



A Novel Height-Adjustable Nano-Hydroxyapatite/Polyamide-66 Vertebral Body for Reconstruction of Thoracolumbar Structural Stability After Spinal Tumor Resection

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■ **BACKGROUND:** Reconstruction of thoracolumbar structural stability is a formidable challenge for spine surgeons after vertebral body tumor resection. Various disadvantages of the currently used expandable or nonexpandable cages have limited their clinical applications. We sought to develop a novel prosthesis for clinical use and assess its preliminary clinical outcome in reconstruction of thoracolumbar structural stability after spinal tumor resection.

■ **METHODS:** Using data obtained from a retrospective analysis of the morphological characteristics of the thoracolumbar vertebrae and endplates in previously reported studies, we modified the nano-hydroxyapatite/polyamide-66 (n-HA/PA66) strut into a novel height-adjustable vertebral body. A retrospective study was performed of 7 patients who had undergone reconstruction of thoracolumbar structural stability with this novel prosthesis from August 2016 to January 2017.

■ **RESULTS:** A novel height-adjustable vertebral body (AHVB) composed of n-HA/PA66 with 2 separate components with a 163° contact surface at each end was manufactured. The height-adjustable range was 28–37 mm. No significant implant-related complications were observed in the process of operation. All patients experienced a significant reduction in pain, with the visual analog scale score decreasing from 7.9 to 4.0. Neurological improvement was assessed using the Frankel grading system after surgery. Post-operative radiographic and computed tomography/magnetic

resonance imaging findings indicated that the operated segment was stable, the outcome of kyphosis correction was good, and no prosthesis subsidence or dislocation was observed.

■ **CONCLUSION:** This novel prosthesis has many advantages in the reconstruction of height, lordosis, and alignment after thoracolumbar spinal tumor resection and has a favorable prospect for clinical application.

INTRODUCTION

Both primary and metastatic spine tumors are devastating conditions and can damage the vertebrae, pedicles, and posterior elements, leading to instability of the spinal column. This instability leads to acute spinal cord compression and kyphosis.¹⁻³ Although advances have been made in surgical techniques and devices, anterior spinal column reconstruction after vertebrectomy remains a major challenge for spine surgeons.^{4,5} Many implant-related complications such as nerve root sacrifice,⁶ nonunion, and subsidence of cages^{2,7-9} were frequently observed.

To address these issues, various implants and artificial materials have been developed.^{2,10} Titanium mesh cages can provide the greatest resistance to axial load and have been widely used in surgery for >20 years. However, stress shielding and a high subsidence rate are still of great concern, which hinder the likelihood of this cage from becoming an ideal reconstruction device.⁹ The expandable

Key words

- Deformity
- Endplate geometry
- Nano-hydroxyapatite/polyamide-66
- Reconstruction
- Spinal tumor
- Vertebral body

Abbreviations and Acronyms

- AHVB:** Height-adjustable vertebral body
CT: Computed tomography
MRI: Magnetic resonance imaging
n-HA/PA66: Nano-hydroxyapatite/polyamide-66
VAS: Visual analog scale

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cage incorporates a wider footprint than the comparable titanium mesh cage and, therefore, can provide immediate spine stability by excellent defect adaptation. Nonetheless, an additional end-cap is always needed to achieve normal anatomical alignment. However, it does not always sufficiently match the morphology of the thoracolumbar endplate because the degree of the device is usually fixed. In contrast, most currently used prostheses are made of titanium alloy materials, which have a much greater elastic modulus than the natural bone. This characteristic often induces a stress shielding effect and bone resorption, thus interfering with bone fusion.^{11,12}

The use of biological materials has long been attempted. Nano-hydroxyapatite/polyamide-66 (n-HA/PA66) is a biomimetic biomaterial composite synthesized from the polar polymer PA66 and nano-scale HA that has been approved for clinical application for several years. The n-HA/PA66 strut has been widely used for spinal reconstruction, with satisfactory clinical outcomes.^{12,13} However, most of these were designed to a unified specification with a non-adjustable height and hollow columnar structure. Additional bone grafts are needed to fill in the strut; therefore, it will often be necessary to trim the strut to an appropriate size.

Theoretically, an ideal interbody structural support should be designed for ease of implantation and provide an optimal mechanical and biological environment for fusion.^{14,15} To design such an ideal prosthesis, many morphological and biomechanical studies of thoracolumbar endplates have been performed. The results have shown that the incidence of subsidence and several of the reported complaints are significantly related to the small footprint and surface area of contact, cage material, and geometry. Thus, a better understanding of the biomechanical and morphological properties of the vertebral endplates is clinically important, in particular, to provide crucial information on the design of spinal instrumentation.^{14,16,17} However, to the best of our knowledge, few properly fitting, expandable vertebral cages were designed in previous studies. Our primary goal in the present study was to design a novel height-adjustable vertebral body (AHVB) and evaluate its preliminary clinical application. We expected that this rational design process and proper application would greatly reduce the occurrence of implant-related complications and help achieve good clinical outcomes.

