Tridimensional Study of the Vertebral Body in Osteoporotic Vertebral Fractures Treated with Percutaneous Vertebroplasty.

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Abstract

Many studies analyze the increase in vertebral body height after percutaneous vertebroplasty (PVP) in the sagittal plane. However, the vertebral body is a three-dimensional structure. The aim of this study is to determine if there is a volume change in the vertebral body after PVP, and to determine possible differences according to the spine segment treated. This prospective study included 25 patients (51 vertebrae, BMI 26.4kg/m^2, T-score − 2.6) treated with PVP. The volumetric study was performed with MRI pre and post-surgery. We studied the amount of injected cement, the volume of cement inside the vertebral body, the fractured vertebra volume, percentage of volume loss, percentage of volume restoration and percentage of bone filling. Thoracolumbar fractures predominated. The average volume of injected cement was 3.6ml (range, 0.9–6.5). The volume loss was 4.1±3.3ml (16.2%). In the vertebral body, there was an increase in volume after PVP (difference + 1.6±1.6ml, 95% CI 1.1–2.03). Volume restoration was 1.6±1.6ml. Percentage of bone cement filling was 13.3%±4.5. There were no differences between the spine segments treated ($P > 0.05$). PVP increases the volume of the fractured vertebra approximately 40% of the volume loss. The volumetric changes after PVP were similar in the different spine segments treated.

Introduction

The main goal of percutaneous vertebroplasty (PVP) is to relieve pain and stabilize vertebral fractures[1,2]. Secondarily, this technique achieves a restoration of the vertebral body height that may reach 1.2-2.3mm[3–6]. On the other hand, the main objective of percutaneous kyphoplasty (PKP) is to relieve pain, stabilize the vertebral fracture and restore vertebral body height[7,8]. When using this technique, the vertebral height restoration varies from 1.4-5.1mm[3,4]. In practice, no difference between these two techniques for vertebral height restoration has been found. A systematic review of 69 clinical studies reported that both techniques were able to relieve pain (PVP in 87% and PKP in 92% of patients)[9].

In the literature, several techniques are reported to achieve restoration of vertebral body height[4,10,11]. However, it is not clear which is the best method to measure the restoration of vertebral body height. Many studies determine the height of the vertebral body in the sagittal plane, in its anterior, middle and posterior zones[4,5,12,13]. Some authors analyze correction of kyphosis angle[10,14] while others use both methods[2,15,16]. However, the vertebral body is a three-dimensional structure and these measurement techniques can underestimate the correction that may occur. For this reason, studies that evaluate the volume of the vertebral body are now appearing in the literature[17,18].

The objective of this study is to assess the volumetric change that occurs in the vertebral body after PVP and to determine if there are differences in the volumetric study, according to the vertebral segment affected. Our hypothesis was that although the literature describes no significant height restoration of vertebral body after percutaneous vertebroplasty (using x-rays), there are changes in vertebral volume and which that might be different depending on the vertebral body treated.

Materials And Methods

Approval for this prospective study was given by the Regional Ethical Review Board at our institution (University of Navarra, reference code, 2018.044). Before participating, informed consent was obtained from all subjects. In addition, the study was conducted in accordance with the 1975 Helsinky Declaration, revised in 2013.

Patient selection

Our cohort consisted of patients who had been treated for painful osteoporotic vertebral compression fractures (OVCFs) over the period February 2015 to June 2019.

Recruitment criteria were: acute OVCFs, failure of conservative treatment (non-steroidal anti-inflammatory drugs, soft orthosis and lumbar exercises for at least 4 weeks or less if uncontrollable pain), progressive collapse of the vertebral body, cement augmentation without instrumentation and MRI before and after surgery. The patients were excluded if they did not have the inclusion criteria, if they had a vertebral fracture secondary to oncological disease, or if cement augmentation was associated to instrumentation and no complete MRI study was available. Twenty-five patients (51 vertebrae) were included. All patients were treated with PVP with polymethyl methacrylate –PMMA– cement (Vertecem V + Cement Kit, DePuy Synthes, Oberdorf, Switzerland).

The locations and numbers of the treated vertebral bodies were as follows: T6 (n = 2), T7 (n = 4), T8 (n = 4), T9 (n = 2), T10 (n = 2), T11 (n = 3), T12 (n = 5), L1 (n = 9), L2 (n = 6), L3 (n = 6), L4 (n = 5) and L5 (n = 4). The demographic parameters of our cohort are shown in Table 1.

