Pilot Study

Treatment of Thoracolumbar Type A3 Fractures Using a Percutaneous Intravertebral Expandable Titanium Implant: Long-term Follow-up Results of a Pilot Single Center Study

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Background: There are controversies about the optimal management of AO subtype A3 burst fractures. The most common surgical treatment consists of posterior fixation with pedicle screw and rod augmentation. Nevertheless, a loss of correction in height restoration and kyphotic reduction has been observed.

Objectives: The aim of this study was to assess long-term outcomes of a minimally invasive technique using a percutaneous intravertebral expandable titanium implant (PIETI).

Study Design: This prospective, single center, pilot study was carried out on a consecutive case series of 44 patients with acute (< 2 weeks) traumatic thoracolumbar fractures AO type A3. The average follow-up was 5.6 years

Setting: A single center in Castilla y Leon, Spain

Methods: Clinical outcomes (pain intensity on visual analog scale [VAS], Oswestry Disability Index [ODI], analgesic consumption) and radiographic outcomes (anterior/mid/posterior vertebral body height, vertebral area, local kyphosis angle, traumatic regional angulation) were analyzed before surgery, at one month after surgery, and at the end of the follow-up period.

Results: At one-month postsurgery, significant improvements in VAS score and ODI score were observed. PIETI achieved significant vertebral body height restoration with median height increases of 2.9 mm/4.3 mm/2.3 mm for anterior/middle/posterior parts, respectively. Significant correction of the local kyphotic angle and improvement of the traumatic regional angulation were accomplished. All these improvements were maintained throughout the follow-up period. The only complication reported was a case of cement leakage.

Limitations: In our opinion, the main limitation of the study is the small number of patients. However, the sample is superior to that shown in other papers.

Conclusions: This study showed that using a PIETI in the treatment of fractures type A3 is a safe and effective method that allows marked clinical improvement, as well as anatomical vertebral body restoration. Unlike with other treatments, results were maintained over time, allowing a better long-term clinical and functional improvement. The rate of cement leakage was lower than other reports.

Keywords: Traumatic thoracolumbar fractures, burst fractures, AO type A3 fractures, kyphoplasty, percutaneous intravertebral expandable titanium implant

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More than half of traumatic spinal fractures are thoracolumbar burst fractures, the AO subtype A3 being the most prevalent (1). There is no general consensus on the most optimal management of such fractures.

There are few articles reporting isolated kyphoplasty (KP) techniques for the treatment of vertebral A3 fractures (1-3) as these procedures were contraindicated for such fractures due to the high risk of channel leakage related to posterior wall involvement.

In order to improve the effectiveness of vertebral augmentation procedures and reduce complications (1,4-6), new minimally invasive techniques have been introduced. Among them we have a surgical procedure using a percutaneous intravertebral expandable titanium implant (PIETI) (SpineJack®, Stryker, Kalamazoo, MI). This implant allows an anatomical restoration of the fractured vertebra including the reduction of the cortical ring, as well as the anatomical restoration of the vertebral plate (Fig. 1). The stabilization of the fractured vertebra is achieved by using a high viscosity injectable polymethylmethacrylate (PMMA) cement (Cohesion®, Vexim SA, France). We have previously shown in osteoporotic vertebral compression fractures that results of PIETI, with respect to ballon kyphoplasty (BKP), have been shown superior in terms of vertebral height restoration and maintenance over time (5,7). The experience and results obtained in lower grade vertebral compression fractures has allowed us to transfer this technique to type A3 fractures.

However, PIETI, by decreasing the volume of cement needed and the unidirectional craniocaudal direction of forces, allows this implant to be used for the treatment of A3 fractures. This pilot, prospective, single center study is the first study assessing the long-term outcome of results obtained with this implant in these types of fractures.

