Efficiency of a Novel Vertebral Body Augmentation System (Tektona™) in Non-osteoporotic Spinal Fractures

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Abstract

Background

The restauration of the local kyphosis is crucial for spinal fractures outcomes. Recently, the Tektona™, (Spine Art) system, constituted by a flexible lamella for reduction has emerged as a promising solution for osteoporotic fractures. However, no study has yet focused on its results on traumatic fractures.

Methods

A retrospective longitudinal study on prospectively collected data was conducted on 53 patients. The data collected were clinical, surgical and scannographic (measurement of AVH, MVH and PVH (anterior/medium/posterior vertebral height), and RTA (regional traumatic angle) in°), preoperatively, early post-operative and at follow-up.

Results

Fractures were mainly located at the upper lumbar spine and were Magerl A3.1 type for 51%.

The mean RTA was 12° in pre-operative, 4° in post-operative ($p=2e^{-9}$), and 8° at the last follow-up (*p=0,01*). The mean correction of RTA for the fixation group was -10±6° versus -7±4° for the vertebroplasty alone group *(p=0,006).* The mean correction for fractures located at T10-T12 was -9±3°, -9±5° for L1, -8±3° for L2 and -5±3° for L3-L5 *(p=0,045).*

Conclusions

The Tektona® system appears to be efficient for acute thoraco-lumbar fractures, comparable to other available systems, allowing a real intracorporeal reduction work. Its relevance, especially in the long term needs further investigation. The association of a percutaneous fixation allow to obtain a better correction of the RTA but did not seem to prevent the loss of correction at follow-up.

Background

Traumatic vertebral fractures are a matter of public health, considering its incidence and the disability induced, notably in terms of return to work and back pain [1]. In Magerl A fractures, the restauration of the sagittal alignment appears to be crucial [2, 3]. Kyphoplasty as a treatment of Magerl A fractures has been at first described by Belkoff et al. and used initially in metastatic patients, before an exponential use in osteoporotic fractures, replacing cimentoplasty in some indications [4–6]. Kyphoplasty has also been used as an alternative to reduction and fixation in Magerl A traumatic fractures, on nonosteoporotic patients [7–9]. The goals of a kyphoplasty for traumatic Magerl A fractures are the restauration of the vertebral shape and the local kyphosis, with a mini-invasive treatment. Its advantage over internal fixation may therefore be the reduction of complications related to the instrumentation (rob breakage, infection, screw loosening…) and leaving free the discs adjacent to the fracture [10, 11]. Additionally, Magerl A fractures have been described as strictly bony fractures, and the proper reduction of the vertebral body reduction seems to reduce the risk of secondary disc degeneration [12, 13]. However, most of the available device only allow one try for the corporeal reduction, device with a nonrepeatable reducing movement and does not allow to target the area to be reduced.

A decade ago, a new vertebroplasty solution has been launched. The Tektona ™, (Spine Art) system is a percutaneous vertebral body system. It is constituted by a flexible lamella, that can be orientated in several plans and used several times in the same procedure into the vertebral body, to reduce the fracture and limit the vertebral kyphosis. However, this new device has, at our knowledge, only been studied in two studies. The first one, by Krüger et al. was a cadaveric study, comparing the Tektona® to a standard balloon kyphoplasty concluded to promising results [14]. Secondly, Marcia et al. described a cohort of 30 patients, with encouraging results in terms of clinical scores and vertebral body height (VBH) restoration but only on a osteoporotic population [15]. Is the Tektona reliable in terms of sagittal correction on acute vertebral fractures?

The main goal of this study was to measure the efficiency, in term of vertebral body reduction of the Tektona®, on a non-osteoporotic spinal fracture cohort.

Methods

- Patients

The files of all patients treated in a single spinal surgery center between January 2015 and April 2021 treated by Tektona vertebral body augmentation system have been systematically reviewed. This was a retrospective longitudinal study on prospectively collected data. The files of 53 patients have been included. The flow-chart is available as Fig.1.