Table 1
Characteristics of the patients

Number of vertebrae		**51**	
Gender			
Male		5 (20%)	
Female		20 (80%)	
Age (range)		72.3 (55–87)	
BMI[1] (range)		26.4 (17.4–38.2)	
Spine T-Score (range)		-2.6 (-5 - -1.3)	
Time with vertebral fracture (days)		46 (17–180)	
Fracture level	**Thoracic (T1-T10)**	**Thoraco-lumbar (T11 – L2)**	**Lumbar (L3-L5)**
Total vertebral fracture treated	14	23	14
Fracture type*			
Wedge, n = 13 (%)	8 (61.5)	3 (23)	2 (15.5)
Biconcave, n = 37 (%)	5 (13.5)	20 (54)	12 (32.5)
Crush, n = 1 (%)	1 (100)	-	-
Fracture severity*			
Mild deformity, grade I, n = 16 (%)	5 (31.2)	7 (43,7)	4 (25.1)
Moderate deformity, grade II, n = 12 (%)	4 (33.3)	4 (33.4)	4 (33.3)
Severe deformity, grade III, n = 23 (%)	5 (21.7)	12 (52.1)	6 (26.2)
Trocars			
10G, n = 39 (%)	3 (7.7)	22 (56.4)	14 (35.9)
12G, n = 12 (%)	11 (91.6)	1 (8.4)	-
IVVC[2], n = 11	3 (27.2%)	6 (54.5%)	2 (18.3%)
Cement injected (range)	2.2 (0.9–4)	4.1 (2.1–6.5)	4.4 (3.5–6)
Cement inside the vertebral body (range)	1.57 (0.4–3.5)	3.5 (2–5.9)	3.7 (2.2–5.4)
Cement leakage			
Vertebral pedicle (%)	2 (14.3)	-	-

Number of vertebrae		51	
Interverterbral discal (%)	1 (7.1)	3 (13)	3 (21.5)
None (%)	11 (78.6)	20 (87)	11 (78.5)

[1]BMI: Body mass index

[2]IVVC: Intravertebral vacuum cleft

*According Genant classification[19].

We studied the type of vertebral fracture according to the Genant classification[19], the type of trocar used, volume of cement injected, presence or absence of cement leakage during surgery, vertebral volume pre and post-surgery and cement volume in the vertebral body after surgery.

Description of the surgical technique

Surgical treatment was performed under general anesthesia in prone position. We did not perform any maneuver to restore the vertebral height before or during the procedure. Two imaging systems (SIEMENS Arcadis Orbic and SIEMENS Arcadis Varic) perpendicular to each other and centered on each vertebra were used.

All PVPs were performed through a bilateral transpedicular approach. We used two types of trocars (10-gauge or 12-gauge) with diamond tip (Vertebroplasty Needle Kit, DePuy Synthes, Oberdorf, Switzerland) according to the pedicular size. Normally, we used 12-gauge trocars for thoracic segment (T1-T10) and 10-gauge trocars for thoraco-lumbar (T11-L2) and lumbar (L3-L5) segments. Under fluoroscopic guidance, cement was injected. The cement injection continued until the vertebral body was filled toward the posterior 25% of the vertebral body or until leakage occurred. After cement injection, the patient remained prone on the table for approximately 20 minutes.

Postoperative care

The immediate postoperative care consisted of relative bed rest, walking with a soft orthosis and thromboprophylaxis with low molecular weight heparin (3500 UI Bemiparin Hibor®) for 15 days. The patient was discharged on the day following the operation.

Imaging technique

We used presurgical standing X-ray to determine the type of vertebral fracture. Moreover, we performed preoperative and post-operative MRI with a 3 Tesla imager (SKYRA, Siemens, Erlangen, Germany). A minimum of one sagittal T2-weighted and sagittal T1-weighted sequences was obtained. The imaging matrix was 512x512 and section thicknesses were 3 mm with intersection gap of 0.2 mm. The post-operative MRI was obtained 4–6 weeks post-surgery.

Image assessment

The raw MRI data were transferred to Horos v3.3.3 software. To determine the volume of the vertebral body at pre-surgical and post-surgical times, the perimeter of the vertebral body in each sagittal section was determined in a T1-weighted sequence (Fig. 1). An average of seven sagittal sections was analyzed, for each vertebra. With this information, the program calculated pre-surgical and post-surgical vertebral volume (Fig. 2). In contrast, in order to calculate the volume of cement present in the vertebral body after PVP, the perimeter of the bone cement was determined in a T1-weighted sequence in each of the sagittal sections that included the vertebral body (Fig. 3). Volumetric study was performed in milliliters (ml). In order to prevent any magnification bias when measuring these volumes, we measured, before and after surgery, the volumes of the superior (SVA) and inferior vertebrae adjacent (IVA) to the fractured vertebra. The average of SVA and IVA was the estimated pre-fracture vertebral volume (pFVV). The difference between post-surgical and pre-surgical volumes of the fractured vertebra was the restored vertebral volume (RVV). With these parameters we calculated the percentage of volume loss (VL), the percentage of volume restored in the fractured vertebra (VRFV) and the percentage of bone cement filling (BCF). It was calculated with the following formulas:

$$VL = \frac{pFVV - Fractured\ vertebral\ volume\ before\ surgery}{pFVV}\ x\ 100$$

$$VRFV = \frac{RVV}{Fractured\ vertebral\ volume\ after\ surgery}\ x\ 100$$

$$BCF = \frac{Cement\ inside\ of\ vertebral\ body}{Fractured\ vertebral\ volume\ after\ surgery}\ x\ 100$$

Presence of cement leakage into the adjacent intervertebral disc and veins was defined as any contrast beyond the cortical margin of the vertebral body seen on postoperative MRI or X-ray studies. The amount of bone cement that remained outside the vertebral body was determined as the difference between the cement injected and the cement volume inside of the vertebral body.

