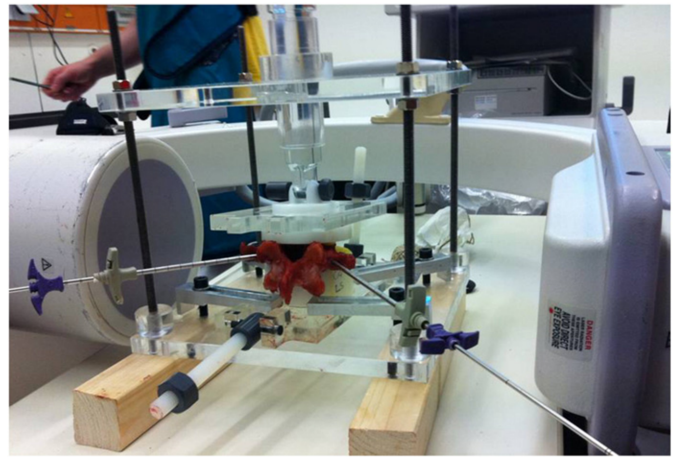

Fig. 1. Setting during surgery. The vertebral body is positioned in the custom made loading frame, loaded with 100 N. In this picture the image intensifier is placed for lateral imaging. The embedded endplates and holding devices for the vertebral body is clearly visible. The set-up for the fracture creation was similar regarding holding devices and load transfer.

The axial load was continuously increased (1 mm/min load application velocity) until the height of the anterior edge of the vertebral body was reduced by 40% of the initial measured values. The load was maintained for 15 min. The maximum load that was needed to create the fracture, the load at the time when 40% of height reduction was achieved as well as the loads after 15 min was recorded.

After 15 min the load was manually decreased to 100 N. The distances at 40% and after reducing the load to 100 N were also recorded. The vertebral bodies were then fixed in this position on a radiolucent clamp. The clamp was a custom made device that is radiolucent and able to fix the vertebral bodies in a certain position during processing, CT-imaging and transporting to make sure that no spontaneous change of height occurs. After clamping at the 100 N position a post-fracture computed tomography was carried out. Anterior and central heights of the vertebral bodies were measured.

Short description of the techniques used:

Balloon kyphoplasty (Kyphon, Medtronic)

In Balloon kyphoplasty, two guide wires are placed through both pedicles using Jamshidi-Needles, Kyphon, Medtronic, Sunnyvale, CA, USA. After insertion of two working cannulae, two inflatable bone tamps were advanced into the broken vertebral body. They were inflated until height restoration was observed. The bone tamps were then deflated and withdrawn. The cavity was filled with KyphX® HV-R™ Viscosity, Radiopaque Bone Cement, Kyphon, Medtronic, Sunnyvale, CA, USA High Viscosity, Radiopaque Bone Cement, according to the manufacturer's recommendations or instructions for use.

SpineJack® (Vexim)

The SpineJack® implant is made of titanium alloy (Ti6Al4V). Access into the vertebrae using the SpineJack® device is similar to Balloon kyphoplasty. After insertion of the two guide wires, the pedicle and vertebral body is reamed to achieve a space for the insertion

of the implant. After reaming, the later position of the implant is simulated by a template. The position of the template is controlled in two planes by a C-arm. The template is replaced by the implants. The implant is opened in the cranio-caudal direction using visualization with an image intensifier in two planes. After positioning and opening of the implant, Cohesion® (Vexim, Balma, France) bone cement is injected under fluoroscopic control in two planes.

2.3. Instrumentation

All procedures were performed by the same surgeon using an image intensifier. The placement of the k-wires was monitored by fluoroscopic control in 3 planes (a.p., lateral and cranio-caudal) by turning the clamped vertebral bodies under the image intensifier.

As previously described, the vertebral bodies were fixed in a radiolucent clamp after fracture creation and reduction of the axial load to 100 N (Fig. 1). After post fracture computed tomography, the clamped vertebral bodies were placed in a custom made loading frame. This frame allowed fluoroscopic control in 2 planes as well as constant loading with a preload of 100 N. The axial force was again centered in the sagittal midline at the end of the anterior third of the vertebral body (Fig. 1). After positioning of the specimens in the loading frame a load of 100 N was applied, the clamp was loosened and the load was kept during the instrumentation until the cement completely set.

