

## Percutaneous Vertebroplasty for the Treatment of Osteoporotic Vertebral Compression Fractures: A Preliminary Report

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**Background:** This report assesses the efficacy and safety of percutaneous vertebroplasty for osteoporotic vertebral compression fractures and reports on preliminary results of its use.

**Methods:** The technique was used on 50 patients with 86 painful vertebral fractures, all of which had failed to respond to earlier conservative medical treatment. The technique involves percutaneous puncture of the involved vertebra via a transpedicular approach followed by injection of polymethyl methacrylate (PMMA) into the compressed vertebra. Patients were asked to quantify their degree of pain on Huskisson's visual analogue scale (VAS) to assess the clinical symptoms and surgical results.

**Results:** The procedures were technically successful in all patients, and no complications relating to either the anesthesia or the surgical procedure were reported. The quantity of PMMA injected per vertebral body varied from 2.5 to 12 ml according to both the position of the damaged vertebra(e) and the severity of the compression fracture. Pain, as assessed on the Huskisson's VAS, decreased from 82 ± 15 mm at the baseline to 37 ± 22 mm on the first post-operative day, and 32 ± 19 mm at 1 month. Reductions in pain from the baseline to the first day and to 1 month were both statistically significant ( $p < 0.05$ ). All patients were able to return to their previous activity and quality of life.

**Conclusion:** Through the expertise and attention of experienced surgeons, percutaneous vertebroplasty appears to provide a very good surgical choice for patients with vertebral compression fractures, as this surgical procedure is able to eliminate the risk of major spinal surgery, and through prompt pain relief, may provide early mobilization and rehabilitation for elderly polymorbid patients.

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**Key words:** vertebroplasty, osteoporosis, vertebral compression fracture, polymethyl methacrylate.

With the aging of the Taiwanese population, it is reasonable to assume that vertebral compression

fractures due to preexisting primary or secondary osteopenia will increase every year. These

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vertebral fractures frequently produce persistent, often excruciating, pain, which may significantly influence patient morbidity and impair the quality of life. While external bracing, analgesics, and bed rest may be all that we could have prescribed for these patients in the past, for some patients, however, a constant requirement for narcotics and an extended period of bed rest may be necessary for effective pain control, with such activity possibly inducing further osteoporotic vertebral compression fractures.<sup>(1,2)</sup>

Galibert first described percutaneous vertebroplasty using polymethyl methacrylate (PMMA) in 1987.<sup>(3)</sup> Initially, the technique was selected for vertebral hemangiomas in order to prevent associated vertebral crushing. More-recent indications for this new therapeutic method have extended its use to other pathological entities such as vertebral metastases, myelomas, lymphomas, Langerhans histiocytosis, and osteoporotic vertebral compression fractures in order to achieve vertebral stabilization and associated pain control.

We first began to treat osteoporotic vertebral compression fractures with percutaneous PMMA vertebroplasty in June 2001. We treated 50 patients with 86 painful osteoporotic compression-fractured vertebrae over the subsequent 3-month period. In this paper, we describe the process for patient selection, the therapeutic techniques adopted, technique-associated complications, and our preliminary results as well as a review of the relevant literature.

## METHODS

Patient selection was limited to those persons with focal, intense, deep pain associated with plain film evidence of a new or progressive vertebral compression fracture. Often the pain radiated along the ribs to the chest or abdomen. A physical examination was conducted in order to determine each patient's general condition, and also the ability of the subject to tolerate lying prone for 1 to 2 hours. A neurological examination was performed to evaluate possible radicular symptoms. All patients revealed plain x-ray film evidence of progressive or recently occurring vertebral-body compression fractures, the relative dimensions of which appeared to correspond well to the respective level of pain. If there was no

evidence of radicular symptoms, a percutaneous vertebroplasty was advised for patients. Once the patient was accepted for vertebroplasty treatment, a spinal computer tomograph scan and/or magnetic resonance image may have been obtained to assess the relative degree of continuity of the posterior vertebral wall and to exclude any other causes of pain. The surgical team went to great lengths to explain the intended surgical procedure to the patients and discussed specific features of the surgical procedure, the subsequent prognosis, and the potential risks and benefits of the procedure with patients and their families.