Fig. 1. *Titanium expansive implant.*

In a recent long-term study, vertebral height restoration/kyphotic correction observed with PIETI was still evident at 36 months with a prominent mean correction of the anterior and central vertebral height and a significant correction of the vertebral body angle (5). In addition, this long-term effect is obtained by injecting a lesser amount of cement compared to what would be necessary with other techniques, thereby potentially reducing the possibility of complications due to cement leaks (8).

Methods

Patient Population

Data were collected prospectively in a single center from a consecutive case series of 44 patients with traumatic A3 thoracolumbar fractures (according to the AO Spine Thoracolumbar Classification System) treated surgically using an intravertebral implant of expandable titanium (SpineJack®) between October 2008 through December 2013. All patients suffered from fresh fractures (< 2 weeks) resulting from a high-energy trauma. Follow-up of patients was carried out according to the investigator's standard care practice without any further investigation required by the protocol. Prior to surgery, all patients underwent a complete physical examination, including a detailed medical history and a complete radiological examination with simple x-rays, computed tomography and magnetic resonance imaging to confirm the presence, location, and severity of the thoracolumbar fractures.

Surgical technique. The surgery was performed within the first 2 weeks postfracture. Patients were operated on while under general anesthesia using a biportal transpedicular approach with the use of biplane fluoroscopy. The operative technique has been already described in a previous study (9). The cement volume injected was recorded. Patients were mobilized under supervised physiotherapy on the first day after surgery and were discharged on the same day.

Outcome measures. Outcomes were evaluated at baseline (before surgery), at one month after surgery, and then over a 5-year follow-up period postsurgery. The schedule of visits over one year following surgery was not imposed by the protocol, but from the end of the first year after the procedure, patients underwent

yearly visits. Preoperative and follow-up radiological evaluations measured anterior vertebral body height, middle vertebral body height, and posterior vertebral body height of the fractured vertebra; as well as local vertebral kyphosis angle, vertebral body area, and traumatic regional angulation. At the same time points, all patients were clinically evaluated using a visual analog scale (10) and the Oswestry Disability Index (ODI) (11) to assess pain intensity and functional capacity, respectively. Each patient's analgesic consumption was also recorded.

Statistical analysis. All statistical analyses were performed at the 0.05 global significance level using 2-sided tests. Efficacy endpoints were analyzed in all successfully implanted patients. Within-group tests were used to assess the evolution of efficacy parameters at each follow-up visit compared to baseline. Between-group comparison "male versus female" patients was done using Student's t test or Wilcoxon's test for quantitative parameters, and Chi-square test or Fisher's exact test or McNemar's test for qualitative parameters.

This study was conducted in accordance with the Declaration of Helsinki, including amendments as well as the International Council for Harmonization Good Clinical Practice guidelines, the European Standard EN ISO14155/2003- 2011, and the laws and regulations of the country in which the research was conducted. All patients gave their informed consent before enrollment. Ethical approval from local authorities was obtained.

Results

Demographics, preoperative characteristics, and the vertebral level treated are shown in Table 1. Radiographic parameters (Figs. 2 and 3) showed that the treatment with PIETI achieved vertebral body height restoration, improved local and regional kyphotic angles, and increased vertebral body area. The only significant difference found between men and women were the correction in traumatic regional angulation. It was significantly better in men than in women one month after surgery (median: -6.89° vs -4.77°; P = 0.024) and at the final follow-up (median: -7.43° vs -5.00°; P = 0.028). Until the end of the follow-up period, this surgical technique was able to maintain the obtained postprocedure height of the 3 vertebral body parts.

With respect to clinical parameters of pain and function (Fig. 4), a substantial improvement in pain and disability was observed at one month postsurgery and it was maintained throughout the follow-up period. At the end of the observation period, the decrease in ODI score was significantly more marked in women than in men with a 10-point median difference (P = 0.015).

This marked clinical improvement was reflected in the high percentages of patients who did not take any analgesics at one month after surgery (75.0%) and at the end of the follow-up period (90.9%).