To obtain a relevant result, clinical judgment was used to proceed with or stop the cement injection in the groups with the maximum cement volumes. The aim of cement augmentation in the maximum volume groups in this experimental setting was to fill the vertebral body as much as possible. Cementing was stopped when leakage was observed. The rationale was to fix the specimens as solidly as possible after treatment. This technique was used in the BKP as well as in the SpineJack® maximum cement group.

After the cement had completely hardened the clamp was closed again, the load was released and a post treatment computed tomography was performed. After computed tomography cyclic loading was performed using a servohydraulic Test Bench (Bose Electroforce LM2 Test Bench, Bose, Friedrichsdorf, Germany) with 10,000 cycles (1 Hz, 100–600 N) according to previously used loading protocols in this field (Kettler et al., 2006; Wilke et al., 2006). The load was again transferred by a pivot mounted pressure plate that was placed on the plastic holding device on the superior vertebral endplate (Fig. 1). The main vector of the axial force was centered in the sagittal midline at the end of the anterior third of the vertebral body. Rotational forces were not applied or measured.

The fourth computed tomography was performed after the loading. In all CT scans anterior and central heights of the vertebral body were measured and compared.

3. Results

For all parameters determined, the results are expressed as means, ranges and standard deviations (SD). The test of significance between results from study pairs was conducted by using Tukey's test with significance $P < 0.05$. Tukey's test is essentially a t-test, except that it corrects the type I error rate when multiple comparisons are being made. Tukey's test is more suitable for multiple comparisons than performing a series of t-tests.

In all vertebral bodies compression fractures could be established. According to the OTA classification they were all A-type fractures. The average force needed to create the fracture was 3090.9 N (range 1371.3–5810.0 N; SD = 1012.0). The average axial force that was recorded when the anterior height of the vertebral bodies was reduced by 40% and the loading frame was stopped was 2514.4 N (range 841.0–4522.0 N; SD = 1081.0). After 15 min the recorded loads (with fixed loading frame) reduced themselves to 1525.3 N (range 490.0–2752.0 N; SD = 693). After manually moving back the traverse until a load of 100 N was reached the average distance on the traverse was 1.4 mm (range 0.6–2.6 mm; SD = 0.55 mm).

The average maximum pressure of the Balloons during inflation was 218.9 psi (120–350 psi; SD = 62.7), the average total volume of both Balloons used for inflation was 10.1 ml (range 8–14 ml; SD = 1.67). The average cement volume used in the Balloon-kyphoplasty group was 8.3 ml (range 6–10.5 ml; SD = 1.28). The average cement volume used in the maximum cement SpineJack group was 9.6 ml (range 7.2–12.6 ml; SD = 1.84). The difference in the injected cement volumes in between these groups was not significant ($P = 0.09$). The average cement volume used in the group with only cement around the SpineJack was 1.8 ml (range 1.3–2.4 ml; SD = 0.32). The difference in the injected cement volumes in between the SpineJack groups with maximum or small cement was significant ($P < 0.05$).

The average anterior and central heights measured as percentages of the initial unfractured vertebral bodies are listed in Table 1. Figs. 2 and 3 show the heights in bar graphs. Using Tukey's test for statistical analysis between all four groups there was a statistical difference for anterior height restoration between the groups BKP vs. NoC ($P = 0.01$) and BKP vs. CiSJ ($P = 0.019$). All other differences for anterior or central heights after fracture, treatment or loading showed no statistical significance ($P > 0.05$).

All CT scans were analyzed for deployed heights and position of the SpineJack® implant. At first the deployed heights of the SpineJack® implant were measured before and after recompression. Compression or failure of the implants was not seen. Cutting through of the endplates was not seen in any case.