The inclusion criteria were:

- Magerl A vertebral body fracture, between T7 and L5
- Patients over 18 years and under 65 years
- Pre-operative CT-scan at the fracture level and early (<3 months) and at follow-up postoperative CT-scan (before the instrumentation removal).

The exclusion criteria were:

- Osteoporotic fractures (Hounsfield Unit (HU) in L1 <150) [16]. If L1 was fractured, the measure was realized in L2.
- Lack of follow-up.

- Surgical technic

All surgical indications were validated in surgical staff meeting. All patients were operated in prone position, under fluoroscopic guidance (C-arm). Jamshidi were introduced in both pedicle of the fractured vertebra, then replaced by a K-wire, to allow the penetration of the working cannula. The reduction instrument was then inserted into the vertebral body using the ancillary device. The vertebral reduction was obtained with the progressive flexion of the flexible lamellas. The placement of the lamella under the fracture was controlled by fluoroscopy. The reduction movement was repeated until a satisfying image was obtained. The Fig. 2 illustrate the progressive reduction that can be achieved by the increase of the lamella bend. The cement (PMMA, Mendec Spine HV System, Tecres, Italie) was then inserted in the space thus created by the reduction. An example of per-operative use is displayed as Fig.3. When additional fixation was needed due to the characteristic of the fracture, percutaneous pedicle fixation was realized after the kyphoplasty, in the same operating time.

- Data

The data collected were demographic, clinical, surgical, and radiologic. The demographic data were the age, the sex and the delay between the trauma and the surgery. The clinical data were related to the fractures: level, type according to Magerl [17]. The surgical data collected were the delay between the trauma and the surgery, the level of the vertebroplasty, the association to a percutaneous fixation and the surgical complications.

The scannographic study of the patients comprised, pre-operatively, at early and last- follow-up, according to the department protocol for all vertebral fractures, the measurement of AVH (anterior vertebral height) in millimeters (mm), MVH (anterior vertebral height) in mm, PVH (posterior vertebral height), and TRA (traumatic regional angle) in°. The TRA is defined as regional kyphosis (RK) – physiological regional angle (PRA) defined by Guigui et al. [18, 19] . The regional kyphosis was measured on Carestream by two senior surgeons, according to the Cobb angle method.

- Statistics

Values of AVH, MVH, PVH and TRA were compared between the 3 times of analysis. A sub-group analysis between patients with associated fixation and without has also been realized. The statistical analysis was realized on Excel Stat. Student t-test were used to compare series, $p<0,05$ was considered statistically significant.

Results

- Cohort description :

Among the 53 patents analyzed, 36 patients (68%) were male and 17 (32%) were female. The mean age at the time of the surgery was 41±14 years; [18;64]. The mean delay between the trauma and the surgery was 2,3±1,7 days; [0;10]. All patients had an early post-operative CT scan, whereas only 29 had a late CT-scan, at a mean follow-up of 17 months. The mean pre-operative bony density was 223±42 HU.

Fractures were predominantly located at the upper lumbar spine: L1 for 18 patients (34%) and L2 for

14 patients (26%), Fig 4A. Most fractures were either A3.1 according to Magerl (27 patients, 51%) or A1.3 (12 patients, 23%), (Fig. 4B). Twenty patients (38%) had a percutaneous fixation 1+1 associated to the kyphoplasty.

Vertebral loss of height was mainly anterior and median (Fig.4C). The relative anterior body height compared to the posterior was equal to 70±4,3% [46, 104] and 66±3,8% [41;93] for the relative medium body height.

Complications occurred in 5 patients (10%), consisting in 3 anterior cement leaks and 2 posterior cement leaks. None of these patients were symptomatic and no surgical re-intervention had to be performed.

- Radiological results:

The mean RTA was 12° in pre-operative, 4° in post-operative and 8° at the last follow-up. The difference between pre-operative and early post-operative results were statistically significant ($p=2e^{-9}$), as well as the difference between early and late RTA (*p=0,01*), (Fig. 5A).

