



Clinical evaluation of Crosstrees pod kyphoplasty in the treatment of osteoporotic vertebral compression fractures

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Although percutaneous vertebroplasty and balloon kyphoplasty have improved the management of osteoporotic vertebral compression fractures (OVCFs), these techniques still suffer from inherent disadvantages and complications, such as cement leakage. This prospective pilot study evaluated the clinical outcomes of 15 OVCF patients treated with a new technique, the Crosstrees® pod kyphoplasty (C-pod kyphoplasty). This is in fact a balloon kyphoplasty, where the balloon is filled with cement, then opened and removed. The VAS for back pain decreased significantly from 8.9 ± 1.4 preoperatively to 2.1 ± 1.3 at 24hrs postoperatively, and to 2.2 ± 1.5 at final follow-up ($p = 0.001$). Likewise, the ODI score decreased significantly from 86.1 ± 8.7 preoperatively to 30.5 ± 7.5 at 24 h, and to 32.8 ± 8.3 at final follow up ($p = 0.001$). The average vertebral height increased significantly from 14.50 ± 1.34 mm preoperatively to 23.20 ± 1.12 mm 24 h postoperatively and to 22.82 ± 0.85 mm at final follow-up ($p = 0.002$). The kyphotic angle decreased significantly from preoperatively ($28.50 \pm 1.85^\circ$) to 24 h postoperatively ($11.30 \pm 1.40^\circ$) and to final follow-up ($12.48 \pm 0.70^\circ$) ($p = 0.005$). Cement leakage, infection, pulmonary embolism or nerve injury were not seen. The C-pod kyphoplasty may be an effective minimally invasive procedure to treat OVCFs, with a decreased complication rate compared with vertebroplasty and balloon kyphoplasty.

Keywords : percutaneous vertebroplasty ; balloon kyphoplasty ; Crosstrees pod kyphoplasty ; osteoporotic vertebral compression fracture.

INTRODUCTION

The rising incidence of osteoporotic vertebral compression fractures (OVCFs) in elderly populations is a serious health problem. The annual age-standardised incidence of OVCFs is approximately 5.7 per 1000 in male populations and 10.7 per 1000 in female populations. OVCFs often lead to chronic pain and functional impairment, which have adverse impacts on quality of life and social well-being (8,20). The introduction of two surgical techniques, percutaneous vertebroplasty and balloon kyphoplasty, was a major advance in the management of OVCFs. They provided rapid pain relief, indirectly augmented pulmonary function, and improved the quality of life (13,17). Percutaneous vertebroplasty, first described by Galibert *et al* (6) in 1987, strengthens the vertebral body through injection of viscous polymethylmethacrylate (PMMA).

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Although vertebroplasty is generally regarded as an effective technique, leading to a satisfactory clinical outcome, complications such as cement leakage may occur, as the cement is typically injected under relatively high pressure. Cement leakage may result in serious complications such as pulmonary embolism, renal embolism, and even cardiac perforation in some cases (2,12,18). Balloon kyphoplasty, introduced by Reily *et al* (7), involves insertion of an inflatable balloon percutaneously into the fractured vertebral body to create a cavity that restores vertebral height (7). After removal of the balloon, cement is injected into this preformed cavity, so that the risk of cement leakage decreases, which has been confirmed by several authors (4,10).

Despite the fact that balloon kyphoplasty has become prevalent, and that it improves quality of life, cement leakage remains a small yet significant problem (1). Although some researchers argue that cement leakage has often no clinical relevance, a meta-analysis by Eck *et al* (3) demonstrated that it occurred in 7% of all the vertebral body procedures. Leakage events were reported as high as 10.2% in the study by Gaitanis *et al* (5). Given the widespread use of this technique, even this low rate of complication leaves a large number of people who will continue to suffer or need a second procedure.