Clinical outcome

To determine if the PVP leads to a significant improvement in pain reduction, we used the visual analogic scale (VAS) at the preoperative stage, one-day post-surgery and at first check-up (4–6 weeks post-surgery).

Statistical analysis of data

Descriptive statistics of the sample were obtained. The Shapiro-Wilk test confirmed normal distribution of the variables. We used a paired sample t-test or Wilcoxon test, depending on the utilization criteria, to analyze differences between preoperative and post-operative vertebral volume and the differences in VAS scale.

A 0.05 level of probability was accepted as criterion for statistical significance for all statistical tests. All statistical tests were carried out using Stata software 12.0 version for Macintosh (Data Analysis and

Statistical Software, Texas, USA).

Results

The average time from diagnosis to surgery was 46 days (range, 17–180). Mean Body Mass Index (BMI) was 26.4 kg/m^2 (range, 17.4–38.2), and mean T-score was − 2.6 (range, -5 - -1.3). The number of patients with a spinal T-score of lower than − 2.5 was 17 (68%), between − 1 and − 2.5 was 8 (32%) and no patients had a T-score superior to -1.

Fracture level was categorized as thoracic (T1-T10), thoracolumbar (T11–L2), and lumbar (L3-L5). Thoracolumbar injury predominated, being found in 23 vertebrae (45%). According to the Genant classification[19], 37 vertebral injuries were biconcave type (72.5%), 13 vertebral injuries were wedge type (25.5%) and 1 injury was crush type (2%).

The average volume of injected cement was 3.6ml (range, 0.9–6.5). Of this, 3ml (range, 0.4–5.9) were inside the vertebral body. The rest (0.6ml) was located in the trocar or had leaked out of the vertebral body. Cement leakage occurred in only 9 vertebrae (17.6%).

The volume of the upper and lower vertebrae adjacent to the fractured vertebra was similar pre and post-surgery (upper vertebra: difference 0.02±0.1, 95% CI -0.02-0.05, lower vertebra: difference 0.05±0.2, 95% CI -0.03-0.12, Table 2). The estimated pre-fracture vertebral volume (pFVV) was 25.3±9.4ml. The difference between the pFVV and the pre-surgery volume was 4.1±3.3ml (Fig. 4). Therefore, the percentage of volume loss was 16.2%±0.1 (Table 2 and Fig. 4). There was a volume increase in the fractured vertebrae after PVP (21.2ml pre-surgery versus 22.8ml, difference + 1.6±1.6ml, 95% CI 1.1–2.03, Table 2 and Fig. 4), approximately 40% of the volume loss (Table 2 and Fig. 4). The mean percentage of bone cement filling in the vertebral body was 13.3%±4.5 (Table 2).

Table 2
Volume (ml) characteristics before and after vertebral augmentation

	Pre-surgery	Post-surgery	Difference	95% CI
Superior vertebra adjacent (SVA)[1]	22.5 ± 9.7	22.6 ± 9.6	0.02 ± 0.1	-0.02 to 0.05
Inferior vertebra adjacent (IVA)[1]	28.1 ± 9.8	28.1 ± 9.7	0.05 ± 0.2	-0.03 to 0.12
Fractured vertebra volume	21.2 ± 9.1	22.8 ± 9.1	1.6 ± 1.6	**1.1 to 2.03**
Percentage of volume loss (VL)[2]	16.2% ± 0.1%	-	-	-
Percentage of volume restored in the fractured vertebra (VRFV)[3]	-	39.1%	-	-
Percentage of bone cement filling (BCF)	-	13.3% ± 4.5	-	-

[1] The average between superior and inferior vertebra adjacent to vertebral fracture was estimated pre-fracture vertebral volume (pFVV). It was 25.3±9.4ml in general.

[2] The quotient between the difference of pFVV and fractured vertebral volume before surgery with pFVV was percentage of volume loss. It was 4.1±3.3ml in general (16.2%).

[3] The quotient between the difference post-surgical and pre-surgical volumes with fractured vertebral volume after surgery was percentage of volume restored in the fractured vertebra. It was + 1.6±1.6ml (39.1% of volume loss) in general.