The only complications we found were cement leakages (6 minor paravertebral leakages diagnosed by computed tomogrpahy and one intradiscal leakage). There was no leakage into the spinal canal, neural foramina, or epidural space.

Table 1. *Demographics, preoperative characteristics, surgical procedure.*

	Women (n = 29)	Men (n = 15)	Total (n = 44)	*P* value
Age at surgery (years)				
Mean (SD)	58.1 (8.7)	52.9 (10.9)	56.4 (9.7)	0.092 (Student)
Median (min; max)	57 (34; 78)	54 (34; 67)	57 (34; 78)	
BMI (kg/m²)				
Mean (SD)	30.8 (3.6)	27.9 (5.1)	29.8 (4.4)	0.048 (Wilcoxon)*
Median (min; max)	31 (24; 37)	28 (26; 29)	29 (14; 37)	
Known osteoporosis				
n (%)	9 (31.0%)	0	9 (20.5%)	
Treated vertebral level				
T11	1 (3.4%)	1 (6.7%)	2 (4.5%)	0.339 (Fisher)
T12	2 (6.9%)	2 (13.3%)	4 (9.1%)	
L1	11 (37.9%)	8 (53.3%)	19 (43.2%)	
L2	10 (34.5%)	1 (6.7%)	11 (25.0%)	
L3	4 (13.8%)	2 (13.3%)	6 (13.6%)	
L4	1 (3.4%)	1 (6.7%)	2 (4.5%)	
Cement volume (mL)				
Mean (SD)	3.87 (0.46)	3.61 (0.21)	3.78 (0.41)	0.023 (Wilcoxon)*
Median (min; max)	3.80 (3.00; 4.80)	3.60 (3.00; 4.00)	3.60 (3.00; 4.80)	
Duration of follow-up (months)				
Mean (SD)	70.07 (15.82)	60.53 (13.41)	66.82 (15.57)	0.058 (Wilcoxon)*
Median (min; max)	72.0 (48.0; 100.0)	56.0 (48.0; 103.0)	60.0 (48.0; 103.0)	

* This test was used instead of Student's t test because data were not normally distributed (Shapiro Wilk's test).

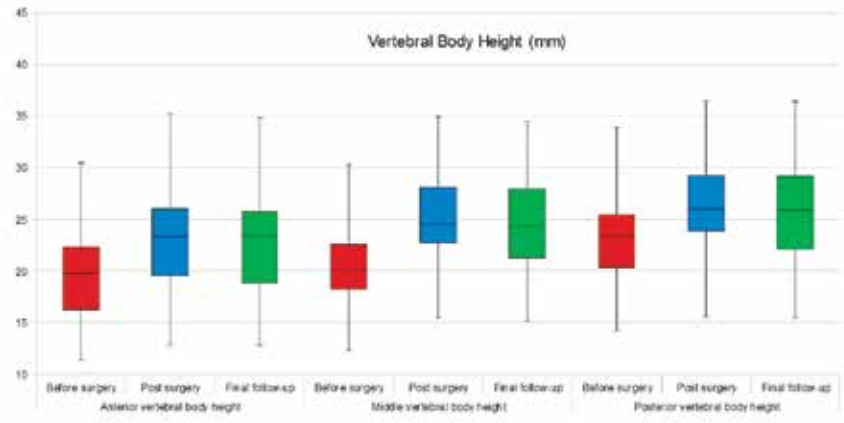

Fig. 2. *Anterior, middle and posterior vertebral body height before surgery, at one-month postsurgery and at final follow-up. These box plots display the distribution of data based on minimum, first quartile, median, third quartile, and maximum.*
$P < 0.001$

