

# Long-term outcome of polymethylmethacrylate-augmented screw fixation in the treatment of thoracolumbar spinal tuberculosis in elderly patients with severe osteoporosis

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## Research article

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# Abstract

**Background:** to evaluate the safety and efficacy of Polymethylmethacrylate-augmented screw fixation (PASF) in the treatment of elderly patients with thoracolumbar spinal tuberculosis accompanied with severe osteoporosis.

**Methods:** 34 elderly patients with thoracolumbar spinal tuberculosis accompanied with severe osteoporosis underwent PASF after anterior or posterior debridement and bone grafting in our hospital from January 2010 to January 2012. The follow-ups were performed at 1, 3, 6, and 12 months postoperatively and then annually thereafter. The segmental Cobb angle was measured to evaluate kyphosis improvement. The laboratory examination including ESR and CRP was also monitored. The pre- and postoperative VAS score, ODI score, and neurological function of ASIA scale were also recorded.

**Results:** The included 21 patients completed the operation successfully. In all patients with neurological dysfunction, the ASIA grade improved by at least 1 grade. One month postoperatively, the VAS score, ODI, segmental Cobb angle, ESR, and CRP were significantly improved compared with those preoperatively ( $P < 0.05$ ); there was no significant difference in the values at 1 month postoperatively and last follow-up ( $P \geq 0.05$ ). There were no complications such as implant failure, proximal junctional kyphosis, or recurrence of tuberculosis at the minimum 5-year follow-up.

**Conclusion:** For elderly patients with thoracolumbar spinal tuberculosis complicated with severe osteoporosis, after anterior or posterior debridement and bone grafting, together with postoperative systematic anti-tuberculosis and anti-osteoporosis treatments, PASF is safe and effective without catastrophic complications such as intraspinal cement leakage. During the 5-year follow-up, there was no tuberculosis recurrence or implant failure.

## Background

The incidence of spinal tuberculosis is high, accounting for approximately 50% of bone and joint tuberculosis, especially in elderly patients.<sup>1</sup> An epidemiological survey in 2017 showed that, of the 2789 cases of spinal tuberculosis diagnosed in the United States from 2002 to 2011, approximately 25% were elderly patients aged > 65 years.<sup>2</sup> Most of the elderly patients with spinal tuberculosis have more complications, poor physical tolerance, and higher disability and mortality rates after surgical treatment. Additionally, elderly patients with accelerated bone turnover and increased bone mass loss often have osteoporosis. For elderly patients with spinal tuberculosis, poor nutritional status further aggravates the degree of osteoporosis. In recent years, studies have also pointed out that tuberculosis infection is a high risk factor for secondary osteoporosis.<sup>3</sup> For patients with osteoporosis, especially severe osteoporosis, after internal fixation and reconstruction, the loose trabeculae are difficult to provide sufficient holding force to the screws, and loosening and failure of implants can easily occur postoperatively. Therefore, for elderly patients with spinal tuberculosis, osteoporosis is a problem that cannot be ignored in the treatment process.

Polymethylmethacrylate-augmented screw fixation (PASF) has been successfully used in the treatment of osteoporotic degenerative thoracolumbar disorders, and satisfactory clinical results have been observed.<sup>5</sup> However, for spinal tuberculosis, previous case reports suggest that the spread of tuberculosis occurs after intravertebral injection of bone cement.<sup>6-9</sup> To our knowledge, no reports have explored whether PASF is safe and effective for elderly patients with thoracolumbar spinal tuberculosis accompanied with severe osteoporosis. Thus, we aimed to retrospectively evaluate the safety and efficacy of PASF in the treatment of elderly patients with thoracolumbar spinal tuberculosis accompanied with severe osteoporosis.

