A prospective comparative study of kyphoplasty using the Jack vertebral dilator and balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures

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This study prospectively compared the efficacy of kyphoplasty using a Jack vertebral dilator and balloon kyphoplasty to treat osteoporotic compression fractures between T10 and L5. Between 2004 and 2009, two groups of 55 patients each underwent vertebral dilator kyphoplasty and balloon kyphoplasty, respectively. Pain, function, the Cobb angle, and the anterior and middle height of the vertebral body were assessed before and after operation. Leakage of bone cement was recorded. The post-operative change in the Cobb angle was significantly greater in the dilator kyphoplasty group than in the balloon kyphoplasty group (-9.51° (SD 2.56) vs -7.78° (SD 1.19), p < 0.001). Leakage of cement was less in the dilator kyphoplasty group. No other significant differences were found in the two groups after operation, and both procedures gave equally satisfactory results in terms of all other variables assessed. No serious complications occurred in either group.

These findings suggest that vertebral dilator kyphoplasty can facilitate better correction of kyphotic deformity and may ultimately be a safer procedure in reducing leakage of bone cement.

Percutaneous kyphoplasty can relieve pain, restore vertebral height with a low risk of leakage of bone cement. In contrast, percutaneous vertebroplasty does not facilitate restoration of vertebral height and is associated with a high risk of leakage cement.1-7

Although there are many methods of application for percutaneous vertebroplasty,8,9 balloon kyphoplasty is the most widely used and intensively studied. Despite this, leakage of bone cement remains a complication, with rates as high as 8% reported.5,10-14 This is a potentially serious complication, with leakage into the spinal canal leading to paralisis, and leakage into blood vessels possibly causing emboli to the lung, kidney or brain.15-18

The vertical diameter of the pedicle in the thoracolumbar spine is about twice that of the transverse diameter of the pedicle in the thoracolumbar spine.19-22 With reference to this anatomical relationship, we designed a new mechanical reduction system named the Jack vertebral dilator (SuZhou Xinrong Best Medical Instrument Co Ltd, Jiangsu, China). This makes use of mechanical expansion, using a backward-pulling force by twisting the handle of the device to produce upper and lower expansive forces. This facilitates restoration of vertebral body height and corrects the kyphotic deformity. Bone cement is then injected into the cavity formed after the removal of the dilator to maintain the reduction. The dilating channel created in the pedicle is larger with the dilator than with balloon kyphoplasty, and the cross-sectional area is more than doubled. The use of a larger catheter allows bone cement to be injected at a later, more viscous stage, which should reduce the rate of leakage. It has previously been suggested by Denaro, Longo and Denaro23 that to minimise the risk of complications due to extravasation with balloon kyphoplasty, bone cement should be injected ‘while it is the consistency of toothpaste’.

In order to investigate the efficacy of dilator kyphoplasty in restoring vertebral body height, correcting deformity, improving related functions and reducing the rate of cement leakage, we carried out a comparative study of dilator and balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures.

Patients and Methods

Between October 2004 and August 2009, 160 patients with osteoporotic vertebral fractures were treated in our department. Of these, 110 underwent kyphoplasty for fractures between T10 and L5 which were less than three months old, in which the posterior wall was relatively complete and there was no spinal cord injury.
Patients were excluded if the fracture was more than three months old; there was loss of more than two thirds vertebral body height, the posterior wall was incomplete, with significant posterior displacement of the fracture fragment, if there was accompanying injury to the spinal cord or nerve roots, vertebral infection, coagulopathy or vascular embolism, or severe organ dysfunction.

The CT scan in each case showed that the posterior wall of the affected vertebral body was complete and there was no posterior displacement of the fracture fragment. The affected vertebral body was evident as a low signal on T1WI and a high signal on T2WI and fat-suppression MRI. The vertebral body causing pain was identified using a combination of assessment by a visual analogue scale and physical examination. Pre-operative dual-energy x-ray absorptiometry (DXA) scanning revealed that the mean T value was less than -2.5.

A total of 110 patients were prospectively randomly divided into two groups, dilator (n = 55) and balloon kyphoplasty (n = 55), each group were matched for gender, age and the duration of disease and agreed to attend for follow-up examination. This study was approved by the institutional Internal Review Board and informed consent was obtained from all patients prior to participating in the study.

