Transpedicle body augementer in painful osteoporotic compression fractures

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Abstract Osteoporotic compression fractures (VCFs) can result in progressive kyphosis and chronic pain. Polymethylmethacrylate has been used for augmentation of VCFs; however, there are cement complications, and long-term fracture healing is unknown. The transpedicle body augementer (TpBA), a porous titanium spacer, has been reported as an internal support to reconstruct the vertebral body combining short segment fixation in burst fracture. We retrospectively reviewed radiographic and clinical results of TpBA vertebroplasty for single symptomatic VCF in 80 patients. Manual reduction and TpBA vertebroplasty via a paramedian incision with blunt dissection was done. Mean age was 72.3 years (range 51–87 years), and female–male ratio was 66:14. The mean symptom duration was 5 months,

and follow-up 44 months. Peri-operative variables and radiographic and clinical results were evaluated. The average operation time was 26.1 min, blood loss 92 cc, and hospitalization 2.3 days. No patient had neurological deterioration. TpBA was found sinking into vertebral body initially, then locked by residual cortex, and finally stabilized within the vertebra. There was no dislodgement of TpBA in the final visit. Sixty-two patients (77.5%) could walk within 3–6 h after operation and the others within 24 h. The anterior vertebral restoration was 8.0 mm initially and 6.1 mm at final follow-up. Wedge angle correction was 11.5° initially and 9.4° at final follow-up. Pain, by the visual analog scale, was 8.6 pre-operatively, 2.5 at day 7 follow-up, and 2.9 at final follow-up. By the questionnaire, 72 of 76 respondents reported a decrease in discomfort after TpBA vertebroplasty, and 63 of 76 patients reported a return to normal activity after operation. The final satisfaction rate was 93.4%. TpBA vertebroplasty led to early and medium-term clinical improvement and anatomic restoration of painful VCFs.

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Introduction

Vertebral compression fractures (VCFs) pose a significant clinical problem causing pain [9], spinal deformity [22], reduced pulmonary function [30], reduced mobility [8, 37, 46], and an increase in mortality [24]. Traditional treatments for patients with VCFs include bed rest, analgesia, and bracing. These treatments do nothing to restore spinal alignment and

reduced mobility can increase the rate of demineralization [22].

Though polymethylmethacrylate (PMMA) vertebroplasty or kyphoplasty has been reported to treat VCFs with good clinical results [10, 12, 19, 28, 43] and correction of deformity [5, 29, 44], some complications have been reported [3, 4, 11, 14, 27, 39, 41] which cannot be completely avoided. Cement extravasation in vertebroplasty is the most frequent problem, which has been reported in 38% [49] to 72.5% [11] malignant VCFs and 30% [23] to 65% [10] of osteoporotic VCFs. Although most symptoms are minor, a few severe complications have been noted, including pulmonary embolism in 2.9% [19] to 4.6% [7] of patients after percutaneous vertebroplasty or kyphoplasty, case reports of deep-seated infection [51], postprocedure acute respiratory distress syndrome [50], palsy [18], and death [6, 49]. To minimize cement leakage, modified techniques have been suggested such as decreased cement dose [40, 45], lower pressure [1], and higher cement viscosity [1]. However, the techniques used to prevent immediate complications may induce long-term complications. Insufficient cement dose cannot prevent further body collapse, which may induce secondary kyphosis, posterior cortex collapse, and cord compression [34]. A doughy cement and low-pressure procedure may prevent good bone–cement interdigitation [25, 42] and cause long-term loosening of the cement block. In Kümmell's disease [21, 26], there are fibrocartilaginous membranes [21] on the fracture surface, which may prevent cement–bone interdigitation and could lead to cement loosening and dislodgement [47]. However, mature techniques and the appropriate timing of cement application is hard to coordinate in general practice. In addition, vertebral restoration is usually not as good as expected [18]. Prevention of cement complications, restoration and maintenance of the vertebral height, and resolution of pain by VCFs through a minimally invasive method have yet to be developed.

The transpedicle body augments (TpBA) with manual reduction may provide a new option for treating VCFs. Manual reduction and TpBA have been reported to restore burst fractures and Kümmell's disease with cord compression successfully [31–34]. The concept is that a fractured body can be reduced by manual reduction and reconstructed with TpBA via a posterior approach. The collapsed body can be supported internally to allow long-term fracture healing. Bilateral TpBA augmentation combined with short segment fusion in treating burst fractures had average operation time 66.1 ± 12.1 min and blood loss 216 ± 65 cc [32]. Theoretically, unilateral single TpBA

augmentation alone through a paramedian 3-cm-long incision should be with shorter operation time and less blood loss, which should be good for geriatric patients.