## Material And Methods

### Study patients

This study was approved by the institutional review board of our hospital, and informed consent was obtained from all patients. Inclusion criteria were as follows: definite thoracolumbar spinal tuberculosis with severe back pain (visual analog scale (VAS) score > 6) or neurological dysfunction; age  $\geq 60$  years, preoperative lumbar bone mineral density (BMD)  $\leq -3.5$ ; preoperative computed tomography (CT) and/or magnetic resonance imaging (MRI) showed bony destruction and paravertebral abscess (figure.1 and 2A); and preoperative needle aspiration and/or postoperative pathological results confirmed *Mycobacterium tuberculosis* infection. Exclusion criteria included age < 60 years, BMD  $> -3.5$ , active pulmonary tuberculosis, malignant disease such as multiple myeloma and metastatic bone tumor, and follow-up time < 5 years.

A total of 34 elderly patients with thoracolumbar spinal tuberculosis accompanied with severe osteoporosis underwent PASF after anterior or posterior debridement and bone grafting in our hospital from January 2010 to January 2012. Twenty-one patients were eventually included in our study, including 8 men and 13 women. The average age and BMD were  $66.3 \pm 5.2$  years and  $-3.9 \pm 0.3$ , respectively. Regarding lesion segments, 12 patients had single-level lesions, 5 had two-level lesions, and 4 had multi-level (>3) lesions. In terms of lesion location, 12 patients had thoracic tuberculosis, 3 had thoracolumbar tuberculosis, and 6 had lumbar tuberculosis. According to the American Spinal Injury Association (ASIA) scale, neurological functions of all patients were classified as grades A (n = 2), B (n = 5), C (n = 7), D (n = 4), and E (n = 3).

### Preoperative preparation

The high-protein diet was recommended for patients with malnutrition and, if necessary, blood transfusion was performed to correct anemia. For the patients without drug resistance, the five-combination chemotherapy regimen is recommended, including isoniazid, rifampicin, streptomycin, ethambutol, and pyrazinamide, whereas those with drug resistance, the sensitive anti-tuberculosis drugs were selected according to the results. Levofloxacin hydrochloride or amikacin sulfate was used when there was multiple drug resistance. Surgical treatment was performed when erythrocyte sedimentation

rate (ESR) < 60 mm/h, C-reactive protein (CRP) < 30 mg/L, or hemoglobin  $\geq$  100 g/L, or when severe back pain or progressive neurological deficit was present.

### **Surgical procedure**

According to the lesion location, extrapleural, combined thoracoabdominal, or extraperitoneal approach was applied in different patients. The surgical incision was selected at the left side or with severe vertebral collapse or more pus accumulation. After thorough debridement, the purulent cavity was washed with hydrogen peroxide, 10% povidone-iodine, and saline. The sclerotic bone of the diseased vertebra was scraped with a curette to ooze blood on the surface, the autologous iliac bone was trimmed into three cortical bone pieces of appropriate size and embedded in the defect for bone graft fusion. For patients with huge abscess or single-level lesion, anterior fixation was used, whereas for those with lesions involving > 2 segments, additional posterior fixation was used after anterior or posterior debridement. Only the vertebrae adjacent to the diseased vertebrae without an abnormal signal on MRI at T2WI were selected for bone cement augmentation, which was performed under C-arm fluoroscopic guidance. For indwelling drainage tube, the wound was sutured layer by layer.

### **Postoperative care**

The drainage tube was removed when the drainage volume was < 50 ml/24 hours postoperatively. Patients were advised to stay in bed within 1 week postoperatively, and brace fixation was performed within 3 months postoperatively. Standardized anti-osteoporosis therapy (combined with calcium, vitamin D, and bisphosphate drugs) was provided 3 years postoperatively.

The first 3 months of anti-tuberculosis treatment with quadruple therapy (isoniazid, rifampicin, streptomycin, ethambutol or pyrazinamide) were followed by isoniazid and rifampicin maintenance for at least 9 months after the inflammatory index returned to normal. The drug regimen can be adjusted according to drug sensitivity test and side effects such as liver and kidney dysfunction. The indications of drug withdrawal were as follows: symptoms of tuberculosis poisoning disappeared, ESR and C-reactive protein tended to normalize, and the paravertebral abscess was obviously absorbed as detected in the imaging examination.