METHODS

Design of a Novel AHVB

Data regarding the morphological characteristics of the thoracolumbar vertebrae and endplates were obtained from the related studies.^{11,14,16-26} From this information, we modified the n-HA/PA66 strut¹² and designed a AHVB (Figure 1). It is composed of 2 independent parts: part 1 and part 2. Part 1 is a partial hollow structure as the base and part 2 is a solid columnar structure as the top cap. A channel is present in the bottom of part 1 for injection of the bone cement to change the height of the vertebral body and meet the surgical requirements (Figure 2).

Clinical Application

Patient Demographic Data. We included 7 patients (2 males and 5 females; age range, 11–65 years) with thoracolumbar tumors who had undergone AHVB reconstruction at our spinal tumor center from August 2016 to January 2017 in the present study. The institutional

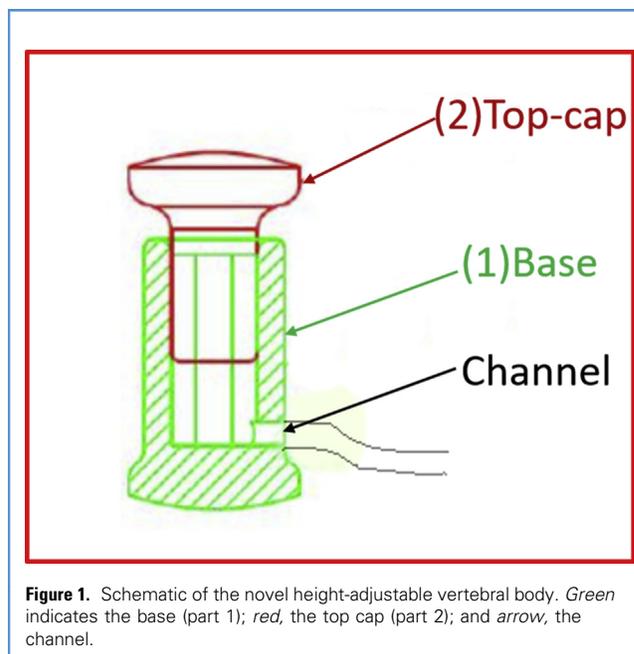


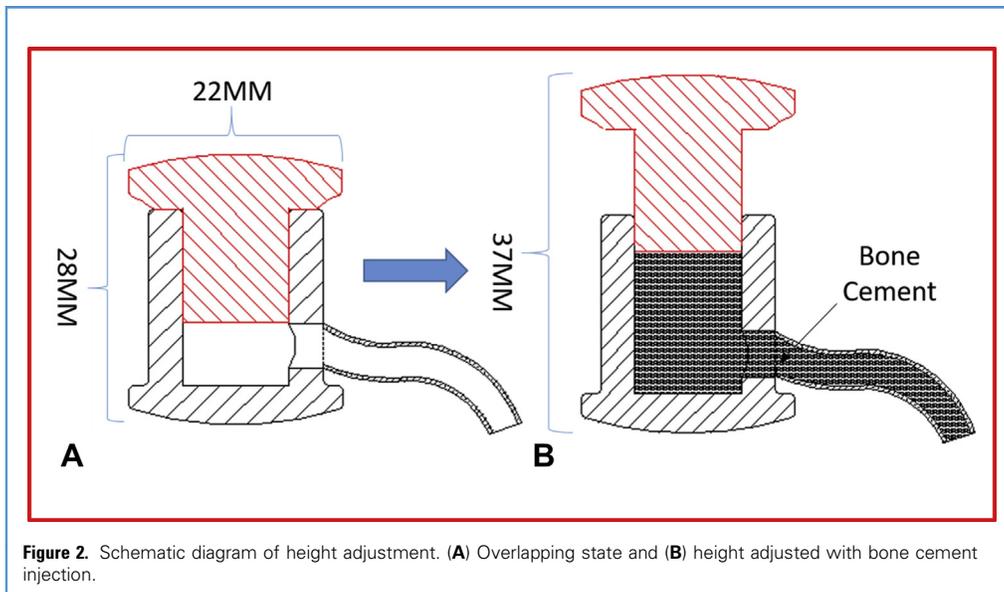
Figure 1. Schematic of the novel height-adjustable vertebral body. Green indicates the base (part 1); red, the top cap (part 2); and arrow, the channel.

review board of our hospital approved the experimental protocol, and the patients or their families or guardians provided written informed consent before initiation of the present study.