Dependent on the cement volume used there were differences in the rotation of the SpineJack® tool. The average rotation of the SpineJack® in the No-Cement group was 6.85° (range 0.80° to 28.05°; SD = 8.50). The average rotation of the SpineJack® in the Cement inside SJ group was 2.60° (range 0.15° to 6.20°; SD = 2.25°). The average rotation of the SpineJack® in the Max-Cement group was 2.02° (range 0.30° to 5.00°; SD = 1.43). There were no significant differences between the groups: NoC and CiSJ ($P = 0.243$); NoC and MAX ($P = 0.149$) and CiSJ and MAX ($P = 0.947$).

4. Discussion

The first treatment goal of cement augmentation was pain reduction in painful hemangiomas (Galibert et al., 1987). After successful and promising results the indication was extended for painful osteoporotic fractures. Because of a high grade of cement leakage Balloon kyphoplasty was developed to create a void prior to cement injection with the idea of injecting cement with higher viscosity in a preformed void using less pressure (Hulme et al., 2006). Additionally Balloon kyphoplasty offered the theoretical opportunity to restore the vertebral

Table 1
Measurements of vertebral body heights in percentages of the initial values (100%) (after fracture, after treatment and after cyclic loading) for all four treatment groups.

	Balloon Kyphoplasty Mean/SD	SpineJack No cement Mean/SD	SpineJack Intermediate cement Mean/SD	SpineJack Maximum cement Mean/SD
After fracture				
Anterior (% of initial height)	82.33/6.12	82.40/6.54	77.13/8.85	76.67/5.48
Central (% of initial height)	85.66/5.15	87.30/8.04	83.88/6.62	83.56/5.55
After treatment (mm)				
Anterior (mm)	85.56/5.25	96.20/6.14	96.0/8.09	93.44/7.86
Central (mm)	93.89/5.97	100.20/7.66	101.13/3.90	99.56/6.71
After cyclic loading				
Anterior (mm)	85.33/6.69	87.30/7.38	87.0/11.51	92.0/7.54
Central (mm)	92.0/6.44	93.80/5.79	94.25/7.48	98.56/6.88

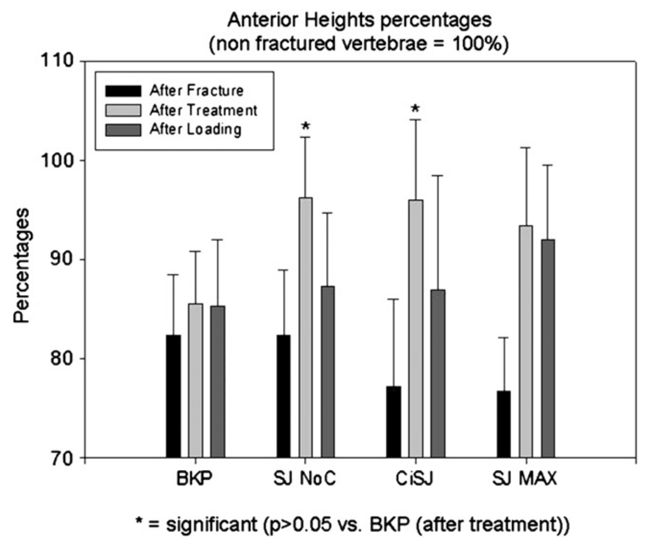

Fig. 2. Anterior heights of the vertebral bodies. Results for the four groups (BKP = Balloon kyphoplasty, SJ NoC = SpineJack® without Cement, CiSJ = cement inside SpineJack® and SJ Max = SpineJack® with maximum cement). CT scans were taken at four time points. The bars represent the median percentage of the initial heights measured before fracture at three time points (black = after fracture, light gray = after treatment and dark gray = after cyclic loading).

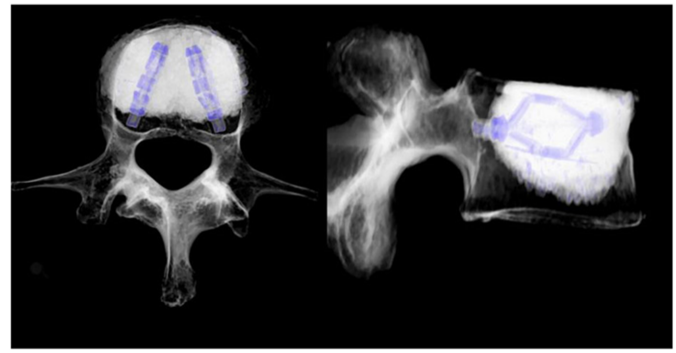

Fig. 4. Representative three dimensional reconstructions of a vertebral body treated with the SpineJack® implant. A) = top view, B) = lateral view. The vertebral body, cement (white) and implants (blue) are clearly visible.

