European Radiology (2019) 29:4050–4057
https://doi.org/10.1007/s00330-018-5867-3

INTERVENTIONAL

Evaluation of pain reduction and height restoration post vertebral augmentation using a polyether ether ketone (PEEK) polymer implant for the treatment of split (Magerl A2) vertebral fractures: a prospective, long-term, non-randomized study

Georgios Velonakis[1] · Dimitrios Filippiadis[1] · Stavros Spiliopoulos[1] · Elias Brountzos[1] · Nikolaos Kelekis[1] · Alexis Kelekis[1]

Received: 14 August 2018 / Revised: 5 October 2018 / Accepted: 25 October 2018 / Published online: 3 December 2018

Abstract

Objectives The purposes of the study were to evaluate the safety and long-term efficacy of augmented vertebroplasty using a polyether ether ketone (PEEK) implant, for the treatment of lumbar or thoracic vertebral fractures (A2 according to the Magerl's AO classification) and to analyze pain reduction, height restoration, and complications during a 2-year follow-up period.

Methods Prospective non-randomized evaluation was performed for 21 painful split vertebral fractures (20 patients, 14 females, 6 males; mean age 72.80 ± 10.991) treated with percutaneous vertebral augmentation using a PEEK device, under fluoroscopic guidance. Pain before the procedure and after 6, 12, and 24 months was evaluated using a numeric visual scale (NVS) questionnaire. Imaging was performed by CT and X-rays. The minimum craniocaudal diameter at the level of the fracture and the maximum craniocaudal diameter at the middle of the fractured vertebra were measured. Statistical analysis was performed to evaluate pain decrease and height restoration.

Results Successful implant positioning was achieved in all cases. No major clinical complications were observed. Comparing the mean pain scores at baseline (8.69 ± 1.138) and the first day after the treatment (1.19 ± 1.424), there was a decrease of 7.50 NVS units ($p < 0.001$). Minimum and maximum vertebral body heights were increased after the procedure 56.58% and 13.7% respectively ($p < 0.001$). Both pain relief and height restoration remained statistically significant ($p < 0.001$) during the follow-up period.

Conclusion A2 Magerl thoracic or lumbar fractures could be successfully treated with PEEK implant-assisted vertebral augmentation. Randomized studies with larger sample sizes should be done to confirm the effectiveness of the technique.

Key Points

- *Vertebral augmentation using a PEEK implant for the treatment of A2 Magerl lumbar or thoracic vertebral fractures seems to be effective both in terms of pain reduction and height restoration.*
- *Effects on pain reduction and height restoration have a long-term duration.*
- *The technique seems to be safe for the treatment of A2 Magerl fractures, without major complications in our study group.*

Keywords Vertebroplasty · Spinal fracture · PEEK

Abbreviations

NVS	Numeric visual scale
PEEK	Polyether ether ketone
PMMA	Polymethylmethacrylate
STIR	Short-TI inversion recovery

✉ Georgios Velonakis
giorvelonakis@gmail.com

[1] 2nd Department of Radiology, Attikon General University Hospital, National and Kapodistrian University of Athens, Rimini 1, Haidari, 12462 Athens, Greece

Introduction

Percutaneous vertebral augmentation techniques are part of the available therapies for the treatment of painful vertebral fractures refractory to conservative treatment [1–3]. Benign indications for vertebroplasty include painful osteoporotic

fractures refractory to medical treatment and acute stable A1 (according to Magerl's AO classification) and A3 traumatic fractures [4]. The best indication for percutaneous kyphoplasty is traumatic acute vertebral compression fracture (particularly A.1).

However, the treatment of A2 vertebral fractures is controversial. A2 fractures are fractures of both superior and inferior endplates without involvement of the posterior wall of the vertebral body. They are relatively rare, accounting for 3.46% of vertebral fractures (5.23% of type A fractures) [5]. They are divided into A2.1 (sagittal split fracture), A2.2 (frontal spit fracture), and A2.3 (pincer fracture, in which the central part of the vertebral body is crushed) [5]. A2 fractures (especially A2.3) have the potential to end with a non-union because of the impacted disk material and endplate fragments within the fracture and the subsequent marked anterior dislocation of the anterior fragment [5–7]. Treatment options include either corset or internal fixation [7, 8]. Conservative treatment carries the risk of pseudoarthrosis formation [5] and requires long periods of bed rest, while surgery has a relative high rate of complications [9].

Limited data exists in the literature for the percutaneous treatment of the rare type A2 vertebral fractures. In one study evaluating the efficacy of vertebroplasty for the treatment of split fractures, the authors reported promising results during a short (6 months) follow-up period [10]. However, some authors suggest the combination of percutaneous osteosynthesis with vertebroplasty, due to the persistent risk of non-union after vertebroplasty alone [11]. Moreover, some authors insist that vertebroplasty carries a moderate risk of cement leakage to the disk space [10], which in severe osteoporosis can lead to the collapse of the adjacent vertebral bodies [4]. On the other hand, the use of kyphoplasty for the treatment of Magerl A2 fractures is controversial because of the possibility of anterior fragment displacement during balloon inflation [10], resulting in kyphotic deformity at the treated level.

