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IDEAS AND TECHNICAL INNOVATIONS

The pedicle instrumentation and percutaneous elevation (Pi.Pe): a new cementless surgical technique in type A post-traumatic vertebral fractures

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Abstract

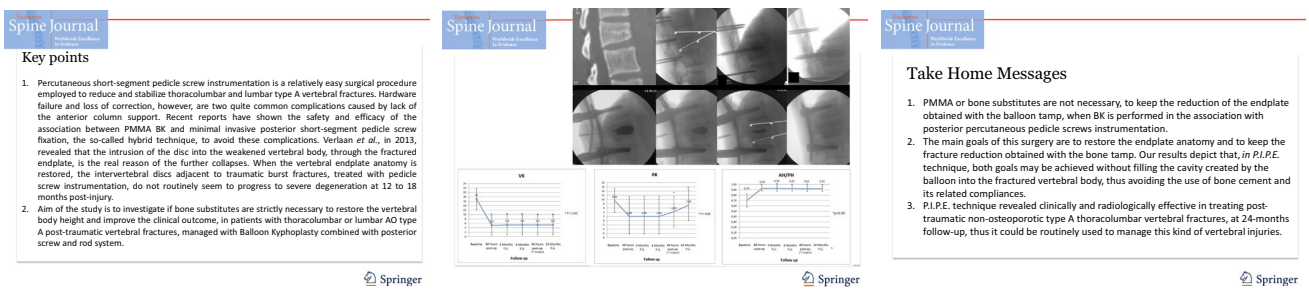
Purpose To investigate if bone substitutes are strictly necessary to restore the vertebral body height and improve the clinical outcome, in patients with thoracolumbar or lumbar AO type A post-traumatic vertebral fractures, managed with balloon kyphoplasty combined with posterior screw and rod system.

Methods 105 patients with post-traumatic thoracolumbar spine fracture were recruited. At baseline, the patients underwent a CT and an MRI of the spine. Clinical evaluation was performed, using the Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI), at baseline, 48 h after surgery, at 3-month follow-up (FU), 6-month FU, 48 h after the instrumentation removal and at 24-month FU. At each FU, VK, regional kyphosis (RK), central wall (MH/PH) and anterior wall (AH/PH) heights were assessed on lateral spine X-rays. At 6-month FU, a CT scan of the spine was performed to investigate the fracture healing. The posterior instrumentation was removed 7 months after surgery (range 6–10 months).

Results A significant reduction of mean VAS ($p < 0.05$) and ODI ($p < 0.05$) was observed after surgery; no impairment of these scores was observed after the instrumentation removal. A significant correction of VK, RK, AH/PH and MH/PH was recorded after surgery; no significant changes of these values were noticed at subsequent FU. After the instrumentation removal, only an RK impairment was recorded, but it was not significant.

Conclusions PMMA or bone substitutes are not necessary to keep the reduction of the endplate obtained with the balloon tamp, when BK is performed in the association with posterior percutaneous pedicle screws instrumentation.

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.



Keywords Percutaneous pedicle screw · Vertebral fracture · Cementless kyphoplasty · P.I.P.E. technique · Bone substitutes

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Introduction

Percutaneous vertebroplasty (PV) was originally described in 1987 by Galibert, et al., who described the efficacy of this minimally invasive technique in the treatment of painful vertebral haemangiomas [1]. Balloon kyphoplasty (BK) was introduced later as a modification of PV, in which a balloon tamp is inflated in the vertebral body, to compress the cancellous bone and create a cavity, which is subsequently filled with polymethylmethacrylate (PMMA) [2].

Currently, PV and BK are commonly used in the treatment of AO type A acute osteoporotic vertebral fractures, as they have shown a positive impact on back pain relief and quality life improvement [3, 4].

The management of AO type A post-traumatic thoracolumbar vertebral fractures (VF), however, is still matter of debate. Both conservative and surgical treatments have been described, but a significant number of patients complains persistent back pain and a reduced mobility, several months after the trauma, with a consequently long-term recovery, an impaired quality of life and high health and social care costs [8, 9]. Only a few studies have evaluated the effectiveness of PV and BK in the treatment of post-traumatic VF, due to the higher risk of PMMA observed in this pattern of spine injuries, compared with osteoporotic spine lesions [5–7].

