

Received: 2018.07.02
Accepted: 2018.09.18
Published: 2019.01.06

Effect of Dome-Shaped Titanium Mesh Cages on Cervical Endplate Under Cyclic Loading: An *In Vitro* Biomechanics Study

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Source of support: This work was supported by the Key R & D Project of Shaanxi Province (No. 2017ZDCXL-SF-01-05)

Background: This study aimed to verify the anti-subsidence ability of dome-shaped titanium mesh cage (TMC) used in anterior cervical corpectomy and fusion (ACCF).





Material/Methods: Thirty fresh human cervical vertebrae specimens were collected and randomly harvested into 2 groups: the traditional TMC group and the dome-shaped TMC group. The bone mineral density (BMD) of the specimens was recorded. Each group was biomechanically tested in axial compression with a cyclically loading range from 60 to 300 N at 0.5Hz for 10 000 cycles. The displacement data of the 2 groups were recorded every 10 cycles.

Results: There was no significant difference in bone mineral density between the 2 groups of cervical specimens. The traditional TMC group stabilized at 535 ± 35 cycles while the dome-shaped TMC group stabilized at 1203 ± 57 cycles, which showed that the rate of subsidence of the dome-shaped TMC group was significantly slower than that of the traditional TMC group ($p < 0.05$). After reaching stability, both groups had a more gradual and sustained growth. The peak displacement during fatigue testing was -2.064 ± 0.150 mm in the traditional TMC group and -0.934 ± 0.086 mm in the dome-shaped TMC group, which showed a significant difference ($p < 0.05$).

Conclusions: The dome-shaped TMC showed a smaller subsidence displacement and a gentler subsidence tendency following the same cyclic loading (compared to the traditional TMC). From a biomechanical point of view, the dome-shaped TMC has stronger anti-subsidence ability due to its unique structural design that closely matches the vertebral endplate.

MeSH Keywords: **Bone Density • Compressive Strength • Fatigue • Prosthesis Design • Spinal Fusion**

Full-text PDF: <https://www.medscimonit.com/abstract/index/idArt/911888>

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Background

The titanium mesh cage (TMC) is widely used for intervertebral reconstruction in anterior cervical corpectomy and fusion (ACCF) [1–5]. Because of its excellent decompression effect, high fusion rate, the ability to reconstruct the height of the cervical spine, and avoiding the need for a bone graft harvest and the complications at the donor site, ACCF with TMCs has been recognized as the criterion standard for the treatment of cervical spondylotic myelopathy and severe degenerative cervical disease.

However, the occurrence of several kinds of complications following ACCF has been observed by relevant reports [1–6]. TMC subsidence, defined as the loss of vertebral height due to the insertion of the TMC into the adjacent vertebral endplates, is one of the most common serious complications. Clinical outcomes have shown a high rate of up to 93.3% [3] of TMC subsidence following ACCF. Severe TMC subsidence, defined as the loss of vertebral height over 3 mm, has been reported to be as high as 19%, and can lead to multiple severe complications [1,3,6–9] such as neck pain, internal fixation displacement, titanium plate fracture, cervical kyphotic deformity, intervertebral foramen stenosis, and corresponding segmental neurological symptoms relapse, which may require a second surgery.

In recent years, the literature has reported that the matching degree of TMC and endplate of the vertebral body was considered to be an important factor affecting TMC subsidence [10–17]. Increasing TMC-endplate interface area, processing TMC sharp edges, and replacing the end ring of TMC with a 12° oblique angle on the bottom are effective measures to reduce TMC subsidence. Therefore, we designed a dome-shaped TMC to match the shape of the human cervical endplate, which can theoretically reduce TMC subsidence.

This study was designed to simulate the biomechanics of the TMC-endplate interface *in vitro* by cyclic fatigue loading, and to verify the anti-subsidence ability of dome-shaped TMC.

