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Title: Repeat Needle Insertion in Vertebroplasty to Prevent Re-collapse of the Treated Vertebrae

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Keywords: osteoporosis, vertebral compression fractures, vertebroplasty, re-collapse, repeat needle insertion.

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**Abstract:** Purpose: Patients with un-relieved pain after vertebroplasty due to re-collapse of the cemented vertebrae have been reported. Here we report a technique of vertebroplasty that can reduce the incidence of re-collapse at the cemented vertebrae.

**Materials and Methods:** Between March 2002 and September 2008, 134 patients with 205 painful vertebral compression fractures underwent vertebroplasty in our institutes. The indication of using this technique was unfilled area more than 25% of the vertebral body height in lateral radiograph. The vertebroplasty procedure was performed according to the technique described by Jensen. If the unfilled area was more than 25% of the vertebral body height in lateral radiograph, another needle would be inserted aiming at the unfilled area. As outcome measurement, a visual analog scale with 10 divisions and plain radiographs (to measure the anterior vertebral body height of cemented vertebrae) were used.

**Results:** Thirteen vertebrae were treated with this technique. The mean age was 74.4 years. The immediate post-vertebroplasty anterior vertebral height was  $24.92 \pm 3.59$  mm, changed to  $23.52 \pm 3.54$  mm at final follow-up. The visual analog scale decreased from a mean of 8.7 before vertebroplasty to 2.3 at final follow-up. The follow-up duration ranged from 15 to 38 months (mean 18.5 months).

There was no case of re-collapse of the cemented vertebrae, and no procedure-related complications.

**Conclusion:** In the treatment of vertebral compression fractures by percutaneous vertebroplasty, repeat needle insertion to the unfilled area may be helpful to decrease the incidence of re-collapse of cemented vertebrae if the unfilled area is more than 25% of the vertebral body height in lateral radiograph.

## Conflict of Interest Disclosure Form

Article Title: **Repeat Needle Insertion in Vertebroplasty to Prevent Re-fracture of the Treated Vertebrae**

Authors: Yen-Jen Chen, Wen-Hsien Chen, Hsien-Te Chen, Horng-Chaung Hsu.

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No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

Name: Yen-Jen Chen

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Date: Oct. 2, 2010

Dear Editors:

Enclosed is one copy of “**Repeat Needle Insertion in Vertebroplasty to Prevent Re-collapse of the Treated Vertebrae**“, by YJ Chen, WH Chen, HT Chen and HC Hsu. The paper is submitted to be considered for publication as a technical note in your journal. Neither the entire paper nor any part of its content has been published or has been accepted by another journal. The paper is not being submitted in its entirety or in part to any other journal.

We believe the paper may be of particular interest to your readers because re-collapse of cemented vertebrae after vertebroplasty might occur in osteoporotic patients. Patients with un-relieved pain after PV have also been reported. Here we describe a new idea of vertebroplasty that can reduce the incidence of re-collapse of the cemented vertebrae and increase the success rate of vertebroplasty.

No part of this article has been sent by mail.

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All authors have no conflicts of interest.

Thank you for your attention to this article.

Sincerely yours,

Yen-Jen Chen, M.D.

Dear Editor:

I have answered the reviewers' comments as follows.

## **Response to Reviewers' Comments**

### **Reviewer #1:**

This technical note is focused on the problem of cement filling in osteoporotic VCF. The authors propose a second needle approach in case with poor cement filling with the first needle. This is interesting but some technical and methodological points need to be clarified and explained :

- Vertebroplasty is classically commonly performed with a bipedicular approach. What is really different and new in this series ?

### **Response:**

The concept of this study is: sometimes the cemented vertebrae will re-collapse and result in recurrence of pain that needs further management. Uni-pedicular or bi-pedicular approach is not always enough; we need to insert extra needle to fill the unfilled area on the lateral radiograph to prevent re-collapse of cemented vertebrae **during the same procedure**. (It's not good to treat it again **after** the cemented vertebra was collapsed.)