Thus, the search for a minimally invasive technique that could improve the management of post-traumatic VF, in order to achieve a good functional outcome and a low rate of intra- and post-operative complications, is gaining an increasing importance.

Percutaneous short-segment pedicle screw instrumentation is an easy surgical procedure that could be performed to reduce and stabilize thoracolumbar post-traumatic type A VF. The hardware failure and the loss of reduction, however, are two quite common complications that could be observed in this technique because of the lack of the anterior column support [10, 11].

Transpedicular spongioplasty is a surgical procedure, originally described by Daniaux in 1986, which aims to overcome the failure of posterior short-segment instrumentation, by associating transpedicular autologous bone grafting to posterior stabilization [12]. Subsequent studies have shown that transpedicular spongioplasty has a low reliably and reproducibly in the prevention of kyphosis recurrence [13, 14].

Recent reports have demonstrated that BK with PMMA can be safely associated with posterior percutaneous instrumentation, in the management of post-traumatic type A VF [15, 16]. Nonetheless, there is a lack of evidence that the vertebral body height restoration, observed after this surgical procedure, depends on the cement injection into the fractured vertebral soma, rather than on the surgical technique itself.

This study aims to investigate if bone substitutes are strictly necessary to restore the vertebral body height and improve the clinical outcome, in patients with thoracolumbar or lumbar AO type A post-traumatic VF managed with BK combined with posterior screw and rod system.

Material and method

Patients and methods

Between March 2010 and November 2015, 105 patients (62 males, 43 females, with an average age of 29.2; range 14–48 years old) with post-traumatic and non-osteoporotic thoracolumbar or lumbar spine fractures were treated with cementless balloon kyphoplasty, combined with posterior screw-rod system. The acronym "P.I.P.E." that means *Pedicle Instrumentation and Percutaneous Elevation* was used to identify this technique. The clinical study proposal was approved by the medical ethical committee of the authors' Institution.

Inclusion criteria were: type A thoracolumbar or lumbar vertebral fractures; absence of neurological deficit; one or more of these features (signs of vertebral instability; an anterior body wall compression > 50° or a vertebral kyphosis > 15°).

Exclusion criteria were: the absence of a traumatic event; osteoporosis, defined as lumbar or hip *T* score < − 2.5; history of spinal infections; pre-existent disease that could compromise surgical procedure, like previous vertebroplasty at the involved vertebrae; pregnancy; history of malignant neoplasm; BMI > 30; scoliosis > 40°; metal allergies; any contraindication to CT.

All patients were assessed clinically and radiologically at baseline, 48 h after surgery, at 3-month follow-up, at 6-month follow-up, 48 h after posterior instrumentation removal and at 24-month follow-up. Clinical evaluation was performed using Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI).

Lateral spine X-ray was performed at baseline and at each follow-up in order to measure: anterior-to-posterior vertebral body height (AH/PH); medial-to-posterior vertebral body height (MH/PH); vertebral kyphosis (VK) and regional kyphosis (RK).

At recruitment, the patients underwent a CT scan and an MRI of the spine to correctly classify the fracture. At 6-month follow-up, another CT scan was assessed to check the bone healing of the fracture, in order to plan the removal of the instrumentation, which was always performed before the onset of facet joints arthrosis.