Table 3 shows the vertebrae body volumes taking into account the vertebral segment. There was no change in the volumes of the vertebrae adjacent to fractured vertebrae after the intervention ($P > 0.05$, Table 3). The percentage of volume loss was similar between the segments ($P = 0.535$, Kruskal-Wallis test). After PVP, there was an increase in volume in the fractured vertebrae which was greater in the lumbar segment, followed by the thoracolumbar segment and, finally, the thoracic segment (+ 1.8ml, + 1.7ml and + 1.2ml, respectively, Table 3). However, there were no significant statistical differences ($P = 0.541$, Kruskal-Wallis test). The percentage of volume restored relative to volume loss was greater in the thoracic segment, followed by the lumbar segment and, finally, the thoracolumbar segment (44.5%, 39%, 36%, respectively, Table 3) without any statistical difference between the segments ($P = 0.435$, Kruskal-Wallis test). The mean percentage of bone cement filling in the vertebral body was higher in the thoracolumbar segment, followed by the thoracic segment and, finally, the lumbar segment (14.7%, 13.9% and 12.2%, respectively, Table 3) without statistical differences ($P = 0.322$, Kruskal-Wallis test).

Table 3
Volume (ml) before and after vertebral augmentation taking into account the operated vertebral segment.

	Pre-surgery	Post-surgery	Difference	95% CI
Thoracic (T1-T10), n = 14				
Superior vertebra adjacent (SVA)[1], SD	11.1 ± 3.1	11.2 ± 3.1	-0.03 ± 0.1	-0.1 to 0.03
Inferior vertebra adjacent (IVA)[1], SD	14.5 ± 3.3	14.6 ± 3.2	-0.05 ± 0.5	-0.35 to 0.23
Fractured vertebra volume, SD	10.1 ± 3.6	11.3 ± 3.7	1.2 ± 0.7	**-1.59 to -0.83**
Percentage of volume loss (VL)[2]	21% ± 0.1	-	-	-
Percentage of volume restored in the fractured vertebra (VRFV)[3]	-	44.5%	-	-
Percentage of bone cement filling (BCF)	-	13.9% ± 5.7	-	-
Thoraco-lumbar (T11 – L2), n = 23				
Superior vertebra adjacent (SVA)[1], SD	23.2 ± 5.7	23.2 ± 5.6	-0.03 ± 0.2	-0.09 to 0.03
Inferior vertebra adjacent (IVA)[1], SD	32.3 ± 5.8	32.4 ± 5.8	-0.05 ± 5.8	-0.11 to 0.01
Fractured vertebra volume, SD	23.1 ± 6.1	24.8 ± 6.1	1.7 ± 1.2	**-2.12 to -1.07**
Percentage of volume loss (VL)[2]	16.9% ± 0.1	-	-	-
Percentage of volume restored in the fractured vertebra (VRFV)[3]	-	36%	-	-
Percentage of bone cement filling (BCF)	-	14.7% ± 4.3	-	-
Lumbar (L3-L5), n = 14				
Superior vertebra adjacent (SVA)[1], SD	32.9 ± 6.3	32.8 ± 6.4	0.01 ± 0.1	-0.04 to 0.08
Inferior vertebra adjacent (IVA)[1], SD	34.7 ± 4.8	34.7 ± 4.7	-0.03 ± 0.1	-0.11 to 0.03
Fractured vertebra volume, SD	29.2 ± 6.1	31 ± 4.9	1.8 ± 2.6	**-3.34 to -0.29**

	Pre-surgery	Post-surgery	Difference	95% CI
Percentage of volume loss (VL)[2]	13.6% ± 0.1	-	-	-
Percentage of volume restored in the fractured vertebra (VRFV)[3]	-	39%	-	-
Percentage of bone cement filling (BCF)	-	12.2 ± 3.6	-	-

SD: standard deviation

[1] The average between superior and inferior vertebra adjacent to vertebral fracture was estimated pre-fracture vertebral volume (pFVV).

[2] The quotient between the difference of pFVV and fractured vertebral volume before surgery with pFVV was percentage of volume loss.

[3] The quotient between the difference post-surgical and pre-surgical volumes with fractured vertebral volume after surgery was percentage of volume restored in the fractured vertebra.

The average scores on the visual analogue scale (VAS) preoperative, 24h post-operative and first revision (at 4–6 weeks post-surgery) were 7.5, 1.7 and 0.9, respectively.

Discussion

This prospective study analyzed volumetric changes in the vertebral body after PVP without maneuvering or using reduction devices. We found that there was an increase in the vertebral volume after PVP and there were no differences between the vertebral segments treated (thoracic, thoracolumbar and lumbar).

All our patients were treated with PVP. We did not use percutaneous kyphoplasty (PKP) because the literature shows that PKP requires more surgical time (which is harmful in elderly patients), the height restoration depends of the fracture time evolution and it is more expensive, which is why several studies recommend using PVP over PKP[20–22].

