# **CLINICAL RESEARCH**

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Authors' Contribution:       BCE f i Teng Lu         Statuy Design A       BcD 2       Chao Liu         Bada Collection B       F i Badohui Yang B         Data Interpretation D       Jiantao Liu         Ausscript Preparation E       F i Badohui Yang B         Data Interpretation E       Dong Wang         CDr i Haopeng Li       AEG i Xijjing He         AEG i Xijing He, e-maik He_Xijing@126.com       This work was supported by the National Natural Science Foundation of China (81571209)         Background:       The aim of this study was to evaluate the clinical and radiological outcomes of the use of a new 3D-prin anatomy-adaptive titanium mesh cage (AA-TMC) for single-level anterior cervical corpectory and fusion (AI in patients with cervical spondylotic myelopathy (CSM) and ossification of the posterior longitudinal ligar (OPLL).         Material/Methods:       We retrospectively reviewed the records of 15 consecutive patients who underwent ACCF surgeries with AA-i implantation. The Japanese Orthopedic Association (IOA) scoring system, a visual analogue scale (VAS), mean interverterbara height (MIBH) of the surgical segments, and the surgical segment angle (SSA) were corded preoperatively, immediately after surgery (ROLOS), and 26.85±1.25 at the last follow-up visit (P<0.05). At the last follow-up vis	ng University
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# Background

For the surgical management of short-level cervical spondylotic myelopathy (CSM), an anterior approach is advocated due to its direct removal of the anterior compression and satisfactory clinical outcomes. Both anterior cervical discectomy and fusion (ACDF) and anterior cervical corpectomy and fusion (ACCF) can achieve sufficient decompression, restoration of intervertebral height, and reconstruction the cervical lordosis [1-3]. When the compression is limited to the disc level, ADCF is superior to ACCF due to its better reconstruction of cervical lordosis, shorter hospital stay, less blood loss, and fewer postoperative complications. However, when the anterior compression is expanded to the vertebral body level, such as in osteophyte and ossification of the posterior longitudinal ligament (OPLL), ACCF is more suitable than ACDF because it offers adequate visual exposure and can achieve sufficient decompression at the vertebral body level [1-3].

Many struts have been developed and used for the reconstruction of the vertebral body after corpectomy. Autografts, such as iliac crest grafts and fibula grafts, were first used for vertebral body reconstruction. The autograft has been regarded as the criterion standard among graft materials for decades due to its satisfactory bony fusion rate [4]. However, approximately 25% of donor site complications, such as blood loss, hematoma, infection, and donor site pain, may restrict its widespread use [5,6]. To address these complications, the allograft was developed and used as an alternative for vertebral body reconstruction. Although it avoids donor site complications, the use of allografts has been found to be associated with low fusion rates and high rates of graft collapse [7,8].

The use of a titanium mesh cage (TMC) filled with cancellous morselized bone was first introduced in 1986 [9]. Since then, TMC use has been widespread due to the advantages of a high bony fusion rate and the avoidance of donor site complications [3,9,10]. However, recent studies have observed a high rate of TMC subsidence during follow-up [11-18]. Furthermore, among patients who underwent ACCF, severe subsidence of TMC (>3 mm) has been observed in up to 30.8% of patients, which can lead to multiple related complications [12,15,16,18]. Due to severe TMC subsidence, the cervical curvature in some patients can significantly change, resulting in kyphosis [2,3]. The intervertebral foramen and the ligamentum flavum can shrink and bend again, inducing neck-shoulder pain and neurological deterioration [12,15]. TMC subsidence can also increase the stress load on the anterior plate and screws, which can cause severe internal fixation failures, such as screw breakage and plate extrusion [11,14,15,18-20]. Thus, it is imperative to take measures to prevent TMC subsidence to avoid the related complications and to achieve satisfactory clinical outcomes.



Figure 1. After trimming, sharp footprints exist on the end of the conventional TMC.