The unfilled area we mentioned here is focus on **lateral radiograph**, not on AP view. Hemi-vertebra filling can also get good result if the filling in lateral view is enough. If the fractured vertebra is filled completely with uni-pedicular or bipedicular approach, then it's not necessary to insert another needle (repeated needle). Not all vertebroplasty need to insert the repeated needle, **only a small percentage of patients** undergoing vertebroplasty (13 in 205 treated vertebrae in this study) **will need it**. The needles in **bipedicular** approach are inserted **before** cement injection and aiming to the **same level** in lateral radiograph. However, the repeated needle is inserted **after** cement injection and aiming to the unfilled area. We can't predict which area will not be filled after cement injection, so we can't insert the needle (so called the repeated needle) in advance as in bipedicular approach. By the way, the repeated needle is not always the second needle, it may be the third needle or even the fourth needle, depends on the filling condition of cement. As we demonstrated in figure 1A and 1B, there are two needles in the vertebral body (bipedicular approach). After injection of cement, the lower part of vertebral body is not filled by cement. So the third needle is inserted aiming to the unfilled area. This is a new concept and totally different to bipedicular approach.

- Technique of approach and vertebral puncture with the second needle. Same puncture ? Or different entry point ? It seems difficult to insert two 11G needle in all vertebrae through the same pedicle. Authors should provide some clarification about this second puncture.

**Response:**

It's **not** inserting 2 needles in one pedicle at the same time. Before inserting the second needle, the first needle should be removed (because the needle is filled with cement). We can use the same side, same or different entry point, but just change the **direction** of needle; we can also approach from the contra lateral side with the needle aiming to the unfilled area. The entry point of the second needle (repeated needle) is not important. What's important is the **direction** of the needle. **However, if the second needle (repeated needle) is difficult to insert due to safety reason, we will give it up.**

We **revised** it as follows: If the unfilled area was more than 25% of the vertebral body height in lateral radiograph, another needle was inserted (the first needle should be removed) aiming at the unfilled area (Fig. 1). We can use the same side, same or different entry point, but just change the direction of needle; we can also approach from the contra lateral side with the needle aiming to the unfilled area. The procedure was considered complete when the unfilled area was less than 25% of the vertebral body height in lateral radiograph.

- The follow-up duration and methodology should be described, because the outcome is evaluated with VAS and vertebral height.

**Response:**

Thank you very much.

**We revised Materials and Methods as below:**

Between March 2002 and September 2008, 134 patients with 205 painful VCFs underwent vertebroplasty in our institutes. The indications for vertebroplasty were severe pain that was not responsive to medical treatment, and MRI confirmed active edematous lesions (hyper-intensity-signal on short-tau inversion recovery (STIR) sequence and/or contrast enhancement on fat-suppressed gadolinium-enhanced T1-weighted imaging). The indication of using this technique was inadequate cement filling (unfilled area more than 25% of the vertebral body height in lateral radiograph). All patients were evaluated at our outpatient clinics at 1 week and 1, 3, and 6 months after the procedure. As outcome measurement, a visual analog scale (VAS) with 10 divisions and plain radiographs (to measure the anterior vertebral height of cemented vertebrae) were used. The anterior vertebral body height of fractured vertebra was

measured based on the techniques used by McKiernan [3]. In order to remove the inter-radiographic magnification error, we match each index VCF to the referent vertebra on the pre-vertebroplasty lateral radiograph. Each index-referent vertebral pair remained constant throughout the analysis. In post-vertebroplasty and final follow-up lateral radiographs, dimensions of the index vertebra were expressed as percentage of the analogous dimension of the referent vertebra, and then scaled to the absolute dimensions of the original pre-vertebroplasty lateral radiograph. This cancels out any residual inter-radiographic magnification error and allows for direct radiographic comparisons.

