Vertebral body reconstruction system B-Twin® versus corset following non-osteoporotic Magerl A1.2 thoracic and lumbar fracture. Functional and radiological outcome at 12 month follow-up in a prospective randomized series of 50 patients

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Keywords
Vertebral compression fracture; Magerl A1.2; Vertebral body reconstruction (VBR); B-Twin®; Vertebroplasty; Percutaneous

Summary
Introduction: Kyphoplasty and percutaneous vertebroplasty are two effective procedures for osteoporotic vertebral compression fractures, but there have been few publications on their use in non-osteoporotic forms. B-Twin® vertebral body reconstruction is a new minimally invasive vertebral body reconstruction technique developed for non-osteoporotic vertebral compression fractures of the thoracolumbar junction and lumbar spine.

Objectives: The present study describes this novel technique and assessed efficacy compared to a conservative method.

Patients and methods: Inclusion criteria were: Magerl type A1.2 non-osteoporotic thoracolumbar or lumbar spinal compression fractures in patients aged over 18 years, free of neurologic compromise. Patients were randomized to management by corset (group 1) or by the B-Twin® spacer (group 2). Follow-up used a visual analog scale (VAS) to assess pain, the Oswestry Disability Index (ODI) and, on radiology, the vertebral (VK) and regional (RK) kyphosis angles and anterior and medial height indices at baseline, 3 months and 12 months.

Results: Group 1 comprised 26 patients; group 2 comprised 24 patients, with 44 implants. In group 1, mean VK was 10.7° (±1.73°) at baseline, 11.9° (±1.56°) at 3 months and 12.3° (±1.6°) at 12 months. Mean RK was respectively 9.7° (±0.47°), 11.1° (±1.07°) and 11.8° (±1.27°). Mean medial height (medial-to-posterior [MH/PH] height ratio was respectively 0.75 [±0.05], 0.70 [±0.06] and 0.65 [±0.04]). Mean anterior height (anterior-to-posterior [AH/PH] height ratio) was respectively 0.79 [±0.06], 0.76 [±0.05] and 0.73 [±0.05]). Mean VAS score was respectively 8.6 (±0.52), 3.8 (±0.82) and 2.3 (±0.83). In group 2, mean VK was 13.8° (±0.47°)

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**Introduction**

In 1987, Galibert et al. described the technique of percutaneous vertebroplasty using acrylic cement to prevent vertebral collapse under invasive vertebral hemangioma [1]. Currently, vertebroplasty and kyphoplasty are the most frequent treatments for osteoporotic vertebral compression fractures, as they considerably reduce pain [2—4]. A risk of acrylic cement (polymethylmethacrylate [PMMA]) leakage in epidural or discal space has been reported, associated with fractures of the posterior cortex and vertebral plates [5—7]. There are few reports of such techniques being applied in non-osteoporotic traumatic fractures. Associated cementoplasty and short posterior instrumentation was investigated to strengthen the anterior spine and prevent implant failure and reduction loss [8].

Traumatic compression fractures lead to pain, immobilization and impaired quality of life, sometimes with very prolonged convalescence. Thus, healthy bone fractures, like osteoporotic fractures, can usefully be treated by these minimally invasive techniques to restore a pain-free, stable and balanced spine. There is a controversy as to the best means of achieving these goals [9]. Surgical or non-surgical methods may be used.

The present study sought to assess the efficacy of a new vertebral body reconstruction technique in non-osteoporotic fractures of the posterior cortex and vertebral plates [5—7]. Incision and entry point are similar to those in other vertebroplasty procedures. An 11G Jamshidi introducer is inserted percutaneously in the pedicle, at 3 o’clock for the right pedicle and at 9 o’clock for the left. As it emerges forward from the pedicle, it is introduced into the vertebral body for about 2 mm, parallel to the inferior plate, staying a few millimeters below the superior plate. The stylet is then withdrawn and a 1.2 to 1.4 mm K-wire is inserted via the introducer up to the anterior third of the vertebral body. A second introducer and a 6 mm cannula are then inserted on the wire and introduced in the pedicle. The introducer is then withdrawn and a 5.5 mm cannulated drill is inserted along the wire up to the anterior third of the vertebra. Then introducer and guide-wire are withdrawn and the 5 mm diameter B-Twin® spacer is introduced in the work space and optimally positioned within the vertebral body. Once in position, it is opened by turning its handle until the final configuration is achieved. After expansion, the implant is separated from the ancillary. Cement (Kyphx PMMA- Kyphon-Medtronic Elmdown Ltd, London, UK) is then injected (about 1 mL per implant). The opening procedure induces the intended configuration in lordosis, reducing and stabilizing the fracture, like an internal fixator and creating a space into which the cement can be injected under good control, at very low pressure; this reduces the risk of leakage and attendant neurological complications, either by