### **Radiographic And Clinical Evaluation**

The follow-ups were performed at 1, 3 and 12 months postoperatively and then annually thereafter. Besides the plain radiography, thoracolumbar CT and MRI were performed to evaluate bone graft fusion and paravertebral abscess absorption (figure.2B-D, 3, and 4). The segmental Cobb angle was measured to evaluate kyphosis improvement. The laboratory examination including ESR, and CRP was also monitored. The pre- and postoperative VAS score, Oswestry disability index (ODI) score, and neurological function of ASIA scale were also recorded. The criteria for clinical cure of tuberculosis<sup>10</sup> were as follows: absence of tuberculosis poisoning symptoms and low back pain; good nutritional status without hypoproteinemia or anemia; radiographic examination showing abscess disappearance with satisfactory bone graft fusion; and normal ESR and CRP levels.

## Statistical analysis

All parametric data are presented as mean  $\pm$  standard deviation. Analysis of variance and  $\chi^2$  test were used to determine the significance of the study parameters for enumeration and categorical data between groups, respectively. All statistical analyses were performed using SPSS, version 19.0 software (IBM Corp., Armonk, New York, USA). A difference of  $P < 0.05$  was considered to indicate statistical significance.

## Results

The included 21 patients completed the operation successfully. Average operative time was  $200 \pm 25$  min and mean intraoperative blood loss was  $514 \pm 105$  ml. Postoperative pathological examination results supported the diagnosis of spinal tuberculosis. Average follow-up time was  $63.8 \pm 1.5$  months. Postoperative pain and tuberculosis poisoning symptoms improved in all patients, and paravertebral abscess was absorbed, achieving the cure criteria of spinal tuberculosis.<sup>10</sup> In all patients with neurological dysfunction, the ASIA grade improved by at least 1 grade (Table 1). One month postoperatively, the VAS score, ODI, segmental Cobb angle, ESR, and CRP were significantly improved compared with those preoperatively ( $P < 0.05$ , Table 2); there was no significant difference in the values at 1 month postoperatively and last follow-up ( $P \geq 0.05$ ). Only 3 patients had asymptomatic bone cement leakage into the paraspinal vein. No serious complications such as intraspinal cement leakage, pulmonary cement embolism, or neurovascular injury occurred. There were no complications such as implant failure, proximal junctional kyphosis, or recurrence of tuberculosis at the minimum 5-year follow-up.

Table 1  
ASIA classification of neurological function in 21 patients before operation and at the last follow-up

Preoperative ASIA scale	n	ASIA scale at the last follow-up				
		A	B	C	D	E
A	2	0	0	1	1	0
B	5	0	0	1	3	1
C	7	0	0	0	2	5
D	4	0	0	0	0	4
E	3	0	0	0	0	3
American spinal injury association (ASIA)						

Table 2

Comparison of observation indexes preoperative, 1 month postoperative and at the last follow-up( $n = 21, \pm s$ )

Observation	ODI (%)	VAS	Cobb (°)	ESR (mm/h)	CRP (mg/L)
Preoperative	48.5 ± 11.2 <sup>#</sup>	6.1 ± 1.1 <sup>#</sup>	30.6 ± 9.3 <sup>#</sup>	79.2 ± 10.7 <sup>#</sup>	27.2 ± 10.1 <sup>#</sup>
1 month postoperatively	28.7 ± 9.2 <sup>*</sup>	2.1 ± 0.7 <sup>*</sup>	17.2 ± 4.2 <sup>*</sup>	31.3 ± 9.2 <sup>*</sup>	12.4 ± 5.8 <sup>*</sup>
last follow-up	15.4 ± 5.8 <sup>*</sup>	1.4 ± 0.4 <sup>*</sup>	19.3 ± 3.3 <sup>*</sup>	13.5 ± 3.7 <sup>*</sup>	3.3 ± 2.1 <sup>*</sup>
F	25.257	29.947	18.294	21.975	19.167
P	0.000	0.000	0.021	0.016	0.019
* compared with preoperative (P < 0.05) and <sup>#</sup> immediately after operation (P < 0.05)					