We analyzed the functional outcomes using Frankel's neurological performance scale and the 10-point visual analog scale (VAS). All patients exhibited signs and symptoms of spinal tumors consistent with the radiographic data, including preoperative computed tomography (CT), magnetic resonance imaging (MRI), and radiography.

The clinical diagnosis and demographic data are presented in Table 1. Of the 7 patients, 2 had lung cancer metastasis and 1 each had hemangioma, multiple myeloma, prostatic cancer metastasis, Ewing sarcoma, and giant cell tumor of bone. Also, 4 patients were classified as neurologically normal (Frankel grade E), 2 as Frankel grade D, and 1 as Frankel grade C. The reconstruction was performed in the thoracic spine (T3, T8, T9, T12) in 4 patients and in the lumbar spine (L1, L2, L5) in 3 patients.

Surgical Procedures. After successful general anesthesia, the patient was placed prone on a radiolucent operating table. A posterior midline incision was made, centered on the affected level, through which standard midline posterior subperiosteal dissection was performed. The pedicle screws were placed under fluoroscopic guidance at 2 levels above and 2 levels below the vertebral body lesion. A rod was placed temporarily to connect the screws on the side contralateral to the planned transpedicular approach. Full decompression with resection of the posterior elements was achieved, and vertebrectomy, including removal of the intervertebral discs above and below, was performed using a combination of a high-speed drill, curette rongeur, and ultrasonic aspiration. Both adjacent vertebral body endplates were preserved. All nerve roots were well kept. Considering the trajectory of the nerve roots, the newly designed prosthesis was carefully inserted into the



vertebrectomy defect and rotated to match the long axis of the spine. Next, an assorted connecting pipe was matched to the thread entrance of the screw. The bone cement was injected to adjust the height of the cage to restore the anterior column height and correct the deformity in situ (Figure 3 and Supplemental Video 1 [demonstrating the process of implantation of AHVB]). After solidification of the bone cement, another rod was fitted, and bilateral compression was applied to the posterior instrumentation to secure the AHVB. The implant position was confirmed under fluoroscopic guidance.

The patient was advised to undergo radiographic assessment of the surgical segment and adjacent vertebrae by radiography and CT or MRI. Regular assessments were performed at 0, 3, 6, and 12 months after surgery, and the follow-up period was

defined as the interval from the date of surgery to death or September 1, 2017 for surviving patients. The neurological status was assessed using the Frankel score, and radicular low back pain was graded using the VAS. Height loss of the fused segment was measured as the difference between the immediate postoperative measurement and the last follow-up measurement. Subsidence was defined as a height loss of >3 mm. The thoracolumbar Cobb angle was defined as the angle formed between the superior endplate of the upper vertebra and the inferior endplate of the lower vertebra. Internal fixation stability was evaluated. Postoperative complications, including cerebrospinal fluid leakage, infection, pleural effusion, and internal fixation-related complications, were recorded. Descriptive statistics (mean ± standard deviation) were obtained for the quantitative variables.


 Video available at
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Table 1. Patient Demographic Data*

Patient	Age (years), Sex	Diagnosis; Level	Cage Span	Instrumentation	Follow-Up (months)	Frankel Grade		VAS Score		Complication
						Preop	Postop	Preop	Postop	
1	61, M	Hemangioma; T3	T2–T4	T1–T5	12	E	E	7	4	Left pleural effusion
2	55, F	MM; T8	T7–T9	T6–T10	6	D	E	8	3	None
3	65, F	LCa met; L5	L4–S1	L3–Ilium	3	C	D	10	7	None
4	61, M	PCa met; L1	T12–L2	T11–L3	8	D	E	9	3	None
5	52, F	LCa met; T9	T8–T10	T7–T11	7	E	E	8	5	Pulmonary infection
6	56, F	GCT; T12	T11–L1	T10–L2	9	E	E	7	4	None
7	11, F	ES; L2	L1–L3	T12–L4	11	E	E	6	2	None

Preop, preoperative; Postop, postoperative; VAS, visual analog scale; M, male; F, female; MM, multiple myeloma; LCa, lung carcinoma; met, metastasis; PCa, prostate cancer; GCT, giant cell tumor of bone; ES, Ewing sarcoma.
 *All 7 patients underwent a posterior approach.