The mean evolution between pre-operative and early post-operative AVH was +27; ±30%; [-19; 131], ($p=2e^{-6}$) and between early and late post-operative was -6; ±13%; [-32; +29], (*p=0,20*), (Fig. 5B).

The mean evolution between pre-operative and early post-operative MVH was +15; ±13%; [-23; 57], ($p=7e^{-5}$) and between early and late post-operative was -12; ±18%; [-75; +13], (*p=0,16*), (Fig. 5C).

The mean PVH was not different between the 3 times of analysis: 24,3±3,3° in pre-operative, 25±2,9° in early post-operative and 24±4,2° in late post-operative (*p=0,7*), (Fig. 5D).

The mean correction of RTA for the sub-group of patients that had a percutaneous associated fixation (fixation group) was -10±6° versus -7±4° for the vertebroplasty alone group. This difference was statistically significant *(p=0,006).* At last follow-up, the loss of correction for the sub-group of patients that had a percutaneous associated fixation (fixation group) was +3,7°±7° versus +3,8±8° for the vertebroplasty alone group; this difference was not statistically significant *(p=0,97).*

The mean correction for fractures located at T10-T12 was -9±3°, -9±5° for L1, -8±3° for L2 and -5±3° for L3-L5. There were a statistically significant difference of correction for fracture below L2 *(p=0,045).*

The mean correction for Magerl A1 fractures was -8±5° and -8±3° for A3 fractures. The difference was not statistically significant *(p=0,88)*.

Discussion

These results show a clear reduction of the RTA obtained by Tektona® vertebroplasty, with or without associated percutaneous fixation, for Magerl A fracture between T10 and L2. The loss of correction at follow-up was measured at 4°, after obtaining 8° of RTA reduction by the procedure. The anterior vertebral body height seems to be better reduced by the procedure than the medium superior vertebral endplate depression (+27; ±30% versus +15; ±13%). The association of a percutaneous fixation allow to obtain a better correction of the RTA but did not seem to prevent the loss of correction at follow-up.

The 8° of restauration of RTA at early post-operative analysis is comparable to other series of traumatic fractures treated by kyphoplasty in the literature (-4° for Garnon et al; -11° for Maestrettri et al.; -7° for Crandall et al. ; -6° for Garnier et al.; - 6° for Teyssédou et al.) [7–9, 11, 20]. The advantage of the Tektona® reduction system seems to lie in the design itself. Indeed, to reduce the endplate depression, one need to apply the principles of general traumatology, trying all needed maneuver to obtain the maximum correction of the endplate depression. However, to date, none of the kyphoplasty devices allows to have an oriented, repeatable, reduction maneuver. The Tektona® system is the first device allowing to do so, even in the rare inferior end plate traumatic fracture (by a 180° rotation of the device).

The loss of correction (4°) at a mean follow-up of 17 months is also comparable to the results presented in these studies. The Tektona system seems to permit a satisfying correction of the AVH (+27; ±30%), while the correction of the medium body height seems perfectible (+15; ±13%). The correction of the middle vertebral body height is indeed one of the main challenges, especially in burst fractures (A3.3), whereas anterior vertebral heigh is subject to an important heterogeneity due to measurement bias [21]. Another highlight of the study is that if these results are promising for fractures between T10 and L2, the results are more mitigated for fracture below L2. That may be explained by the higher among of axial load in the lower lumbar spine. However, surgeon must be aware of the more mitigated results below L2 and carefully choose the indication of kyphoplasty in this region.

There are some limitations to this study. The retrospective design of the study indeed comprises inherent bias. The quantity of cement injected would have been an interesting data to correlate to the loss of correction. The lack of clinical data is regrettable, but clinical results seems to correlate with sagittal angulation in spinal fractures, at early as well as in long-term perspective [22–24].

Conclusions

In conclusion, the Tektona® system seems to be an interesting device for acute fractures between T10 and L2, with a correction that seems comparable to other available systems, but promising possibilities of technical use development.