An alternative percutaneous technique for the treatment of split vertebral fractures could be the implant-assisted vertebral augmentation. Few cases of split fractures successfully treated with stent placement have been reported [12]. The Kiva vertebral compression fracture treatment system (Benvenue Medical Inc.) uses a polyether ether ketone (PEEK) polymer implant deployed in the cancellous bone at the midline of the vertebral body. The effectiveness of the Kiva system on vertebral height and wedge deformity restoration, mainly for A1 fractures, was shown in two randomized trials [13, 14]. To the best of our knowledge, there is limited data for the use of implants in patients suffering from painful A2 vertebral fractures.

The purposes of our study were to evaluate the safety and long-term efficacy of augmented vertebroplasty using a PEEK implant for the treatment of A2 lumbar or thoracic vertebral fractures and to analyze pain reduction, height restoration, and complications during a 2-year follow-up period.

Materials and methods

All the patients were informed about the technique, the possible benefits, and complications. A written informed consent for both the procedure and the study was obtained. The study was conducted according to the Declaration of Helsinki and approved by the institution's ethical committee. This is a prospective non-randomized trial.

During a 60-month period (January 2011–December 2015), 21 painful post-traumatic vertebral fractures (20 patients, mean age 72.80 ± 10.991; 6 males, mean age 65.67 ± 14.067; and 14 females, mean age 75.86 ± 8.179; including 9 patients with osteoporosis) were treated with bone augmentation with PEEK polymer, using the Kiva device.

Inclusion criteria were A2 lumbar or thoracic vertebral fracture, pain ≥ 7 NVS units, bone marrow edema at the fractured vertebra on MRI, point tenderness at the reference level during clinical examination, and failure of the conservative treatment. Failure of the conservative treatment was defined as pain duration of more than 3 weeks, despite the use of analgesic medications and bed rest.

Exclusion criteria were untreatable coagulopathy; active, systemic or local infections; patient unwilling to consent to the procedure; and nerve root pain or neurological deficit due to the fracture. Malignant fractures (six patients) were excluded from the study.

Each patient underwent coagulation laboratory tests and physical examination. During the physical examination, a marker was placed on the skin at the level of tenderness during tapping of the spinous processes, and radiographs were obtained in order to ensure pain origin from the fractured vertebra. All patients had a pre-interventional MRI, indicating bone edema (hyperintensity on short-TI inversion recovery [STIR] images, hypointensity on T1) at the level of pain. Spinal CT was obtained in order to evaluate the fracture, to measure the baseline values of vertebral height, and to categorize the fracture according to Magerl's AO classification. Evaluation of all imaging studies in correlation with the medical record was performed before each procedure by three interventional radiologists.

Technique

Under fluoroscopic guidance and unilateral "transpedicular" approach, a working cannula and coaxially the Kiva system were introduced in the vertebral body. The coil was advanced to create a path through the cancellous bone guiding the implant which deployed as a stacked cylindrical column centered at the vertebral body's midline. The implant remained in the vertebral body after coil retraction. Polymethylmethacrylate (PMMA) bone cement was injected through a delivery system and flowed through small slots directed centrally in the implant, under continuous fluoroscopy (Fig. 1). Additional