Material and Methods

Preparation for TMC models and underplate

All the TMC models and underplates were constructed using a selective laser melting 3D printing machine (BLT-S300, Bright Laser Technologies, Xi'an, China). The underplate is detachable and designed with an oblique angle of 12° on the top (Figure 1C). TMC models were divided into 2 groups (Figure 1A, 1B): (1) A dome-shaped TMC model with an oblique angle of 12° and spurs on the bottom, and a clamping piece on the top; and (2) A traditional TMC model with a clamping piece on the top.

Preparation for human cervical specimens

Eight human cervical specimens were harvested. We took 1 more segment on both sides of the specimens when harvesting (C2–T1) to preserve the integrity of the C3–C7 cervical body. X-ray examination was performed to exclude cervical spine deformity, severe degeneration, and obvious osteoporosis. Six fresh cervical specimens were finally obtained (mean age 35.7 years, range 27–43 years, 3 males and 3 females).

The 6 fresh cervical specimens were stored at –20°C [18] until fatigue testing to ensure their biomechanical properties. We sprayed 0.9% saline every 15 min to keep the specimen fresh during the preparation and fatigue testing. The specimens were defrosting at room temperature before fatigue testing. The muscle tissue around the vertebral body was removed. The vertebral bodies were dissected through the ligament and intervertebral disc. The intervertebral disc and cartilage were removed carefully with a curette to guarantee the integrity of the endplate. The pedicle of the vertebral arch was severed with a bone saw. The laminae, transverse processes, and spinous processes were removed, leaving only the C3–C7 vertebral bodies (N=30). The BMD of all the vertebral bodies were determined using dual energy X-ray absorptiometry (DEXA, Medix-90, Medilink, France). For all measurements, the vertebral bodies were positioned in a plastic container and surrounded by granular substances to simulate the soft tissues around the vertebral body [3,9,19].

Thirty vertebral bodies were randomly divided into 2 groups: the traditional TMC group and the dome-shaped TMC group (Table 1). Each vertebral body was fixed on a polymethyl methacrylate (PMM) base to provide a stable interface between the vertebral body and the underplate without damaging the structure of the vertebral body, in order to prevent the vertebral body from being unstable due to poor contact between the vertebral body and the underplate during the fatigue testing. We kept the superior endplate of each vertebral body parallel to the superior surface of the underplate to simulate the physiological cervical angle following ACCF surgery (Figure 1D).

Biomechanical testing

Uniaxial quasi-static compression testing was performed at the State Key Laboratory of Mechanical Structure Strength and Vibration (Xi'an Jiaotong University, Xi'an, China). All tests were performed using a servo hydraulic testing machine (858 Mini-Bionix Testing Machine, MTS Systems, Minneapolis, MN, USA). Each of the vertebral bodies was placed on the testing machine to be tested (Figure 2A). The position of the polymethyl methacrylate base was adjusted to ensure that the TMC models interacted with the first two-thirds of the endplate during the testing. The test procedure was designed to