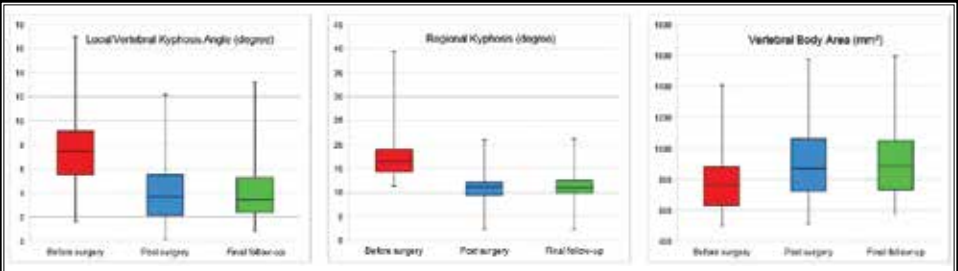

Fig. 3. *Local vertebral kyphosis angle, regional kyphosis, and vertebral body area before surgery, at one-month postsurgery and at final follow-up. These box plots display the distribution of data based on minimum, first quartile, median, third quartile, and maximum.*
$P < 0.001$

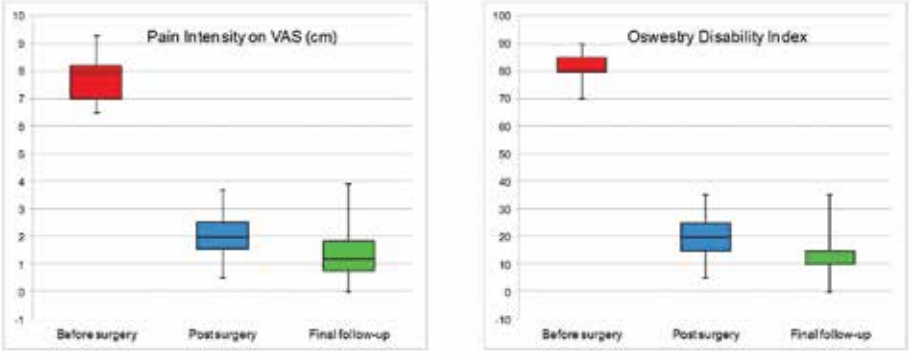

Fig. 4. *Pain intensity and disability before surgery, at one-month postsurgery and at final follow-up. These box plots display the distribution of data based on minimum, first quartile, median, third quartile, and maximum.*
$P < 0.001$

Discussion

Most studies investigating the benefits of kyphoplasty do not include type A3 fractures (7). This is because when performing a BKP, a cavity is created inside the fractured vertebra which causes the preferential flow of cement into the cavity rather than into the medullary bone adjacent to the fracture (12). This cement flow limits the interdigitation of cement into the bony trabeculae (12). In the case of A3 fractures that have posterior wall fractures by definition, the possibility of cement migration into the spinal canal is much higher and that is why many surgeons do not consider them suitable for treatment with BKP (1).

This is the first work that considers both the radiographic and clinical changes that occur after the treatment of A3 fractures using PIETI. With this technique, previous data showed that it is possible not only to reduce the fracture but also to maintain the restoration of the vertebral endplate in the long term. This implant concept is based on the "in situ fracture reduction" principle, whereby an intravertebral body implant is expanded in situ to potentially restore the anatomy of the vertebral body me-

chanically. The device is inserted transpedicularly into the fractured vertebral body in an unexpanded format. After insertion into the vertebral body, the implant is expanded using a specially designed tool. Longitudinal compression of the device causes the implant to open in the inferior-superior direction. Afterwards, conventional PMMA bone cement is injected to stabilize the restored vertebra. Thereby, there is cranio-caudal expansion control, where the distraction effect is made by expanding the implant wings in a superoinferior direction (Figs. 5-7). In this way, healthy medullary bone still exists on both sides, which facilitates the diffusion of the cement in the vertebral body, thus reducing the risk of extravasation into the fracture clefts extending through the posterior vertebral body wall.

