

# Comparison of vertebroplasty using directional versus straight needle

Wai Cheong Soon, Ryan K Mathew and Jake Timothy

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## Abstract

**Background:** Percutaneous vertebroplasty is a minimally invasive procedure that can be performed to treat pain and immobility associated with vertebral compression fractures. Previous studies have shown that a single injection can achieve adequate fill across the midline of the vertebral body.

**Purpose:** To compare the radiological outcomes of using a novel steerable needle with using a conventional, straight needle in unipedicular vertebroplasty.

**Material and Methods:** Data were collected from 19 patients who were operated at our institute between 1 September 2010 and 31 March 2011. Outcomes were measured in terms of radiological evidence of midline crossing of cement. The available pre- and postoperative pain scores and complications were reviewed. Student's t-test was used to compare mean cement projection across the midline in both groups with  $P < 0.05$  considered to be statistically significant.

**Results:** Mean fill across the midline was significantly greater with the steerable needle (58%) compared with the straight needle (35%) ( $P = 0.046$ ). Cement leakage was higher with the steerable needle (44% versus 30%); however no clinical complications were reported in either group.

**Conclusion:** Percutaneous vertebroplasty using a directional needle is an excellent example of advancement and refinement in spinal surgery without increased clinical risk. Our results indicate that the novel technique can potentially provide better radiological outcomes when compared with a straight needle. A larger, randomized multicenter prospective trial would be valuable in confirming these findings.

## Keywords

Vertebroplasty, spine, surgery

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## Introduction

Percutaneous vertebroplasty is a minimally invasive and relatively safe procedure that aims to treat symptoms of pain and immobility in patients with vertebral compression fractures (VCF). The main symptoms of vertebral fractures include acute onset back pain, loss of vertebral body height, spinal immobility, and deformity (1). In addition, affected patients may also experience neurological dysfunction symptoms related to cord compression.

Percutaneous vertebroplasty is a procedure which involves the injection of polymethylmethacrate (PMMA) cement into the vertebral body. This procedure was first successfully performed in France in 1984 on a female patient who suffered from a painful

hemangioma in the cervical spine (2). It is used to relieve pain caused by VCFs that fail to respond to conventional medication therapy such as paracetamol, NSAIDs, and opioid analgesics.

The Osseon directional needle (Osseon Therapeutics, Santa Rosa, CA, USA) was designed to provide the operator with better control over the direction of the delivery needle. The dynamic range of motion of the Osseon needle (0–100 degrees of tip flexion) (Fig. 1)

Department of Neurosurgery, Leeds General Infirmary, Leeds, UK

### Corresponding author:

Wai Cheong Soon, Department of Neurosurgery, Leeds General Infirmary, Leeds LS3 1DX, UK.  
Email: waicheong88@gmail.com





**Fig. 1.** Example of Osseon steerable needle (Needle tip can be flexed in the range of 0–100 degrees) (3).

allows for better access to the entire vertebral body and increased midline crossing of the injected cement (3). For the appropriately trained operator, the novel needle provides little more technical challenge than a standard needle.

It remains paramount to continue to identify ways to improve the technique, safety, and clinical efficacy of this procedure. A recent study that reviewed 1081 cases in the United States and 131 patients in Europe found that physicians' and patients' satisfaction with the directional needle have generally been high. It was also found that navigating more complex vertebral levels (e.g. upper thoracic) using the directional needle has been judged superior to the straight needle (4). Other than this study, no other research has been carried out to compare the directional and the straight needle. This retrospective study was designed to compare clinical data and radiological outcome of vertebroplasty using a steerable needle with vertebroplasty using a straight needle. Outcomes were measured in terms of radiological evidence of midline crossing of cement, intra- and postoperative complications, and pre- and postoperative pain scores.