We hope to confirm that TpBA augmentation for VCFs can be completed with limited blood loss and operation time, restore vertebral body height, and correct wedge angle, and lead to good clinical results.

Materials and methods

We retrospectively reviewed 90 consecutive TpBA vertebroplasties performed in 90 patients between April 2000 and October 2004. The inclusion criteria for surgery included painful primary osteoporotic VCFs unresponsive to nonoperative methods. All the indications and contraindications for TpBA augmentation are included in Table 1. The inclusion criteria for this report required: functional status limited to Frankel E [15], single level, and a nonpathological fracture. The mean duration of symptoms was 5 months (range 14 days–36 months). Symptomatic levels were identified by correlating the clinical data with MRI findings of marrow signal changes consistent with compression fractures. Magnetic resonance imaging was also used to confirm the presence of a wedge compression fracture. Peri-operative variables and TpBA augmentation complications were recorded and analyzed. The follow-up rate was 88.9%. Six patients died of unrelated medical illnesses and four patients were lost to follow up. These ten patients were excluded from this retrospectively study (i.e., 80 patients with 80 TpBA vertebroplasties were included). The mean patient age was 72.3 years (range 51–87 years), and the women to men ratio was 66:14 (Table 2). The mean follow-up period was 44 months (range 16–66 months).

A standard monitor system was set up for all patients. The principle of anesthesia selection is that all patients received general anesthesia because it helps manual reduction. Local anesthesia was only chosen in patients who were not good for general anesthesia. General anesthesia was induced by administration of fentanyl (1.5–2 mcg/kg), propofol (1–2 mg/kg), and succinylcholine (1–2 mg/kg). Atracurium provided muscle relaxation. Anesthesia was maintained with inhalation drug (sevoflurane) and titrated to maintain hemodynamic stability.

All patients initially underwent manual reduction. Patients were changed from supine to prone position first and C-arm fluoroscopy used to locate the fracture site and monitor the TpBA insertion. Manual reduction was done by five people. One anesthesiologist held the patient's head, two assistants held the patient's

Table 1 The indications and contraindications for TpBA augmentation

Indications	Contraindications
1. Painful osteoporotic compression fractures refractory to nonsurgical therapy	1. Infections
2. Stage I and II Kümmell's disease [34] (delayed traumatic vertebral collapse, nonunion of compression fracture with pseudarthrosis), i.e., with intact posterior vertebral cortex. In stage III, i.e., posterior cortex breakage, TpBA augmentation should be combined with short segment fixation [33]	2. Uncorrectable coagulopathy
3. Unstable compression fractures showing dynamic changes at the wedge deformity	
4. Secondary deformity due to multiple compression fractures. Further vertebral collapse may cause respiratory or gastrointestinal compromise or alternation of center of gravity with tending to fall down	
5. Osteolytic vertebral lesions with fracture or impending risk of fracture due to metastasis or primary tumor. Metastatic lesions of renal cell carcinoma should be treated with pre-operative embolization	

shoulders, one assistant held the patient's legs, and the surgeon compressed the fractured vertebra. Manual reduction began with gentle traction and elevation of the trunk by the shoulder assistants, and the surgeon gradually increased the pushing force simultaneously to counter the elevation force. The patient was then returned to a prone position. The acute or nonunion compression fractures were reduced easily by the manual procedure, leaving a substantial bony defect in the vertebral body.

The TpBA augmentation was performed through a paramedian incision of 3 cm in length with muscle splitting and blunt dissection. A guiding pin was first inserted and confirmed by C-arm fluoroscopy. Unilateral pedicle tunnel on the more painful side flanking the vertebral body was made by an awl, followed by serial custom-made dilators to prepare for the passage of TpBA (a porous titanium spacer, Merries International Inc., Taipei, Taiwan) (Fig. 1). The concept of

safe zone [31] for TpBA is that lateral and superior cortices of the pedicle can be violated without neural or vascular injury. Actually, the osteoporotic pedicle is usually so soft that pedicles can be dilated laterally and superiorly without brittle breakage. The bony defect in the fractured vertebral body was filled through the pedicle tunnel [13] with mercerized allograft. Then TpBA was inserted into the vertebral body through the pedicle tunnel, and bone graft was used to fill up the pedicle tunnel space (Fig. 2). No hemovac drainage was needed. The selection of TpBA size was based on the pre-operative pedicle measurement on the CT section and plain anteroposterior radiography. Patients wore a thoracolumbar brace for 3 months. After discharge, patients were followed up regularly. Operation