Recently an alternative technique was introduced : the Crosstrees® pod kyphoplasty (C-pod kyphoplasty). It involves insertion of an inflatable Crosstrees® pod into the vertebral body, after which bone cement is injected to correct the spinal deformity. Subsequently the balloon is opened and removed. This technique might reduce the incidence of perioperative complications, in particular the incidence of cement extrusion. However, the clinical outcome of this new procedure has not yet been documented. The authors tried to fill this void.

PATIENTS AND METHODS

Patients

Fifteen consecutive C-pod kyphoplasty procedures were performed in 15 patients (12 women, 3 men), between December 2007 and April 2010. Their mean age was 72.2 years (range : 56-82). All the patients underwent radiographic examination (Arcadis Orbic 3D,

Siemens, Germany) and magnetic resonance imaging (MRI, Trip 3.0T, Siemens, Germany) to identify the symptomatic levels : T9 (1), T11 (2), T12 (5), L1 (5), L2 (2). Dual-energy X-ray absorptiometry (Lunar DPX-IQ, Lunar, USA) confirmed the diagnosis of osteoporosis.

Surgical technique

An orthopaedic surgeon competent in these techniques performed all the surgical procedures after obtaining informed consent from the patients. The intervention involving the use of the Crosstrees® pod system (Crosstree Inc., Boulder, USA) was carried out under local anaesthesia in all the patients. It included the following steps (Fig. 1) : (a) local anaesthesia administered to the periosteum at the pedicle ; (b) percutaneous insertion of the piercing needle into the vertebral body through the vertebral pedicle ; (c,d) confirmation of the correct position of the piercing needle in the vertebral body under biplanar radiograph ; (e) insertion of the core needle ; (f) placement of the sleeve of the Crosstrees pod system through the core needle to the vertebral pedicle ; (g) insertion of the fine bone drill into the vertebral body through the sleeve ; (h) correct position of the fine bone drill in the vertebral body ; (i) removal of the fine bone drill and insertion of the Crosstrees® pod ; (j,k) injection of PMMA cement into the vertebral body ; (l) opening and removal of the balloon.

Clinical parameters

All intraoperative and perioperative complications were recorded. A complete neurological evaluation was carried out within 24 hours of the procedure. Outcome assessment (clinical and radiological) was carried out preoperatively, 24 hrs after surgery, and at final follow-up (12 months). This included the visual analog scale (VAS) for back pain (10 = worst possible pain) and the Oswestry Disability Index (ODI). Vertebral height and kyphotic angle were measured on the lateral radiographs, as described by Pflugmacher *et al* (16). Any incidence of cement leakage was recorded during the procedure and further evaluated with plain radiographs after the procedure.

Statistical analysis

The Statistical Package for Social Sciences 12.0 software (SPSS Inc. Chicago, USA) was used. The pre- and postoperative VAS and ODI scores were compared with a Wilcoxon signed rank test (paired nonparametric