height and to improve the sagittal alignment. Several clinical studies have shown that these theoretical improvements cannot be transferred to the clinical setting universally (Hulme et al., 2006). Voggenreiter et al. (2005) have shown that 50% of the height restoration after Balloon kyphoplasty is achieved by positioning the patient prone. This effect also accounts for the height restoration that can be observed in other cement augmentation procedures. Another 50% of the regained height is due to the Balloon kyphoplasty procedure itself. One has to say constrictively that the height that was gained by inflation of the Balloons significantly decreased after deflation of the Balloons (Voggenreiter, 2005).

The Balloons were also used for restoring the endplate anatomy or to remove disc material from the vertebral body to improve bone healing. Oner et al. (2006) and Verlaan et al. (2005) described the concept of Balloon Assisted Endplate Reduction (BAER). Verlaan et al. (2005) found comparable results as Voggenreiter (2005). The reduction of the endplates that was achieved by inflation of the Balloons could not be maintained completely after deflation. The goal of height restoration and "anatomical" reposition of the endplates becomes more interesting in unstable fractures, burst fractures (Kruger et al., 2010) or in the treatment of younger patients (Maestretti et al., 2007).

There are several explanations why the height that can be achieved besides positioning of the patient during Balloon inflation cannot be maintained after deflation of the Balloon. One reason is the compressive forces that act on the spine after deflation of the Balloon. To our knowledge there are no present studies that describe or objectify these forces. Another reason is the ligamentotaxis that will act in the opposite direction than the expansion forces. There is only little knowledge on how much pressure acts on the broken vertebral body in prone position. The spinal load calculated on the L4–L5 disc was 144 N in prone (Sato et al., 1999). In our specimens with vertebral compression fractures and a reduction of the anterior height of 40% we observed that the vertebrae virtually acted like sponges and tended to reexpand after reduction of the load. After manually moving back the traverse until a load of 100 N was reached the average distance on the traverse was 1.4 mm (range 0.6–2.6 mm; ±0.55 mm). This height restoration was spontaneous without manipulation or intravertebral expansion of a device. This spontaneous reexpansion makes a continuous load on the vertebral bodies mandatory. For this reason different authors have used continuous loads on the vertebral bodies during manipulation (Kettler et al., 2006; Rotter et al., 2010; Wilke et al., 2006). If this load is not applied, a height restoration will be measured that is not related to the device or technique used and will result in not representative values. We decided for the lowest force used in the quoted literature which was 100 N.

The interdigitation of the cement as well as the cement volume used have been discussed as reasons for primary stability as well as for recompression of the treated vertebral body (Krüger et al., 2012). Most scientists and clinicians agree that pain control, which remains the main goal in the treatment of osteoporotic vertebral compression fractures by means of vertebroplasty and Kyphoplasty, is independent of the cement volume used. In some fractures, especially in fresh or mobile fractures, burst fractures or traumatic fractures in patients with osteoporosis, the cement has an important stabilizing function. It is still controversial how much cement should be used. Some authors believe in complete filling of the vertebral body (as much as possible), some authors believe that a lot of cement has a negative influence on bone healing or might even increase the rate of adjacent fractures since the elastic module of the treated vertebral body is increased.