Table 2 Patient demographics

Fracture location	Case no.	Age (years) (range)	Female to male ratio
T5	1	72	1:0
T7	2	73 (71–75)	2:0
T8	4	72.5 (69–80)	3:1
T9	5	74.4 (68–82)	3:2
T10	2	73.5 (72–75)	2:0
T11	11	74.4 (55–87)	7:4
T12	21	68.5 (52–86)	19:2
L1	15	69.3 (53–86)	15:0
L2	10	66.3 (54–79)	8:2
L3	7	70.9 (51–80)	4:3
L4	2	72.5 (72–73)	2:0
Total	80	72.3 (51–87)	66:14

Fig. 1 The dilators for pedicle tunnel preparation and TpBA device

Fig. 2 Flow charts of TpBA augmentation by lateral (A), transverse (B), and posterior (C) views. The incision wound (D1), fluoroscopic view of TpBA augmentation (D2), and operation scar (D3) are shown at the end

time, blood loss, hospitalization, and complications were documented.

In local anesthesia, demerol (1–1.5 mg/kg) was injected intramuscularly 30 min pre-operatively, and then manual reduction was done gently within the patient's tolerance. For TpBA augmentation, 2%

xylocaine with adrenaline (1:200,000) was injected into the skin and subcutaneous layers for incision of the skin and fasciae. After the muscles were split by blunt dissection, the facet capsule and surrounding soft tissue were anesthetized, there was little pain felt during pedicle tunnel preparation. The following procedures

Fig. 3 An 80-year-old female with T8 osteoporotic compression fracture with progressive costal neuralgia with referred chest wall pain for 2 months received TpBA augmentation. A pre-operative neutral lateral radiograph (**a**) and T2-weighted MRI sagittal image (**b**) showed body architecture destruction. The anteroposterior (**c**) and lateral views (**d**) of 2-year follow-up showed good restoration. The patient was symptom relieved immediately after surgery and maintained well to final follow-up

were same as in general anesthesia. Local anesthesia is not suggested before operators become skilled in TpBA augmentation.

Pre-operative spine radiographs were taken with the patient in the supine position. Serial radiographs (supine anteroposterior and lateral radiographs centered on the involved level) were taken postoperatively. Flexion and extension radiographs were taken after 1 year and at the final follow-up visit. In the radiographic analysis, wedge angle of the fractured vertebral body was measured as described previously by Verlaan et al. [48]. The radiographic parameters were measured on neutral thoracolumbar radiographs of 80 patients before the operation, immediately postoperatively, and at the final follow-up. All digitization and measurements were done by the same experienced research assistant in EBM viewer software (EBM Technologies Inc., Taipei, Taiwan) with an accuracy of ± 0.1 mm. Repeat measurements of the same vertebral levels after a 10-day interval with the same observer demonstrated an error of ± 1.2 mm in height and 2.2° in wedge angle.

Clinical results were assessed by questionnaires and clinical observation. Between August 2005 and January 2006, each patient was called or mailed to return to our institution for the questionnaire. Finally, 76 patients (95%) completed the questionnaires. The other patients did not feel able to answer the questionnaire.

The patients were asked to quantify their degree of pain on the visual analog scale (VAS) (0 = no pain; 10 = worst pain) before operation, 3, 7, and 30 days after operation, and at present. All these 76 patients independently completed a questionnaire to describe if they felt better, the same, or worse after operation; whether they had returned to their pre-fracture function (a yes/no question); how satisfied they felt with this operation (a scale of 0 = completely dissatisfied to 10 = completely satisfied).

Analysis of variance (ANOVA) was used for statistical analysis of pain VAS, wedge angle, and anterior vertebral height among the data of pre-operative, immediate, and final follow-up. Significant differences were further assessed using Duncan's multiple range tests. A Student's paired *t* test was done between the immediate and final corrections of wedge angle and anterior vertebral height. All the data presented are reported as mean $\pm$ standard deviation. The level of statistical significance was set as $P < 0.05$.

Results

All 80 patients tolerated the new surgical technique well with limited blood loss and operation time. All