Abbreviations

AVH: anterior vertebral height

CT: computed tomography

MVH: medium vertebral height

PVH: posterior vertebral height

RTA: regional traumatic angle

VBH: vertebral body height

Declarations

Ethics approval and consent to participate: This study is part of routine patient care and does not require ethic approval (not subject to the Jardé French law). This study was conducted in accordance to the rules of Helsinki declaration.

Consent to participate: This study is part of routine patient care and does not require consent to participate.

Consent for publication: Not applicable

Availability of data and material: The data are available as supplementary material

Competing interest: HPM received royalties from SpineArt®; the other authors do not have any conflict of interest to disclose

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Authors contributions: LMH, NB, MCA and MK collected the data. YM, LMH and RP analyzed the data. LMH wrote the manuscript. RB and HPM supervised the work. All authors read and approved the final manuscript

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References

1. Oner C, Rajasekaran S, Chapman JR, et al (2017) Spine Trauma-What Are the Current Controversies? J Orthop Trauma 31:. https://doi.org/10.1097/BOT.0000000000000950
2. Mayer M, Ortmaier R, Koller H, et al (2017) Impact of Sagittal Balance on Clinical Outcomes in Surgically Treated T12 and L1 Burst Fractures: Analysis of Long-Term Outcomes after Posterior-Only and Combined Posteroanterior Treatment. Biomed Res Int 2017:. https://doi.org/10.1155/2017/1568258
3. Kraemer WJ, Schemitsch EH, Lever J, et al (1996) Functional Outcome of Thoracolumbar Burst Fractures Without Neurological Deficit. J Orthop Trauma 10:. https://doi.org/10.1097/00005131-199611000-00006

4. Belkoff SM, Mathis JM, Fenton DC, et al (2001) An ex vivo biomechanical evaluation of an inflatable bone tamp used in the treatment of compression fracture. Spine (Phila Pa 1976) 26:. https://doi.org/10.1097/00007632-200101150-00008
5. Pumberger M, Schitz F, Bürger J, et al (2020) Kyphoplasty Restores the Global Sagittal Balance of the Spine Independently from Pain Reduction. Sci Rep 10:. https://doi.org/10.1038/s41598-020-65798-0
6. Cao Z, Wang G, Hui W, et al (2020) Percutaneous kyphoplasty for osteoporotic vertebral compression fractures improves spino-pelvic alignment and global sagittal balance maximally in the thoracolumbar region. PLoS One 15:. https://doi.org/10.1371/journal.pone.0228341
7. Garnier L, Tonetti J, Bodin A, et al (2012) Kyphoplasty versus vertebroplasty in osteoporotic thoracolumbar spine fractures. Short-term retrospective review of a multicentre cohort of 127 consecutive patients. Orthop Traumatol Surg Res 98:. https://doi.org/10.1016/j.otsr.2012.03.018
8. Crandall D, Slaughter D, Hankins PJ, et al (2004) Acute versus chronic vertebral compression fractures treated with kyphoplasty: Early results. Spine J 4:. https://doi.org/10.1016/j.spinee.2004.01.003
9. Maestretti G, Cremer C, Otten P, Jakob RP (2007) Prospective study of standalone balloon kyphoplasty with calcium phosphate cement augmentation in traumatic fractures. Eur Spine J 16:. https://doi.org/10.1007/s00586-006-0258-x
10. Hartmann F, Gercek E, Leiner L, Rommens PM (2012) Kyphoplasty as an alternative treatment of traumatic thoracolumbar burst fractures Magerl type A3. Injury 43:. https://doi.org/10.1016/j.injury.2010.03.025
11. Teyssédou S, Saget M, Gayet LE, et al (2016) Radiologic study of disc behavior following compression fracture of the thoracolumbar hinge managed by kyphoplasty: A 52-case series. Orthop Traumatol Surg Res. https://doi.org/10.1016/j.otsr.2015.11.011
12. Barut N, Marie-Hardy L, Bonaccorsi R, et al (2019) Immediate and late discal lesions on MRI in Magerl A thoracolumbar fracture: Analysis of 76 cases. Orthop Traumatol Surg Res. https://doi.org/10.1016/j.otsr.2019.03.008
13. Marie-Hardy L, Barut N, Sari Ali H, et al (2020) Evaluation of disc degeneration adjacent to AOspine A fractures: Pre-and post-operative MRI analysis. SICOT-J 6:. https://doi.org/10.1051/sicotj/2020032
14. Krüger A, Bäumlein M, Knauf T, et al (2021) Height and volume restoration in osteoporotic vertebral compression fractures: a biomechanical comparison of standard balloon kyphoplasty versus Tektona® in a cadaveric fracture model. BMC Musculoskelet Disord 22:. https://doi.org/10.1186/s12891-020-03899-7
15. Marcia S, Piras E, Hirsch JA, et al (2021) Efficacy of a Novel Vertebral Body Augmentation System in the Treatment of Patients with Symptomatic Vertebral Body Fractures. Cardiovasc Intervent Radiol 44:. https://doi.org/10.1007/s00270-020-02658-4
16. Jang S, Graffy PM, Ziemlewicz TJ, et al (2019) Opportunistic osteoporosis screening at routine abdominal and Thoracic CT: Normative L1 trabecular attenuation values in more than 20 000 adults. Radiology 291:. https://doi.org/10.1148/radiol.2019181648