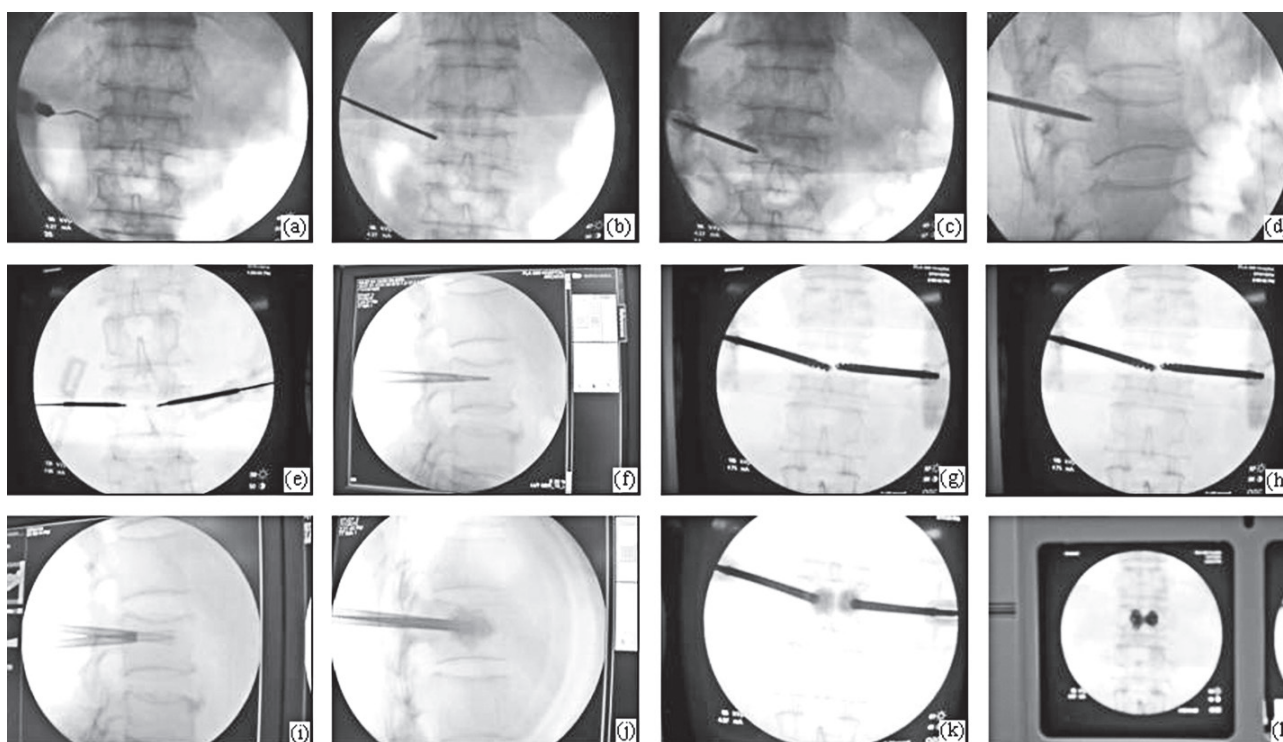


Fig. 1. — (a) local anaesthesia ; (b) insertion of the piercing needle into the vertebral body through the pedicle ; (c) and (d) correct position of the piercing needle confirmed under biplanar control ; (e) insertion of the core needle ; (f) sleeve of the Crosstrees pod system through the core needle ; (g) fine bone drill into the vertebral body through the sleeve ; (h) correct position of the fine bone drill ; (i) removal of fine bone drill and insertion of Crosstrees pod ; (j) and (k) injection of cement ; (l) opening of the balloon and removal of the balloon.

analysis). The pre- and postoperative vertebral height and kyphotic angle were compared with a paired Student's t test. Statistically significant differences were defined at a 95% confidence level.

RESULTS

Complications

Cement leakage, infection, pulmonary embolism or nerve injury were not noted.

Clinical outcome

The average operation time was 45 minutes per vertebral body (range : 36-58). All patients experienced rapid relief of back pain and were fully active the day after the procedure. The VAS score decreased significantly from 8.9 ± 1.4 preoperatively

to 2.1 ± 1.3 at 24 h, and to 2.2 ± 1.5 at final follow-up ($p = 0.001$) (Table I). Likewise, the ODI score decreased significantly from 86.1 ± 8.7 preoperatively to 30.5 ± 7.5 at 24h, and to 32.8 ± 8.3 at final follow-up ($p = 0.001$) (Table I). Interestingly, the VAS and the ODI scores, obtained at 24 h and at final follow-up, did not differ significantly, which confirms that the results were lasting.

Radiographic outcome

The average vertebral height increased significantly from preoperatively (14.50 ± 1.34 mm) to 24 h postoperatively (23.20 ± 1.12 mm) and to final follow-up (22.82 ± 0.85 mm) ($p = 0.002$) (Table II) (Fig. 2, 3). The kyphotic angle decreased significantly from preoperatively ($28.50 \pm 1.85^\circ$) to 24 h postoperatively ($11.30 \pm 1.40^\circ$) and to final follow-up ($12.48 \pm 0.70^\circ$) ($p = 0.005$) (Table II) (Fig. 2, 3).