## Discussion

The postoperative curative effect was satisfactory, and the paravertebral abscess was absorbed dramatically. Although the loss of segmental Cobb angle was 2.6° during the final follow-up, the VAS, ODI, and ASIA scores of all 21 patients were significantly improved compared with the scores preoperatively, and there was no recurrence of tuberculosis at the long-term follow-up. No serious complications such as intraspinal cement leakage, pulmonary cement embolism, or neurovascular injury occurred in all patients. There were no complications such as implant failure, proximal junctional kyphosis, or recurrence of tuberculosis at the minimum 5-year follow-up. These findings suggest that, for elderly patients with thoracolumbar spinal tuberculosis complicated with severe osteoporosis, after anterior or posterior debridement and bone grafting, PASF is effective and safe.

Spinal tuberculosis is a major cause of paraplegia in developing countries, and older people are at high risk of contracting the disease.<sup>11</sup> Given that the elderly have many complications, such as poor physical tolerance and osteoporosis, it is particularly difficult to deal with senile spinal tuberculosis in clinical setting. Elderly patients with spinal tuberculosis usually have the following characteristics: owing to the existence of low back pain or neurological dysfunction, patients prefer to stay in bed, and reduced activity may aggravate the degree of osteoporosis, forming a vicious circle<sup>12</sup>; the nutritional status of elderly patients is sometimes poor, and most patients are complicated with hypoproteinemia and anemia, especially those with spinal tuberculosis. The accumulation of *M. tuberculosis* leads to poisoning symptoms affecting patients' appetite and inducing fever. Insufficient protein intake and increased metabolism due to fever can reduce serum protein levels, leading to hypoproteinemia<sup>13</sup>; immunity function and compliance to systematic anti-tuberculosis treatment are really poor for elderly patients, most are complicated with huge abscess, sinus, and dead bone formation, and the value of conservative treatment is limited; tuberculosis recurrence is relatively high after the surgical intervention; in elderly

patients with severe osteoporosis, multiple fractures of the thoracolumbar spine may coexist with tuberculosis. Most patients had severe kyphosis and/or neurological dysfunction when they sought medical care. The main purpose of the operation is to thoroughly remove the necrotic tissue and pus, relieve spinal cord compression, rebuild spinal stability, effectively control the disease, shorten treatment duration, and improve patients' quality of life.<sup>14</sup> If reconstruction in such patients are performed using traditional implants, the loose cancellous bone of the vertebral body finds it difficult to provide sufficient holding force; further, the risk of implant failure is higher than that without osteoporosis, and the possibility of serious complications, such as bone nonunion and kyphosis aggravation, is increased.<sup>15-16</sup> Burval et al. have found that the strength of pedicle screw fixation in patients with osteoporosis is only 40%-80% lower than that in people with normal bone mass.<sup>17</sup> To overcome this problem, there are many ways to enhance the holding force of screws, such as increasing the length and diameter of screws, use of expansion screws or bone cement reinforced screws, and so on.<sup>18-19</sup> However, some studies have pointed out that deeper screw placement may increase the risk of damage to anterior vital vessels and viscera, and the utilization of larger diameter screws may lead to burst fracture of the pedicle causing nerve root pinching.<sup>20</sup> Expansion screw has been modified into expandable pedicle screw to prevent screw pullout. However, there is a certain loosening rate of the expandable pedicle screw in clinical practice, and the strength is lower than that of the bone cement reinforced screw.<sup>19</sup> Two studies<sup>21-22</sup> proved that bone cement reinforcement has a significant advantage in terms of biomechanics and can significantly improve the axial anti-pullout force of pedicle screws, especially for patients with osteoporosis. When 2.5 cm<sup>3</sup> bone cement is injected into normal and osteoporotic vertebrae, the pullout force of screws can be increased by approximately 120% and 156%, respectively. Choma et al.<sup>23</sup> considered that the holding force of pedicle screws strengthened with 2-ml bone cement can be increased 5 times. For elderly patients with both osteoporosis and degenerative spine diseases, application of bone cement reinforced screws provided satisfactory clinical results. Moon et al.<sup>5</sup> have followed up 37 patients with thoracolumbar degenerative diseases accompanied with osteoporosis for 3 years, and found that the effect of bone cement reinforcement was satisfactory, and 34 of the 37 patients had satisfactory bone graft fusion. Liu et al.<sup>24</sup> utilized PASF in elderly patients with fracture and found no complications, such as internal fixation loosening or increased Cobb angle at the 95-month follow-up. Hu et al.<sup>4</sup> found that bone cement reinforcement can significantly improve the stiffness and strength of spinal internal fixation, which is conducive to the maintenance of spinal stability and promote bone graft fusion, which is among the key factors determining the long-term clinical outcome.