17. Magerl F, Aebi M, Gertzbein SD, et al (1994) A comprehensive classification of thoracic and lumbar injuries. Eur Spine J. https://doi.org/10.1007/BF02221591
18. Mazel C, Ajavon L (2018) Malunion of post-traumatic thoracolumbar fractures. Orthop. Traumatol. Surg. Res. 104
19. Guigui P, Levassor N, Rillardon L, et al (2003) Valeur physiologique des paramètres pelviens et rachidiens de l'équilibre sagittal du rachis. Rev Chir Orthop Traumatol 89:
20. Garnon J, Doré B, Auloge P, et al (2019) Efficacy of the Vertebral Body Stenting System for the Restoration of Vertebral Height in Acute Traumatic Compression Fractures in a Nonosteoporotic Population. Cardiovasc Intervent Radiol 42:. https://doi.org/10.1007/s00270-019-02265-y
21. Jing Z, Dong J, Li Z, Nan F (1234) Single balloon versus double balloon bipedicular kyphoplasty: a systematic review and meta-analysis. Eur Spine J 27:2550–2564. https://doi.org/10.1007/s00586-018-5631-z
22. Koelé MC, Lems WF, Willems HC (2020) The Clinical Relevance of Hyperkyphosis: A Narrative Review. Front. Endocrinol. (Lausanne). 11
23. Lee JH, Lee DO, Lee JH, Lee HS (2014) Comparison of radiological and clinical results of balloon kyphoplasty according to anterior height loss in the osteoporotic vertebral fracture. Spine J 14:. https://doi.org/10.1016/j.spinee.2014.01.028
24. Hoyt D, Urits I, Orhurhu V, et al (2020) Current Concepts in the Management of Vertebral Compression Fractures. Curr. Pain Headache Rep. 24