## Material and Methods

This is a retrospective study looking at the medical records of 23 patients who underwent vertebroplasty for vertebral compression fractures (VCF) using either the directional Osseon needle or straight Stryker needle at our institute between 1 September 2010 and 31 March 2011. All patients with VCFs caused by osteoporosis, trauma, primary cancer, and metastatic cancers between September 2010 and March 2011 were included in the study. Patients who underwent kyphoplasty or vertebroplasty using other types of needles were excluded from the study. The medical notes of patients who fitted the inclusion criteria were obtained from the Medical Records Department.

Prior to data collection, a pro forma was designed to record patient age, gender, diagnosis, preoperative analgesia, spinal levels treated, type of needle and cement, procedure time, pre- and postoperative pain scores, complications, follow-up, and radiological

imaging findings. Information was supplemented using the theatre logbook, a Trust electronic patient database, and radiology system. The data were analyzed using the Microsoft Excel statistical function and Statistical Package for the Social Sciences (SPSS version 17 statistical software, IBM, Armonk, NY, USA)

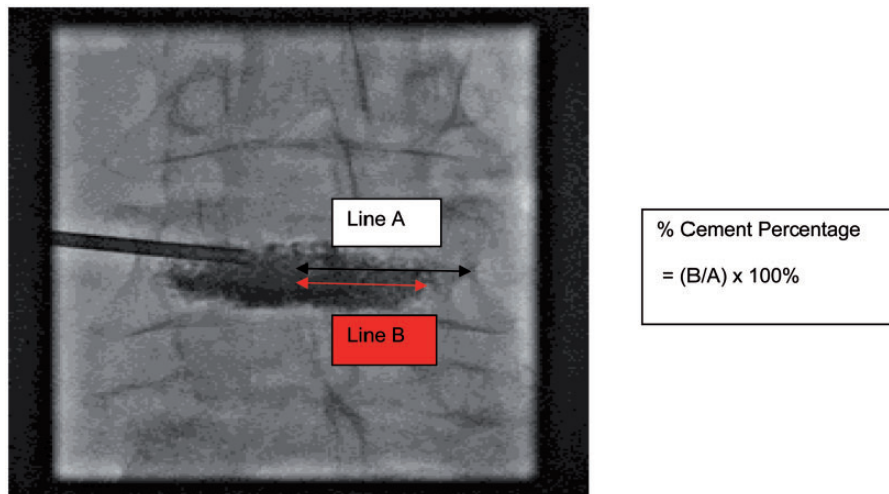
All of the procedures were performed under conscious sedation using a combination of fentanyl, midazolam, and local anesthetic. Cement injection can be performed in less than 1 h using local anesthesia with sedation. A specially designed needle (Jamshidi) is used to deliver cement through the skin into the targeted vertebral body. Vertebroplasty using the straight or directional needle is set up and approached in a similar technical manner. Initially, the patient is placed in a prone position during injection of cement. After the cement has been injected into the target area, the patient is then placed in a supine position in the recovery area for approximately 1 h to allow the cement to harden. The procedure is closely monitored with intraoperative fluoroscopy to ensure that the needle placement and cement injection are accurate. With the directional needle, the operator can steer and navigate easily through the vertebral body. This creates a void which allows the operator to then fill with cement. Patients are usually discharged on the same day.

The percentage of cement projection across the midline was calculated using one of the calibration features on the Picture Archiving and Communication System (PACS). A line is first drawn between the midline (level of the spinous process) and the edge of the vertebral body. A second line is drawn between the midline and where the radio-opaque cement ends (Fig. 2). A ratio between these two lines is then calculated to determine the percentage of cement projection across the midline. In both groups, a transpedicular approach is used to deliver the polymethylmethacrylate (PMMA) into the vertebral body. In every case the same surgeon placed the needle tip in the midline of the vertebral body. The volume of cement injected ranged from approximately 3–5 mL. The Visual Analogue Scale (VAS) for pain was used to measure pain relief in patients post-operatively (0, no pain relief; 10, complete pain relief).

Patients who underwent percutaneous vertebroplasty using either the directional needle or the straight needle were diagnosed with either osteoporosis, metastatic spinal disease, multiple myeloma or hemangioma (Table 1).