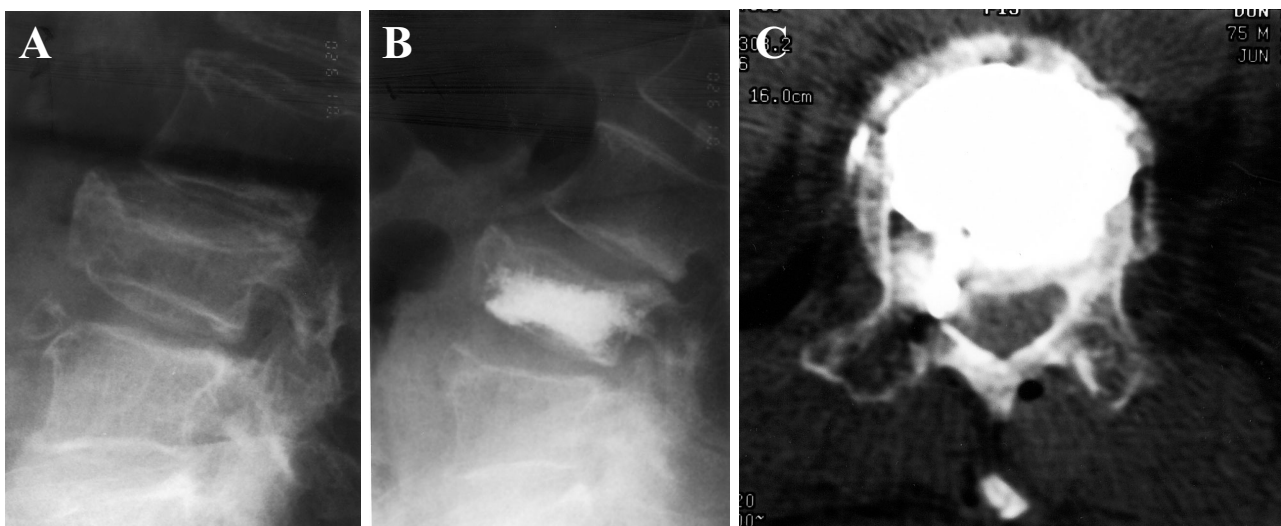
Clinical symptoms and surgical results were assessed by asking patients to quantify their degree of pain on Huskisson's visual analogue scale (VAS: 0 mm = no pain; 100 mm = the worst pain possible) on 3 separate occasions: before vertebroplasty, the first day after vertebroplasty, and 1 month after vertebroplasty. The group's VAS values were compared using the Wilcoxon signed rank non-parametric test.

**Surgical technique:** We performed the percutaneous vertebroplasty procedure in the hospital's operating theatre, in order to effectively monitor the patient's physical condition and to perform the surgical procedure under strict sterile conditions. Each patient received general endotracheal anesthesia and was then placed in a prone position. The vertebral body (to be treated) was localized under fluoroscopic guidance, and the skin overlying the area was prepared and draped. The fluoroscope was used for continuous monitoring of the procedure in both the anteroposterior and lateral directions. A small skin incision over the center of the pedicle oval was made with a #11 scalpel blade. A disposable 11 G match-ground bevelled tip introduction needle (Stryker Instruments, Kalamazoo, MI, USA) was positioned with its tip in the center of the oval and was advanced until the stylet tip abutted the bone. The lateral fluoroscope showed the tip at the level of the upper and midpoint of the pedicle. The needle placement clearly required frequent checking with the fluoroscope to ensure that an appropriate location was maintained. The tip of the needle was normally placed in the anterior 1/2 of the vertebral body. On some occasions, bilateral needles were inserted into a patient's treated vertebra. Prior to injecting the

PMMA, venography was conducted in order to prevent the needle from directly penetrating the basivertebral venous plexus, to ensure continuity of the vertebral wall, and to preview the material location. Three milliliters of iohexol (300 mg I/ml) was delivered via each needle and under direct and constant fluoroscopic monitoring. Rapid flow of contrast material into the basivertebral venous plexus typically indicates improper placement of the needle tip, which normally warrants subsequent needle adjustment. Once the correct placement of needles was confirmed, the bone-cement injection process commenced.

To prepare the cement, 5 cm<sup>3</sup> of sterile barium sulfate powder was placed into a disposable plastic bowl; the powder then needed to be pulverized more completely prior to mixing as this material has a propensity to clump. Fifteen cubic centimeters of PMMA powder was mixed with the pulverized barium sulfate, and the mixture was then ground with a pestle. One half of the liquid agent (monomer) was aspirated into a 10-ml plastic syringe, and the unused portion was left in the glass bottle in which it was supplied. The liquid agent was added to the powder, and the slurry was mixed with a tongue blade until a

thin semi-liquid consistency was achieved. Once the cementing material was sufficiently well mixed, and the desired consistency reached, the mixture was poured into the plunger end of two 5-ml syringes. The two 5-ml syringes were then both attached tightly to the bilateral needles at the same time. Injection of the cement was performed by alternating bilaterally and under lateral and/or anteroposterior fluoroscopic guidance. Injection of the cement continued until no further material could be accommodated in the desired location, and no leakage of cement had been noted. Upon completion of the injection procedure, the needles were removed, and hemostasis at the puncture sites was achieved by applying gentle pressure for 10 min. Following completion of the procedure, the patient was placed in a supine position and allowed to recover from the general anesthesia. Post-surgery, the majority of the preexisting pain was relieved within 24 hours, and the patient was advised to remain in bed. Generally, the patient was noted to be able to change position frequently on the first day post surgery. On the following day, a spinal radiograph and/or spinal computed tomography (CT) scan were performed (Fig. 1), and the patient was able to get up from the bed and walk