The emergence of new infection of tuberculosis or the spread of original infection after injecting bone cement into the fractured vertebral body has been reported in several case reports<sup>6-9</sup>, suggesting that injecting bone cement into the vertebral body of patients with infection or suspected infection is worrisome. However, there has been no study that has evaluated the safety and efficacy of PASF in treatment of elderly patients with thoracolumbar spinal tuberculosis accompanied with severe osteoporosis. Therefore, we mainly refer to the results of MRI in the selection of bone cement-reinforced

vertebrae, but only in the vertebrae that are closest to the lesion and have no significant high signal intensity on T2 and fat compression sequences.

For elderly patients with severe osteoporosis, whether the injection of bone cement into the vertebral body will increase the risk of cement leakage and whether it will have an impact on tuberculosis treatment is another focus of this study. In the study of Martín<sup>25</sup>, Philippe<sup>26</sup>, and Guo<sup>27</sup>, bone cement leakage is mostly asymptomatic vascular leakage, which was similar to our study. We believe that the bone cement leakage is related to cement viscosity, injection volume, and distribution location. Low viscosity and over-injection of the cement will increase the symptomatic bone cement leakage risk. When the cement distribution was located at the back of vertebral body, the risk of leakage into the spinal canal increases, causing symptoms of spinal cord compression. Philippe et al.<sup>26</sup> thought that an appropriate amount of bone cement (approximately 2.5 ml) could provide an ideal anti-pullout force of screws. However, Liu et al.<sup>18</sup> thought that only the injection volume of bone cement controlled between 1.5 and 3.0 ml are safe and effective. In this study, we preferred to inject bone cement at the drawing period, and the injected amount was controlled within 1.5 ml. Therefore, there were no serious complications, such as intraspinal canal or pulmonary embolism, in this study.

It should be taken into account that surgery can only accelerate patients' recovery, and drug treatment is the fundamental and key to cure spinal tuberculosis. We recommend at least 1 year of anti-tuberculosis treatment until the indications of drug withdrawal are fulfilled. Despite bone cement injection into the vertebral body, no spread or recurrence of tuberculosis infection was found at > 5-year follow-up. Toyone et al.<sup>28</sup> reported that there is a high incidence of adjacent segment fractures within 2 years after spinal internal fixation. Besides osteoporosis, it was associated with the increase of mechanical stress to the adjacent level. No proximal junctional kyphosis occurred in our cases. We speculated that, in addition to full-course anti-tuberculosis treatment, systematic anti-osteoporosis treatment during each follow-up visit should be ensured.

## Limitation

The main limitation of the study is its single-center, small-sample case series. However, in view of this study's long-term follow-up period, as having the largest sample size to date, the safety and efficacy of PASF in the treatment of elderly patients with thoracolumbar spinal tuberculosis accompanied with severe osteoporosis were evaluated for the first time. This conclusion has a certain value, but still needs further verification through a follow-up prospective randomized control study.

## Conclusion

For elderly patients with thoracolumbar spinal tuberculosis complicated with severe osteoporosis, after anterior or posterior debridement and bone grafting, together with postoperative systematic anti-tuberculosis and anti-osteoporosis treatments, PASF is safe and effective without catastrophic

complications such as intraspinal cement leakage. During the 5-year follow-up, there was no tuberculosis recurrence or implant failure.