**Results:** The follow-up duration ranged from 15 to 38 months (mean 18.5 months). The height decrement was  $1.40 \pm 1.41$  mm (range, -0.67 to 3.37 mm). There was no case of re-collapse in these 13 cemented vertebrae, and no procedure-related complications.

#### **Reviewer #2:**

Although the idea of the authors can vaguely be followed, and even might bear some practical value, this manuscript is far away from any scientific work.

The manuscript misses any serious concept. Materials and methods are not defined clearly. Scores are not defined, follow up is not defined. The threshold of 25% as argued is questionable and far away of any scientific purpose. The study question, as far as it can be found at all, is not answered, and no conclusions can be drawn from the presented data, even on the basis of a technical note. No comparison can be drawn to a control group. These are just a few criteria, that make up an acceptable manuscript.

As presented the manuscript would need complete and professional rewriting.

#### **Response:**

The concept of this study is: sometimes the cemented vertebra will re-collapse and result in recurrence of pain that needs further management. Uni-pedicular or bi-pedicular approach is not always enough; we need to insert extra needle to fill the unfilled area on the lateral radiograph to prevent re-collapse of cemented vertebra **during the same procedure.** (It's not good to treat it again **after** the cemented vertebra was collapsed.) The idea in this study bears important clinical value; I'll do my best to revise it. Please re-consider it. Thank you very much.

As we know, there are still many controversies in vertebroplasty. Even after the publication of 2 randomized clinical trials in New England Journal of Medicine, **the debate is still going**. Because inadequate filling only occurred in a small percentage of patients undergoing vertebroplasty (13 in 205 treated vertebrae in this study), it's not easy to define all things clearly. That's why we submit this study in Technique Note, not in Original Clinical Research.

There is no any scientific evidence to support the use of 25% as the threshold. Why not 10%, 30%, or 40%? If we use 40% as the threshold, the unfilled area is too much, and then the incidence of re-collapse will be higher. If we use 20% or even 10% as the threshold, it's difficult to insert another needle in such narrow area. So we use 25% as the threshold. (It's somewhat like the "anterior third" in "The needle was advanced toward to the **anterior third** of the vertebral body"; and "posterior quarter" in "the procedure was terminated immediately if cement reached the **posterior quarter** of the vertebral body"; no good evidence to support these 2 numbers too.) The key point in this study is to fill the fractured vertebra as much as possible in lateral radiograph to prevent re-collapse of the treated vertebra. The threshold is just a rough number, not an exact number. But we still need a number as a criteria.

Because this study focuses on re-collapse of the cemented vertebra, the key point of follow-up is X-ray. That's why we didn't describe too much about quality of life (such as the score of the Roland–Morris Disability Questionnaire), only the X-ray results and VAS were mentioned.

#### **We revised Materials and Methods as below:**

Between March 2002 and September 2008, 134 patients with 205 painful VCFs underwent vertebroplasty in our institutes. The indications for vertebroplasty were severe pain that was not responsive to medical treatment, and MRI confirmed active edematous lesions (hyper-intensity-signal on short-tau inversion recovery (STIR) sequence and/or contrast enhancement on fat-suppressed gadolinium-enhanced T1-weighted imaging). The indication of using this technique was inadequate cement filling (unfilled area more than 25% of the vertebral body height in lateral radiograph). All patients were evaluated at our outpatient clinics at 1 week and 1, 3, and 6 months after the procedure. As outcome measurement, a visual analog scale (VAS) with 10 divisions and plain radiographs (to measure the anterior vertebral height of cemented vertebrae) were used. The anterior vertebral body height of fractured vertebra was measured based on the techniques used by McKiernan [3]. In order to remove the inter-radiographic magnification error, we match each index VCF to the referent



vertebra on the pre-vertebroplasty lateral radiograph. Each index-referent vertebral pair remained constant throughout the analysis. In post-vertebroplasty and final follow-up lateral radiographs, dimensions of the index vertebra were expressed as percentage of the analogous dimension of the referent vertebra, and then scaled to the absolute dimensions of the original pre-vertebroplasty lateral radiograph. This cancels out any residual inter-radiographic magnification error and allows for direct radiographic comparisons.