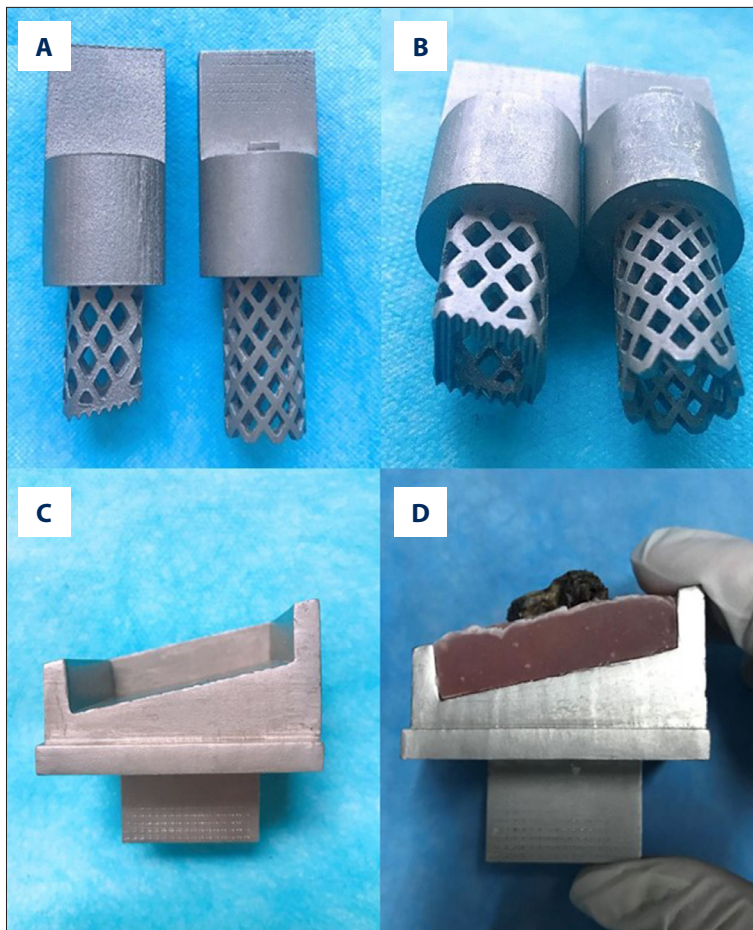


Figure 1. (A, B) The 2 groups of the TMC model. The one on the left is a dome-shaped TMC model with an oblique angle of 12° and spurs on the bottom. The one on the right is a traditional TMC model. Both models have a clamping piece on the top. (C) The underplate is detachable and designed with an oblique angle of 12° on the top. (D) The superior endplate of the cervical body is placed parallel to the sloping surface of the underplate.

simulate a reasonable physiological axial compression procedure following ACCF surgery. For the 2 groups, the superior endplate of each vertebral body was biomechanically tested. A range-controlled cyclic load with a sine wave type was applied on the superior endplate of each vertebral body by the testing machine. The range of the cyclic load was set to 60–300 N to simulate the load of the surgical segment of the cervical vertebral body following ACCF.

The protocol consisted of 2 phases. In the first, a persistent compressive loading was applied with a load of 60 N for 20 min to relieve the creep of fresh specimens after thawing. In the second phase, a sinusoidal compressive load in the range of 60–300 N was applied at 0.5 Hz for 10 000 cycles to simulate an early postoperative period and to promote endplate fatigue. During the second phase, displacement data were recorded at the maximum load every 10 cycles (Figure 2B).

Data and statistical analysis

All data were statistically analyzed using SPSS software and the results were expressed as mean \pm standard deviation. The independent-samples *t* test was used to compare the BMD,

peak displacement, and the number of cycles reaching stability in the 2 groups. The significance level was $p < 0.05$ for all tests.

Results

Bone mineral density

The average BMD for all vertebral bodies was 196.9 ± 13.3 mg/cm³ (range from 170.6 mg/cm³ to 218.8 mg/cm³). The average BMD was 193.5 ± 11.8 mg/cm³ (range from 178.1 mg/cm³ to 213.3 mg/cm³) in the traditional TMC group, and 200.3 ± 14.3 mg/cm³ (range from 177.50 mg/cm³ to 218.80 mg/cm³) in the dome-shaped TMC group. No significant difference was found in BMD between the 2 groups ($p < 0.05$).

Fatigue testing

The displacement data were plotted against the number of cycles (Figure 3). Both groups showed a rapid subsidence at the beginning of the testing. The dome-shaped TMC group stabilized at 1203 ± 57 cycles while the traditional TMC group stabilized at 535 ± 35 cycles (Figure 4), which showed a significant

Table 1. All vertebral bodies were divided into 2 groups: the traditional TMC group and the dome-shaped TMC group. The information about each vertebral body was recorded.