In our study, the use of PIETI allowed us to obtain statistically significant improvements in radiographic and clinical parameters one month after surgery. For pain, the 74.7% decrease is more than twice the 30% change from baseline which is considered a clinically significant improvement (13). These results were maintained over the follow-up period without significant losses in vertebral body height restoration and no deterioration in angle corrections. Painkillers for the reason of back pain were used in one-fourth of patients one month after surgery and only in 9.1% of patients at the end of the follow-up period. Moreover, this implant displayed an excellent safety profile with only one case of cement leakage.

Statistically significant differences were observed between men and women in the evolution of the ODI score and traumatic regional angulation, but the difference in ODI at the end of the follow-up period was not clinically significant. With respect to traumatic regional angulation, the difference between genders cannot be explained with the current data. In future studies, the potential influence of factors such as muscle strength, body mass index, and paravertebral muscle fat infiltration should be taken in consideration in the design of the study.

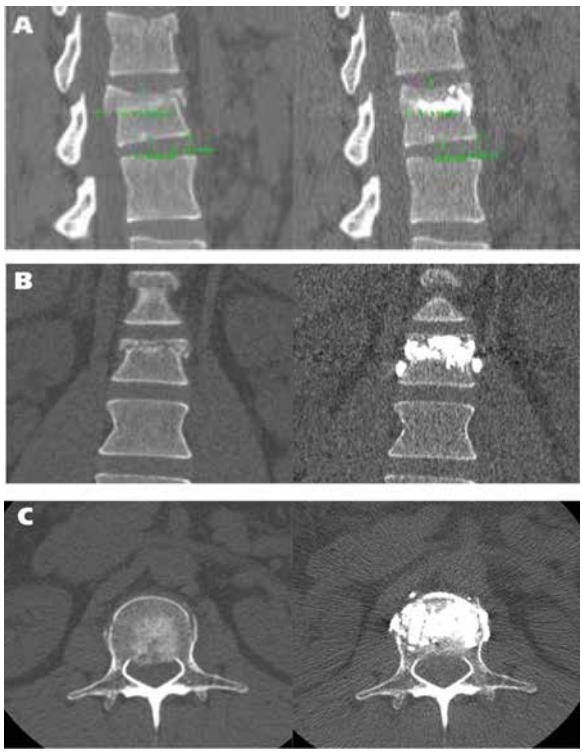

Fig. 5. *Preoperative and postoperative lateral computed tomography (CT) scan (5A), preoperative and postoperative anteroposterior CT scan (5B), operative CT scan (5C).*

Fig. 6. *Full standing x-ray.*

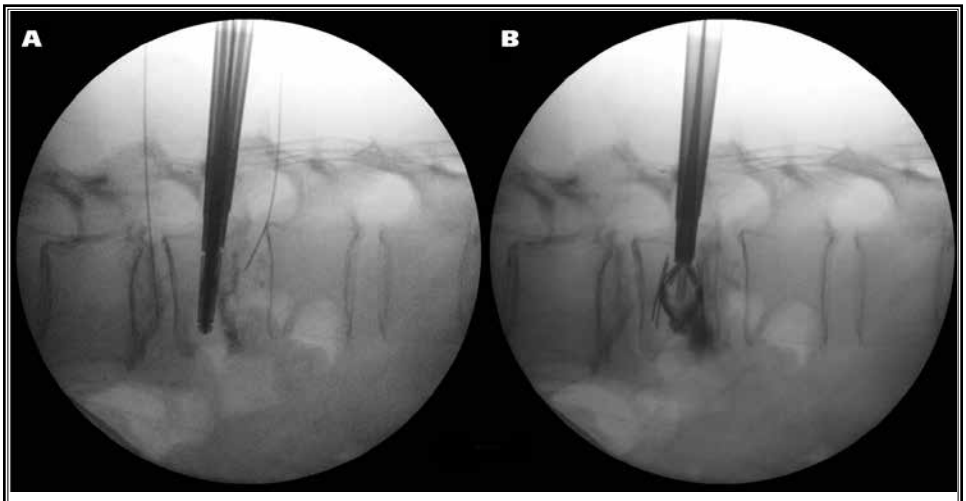

Fig 7. *Mechanism of vertebral reduction by titanium expansive implant. Closed implant (A) and open implant without PMMA cement (B). The implant has a craniocaudal opening mechanism that allows the reduction of vertebral height. By increasing vertebral height it also allows the retropulsion reduction.*

Our study involved a larger sample size of patients and a much longer follow-up period than previous published studies. Moreover, differences in assessment criteria and timelines for follow-up visits make comparisons between studies difficult.