**Results:** The follow-up duration ranged from 15 to 38 months (mean 18.5 months). The height decrement was  $1.40 \pm 1.41$  mm (range, -0.67 to 3.37 mm). There was no case of re-collapse in these 13 cemented vertebrae, and no procedure-related complications.

As I mentioned in the text, the **limitation of this study** was small case number and no control group. This was because inadequate filling only occurred in a small percentage of patients undergoing vertebroplasty (13 in 205 treated vertebrae in this study), and we **couldn't predict in advance** when inadequate filling will happen. Although there are many limitations in this study; however, the idea in this study is important. It may do some help to other interventionalists. Please re-consider it. Thank you very much.

Thank you for your comments

Best Regards,

Yen-Jen Chen, MD.

## **Repeat Needle Insertion in Vertebroplasty to Prevent Re-collapse of the Treated**

### **Vertebrae**

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**Repeat Needle Insertion in Vertebroplasty to Prevent Re-collapse of the Treated**

**Vertebrae**

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1           **Abstract**  
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4           **Purpose:** Patients with un-relieved pain after vertebroplasty due to re-collapse of the  
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7           cemented vertebrae have been reported. Here we report a technique of vertebroplasty  
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10           that can reduce the incidence of re-collapse at the cemented vertebrae.  
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13           **Materials and Methods:** Between March 2002 and September 2008, 134 patients  
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15           with 205 painful vertebral compression fractures underwent vertebroplasty in our  
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17           institutes. The indication of using this technique was unfilled area more than 25% of  
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19           the vertebral body height in lateral radiograph. The vertebroplasty procedure was  
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21           performed according to the technique described by Jensen. If the unfilled area was  
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23           more than 25% of the vertebral body height in lateral radiograph, another needle  
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25           would be inserted aiming at the unfilled area. As outcome measurement, a visual  
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27           analog scale with 10 divisions and plain radiographs (to measure the anterior vertebral  
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29           body height of cemented vertebrae) were used.  
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42           **Results:** Thirteen vertebrae were treated with this technique. The mean age was 74.4  
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44           years. The immediate post-vertebroplasty anterior vertebral height was  $24.92 \pm 3.59$   
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46           mm, changed to  $23.52 \pm 3.54$  mm at final follow-up. The visual analog scale  
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48           decreased from a mean of 8.7 before vertebroplasty to 2.3 at final follow-up. The  
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50           follow-up duration ranged from 15 to 38 months (mean 18.5 months). There was no  
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58           case of re-collapse of the cemented vertebrae, and no procedure-related  
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1 complications.  
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4 **Conclusion:** In the treatment of vertebral compression fractures by percutaneous  
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7 vertebroplasty, repeat needle insertion to the unfilled area may be helpful to decrease  
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10 the incidence of re-collapse of cemented vertebrae if the unfilled area is more than  
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13 25% of the vertebral body height in lateral radiograph.  
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23 **Key words:** osteoporosis, vertebral compression fractures, vertebroplasty, re-collapse,  
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26 repeat needle insertion.  
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1           **Introduction**  
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4           Percutaneous vertebroplasty (PV) is usually effective for pain relief in patients with  
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7           osteoporotic vertebral compression fractures (VCFs); however, unrelieved pain after  
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10          PV has been reported [1, 2]. Absence or inadequate filling of cement in the unstable  
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13          fractured area of the vertebral body might explain this observation [1]. Here we report  
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16          a technique of vertebroplasty that can reduce the incidence of re-collapse at the  
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19          cemented vertebrae.  
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22           **Materials and Methods**  
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24           Between March 2002 and September 2008, 134 patients with 205 painful VCFs  
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26          underwent vertebroplasty in our institutes. The indications for vertebroplasty were  
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29          severe pain that was not responsive to medical treatment, and MRI confirmed active  
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32          edematous lesions (hyper-intensity-signal on short-tau inversion recovery (STIR)  
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35          sequence and/or contrast enhancement on fat-suppressed gadolinium-enhanced  
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38          T1-weighted imaging). The indication of using this technique was inadequate cement  
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41          filling (unfilled area more than 25% of the vertebral body height in lateral radiograph).  
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44          All patients were evaluated at our outpatient clinics at 1 week and 1, 3, and 6 months  
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47          after the procedure. As outcome measurement, a visual analog scale (VAS) with 10  
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50          divisions and plain radiographs (to measure the anterior vertebral height of cemented  
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53          vertebrae) were used. The anterior vertebral body height of fractured vertebra was  
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1 measured based on the techniques used by McKiernan [3]. In order to remove the  
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4 inter-radiographic magnification error, we match each index VCF to the referent  
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7 vertebra on the pre-vertebroplasty lateral radiograph. Each index-referent vertebral  
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10 pair remained constant throughout the analysis. In post-vertebroplasty and final  
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13 follow-up lateral radiographs, dimensions of the index vertebra were expressed as  
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16 percentage of the analogous dimension of the referent vertebra, and then scaled to the  
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19 absolute dimensions of the original pre-vertebroplasty lateral radiograph. This cancels  
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23 out any residual inter-radiographic magnification error and allows for direct  
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26 radiographic comparisons.