**Patients and methods**

**Procedure**

The B-Twin® device (Disc-o-tech Ltd., Israel) was developed by R. Gepstein in 2001 and reported on in 2003 as an intervertebral spacer indicated in degenerative discopathy [10]. It was also recommended in certain spinal fractures. It comprises two parts: the expandable B-Twin® implant and an expandable and movable fitting ancillary. The former is a titanium tube which, when shortened, opens to produces spike-like radial fins along the tube. If it is positioned just under the vertebral plate, the spikes will raise the subchondral cortical bone, thus reconstructing the surface destroyed by the compression fracture (Fig. 1).

The device has a trapezoid shape. It comes in various sizes and lengths. In all models, the anterior diameter is always 1.5 mm greater than the posterior diameter. Opening thus induces a preconfigured lordosis in the fractured vertebra. The shortening involved in opening the implant means that it is 4 mm longer when closed than open. Final implant diameter is determined by the initial length of the closed implant. The model is to be chosen according to the length allowed by the individual vertebral body and this point needs to be included in the operative plan. The appropriate size is chosen based on the dimensions of the fractured vertebra and adjacent level on AP and lateral X-ray and CT or MRI images.

Implantation under image intensification uses a uni- or bilateral transpedicular percutaneous approach at vertebral levels T10 to L5 [11]. Incision and entry point are similar to those in other vertebroplasty procedures. An 11G Jamshidi introducer is inserted percutaneously in the pedicle, at 3 o’clock for the right pedicle and at 9 o’clock for the left. As it emerges forward from the pedicle, it is introduced into the vertebral body for about 2 mm, parallel to the inferior plate, staying a few millimeters below the superior plate. The stylet is then withdrawn and a 1.2 to 1.4 mm K-wire is inserted via the introducer up to the anterior third of the vertebra. A second introducer and a 6 mm cannula are then inserted on the wire and introduced in the pedicle. The introducer is then withdrawn and a 5.5 mm cannulated drill is inserted along the wire up to the anterior third of the vertebra. Then introducer and guide-wire are withdrawn and the 5 mm diameter B-Twin® spacer is introduced in the work space and optimally positioned within the vertebral body. Once in position, it is opened by turning its handle until the final configuration is achieved. After expansion, the implant is separated from the ancillary. Cement (Kyphx PMMA- Kyphon-Medtronic Elmdown Ltd, London, UK) is then injected (about 1 mL per implant). The opening procedure induces the intended configuration in lordosis, reducing and stabilizing the fracture, like an internal fixator and creating a space into which the cement can be injected under good control, at very low pressure; this reduces the risk of leakage and attendant neurological complications, either by

direct compression or by an exothermic effect during polymerization of the methylmethacrylate (PMMA) [4,6,7]. One or two implants may be used per level.

Study population

Between March 2004 and March 2007, 50 patients (32 male, 18 female) presenting with Magerl type A1.2 thoracic or lumbar spinal fracture [12] were included in the study. Fracture site was T12 (n = 12), L1 (n = 22), L2 (n = 11) or L3 (n = 5). Mean post-trauma interval was 6 days (range, 4—18 days). Exclusion criteria were: neurologic lesion, absence of trauma, osteoporosis on DEXA absorptiometry, posterior vertebral wall or pedicle rupture on CT and preexisting pathology liable to hinder surgery (previous vertebroplasty on the affected vertebra, bone tuberculosis, pregnancy, surgery site infection, obesity, greater than 40° scoliosis and metal allergy.

The study was approved by our center’s clinical research ethics committee. Patients all gave informed consent. Two groups were randomized: group 1 received conservative treatment by 4—6 weeks hyperextension cast; group 2 was treated using the B-Twin® intra-body expansion spacer, with upright posture as of the day following surgery, without corset. Group 1 comprised 26 patients: 18 male, eight female; aged 18 to 56 years (mean, 38 years). Group 2 comprised 24 patients: 14 male, 10 female; aged 19 to 60 years (mean, 42 years). Implantation was bilateral in 20 patients and unilateral in four. No patients refused to participate ahead of randomization.