Fig. 4 An 82-year-old female with T12 osteoporotic compression fracture for 4 weeks received TpBA augmentation. **a** A pre-operative neutral lateral view radiograph and **b** T2-weighted MRI sagittal image showed bony collapse of T12 vertebrae. The lateral view (**c**) of immediate follow-up demonstrated good restoration. The neutral anteroposterior and lateral radiographs (**d, e**) at 1-year follow-up showed good fracture healing

patients subjectively reported immediate relief of their typical fracture pain, and no patients complained of worse pain at the treated levels. The ratio of general to local anesthesia used was 78:2. Hospitalization was 2.3 ± 1.2 days (range 6 h–7 days). The operation time was 26.1 ± 5.1 min (range 15–40 min). The blood loss was 92 ± 65 cc (range 20–250 cc). Sixty-two (77.5%) patients started walking within 3–6 h after operation and the others (22.5%) within 24 h. The complications included one deep vein thrombosis and two skin edge necroses, which received debridement. No deep wound infection was found. Neural deterioration and root irritation were not found after TpBA augmentation. No dislodgement or loosening of any TpBA was found at the final visit. There were 15 new (9 adjacent and 6 remote) compression fractures (18.8%) during follow-up. Six patients underwent TpBA augmentation while four patients had cement vertebroplasty. The other five patients refused further operations.

The restoration of anterior vertebral height and wedge angle correction was achieved and maintained well by TpBA augmentation (Figs. 3, 4, 5). The anterior vertebral height and wedge angle at pre-operative, immediate postoperative, and final intervals were improved ($P < 0.001$ in all cases) (Table 3). The final corrections of anterior body height were less ($P < 0.001$) than the immediate postoperative corrections (Table 3). Similarly, the final corrections of the wedge angle were less ($P < 0.001$) than that achieved immediately postoperatively. However, there was only 1.9 mm loss of anterior body height correction and 2.1° loss in wedge angle correction in the final follow-up, which may not have much clinical significance.

The early and medium-term clinical outcomes were satisfactory. Two patients had unstable gait at the final visit due to cerebral strokes, which we considered unrelated to the TpBA augmentation. Other patients

Fig. 5 A 70-year-old man with L2 osteoporotic compression fracture for 3 weeks received TpBA augmentation. **a** A pre-operative neutral lateral view radiograph and **b** T2-weighted MRI sagittal image showed body architecture destruction. The lateral view (**c**) of immediate follow-up showed good body restoration. The neutral anteroposterior and lateral radiographs (**d, e**) at 18-month follow-up showed mild sinking of TpBA and good fracture healing. The patient was symptom free and lived independently

remained normal ambulence. The sequential average pain VAS in 76 respondents at pre-operative, 3-day, 7-day, 30-day, and final follow-up were 8.6 ± 1.1 , 3.8 ± 1.2 , 2.5 ± 1.0 , 2.3 ± 0.8 , and 2.9 ± 2.1 , respectively, which revealed a reduction in pain intensity after TpBA augmentation ($P < 0.001$, by ANOVA test). By the questionnaire, 72 of 76 respondents reported a decrease in discomfort after TpBA augmentation, and 63 of 76 patients reported a return to normal activity after operation. Forty-seven patients (61.8%) were satisfied (5–8, on a scale of 0–10) and 24 patients (31.6%) were very satisfied (9–10, on a scale of 0–10) after TpBA augmentation. Only 5 (6.6%) of the 76 respondents were dissatisfied due to cerebral stroke (1 patient) and new compression fractures without

further treatment (4 patients). The average satisfaction score was 7.4 ± 2.0 .

Discussion

The TpBA augmentation may provide a new option to treat VCFs. Though cement vertebroplasty [19, 23] or kyphoplasty have achieved good results in treating VCFs [5, 29, 44], severe complications have been reported [27, 39] and the long-term results are unknown. Reconstruction with structural bone graft and instrumentation may be performed in patients with concurrent spinal instability or neurological compromise from an anterior or posterior approach; however, the success

Table 3 Results of radiographic analysis

	Anterior body height (mm)	Wedge angle (degree)
Pre-operative	17.8 ± 2.7	13.6° ± 4.2°
Immediate follow-up	25.8 ± 3.9	2.1° ± 1.1°
Final follow-up	23.9 ± 2.4	4.2° ± 1.6°
ANOVA ^a <i>P</i> value	3.41E-43	1.02E-79
Duncan's multiple range test ^b	A, B, C	A, B, C
Immediate correction	8.0 ± 4.1	11.5° ± 3.9°
Final correction	6.1 ± 3.1	9.4° ± 3.1°
Paired <i>t</i> test ^c <i>P</i> value	5.81E-14	9.64E-22

A: pre-operative status versus immediate follow-up period, B: immediate follow-up versus final follow-up, C: final follow-up versus pre-operative status

^a ANOVA was done among pre-operative, immediate, and final follow-up data

^b Significant at *P* < 0.05

^c Paired *t* test: between immediate and final corrections

of these techniques is limited by the patient's poor bone quality and general medical condition. Manual reduction and TpBA is known to be successful in treating burst fractures [32] and Kümmell's disease with cord compression [33]. The concept is that the fractured body can be reduced by manual reduction and reconstructed with TpBA and bone graft via posterior approach. Because it is minimally invasive, TpBA augmentation is good for geriatric patients. Furthermore, all cement-related complications in vertebroplasty or kyphoplasty can be prevented by this procedure. Our retrospective study showed that TpBA augmentation was a well-tolerated and effective procedure for the treatment of painful VCFs. TpBA augmentation is associated with clinical improvement in pain, successful restoration of vertebral body height, and correction of wedge angle.