Group	Specimens					Subsidence peak displacement (mm)
	No.	Age (years)	Gender	Segment	BMD (mg/cm ³)	
Traditional TMC group	1	31	M	C3	194.4	-2.15
	2	31	M	C5	196.5	-1.98
	3	31	M	C6	200.9	-1.95
	4	40	M	C4	203.6	-1.97
	5	40	M	C5	213.3	-2.05
	6	43	M	C5	201.8	-2.12
	7	35	F	C4	170.6	-2.30
	8	35	F	C5	184.2	-2.03
	9	35	F	C6	178.1	-2.04
	10	38	F	C4	179.0	-2.43
	11	38	F	C7	185.3	-1.85
	12	27	F	C3	191.3	-2.12
	13	27	F	C5	202.7	-2.09
	14	27	F	C6	202.5	-1.88
	15	27	F	C7	197.7	-2.00
Dome-shaped TMC group	16	31	M	C4	208.2	-0.9
	17	31	M	C7	202.2	-0.87
	18	40	M	C3	214.8	-0.81
	19	40	M	C6	218.5	-0.88
	20	40	M	C7	218.8	-0.97
	21	43	M	C3	208.9	-1.11
	22	43	M	C4	214.1	-1.00
	23	43	M	C6	207.4	-0.99
	24	43	M	C7	203.0	-1.02
	25	35	F	C3	177.5	-0.99
	26	35	F	C7	188.9	-0.87
	27	38	F	C3	179.7	-0.96
	28	38	F	C5	186.1	-0.93
	29	38	F	C6	185.3	-0.93
	30	27	F	C4	190.7	-0.78

F – Female; M – Male; BMD – bone mineral density. No significant difference was found in the BMD between the 2 groups ($p>0.05$).

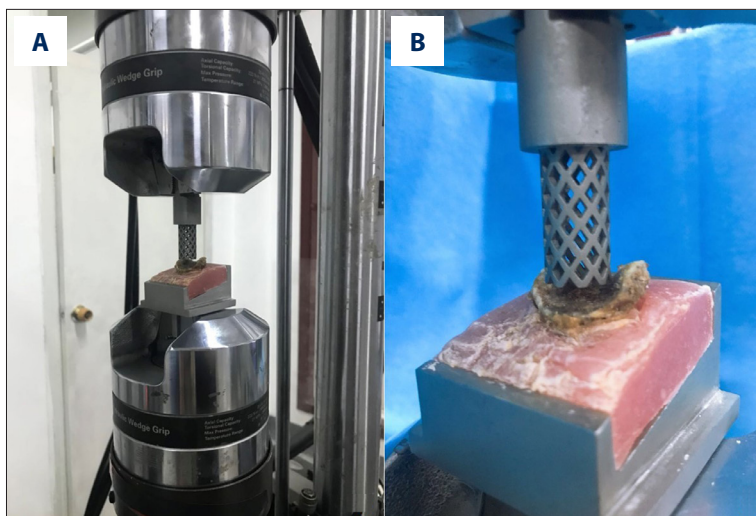


Figure 2. (A) TMC models were clamped to the pressurizing end of the testing machine, and each vertebral body fixed by polymethyl methacrylate base was put on the underplate, which was fixed to the fixed end of the testing machine. (B) A traditional TMC under testing. The cyclic compressive load force and frequency was controlled by a computer. The displacement data during fatigue testing were measured and recorded by an integrated displacement sensor.

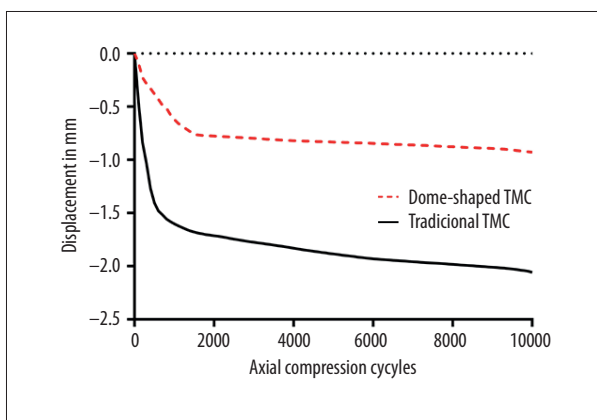


Figure 3. The average subsidence for the 2 groups at the maximum load. Greater than 50% of the subsidence occurred in the initial 2000 cycles.