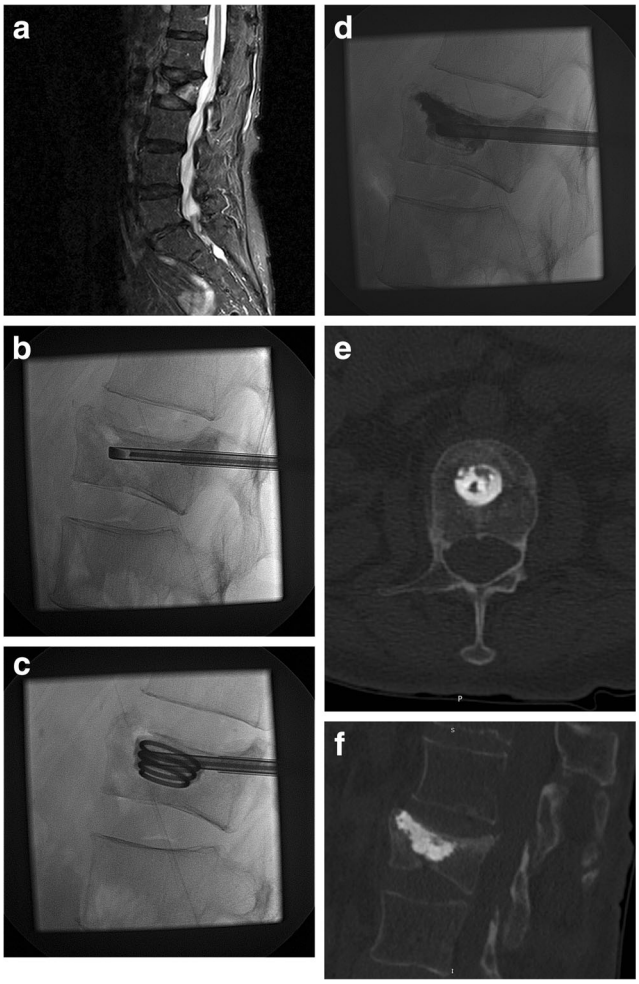

Fig. 1 **a** MR image of the spine showing an L3 vertebral split fracture (A2.2 according to the Magerl classification), with high signal intensity on T2 STIR sagittal images, due to bone edema. **b** Under fluoroscopic guidance and a unilateral transpedicular approach, a working cannula is introduced in the vertebral body. **c** The coil is advanced to create a path through the cancellous bone guiding the implant. **d** PMMA cement is injected through a delivery system under fluoroscopy. **e** CT after 24 months shows the Kiva implant into the vertebral body. **f** CT (sagittal reconstruction) after 24 months shows height restoration of the vertebral body

vertebroplasties in other levels were performed in the same session, if needed [15]. All vertebral augmentations were performed by the same interventional radiologist. The procedures were performed under epidural or general anesthesia depending on the anesthesiologist's decision, taking into account the level of the fracture, the patient's general status, and the comorbidities. Although standard vertebroplasty can be performed under local anesthesia [16], limited data exists for implant-assisted vertebral augmentation, treatment of multiple levels, and 8–11-gauge needles (required in the Kiva procedure). Heart rate, pulse oximetry, and blood pressure were monitored continuously. The patients were hospitalized overnight and were discharged the next morning after physical examination and spinal CT.

Outcomes

Pain, mobility, and vertebral height were recorded at baseline and at the first day after the procedure, as well as at 3-, 6-, 12-, and 24-month follow-up periods. An inventory containing a numeric visual scale (NVS) questionnaire was used for pain evaluation (0 indicating no pain and 10, maximum pain). This inventory included questions concerning the pain itself and its influence upon the patient's activity (sleep, occupation and housework, walking) and mobility impairment. Pain reduction of more than 4 NVS units was considered clinically significant response to the treatment. The proportion of patients achieving a NVS score of less than 4/10 was also recorded.

Imaging was performed by CT and X-rays. All height analyses and measurements were performed by consensus of three radiologists with 21, 16, and 11 years of experience. The minimum craniocaudal diameter at the level of the fracture and the maximum craniocaudal diameter at the middle of the fractured vertebra were measured. The middle of the vertebral body was defined as the area between the anterior 6 mm and the posterior 6 mm of the vertebral body. Given the morphology of A2 Magerl fractures, and the integrity of the posterior column, the middle of the vertebral body is more deformed, particularly in A2.3 fractures. Thus, the minimum craniocaudal diameter at the level of the fracture was reduced in all fractures, while the maximum craniocaudal diameter at the middle of the fractured vertebra was reduced in most fractures (mainly in A2.3). Measurements were performed on CT sagittal reconstructions and confirmed on X-ray. Finally, in each patient, the height of a normal-appearing vertebral body was measured, at least two levels away from the treated vertebra, or any other vertebra that had undergone any intervention in the past. These control measurements were used in order to better evaluate the height of the treated vertebral body during the follow-up period and to compare with the "normal" effects of aging. Additionally, it eliminated technical bias due to different projections of the standard X-ray during acquisition. In one case, a new fracture occurred during the follow-up period at the control vertebra; thus, another vertebral body was considered as the control one retrospectively.

Vertebroplasty complications are mainly attributed to cement leakage or migration [17]; thus, cement extravasation and implant migration were recorded. Complications were recorded and classified according to the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) classification system [18].

Statistical analysis

Data was summarized using the mean value and standard deviation (mean ± standard deviation). Pain scores and height measurements prior to and post therapy were compared using paired-samples *t* test and ANOVA. The corrections used to

combat the violation of the assumption of sphericity were the lower-bound estimate, the Greenhouse-Geisser correction, and the Huynh-Feldt correction. Multivariate analysis was performed in order to evaluate the role of confounding factors on final results. *P* values < 0.05 were considered to indicate a statistical significance. For the performance of a power calculation, pain reduction of more than 4 NVS units was considered clinically significant. Using an estimated mean pain score of 8 NVS units prior to the intervention and a potential sample of 15 patients, the power was calculated 99.9%. Sample size calculation using the height measurements of an old case was also performed, suggesting a sample of 17 patients for a power of 80%. Statistical analyses were performed with SPSS Statistics 22 (IBM Corp).

