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Original Article

Biomechanics characteristic of shape memory alloy expandable vertebrae stents (SMA-EVS) and kyphon baloon in spine surgery

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Abstract: The improved surgical techniques and the emerging new biomaterials have brought promising development for the treatment of spinal trauma and vertebralfracture. For the advantages that rigid stability, maintaining power lines, restore lordosis, reduce postoperative braking time, increase fusion rate, early rehabilitation, rigid internal fixation has become the standard non-surgical treatment for spinal disorders. In this study, we observed the preliminary mechanical properties of the independently developed Shape Memory Alloy Expandable Vertebrae Stent (SMA-EVS) and kyphon balloon for the spinal surgery.We conducted preliminary pressure tests on one three-petal SMA-EVS, one four-petal SMA-EVS and one five-petal SMA-EVS with the thickness of 1.0 mm, two five-petal SMA-EVS and one six-petal SMA-EVS with the thickness of 0.8 mm. Then, the change of stress-displacement curves were observed respectively and compared to that of kyphon balloon. The results showed that the stress-displacement curve of SMA-EVS was sigmoid while the curve of kyphon balloon was linear. For SMA-EVS, the tension of stent increased when pressure increased. When the stents were compressed by 7 mm to the maximum extent, the range of tension was 100-246N. All the tested SMA-EVS haven't broken when being compressed completely. When the compressed stents were put into warm water, they expanded completely without the loss of heights. In conclusion, the biomechanics characteristics of SMA-EVS were different from kyphon balloon. SMA-EVS could be the good candidate for initial restoration, expansion and support of the broken centrum because of its good initial tension and terminal elasticity.

Keywords: Vertebral fracture, kyphoplasty, kyphon balloon, shape memory alloy expandable vertebrae stent

Introduction

Painful spinal trauma and vertebral fracture can be a significant burden for patients and their family, which seriously impair physical function and quality of life [1]. Conservative treatments may lead to further mood or mental alterations while alleviate the patients' suffering symptom. In addition, non-surgical therapymay lead to deformity of the fractured vertebra body [2, 3]. A large prospective study proved that the mortality rate increases with the number of vertebrae fractured in vertebral body compression fractures patients [4]. The improved surgical techniques and the emerging new biomaterials have brought promising development for the treatment of spinal trauma and vertebral fracture. For the advantages that rigid stability, maintaining power lines, restore lordosis, reduce postoperative braking time, increase fusion rate, early rehabilitation, rigid internal fixation has become the standard non-surgical treatment for spinal disorders. However, a second surgical trauma for removing the fixation needles is needed after internal fixation, especially in posterior pedicle approach. This would cause damage to the spine along with loss of the vertebral height.

There are, however, new minimally invasive techniques that have been developed to help stabilize the fractured vertebra and, more importantly, decrease the pain and improve the function of individuals debilitated by painful

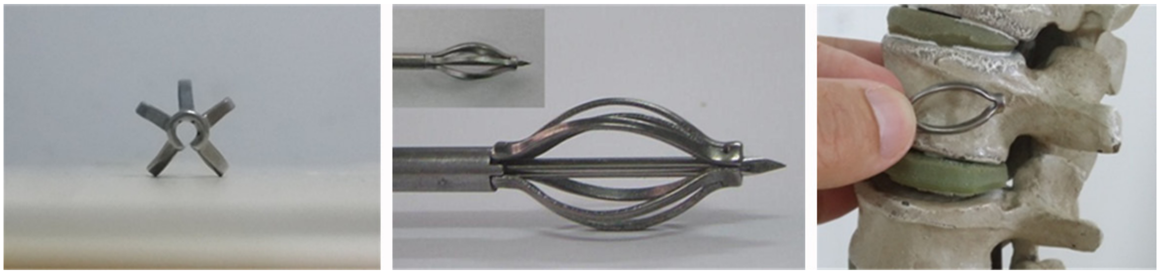

Figure 1. Samples of SMA-EVS.

Table 1. The characteristic of EVS stent (mm)

3 pieces		4 pieces		5 pieces		6 pieces	
Thickness	Width	Thickness	Width	Thickness	Width	Thickness	Width
-	-	0.8	1.95	0.80	1.75	0.80	1.60
1.0	2.5	1.0	1.95	1.0	1.75	1.0	1.60

vertebral fractures. As the development of-memory alloy stent biomaterial, EVS and Kyphon balloon-kyphoplasty are exciting new options for pain relief and improvement of function for the treatment of painful vertebral fractures [5, 6]. Kyphon balloon-kyphoplasty can help decrease pain and improve function, as well as has the potential to improve the long-term clinical results for the treatment of painful osteoporotic compression fractures [7, 8]. As to EVS, further researches are needed to understand its mechanisms and efficiency for the treatment of painful vertebral fractures.