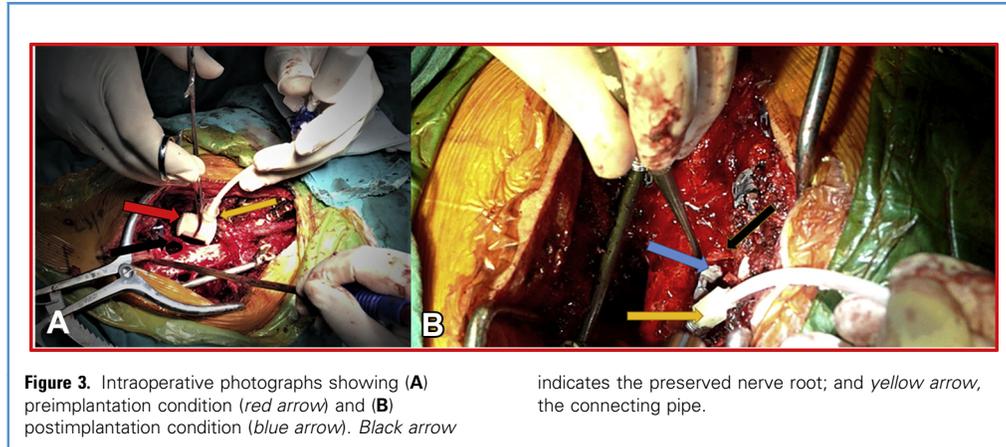


Figure 3. Intraoperative photographs showing (A) preimplantation condition (red arrow) and (B) postimplantation condition (blue arrow). Black arrow

indicates the preserved nerve root; and yellow arrow, the connecting pipe.

RESULTS

Using the thoracolumbar and endplates data obtained from the previously reported studies, a novel AHVB was produced, which consisted of 2 distinctive components: a hollow structure and a matched solid top cap. Before implantation, they were assembled in a nested fashion in vitro with a minimum height of 28 mm. When the AHVB was placed in the right position, the 2 parts could be expanded by injection of the bone cement to, conservatively,

reach 37 mm. The curvature of the contact surface was 163° , and the contact surface diameter was 22 mm (Figure 2). The contact surface area was 352.8 mm^2 . At the bottom of the AHVB, a screw thread entrance was built, such that the bone cement could be injected to achieve the correct height setting.

Altogether 7 patients were treated with this AHVB, in addition to the pedicle screw fixation system. No instance of cage or hardware failure occurred during surgery. All patients achieved

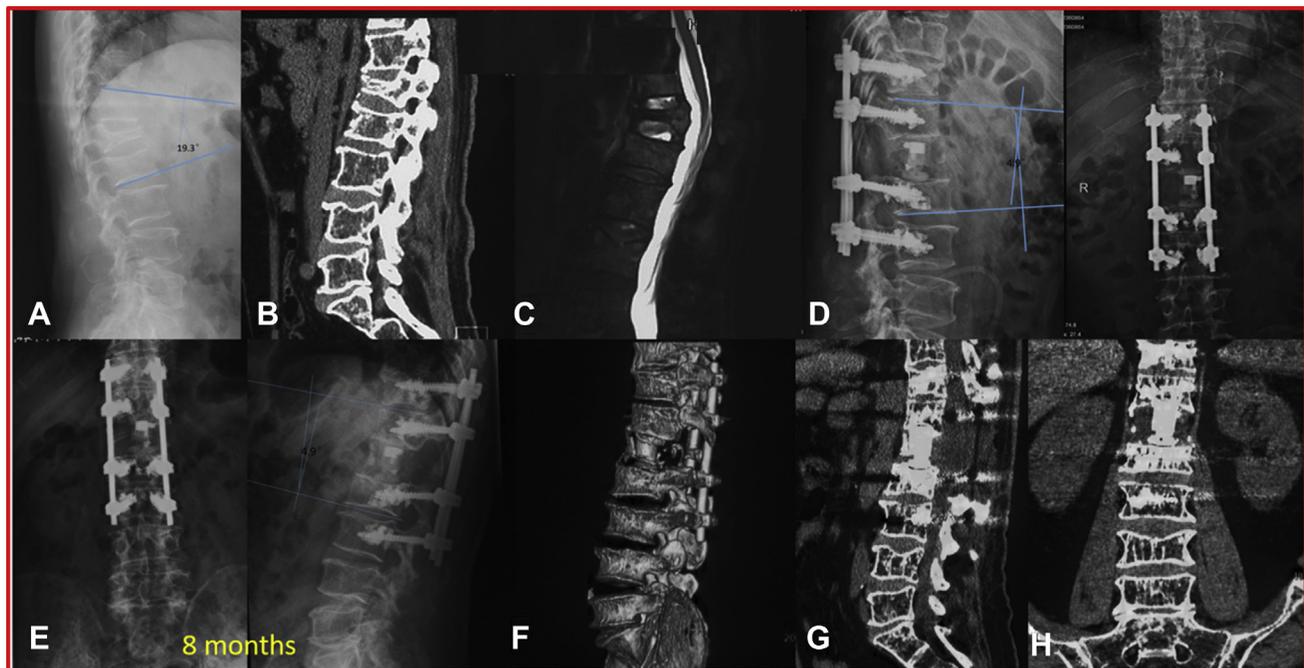


Figure 4. Imaging studies of a 61-year-old man with a diagnosis of prostate cancer metastasis. Preoperative thoracolumbar (A) radiographic, (B) computed tomography (CT), and (C) magnetic resonance imaging studies demonstrating tumor-induced destruction of the L1 vertebral body and kyphosis (Cobb angle, 19.3°). The patient underwent L1 spondylectomy and fusion with the height-adjustable vertebral body (AHVB). (D) The kyphosis was corrected, with Cobb angle improvement from 19.3° to 4.9° .