Results

Successful implant delivery and position was achieved in all 21 treated vertebral bodies. One patient had 2 vertebral fractures treated with Kiva-assisted vertebral augmentation in the same session. The procedure was performed on the following vertebrae: T8 ($n = 2$), T12 ($n = 3$), L1 ($n = 5$), L2 ($n = 4$), L3 ($n = 4$), and L4 ($n = 3$). Standard vertebroplasty in additional levels (up to 4) was performed during the same session in 8 patients, in order to treat other types of compression fractures [15]. There was no adjacent-level vertebroplasty.

Mean follow-up was 25.24 months. One patient refused to undergo any imaging at 12 and 24 months, although he reported minimal pain scores (1 and 2 NVS units respectively) during physical examination. Two patients died 10 months and 19 months after the procedure due to causes irrelevant to vertebral augmentation. One patient failed to come for the 24-month follow-up because of dementia. Four patients visited our department for other reasons after the follow-up period; nonetheless, clinical evaluation was performed and CT images were obtained 30, 43, 46, and 63 months after the intervention.

All patients reported clinically significant pain relief (more than 4 NVS units). All patients reported pain scores of less than 4/10 post treatment, except one, who reported a pain score of 4/10 the day after the treatment (10/10 at baseline). Overall mobility was improved in all patients. Comparing the mean pain scores at baseline (8.69 ± 1.138 NVS units) and the first day after the treatment (1.19 ± 1.424), there was a decrease of 7.50 NVS units in terms of pain reduction and life quality and this difference was statistically significant ($p < 0.001$). Pain relief remained clinically significant for the whole follow-up period, with mean pain scores of 1.13 ± 1.408, 1.56 ± 1.632, 1.44 ± 1.413, and 2.06 ± 2.175 after 3, 6, 12, and 24 months respectively ($p < 0.001$) (Fig. 2).

In order to better evaluate pain relief of Kiva-assisted vertebral augmentation, statistical analysis was also performed after excluding the eight patients who had undergone additional standard vertebroplasty in different levels in the same session. The results were similar. The mean pain score decreased from 8.40 ± 1404 NVS units at baseline to 0.73 ± 1.280 after 1 day ($p < 0.001$) (mean pain decrease 7.67 ± 1.633), and pain relief remained statistically significant during the follow-up period (0.79 ± 1.22, 1.07 ± 1.439, 1.23 ± 1.423, and 2.00 ± 1.700 at 3, 6, 12, and 24 months respectively).

Comparing the minimum vertebral height at baseline (8.04 ± 3.249 mm) and the first day after the procedure (12.61 ± 3.006 mm), there was a mean height increase of 4.56 mm (56.58%), which was statistically significant ($p < 0.001$). Minimum vertebral height restoration remained statistically significant ($p < 0.001$) during the follow-up period, with minimum heights of 12.23 ± 3.251 mm, 11.94 ± 3.097 mm, and 11.60 ± 3.214 mm, at 6, 12, and 24 months respectively (Fig. 3). As far as maximum height at the middle of the vertebral body is concerned, there was a statistically significant increase of 2.07 mm (13.7%) between the height at baseline (15.12 ± 3.570) and the day after the intervention (17.19 ± 2.980). Maximum heights were almost constant during the follow-up period (17.12 ± 2.971 mm, 17.02 ± 2.980 mm, and 16.91 ± 2.951 mm after 6, 12, and 24 months respectively). No statistically significant differences in height loss were noticed comparing minimum vertebral height ($p = 0.48$), maximum vertebral height ($p = 0.51$), and control vertebral height during follow-up (Fig. 4). There were no correlation of the patient's age, weight, and height upon pain relief and vertebral height restoration.

Mild cement extravasation to the intervertebral disk was noticed in four cases and required no additional therapy (grade 1 according to the CIRSE classification system for complications [18]). Neither cement leakage to the central canal nor symptomatic or clinically significant cement extravasations occurred. There was no adjacent-level vertebral fracture during the follow-up period. One new fracture occurred in a vertebra two levels below the treated vertebral body after 1 year. Late complication was considered an anterior displacement of the fragment noticed after 6 months, resulting in an increase of 5 mm in the distance between the fragments, probably because of delayed union. This displacement was clinically silent and remained stable during the rest of the follow-up period. No other fragment displacement or pseudoarthrosis formation was identified. Partial implant migration to the intervertebral space was noticed in one patient, 6 months after the intervention, without causing any symptoms and without any further migration during the follow-up. No perioperative deaths or other major clinical complications (grade 2–6 according to the CIRSE classification system) were observed.