Figures

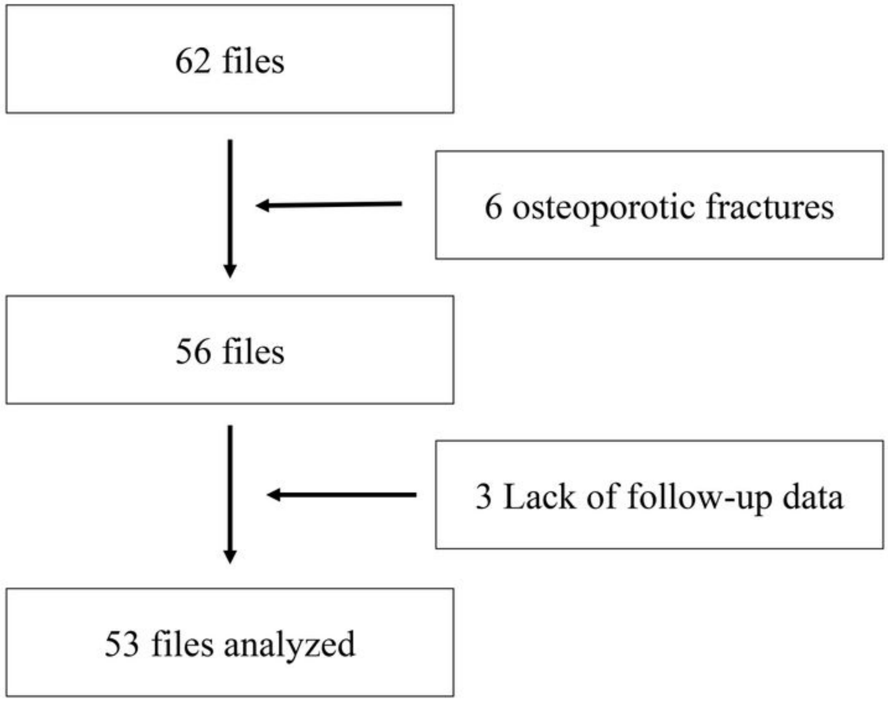

Figure 1

Flow-chart of the study

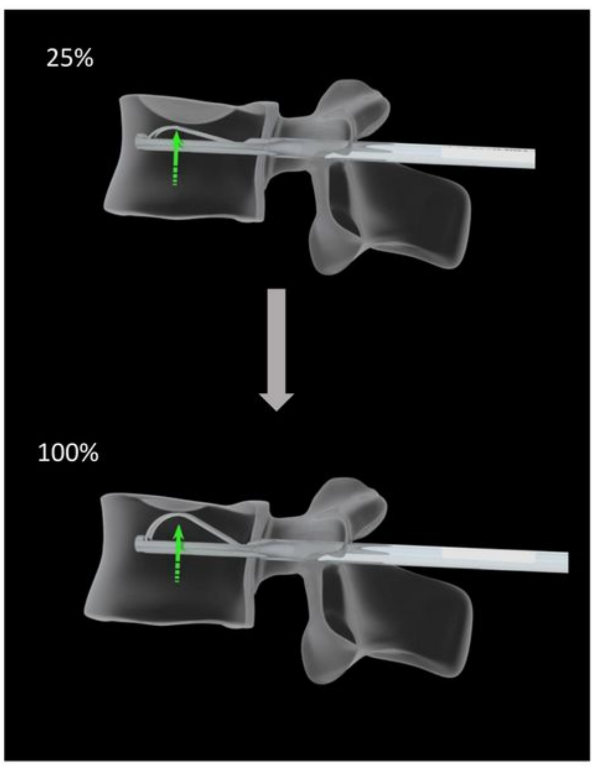

Figure 2

Scheme illustration the flexible lamella of the Tektona system progressive bend allowing to control the strength of reduction needed.