## 27 **Technique**

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33 The vertebroplasty procedure was performed according to the technique  
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36 described by Jensen et al [4]. However, we made some modifications. In Jensen's  
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39 technique, the needle moves parallel to the superior and inferior edges of the pedicle,  
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42 or in a slightly descending course through the pedicle. In our technique, the needle  
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45 travels toward the "responsible area" (hypo-intensity in T1-weighted magnetic  
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48 resonance (MR) image and/or hypo-intensity in contrast-enhanced T1-weighted  
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51 image).

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55 Patients were placed in the prone position on four-poster frame radiolucent  
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58 table, and the procedure was performed under local or general anesthesia. An 11-G  
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1 bone marrow biopsy needle (Hakko Electric Machine Works Co., Nagano, Japan) was  
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4 used to puncture the fractured vertebra through the pedicles. The needle was advanced  
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7 toward the responsible area and to the anterior third of the vertebral body under  
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10 fluoroscopic guidance. Bone cement was prepared and injected into the vertebral body  
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13 under fluoroscopic monitor; the procedure was terminated immediately if cement  
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16 reached the posterior quarter of the vertebral body, or if significant leakage into the  
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19 disc space occurred. If the unfilled area was more than 25% of the vertebral body  
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22 height in lateral radiograph, another needle was inserted (the first needle should be  
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25 removed) aiming at the unfilled area (Fig. 1). We can use the same side, same or  
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28 different entry point, but just change the direction of needle to the unfilled area; we  
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31 can also approach from the contra lateral side with the needle aiming to the unfilled  
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34 area. The procedure was considered complete when the unfilled area was less than  
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39 25% of the vertebral body height in lateral radiograph.  
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## 42 **Results**

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45 We have used this technique in 13 vertebral bodies of 13 patients – twelve female  
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48 and one male. The mean age was 74.4 years (range, 64.5 to 83.5 years). The locations  
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51 of the inadequately filled vertebrae were: T10 (1), L1 (3), L2 (6), L3 (1), L4 (1) and  
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55 L5 (1). Two vertebrae had an intravertebral vacuum cleft sign. The pre-procedure  
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58 anterior vertebral body height was  $18.56 \pm 5.12$  mm (mean  $\pm$  standard deviation)  
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1 (range, 11.09 to 26.63 mm), increased to  $24.92 \pm 3.59$  mm (range, 19.81 to 29.90 mm)  
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4 post-vertebroplasty, and  $23.52 \pm 3.54$  mm (range, 18.19 to 29.05 mm) at final  
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7 follow-up. Pain assessed by the VAS significantly ( $P < 0.001$ ) decreased from a mean  
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10 of 8.7 before vertebroplasty to 2.7 after vertebroplasty, and 2.3 at final follow-up. The  
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13 follow-up duration ranged from 15 to 38 months (mean 18.5 months). The height  
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16 decrement was  $1.40 \pm 1.41$  mm (range, -0.67 to 3.37 mm). There was no case of  
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20 re-collapse in these 13 cemented vertebrae, and no procedure-related complications.  
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## 22 **Discussion**