**Design of the Jack vertebral dilator.** The dilator is composed of an anterior component producing a dilating force and a posterior component which produces a tensile or thrusting force. Two devices were used. The larger was 5.3 mm × 8 mm in size; after complete expansion its height was 19 mm with a volume of 2.5 ml. The small dilator was 4.8 mm × 7 mm in size, with a height after expansion of 16 mm and a volume of 2.0 ml.

The anterior part includes the head, neck and waist, which are connected by a hinge (Figs 1a and 1b). The head is in the shape of a racket or rectangle. There is a tension bar across the centre of the anterior part of the dilator, two supporting rods are located bilaterally at the front end of the tension bar, and the supporting rod is connected to the tension bar and head with a pin. There are two pairs of supporting rods, which allow the device to be propped open or closed. The distal pair of supporting rods can also move the upper and lower ends parallel to each other. When the tension bar is pushed to the distal part, the supporting rod closes the head of the dilator. When the head is completely closed, the whole or part of the tension bar and the bilateral supporting rods are placed in the recess medial to the head and neck. When the tension bar is pulled to the proximal part, the supporting rod props open the head of the dilator in parallel.

The posterior part of the dilator includes a pipe connector, a handle and a rotary handle (Fig. 1c). There is a tension bar across the centre of the connector. The centre of the rotary handle is connected to the tension bar. When the rotary handle is rotated clockwise, the tension bar produces a tensile force by moving to the proximal end. When it rotates anti-clockwise, the tension bar produces a thrusting force by moving to the distal end. The number highlighted by the indicator on the scale in the posterior part of the handle is the distance which the dilator head has been distracted.

**Surgical procedure.** *Vertebral dilator kyphoplasty.* A transpedicular approach is used to access the vertebral bodies. The patient is placed prone on the operating table and local anaesthesia is used. The C-arm is adjusted so that there is no bilateral shadow on the affected vertebral body, and the shapes of the pedicles are symmetrical with the same distance to the spinous process. Using the anteroposterior view, a hollow needle is introduced into the lateral margin of the pedicle at 3 o’clock on the right side and 9 o’clock on the left. When the tip of the needle reaches the posterior vertebral wall on the lateral view, it is located at the medial margin of the pedicle on the anteroposterior view. An 11-G guide wire is then inserted through the needle and dilators and a 5.1 mm or 5.6 mm working tube is introduced along the guide wire (Fig. 2a). The distal end of the working tube is inserted as far as the posterior margin of the vertebral body. A hand drill is placed through the working tube until the tip is 3 mm to 5 mm from the anterior margin of the vertebral body on the lateral view, and hence located near the margin of the spinous process on the anteroposterior view. Further dilators and then a working tube of 5.1 mm × 7.3 mm or
5.6 mm × 8.3 mm with an oval cross-section are inserted over the guide-wire (Fig. 2b). An opening device with a solid centre of the same size and shape as the dilator is then inserted into the prepared channel within the vertebral body by tapping. The vertebral dilator is then placed in the posterior half of the vertebral body along with the oval working tube, and then rotated through 90°C to position the relatively wide part of the dilator head completely within the vertebral body against the upper and lower end plates. The ideal position is such that the anterior part of the dilator is 3 mm to 5 mm from the anterior wall of the vertebral body. The rotary handle is then rotated clockwise to expand the dilator, with the extent read on the scale (Fig. 2c). When the upper and lower end-
plates of the affected vertebral body are parallel or nearly parallel to each other (Fig. 2d), rotation of the dilator is stopped. The rotary handle is then rotated anti-clockwise to gradually close the dilator until the indicator is located at the starting point of the scale. It is then rotated through 90° and removed. Polymethylmethacrylate (PMMA) is prepared to an early dough stage and then injected through a 4.5 mm catheter into the cavity in the vertebral body (Figs 2e and 2f). If cement leakage is observed during injection the procedure is discontinued. The same procedure is carried out on the opposite side. Patients remain on bed rests for at least one hour after surgery.

**Balloon kyphoplasty.** The patient is placed in prone position on the operating table and local anesthesia is used under C-arm guidance. A transpedicular approach is used (2 o’clock on the right, 10 o’clock on the left side). During surgery, the working tube is placed into the vertebral body at a distance in excess of 2 mm to 3 mm from the posterior wall of the vertebral body. A fine bone drill is inserted, with the working tube, to a distance of 2 mm to 3 mm from the anterior wall of the vertebral body. The balloon is inserted after removal of the bone drill. The balloon is dilated gradually under the fluoroscopic guidance. Dilation is stopped and the balloon is removed after restoration of vertebral height or when the balloon reaches the upper and lower end plates. Bone cement at the late stage is injected under low pressure. The injection is stopped if there is leakage of cement. The injection catheter is removed after the cement had polymerised. The operation is completed after ten minutes of observation when vital signs are stable.