## Abbreviations

Polymethylmethacrylate-augmented screw fixation (PASF)

visual analog scale (VAS)

bone mineral density (BMD)

computed tomography (CT)

magnetic resonance imaging (MRI)

American Spinal Injury Association (ASIA)

erythrocyte sedimentation rate (ESR)

- reactive protein (CRP)
- Oswestry disability index (ODI)

## Declarations

**Ethics approval and consent to participate:** The Medical Ethics Committee of Honghui Hospital of Xi'an Jiaotong University approved the study in accordance with the relevant guidelines and regulations. Informed consent was obtained from all patients.

**Consent for publication:** Not applicable

**Availability of data and materials:** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Competing interests:** The authors declare that they have no competing interests.

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**Author's contributions:** Ding-Jun Hao and Yuan-Ting Zhao conceived the study design. Bao-Rong He, Long-Gang Gong, Peng Liu, Tuan-Jiang Liu, Xiang-Fu Wang, Dongmei Wei, Han-Lin Gong, Jian-Min Wei, Hao Chen, Lei Chu and Peng Zou supervised the data collection. Jun-Song Yang drafted the manuscript. Bao-Rong He contributed to the revision. Yuan-Ting Zhao is responsible for this article.

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## Figures

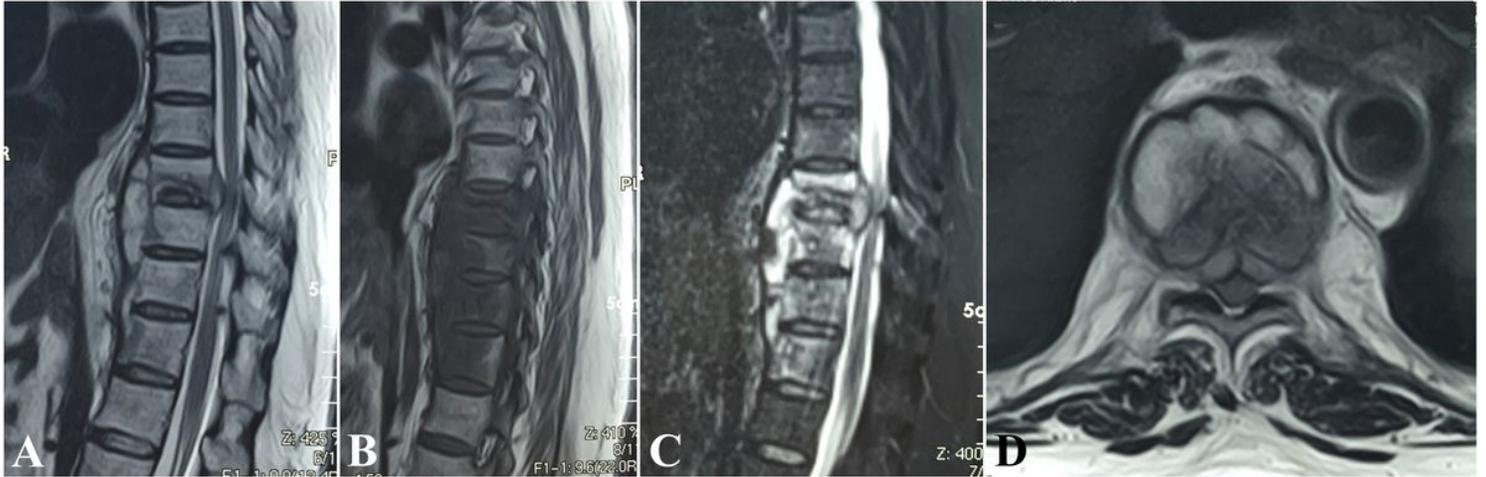


Figure 1

The preoperative MRI of a case of thoracic TB with grade D of ASIA showed the lesion located at T8-T11, which showed high signal at T2WI (A) and fat suppression sequence (B), and hyposignal at T1WI (C). The spinal cord at the level of T8/9 was compromised by the intraspinal canal abscess. The paravertebral abscess was also detected at the axial plane (D).