## Statistical analysis

Student's t-test was used to compare mean cement projection across the midline in both groups with  $P < 0.05$  considered to be statistically significant.



**Fig. 2.** Method for percentage calculation of midline cement projection. A line is first drawn between the midline (level of the spinous process) and the edge of the vertebral body. A second line is drawn between the midline and where the radio-opaque cement ends.

**Table 1.** Diagnoses of patients.

	Directional needle	Straight needle
Osteoporosis	6	6
Metastatic spinal disease	1	2
Multiple myeloma	1	2
Hemangioma	1	–

## Results

In total, medical notes were obtained for 23 patients, four of which were omitted due to missing information. There were a total of 19 vertebroplasty cases: nine who underwent vertebroplasty using the directional needle and 10 who underwent vertebroplasty using the standard needle (Table 2).

The age of patients in the directional needle group was in the range of 41–97 years with a mean of 60.44 years. There were a total of five women and four men in the directional needle group. The age of patients in the straight needle group was in the range of 42–84 years with a mean of 67 years. In the straight needle group, 90% of the patients were women.

In the directional needle group, 12 levels of vertebrae treated compared to 21 levels of vertebrae in the straight needle group and the distribution of levels treated is depicted in Fig. 3.

The average percentage of cement projection across the midline in the directional needle group where 12 levels of vertebrae were treated was 58%. This value is significantly higher than the percentage of cement projection across the midline in the straight needle

**Table 2.** Patient demographic details.

	Directional needle	Straight needle
Patients (n)	9	10
Age of patients (years) (range)	60.4 (41–97)	67.0 (42–84)
Gender	5 F, 4 M	9 F, 1 M
Vertebral levels treated	12 (1–3)	21 (1–4)
Distribution of levels treated	6 thoracic, 6 lumbar	11 thoracic, 10 lumbar
Preoperative pain score	(n = 4)	(n = 7)
Postoperative pain score	(n = 3)	(n = 6)
Cases of cement extravasation (%)	44	30
Complications	0	0
Cement projection across midline* (%)	57.50	34.50

\* $P = 0.046$ .

group by 23% ( $P$  value = 0.046) where 21 levels of vertebrae were treated.

In the directional needle group, only four out of nine patients' preoperative pain scores were documented. Out of these four, only three postoperative pain scores were documented in the medical records. In the straight needle group, only seven out of 10 cases had a documented preoperative pain score. Six out of seven of these cases had documented postoperative pain scores.