Technique description

The surgical treatment was performed with the patient in prone position on a carbon fiber radiolucent operating tabletop, under general anaesthesia. A minimally invasive posterior approach was used; an X-ray image intensifier was employed by an experienced radiological technologist. Under C-arm control, the fractured vertebra and the entry point of the pedicle screws were identified. A skin incision of about 3 mm was made bilaterally over the pedicles of the injured vertebra. Bilateral percutaneous monoaxial pedicle screws were placed one or two levels above and below the fractured vertebral body. Two levels above and below were used only at the thoracolumbar junction, where the compression forces act more anteriorly [11]. Under fluoroscopic guidance, a kyphoplasty trocar was introduced along the pedicle of the injured vertebra and it was placed just beyond the posterior vertebral wall. A kyphoplasty balloon was then advanced into the vertebral body and slowly inflated, to allow both fracture reduction and vertebral height restoration. A rod of the adequate length and diameter (Longitude System. Medtronic, Minneapolis, Minnesota, USA) was than percutaneously implanted, intersecting the screw heads along a geometrically constrained pathway. The reduction of the rod into the screw tulip was finally performed and the closure top is subsequently fully tightened to shear and remove all screw extender sleeves. The balloon was then deflated and removed without filling the cavity (Fig. 1).

Statistical analysis

Power analysis was performed to identify the adequate sample size. The Kolmogorov–Smirnov test was performed to check the normality of the data distribution. Paired *t* test was used to assess the significance of the differences between pre- and post-operative measurements. The data are presented in terms of mean value and standard deviation (SD); a $p < 0.05$ was considered significant.

Results

105 patients (62 males, 43 females; average age 29.2; range 14–48 years old) were recruited for the current study. Power analysis revealed that the sample size was adequate. The site of fractures was L1 (40), T12 (25), L2 (11), T11(8), T10 (7), L4 (6), L3 (5), T9 (2), T8 (1). The mean time from the trauma, at surgery intervention, was 4 days (range 2–8 days). The main data of the study are summarized in Table 1.

The first operating time was 120 min (range 60–300 min). The maximum pressure of the balloons varied between 200 and 380 psi, within the safe operating range for the balloons (Medtronic, Minneapolis, Minnesota, USA). The