(E) Plain radiograph 8 months after surgery showing a stable vertebral height and Cobb angle of 4.9° . (F) Three-dimensional CT, (G) sagittal view, and (H) coronal view CT scans showing that the cavity of the interface between the AHVB and lower endplate was relatively small. No obvious signs of cage migration or subsidence were found at the 8-month follow-up examination.

immediate stability postoperatively. No significant complication related to cage placement occurred, and no thoracic or lumbar nerve root required sacrifice.

At the end of the follow-up period, no implant-related complication had been observed. In all 7 patients with a diagnosis of a spinal tumor before surgery, the pain was significantly alleviated or had disappeared with a clear decrease in the VAS scores. Their pain levels decreased from 7.9 points preoperatively to 4 points at the final follow-up visit. Also, the pain had been relieved by ≥ 1 neurological grade after surgery for patients with a classification of Frankel grade D or less before surgery. In patient 1, the kyphosis was corrected remarkably, and the L1–L3 Cobb angle had improved from 19.3° preoperatively to 4.9° at the final follow-up examination (Figure 4). Various degrees of kyphosis and lordosis in the other patients were also corrected successfully (Figure 5). No tumor recurrence was noted in any patient. One patient with L5 lung cancer metastasis had died of progression of systemic malignant disease at 3 months after surgery without spinal symptoms. The postoperative CT scan in the 3 surviving patients in our series showed good alignment of the AHVB, proper placement of the hardware, and a tight fit of the AHVB to the host bone, with no loss of fused segmental height or subsidence of AHVB observed. The postoperative complications observed in our series included left pleural effusion in 1 patient, which was treated with drainage of the pleural cavity. Pulmonary infection developed in 1 patient, which was successfully treated with intravenous antibiotics.

CASE DESCRIPTION: PATIENT 1

A 61-year-old man presented with severe low back pain, bilateral lower extremity weakness, and urinary incontinence. The neurological examination revealed Frankel grade D at his initial presentation. He was known to have had underlying prostate cancer for < 2 months. The MRI and CT scans of the thoracolumbar spine revealed severe tumor-induced destruction of the L1 vertebral body and kyphosis. A biopsy performed at another hospital confirming the diagnosis of prostate cancer metastasis. The patient underwent single-stage spondylectomy tumor resection and reconstruction of the stability of 3 spinal columns. An AHVB was inserted, spanning T12–L2. To supplement the posterior reconstruction, dorsal screw and rod instrumentation was required. Postoperative radiography showed correction of the deformity and confirmed the stability. The patient's pain was significantly reduced, and his neurological grade had improved to Frankel grade E postoperatively. During the 8-month follow-up period, the patient showed no evidence of tumor recurrence or internal fixation failure.

DISCUSSION

An increasing number of patients have been recognized to have various spine tumor diseases, both benign and malignant.^{27–29} The spinal column is the most common site of bone metastasis and primary tumors. Bony destruction and pathologic vertebral compression fracture render the spinal column unstable, leading to