**Outcome measures.** Pain was evaluated using a visual analogue scale (VAS) where a score of zero indicated ‘no pain’ and a score of ten indicated ‘severe pain’. Function was assessed using the Oswestry Disability Index (ODI)28 with all patients required to complete the Chinese version of this.

Anteroposterior and lateral radiographs were taken to observe the distribution of bone cement in the vertebral body and any leakage. Anterior and middle heights of the affected vertebral body and the Cobb angle were also measured.

**Statistical analysis.** Categorical variables were compared by the chi-squared and Fisher’s exact tests and are presented as number and %. Baseline continuous variables were compared by independent two-sample t-tests and are presented as means and SD. Paired t-tests were used to compare measurements before and after surgery in each group. Analysis of covariance was performed to determine between-group differences in the mean change in measurements between baseline and after surgery. This was because of a significant between-groups difference in the Cobb angles and the VAS at baseline. All statistical assessments were two-sided and evaluated at a statistical significance of p = 0.05. Statistical analyses were performed using SPSS 15.0 statistical software (SPSS Inc., Chicago, Illinois).

**Results**

Table I shows the demographic and baseline characteristics of the patients in the two groups. There were no significant differences between the groups in age, gender distribution, bone cement volume, location of vertebral bodies, anterior height, middle height or ODI.

Significant differences in the Cobb angle (p = 0.013) and the VAS (p = 0.004) were found (p < 0.05). The mean duration of back pain was 0.7 months (0.2 to 1.5) in the dilator kyphoplasty group and the mean follow-up 13 months (3 to 24). The mean duration of back pain was 0.6 months (0.1 to 1.5) in the balloon kyphoplasty group and the mean follow-up 22 months (3 to 48). The procedure was performed successfully in all patients. For each vertebral body there were no statistically significant differences between the two groups in terms of intra-operative variables, including operation time, blood loss, and the volume of bone cement injected.

The mean changes from baseline to after surgery are summarised in Table II for both groups. The mean changes in the Cobb angle, anterior height, middle height, VAS and ODI from before surgery to post-operatively were significant in both groups (all p < 0.001). There was a statistically significant difference in the change in the Cobb angle between the groups. It was more pronounced in dilator kyphoplasty patients (analysis of covariance, p < 0.001). No other differences between the groups were found, except in the anterior and middle heights.

There were no cases of infection, nerve root or cord injury, pulmonary embolism or other complications in either group. In the dilator kyphoplasty group there were two asymptomatic small leaks of bone cement in one vertebral body. In the balloon kyphoplasty group leakage occurred in four vertebral bodies, but without clinical symptoms.

**Discussion**

In this study we compared the efficacy of balloon with the newly developed dilator kyphoplasty for the treatment of osteoporotic fractures between T10 and L5. Both techniques were found to be effective, as indicated by changes in vertebral body height. The length of the procedure, blood loss and the volume of cement injected were similar, but less leakage of bone cement was detected with dilator kyphoplasty.

Balloon kyphoplasty is widely used and can produce an excellent therapeutic effect, restoring vertebral height, and reducing leakage of cement compared with percutaneous vertebroplasty. A previous study involving approximately 70 vertebral bodies in 30 patients found that the mean restoration of vertebral height following balloon kyphoplasty was 2.9 mm, with restoration of one-third of the loss in height.27 Leakage of cement occurred in 8.6%, and the mean correction of kyphosis was 3.4°.29 Other studies have reported similar findings,3,10-14 and that percutaneous vertebroplasty and balloon kyphoplasty can both restore vertebral body height.19,30 In our study the vertebral height
was restored in both groups, probably because most patients underwent surgery shortly after the fracture had occurred. They were placed prone on the operating table, and the fracture was reduced considerably after cushions were placed under the chest and iliac spine. Although both procedures facilitated correction of the Cobb angle, the mean correction was significantly greater \((p < 0.001)\) in the dilator kyphoplasty group, with better restoration of the anterior vertebral height.