Discussion

The results of our study indicate the effect on pain relief of Kiva-assisted vertebral augmentation in the treatment of A2

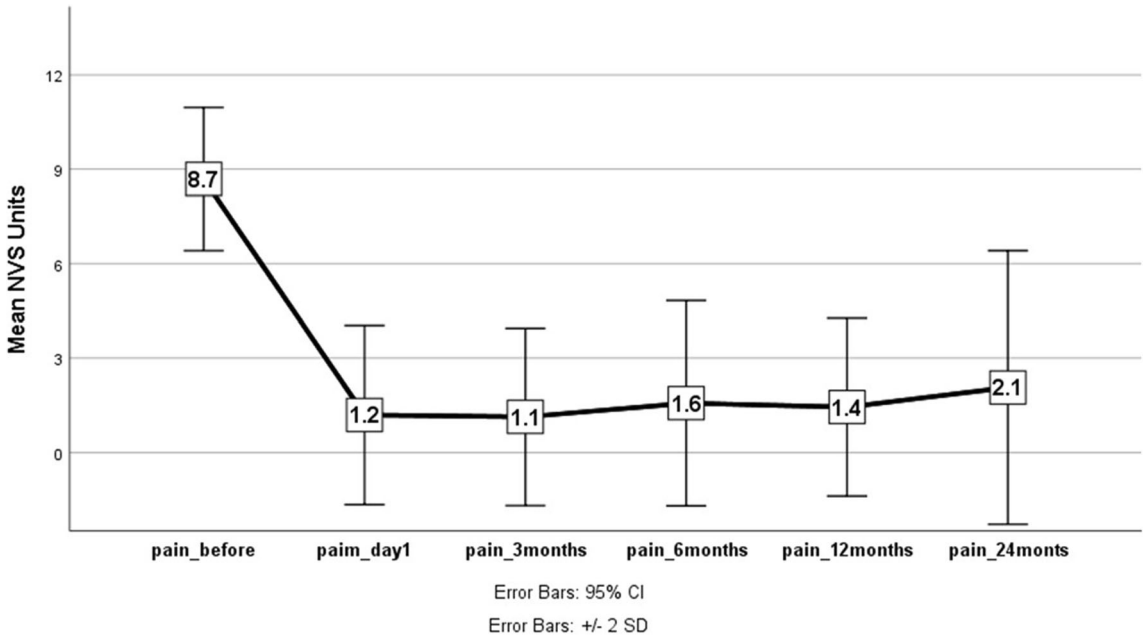

Fig. 2 Mean pain scores (NVS units) before the intervention and during the follow-up period: There was a decrease of 7.5 NVS units the first day after the procedure ($p < 0.001$). Pain relief remained clinically and statistically significant for the whole follow-up period. NVS, numeric visual scale

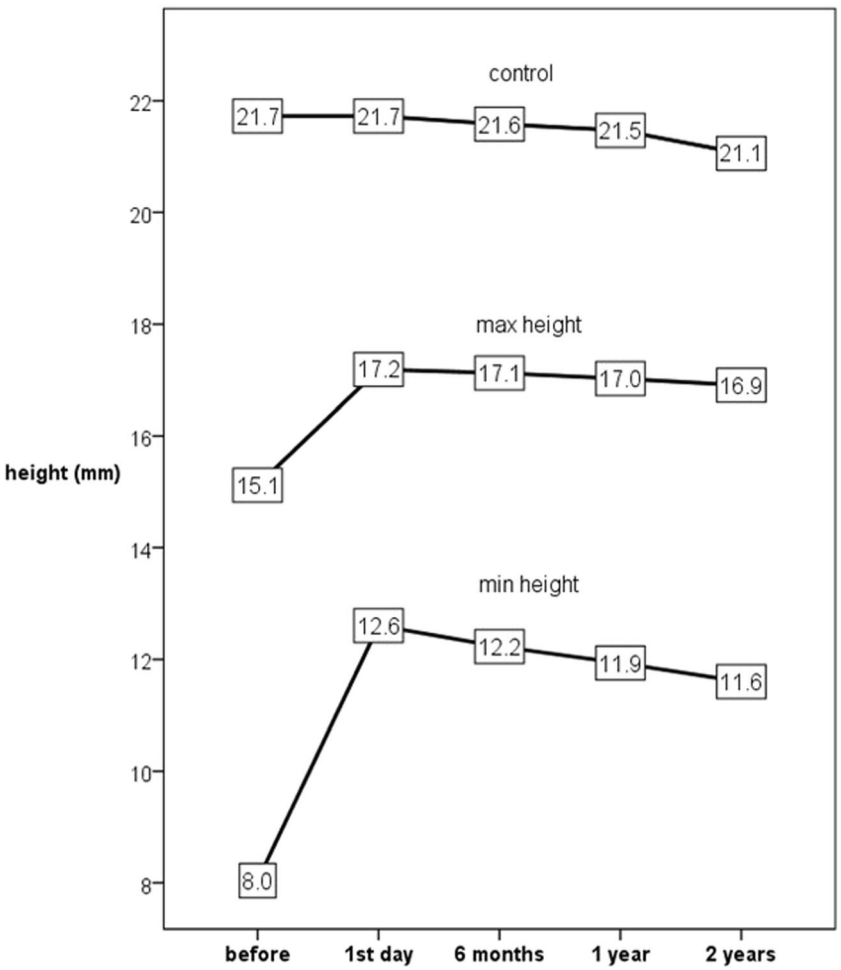

Fig. 3 Graph shows restoration of min and max height after the intervention. There was no statistically significant height loss during the 24-month follow-up period compared with control vertebral height. Min height, the minimum craniocaudal diameter at the level of the fracture. Max height, the maximum craniocaudal diameter at the middle of the fractured vertebra. The middle of the vertebral body was defined as the area between the anterior 6 mm and the posterior 6 mm of the vertebral body. Control, the height of a normal-appearing vertebral body, at least two levels away from the treated vertebra or any other vertebra that had undergone any intervention in the past