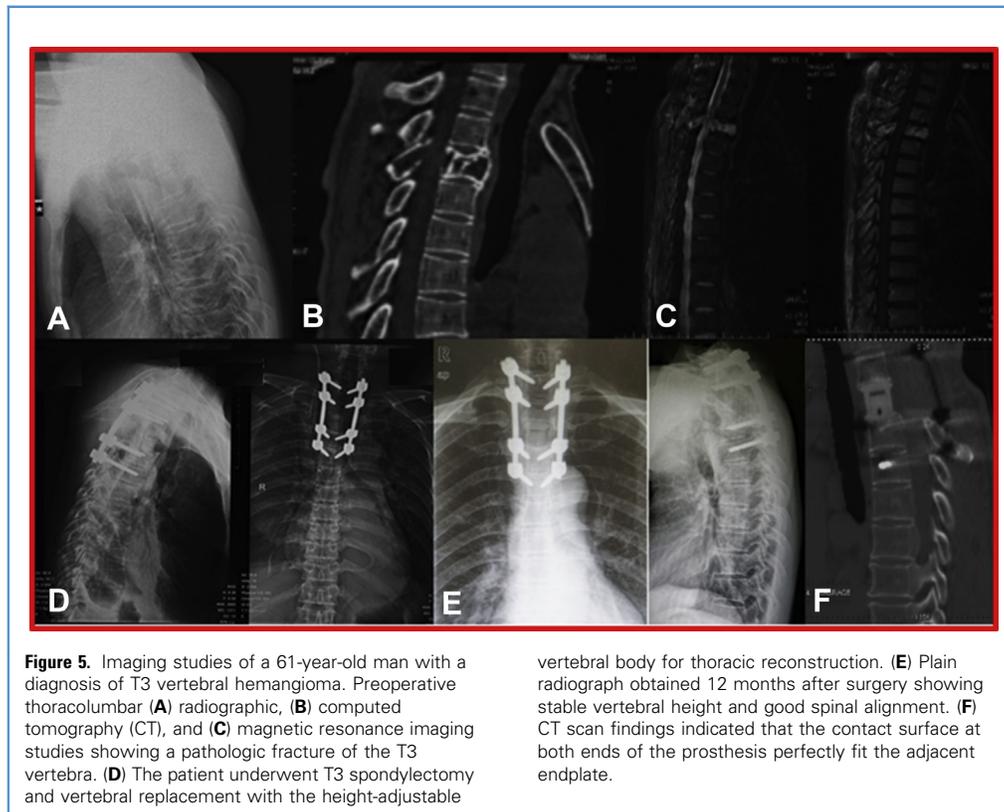


Figure 5. Imaging studies of a 61-year-old man with a diagnosis of T3 vertebral hemangioma. Preoperative thoracolumbar (A) radiographic, (B) computed tomography (CT), and (C) magnetic resonance imaging studies showing a pathologic fracture of the T3 vertebra. (D) The patient underwent T3 spondylectomy and vertebral replacement with the height-adjustable

vertebral body for thoracic reconstruction. (E) Plain radiograph obtained 12 months after surgery showing stable vertebral height and good spinal alignment. (F) CT scan findings indicated that the contact surface at both ends of the prosthesis perfectly fit the adjacent endplate.

severe low back pain, acute cord compression, and spinal deformity.¹ Spinal surgery is the most rapid method for relieving acute spinal cord compression and is often necessary in the case of spinal instability. Advances in surgical techniques and instrumentation have made palliative circumferential decompression and 3-column instrumented stabilization possible.^{5,27,28,30-32} However, large bony defects after vertebrectomy constitute a considerable challenge to reconstructive surgery.

To manage large bony defects, many bone grafting materials, including autografts, allografts, and bone cement, and implants, including titanium cages, ceramic–glass, and carbon fiber spacers, have been developed and used in the past decade.² However, owing to limited resources and spread of infections, the use of autografts and allografts has been restricted in clinical practice.³³ Hence, synthetic bone substitutes have been increasingly used in bone reconstruction techniques.^{13,34} n-HA/PA66 is a biomimetic biomaterial developed for clinical use since 2005. Owing to its good mechanical performance and biological safety, it has been widely used as a bone substitute.^{12,35,36} In the present study, we used the same porous n-HA/PA66 composite reported in previous studies to fabricate our novel AHVB in the hopes that it would result in a high long-term fusion rate.^{12,13}

Some implants, such as carbon fiber cages and ceramic–glass constructs, are rarely used owing to their disadvantages.³⁷ Vertical metallic mesh cages have become a viable option for anterior column support with minimal complications and have been widely used in clinical practice.⁸ Nevertheless, some observed disadvantages such as subsidence into adjacent vertebral bodies and lateral displacement are known to cause serious problems, including collapse of the vertebral body, progression of kyphosis, and fusion failure owing to the limited interface contact, sharp edge of both ends, and large difference in elastic moduli.^{7,9,32,38-41} To increase the interface strength, a titanium mesh cage with a large diameter and augmentation of an internal end ring system has been recommended.⁷ However, this size change causes difficulty with implanting the prostheses and increases the incidence of implant-related complications.⁴² In the present study, we designed an AHVB with a diameter of 22 mm and surface area of 352.8 mm². This size can cover $\geq 30\%$ of the largest contact surface area of the L5 endplate, will match with most thoracolumbar endplates, and can provide sufficient coverage, significantly enlarging the contact area. The design of this contact surface should also avoid the stress concentration and prevent the occurrence of subsidence.

Additionally, most titanium mesh cages or expandable cages are composed of titanium alloy. However, because the titanium alloy has a significantly greater elastic modulus than the natural cortical bone and any other bone graft inside the strut,¹² it can easily result in a stress shielding effect, causing bone absorption and failure of internal fixation. In the present study, the AHVB was composed of n-HA/PA66. This single material can eliminate the use of an additional bone graft, reducing the risk of the stress concentration induced by bone graft sorption. Because n-HA/PA66 has a similar elastic modulus to that of natural bone,^{34,35} it can help reduce the subsidence rate effectively.