The discussion about which kind and how much cement should be used in younger patients is even more controversial. Some authors do not recommend cementing techniques in young patients since the

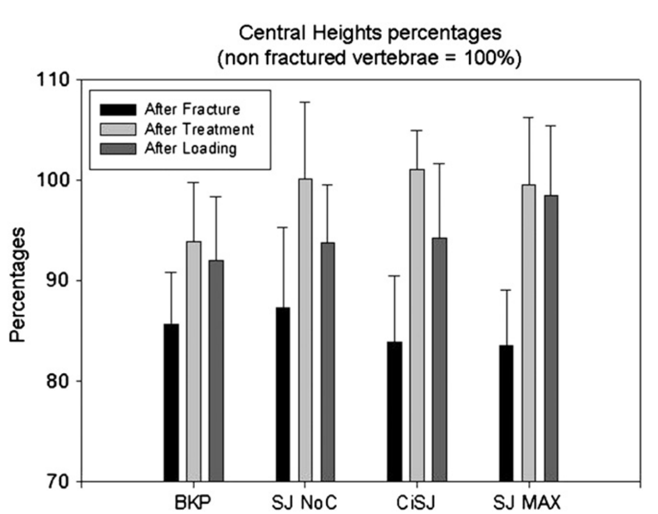

Fig. 3. Central heights of the vertebral bodies. Results for the four groups (BKP = Balloon kyphoplasty, SJ NoC = SpineJack® without cement, CiSJ = cement inside SpineJack® and SJ Max = SpineJack® with maximum cement). CT scans were taken at four time points. The bars represent the median percentage of the initial heights measured before fracture at three time points (black = after fracture, light gray = after treatment and dark gray = after cyclic loading).

long term effects are unknown. Other authors use cementing techniques in young patients and report encouraging results (de Falco et al., 2005; Maestretti et al., 2007). Independent from the techniques used, there is consensus that the future directions in young patients should aim on reduction of cement volumes and preserving the trabecular bone.

As mentioned above Balloon kyphoplasty was designed to improve patients' safety. Especially the cement leakage that occurred in percutaneous vertebroplasty was addressed by this technique (Hulme et al., 2006). By inflation of the Balloon the surrounding trabecular bone is compressed by high pressure. A void is created in which the cement, which is of higher viscosity than in Vertebroplasty can be injected. The side effect of the Balloon was the potential ability to achieve height restoration, especially in mobile fractures. In most cases in which the Balloons are used as an intravertebral reduction device, two Balloons are used. This also corresponds to the manufacturer's advice. The position or direction in which the Balloons will expand during inflation cannot directly be controlled by the surgeon. If used with a bipedicular approach the inflation pattern still is very similar in most cases of osteoporotic bone with reduced strength of the remaining trabecular structures. The Balloons expand until they touch in the middle of the vertebral body (so called "kissing Balloons") afterwards they expand to the lateral wall of the vertebral body and towards the endplates. To achieve height restoration in potentially mobile fractures the Balloons have to be inflated with bigger volumes. So the real question for the surgeon is actually not how much cement he wants to use, but how much the Balloons should be inflated to observe height restoration. The inflation in mobile fractures is stopped when the optimal height restoration is achieved. The created void has to be filled with cement afterwards.

The idea of the SpineJack® as an intravertebral reduction device aims at the restoration of the sagittal balance as well as at the reduction of the endplates. The SpineJack® is positioned so that the wings can be opened sequentially in a cranio-caudal direction. Once the height restoration is achieved, the expansion is stopped and cement is injected to stabilize the vertebral body. To date, the device is not intended to be used as a "stand-alone device" without cement. It is unclear how much cement is sufficient to support the SpineJack® after expansion.

All surgical procedures could be performed without technical problems. All the equipment worked without technical difficulties. The processing and imaging using the custom made radiolucent clamps went according to the protocol without technical or systemic difficulties. The cyclic loading with 10,000 cycles (100–600 N, 1 Hz) could also be performed without technical complications.

The restored height under a preload of 100 N was significantly higher in the SpineJack® group, compared to the Balloon-Kyphoplasty group (Figs. 2 and 3). In the figures it is remarkable that the height restoration was better for all SpineJack groups compared to BKP. In the central reconstruction of the central height, an almost "anatomical" reconstruction (100% of the nonfractured vertebrae) was possible. It seems that in this setting with a constant preload of 100 N the intravertebral reduction device that is kept in place results in better height reconstruction during surgery. Comparing the maximum cement volume that was used in the groups we found no significant difference ($P = 0.09$) between the Balloon kyphoplasty (mean volume 8.3 ml; range 6–10.5 ml; $SD = 1.28$) and Maximum Cement SpineJack® group (mean volume 9.6 ml; range 7.2–12.6 ml; $SD = 1.84$). The average amount of cement used in the SpineJack group was higher, the reason for this is based on the significantly increased height restoration in the group. Increasing the height and parallel to the vertebral body volume, higher cement volumes can be injected if maximum filling of the vertebral body is aimed for.