**Fig. 1** (A) Preoperative lateral radiograph revealing an L1 severe osteoporotic compression fracture with marked kyphosis. (B) Postoperative lateral radiograph revealing the presence of cement within the vertebral body, and demonstrating slight regaining of anterior vertebral body height. (C) Axial CT scan at L1 revealing the radiopaque cement filling the vertebral body.

about with the support of a thoracolumbar brace with no apparent tenderness.

## RESULTS

Fifty patients (39 women and 11 men) with a total of 86 compression fractures and who were suffering from disabling back pain refractory to analgesic therapy were treated in this study (Table 1). The age of study subjects ranged from 47 to 92 (mean, 72.2) years, and their medical treatment period ranged from 1 to 12 months. Forty-eight patients exhibited fractures associated with age-related osteopenia, and 2 patients revealed progressive multiple myeloma of several vertebrae. All patients were experiencing severe pain that limited their mobility and substantially altered their quality of life.

The surgical procedures were technically successful in all patients, as defined by the effective transpedicular puncture of the vertebral body and injection of PMMA, and there were no complications related to the anesthesia or the overall surgical procedure. The quantity of PMMA injected per vertebral body varied from 2.5 to 12 ml, with the volume being dependent upon the location of the vertebral

**Table 1.** Clinical Summary of 50 Patients Treated by Percutaneous Vertebroplasty

Factor	Cases	
	No.	%
Gender		
Male	11	22
Female	39	78
Age (years)		
41-50	2	4
51-60	1	2
61-70	12	24
71-80	20	40
81-90	13	26
> 91	2	4
Pathology		
Osteoporotic	48	96
Multiple myeloma	2	4
Offending level		
Single level	16	32
Double level	32	64
Triple level	2	4

**Table 2.** Level of Treated Compression Fracture and Injection Volume

Level	No. (%)	Injection volume (ml)	
		Min.	Max.
T5	1 ( 1.2)	3	
T6	1 ( 1.2)	2.5	
T11	6 ( 7.0)	4	8
T12	20 (23.2)	4	10
L1	23 (26.7)	3	10
L2	13 (15.2)	3.5	9.5
L3	10 (11.6)	5.5	12
L4	9 (10.4)	3	9.5
L5	3 ( 3.5)	2.5	7

fracture and the severity of the compression fracture (Table 2). Most of the patients in this study were treated via bilateral pedicular puncture. For 16 vertebrae (18.6%), radiographs revealed evidence of PMMA leakage through the endplate fracture site into either the disc space or the paravertebral space, with no evident clinical symptoms.

As assessed by the Huskisson's VAS, pain decreased from 82 ± 15 mm at the baseline to 37 ± 22 mm on the first postoperative day, and 32 ± 19 mm at 1 month. Reductions in pain from the baseline to the first day and to 1 month were statistically significant ( $p < 0.05$ ). There was no statistical difference between the degree of pain on the first postoperative day and at 1-month follow-up. All patients were able to quickly return to their pre-injury levels of activity and quality of life.

## DISCUSSION

Osteoporosis is a disease characterized by low bone mass leading to an increased frequency of low-energy fractures.<sup>(2)</sup> Among the fracture types encountered in osteoporotic patients, vertebral fractures must be given serious consideration by the spinal surgeon, because they are frequent (16% of postmenopausal women suffer such fractures) and typically lead to serious back pain, disability, and an overall decrease in height.<sup>(3)</sup> Conservative therapy for vertebral-compression fractures, including bed rest, external bracing, analgesics, or calcitonin therapy over a period of several weeks, is usually suffi-

cient for pain control. In some cases, however, vertebral compression fractures are responsible for persistent and severe pain requiring the use of narcotics and prolonged bed rest with an overall resultant impaired quality of life.