To design an ideal implant, many researchers have focused on the morphological characteristic of the endplate. Wang et al.²² reported marked morphological asymmetry between the 2 adjacent endplates

of a lumbar intervertebral disc. The size and shape of the vertebral endplate vary considerably between the upper and lower lumbar regions. Duran et al.²⁵ reported that, at all lumbar levels, an increase in the endplate concave angle and a decrease in the concave depth of the vertebral endplate would be detected as disc degeneration increased from grade 1 to 4. Tan et al.¹⁶ quantitatively analyzed the vertebral anatomic features of Chinese Singaporeans and concluded that the vertebral height and endplate area increased steadily from T1 to L4. Because several factors contribute to the morphological differences, it has been challenging to design an implant to match all the different endplates. To the best of our knowledge, only a few prostheses have been designed to perfectly fit the endplate geometry. In our study, we designed the contact surface with a 163° concave angle to match the concavity and curvature of the thoracolumbar endplates. Because spinal tumors can develop at any age, a 163° concave angle design can be expected to meet the major requirement for reconstruction. For those endplates with a concave angle <163°, although the center of the contact surface will experience less stress, the periphery can provide sufficient contact area and strength. In contrast, for those concave angles >163° (Figure 6), we can implant the prosthesis normally without concern for subsidence. Although the stress can concentrate at the center of the contact surface, leading to a slight sinking of the endplate, the remaining contact surface can provide enough support. It was reported that the vertebral body and the associated intervertebral disc height increased from a minimum of 22.4 mm at T1 to a maximum of 54.1 mm at L5.⁴² In present study, we designed the AHVB height to range from 28 to 37 mm to meet the reconstruction needs of single-segment vertebrectomy, which resulted in satisfactory outcomes. The height of the anterior column was restored, and the deformity was efficiently corrected.

Our novel AHVB is assembled in vitro with the 2 parts mutually embedded, and no additional bone grafts are needed for filling in the strut. Injection of only a small amount of bone cement is required through the screw thread entrance to adjust the height to an ideal state. This is an efficient and convenient method for adjusting the height of the AHVB in situ.

The single-stage posterior transpedicular approach is an effective and less-invasive treatment and has been widely used in circumferential thoracolumbar decompression and fixation.^{6,43-48} However, insertion of a cage through this operative route is still technically challenging, especially in the lumbar spine, where the nerve root plays a critical role in lower limb function, and rhizotomy should be considered with caution.⁴⁹ Awwad et al.⁴² analyzed the anatomical features of the thoracolumbar spinal nerve roots and found that the smallest access to the anterior column from the posterior access is the corridor between the spinal nerve and the inferior endplate of the superior vertebral body. This distance increased from 1.74 mm at T1 to 2.74 mm at T11 and to a maximum of 3.0 mm at L5. In their case series, no implant placement-related complication was observed, and no nerve root was sacrificed. Because the height is adjustable, we found insertion of the AHVB implant was considerably easier. More importantly, the initial size of the device is suitable for insertion, and the final size is long enough for anterior column reconstruction.