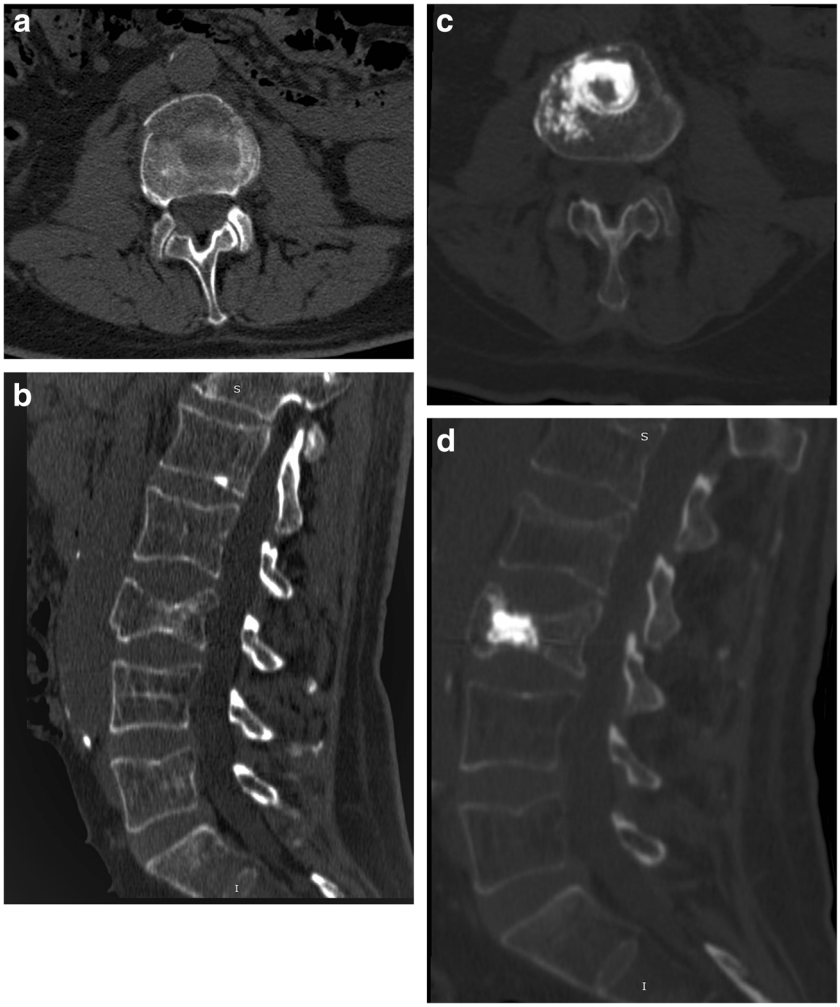

Fig. 4 **a** CT showing the fracture line (Magerl A2.2) at the L3 vertebral body. **b** CT sagittal reconstruction showing the coronal-oriented fracture line at the L3 vertebral body (same case). **c** CT showing the PEEK implant 2 years after the vertebral augmentation. **d** No significant height loss is noticed on CT sagittal reconstruction 2 years after the treatment

Magerl lumbar or thoracic vertebral fractures. Moreover, this technique was effective in height restoration of the vertebral body. Both pain relief and height restoration lasted for the whole follow-up period.

Results are in accordance with previous studies evaluating pain decrease after vertebral augmentation for the treatment of vertebral fractures. Huwart et al [10] reported good results for the treatment of split vertebral fractures by CT and fluoroscopy-guided percutaneous vertebroplasty (dual guidance), without adjacent-level fractures during a 6-month follow-up period. Dual guidance may also be useful and increase safety in Kiva-assisted vertebral augmentation. Other authors confirmed the effectiveness of Kiva-assisted bone augmentation in the treatment of painful vertebral compression fractures [13, 14, 19, 20], or painful osteolytic vertebral metastasis [21], but little evidence exists in the literature either for A2 type of fractures or for long-term stability of the implant. The presence of the implant prevents height loss during the 2-year follow-up period, in contrast to the loss of height reported in the 1-year follow-up after vertebroplasty [22] and kyphoplasty [23]. Moreover, an economic analysis of Kiva-assisted vertebral augmentation showed that this technique may lead to cost savings [24].