Several risk factors have been hypothesized to cause TMC subsidence. The first is osteoporosis because it reduces the endplate thickness and the bony quality of vertebrae, which facilitates the perforation of the TMC into the vertebral body [16,21]. The second risk factor is the use of incorrect surgical techniques during the corpectomy, including over-distraction and excessive endplate removal, which reduce the supporting strength of the adjacent endplates [19,21,22]. In addition to these factors, the inherent defects of the conventional TMC are important causes of subsidence. One such defect is that the conventional TMC must be manually trimmed to a suitable size to fit the intervertebral height. After the trimming, the footprints are typically sharp, and the contact area is relatively small (Figure 1), which results in substantial stress concentrations [12,15,17]. A second defect is that both ends of the TMC are flat and are thus not well matched to the anatomical characteristics of the adjacent endplates (Figure 2) [12,13,15,23]. This mismatching aggravates the stress concentrations and makes the TMC more likely to exhibit subsidence [23]. Therefore, the structure of the TMC should be rationally redesigned to decrease the incidence of subsidence.

Recently, we used a selective laser melting (SLM) 3D printing technique to create a new anatomy-adaptive titanium mesh cage (AA-TMC, China patent number: ZL 201520615823.5). Both ends are designed to accommodate the anatomical characteristics of the endplates. Moreover, the contact area of each end enlarges to further mitigate stress concentrations. The purpose of this study is to evaluate whether the new AA-TMC can prevent postoperative subsidence and achieve satisfactory clinical outcomes in single-level ACCF.

# **Material and Methods**

### **Description of the AA-TMC**

The fabrication workflow of the AA-TMC is divided into the following procedures. First, a 3D digital model of the AA-TMC



Figure 2. Mismatch between the ends of the conventional TMC and the adjacent endplates.

was designed by using Geomagic Studio 12 (Geomagic, USA) and imported into an SLM 3D printing machine (BLT-S300, Laser Manufacturing Engineering Research Center of State Key Laboratory of Solidification Technology, Xi'an, China). Next, titanium alloy powder (Ti6Al4V) was melted layer-by-layer in the BLT-S300 system to construct the AA-TMC. Then, the implant underwent annealing heat treatment to eliminate thermo-stress distortion. The support structures on the AA-TMC were then removed by means of wire-electrode cutting, and sandblasting was applied to remove surface impurities from the implant. A finished AA-TMC product was thus obtained (Figure 3). The AA-TMC has the following 6 notable features. First, the superior end of the AA-TMC has a fornix shape (Figure 3A, 3E). Second, the inferior end of the AA-TMC has an oblique shape with an angle of 13° (Figure 3A, 3E). Third, a supporting ring is constructed on each end of the AA-TMC (Figure 3B, 3C, 3F, 3G). Fourth, in the axial plane, the rear and the bilateral sides of the AA-TMC are relatively flat and heartshaped (Figure 3D, 3H). Fifth, 8 sizes of AA-TMC, with different heights and transversal and anteroposterior diameters, are available such that the surgeon can select the one most suitable for the patient: 23×12×12 mm (height, transversal and anteroposterior diameter), 25×12×12 mm, 27×12×12 mm, 29×12×12 mm, 23×14×14 mm, 25×14×14 mm, 27×14×14 mm, 29×14×14 mm. Sixth, the surface of AA-TMC is rough, as can be observed by electron microscopy (Figure 4).

## Patients

This retrospective case series study was approved by the institutional review board of the Second Affiliated Hospital of Xi'an Jiaotong University. The study was conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all of the subjects. From April 2015 to October 2015, 15 patients with cervical diseases underwent ACCF surgeries with AA-TMC implantation in our department. Preoperatively, all of the patients complained of neck pain, arm radiating pain, or limb dyskinesia. The outcomes of the physical examinations, MRIs, CTs, and X-rays were used for the diagnoses. Table 1 summarizes the patient demographics and disease characteristics. The patient sample included 7 males and 8 females. The average age was 56.1±10.8 (range: 38-80 years), and the average length of postoperative follow-up was 13.4±1.4 months (range: 12–16 months). Among these patients, 13 patients were diagnosed with CSM and 2 patients were diagnosed with OPLL. Two patients also had cervical kyphosis, and 1 patient had comorbid cervical kyphosis and previous cervical dislocation. Regarding the surgical level, C4 corpectomy was performed in 4 patients, and C5 corpectomy was performed in 9 patients, and the remaining 2 patients received C6 corpectomy.