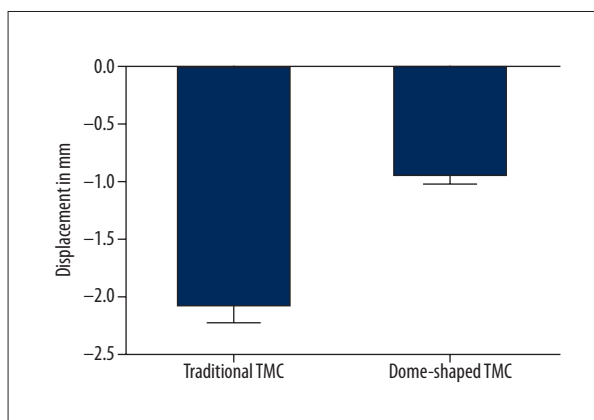


Figure 5. Comparison of the peak displacement between the 2 groups, which shows a significant difference ($p < 0.05$).

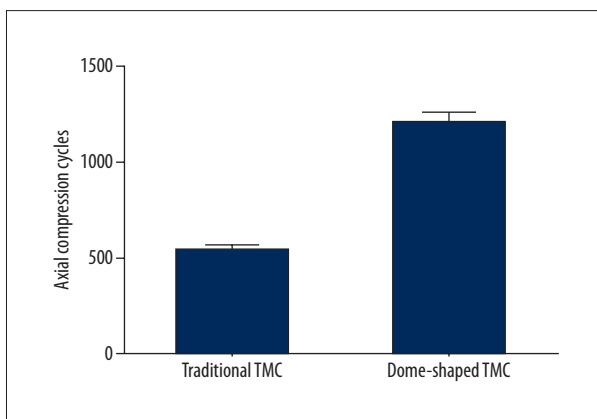


Figure 4. The comparison of the cycles reaching stability between the 2 groups, which shows a significant difference ($p < 0.05$).

difference ($p < 0.05$). The 2 groups showed a more gradual sustained growth after rapidly reaching stability. At the end of fatigue testing, the peak displacement was -0.934 ± 0.086 mm in the dome-shaped TMC group and -2.064 ± 0.150 mm in the traditional TMC group (Figure 5). The dome-shaped TMC group showed a significantly lower peak displacement compared with the traditional TMC group ($p < 0.05$).

Discussion

The treatment effect of ACCF using a TMC has been fully recognized, but it has been observed in recent years that variable degrees of subsidence usually occur in the early postoperative period following ACCF (in the first 6 weeks). This morphological cervical abnormality cannot be taken lightly although early mild subsidence usually does not cause any subjective symptoms or clinical abnormalities in most patients. Severe subsidence usually leads to neck pain, obvious loss of vertebral height, cervical kyphosis deformity, screws loose, or even

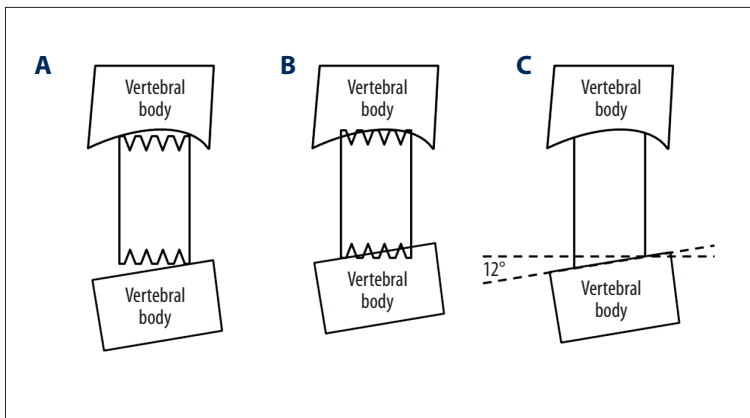


Figure 6. (A) The regular structure of traditional TMC does not match the shape of the vertebral endplate. (B) The using of Traditional TMC often cause subsidence after ACCF, most of which occurs in the lower vertebral body, while a few occur in the upper vertebral body. (C) The unique structures of dome-shaped TMC, including the dome-shape on the top and an oblique angle of 12° and spurs on the bottom, match the endplate of the vertebral body, which theoretically can reduce TMC subsidence.