Many published studies conclude that PVP can increase vertebral height and thus, maintain sagittal balance[2,4,5,12]. As other authors indicate, the restoration of vertebral height can vary from 1.2-2.3mm after PVP[3–6]. However, these articles performed the analysis of vertebral body height in a single cut in the sagittal plane and did not take into account the dynamic mobility (change of vertebral body height according to the position of the patient) in the vertebral body which occurs in 87.5% of the fractured vertebrae[23]. For these reasons, the morphological change which occurs in the vertebral body is not yet well understood and to our knowledge this is the first study that identifies changes in volume restoration depending on the treated segment location.

Unlike previous studies[3–6], our study and that by Andrei et al.[17] analyze the volume of the vertebral body as a whole (three-dimensionally not two-dimensionally) before and after PVP. Andrei et al.[17] concluded that PVP had better radiological and clinical results at one-year follow-up compared to conservative treatment, and there was an increase in the vertebral volume of 0.1ml after PVP. In contrast, we have observed an increase in vertebral volume of 1.6±1.6ml after PVP. In general, there was a loss of vertebral volume of 4.1ml at the time of the fracture that was restored by 1.6ml after PVP (Fig. 4). This means that PVP makes it possible to recover up to 40% of volume loss (Fig. 4).

The optimal volume of bone cement to inject into fractured vertebrae remains controversial and we found no published articles that analyze the real volume of bone cement present in the vertebral body after PVP. In a cadaver study, Belkoff et al.[24] reported that the amount of injected cement depends on the segment of the spine treated, 2.5-3ml in the thoracic segment, 3-4ml in the thoracolumbar segment and 6-8ml in the lumbar segment. Our results were consistent with Belkoff et al.[24], in the thoracic segment we injected a mean of 2.2ml (range, 0.9-4), in the thoracolumbar segment we injected a mean of 4.1ml (range, 2.1–6.5) and in the lumbar segment we injected a mean of 4.4ml (range, 3.5-6) of bone cement.

The percentage of vertebral body volume that must be filled with bone cement to restore the biomechanical characteristics of the fractured vertebra is unknown. Some authors suggest that in order to obtain the best biomechanical status of the vertebra, to achieve adequate restoration of compressive strength or equalized stress distribution in the vertebral body, a filling with bone cement is required of between 13%-16% of the volume of the vertebral body[25–27]. In general, in our results, we obtained a 13.3% ±4.5 vertebral body filling. If we take into account the spinal segment treated, we achieved a filling of 13.9%±5.7 in the thoracic segment, 14.7%±4.3 in the thoracolumbar segment and 12.2%±3.6 in the lumbar segment (Table 3). However, Molloy et al.[27] concluded that strength and stiffness are weakly correlated with the percentage fill volume of injected cement during vertebroplasty.

It has been reported that there is a 22%-88% leakage of bone cement after performing PVP[28], and although most cases are asymptomatic, there could be major complications such as pulmonary embolism or neurological complications. In our study we found cement leaks in 19.6% of the cemented vertebrae. This may be because we determined the presence of bone cement leakage with simple radiology and MRI. None of our patients had neurological or respiratory problems.

There is no relationship between the amount of cement and the functional result. Andrei et al.[17] noted that PVP provides a significant improvement in pain reduction, less requirement for analgesia and allows earlier independent ambulation than with conservative treatment. In our patients we also observed a reduction in progressive pain after PVP (VAS pre-operative, 24 hours post-operative and 4–6 weeks post-surgery were 7.5, 1.7 and 0.9, respectively).

Limitation

This study has limitations. First, a relatively small group of patients was studied, we analyzed 25 patients including 51 vertebrae. The cost of MRI is expensive, thus limiting the number of patients included. Second, the MRI is prone to inaccuracy when calculating the volume of osseous structures. Moreover, MRI does not allow differentiating between cortical and cancellous bone as well as CT scans do, and this differentiation might be distorted due to artifacts created by the PMMA cement. The gold-standard technique for making volumetric measurements is CT-scan. However, our Ethics Committee did not authorize the use of CT to measure the vertebral volume and they proposed the MRI as an alternative. Third, we included vertebrae with intervertebral vacuum cleft, but these vertebrae are homogeneously distributed over the three segments of the spine. Fourth, we determined cement leaks with plain radiography and MRI although CT scan has a higher sensitivity in diagnosing cement leakages. We did not use CT for the reasons exposed in the third point and furthermore, it was not part of the objective of the study. Fifth, we measured the vertebral volume at 4–6 weeks after surgery because we wanted to analyze the vertebral volume after subjecting the vertebral body to the axial load which it normally supports.

Conclusion

Our results show that PVP produces an increase of volume in the fractured vertebra, achieving restoration up to 40% of the volume lost due to the fracture, and allowing an optimal cement filling of the vertebral body to be biomechanically competent. However, there was no differences between vertebral spine segments treated in the volume loss, the volume restored or the percentage of bone cement filling.

Declarations

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AUTHOR CONTRIBUTIONS

J.P., M.A designed the study. J.P, R.L and M.A carried out data collection. J.P performed data analysis. All authors wrote the manuscript, critically reviewed and revised the manuscript for content and approved the manuscript for publication.