Figure 3. (A-H) Images of the redesigned AA-TMC.

#### Surgical technique

Each patient was placed in the supine position, and the neck was kept slightly extended. The standard anterior right-sided approach was applied to expose the anterior cervical spine. After using X-ray imaging to identify the targeted vertebral body, the anterior longitudinal ligament was cut off, and a Caspar distractor was placed on the adjacent vertebral body to distract the surgical segment. Next, the discectomies, the corpectomy, and the excision of the posterior longitudinal ligament were performed in the surgical segment to achieve complete decompression. The cancellous bone from the excised vertebral body was used as autologous bone graft material. Using a high-speed drill and curettes, the cartilage on the endplate was carefully removed, and the cortical bone of the endplates was exposed. After that, the surgeons chose a suitably sized AA-TMC and filled it with cancellous morselized bone (Figure 5D). Then, the AA-TMC was inserted into the intervertebral space. Finally, the Caspar distractor was removed, and the anterior cervical plate and screws were placed to stabilize the surgical cervical segment. Postoperatively, all of the patients were asked to wear a cervical collar for 2 months.

#### The assessment of clinical and radiological outcomes

Clinical and radiological outcome data were collected preoperatively, immediately after surgeries, at 6 months after surgery, and at the last follow-up visit. The Japanese Orthopedic Association (JOA) scoring system was used to evaluate the functional neurologic status of the patients. The visual analogue scale (VAS) was used to assess arm and neck pain. Regarding the assessment of radiological outcomes, the surgical segmental angle (SSA) was recorded to assess the restoration of the cervical segmental alignment. The SSA was defined as the angle between the superior endplate of the cephalad adjacent vertebral body and the inferior endplate of the caudal adjacent vertebral body. The anterior and posterior intervertebral heights of the surgical segments were measured and used for calculating the mean intervertebral height (MIBH). The anterior intervertebral heights were defined as the distances between the anterior points of the inferior endplate of the cephalad adjacent vertebral body and the anterior points of the superior endplate of the caudal adjacent vertebral body. The posterior intervertebral heights were defined as the distances between the posterior points of the inferior endplate of the cephalad adjacent vertebral body and the posterior points of the superior endplate of the caudal adjacent vertebral body. An MIBH loss of more than 3 mm was classified as severe subsidence.



Figure 4. Electron microscope images of the AA-TMC surfaces.

The flexion and extension lateral radiographs were used to assess the bony fusion status. Solid fusion was defined as no movement between the adjacent endplates and the AA-TMC. The formation of mature bony trabeculae between the adjacent endplates and the AA-TMC was observed. If the fusion status was questionable, CT scans were performed for further clarification.

#### **Statistical analysis**

The quantitative data, including age, length of follow-up, the JOA score, the VAS score, the SSA, and MIBH, are presented as the mean  $\pm$  standard deviation. SPSS 18.0 (SPSS, Chicago, IL, USA) was used for the statistical analysis. The preoperative outcome, outcome immediately after surgery, and last follow-up outcome for the JOA score, VAS score, SSA, and MIBH were compared using univariate ANOVA tests. The Student-Newman-Keuls test was used for post hoc multiple comparisons. A P value of less than 0.05 was considered statistically significant.

# Results

After surgery, all of the patients were relieved from neck pain and neurological symptoms. Table 2 summarizes the clinical and radiological outcomes of the patients. The mean VAS of the patients was  $6.8\pm1.26$  preoperatively and significantly decreased to  $2.47\pm1.3$  postoperatively (P<0.05). At the final follow-up, the mean VAS had further decreased to  $1.67\pm1.18$ (P<0.05). The mean JOA score was  $10.47\pm2.07$  preoperatively and increased significantly to  $13.6\pm1.96$  postoperatively (P<0.05). At the final follow-up, the mean JOA score had further increased to  $14.9\pm1.39$  (P<0.05).