Figure 7. The design of the dome-shaped TMC.

fractures. Serious complications such as recurrence of neurological symptoms may also occur if the height of the intervertebral foramen reduces. At the moderate or late stage (6 weeks to 6 months), the contact area of the TMC and cancellous bone increases because the TMC is inserted into the vertebral endplate, which leads to resistance caused by the vertebral body to the TMC. On the other hand, a strong connection has been formed between the vertebral body and the TMC. Therefore, the subsidence tends to be stable or no more subsidence occurs.

This biomechanical test was performed *in vitro* to evaluate the biomechanical effects of traditional TMCs and dome-shaped TMCs on the lower vertebral endplates before a strong connection has been formed between the vertebral body and TMC (in the first 6 weeks) [2,20]. The load on the cervical vertebral body is determined by factors such as head weight, neck muscle strength, and specific activity of the neck in the human body [13]. Neck flexion, extension, rotation, and lateral bending are all non-axial movements resulting in action points of force in different directions of motion applied on the vertebral body. In spite of this, the force on the endplate surface of the upper endplate of the lower vertebral body can be regarded as a cyclic load that changes periodically within a certain range. Therefore, the load on a cervical vertebral

body can be simulated by axial cyclic loading in a controlled range [10,13,21]. The cyclic loading protocol used in this experiment was designed to simulate the cervical loading during daily activities in the early postoperative period following ACCF, and to simulate the fatigue and damage accumulated in daily activities through 10 000 cycles in a limited time.

Substantial investigation of causes of TMC subsidence has yet to be done, including the age increase, loss of bone mass, removal of endplates, the shape of endplates, inappropriate placement of TMCs in surgery, and sharp edges caused by TMC trimming [9,10,16,22–24]. All of these can be classified into 3 factors: (1) Factors of TMC, (2) Condition of vertebral body, and (3) Factors of surgical operation.

The disadvantages of the traditional TMC are mainly reflected in 2 points [10,25]: (1) The regular structure of the 2 ends does not match the shape of the vertebral endplate (Figure 6), and (2) The sharp edges after trimming tend to cause stress concentration. The dome-shaped TMC developed by our research group is designed to fit the curved surface of the endplate, and a 12° oblique angle was designed to simulate human cervical at the same time (Figure 7). Lu Teng et al. [10] showed that the end ring structure and 12° oblique angle design can increase by 53.8% the maximum load the vertebral body can

withstand, which are also recommended to apply in TMC to reduce subsidence rate following ACCF. The spurs on the underplate were designed to increase the contact area between the underplate and the vertebral endplate surface, converting a point contact to a face contact, which can theoretically reduce the pressure on the endplate surface, eventually decreases the extent of subsidence, and forms a more stable connection. In addition, both sides of the new dome-shaped titanium cage are flat rather than curved and can be more closely attached to the vertebral bone on both sides during surgery, which theoretically leads to a stronger combination between the dome-shaped TMC and vertebral bodies during the early postoperative period. The holes on both sides are also more conducive to the bones growing into the dome-shaped TMC to form a stronger connection. The posterior surface is designed to have a convex curved surface to prevent the spinal cord from being pressed. From a biomechanical perspective, the displacement-cycles curve of the dome-shaped TMC showed a smaller subsidence displacement and a more gradual subsidence rate, which means a stronger anti-subsidence ability.