Other types of implants for the treatment of vertebral fractures have been also studied for their efficacy in pain reduction and height restoration. Vertebral augmentation with nitinol endoprosthesis [25] and Spine Jack® (Vexim) [26] was effective for the treatment of A1 Magerl vertebral fractures, providing pain relief and vertebral height gain. Vertebral augmentation with the SpineJack® seems able to correct structural deformities in chronic Magerl A.3 fractures [27]. Although Vertebral Body Stenting® (DePuySynthes), OsseoFix® (ATECspine), and SpineJack® have been also used for the treatment of A1 and A3.1 vertebral fractures, authors suggest that they are not indicated for the treatment of A2 fractures [28]. To our knowledge, limited data exists for the evaluation of these devices for the treatment of split vertebral fractures.

During the follow-up period, there were no new fractures in the adjacent levels. The lack of adjacent-level fracture compared to the incidence of new fractures after vertebroplasty published in the literature [29] is an observation that requires further investigation. The KAST study revealed a positive

trend in adjacent-level fracture for Kiva-assisted vertebral augmentation compared to balloon kyphoplasty [14]. Although the risk of adjacent vertebral fractures related to vertebral augmentation is controversial [30], our study suggests the need of control trials to evaluate the potential superiority of Kiva.

Limitations of the study include the relatively small sample size and the lack of a control group undergoing vertebroplasty or kyphoplasty (non-randomized design). However, A2-type fractures are rare and, to our knowledge, this is the first study to evaluate both height restoration and pain relief achieved by vertebral augmentation in split vertebral fractures, including a long follow-up period. Another limitation is the lack of acute fractures, despite the encouraging results reported for vertebroplasty in acute fractures of the Magerl A class [31]. Although present guidelines on bone augmentation stipulate that percutaneous implant treatment should be performed in acute settings (less than 1 week) otherwise trial balloons should be used [4], this recommendation refers to the use of vertebral bone stenting and not to the use of the rigid PEEK implant, which can be delivered in more sclerotic conditions. Our study showed that even after 3 weeks, we were able to deploy the implant and achieve height restoration. An additional limitation is the inclusion of patients who had undergone standard vertebroplasty in different levels in the same session; thus, pain reduction could be partially the effect of standard vertebroplasty. Statistical analysis was also performed after excluding these patients. The results were similar and pain reduction remained statistically significant. A final limitation was that we did not asses the kyphotic correction, because we believe that the main goals of the treatment of split fractures is pain relief and restoration of the central part of the vertebral body, in order to avoid subsequent degradation and non-union.

Our study suggests that A2 Magerl thoracic or lumbar fractures, without a neurological deficit, could be successfully treated with vertebral augmentation using the Kiva implant. This technique seems to be safe with long-lasting results upon pain reduction and height restoration. Further, randomized studies, including a larger number of patients, should be done to confirm the effectiveness of this procedure.

Funding The authors state that this work has not received any funding.

Compliance with ethical standards

Guarantor The scientific guarantor of this publication is Alexios Kelekis.

Conflict of interest The authors of this manuscript declare no relationships with any companies whose products or services may be related to the subject matter of the article.

Statistics and biometry No complex statistical methods were necessary for this paper. One of the authors has significant statistical expertise.

Informed consent Written informed consent was obtained from all subjects (patients) in this study.

Ethical approval Institutional review board approval was obtained.

Methodology
- Prospective
- Observational
- Performed at one institution

References

1. Barr JD, Jensen ME, Hirsch JA et al (2014) Position statement on percutaneous vertebral augmentation: a consensus statement developed by the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS). J Vasc Interv Radiol 25(2): 171–181
2. Clark W, Bird P, Gonski P et al (2016) Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicentre, randomised, double-blind, placebo-controlled trial. Lancet 388(10052):1408–1416
3. Santiago FR, Kelekis A, Alvarez LG, Filippiadis DK (2014) Interventional procedures of the spine. Semin Musculoskelet Radiol 18(3):309–317
4. Tsoumakidou G, Too CW, Koch G et al (2017) CIRSE guidelines on percutaneous vertebral augmentation. Cardiovasc Intervent Radiol 40(3):331–342
5. Magerl F, Aebi M, Gertzbein SD, Harms J, Nazarian S (1994) A comprehensive classification of thoracic and lumbar injuries. Eur Spine J 3(4):184–201
6. Aebi M (2010) Classification of thoracolumbar fractures and dislocations. Eur Spine J 19(1):2–7
7. De Boeck H, Opdecam P (1999) Split coronal fractures of the lumbar spine. Treatment by posterior internal fixation and transpedicular bone grafting. Int Orthop 23(2):87–90
8. Kim BG, Dan JM, Shin DE (2015) Treatment of thoracolumbar fracture. Asian Spine J 9(1):133–146
9. Jutte PC, Castelein RM (2002) Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations. Eur Spine J 11(6):594–598
10. Huwart L, Foti P, Andreani O et al (2014) Vertebral split fractures: technical feasibility of percutaneous vertebroplasty. Eur J Radiol 83(1):173–178
11. Amoretti N, Huwart L (2014) Combination of percutaneous osteosynthesis and vertebroplasty of thoracolumbar split fractures under CT and fluoroscopy guidance: a new technique. Cardiovasc Intervent Radiol 37(5):1363–1368
12. Fürderer S, Schnurr C, König D (2010) Minimal invasive transvertebral reduction and stabilisation of coronal split fractures. The Internet Journal of Minimally Invasive Spinal Technology 4:1 Available via http://ispub.com/IJMIST/4/1/9250. Accessed 5 Oct 2018
13. Korovessis P, Vardakastanis K, Repantis T, Vitsas V (2013) Balloon kyphoplasty versus KIVA vertebral augmentation—comparison of