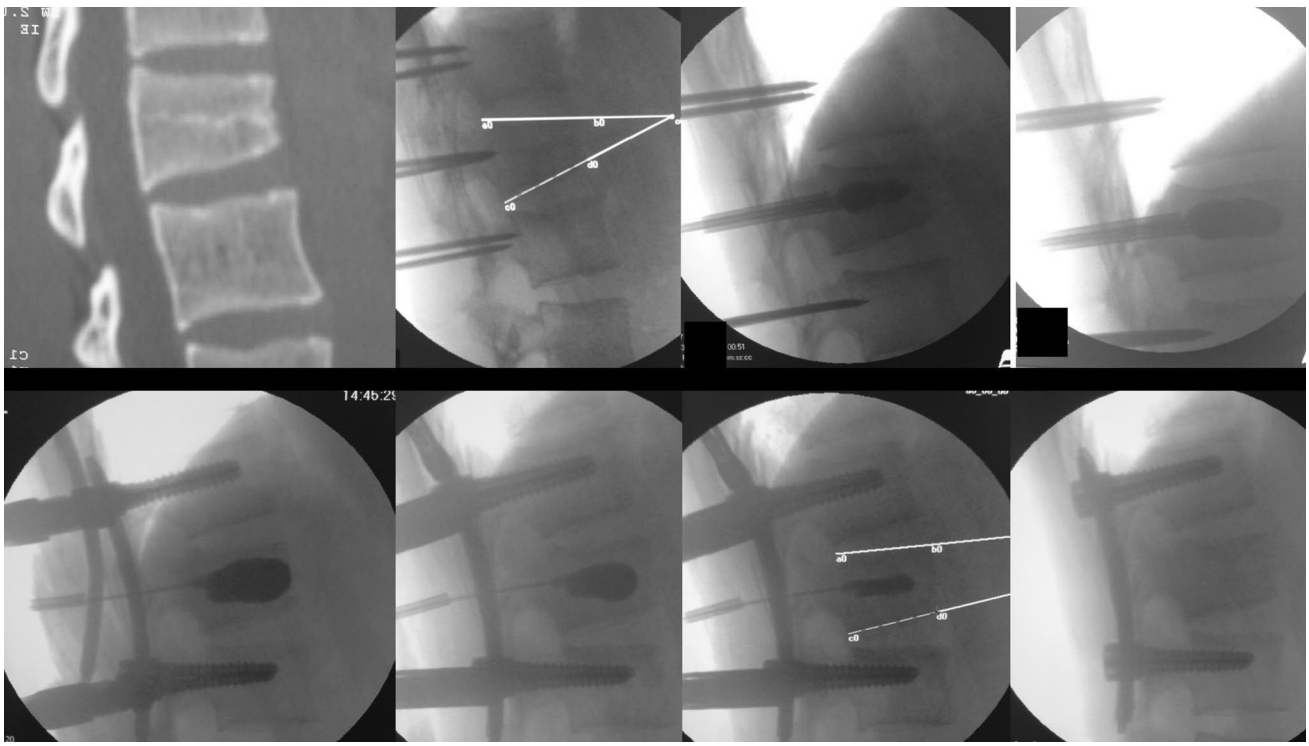

Fig. 1 CV male, L1 post-traumatic fracture. Main fluoroscopic images of P.I.P.E. technique

Table 1 Main data of the study

	VK	RK	AH/PH	MH/PH	VAS	ODI
Pre-operative						
Mean ± SD	17 ± 4.84	9.6 ± 5.7	0.7 ± 0.12	0.82 ± 0.1	8.5 ± 0.8	86.2 ± 8.16
Range (max–min)	25–10	21–1	31–15	0.94–0.62	9–7	
CI 95%	2.86	3.37	0.07	0.06	0.48	4.82
1st surgery (48 h post-op)						
Mean ± SD	5.10 ± 4.44	2.00 ± 8.38	0.93 ± 0.05	0.95 ± 0.01	8.90 ± 0.7	87.30 ± 7.94
CI 95%	2.62	4.95	0.03	0.01	0.41	4.69
p	0.001	0.003	0.001	0.001	0.84	0.92
3 months F.U.						
Mean ± SD	5.30 ± 4.52	2.00 ± 8.38	0.93 ± 0.06	0.95 ± 0.02	4.4 ± 1.2	33.2 ± 14.6
CI 95%	2.67	4.95	0.03	0.01	0.71	8.55
p	0.001	0.003	0.001	0.001	0.001	0.007
6 months F.U.						
Mean±SD	5.3 ± 4.52	2 ± 8.38	0.92 ± 0.07	0.95 ± 0.02	1.90 ± 1.22	13.4 ± 14.8
CI 95%	2.67	4.95	0.03	0.01	0.72	8.75
p	0.001	0.003	0.001	0.001	0.001	0.001
2nd surgery (48 h post-op)						
Mean ± SD	5.3 ± 4.52	4.2 ± 7.39	0.92 ± 0.05	0.95 ± 0.02	4.3 ± 1.35	36.1 ± 14.38
CI 95%	2.67	4.37	0.03	0.01	0.80	8.50
p	0.001	0.009	0.001	0.001	0.002	0.006
24 months after 1st surgery post-operative F.U.						
Mean ± SD	5.3 ± 4.52	7.4 ± 7.26	0.92 ± 0.05	0.95 ± 0.02	1.1 ± 0.94	7 ± 7.28
CI 95%	2.67	4.29	0.03	0.01	0.56	4.30
p	0.001	0.03	0.001	0.001	0.001	0.001

hospital stay averaged 8 days (range 4–15 days). A significant improvement of VAS-back pain ($p = 0.001$) and ODI ($p = 0.007$) scores was recorded at 3 month follow-up and at subsequent follow-ups (Figs. 2, 3).

The mean preoperative VK was 17° ± 4.84°; intraoperatively, after that BK was performed, it decreased to 5.10° ± 4.44°, with a mean deformity correction of 11.9° ($p < 0.05$). No significant loss of correction has been depicted after that the balloons were deflated, to place the vertebral pedicle screws. At subsequent follow-ups, no significant changes of mean VK were recorded at the subsequent follow-ups (Fig. 4).

Mean regional kyphosis (RK), measured at the level of the fracture, was 9.60° ± 5.7° at recruitment; after surgery, a significant improvement was recorded (mean ± SD 2° ± 8.38°) and no significant loss of correction was measured at 3- and 6-month follow-up (Fig. 5).