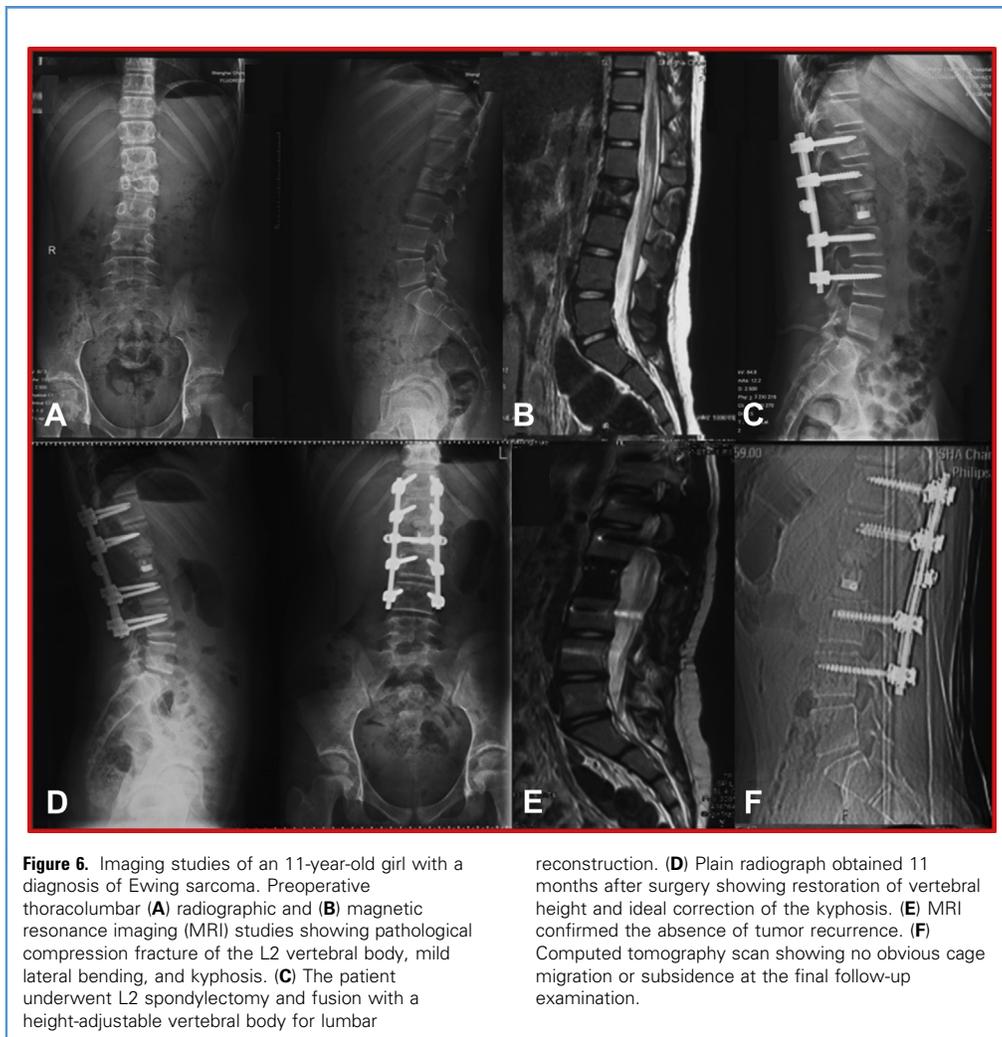


Figure 6. Imaging studies of an 11-year-old girl with a diagnosis of Ewing sarcoma. Preoperative thoracolumbar (A) radiographic and (B) magnetic resonance imaging (MRI) studies showing pathological compression fracture of the L2 vertebral body, mild lateral bending, and kyphosis. (C) The patient underwent L2 spondylectomy and fusion with a height-adjustable vertebral body for lumbar

reconstruction. (D) Plain radiograph obtained 11 months after surgery showing restoration of vertebral height and ideal correction of the kyphosis. (E) MRI confirmed the absence of tumor recurrence. (F) Computed tomography scan showing no obvious cage migration or subsidence at the final follow-up examination.

Graillon et al.³² reported that subsidence occurred in 35% expandable cages postoperatively; however, no implant subsidence was observed in our study. The stability and deformity correction using our AHVB reconstruction technique were confirmed at the last follow-up observation. Radiographic analysis of the Cobb angle showed that the lumbar lordosis had been restored and that correction of the kyphosis deformity was well maintained.

Compared with titanium mesh cages and other metallic expandable cages, the AHVB has the advantage of a composition and structure analogous to those of natural bone. No additional autografts or allografts were required needed to fill the cage. The elastic modulus of the n-HA/PA66 is similar to that of natural bone and, thus, can avoid the stress shielding effect caused by some metallic implants, which can be beneficial in avoiding the occurrence of subsidence. The design of the 163° concave angle of the contact surface and the sufficient contact area play a role in transferring stress and reducing the stress concentration, thereby preventing the appearance of endplate microcracks.

The short mean follow-up period of 8 months and the limited case number were limitations of our study. Additional mechanical

tests with different height adjustments of this AHVB are required. Also, longer follow-up periods and greater numbers of patients are required to determine the incidence and severity of any late complications compared with other implants.

However, the AHVB appears safe and effective despite these limitations. These results are promising because the AHVB provided immediate stability and reduced the intra- and postoperative complications. We believe that the use of this AHVB in spinal tumor reconstruction will be worthwhile for the following reasons. First, the design process is reasonable, and the prosthesis is suitable for the thoracolumbar vertebral endplate anatomical structure. Second, placement for reconstruction is easier through a 1-stage posterior surgical approach. Third, the material used is comparable to that of human bones. Fourth, the height is adjustable. Finally, our AHVB is able to restore the anterior column height and correct the deformity.

CONCLUSION

Our results have shown that it is practical to design a novel AHVB with consideration of the morphology of the thoracolumbar

endplate. The design of the prosthesis can meet most needs of anatomical endplate fitting. The large contact area and height-adjustable design make it possible to maintain spinal stability and correct the deformity. It is an efficient and effective product

for reconstruction of height, lordosis, and alignment after tumor resection from the thoracic to lumbar spine. Our early results were promising, and long-term studies are needed to confirm our findings.

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