2 techniques for osteoporotic vertebral body fractures. Spine (Phila Pa 1976) 38(4):292–299
14. Tutton SM, Pflugmacher R, Davidian M, Beall DP, Facchini FR, Garfin SR (2015) KAST study: the Kiva system as a vertebral augmentation treatment—a safety and effectiveness trial: a randomized, noninferiority trial comparing the Kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. Spine (Phila Pa 1976) 40(12):865–875
15. Mailli L, Filippiadis DK, Brountzos EN, Alexopoulou E, Kelekis N, Kelekis A (2013) Clinical outcome and safety of multilevel vertebroplasty: clinical experience and results. Cardiovasc Intervent Radiol 36(1):183–191
16. Bonnard E, Foti P, Kastler A, Amoretti N (2017) Percutaneous vertebroplasty under local anaesthesia: feasibility regarding patients' experience. Eur Radiol 27(4):1512–1516
17. Kelekis AD, Somon T, Yilmaz H et al (2005) Interventional spine procedures. Eur J Radiol 55(3):362–383
18. Filippiadis DK, Binkert C, Pellerin O, Hoffmann RT, Krajina A, Pereira PL (2017) Cirse quality assurance document and standards for classification of complications: the Cirse classification system. Cardiovasc Intervent Radiol 40(8):1141–1146
19. Otten LA, Bornemnn R, Jansen TR et al (2013) Comparison of balloon kyphoplasty with the new Kiva® VCF system for the treatment of vertebral compression fractures. Pain Physician 16(5):505–512
20. Olivarez LM, Dipp JM, Escamilla RF et al (2011) Vertebral augmentation treatment of painful osteoporotic compression fractures with the Kiva VCF Treatment System. SAS J 5(1):114–119
21. Anselmetti GC, Manca A, Tutton S et al (2013) Percutaneous vertebral augmentation assisted by PEEK implant in painful osteolytic vertebral metastasis involving the vertebral wall: experience on 40 patients. Pain Physician 16(4):397–404
22. Heo DH, Chin DK, Yoon YS, Kuh SU (2009) Recollapse of previous vertebral compression fracture after percutaneous vertebroplasty. Osteoporos Int 20(3):473–480
23. Kim YY, Rhyu KW (2010) Recompression of vertebral body after balloon kyphoplasty for osteoporotic vertebral compression fracture. Eur Spine J 19(11):1907–1912
24. Beall DP, Olan WJ, Kakad P, Li Q, Hornberger J (2015) Economic analysis of Kiva VCF treatment system compared to balloon kyphoplasty using randomized Kiva Safety and Effectiveness Trial (KAST) data. Pain Physician 18(3):299–306
25. Anselmetti GC, Manca A, Marcia S et al (2014) Vertebral augmentation with nitinol endoprosthesis: clinical experience in 40 patients with 1-year follow-up. Cardiovasc Intervent Radiol 37(1):193–202
26. Vanni D, Pantalone A, Bigossi F, Pineto F, Lucantoni D, Salini V (2012) New perspective for third generation percutaneous vertebral augmentation procedures: preliminary results at 12 months. J Craniovertebr Junction Spine 3(2):47–51
27. Premat K, Vande Perre S, Cormier É et al (2018) Vertebral augmentation with the SpineJack® in chronic vertebral compression fractures with major kyphosis. Eur Radiol. https://doi.org/10.1007/s00330-018-5544-6
28. Vanni D, Galzio R, Kazakova A et al (2016) Third-generation percutaneous vertebral augmentation systems. J Spine Surg 2(1):13–20
29. Komemushi A, Tanigawa N, Kariya S et al (2006) Percutaneous vertebroplasty for osteoporotic compression fracture: multivariate study of predictors of new vertebral body fracture. Cardiovasc Intervent Radiol 29(4):580–585
30. Khosla A, Diehn FE, Rad AE, Kallmes DF (2012) Neither subendplate cement deposition nor cement leakage into the disk space during vertebroplasty significantly affects patient outcomes. Radiology 264(1):180–186
31. Amoretti N (2018) Early percutaneous vertebroplasty helps motorsport professionals to resume competition soon after vertebral fracture. Eur Radiol 28(7):2870–2871