DECLARATION OF CONFLICTING INTERESTS

The authors declares that there is no conflict of interest.

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Figures

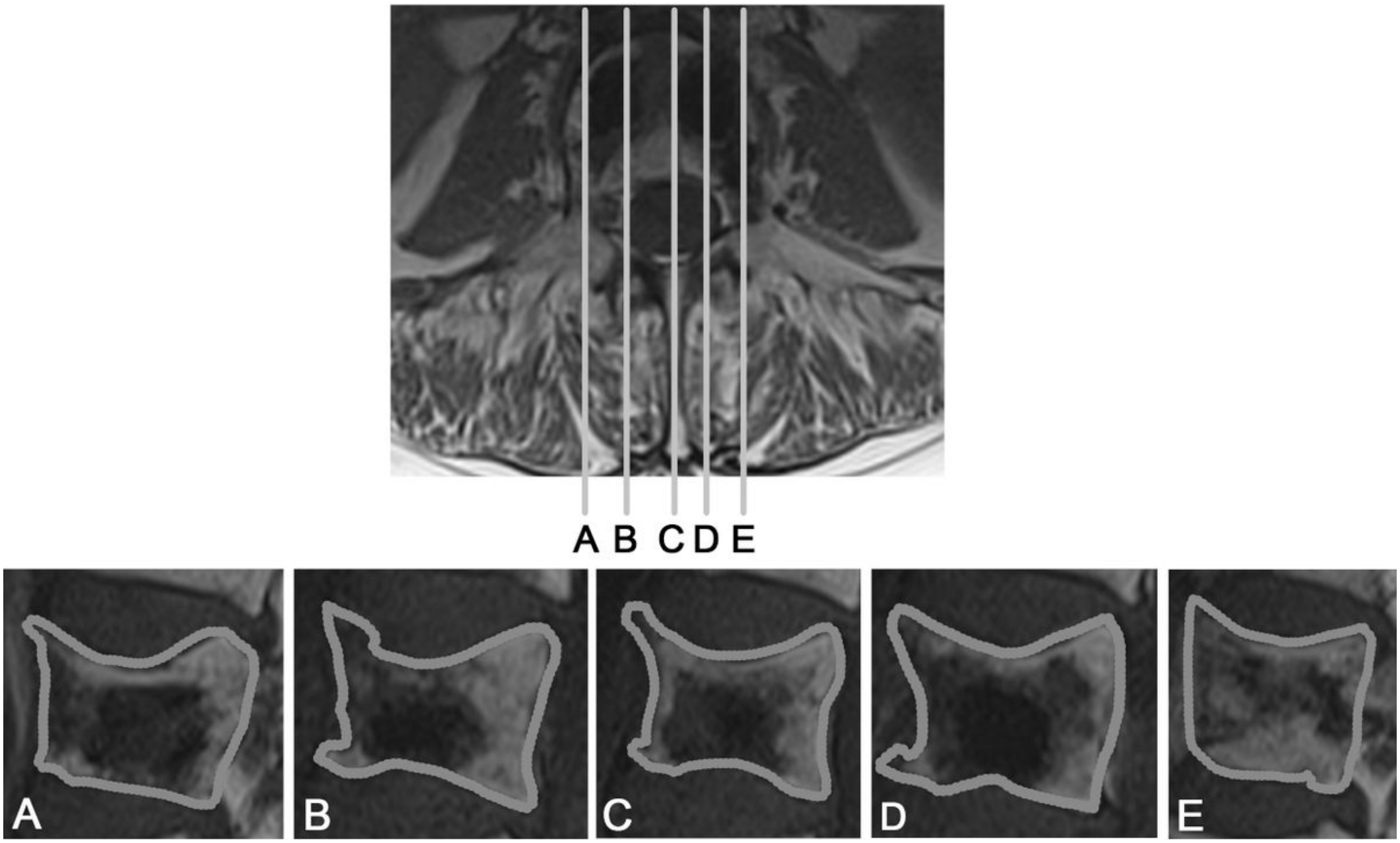

Figure 1

Vertebral volume assessment. The vertebral volume was determined by delimiting the perimeter of the vertebral body in each sagittal section with T1-weighted sequence (A-E).