Figure 1  The expandable system (A/B) comprises a titanium tube implanted in its closed position using a dedicated ancillary (C). The ancillary is also used to open the device by axial compression which deforms the implant, producing radial fins.

Figure 2  In this L1 fracture (A), two devices were implanted on a transpedicular approach. Postoperative AP and lateral X-ray (B) shows good fracture reduction.
All patients were assessed clinically and radiologically, at baseline and at 3- and 12-month follow-up (Fig. 2). Pain intensity was assessed on a visual analog scale (VAS) from 0 (no pain) to 10 (unbearable pain). The Oswestry Disability Index (ODI) [13] was also used for the 3- and 12-month clinical assessments. Magerl classification [12] on preoperative AP and lateral X-ray and CT of the fractured vertebra was performed by a single examiner in all cases. The AH/PH MH/PH indices (anterior-to-posterior and medial-to-posterior vertebral body height, respectively) were systematically measured from lateral views. Vertebral (VK) and regional (RK) kyphosis were measured as the angle subtended by the cranial and caudal plates of the fractured and of the underlying vertebra, respectively [14—16].

Statistical analysis used SPSS 11.0 software (SPSS Inc., Chicago, IL) to compare the two groups by t-test with respect to VK, RK, VAS and ODI with a confidence interval of 95% (P < 0.05).

Results

No patients were lost to follow-up at 1 year. Table 1 shows the radiological and Table 2 the clinical results. In group 2 (managed surgically), VAS scores were significantly reduced between 3 and 12 months (P < 0.05); pain reduction was greater in group 2 than in group 1 (managed conservatively). ODI scores showed significantly greater improvement in quality of life at 6 and 12 months in group 2 (P < 0.05).

The increase in vertebral body height induced by B-Twin® was maintained at 6 and at 12 months (P < 0.0001). At 12-month follow-up, no implant migration, device rupture, infection or further bone fracture at the same or an adjacent level was observed. There were no neurological or radicular lesions. There was one case of cement leakage by anterior peridural venous drainage, probably by fluid phase injection; the patient was clinically asymptomatic (Fig. 3).

Discussion

Inter- and intra-observer measurement reproducibility on lateral X-ray and CT is variable. Regional and vertebral kyphosis are the most reliable parameters [14—16]. Interpreting findings for anterior and medial height indices is less sure.

Clinical results (pain, quality of life) and maintenance of local sagittal stability (VK and RK) in the present series were better using B-Twin® vertebral reconstruction technique (group 2) than with conservative treatment (group 1). In group 2, reduction of the fractured vertebra was lasting. In group 1, 15 patients had VAS scores greater than 4 at 12-month follow-up, while group 2 VAS scores were systematically less than 3 in the postoperative phase and less than 1.5 at 12 months.

In group 2, mean VK correction was 9.5°, remaining stable at end of follow-up. Mean RK correction was about 5.4°, also remaining stable at end of follow-up. Anterior vertebral body compression was corrected by about 83.3% postoperatively, with the same correction value found at 12 months.

There is no consensus as to optimal management in Magerl type A vertebral fractures, especially where no neurological defect is associated. Both surgical and conservative methods may be used [17—19]. Many authors recommend conservative treatment by cast in hyperlordosis [9,17,20—23] with 4- to 6-week convalescence following.

Table 1 Comparison between conservative and surgical treatment in A1.2 vertebral body reconstruction.