The mean preoperative ratio AH/PH of the fractured vertebra was 0.70 ± 0.12; post-operatively, it improved to 0.93 ± 0.05 ($p < 0.01$) and no further significant changes were found at 3- and 6-months follow-up (Fig. 6).

The mean preoperative MH/PH of the injured vertebra was 0.82 ± 0.12; post-operatively, a significant change of MH/PH was recorded (mean ± SD 0.95 ± 0.001; $p < 0.01$), while it remained stable at 3- and 6-month follow-ups (Fig. 7).

The CTs scan of the spine, performed 6 months after surgery, showed in all cases a good fracture repair. The instrumentation was consequently removed between 6 and 10 months (average 7 months) after trauma under general anaesthesia, to avoid the facet joints arthrosis (Fig. 8).

The second operating time was 35 min (range 25–50 min). The mean VK, AH/PH and MH/PH remained stable after removal of the screw-rod system (SRS). Only the mean RK registered a loss of correction due to the normal functional recovery of the segment of motion after the instrumentation removal (mean ± SD 2±8.38 before SRS removal; mean ± SD 4.20 ± 7.39 after SRS removal), but it was not statistically significant.

At the last follow-up, i.e. at 24 months after tama and 16 months after the removal of instrumentation, a further improvement of mean VAS (mean ± SD 1.10 ± 0.94) and ODI (mean ± SD 7 ± 7.28) was observed.

In this study, the breakage of the screw-rod system, spine or soft-tissues infection, new fracture at the level of surgery or at adjacent levels, neurological or vascular damage were never observed.

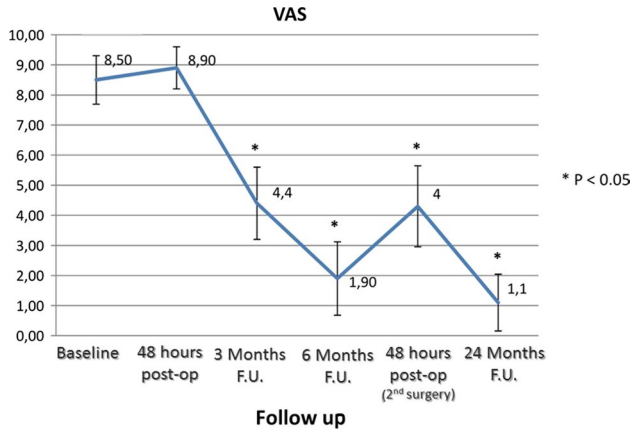

Fig. 2 The mean VAS values at baseline and at subsequent follow-ups. The error bars are represented. *$p < 0.05$, p values refer to the difference between each follow-up versus baseline (paired t test)

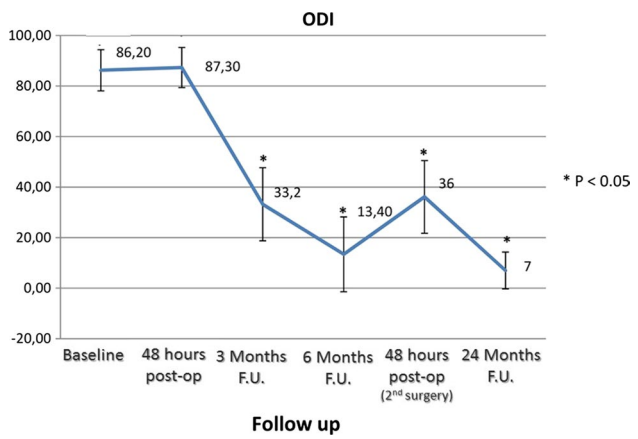

Fig. 3 The mean ODI values at baseline and at subsequent follow-ups. The error bars are represented. *$p < 0.05$, p values refer to the difference between each follow-up versus baseline (paired t test)