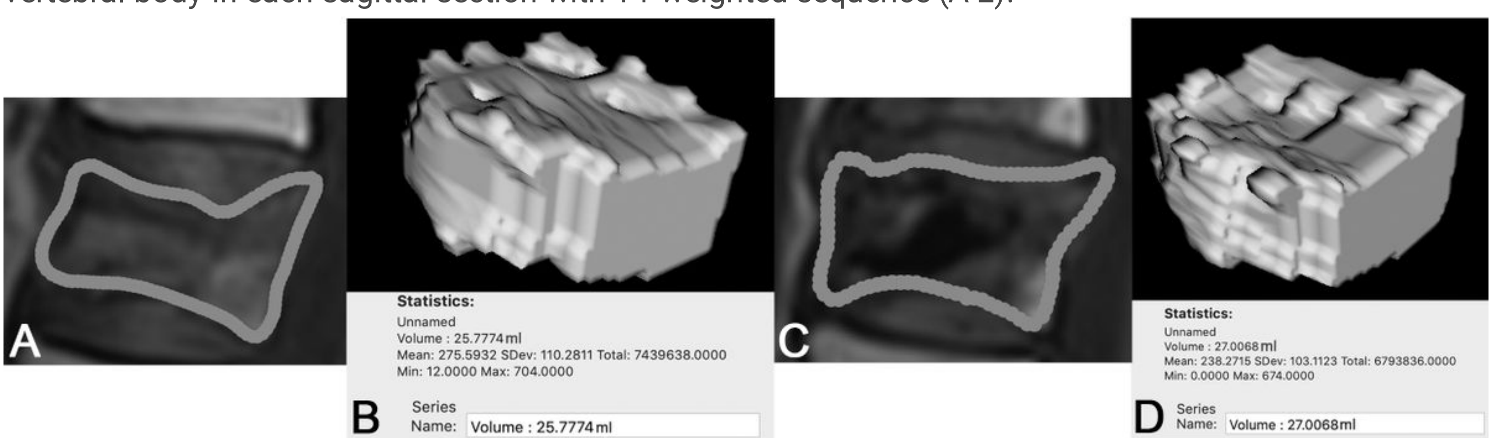

Figure 2

To determine the volume of the vertebral body at the pre-surgical and post-surgical time, the perimeter of the vertebral body in each of the sagittal sections was determined in a T1-weighted sequence (A and C). With this information, the program calculated the pre-surgical and post-surgical vertebral volume (B and D).