<table>
<thead>
<tr>
<th></th>
<th>VK</th>
<th>RK</th>
<th>MH/PH</th>
<th>AH/PH</th>
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<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
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<tr>
<td>Conservative</td>
<td>10.70 ± 1.73(2.79)</td>
<td>9.70 ± 0.97(1.57)</td>
<td>0.75 ± 0.05(0.09)</td>
<td>0.79 ± 0.05(0.08)</td>
</tr>
<tr>
<td>Surgical</td>
<td>13.82 ± 0.47(4.14)</td>
<td>9.82 ± 1.67(3.50)</td>
<td>0.69 ± 0.05(0.10)</td>
<td>0.73 ± 0.04(0.07)</td>
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<tr>
<td><strong>3-month follow-up</strong></td>
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<tr>
<td>Conservative</td>
<td>11.90 ± 1.56(2.51)</td>
<td>11.10 ± 1.07(1.73)</td>
<td>0.70 ± 0.06(0.10)</td>
<td>0.76 ± 0.05(0.08)</td>
</tr>
<tr>
<td>Surgical</td>
<td>4.88 ± 0.65(1.36)</td>
<td>4.47 ± 0.86(1.81)</td>
<td>0.86 ± 0.03(0.06)</td>
<td>0.90 ± 0.03(0.06)</td>
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<td><strong>12-month follow-up</strong></td>
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<tr>
<td>Conservative</td>
<td>12.30 ± 1.60(2.58)</td>
<td>11.80 ± 1.27(2.04)</td>
<td>0.65 ± 0.04(0.06)</td>
<td>0.73 ± 0.05(0.09)</td>
</tr>
<tr>
<td>Surgical</td>
<td>4.88 ± 0.65(1.36)</td>
<td>4.82 ± 0.98(2.07)</td>
<td>0.86 ± 0.03(0.06)</td>
<td>0.90 ± 0.03(0.06)</td>
</tr>
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Vertebral (VK) and regional kyphosis (RK), medial-to-posterior (MH/PH) and anterior-to-posterior (AH/PH) vertebral wall height ratios, at baseline and 3- and 12-month follow-up.
Bohler and Gui [22,23]. Others perform early surgical stabilization [11,18,19,24].

The principle of closed reduction on frame by axial traction and lordosis maintained by corset for 4 to 6 weeks still remains valid [20,21,23], although application may be limited by poor tolerance in certain patients [20,21]. The indication for vertebroplasty initially put forward by its inventors was to prevent collapse of a vertebra invaded by C2 hemangiomatosis [1]. Vertebroplasty and kyphoplasty are at present the most frequent means of treating vertebral compression fractures [2—4].

An option recommended managing such thoracic or lumbar fractures by kyphoplasty with osteoconduction material such as calcium phosphate (CPC). This type of cementoplasty was compared to conservative management by corset. Maestrelli [25] and Huang [26] showed its advantages, with immediate return to everyday activity, without the inconvenience caused by a cast. It has a good effect on pain. Associated surgical risk is minimal. These results suggest that it could be the attitude of choice in patients needing to recover activity levels quickly, showing good maintenance of spinal stability. The B-Twin® expansion system, unlike kyphoplasty, provides a controlled and predefined increase in vertebral body height by directional expansion. The cement procedure induces greater anterior than posterior height, enables the lordosis configuration of the vertebral body to be reproduced. The metal fins stabilize the fracture. The device avoids space closure, creating a predefined space into which cement can be injected at very low pressure. This reduces the risk of leakage, of which some authors are very cautious in the present series. We use a very small amount of acrylic cement (about 1 mL per implant). The reduction is maintained mechanically by the titanium device rather than by the amount of cement, which serves only to prevent reduction loss and limits cement leakage. The fractured vertebra deformity is lastingly reduced. This enables the lordosis configuration of the vertebral body to be restored for a rapid return to everyday activity.

### Table 2: Comparison between conservative and surgical treatment in A1.2 vertebral body reconstruction.

<table>
<thead>
<tr>
<th></th>
<th>3-month follow-up mean ± 95% CI; SD</th>
<th>12-month follow-up mean ± 95% CI; SD</th>
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<tr>
<td></td>
<td>VAS</td>
<td>ODI</td>
</tr>
<tr>
<td>Conservative treatment</td>
<td>3.80 (SD 1.32)</td>
<td>12.50 (SD 1.27)</td>
</tr>
<tr>
<td>Surgical treatment</td>
<td>1.71 (SD 0.59)</td>
<td>9.13 (SD 4.9)</td>
</tr>
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Visual analog scale (VAS) score and Oswestry Disability Index (ODI) at 3- and 12-month follow-up.

Conclusions

In the present preliminary study, the B-Twin® system proved clinically and radiologically effective in treating non-osteoporotic A1.2 thoracic and lumbar spinal fractures at 12-month follow-up. The geometry and directional expansion of the implant maintain reduction and create a space which prevents reduction loss and limits cement leakage. The fractured vertebra deformity is lastingly reduced. This vertebral reconstruction device can be considered as a first-intention option in young patients requiring spinal stability to be restored for a rapid return to everyday activity.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

References