Table I. — Evolution of VAS and ODI score

Time	VAS	ODI score
Preoperatively	8.9 ± 1.4	86.1 ± 8.7
24 h after surgery	2.1 ± 1.3*	30.5 ± 7.5*
At final follow-up	2.2 ± 1.5*	32.8 ± 8.3*

* $p = 0.001$.

Table II. — Evolution of vertebral height and kyphotic angle

Time	Vertebral height (mm)	Kyphotic angle
Preoperatively	14.50 ± 1.34	28.50 ± 1.85
24 h after surgery	23.20 ± 1.12*	11.30 ± 1.40**
At final follow up	22.82 ± 0.85*	12.48 ± 0.70**

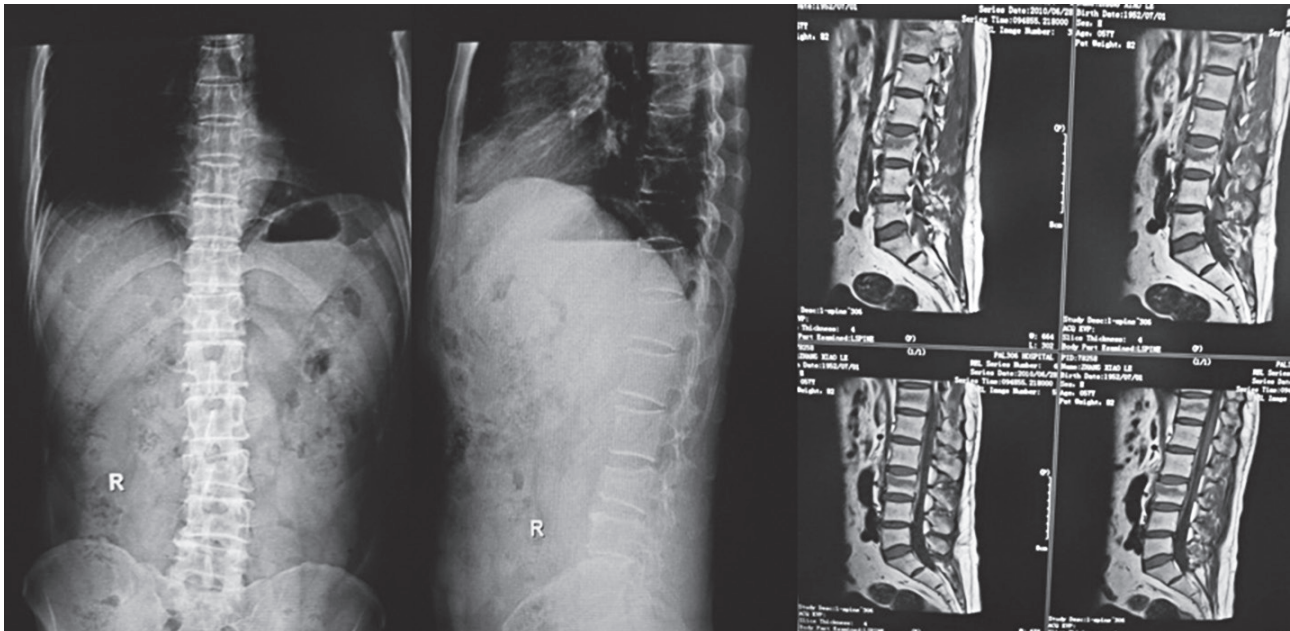
* $p = 0.002$ / ** $p = 0.005$.

Fig. 2. — Osteoporotic compression fractures T12 and L3

In addition, there was no significant difference between the postoperative and final values of vertebral height and kyphotic angle : the results were durable.