Some limitations of our series should be mentioned. Because this was retrospective, accuracy of VAS measures may be compromised due to recall bias. Evaluation was not blinded in this study which would impart observer bias to the final report; however, because the TpBA was clearly visible in radiograms, blinded evaluation of radiographic parameters would be impossible. Further, the clinical results were evaluated by the authors who were not blinded.

In our study TpBA augmentation achieved good medium-term clinical results. TpBA vertebroplasty attains excellent pain relief and restored vertebral height. Though it may be related with restoration of vertebral body, decrease of false motion of fractured segment, decompression of nerve roots, and fracture healing, the detailed mechanism for pain control after this procedure is not yet fully studied.

The TpBA augmentation may provide another option to treat painful osteoporotic compression fracture. Though PMMA vertebroplasty is successful for pain relief in VCFs [2, 10, 14, 38], this technique does not attempt to restore the height of the collapsed vertebral body. The principal limitation of vertebroplasty is cement extravasation, which can be as high as 72.5% in metastases [11] and 65% when used to treat osteoporotic fractures [10]. Kyphoplasty uses an inflatable bone tamp to reduce the vertebral body and create a cavity to be filled with bone cement and thus reduce the risk of extravasation. However, kyphoplasty still has a reported leakage rate of 10.2% in the osteoporotic group and 8.3% in the tumor group [17]. The leakage may cause cord or root compression and induce subsequent fracture with leakage into disc spaces [35]. The unknown long-term result of cement in the osteoporotic spine is another problem. TpBA functions to prevent body recollapse as well as PMMA in the short term. In contrast to the unknown fracture healing after PMMA is used, TpBA augmentation with bone graft theoretically allows potential fracture healing in the long term. The weakness of TpBA augmentation is that patients are asked to wear a brace for 3 months postoperatively. But in our experience, patients can obey this order well.

We found a medium-term subsequent fracture rate of 18.8% after TpBA augmentation, which is similar to the reported natural course for an osteoporotic spine: new compression fractures have been reported as 12% in the subsequent year in patients with one previous compression fracture and 24% in those with two previous fractures [36]. When kyphoplasty is performed there is a wide range of reported subsequent fractures (range 3–29%) [16, 35]. With a mean 11-month follow-up (range 3–33 months), Harrop et al. [20] reported that the incidence of subsequent fractures after kyphoplasty per procedure was 15.1% (34 of 225 procedures); overall incidence per patient was 22.6% (26 of 115 patients). Compared with these results, TpBA augmentation did not increase the adjacent compression fractures.

Sinking and locking of TpBA within the vertebra prevents dislodgement or loosening (Fig. 6). Vertebra is cancellous bone and allows the loaded TpBA to sink while the patient is walking. Most of the sinking happened within the first 2 weeks, which also explains the loss of height reduction observed clinically. The TpBA will be locked by the anterior and posterior residual cortices after sinking into the vertebral body and would be unlikely to move anteriorly or posteriorly. The locked TpBA will then be further stabilized by bone ingrowth. The sinking and bone growth may partially

Fig. 6 Illustration of how **a** transpedicle body augmenter was initially inserted into vertebral body and later **b** sunk into a cortex box (i.e., it will be impossible for it to move backward or forward)

explain an absence of dislodgement or loosening during the follow-up. Another possible explanation is that TpBA within the vertebral body is different from total arthroplasty. It is not a mobile joint, so there is no wear and tear or loosening forces over the TpBA. TpBA initially works like an internal support to maintain body height and support cancellous bone regeneration. In the late stage, TpBA only functions in an emergency to resist further crushing of the vertebral body when it is subjected to an external force.

Conclusion

The TpBA augmentation is a safe and effective operation to restore and stabilize osteoporotic vertebral compression fractures. TpBA augmentation provides body reconstruction without instrumentation or cement usage under general or local anesthesia. The operation time is short, the wound is small, and blood loss is limited. All patients could walk 3–24 h after surgery. TpBA augmentation can be applied in geriatric patients, even in patients with poor bone quality or vulnerable medical conditions. TpBA augmentation was found to associate with improvement in pain, restoration of anterior body height, and correction of wedge fractures for patients with vertebral compression fractures.

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