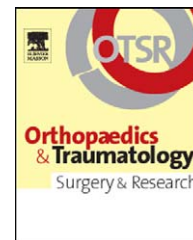




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ORIGINAL ARTICLE

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
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Vertebral body
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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° (± 0.97°), 11.10° (± 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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at baseline, $4.88^\circ (\pm 0.65^\circ)$ at 3 months and $4.88^\circ (\pm 0.65^\circ)$. Mean RK was respectively $9.82^\circ (\pm 1.67^\circ)$, $4.47^\circ (\pm 0.86^\circ)$ and $4.82^\circ (\pm 0.98^\circ)$. Mean MH/PH ratio was respectively $0.69 (\pm 0.05)$, $0.86 (\pm 0.03)$ and $0.86 (\pm 0.03)$. Mean AH/PH ratio was respectively $0.73 (\pm 0.04)$, $0.90 (\pm 0.03)$ and $0.90 (\pm 0.03)$. Mean VAS score was $8.88 (\pm 0.47)$ at baseline, $2 (\pm 1)$ at 1-day post-surgery, $1.71 (\pm 0.88)$ at 3 months and $1.12 (\pm 0.23)$ at 12 months. The increase in vertebral body height in patients managed by B-Twin® was maintained at 6 and 12 months ($P < 0.0001$). The study showed better results with the vertebral spacer than on conservative treatment, with a 95% reduction in bed-rest: 4–6 weeks in the conservative group vs. 2–3 days in the surgical group.

Conclusions: The vertebral body reconstruction technique provided anatomic vertebral body reconstruction and quick return to household activity without resort to a corset. Deformity was durably reduced. At 12-month follow-up, pain reduction and stasis were achieved. The risk of injected cement leakage was slight.

Level of evidence: Level 2 prospective, randomized. Level 2.

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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 vertebral compression fractures in a prospective randomized comparison to a conservative attitude.

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 expansible and movable fitting ancillary. The former is a titanium tube which, when shortened, opens to produce 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

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