The TMC-endplate interface plays an important role in maintaining stability. Most of the postoperative subsidence occurs on the superior endplate of the lower vertebral body [1,2,20,26]. Therefore, the TMC-endplate interface on the bottom was selected as the study object in the present experiment. During the specimen preparation phase, the superior endplate of the vertebral body was completely retained after removing the intervertebral disc and cartilage tissue. The preparation of the endplate has a significant impact on the subsidence of the titanium cage [11,12,15]. If the cortical bone of the endplate is destroyed, the subsidence rate and the severity of subsidence will be significantly increased. Lim et al. [9] showed that the maximum load on a vertebral body specimen with a complete endplate was significantly greater than that of a vertebral body specimen with a damaged endplate. Furderer et al. [27] compared the tendencies of different designs of cervical implants in the biomechanical study of bovine spine specimens, showing that the implant would be able to withstand higher axial load if the bony structure of the endplate was preserved. The mechanical strength of the bone increases with the increase of BMD, so retaining the intact cortical bone can provide more biomechanical support for the implant. To take care of the prevention of subsidence and the strong combination of TMC and bones, the preparation of endplates in ACCF surgery should be balanced by 2 factors: (1) Keep the endplate interface as complete as possible to resist subsidence, and (2) Allow sufficient blood vessels and bone to grow inside the TMC for osseointegration. part of the endplate bone interface must be removed to facilitate osseointegration, but improper removal of the endplate will be more likely to cause subsidence [9,27]. Therefore, how to prepare the endplate interface is very important. Multisite or large-area removal of the endplate will

result in a significant decrease in the maximum load on the vertebral body, which is more likely to cause subsidence. We recommend removing the circular cortical bone in front of the center of the superior endplate of the vertebral body in ACCF surgery to facilitate vascular growing and osseointegration.

The range of cyclic loads during the experiment is equally important. Substantial biomechanical studies of the maximum compression load of the human cervical spine have been reported [22,28–31], which showed a minimum of 852N and a maximum of 3057N for the human cervical spine failure load, and it is easier to cause a vertebral fracture when the load exceeds 50% of the failed load [21,24,32]. To ensure that a safe cyclic load was applied on the cervical vertebral body to simulate the physiological conditions, the maximum cyclic load was set at 300 N. The minimum was considered to be only the weight of the head acting on the cervical vertebra. As a normal adult head weight is 5–6 kg, the minimum value of the cyclic load was set at 60 N. Limiting the cyclic load to within 60–300 N can effectively promote vertebral endplate fatigue, while avoiding damage to the vertebral body caused by excessive load.

In the early postoperative period, no strong connection is formed between the TMC and bone. Therefore, internal fixation of the anterior titanium plates and screws and external fixation of the cervical collar were used to maintain the normal positional relationship between the TMC and the vertebral body. In the late postoperative period, a tight and firm connection between the TMC and the bone has formed, so the subsidence no longer develops. At this time, the titanium plates and screws no longer play a supporting role, and the external fixation, such as the cervical collar, can also be removed. In the experimental process, neither external fixation nor internal fixation was used to maintain the normal relationship between the TMC and the vertebral body. So, degrees of subsidence will inevitably occur under the effect of the cyclic axial compressive load. This explains why degrees of subsidence occurred in all experimental specimens. In spite of this, the dome-shaped TMC has an obviously stronger anti-subsidence ability. We believe that the use of a dome-shaped TMC in ACCF and anterior titanium plates, screws, and cervical collars following ACCF can significantly reduce the occurrence of subsidence.

The literature and our own experiences with patients show that most of the subsidence occurs on the upper endplate surface of the lower vertebral body. Equipment limitations make it difficult to verify the effect of the dome-shaped top. Therefore, we paid more attention to the effect of the 12° oblique angle, which may be a defect. The anti-subsidence of the 12° oblique angle of the dome-shaped TMC was validated, and we think the effect of the dome-shaped cage will be confirmed in clinic use. Although the clinical significance of TMC subsidence is a

debatable point because mild subsidence may not produce obvious discomfort or clinical symptoms, the complications caused by severe subsidence cannot be ignored. In this study, we only performed an *in vitro* biomechanical experiment. However, it is unclear whether the same effect can be achieved in ACCF surgery. Several factor still can affect surgical outcome, such as the position the TMC was placed in. The clinical effect of the dome-shaped TMC needs to be further verified.

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Conclusions

The data show a smaller subsidence displacement and a gentler subsidence tendency with the dome-shaped TMC after the same cyclic loading compared to the traditional TMC. The dome-shaped TMC has stronger anti-subsidence ability due to its unique structural design, which closely matches the vertebral endplate from a biomechanical point of view.

Conflicts of interest

None.