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Technical note

Treatment of vertebral compression fractures with the cranio-caudal expandable implant SpineJack®: Technical note and outcomes in 77 consecutive patients

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ABSTRACT

In vertebral compression fractures, the potential of kyphoplasty for restoring vertebral height is limited by the loss of restored height that occurs when the balloon is deflated and removed. SpineJack® is also inserted percutaneously but is then left within the vertebral body after its expansion to reduce the fracture, thus avoiding loss of correction before the injection of cement. SpineJack® was used in 77 patients to treat 83 recent VCFs (55.4% at L1–L2) due to trauma (59.7%) or osteoporosis (40.3%). Three (3.9%) complications were recorded, but none was related to SpineJack®: there was one case each of symptomatic cement leakage along a secondary pedicular fracture line; infection; and incipient device migration at the beginning of the learning curve. The rate of adjacent fractures was only 2.6%. The 5-year outcomes demonstrate that SpineJack® provides both immediate and long-term benefits in terms of pain relief, functional recovery, and maintenance of vertebral height restoration.
Level of evidence: IV, retrospective study.

1. Introduction

In patients with vertebral compression fractures (VCFs), non-operative treatment is often poorly tolerated. Both vertebroplasty and kyphoplasty performed percutaneously have been found effective over the last few years in treating symptomatic VCFs. Although adverse events are rare with both techniques, vertebroplasty is associated with higher rates of procedure-related complications and cement leakage [1–5]. With kyphoplasty, a disadvantage is the significant loss of restored vertebral height that can occur after balloon deflation [6]. Newly introduced minimally invasive techniques include the cranio-caudal expandable implant SpineJack® (Vexim, Balma, France), which is designed both to restore the original vertebral shape and to stabilise the fractured vertebra via the injection of high-viscosity polymethylmethacrylate (PMMA) bone cement (Cohesion®, Vexim). In two studies of cadaver vertebrae, vertebral height restoration was significantly better with SpineJack® than with kyphoplasty [6,7]. We report our experience acquired with SpineJack® between October 2007 and December 2012.

1.1. Description of the technical procedure

The percutaneous transpedicular approach with fluoroscopic guidance is used to insert the SpineJack® (Fig. 1) device into the vertebral body, under the most caudal part of the collapse. Expansion of the device applies a 500-Newton distraction force to the fracture, along the cranio-caudal axis, similar to a jack. Device expansion is achieved using a specific tool that pulls the two ends of the implant towards each other, shortening the device and deploying the central titanium component. A rack-and-pinion system blocks the expansion of the implant at the desired height, while preventing any loss of correction before the injection of PMMA, which envelops the implants, ensuring definitive stabilisation of the fracture (Fig. 2). In our case-series, although two generations of the SpineJack® device were used (SpineJack® G1 and SpineJack® G2), the same operative technique was followed in every case. The main technological difference between the two generations is that the most recent version has a rack-and-pinion system along the implant retraction axis, to prevent loss of correction after fracture reduction. Fig. 3 illustrates the results obtained on an A3.1 fracture of L1.

1.2. Clinical case-series

The case-series included 77 patients with a mean age of 60.9 years and 83 VCFs treated with 164 SpineJack® devices. Of the 83

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Fig. 1. The SpineJack® implant before and after expansion.

fractures, 51 were due to trauma and 32 to osteoporosis. The time to surgery was less than 15 days in 74.4% of cases. The procedure was performed on a single vertebral body in 71 patients and on two vertebral bodies in 6 patients. The distribution of fracture types in the Magerl classification was as follows: A1, 47.2% (A1.2, 30%); A2, 41.4%; and A3.1, 11.4%. The most frequently affected levels were L1 (32.5%), L2 (22.9%), and T12 (16.9%). Mean hospital stay length was 3.7 days and mean follow-up was 35 months (6 to 67 months). Pain relief was statistically significant ($P < 0.001$), with a pain score decrease from 7.9 pre-operatively to 1.8 post-operatively (Fig. 4).

No complications related to the SpineJack® device were recorded. Of the 77 patients, 3 (3.9%) experienced procedure-related complications. The only case of device migration reflected a technical problem that occurred with an instrument prototype. Post-operative computed tomography (CT) scans showed cement leakage in 11 patients, all of whom had post-traumatic fractures (21.6% of traumatic fractures). Symptoms were present in a single patient, who had nerve root pain due to leakage of the cement along a secondary fracture line in the pedicle. No recurrent compression fractures developed at the treated sites. Adjacent fractures occurred in 2.6% of cases. No re-operations were needed on treated vertebrae. One patient experienced a nosocomial skin infection that was probably due to contamination from an oral infection and had a favourable outcome after antibiotic therapy.

2. Discussion

The results of this 5-year retrospective study show that the SpineJack® procedure is effective for the management of high- and medium-energy fractures. Fracture reduction and stabilisation by combining SpineJack® implantation and cement injection consistently produced immediate improvements.