The height maintenance in the SpineJack® groups was dependent on the cement volume used (Figs. 2 and 3). The more cement was injected, the higher the maintenance was. In osteoporotic or low quality bone the cancellous bone is the least stable part of the vertebral body. Since cement and implants cannot be compressed the trabecular structures around the cement fails. The more cement is used, the bigger the surface and thus the smaller the pressure per surface area is. This results in better height maintenance. If the vertebral body is filled completely with cement no height loss after loading is seen. Interestingly the achieved height after loading was higher in the SpineJack® stand-alone group than in the BKP group. Analyzing the post loading CT scans no failure or breakage of the devices was witnessed. Comparing the CT-scans was relatively easy since the orientation in the vertebral body and cement was facilitated by the anatomy of the implant. The planes of the multiplanar reconstructions were aligned to the axis of the devices. Some degree of twisting of the device was observed in the different groups. The difference in the groups was not significant. Since we measured twisting in the maximum cement group as well (which is theoretically impossible) the measuring method has to be questioned.

The orientation in the BKP group was even more complicated. Identical planes to compare pre- and postloading results regarding cement distribution and compression of the spongious bone around the cement, could not be found.

5. Conclusion

The protocols for creating wedge fractures, and the instrumentation under a constant preload of 100 N led to reproducible results and effects. The study showed that the height restoration was significantly better for the SJ group compared to the BKP group.

Height maintenance in the SJ groups was dependent upon the cement volume. To date, we cannot recommend using the SpineJack® stand-alone in osteoporotic bone. If the bone quality is better or if additional protection of the device (e.g. dorsal instrumentation) is achieved cement volumes might be reduced.

References

Boonen, S., Van Meirhaeghe, J., Bastian, L., Cummings, S.R., Ranstam, J., Tillman, J.B., et al., 2011. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. J. Bone Miner. Res. vol. 26 (no. 7), 1627–1637.

Buchbinder, R., Osborne, R.H., Ebeling, P.R., Wark, J.D., Mitchell, P., Wriedt, C.J., et al., 2008. Efficacy and safety of vertebroplasty for treatment of painful osteoporotic vertebral fractures: a randomised controlled trial [ACTRN012605000079640]. BMC Musculoskelet. Disord. vol. 9, 156.

de Falco, R., Scarano, E., Di Celmo, D., Grasso, U., Guarnieri, L., 2005. Balloon kyphoplasty in traumatic fractures of the thoracolumbar junction. Preliminary experience in 12 cases. J. Neurosurg. Sci. vol. 49 (no. 4), 147–153.

Felsenberg, D., Silman, A.J., Lunt, M., Armbrecht, G., Ismail, A.A., Finn, J.D., et al., 2002. Incidence of vertebral fracture in Europe: results from the European Prospective Osteoporosis Study (EPOS). J. Bone Miner. Res. vol. 17 (no. 4), 716–724.

Galibert, P., Deramond, H., Rosat, P., Le Gars, D., 1987. Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty. Neurochirurgie vol. 33 (no. 2), 166–168.

Hulme, P.A., Krebs, J., Ferguson, S.J., Berlemann, U., 2006. Vertebroplasty and kyphoplasty: a systematic review of 69 clinical studies. Spine (Phila Pa 1976) vol. 31 (no. 17), 1983–2001.

Kallmes, D.F., Comstock, B.A., Heagerty, P.J., Turner, J.A., Wilson, D.J., Diamond, T.H., et al., 2009. A randomized trial of vertebroplasty for osteoporotic spinal fractures. N. Engl. J. Med. vol. 361 (no. 6), 569–579.

Kettler, A., Schmoelz, W., Shezifi, Y., Ohana, N., Ben Arye, A., Claes, L., et al., 2006. Biomechanical performance of the new BeadEx implant in the treatment of osteoporotic vertebral body compression fractures: restoration and maintenance of height and stability. Clin. Biomech. vol. 21 (no. 7), 676–682.