The dilating force produced with the Jack apparatus is larger than that associated with use of a balloon. Initial testing showed this force to be around 400 pounds per square inch (psi), well above that required to distract a fractured vertebral body. The maximum pressure associated with balloon kyphoplasty is 300 psi.\(^{26}\) As the contact surface of the Jack dilator is in the shape of a large racket frame or rectangle, the stress is distributed and both sides are dilated simultaneously. Breakage of the endplate is unlikely to occur. The relatively large dilating force allows the Jack device to restore vertebral height.

Because there may be large fissures at the anterior and lateral walls of the vertebral body, leakage of cement could be a frequent hazard. However, as the dilating channel in the pedicle is slightly thicker with dilator kyphoplasty than with balloon kyphoplasty, the diameter of the catheter for injecting cement is 4.5 mm, with an inner diameter of 3.9 mm, which is larger than the 3.4 mm used with the latter, which has an inner diameter of 2.8 mm. Therefore, cement can be pushed in at the early dough stage during the former procedure, whereas it must be much less viscous for the latter. This should significantly reduce the rate of leakage. In this study we found only two patients in the dilator kyphoplasty group in whom there was a small cement leak from a single vertebral body, whereas there were four instances of leakage in the balloon kyphoplasty group. Leakage was detected by radiographs as opposed to CT scans, which is a more accurate means of assessment (Fig. 2g), so it is possible leakage may have been missed in some cases.

The anterior half of the head of the Jack dilator is relatively wide and about twice its thickness. It was designed according to the anatomical characteristics of the pedicles in the thoracolumbar spine. According to the measurements of vertical and transverse diameters from T10 to L5 (Table III), the ratio between vertical diameter and transverse diameter in the thoracolumbar spine is 2:1. Even though the vertical diameter is similar to the transverse diameter in the L4 and L5 pedicles, the vertical diameter is still equal to or greater than that in the pedicles of L2 and L3; hence the dilator may still be applied. Its head can be placed longitudinally past the pedicle into the posterior half of the vertebral body and then rotated through 90°. The head is propped open after being placed completely within the vertebral body to enlarge the contact area during dilation, and to reduce the pressure, thereby allowing the full

### Table I. Demographic and baseline characteristics of patients in the Jack vertebral dilator kyphoplasty (DKP) and balloon kyphoplasty (BKP) group with results displayed as number, mean values, range, SD or percentage as appropriate

<table>
<thead>
<tr>
<th>Variable</th>
<th>DKP (n = 55)</th>
<th>BKP (n = 55)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (range)</td>
<td>66.2 (58 to 87)</td>
<td>67.3 (56 to 85)</td>
<td>0.405¹</td>
</tr>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16 (29.1)</td>
<td>18 (32.7)</td>
<td>0.680²</td>
</tr>
<tr>
<td>Female</td>
<td>39 (70.9)</td>
<td>37 (67.3)</td>
<td></td>
</tr>
<tr>
<td>Bone cement volume in ml (SD)</td>
<td>5.6 (0.6)</td>
<td>5.8 (0.7)</td>
<td>0.205¹</td>
</tr>
<tr>
<td>Mean operating time in min (SD)</td>
<td>38.8 (7.1)</td>
<td>38.4 (6.2)</td>
<td>0.743¹</td>
</tr>
<tr>
<td>Mean blood loss ml (SD)</td>
<td>25.8 (5.9)</td>
<td>25.1 (5.2)</td>
<td>0.538¹</td>
</tr>
<tr>
<td>Vertebral bodies (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T11</td>
<td>2 (3.6)</td>
<td>5 (8.1)</td>
<td></td>
</tr>
<tr>
<td>T12</td>
<td>19 (34.5)</td>
<td>15 (27.9)</td>
<td></td>
</tr>
<tr>
<td>L1</td>
<td>17 (30.9)</td>
<td>21 (38.2)</td>
<td>0.750²</td>
</tr>
<tr>
<td>L2</td>
<td>11 (20.0)</td>
<td>8 (14.5)</td>
<td></td>
</tr>
<tr>
<td>L3</td>
<td>4 (7.3)</td>
<td>4 (7.3)</td>
<td></td>
</tr>
<tr>
<td>L4</td>
<td>2 (3.6)</td>
<td>2 (3.6)</td>
<td></td>
</tr>
<tr>
<td>Anterior height (mm)</td>
<td>19.3 (3.0)</td>
<td>19.2 (1.9)</td>
<td>0.838¹</td>
</tr>
<tr>
<td>Middle height (mm)</td>
<td>19.2 (2.9)</td>
<td>19.5 (1.8)</td>
<td>0.507¹</td>
</tr>
<tr>
<td>Cobb angle (*)</td>
<td>16.7 (6.4)</td>
<td>19.3 (4.3)</td>
<td>0.013¹</td>
</tr>
<tr>
<td>Visual analogue scale</td>
<td>8.2 (1.1)</td>
<td>7.7 (0.7)</td>
<td>0.004¹</td>
</tr>
<tr>
<td>Oswestry Disability Index</td>
<td>0.8 (0.1)</td>
<td>0.7 (0.1)</td>
<td>0.061¹</td>
</tr>
</tbody>
</table>