Here, we designed a Memory Alloy Stent biomaterial (Shape Memory Alloy Expandable Vertebrae Stent, SMA-EVS), and observed the preliminary mechanical properties of the SMA-EVS and kyphon balloon for the spinal surgery *in vitro*.

Materials and methods

Materials

In total, six pieces of independently designed SMA-EVS are included in this study, including one three-petal EVS, one four-petal EVS and one five-petal EVS made of SMA with the thickness of 1.0 mm and two five-petal EVS and one six-petal EVS made of SMA with the thickness of 0.8 mm. The sample and characteristic of different EVS stents are shown in **Figure 1** and **Table 1** respectively. Due to the purpose of this study was to observe mechanics of EVS and its vertebral body expansion, the preliminary samples did not reach the industrial standardization. Therefore, electronic vernier calipers was used to measure the bracket height of the SMA-EVS (Shown in **Figure 2**).

Biomechanical test

The biomechanical test experiments were performed by orthopedic laboratory of Soochow University. The instrument for biomechanical test of SMA-EVS were shown in **Figure 3**, while the instrument for Kyphon Balloon were shown in **Figure 4**. For the shape of SMA-EVS under the condition of ice water is tubular, with the diameter of the tubular stents is about 5 mm. For the average diameter of these self-designed stents is about 12 mm, the maximal displacement of 7 mm was chosen when measuring the pressure and displacement curve.

Results

Characteristic of SMA-EVS

In this study, six pieces of independently designed SMA-EVS are tested. The thickness of plates and width of petals in different stents were summarized in **Table 1**. As shown in **Figure 2**, the bracket height of three-petal, four-petal and five-petal EVS made of SMA with the thickness of 1.0 mm is 12.88 mm, 11.57 mm and 12.80 mm respectively. Meanwhile, the bracket height of four-petal, five-petal and six-petal EVS with the thickness of 0.8 mm is 12.66 mm, 12.47 mm and 13.55 mm respectively.

Biomechanical test of SMA-EVS and kyphon balloon

All of the SMA-EVS are intact in the mechanical tests without outside intervention. After the completion of mechanical test, the stents

Figure 2. Measurement of EVS samples by electronic vernier calipers.

Figure 3. The biomechanical testing of EVS.

recovered to the former shape when placed in warm water. The pressure and displacement curve of SMA-EVS is roughly "S" shaped (**Figure 5**). One the other hand, the pressure and displacement curve of kyphon balloon was linear (**Figure 6**). For SMA-EVS, the tension of stent increased when pressure increased. When the stents were compressed by 7 mm to the maximum extent, the range of tension was 100-246 N. All the tested SMA-EVS haven't broken when being compressed completely. When the compressed stents were put into warm water, they expanded completely without the loss of heights. After perfusion of 2 ml of liquids intokyphon balloon, the balloon pressure gauge is 100 psi. At the last of biomechanical test, the maximum of displacement of balloon is 5 mm, while the pressure value is 123 N and the balloon pressure gauge is 150 psi (**Table 2**).

In order to further evaluate the use of SMA-EVS for treatment of painful vertebral fractures, we implanted the stents into vertebra *in vitro*. The stents gained expected expansion after the implantation which was confirmed by X-ray imaging tests. (**Figure 7**).

Discussion

Kyphon balloon technology is the most widely used invasive technology for treatment of spinal fractures. The principle of balloon technology is that implant the hydraulic balloon into the fracture vertebral body to get the vertebral body cavity through the hydraulic power compress to the vertebral cancellous bone, and then implant bone cement to fix the vertebral body. The purpose of vertebral body hydraulic expansion is to make a cavity to reduce leakage of bone cement [9, 10].

According to the principle of application of kyphon balloon technology, we designed a shape memory alloy expandable vertebrae stent. In this study, we confirmed that the SMA-EVS could get expansion after implantation into the fracture vertebral body, and make cavity. As for the mechanisms of expansion of EVS in fracture vertebral body, as well as the potential