Kim, K.H., Kuh, S.U., Chin, D.K., Jin, B.H., Kim, K.S., Yoon, Y.S., et al., 2012. Kyphoplasty versus vertebroplasty: restoration of vertebral body height and correction of kyphotic deformity with special attention to the shape of the fractured vertebrae. J. Spinal Disord. Tech. vol. 25 (no. 6), 338–344.

Kruger, A., Zettl, R., Ziring, E., Mann, D., Schnabel, M., Ruchholtz, S., 2010. Kyphoplasty for the treatment of incomplete osteoporotic burst fractures. Eur. Spine J. vol. 19 (no. 6), 893–900.

Krüger, A., Oberkircher, L., Kratz, M., Baroud, G., Becker, S., Ruchholtz, S., 2012. Cement interdigitation and bone-cement interface after augmenting fractured vertebrae: a cadaveric study. Int. J. Spine Surg. vol. 6 (no. 1), 115–123.

Lee, M.J., Dumonski, M., Cahill, P., Stanley, T., Park, D., Singh, K., 2009. Percutaneous treatment of vertebral compression fractures: a meta-analysis of complications. Spine (Phila Pa 1976) vol. 34 (no. 11), 1228–1232.

Lewis, G., 2011. Viscoelastic properties of injectable bone cements for orthopaedic applications: state-of-the-art review. J. Biomed. Mater. Res. B Appl. Biomater. vol. 98 (no. 1), 171–191.

Maestretti, G., Cremer, C., Otten, P., Jakob, R.P., 2007. Prospective study of standalone balloon kyphoplasty with calcium phosphate cement augmentation in traumatic fractures. Eur. Spine J. vol. 16 (no. 5), 601–610.

Oner, F.C., Verlaan, J.J., Verbout, A.J., Dhert, W.J., 2006. Cement augmentation techniques in traumatic thoracolumbar spine fractures. Spine (Phila Pa 1976) vol. 31 (no. 11), S89–S95 (Suppl.).

Rotter, R., Martin, H., Fuerderer, S., Gabl, M., Roeder, C., Heini, P., et al., 2010. Vertebral body stenting: a new method for vertebral augmentation versus kyphoplasty. Eur. Spine J. vol. 19 (no. 6), 916–923.

Sato, K., Kikuchi, S., Yonezawa, T., 1999. In vivo intradiscal pressure measurement in healthy individuals and in patients with ongoing back problems. Spine (Phila Pa 1976) vol. 24 (no. 23), 2468–2474.

Taylor, R.S., Taylor, R.J., Fritzell, P., 2006. Balloon kyphoplasty and vertebroplasty for vertebral compression fractures: a comparative systematic review of efficacy and safety. Spine (Phila Pa 1976) vol. 31 (no. 23), 2747–2755.

Verlaan, J.J., van de Kraats, E.B., Oner, F.C., van Walsum, T., Niessen, W.J., Dhert, W.J., 2005. The reduction of endplate fractures during balloon vertebroplasty: a detailed radiological analysis of the treatment of burst fractures using pedicle screws, balloon vertebroplasty, and calcium phosphate cement. Spine (Phila Pa 1976) vol. 30 (no. 16), 1840–1845.

Voggenreiter, G., 2005. Balloon kyphoplasty is effective in deformity correction of osteoporotic vertebral compression fractures. Spine (Phila Pa 1976) vol. 30 (no. 24), 2806–2812.

Wardlaw, D., Cummings, S.R., Van Meirhaeghe, J., Bastian, L., Tillman, J.B., Ranstam, J., et al., 2009. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. Lancet vol. 373 (no. 9668), 1016–1024.

Wilke, H.J., Mehnert, U., Claes, L.E., Bierschneider, M.M., Jaksche, H., Boszczyk, B.M., 2006. Biomechanical evaluation of vertebroplasty and kyphoplasty with polymethyl methacrylate or calcium phosphate cement under cyclic loading. Spine (Phila Pa 1976) vol. 31 (no. 25), 2934–2941.