Altered biomechanics secondary to vertebral compression resulting from a vertical compression fracture may contribute to, or be responsible for, the subsequent pain syndrome. The osseous elements critical to spinal stability are the vertebral body, end plates, facets, and posterior elements.<sup>(4,5)</sup> The strength of the vertebral body depends upon the subject's age and other pathological processes. Under the age of around 40 years, trabecular bone accommodates approximately 55% of the load share, compared to around 35% as a patient's age exceeds 40; this overall process leads to a decrease in vertebral strength.<sup>(4,5)</sup> Compression forces generated by various loading conditions affect the end plates of the vertebral bodies more than the vertebral walls. End-plate failure occurs centrally, peripherally, or in a combined fashion depending upon the health of the disk. For elderly patients with degenerative vertebral disks, the experienced compression force is transferred to the peripheral portion of the end plate directly outward from the annulus.

The thoracolumbar junction is a zone that lies between the rigid vertebral column, with the associated rib cage, and the relatively mobile lumbar vertebrae. Consequently, energy loads generated throughout the thoracic spine are transferred to this region.<sup>(5)</sup> Depending upon the forces generated on the spine and the direction of the experienced load, failure of some anatomical structures can occur leading to instability. The stress directed to vertebral facets and posterior elements may thus increase resulting in significant spinal instability and subsequently leading to acute or delayed neurological deficits.

Management of these potentially devastating injuries has been and remains controversial. The majority of these injuries are associated with no neurological changes. Typically, patients with such injuries are initially managed with bed rest and analgesics for pain control, and following bed rest, they subsequently should be able to walk around with little or no bracing.<sup>(6)</sup> If pain persists and follow-up radiographs indicate an increased kyphotic deformity as compared to the situation immediately after the

initial injury, a posterolateral fusion could be considered as a viable surgical option to be performed on a delayed basis.<sup>(7)</sup> In our experience with osteoporotic compression fracture of a vertebra, an aggressive conservative treatment regimen has typically resulted in failure, and the resultant ongoing and intractable pain has merely prolonged the patient's bedridden state and limited the patient's daily activities. Constant pain, the loss of independent function, changes in physical appearance, feelings of isolation and a sense of vulnerability, and the perception of an uncertain future are hallmarks of the vertebral compression fracture patient's overall experience. Although recently developed techniques and instrumentation systems now allow for a more-aggressive surgical approach in treating these injuries, major surgery is not suitable for elderly patients, due mainly to the likelihood of the presence of osteoporotic vertebrae and the risks associated with surgery.

PMMA vertebroplasty is a new procedure consisting of the injection of PMMA into the vertebral body of a damaged vertebra for pain relief and bone strengthening of a previously weakened vertebra.<sup>(1,8-15)</sup> Vertebroplasty has been shown to be a promising novel technique for the treatment of aggressive angiomas, bone metastases, and multiple myelomas which elicits rapid and marked pain relief;<sup>(1,8-15)</sup> it is a useful and safe procedure for treating persistent, painful osteoporotic fractures of a vertebra.<sup>(16)</sup> In the European experience, figures of 90%-100% pain relief in the treatment of osteoporotic fractures with percutaneous vertebroplasty have been reported.<sup>(8,10,13,17-21)</sup> Complications of the treatment ranged 0%-5.4%, most of which were relatively minor, with a multidisciplinary approach to patient selection and management being essential.<sup>(17-21)</sup> Two classes of patient are considered appropriate for vertebroplasty treatment: those with chronic pain refractory to medical therapy and bracing, and those with severe, disabling pain as elicited by more-acute fractures.<sup>(20,21)</sup> Treatment of ambulatory patients with acute fractures remains controversial, however. Patients with very severe cardiopulmonary disease or uncorrectable coagulopathy are contraindicated from undergoing vertebroplasty. Severe vertebral compression (above 50% collapse) may not be a contraindication to treatment, however, as the increasing skill and experience of surgeon allow for treatment

of the more severely compressed vertebrae. Prophylactic treatment of noncompressed vertebrae in patients with severe osteoporosis would also appear to be controversial. At present, our principle is to treat those patients with compressed vertebrae who demonstrate obvious clinical symptoms. Although, it would be expected that increased stress might be imposed upon the vertebrae adjacent to the fractured one, thus increasing the likelihood of fracture of the adjacent vertebrae, this has only rarely been reported for patients previously treated with percutaneous vertebroplasty.<sup>(21)</sup>

Different hypotheses exist with respect to the pathophysiology of pain relief following vertebroplasty, including stabilization of microfractures, reduction of mechanical stress, and destruction of neural endings by the cement's mechanical, chemical, cytotoxic, and thermal activity as well as by its anti-inflammation action.<sup>(11,22-29)</sup> In our patients, symptoms were improved via stabilization of the fractured vertebral fragments, enhancement of vertebral strength, and by providing a reduction in mechanical stress to the damaged vertebra. Therefore, percutaneous vertebroplasty is an alternative procedure for the treatment of osteoporotic compression fractures, especially in elderly patients. When conducted by experienced surgeons or neuro-radiologists, percutaneous vertebroplasty can eliminate the need for and risk of major spinal surgery. Prompt pain relief and early mobilization and effective rehabilitation of a compression fracture remain clear possibilities for elderly polymorbid patients.