Regarding the radiological outcomes, no AA-TMC screw or plate breakage occurred and there was no obvious migration in the patients. All of the AA-TMCs were observed in the optimal positions at last follow-up. No revision surgeries were performed in any of the patients. At 6 months after ACCF surgery, the radiographs showed that solid fusion at the surgical level had been achieved in all patients. The mean MIBH was

Patient	Age (years)	Sex	Diseases Surgical level		Length of follow-up (months)
1	38	F	CSM	CSM C5	
2	62	F	CSM	C6	12
3	55	Μ	CSM C5		13
4	46	F	CSR+CK C4		14
5	69	F	CSM C4		13
6	59	Μ	CSM C5		15
7	63	F	CSM C5		13
8	59	Μ	CSM+OCD+CK C5		16
9	80	Μ	CSM C4		14
10	44	F	CSM	C6	14
11	52	Μ	CSM	C5	12
12	56	F	CSM C5		13
13	61	F	CSM C4		12
14	43	Μ	OPLL C5		12
15	54	Μ	OPLL C5		12
Mean ±SD	56.1±10.8				13.4±1.4

#### Table 1. Patient demographics and disease characteristics.

SD – standard deviation; M – male; F – female; CSR – cervical spondylotic radiculopathy; CSM – cervical spondylotic myelopathy; CK – cervical kyphosis; OCD – old cervical dislocation.

21.05±1.99 mm preoperatively. After surgery, it significantly increased by  $6.46\pm0.97$  mm to  $27.51\pm1.44$  (P<0.05). At the last follow-up, none of the AA-TMCs exhibited severe subsidence (>3 mm). The mean MIBH decreased by  $0.66\pm0.31$  mm to  $26.85\pm1.25$  mm (P<0.05). The mean SSA of the patients was  $6.66\pm7.08^{\circ}$  preoperatively. After surgery, it significantly increased by  $7.37\pm5.59^{\circ}$ , reaching  $14.03\pm2.3^{\circ}$  (P<0.05). Although the mean SSA had increased by  $1.07\pm1.02^{\circ}$  to  $15.09\pm2.1^{\circ}$  at the last follow-up, this change was not statistically significant (P >0.05). Figure 5 shows the preoperative, postoperative, and last follow-up radiological outcomes of an illustrative case.

## Discussion

In the present study, the clinical and radiological outcomes demonstrate that the application of the AA-TMC in ACCF can significantly relieve symptoms. Moreover, the AA-TMC can effectively maintain the intervertebral height and restore the cervical segmental curvature in the long term.

At present, a variety of surgical techniques have been used for the treatment of CSM, including ACDF, arthroplasty, ACCF, laminoplasty, and laminectomy with or without fusion [24,25]. However, the optimal surgical approach and technique for the treatment of multilevel CSM remains controversial. Anterior, posterior, and combined anterior and posterior surgical approaches for DCM have all been proposed and encouraged [25,26]. However, for patients with only 1- or 2-level CSM, most surgeons prefer an anterior approach because it can directly decompress the anterior compression, restore the intervertebral height, and reconstruct the cervical lordosis [1–3]. When the compression is not limited to the disc level, ACCF is a more suitable choice due to its adequate visual exposure and sufficient decompression at the vertebral body level (1–3).

Recently, the TMC has been widely used in ACCF. Although the application of TMC can avoid donor site complications and achieve satisfactory clinical outcomes, postoperative TMC subsidence and its related complications should not be overlooked [11–18]. Multiple studies have revealed high rates of TMC subsidence of up to 93.3% [12,15,16,18]. Slight subsidence may improve the fusion rate and cervical lordosis [13]. In addition, it may decrease the tensile strength of the spinal cord. A biomechanics study regarding the tensile loads to failure of the cervical spine has revealed that the mean failure load and



Figure 5. An illustrative case (patient 15). (A, B) MRI and CT images showing that the patient had OPLL. (C) The preoperative SSA and MIBH were 1.98° and 24.14 mm, respectively. (D) During the operation, a suitably sized AA-TMC was chosen and filled with cancellous morselized bone. (E) Lateral radiographs immediately after surgery showed that the MIBH increased to 27.49 mm and that the SSA was restored to 10.