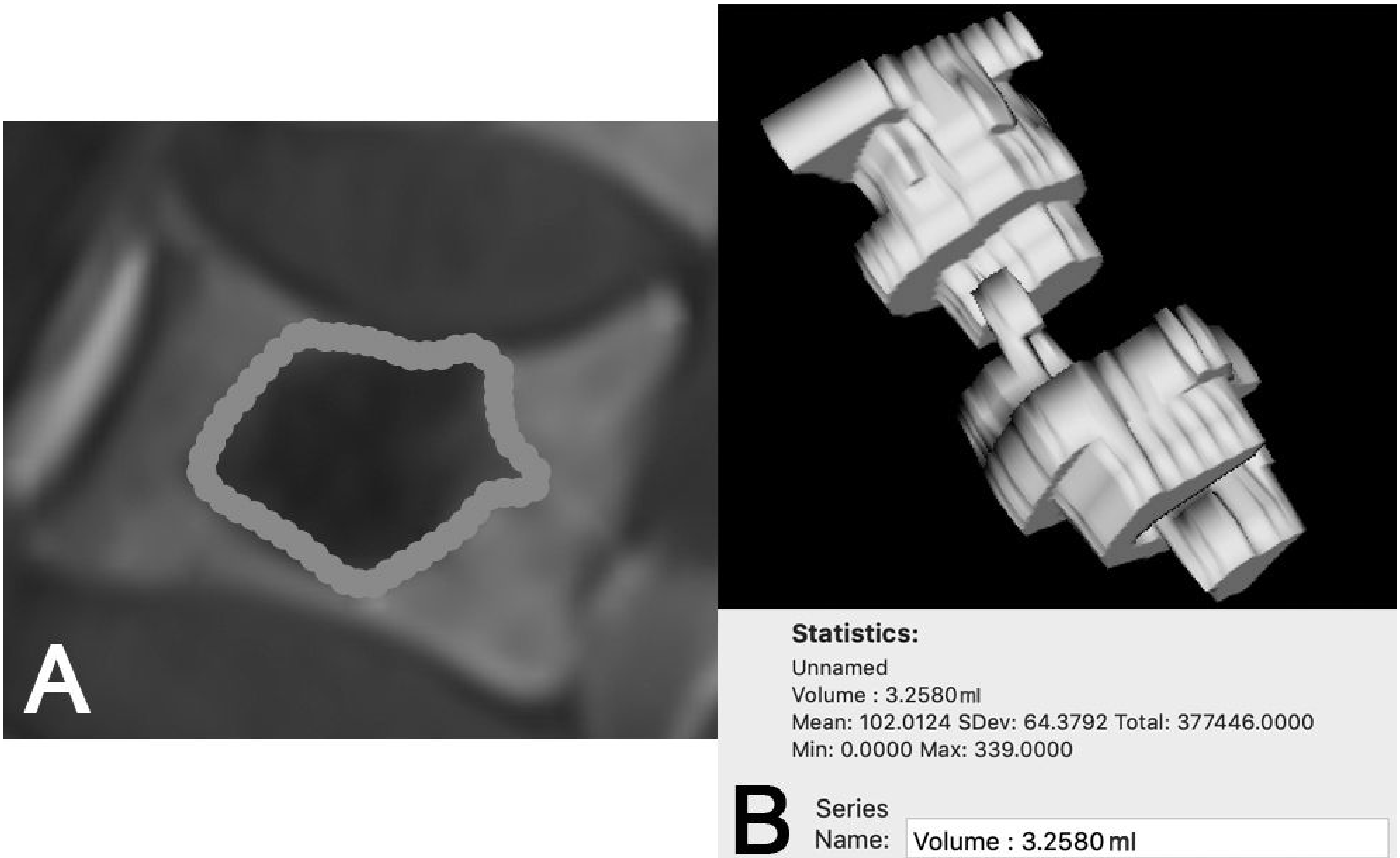

Figure 3

The volume of bone cement present within the body was calculated by measuring the perimeter of the bone cement in a T1-weighted sequence in each of the sagittal sections that includes the vertebral body.

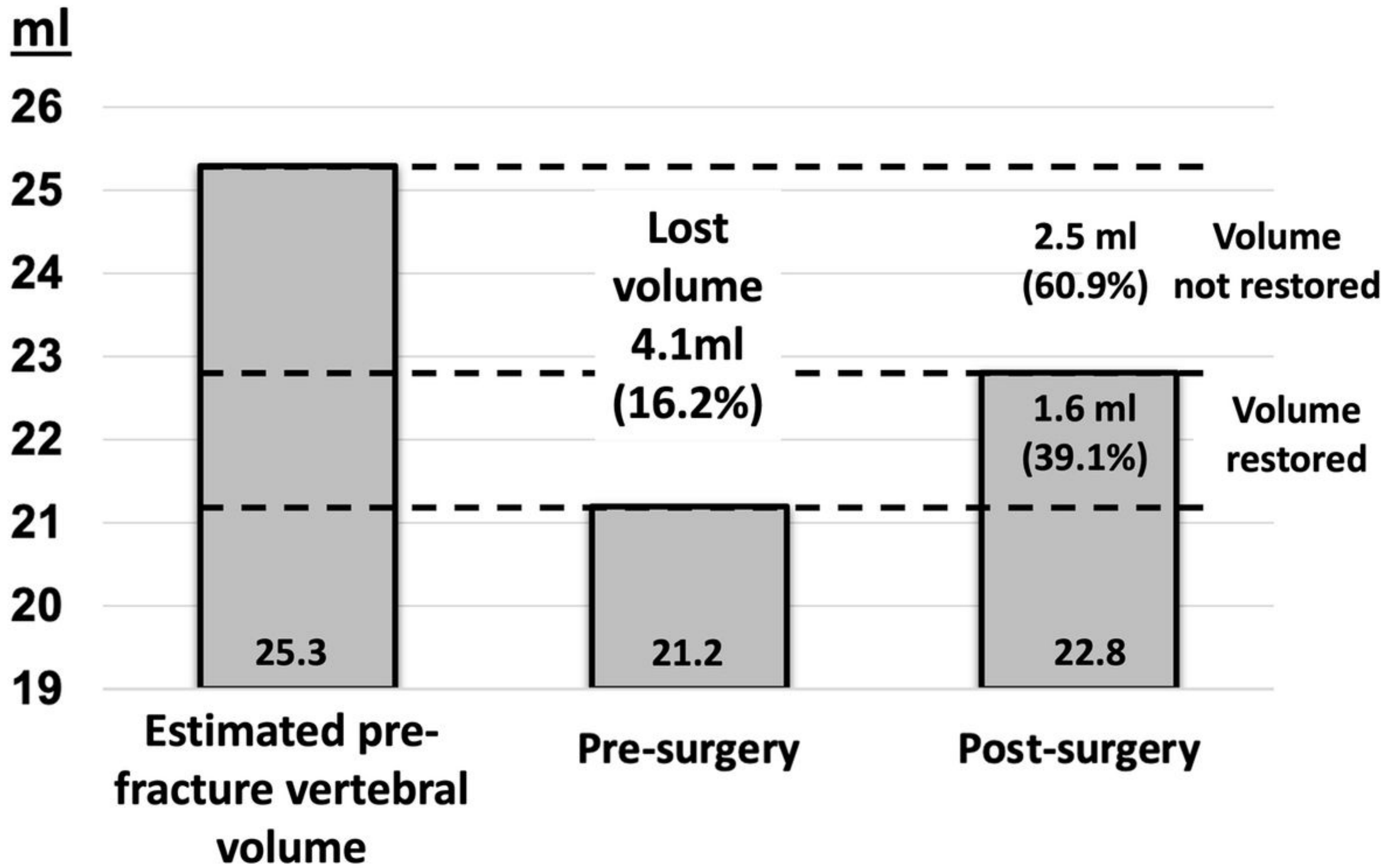

Figure 4

Graphic diagram about the vertebral body volume changing before and after percutaneous vertebroplasty.