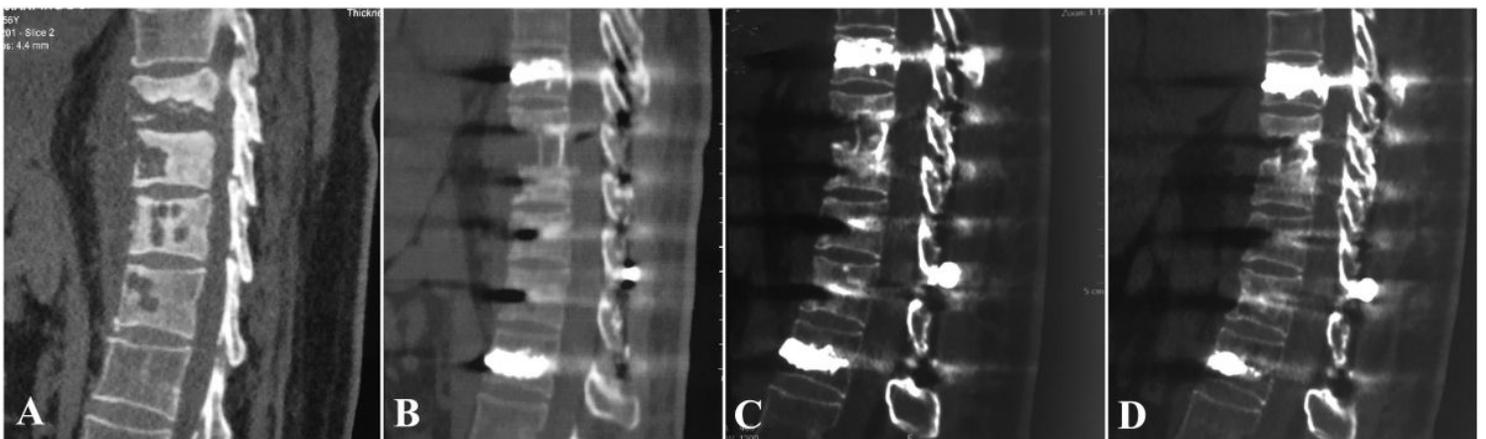
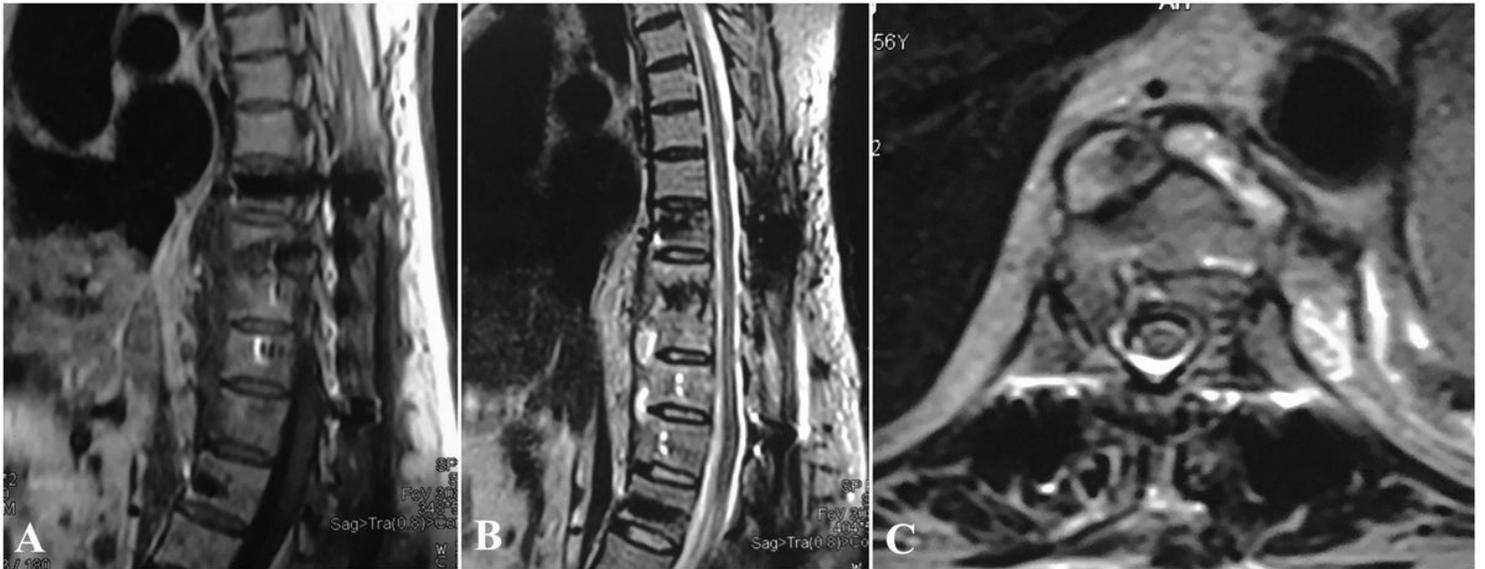