Table 2	Summary	clinical	and	radiological	outcomes.
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Parameters (mean ±SD)	Preoperative	Postoperative	Last fellow-up
VAS	6.6±1.26 <sup>a,b</sup>	2.47±1.3 <sup>a,c</sup>	1.67±1.18 <sup>b,c</sup>
JOA score	10.47±2.07 <sup>a,b</sup>	13.6±1.96 <sup>a,c</sup>	14.9±1.39 <sup>b,c</sup>
мівн (мм)	21.05±1.99 <sup>a,b</sup>	27.51±1.44 <sup>a,c</sup>	26.85±1.25 <sup>b,c</sup>
SSA (°)	6.66±7.08 <sup>a,b</sup>	14.03±2.3ª	15.09±2.1 <sup>b</sup>

SD – standard deviation; VAS – visual analog scale; JOA – The Japanese Orthopedic Association; MIBH – mean interbody height; SSA – surgical segmental angle; <sup>a</sup> the P value of the comparison between the preoperative and postoperative groups is less than 0.05 (statistical significant); <sup>b</sup> the P value of the comparison between the preoperative and last fellow-up groups is less than 0.05 (statistical significant); <sup>c</sup> the P value of the comparison between the postoperative and last fellow-up groups is less than 0.05 (statistical significant); <sup>c</sup> the P value of the comparison between the postoperative and last fellow-up groups is less than 0.05 (statistical significant).

distance of the cervical spine are 3373 N and 27.1 mm, which has a higher resistance ability than does the spinal cord (278 N and 8.9 mm) [27]. When the distraction in the surgical segment is excessive, the spinal cord may suffer from considerable tensile strength, and neurologic injury may result. An appropriate amount of TMC subsidence may relieve this situation. However, if the TMC undergoes severe subsidence (>3 mm), severe complications may result, such as cervical kyphosis,

recurrence of neurological deterioration, and fixation failures, and lead to poor clinical results [12,15,16,18]. Thus, it is imperative to understand the causes of severe TMC subsidence and take measures to address this issue.

The excessive endplate removal during the operation is an important factor that influences the incidence of subsidence. Cheng et al. [28] reported that the mean compressive strength of the deconstructed endplate was significantly lower than that of an intact endplate. Lim et al. [22] found that the mean compressive yield load of the intact endplate was 634 N. When the endplate was partly removed, the mean compressive yield load decreased to 494 N. After the endplate was completely removed, the mean compressive yield load further decreased to 419 N. Thus, the cortical bone of the endplate should be carefully preserved to offer sufficient compressive strength to resist subsidence. Over-cleaning of the endplate should also be avoided to prevent TMC subsidence.

Compared with the conventional TMC, the AA-TMC has some advantages in preventing postoperative subsidence. First, both ends of the conventional TMC are flat. However, studies that assess the cervical endplate geometry have found that the superior endplate is oblique and that most of the inferior endplate is concave [15,23]. This mismatch between the ends of the conventional TMC and the endplates reduces the potential contact area (Figure 2), which results in high stress concentrations at the contact points [12,13,15]. In contrast, both ends of the AA-TMC are in accordance with the adjacent endplates [15,23], which greatly increases the contact area and creates a homogenous stress distribution. Second, to increase the contact area in ACCF, end caps have been added to conventional TMCs [12,29,30]. However, the clinical outcomes show that the subsidence rates remain high and that such capping does not effectively prevent subsidence [12,29,30] because the end caps are flat and are therefore not aligned with the endplates [12,13,15,23]. Thus, only the anterior and posterior rims of the end caps are in contact with the endplate, which does not effectively increase the contact area. In contrast, the rings at both ends of the AA-TMC are in close contact with the endplates, which can effectively increase the contact area with the endplates and evenly distribute the stress. Third, the conventional TMC is typically manually trimmed to a suitable size, which sharpens the footprints of the TMC (Figure 1) [12,15,17]. To address this disadvantage, AA-TMC models with different heights and widths have been designed and constructed. Surgeons do not need to trim the AA-TMC but can instead simply select a suitable size for implantation. This feature avoids the stress concentrations caused by the sharp footprints. Jang et al. [13] reported that most of the TMC subsidence occurs in the posterior part of the vertebral body and can increase the SSA, which contributes to restoring cervical lordosis. However, this restoration is at the expense of the intervertebral height and may result in subsidence-related complications [2,3,11,12,14,15,18–20]. In contrast, the oblique shape of the new AA-TMC and the ring at the inferior end can simultaneously ensure the restoration of cervical lordosis and the prevention of severe subsidence.