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26 In the early stage of our practice, cement was filled into the vacuum only. These  
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29 patients received dramatic pain relief in the beginning; however, the pain would attack  
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32 again later due to re-collapse of the unfilled area. Some of them would need to  
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35 undergo revision vertebroplasty or surgery (Fig. 2). Lin et al [5] reported that if the  
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38 vertebrae are filled inadequately, these residual unfilled spaces may lead to re-collapse;  
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41 and this occurred mainly at the cement-unsupported portion of the vertebral body. The  
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44 reason is that the pressure resulting from rigid cement can damage the marrow  
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47 trabeculae of the unfilled area and result in re-collapse of the vertebrae when these  
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50 vertebrae are osteoporotic and fragile [5].  
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55 In order to solve this problem, we have learned to add extra cement to this unfilled  
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58 area in lateral radiograph by another needle. Why in lateral radiograph only? Knavel  
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1 et al [6] reported that hemivertebral filling is as effective in reducing pain as bilateral  
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4 vertebral filling. Because collapse of vertebral body is mainly in the lateral radiograph,  
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7 the focus of unfilled cement area is on the vertebral body height in lateral radiograph,  
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10 not in anteroposterior view. Why we choose the number of 25%? If the unfilled area  
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13 is less than 25% of the vertebral body height in lateral radiograph, it will be difficult  
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16 to insert another needle into such narrow space. So we use 25% as the threshold.  
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20           With regard to the direction of needle in PV, it is important to determine the  
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23 location that is responsible for the pain in the fractured vertebrae. If there is a vacuum,  
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26 then the vacuum is the responsible area. If there is no vacuum, the responsible area is  
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29 the hypo-intensity area in contrast-enhanced T1-weighted MR image or the  
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32 hypo-intensity area in T1-weighted MR image (Fig. 3). The needle should advance  
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35 toward this area, not routinely to the middle third of the vertebra body. If the needle is  
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38 not aimed at the responsible area, sometimes the cement will not fill this area.  
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42 Consequently, the patient will not have pain relief after PV, as was demonstrated in  
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45 the study of He et al [1].  
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49           The limitation of this study was small case number and no control group. This  
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52 was because inadequate filling only occurred in a small percentage of patients  
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55 undergoing vertebroplasty (13 in 205 treated vertebrae in this study), and we couldn't  
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58 predict in advance when inadequate filling will happen. In the future, we may need  
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1 more studies to support this hypothesis.  
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#### 4 **Conclusion**

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7 In the treatment of vertebral compression fractures by percutaneous  
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10 vertebroplasty, uni-pedicular or bi-pedicular approach is not always enough;  
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12 sometimes we need to insert extra needle to fill the unfilled area to prevent re-collapse  
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14 of cemented vertebra during the same procedure if the unfilled area is more than 25%  
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20 of the vertebral body height in lateral radiograph.  
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## Figure Legends

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6 **Fig. 1.** Two needles are inserted into the mid-part of the vertebral body (A), and  
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8 cement is injected (B). The third needle is inserted aiming at the unfilled part of the  
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10 vertebra (C). Cement is injected into the unfilled area (D).

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18 **Fig. 2.** Lateral radiograph of a 78 year-old man demonstrates L1 compression fracture  
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20 (A). Intra-vertebroplasty lateral radiographs demonstrate the needle insertion (B) and  
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22 cement filling (C). Post-vertebroplasty lateral radiographs demonstrate the  
23  
24 progressive collapse of the unfilled area (D, E).