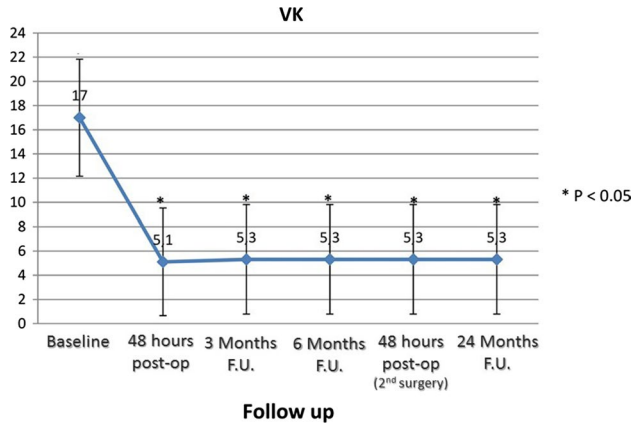

Fig. 4 The mean VK values at baseline and at subsequent follow-ups. The error bars are represented. *$p < 0.05$, p values refer to the difference between each follow-up versus baseline (paired t test)

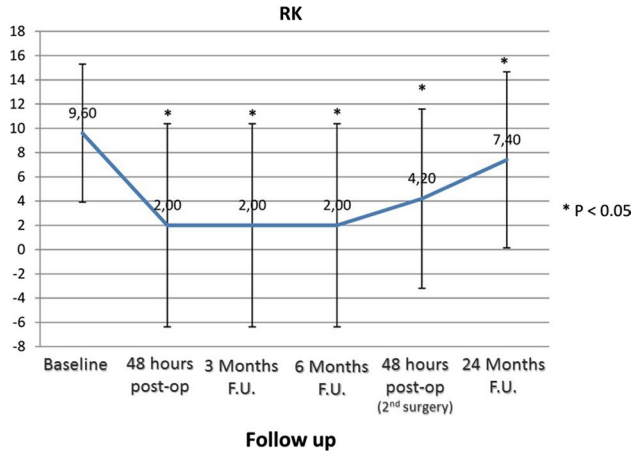

Fig. 5 The mean RK values at baseline and at subsequent follow-ups. After the second surgical procedure, the RK registered a non-significant loss of correction due to the normal functional recovery of the segment of motion after instrumentation removal. The error bars are represented. *$p < 0.05$, p values refer to the difference between each follow-up versus baseline (paired t test)

Discussion

The majority of thoracolumbar and lumbar type A amyelic vertebral fractures can be conservatively treated with bed rest for the first 30 days and subsequent gradual mobilization with a physical support, i.e. a brace or a corset, for about 3 months [17].

Surgical treatment, nonetheless, is recommended in patients with an AO type A vertebral fractures showing one of the following features: signs of instability; an anterior body wall compression greater than 50%; a spinal canal compromise greater than 50% or a vertebral kyphosis > 15° [8]. Different surgical treatments have been proposed to best manage unstable type A vertebral fractures, but the topic is still debated [13–16, 18–21].

Only a few studies have evaluated the efficacy of PV and BK in post-traumatic type A vertebral fractures and the results have been not very encouraging [18, 19]. Gioia et al. treated six patients with post-traumatic type A vertebral fractures (mean age 38) with BK and injection of calcium phosphate cement, without further vertebral stabilization [18]. In this paper the authors underline that, although all the patients had used a brace for 60 days after BK, the improvement of regional kyphosis, recorded immediately after the surgery, resulted totally lost at the first follow up, 45 days after surgery [19].

Percutaneous short-segment pedicle screw instrumentation is a relatively easy surgical procedure employed to reduce and stabilize thoracolumbar and lumbar type A

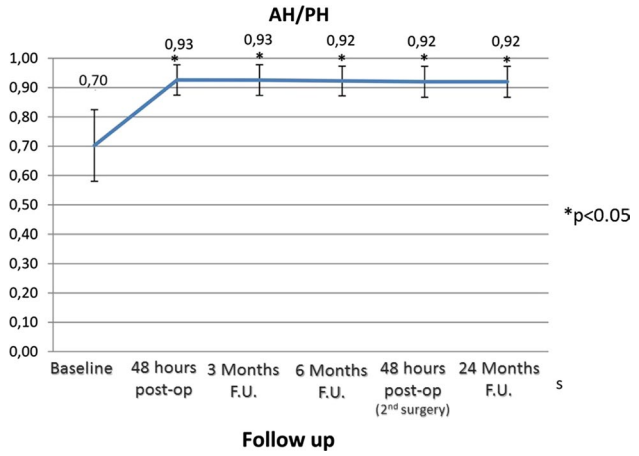

Fig. 6 The mean AH/PH values at baseline and at subsequent follow-ups. The error bars are represented. $*p < 0.05$, p values refer to the difference between each follow-up versus baseline (paired t test)