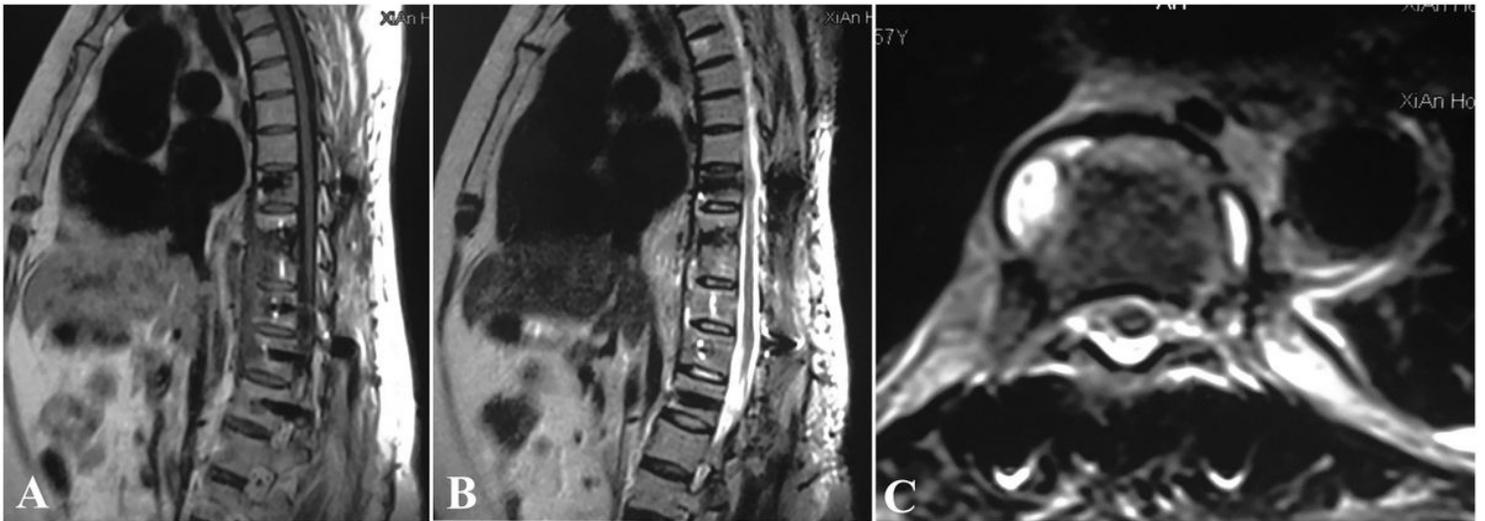
Figure 2

The preoperative sagittal CT showed the bony destruction at the T8-T11 vertebral bodies (A). One month after the operation, the bony graft was stable at the sagittal CT reconstruction, which was fused at the 9-month follow-up (B) and remodeled at the final follow-up (C).



**Figure 3**

At the 6-month follow-up, only the paravertebral abscess was visible at the sagittal plane of T1WI (A) and T2WI (B) and the axial plane (C).



**Figure 4**

At the 18-month follow-up, the paravertebral abscess was disappeared at the sagittal plane of T1WI (A) and T2WI (B) and the axial plane (C)