Carbognin et al (14) reported their preliminary experience with BKP using injection of acrylic cement in 4 patients with type A3 burst fractures. They showed that patients noticed an important clinical improvement after surgery. Despite the clinical improvement, there was a worsening of radiological parameters throughout the follow-up, unlike what occurred in our patients, in whom the improvement was maintained over time (14).

In 2012, Hartmann et al (1) presented the results of a study using kyphoplasty without associated posterior instrumentation. They show a postoperative height restoration to 0.88 with a subsequent loss of height at follow-up to 0.8 and a reduction in regional kyphosis with a loss of correction to -8.1° at follow-up. They presented an associated improvement in pain, but they did not show an improvement in quality of life parameters at the end of the follow-up. Six minor ventrocranial cement leakages into the superior disc space were reported during this study (1).

Short-segment pedicle screw and rod fixation in conjunction with BKP seems to be a feasible option in the management of lumbar burst fractures as shown by Afzal et al (3). One month after surgery, they obtained a significant correction of the kyphosis of 11°. Central and anterior height of the vertebral body were significantly restored using this technique. . Cement leakages were reported in 3 patients, with 2 patients having leakage in the spinal canal, and one patient into the caudal disc space.

Oner et al (2) described the insufficiency of the anterior column as a consequence of the fracture. This mechanism of injury can also lead to internal disc disruption that decreases the anterior support and places more force on the posterior instrumentation. The instrumentation placed posteriorly will only have an effect through the ligamentotaxis, without having any capacity to reduce the vertebral endplate in the central area. Due to this fact, it is useful to use kyphoplasty techniques that reduce not only the cortical vertebrae but also the central vertebral body area. For this, they performed a trial using balloon-assisted endplate reduction and vertebroplasty (VP) with calcium phosphate cement as an adjunct to posterior short segment pedicle screw constructs. They corrected the kyphosis from 11° before surgery to -1.6° after surgery, and to 3.0° after instrumentation removal. Average central body height increased from 66% before surgery to 81% of the estimated intact height after surgery, and they maintained the same recovery up to 80% after instrumentation removal.

Nonetheless, in these studies (2,3), patients underwent the placement of pedicle screws with an inherent greater degree of surgical aggressiveness with the associated risk of malpositioning and the necessity of a second surgery for removal. The placement of the posterior instrumentation was done due to the tendency of balloon deflation to cause loss of vertebral body height as has already been shown in some works (1,4,5). This is precisely the scenario where the use of PIETI has the advantage due to its ability to establish and maintain the vertebral body height restoration. This is due to its self-locking system where once the vertebral height is recovered it cannot re-collapse and the

correction is also maintained over time as has already been described in other studies (5,9,15). With the use of PIETI the effect of restoration of the vertebral height and decreased kyphotic angulation is produced by its direct action on the vertebral endplate, thus achieving a better anatomical restoration. This is in contradistinction to pedicle screw and rod instrumentation where the restoration is produced by the positioning of the patient and distraction. Despite these data, authors such as He et al (16) still advocate the use of kyphoplasty associated with short spinal instrumentations, especially in the elderly. They showed that percutaneous internal fixation with BKP had significant advantages over simple BKP in terms of postoperative lumbar back pain relief and rapid recovery of motor function.