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34 **Fig. 3.** The responsible area in painful osteoporotic compression fracture can be  
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36 demonstrated as area of hypo-intensity in T1-weighted MR image (A) or  
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38 hypo-intensity in contrast-enhanced T1-weighted MR image (B).

Figure 1  
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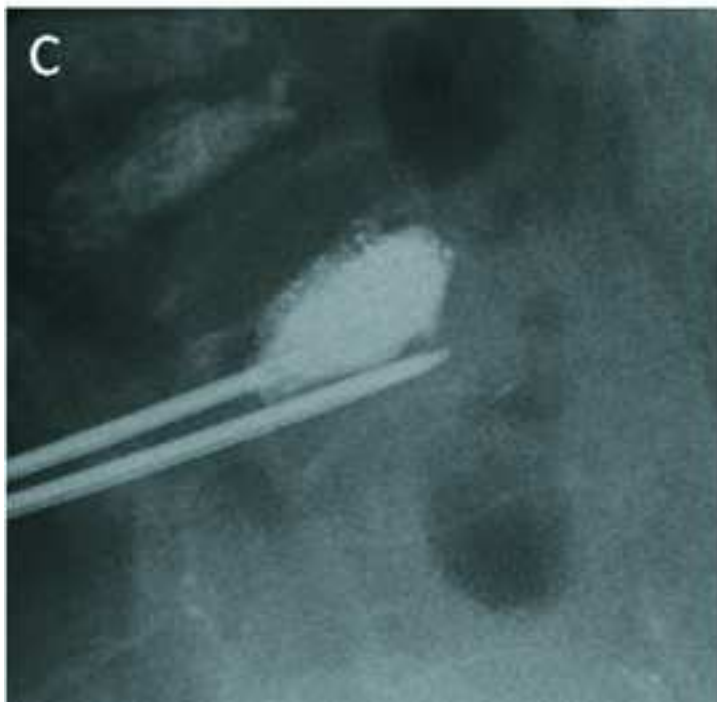
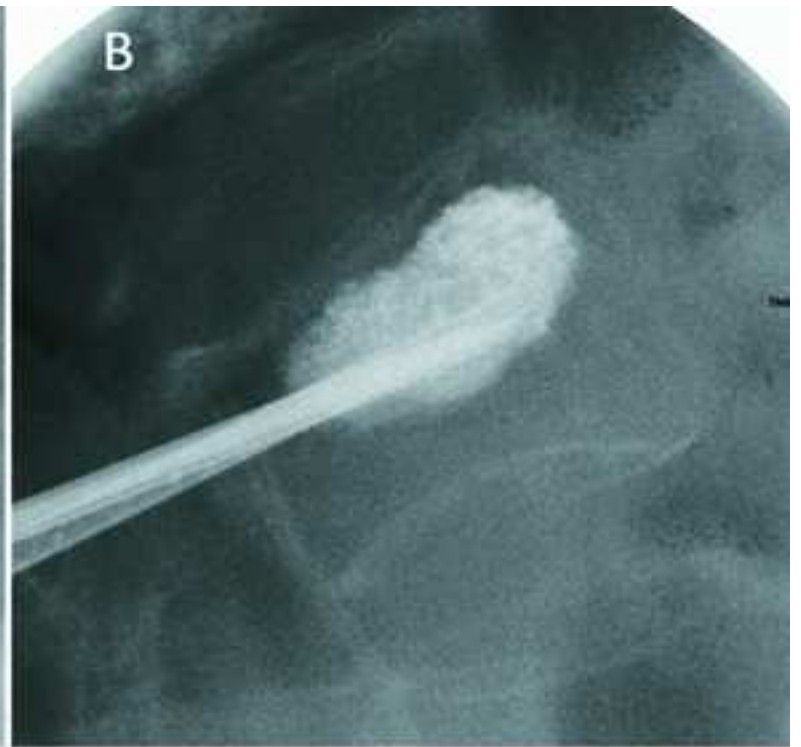