Percutaneous vertebroplasty, however, is not an absolutely safe procedure. There are considerable dangers from the leakage of acrylic cement into the venous system or through a gap of the fractured vertebra into the spinal canal. Cement leakage into the azygous vein or into the inferior vena cava with migration into the lung represents a life-threatening complication of vertebroplasty.<sup>(11,19,22)</sup> Typically, cement spillage occurs through the basivertebral plexus into the anterior internal venous plexus leading to the progressive accumulation of acrylic material within the spinal canal. Bone cement leakage and consequent damage to neural structures by either compressive or thermal effects arising during polymerization of the methyl methacrylate are well

known sources of complications.<sup>(11,19,22,30)</sup> While the pathophysiology of neural damage by a direct compressive effect of bone cement is probably the major source of neurological complications, compromise of neurological functions by thermal and chemical effects still remains the subject of much current debate.<sup>(14,23,24,31,32)</sup> Paravertebral and disc spillage are asymptomatic and often arise in cases of severely compressed vertebrae. Posterior extrusion of bone cement into the spinal canal can typically be eliminated by assuming an appropriate needle position, by achieving a steady injection of cementing material, and by continuous and extensive monitoring of the surgical procedure with the fluoroscope. In our study, the percutaneous vertebroplasty procedure appeared to have been well tolerated by our group of patients, since no clinically related side effects were seen, although leakage of the cement outside the vertebral body was observed in 16 patients (18.6%); this frequency is less than that reported elsewhere for which figures range from 65% to 73%.<sup>(11,16)</sup> With the aid of our specially designed screw syringe compressor, the cementing material was slowly and steadily injected, which was our specific intention. In our study, the injection of cement typically continued until no further cement could be inserted, or the cement began to extrude from the vertebral body. Experience with vertebroplasty has indicated that the initial slow and steady introduction of acrylic cement might reduce the risk of leakage, probably by obliterating the major connection to the basivertebral venous plexus.

In conclusion, our study suggests that vertebroplasty has the potential to achieve a good outcome for patients with a vertebral compression fracture due to osteoporosis, a condition causing severe and persistent pain. When conducted by experienced surgeons, percutaneous vertebroplasty is able to eliminate the need for and risk of major spinal surgery, and through prompt pain relief, early mobilization and effective rehabilitation of a vertebral compression fracture remains a clear possibility for elderly polymorbid patients. Further studies, particularly controlled studies incorporating the long-term follow-up of patients, are required to determine for which patients vertebroplasty is most appropriate.

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# 以經皮膚椎體修補融合術治療骨質疏鬆所造成的脊椎骨折： 初步報告

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- 背景：** 在台灣，因骨質疏鬆所造成的脊椎骨折每年約有六萬人左右，這類骨折大多為壓迫性骨折。而這種椎體壓迫性骨折常都在只是輕微摔倒、意外跌坐就發生；且常會伴隨著嚴重背痛，尤其活動時疼痛常更加劇，而使得病患無法行動，影響日常生活。
- 方法：** 椎體修補融合術是為補強椎體因結構上之不足而導致的脊椎壓迫性骨折。此項手術是將人工骨水泥 (bone cement) 置入受損之椎體內，而增強椎體強度和脊椎之穩定性，以減少病患因脊椎椎體受損而產生的慢性疼痛。
- 結果：** 截至目前為止，我們已經施行於50位病患，共86節椎體修補融合手術。其中48位病患為原發性骨質疏鬆所引起的壓迫性骨折，而次發性骨質疏鬆所引起的壓迫性骨折則有2位。病患男性11位、女性39位，年齡分佈為47-92歲、平均為72.2歲。50位病患都無手術或麻醉的併發症發生。手術後患部疼痛都可有效緩解 (70-90%)，而回復一般日常行走和活動。
- 結論：** 此手術可針對年齡大，骨質疏鬆病患之壓迫性骨折所引起的長期慢性疼痛做一有效的治療，也減少了年紀大病患因疼痛而需長期臥床的時間和其併發症，維持其生活品質和尊嚴。  
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**關鍵字：** 椎體修補融合術，骨質疏鬆，脊椎壓迫性骨折，人工骨水泥。