One of the most noteworthy aspects of PIETI use is the permanent improvement in vertebral body height and angles of regional kyphosis. It has been described that these improvements in anatomy are those that influence the later quality of life of the patients (17) . The FREE study (17) explored the link between vertebral body anatomy correction and quality of life in patients who underwent BKP and showed that patients with the highest kyphotic angulation correction had a higher quality of life improvement than the subgroup having the lowest correction of angulation. In our study we did not assess quality of life parameters, but it would be reasonable to assume that a significant correction of the kyphosis angle will cause a decrease in the tension moments, which means that the paraspinal musculature relax, the posture improves and the incidence of adjacent fractures decreases. It should also be noted that no adjacent fractures were reported in our patients over the long-term follow-up.

It seems important to state that fracture mobility is crucial to the success of the procedure and a key factor is the time elapsed since the occurrence of the fracture, because the shorter the time, the greater the ability to recover the vertebral height. When expandable implants are used in old fractures, there is the possibility that the implant will not expand, as already described by some authors when using other systems (12). So, we believe that the shorter the time to opt for surgical treatment, the better functional results will be achieved, thus enabling patients to recover their normal life.

Cement leaks are the main complication, so one important factor to consider is the quality and type of cement used. Currently, the use of high viscosity PMMA is widespread since it is an inert substance that provides immediate stability to the fracture. In the treatment of A3 fractures, PMMA may be used alone using VP and BKP techniques, or in conjunction with dorsal instrumentation. However, there are some limitations such as the risk of release of monomers into the bloodstream and the stimulation of fibrosis formation at the junction between the bone and the cement. For this reason, high viscosity PMMA has not been completely tested in young patients and the long-term effects in this population are unknown. Despite these data, we did not encounter any problem in younger patients from our series where the average age was 56 years. Other cements that are used are those composed of calcium phosphate. This type of cement has a negligible exothermic reaction during the setting of the cement, so that the possibility of injury to the surrounding tissues is lower. These cements, however, are difficult to handle due to their high viscosity and at present some authors do not recommend their use (18). In our study, the rate of cement leakage is the lowest we have found in the literature for these types of fractures. This observation can be explained by the fact that this type of implant allows the use of a minimum amount of cement to maintain the results over time. These findings correlate with those from Rotter et al(19) who showed that in traumatic wedge fractures of human cadaveric vertebral bodies, it was possible to reduce the amount of cement to 10% of the vertebral body volume when a PIETI is used without compromising the vertebral height after reduction (19). This is in contrast to kyphoplasty that needs a 30% cement volume. (19)

Compared with the few published studies on A3 fractures mentioned above, we would highlight that the present study with data from 44 consecutive patients has the largest sample size and the longest follow-up. The main limitation of our study is the absence of a control group. We could consider this study of PIETI in A3 fractures as a pilot study and our findings should allow us to determine the optimal sample size to assure adequate statistical power in future controlled studies. We did not assess quality of life parameters that might have been interesting to include in the statistical parameters and to investigate a possible correlation with clinical outcomes and radiological results.

Conclusion

This pilot study suggested that the use of PIETI for the treatment of traumatic thoracolumbar burst fractures type A3 is a safe and minimally invasive technique that has the potential to reduce complications from ce-

ment extravasation due to the minimum amount of cement utilized. It appears to be an effective method that allows marked clinical and functional improvements, as well as an anatomical restoration of the vertebral body as reflected by the significant postsurgery height restoration and kyphotic angle reduction. Additionally, unlike with other devices, the restoration was maintained in the long-term follow-up. This technique will allow the clinician to reduce or eliminate the need for posterior instrumentation, thereby reducing the inherent risks of the more invasive pedicle screw and rod placement.

Additional long-term randomized controlled studies with a sufficient number of patients are needed to confirm these encouraging results. In addition, it could be interesting in future studies to combine quality-adjusted life-year (QALY) measures with medical costs in order to estimate the cost-per-QALY associated with such interventions.

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