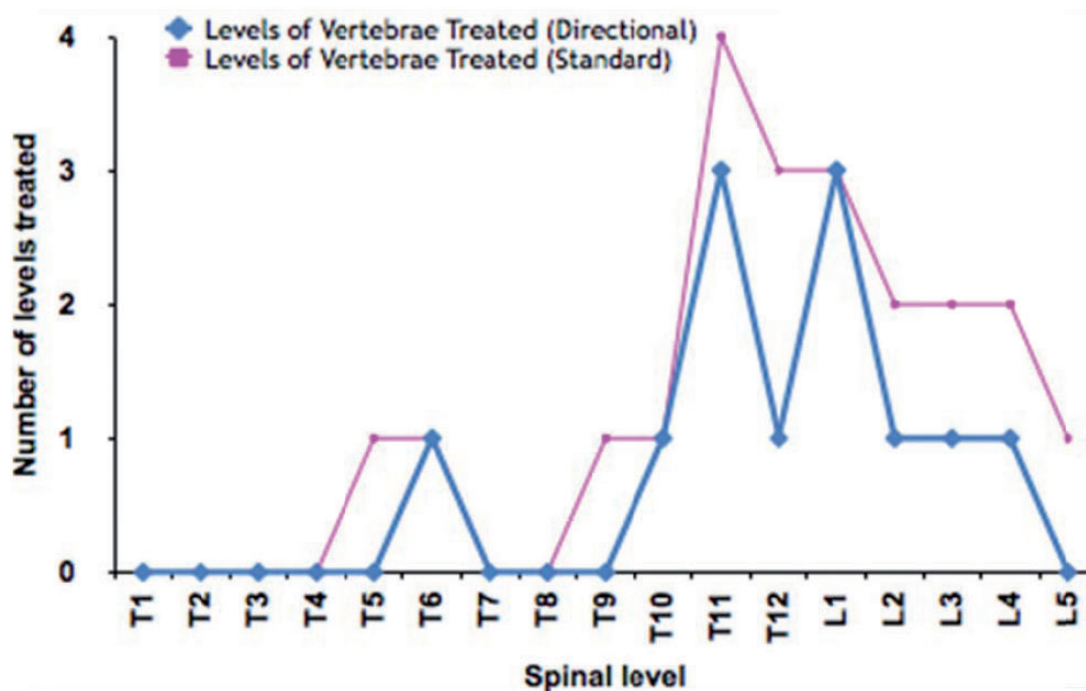


Fig. 3. Distribution of levels treated.

Cement extravasation is defined as cement leakage out of the vertebral body. The cement can leak into the surrounding area around the vertebral body, surrounding veins, and spinal canal. Cement extravasation was observed in 44% of the study population in the directional needle group whereas cement extravasation was seen in 30% of the cases in the straight needle group. However, on the follow-up appointments at 6 weeks, no complications were noted in any of the 19 cases.

## Discussion

Vertebral compression fracture occurs when the bones of the spine undergo insult to their mechanical stability. These fractures can be caused by osteoporosis, trauma, primary, or metastatic spinal disease. It is not uncommon to find multiple vertebral fractures in the same patient that may lead to kyphosis (5). It is estimated that over 200 million people worldwide suffer from osteoporosis (6). In Europe, approximately 30% of postmenopausal women have osteoporosis, of which 40% will experience one or more fragility fracture in their lifetime (7).

In regards to metastatic spinal disease, two-thirds of patients with cancer will develop bone metastasis, with the spine being the most common site (8). Lung, breast, and prostate cancers account for more than 80% of the cases of metastatic bone disease (9). This can be explained by the fact that the vertebral bone marrow

has a rich vascular supply and is prone to hematogenous spread (10).

Much research has been carried out over the years to improve cement delivery, minimize complications, and improve overall clinical outcome. Layton et al. reviewed 1000 consecutively treated vertebral compression fractures to determine both the short- and long-term efficacy of percutaneous vertebroplasty (11). The authors concluded that practitioners can quote a high success rate and low complication rate when making treatment recommendations for painful VCFs based on their results (11).

The mean age were calculated for both groups to ensure that the results between the two groups were comparable. The average age of patients in the directional needle group is 60 years whereas the average age of patients in the straight needle group is 67 years. These findings are consistent with the fact that conditions like osteoporosis, metastatic spinal disease, and multiple myeloma mainly affect the elderly population.

The mean percentage of cement projection across the midline was observed to be significantly higher in the directional needle group when compared with the straight needle group ( $P=0.046$ ). The exact mechanism of pain relief from vertebroplasty is not known, but it has been postulated that it is secondary to the thermal injury of the nociceptive nerve endings that happens during cement injection (12). If this is the case, this



will be a main advantage of the directional needle as a higher cement projection can result in better pain relief as the cement can reach more nerve endings.

It may be argued that a bipedicular approach where two needles are inserted can be used to increase cement filling. However, this is associated with an increased procedural time, increased radiation exposure, and a higher level of morbidity. Knavel et al. found that hemivertebral filling from a unipedicular approach was as effective as bilateral vertebral filling in reducing pain in VCF patients undergoing vertebroplasty (13). This study used the VAS to compare pain scores for 917 vertebroplasty procedures performed. However, the conclusion was based only on approximately 10% of the total number of cases where patients actually had hemivertebral filling. Further studies with larger numbers should be carried out to substantiate the findings of this group. This will improve our understanding of the contribution that increased midline cement projection makes to clinical outcome.