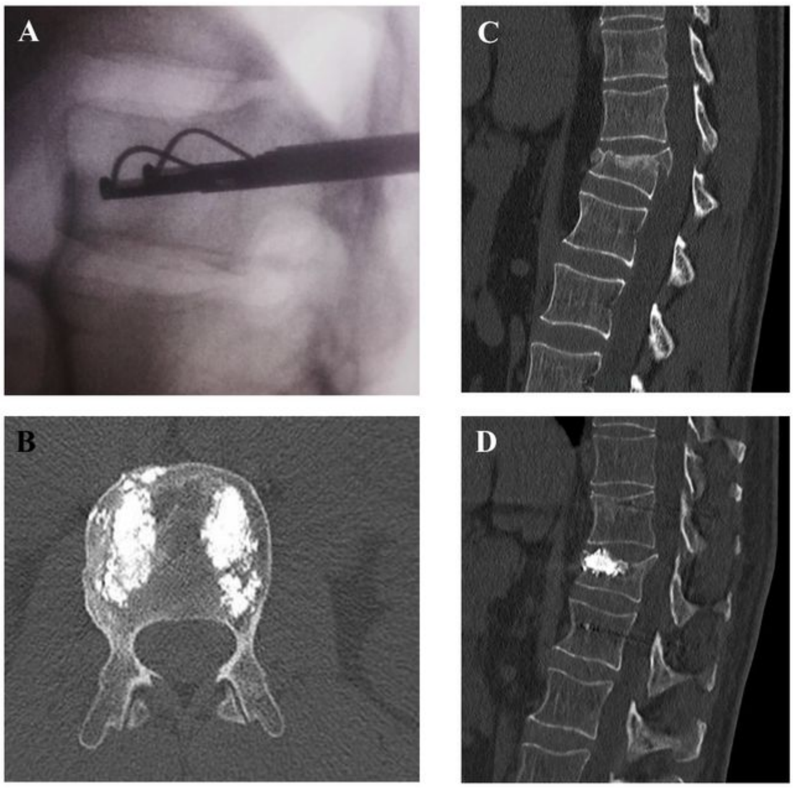

Figure 3

A: Per-operative C-arm imaging of the reduction of the superior endplate by the flexible lamella. B: Axial CT-scan slice of vertebral body cementing. C and D: Same patient, pre- and postoperative imaging after a vertebroplasty by Tektona™.

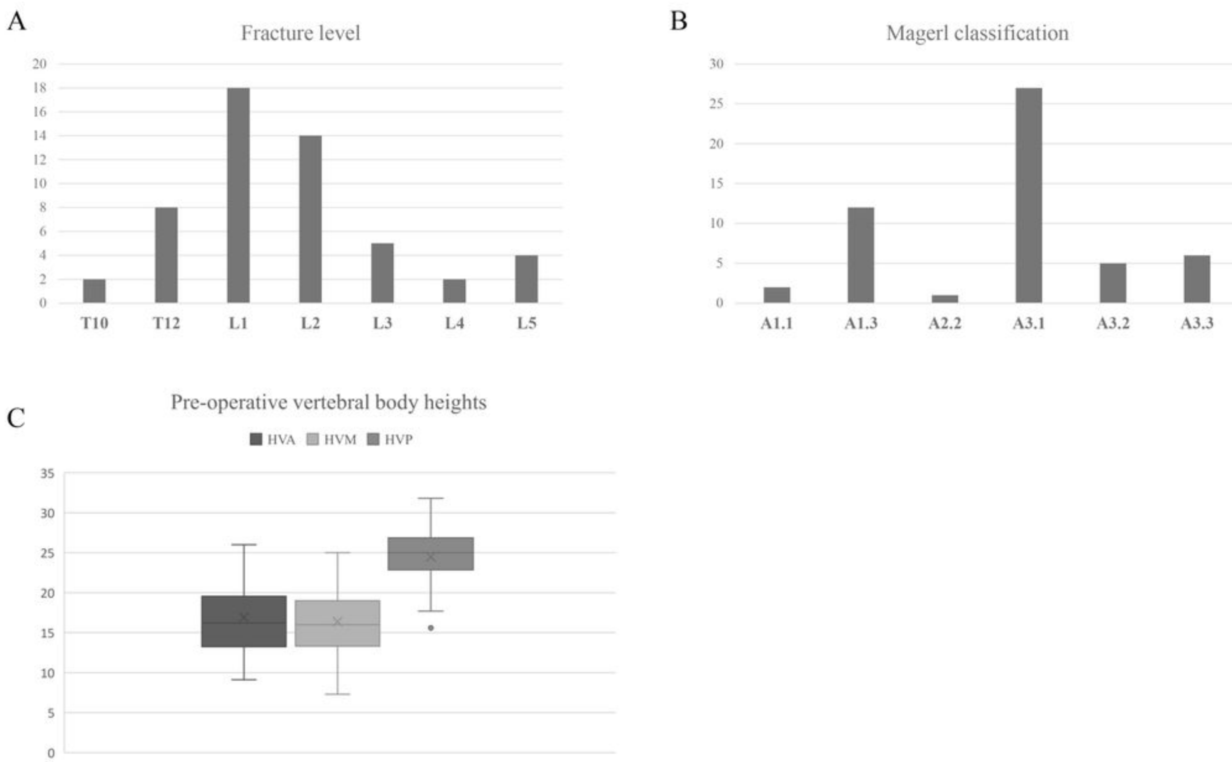

Figure 4

A: Histogram showing the repartition of the fracture's levels. B: Histogram showing the repartition of the fracture's types according to Magerl's classification. C: Box plots showing the vertebral body height (AVH: anterior vertebral height, MVH medium vertebral height and PVH: posterior vertebral height), in millimeters, in pre-operative.