* p-values are based on independent two-sample t-tests,¹ chi-squared test or² Fisher's exact test
use of the vertical and transverse diameters of the pedicle. Hence, pre-operative measurement of the transverse diameter by CT scanning and measurement of the vertical diameter using two- or three-dimensional CT reconstruction is necessary. As the transverse and vertical diameters of the pedicle may be different on either side, both sides should be measured and a dilator of suitable size selected. When there is severe stenosis or pedicular deformity, an extrapedicular or other approach should be taken.

In our study, CT scanning at follow-up revealed clear traces of channels within the pedicles and no instances of breakage.

As the working channel inside the pedicle is thin with balloon kyphoplasty, unilateral puncture is possible. During unilateral puncture, the penetration point on the pedicle should be laterally deviated and the introversion angle should be enlarged simultaneously to allow the distal end of the balloon to cross the midline under the guidance of anteroposterior fluoroscopy. Balloon dilation is accomplished using a hydraulic pressure injection system, whereby the balloon expands in the direction of least resistance inside the vertebral body. As the relatively porous trabecular bone is likely to be compacted first, it is possible that the balloon may expand towards the opposite side during unilateral puncture. Bone cement with a relatively high viscosity can fill the opposite side of the vertebral body during the injection.31 However, Liebschner, Rosenberg and Keaveny32 have found through finite element analysis that unilateral loading of a vertebral body may result in spinal instability, the severity being proportional to the amount of cement injected. Chung et al33 compared patients undergoing unilateral balloon kyphoplasty with those having bilateral injection and found that the latter was better at correcting kyphosis and maintaining correction. As already noted, the dilation channel created in the pedicle with dilator kyphoplasty is larger than with the latter owing to the larger diameter of the instruments. It is difficult to cross the midline with the vertebral dilator during a unilateral pedicle approach, and so a bilateral approach is needed. Also, according to the Denis classification,34 B-type fractures involving the upper endplate are most common, so unilateral injection may result in leakage of cement into the intervertebral space.

Balloon kyphoplasty is an expensive procedure, with the cost of materials for a single level about US$4000.35 In China, the cost of materials for single-level balloon kyphoplasty is US$5900, whereas that for a single-level Jack vertebral dilator is only US$2500. The Jack vertebral dilator is considerably cheaper.

We found that both dilator and balloon kyphoplasties gave excellent results. Both effectively restored the anterior and middle heights of the vertebral body, corrected the kyphotic deformity, relieved pain and improved function. Dilator kyphoplasty was associated with less leakage of

Table II. Comparison of differences in the mean changes with SD from baseline after surgery for the Jack vertebral dilator kyphoplasty (DKP) and balloon kyphoplasty (BKP) group

|               | DKP (n = 55) | BKP (n = 55) | p-value
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Anterior height in mm (SD)</td>
<td>6.42 (2.09)*</td>
<td>5.35 (0.87)*</td>
<td>0.0081</td>
</tr>
<tr>
<td>Middle height in mm (SD)</td>
<td>6.15 (1.98)*</td>
<td>5.37 (1.29)*</td>
<td>0.0436</td>
</tr>
<tr>
<td>Cobb angle (°) (SD)</td>
<td>-9.51 (2.56)*</td>
<td>-7.78 (1.19)*</td>
<td>&lt; 0.0012</td>
</tr>
<tr>
<td>Visual analogue scale (SD)</td>
<td>-6.18 (0.98)*</td>
<td>-5.78 (0.78)*</td>
<td>0.9612</td>
</tr>
</tbody>
</table>

* indicates a statistically significant difference between pre- and post-surgery for each group, as determined by paired t-test (p < 0.05)
† p-values are based on independent two-sample t-tests or ANCOVA
cement, presumably because the cement can be injected at the early dough stage. Although no serious complications occurred in the patients studied, this finding suggests that dilator kyphoplasty may ultimately prove to be a better procedure than balloon kyphoplasty.

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References