In addition to the AA-TMC, other cages whose ends are designed to be in close contact with the endplates have been used for cervical vertebral body replacement. Yang et al. [31] designed and constructed a new 3D-printed porous TMC and used it for cervical vertebra body reconstruction in a sheep model. Both ends featured large contact areas. Additionally, the implant was customized for each sheep, which ensured that both ends were in close contact with the endplates. As a result of these advantageous designs, all of the surgical segments achieved fusion, and no implant exhibited subsidence at the last follow-up visit [31]. Zhang et al. [32,33] used a new nanohydroxyapatite/polyamide 66 (n-HA/PA66) cage in ACCF. The n-HA/PA66 cage had a wide (nearly 3 mm) annular rim, and both ends were designed to align with the endplate. These advantageous elements contributed to a much lower subsidence rate compared with that achieved with conventional TMC [33]. Moreover, Yu et al. [18] recently fabricated a new type of TMC and incorporated it in ACCF. Because both ends were in line with the endplate and a ring was added to increase the contact area, the incidence of subsidence was also significantly suppressed relative to conventional TMC. All of these studies demonstrate that to effectively decrease the incidence of subsidence, both ends of the cage should not only feature large contact areas, but also be aligned with the endplate.

Regarding the structures of both ends, our AA-TMC is similar to the redesigned TMC that Yu et al. presented previously [18]. However, in the horizontal plane, the 2 TMCs are quite different. The AA-TMC is heart-shaped, whereas the TMC that Yu et al. developed is conventionally circular. We suggest that the heart-shaped design has some advantages over the circular design. First, when the diameter is the same, the crosssectional area of the heart shape is larger than that of the circle. Consequently, the heart-shaped TMC has a larger volume for bone grafting and a larger contact area with the endplates. Second, both sides of the AA-TMS are relatively flat and thus offer increased contact area with the remaining vertebral body. This feature is desirable for bony fusion. Third, multiple clinical studies have found that the superior-posterior part of the vertebral body is the most frequent position of subsidence [12,13,15]. This is because the TMC is often placed within the anterior two-thirds of the vertebral body such that the posterior part of the TMC is in the central portion of the vertebral body, which is the weakest region in the vertebral body [28,34,35]. In addition, the posterior part of the vertebral body is usually higher than the anterior part in the sagittal plane (an oblique shape, Figure 2) [13,15]. Thus, the posterior

part bears a greater stress load from the cephalad cervical. Compared with the cross-sectional area of the AA-TMC in the anterior part, that in the posterior part increases more significantly. This can produce increased contact with the central region of the vertebral body and thereby further suppress the stress concentrations in this region.

Another important factor that contributes to solid bony fusion is the rough surface of the AA-TMC formed by melting Ti6Al4V particles. Compared with a smooth titanium surface, a rough surface better accommodates cell adhesion [31,36]. Strong adhesion can result in the rapid settlement and faster differentiation of cells, which is beneficial for osseointegration [36–38].

There are some limitations to the present study. First, this was a retrospective study whose outcomes may have been influenced by biases. In addition, the results were not compared with a control series of patients receiving a conventional TMC

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when undergoing ACCF. Thus, long-term prospective and randomized controlled studies should be carried out to further evaluate the clinical application of AA-TMC.

# Conclusions

The application of AA-TMC in single-level ACCF can significantly relieve the symptoms of CSM and OPLL. The rational design of the AA-TMC can effectively restore the surgical segmental curvature, maintain the intervertebral height, and prevent postoperative subsidence-related complications.

#### **Competing interests**

The authors declare that they have no competing interests regarding the publication of this paper.

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