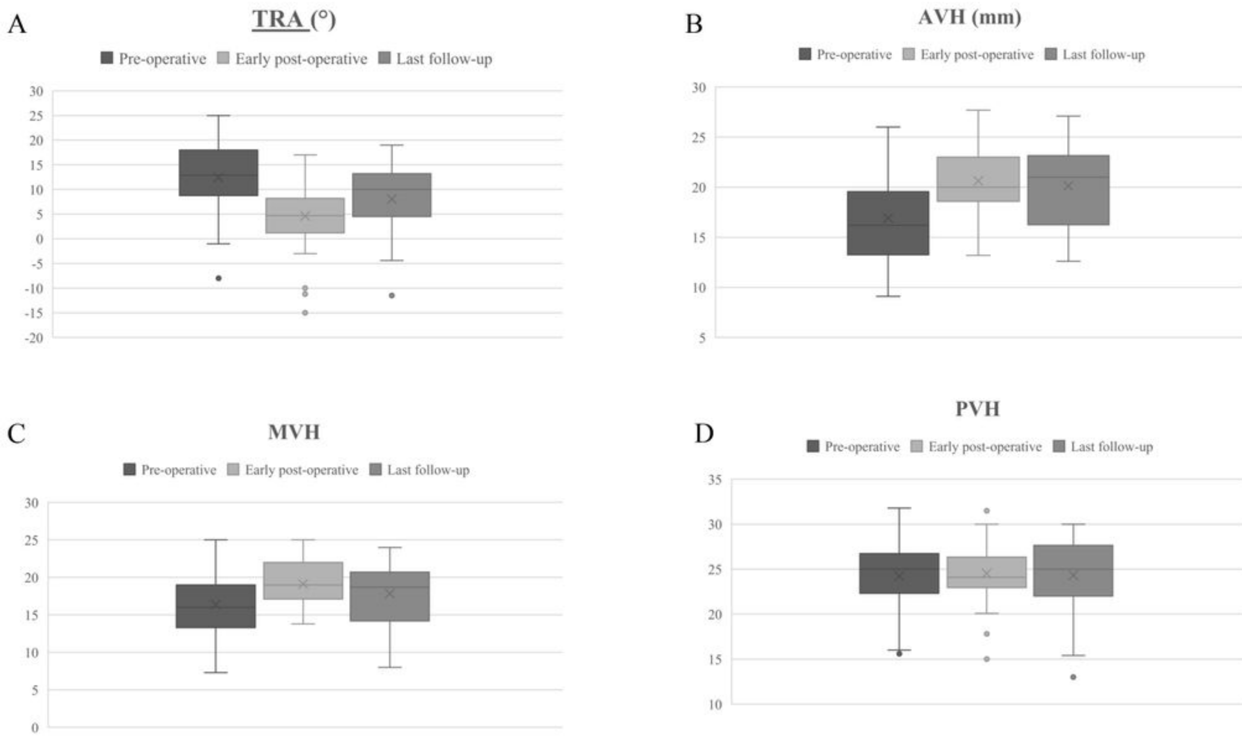

Figure 5

A: Box plots showing the traumatic vertebral angle, in °, at the 3 times of analysis (preoperative, early post-operative and at follow-up). B: Box plots showing the AVH, in mm, at the 3 times of analysis (pre-operative, early post-operative and at follow-up). C: Box plots showing the MVH, in mm, at the 3 times of analysis (pre-operative, early post-operative and at follow-up). D: Box plots showing the PVH, in mm, at the 3 times of analysis (pre-operative, early post-operative and at followup).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Anonymousdata.xlsx