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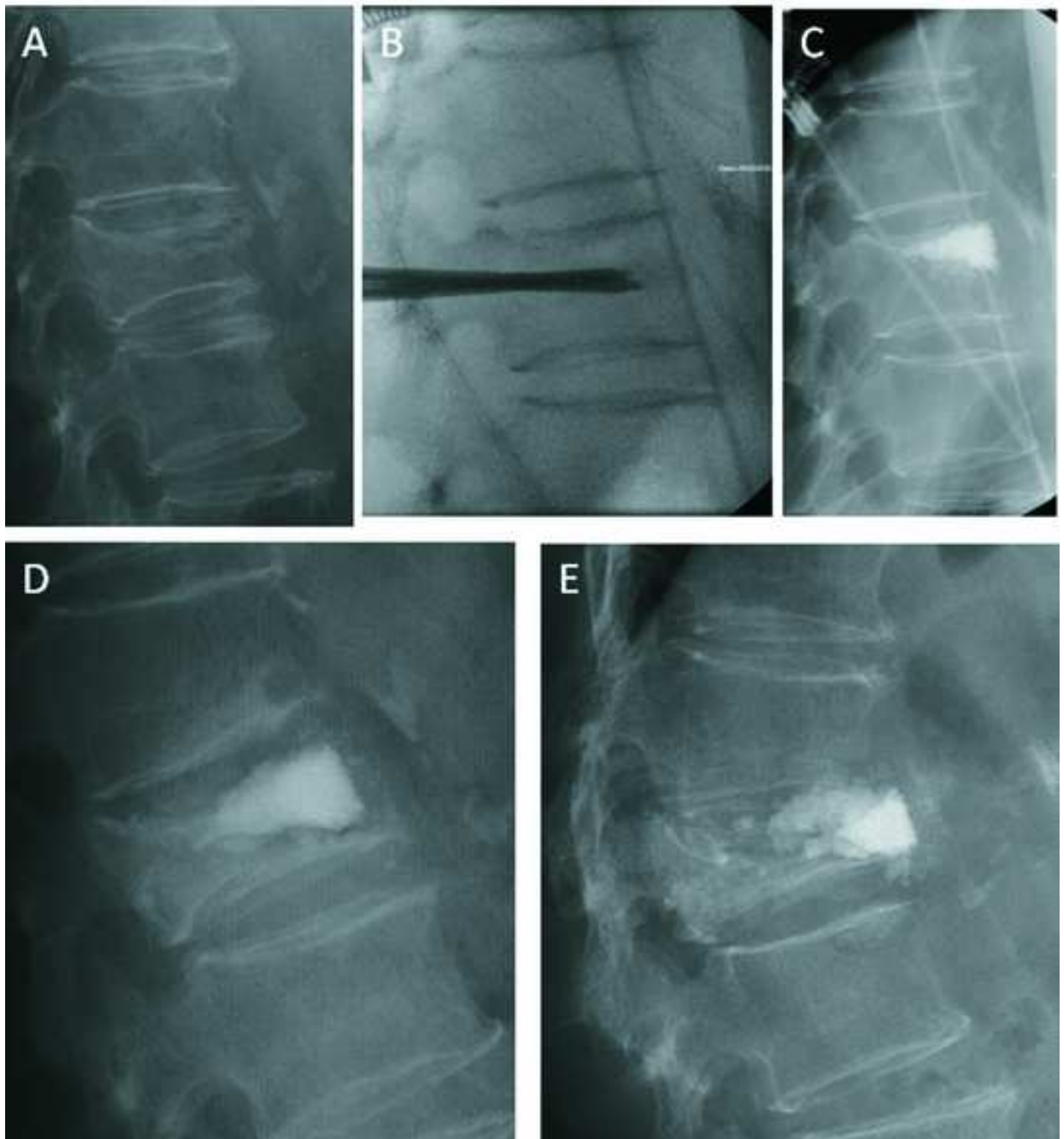


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