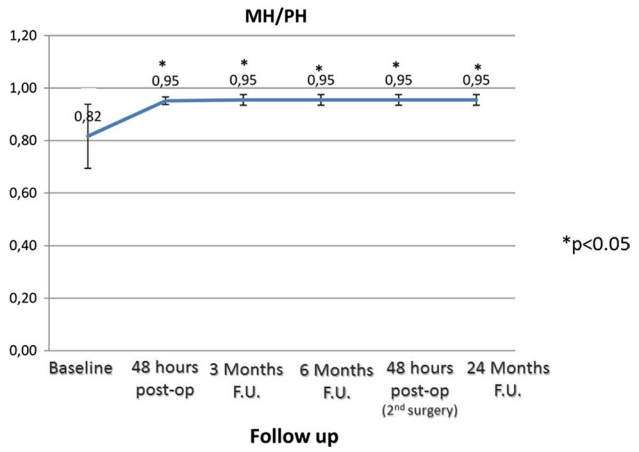

Fig. 7 The mean MH/PH values at baseline and at subsequent follow-ups. The error bars are represented. $*p < 0.05$, p values refer to the difference between each follow-up versus baseline (paired t test)

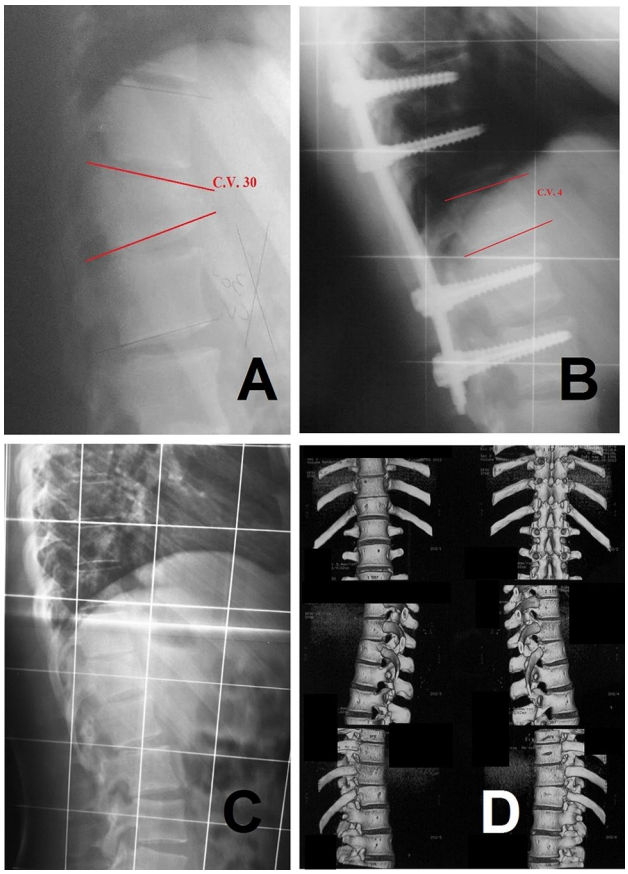

Fig. 8 GN male, 19 year old. T12 post-traumatic fracture. **a** Preoperative lateral view, VK 30°, **b** post-operative lateral view, VK 4°, **c** 6 months FU. Lateral view after second surgery procedure, **d** 6 months CT scan showing the complete bone healing

vertebral fractures. Hardware failure and loss of correction, however, are two quite common complications caused by lack of the anterior column support [13, 14, 20, 21].