DISCUSSION

Osteoporotic vertebral compression fractures are a significant health-care concern in elderly people and become more and more important as the population continues to age (19). Conservative treatments (bracing, pain medication etc.) have inherent limitations. Minimally invasive procedures (vertebroplasty and balloon kyphoplasty) lead to complications and thus provide a strong impetus to improve the surgical technique and to reduce the risk of cement leakage (9,15). Balloon kyphoplasty is currently considered as the optimal method in terms of pain relief,

restoration of vertebral height, and correction of kyphotic deformity (14). However, cement leakage still occurs and is the primary complication, with an incidence of about 10% being reported in previous studies (3,5,11). Some researchers argue that cement leakage often is innocuous, but this does not mean that it should simply be accepted.

The present study is the first pilot study to describe the short term clinical outcome of C-pod kyphoplasty. No cement leakage, infection, pulmonary embolism or nerve injury were observed. The VAS score, the ODI score, the kyphosis angle and the vertebral height all improved significantly, and the effects were lasting.

The technique of C-pod kyphoplasty is similar to that of balloon kyphoplasty. It is relatively easy to control inflation of the Crosstrees® pod (or to

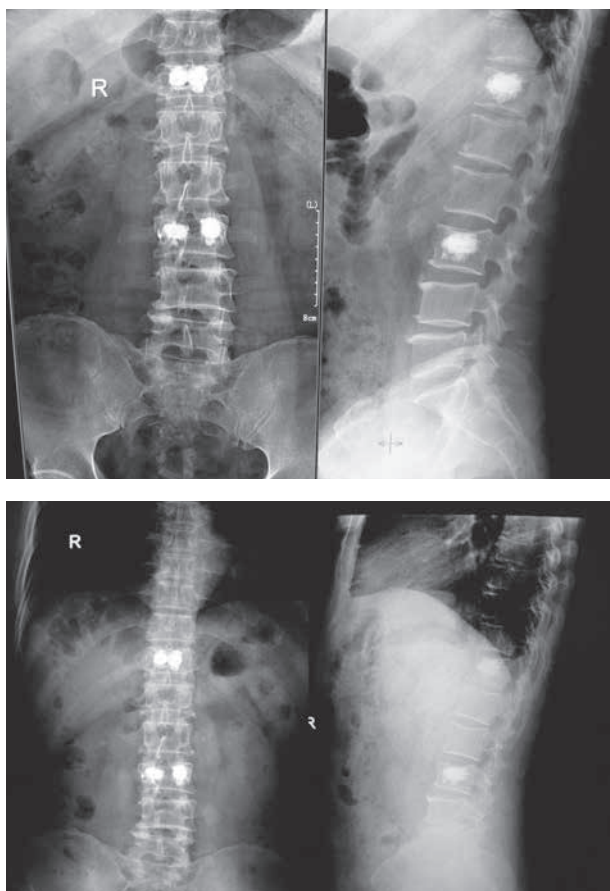


Fig. 3. — Same case after Crosstrees pod kyphoplasty

restore vertebral height) as the Crosstrees® pod, with a previously known shape and volume, is inflated synchronously with the PMMA cement. In addition to managing osteoporotic vertebral compression fractures, C-pod kyphoplasty, in a fashion similar to balloon kyphoplasty, might be useful in managing patients with : (1) symptomatic vertebral burst fractures due to osteoporosis, (2) symptomatic vertebral haemangioma with back pain, (3) neglected vertebral compression fractures with severe kyphotic deformity and back pain, and (4) osteolytic vertebral metastases.

A disadvantage of the C-pod kyphoplasty might be its high cost (~8,000 \$) compared with vertebroplasty (~2,500 \$) and balloon kyphoplasty (~5,000 \$). Moreover, Crosstrees pods are single use, unlike the balloons used for kyphoplasty, which can be used

repetitively. A bilateral insertion requires two devices, further adding to the cost.

The present study has some limitations : the relatively small sample, the lack of randomization, and the relatively short follow-up period. However, the authors believe that this study will promote the C-pod kyphoplasty as a promising technology, warranting further research and randomized controlled trials.

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