The visual analogue scale (VAS) pain score showed a significant decline, which occurred rapidly and proved long-lasting. The pain score improvement was 77% at hospital discharge and increased

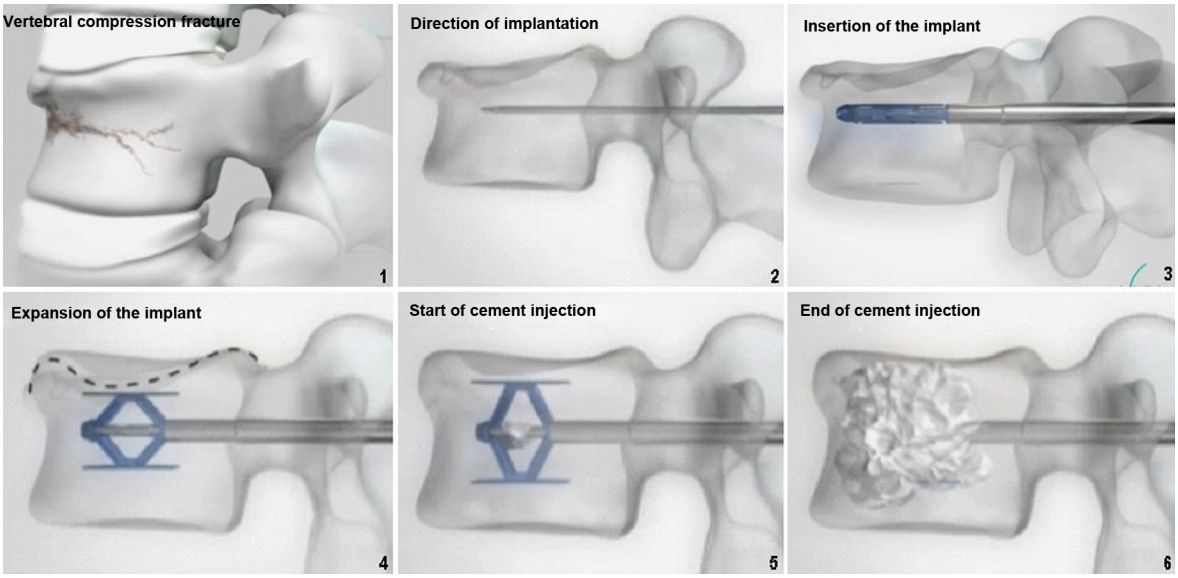

Fig. 2. Mechanism of action of the SpineJack® implant.

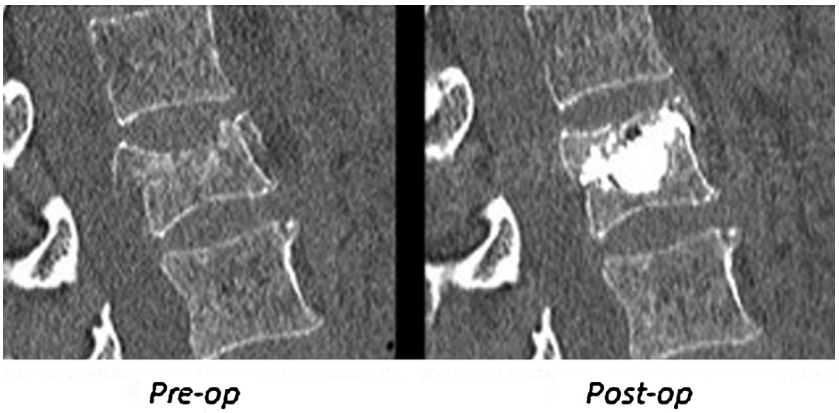

Fig. 3. 64-year-old woman with a post-traumatic type A3.1 fracture of L1. Computed tomography before and after the SpineJack® procedure.

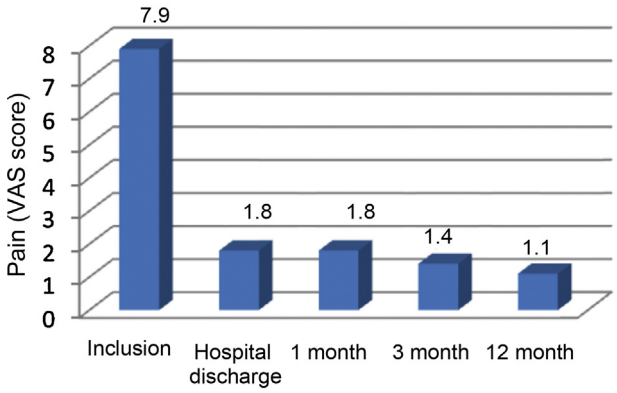

Fig. 4. Pain score changes over time.

gradually to 86% after 1 year. These gains are far greater than the 33% score decrease considered to be clinically significant [8]. The 86% improvement after 1 year was larger than the improvements seen in a study comparing kyphoplasty to the KIVA® VCF system (68% and 67%, respectively) [9]. The VAS score showed a greater mean decrease (6.9 points after 1 year) than reported previously with vertebroplasty and kyphoplasty (mean 4–5 point decrease for both procedures) [4].

This study establishes the safety of the minimally invasive SpineJack® procedure. Thus, only 3 (3.9%) patients experienced procedure-related complications and a single patient had a superficial infection. The cement leakage rate in the subgroup with post-traumatic VCFs (21.6%) was similar to that reported by Maestretti et al. (6/33 fractures, 18.8%) [10]. This result may be ascribable to the very good diffusion of the cement in the vertebra, from one endplate across to the other, along the trabecular network restored by reducing the fracture [11]. The rates of adjacent fractures were 2.4% of treated fractures and 2.6% of patients, i.e., considerably lower than the 10% to 22% rates reported with vertebroplasty and kyphoplasty [3,12].

3. Conclusion

This study establishes the effectiveness of the SpineJack® procedure, which provides immediate and long-lasting pain relief, as well as a rapid return to self-sufficiency. The complication rate is similar to that seen with other vertebral expansion methods, whereas the risk of adjacent fractures is very low.

Disclosure of interest

The author declares that he has no competing of interest.

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