Recent reports have shown the safety and efficacy of the association between PMMA BK and minimal invasive posterior short-segment pedicle screw fixation, the so-called hybrid technique, to avoid these complications [15, 16, 22–24].

Verlaan et al., in 2013, revealed that the intrusion of the disc into the weakened vertebral body, through the fractured endplate, is the real reason of the further collapses. When the vertebral endplate anatomy is restored, the intervertebral discs adjacent to traumatic burst fractures, treated with pedicle screw instrumentation, do not routinely seem to progress to severe degeneration at 12–18 months post-injury [16].

It is unclear, nevertheless, if the vertebral body height restoration depends on the cement injection into the fractured vertebral soma, rather than on the surgical technique itself.

The current study aims to evaluate if bone substitutes are strictly necessary to restore the vertebral body height, in patients with post-traumatic type A vertebral managed with hybrid techniques.

Our results showed that PMMA or bone substitutes are not necessary in hybrid constructs, so the percutaneous pedicle screws stabilization is enough to keep the reduction of the endplate anatomy obtained by BK, without filling the cavity created by the balloon, until the compression fracture is healed.

It is important to note that the complications rate is lower if we compare P.I.P.E. technique with the PMMA BK hybrid technique, as some studies have reported that the use of bone cement increases the rate of subsequent vertebral fractures

and the risk of stress shielding [3, 4, 6, 7]. Moreover, it should be noted that the risk of cement leakage is higher in post-traumatic vertebral fractures, because of the possible vertebral cortex and/or endplate fractures that can be observed in this pattern of injuries.

In the current study, the CT scans performed at 6 month follow-up showed that the cavities in the fractured vertebral bodies were no more detectable due to a complete bony filling. According to this finding, we concluded that bone substitutes are pleonastic in the treatment of post-traumatic Type A vertebral fractures, because their use increases the risk of complication without providing a better long-term outcome.

Moreover, on the basis of the 6-month follow-up CT scans results, we decided to remove the posterior pedicle screw instrumentation to avoid the facet joints arthritis. Prolonged immobilization hinders the diffusion of the synovial fluid within the facet joints, thus accelerating the cartilage degeneration and ossification. The absence of the joint movement indeed promotes the cartilage damage, since it acts as a pump which causes an intermittent hydrostatic pressure change, which is believed to promote the synovial fluid diffusion. Biomechanical loading, furthermore, is strictly necessary for the maintenance of cartilage homeostasis, as confirmed by the rapid proteoglycans loss observed in immobilised or disused joints [25, 26].

Consequently, we believe that the posterior screw instrumentation should be removed as soon as the vertebral fracture repair could be assessed, to avoid the iatrogenic degeneration of the facet joints cartilage and the intervertebral discs.

After the screw-rod system removal, no loss of VK, AH/PH and MH/PH corrections was detected, while a worsening of RK was found, even if it was not statistically significant. This RK change, however, confirms the normal functional recovery of the affected segment of motion and does not affect the functional outcome, as revealed by the mean VAS and ODI scores recorded at 24-months follow-up.

One of the main limitations of this study is the lack of a control group. Moreover, a long-term follow-up should be necessary to confirm the positive impact of the P.I.P.E. technique on the patients' quality of life. Finally, an MRI study, after the posterior instrumentation removal, could be useful to assess the intervertebral disc aspect in patients treated with P.I.P.E. technique.

Conclusions

PMMA cement or bone substitutes are not necessary, when BK is performed in association with posterior screw instrumentation, to treat post-traumatic non-osteoporotic type A thoracolumbar vertebral fractures.

The main goals of this surgery are to restore the endplate anatomy and to keep the fracture reduction obtained with the bone tamp. Our results depict that, in P.I.P.E. technique, both goals may be achieved without filling the cavity created by the balloon into the fractured vertebral body, thus avoiding the use of bone cement and its related compliances.

P.I.P.E. technique revealed clinically and radiologically effective in treating post-traumatic non-osteoporotic type A thoracolumbar vertebral fractures, at 24-months follow-up; thus, it could be routinely used to manage this kind of vertebral injuries.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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