As shown in the results above, a significant proportion of the pre- and postoperative pain scores were not documented in any of the medical records. Unfortunately, this was a retrospective study and some of the data were not documented making this a major limitation to the study. Therefore, the true clinical efficacy of the procedures cannot be determined as there were no sufficient preoperative pain scores to compare the postoperative pain scores with. Of the pain scores available, there was a 100% (30/30) improvement in the directional needle group and 33% (20/60) improvement in the standard needle group. We also recognize that accurate assessment of the impact of vertebroplasty on the level of pain was not feasible as some of the patients in the study were receiving varying amounts of opiate analgesia, NSAIDs, and anti-neuropathic medications as part of palliative care. Given the relatively small numbers of pain scores, it is difficult to assess causality.

The directional needle allows the operator to flex the needle tip up to 100 degrees and provides greater flexibility and maneuverability within the vertebral body. The benefits of greater flexibility using a directional needle is highlighted by Murphy et al. whereby the authors reported successful treatment of lytic osseous metastases with cementoplasty using directional needle in difficult-to-access regions of the pelvis and sacrum (14).

The main disadvantage with the directional needle is the higher incidence of cement leakage when compared to the straight needle. Cement leakage can occur into the epidural veins, discs, intervertebral foramen, perivertebral soft tissues, and spinal canal. There was no statistically significant difference in the incidence of cement leakage between the directional and straight

needle group ( $P$  value = 0.65). Cement extravasation or leakage was seen in 44% and 30% of the directional and straight needle study populations, respectively. It could be argued that these figures seem very high, but on the subsequent follow-up appointments at 6 weeks, no complications were noted in any of the 19 cases studied. Figures for both groups were comparable to those published in the literature (40–50%) (15). There was no cement leakage into the spinal canal in any of the 19 cases which is a very rare complication. Tanigawa et al. only reported cement leakage into the spinal canal in two out of 300 vertebrae that were treated with vertebroplasty (15). Infection, significant bleeding and new adjacent vertebrae fracture were not observed in any of the 19 patients.

Other findings on sub-group analysis showed that T11, T12, and L1 were the most common levels treated in both groups (2). For the directional needle group, levels T11, T12, and L1 represented 58% of the total vertebral bodies treated whereas in the straight needle group, these levels of the vertebral body represented 48% of the total levels of vertebral bodies treated. When the data were examined closely, it became clear that patients who underwent treatment at these levels were mostly diagnosed with osteoporosis-related fractures. Peh et al. reported that T11, T12, and L1 accounted for 52.6% of all vertebral body fractures (16). This is similar to the findings of this study which suggests that our patient group is representative.

Togawa and Lewandrowsky described that more than half of patients with metastatic spinal disease have multiple levels involved (17). Out of these patients, 10–38% have multiple non-contiguous segments involved. Therefore, as opposed to osteoporosis-related fractures, metastatic spinal diseases do not conform to any pattern of vertebral body involvement. Our study would support this finding as metastatic spinal disease, hemangioma, and multiple myeloma did not seem to have any distinguished pattern of vertebral body involvement. With the newly engineered distal needle lumen, the manufacturers reported that the incidence of needle clogging has been reduced to less than 1% and only nine out of 535 levels treated required substitution of the needle for completion of cement delivery (4). From our experience, there were no cases of cement clogging or needle failure in all 12 levels that were treated with the directional needle.

In conclusion, percutaneous vertebroplasty using a directional needle is an excellent example of advancement and refinement in spinal surgery without increased clinical risk. Although we cannot assess the clinical significance of an increased midline cement projection due to the lack of postoperative pain scores and a small number of patients, our results indicates that the novel technique can potentially provide better

radiological outcomes when compared with a standard straight needle. A larger, randomized multicenter prospective trial would be valuable in confirming these findings.

### Conflict of interest

Jake Timothy is supported by the Leeds Musculoskeletal Biomechanical Research Unit (LMBRU).

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