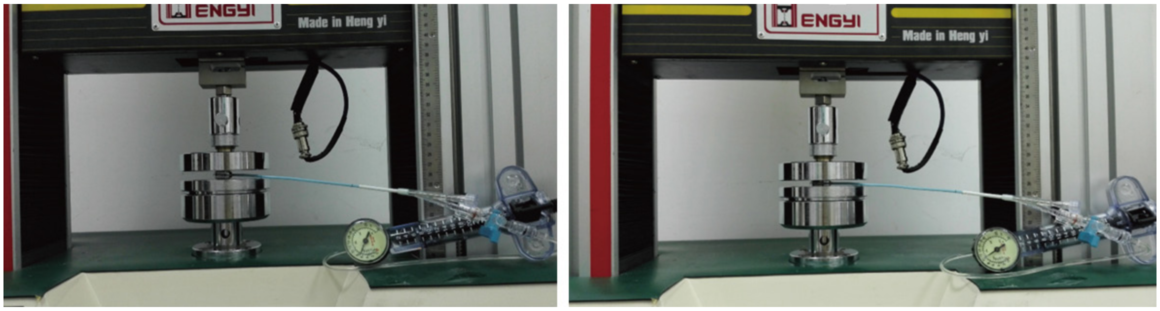

Figure 4. The hydraulic test of Kyphon balloon.

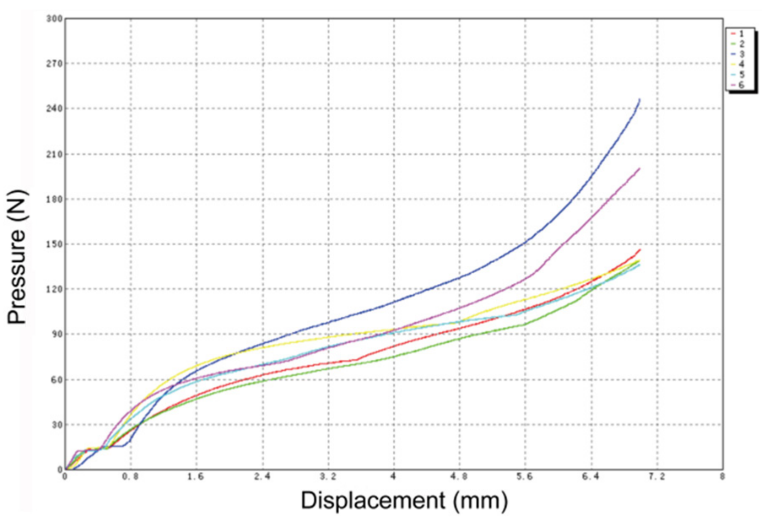

Figure 5. The pressure and displacement curve of EVS biomechanical testing.

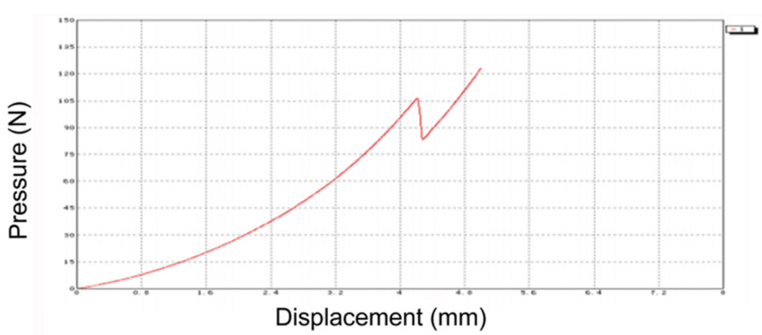

Figure 6. The pressure displacement curve of Kyphon balloon.

effects of stents on the cancellous bone, further comparison and researches are needed [5].

According to the technical parameters of Kyphon balloon and its practical application in osteoporotic vertebral fractures and newly vertebral fractures, we can learn that the working stress of balloon is 80-150 psi. The maximum working stress of Kyphon balloon is 400 psi, that might be equivalent to 2.72 Mpa. In clinical conditions, the expansion stress of Kyphon balloon for treatment of senile vertebral fracture is around 70~120 psi. According to literatures, the maximum of compressive strength that cancellous bone could bear is 4~10 MPa, which is equivalent to 30 MPa.

In this experiment, the stress value of balloon at work status is equal to the force that the hydraulic balloon extruding the vertebral cancellous bone, its working parameters have provided the inside parameters of the vertebral body fracture. How much power are needed when stents expand in the in vertebral cancellous bone and bicuspid valves contact with cancellous bone extrusion open? The working state of the balloon pressure would be the best reference.

This experiment preliminary found that the biomechanics limits of stents is between 100~246 N. In the balloon tests, compression displacement is 5 mm, the inside intensity of pressure in the balloon is 150 psi, and the pressure is 123 N. The balloon, a closed hydraulic capsule, interfaces vertebrae cancellous bone with a

Table 2. The Maximum pressure and displacement of EVS and Kyphon balloon

Sample number	Pressure (N)	Displacement (mm)
EVS-1	146.826	7.001
EVS-2	139.445	7.001
EVS-3	246.801	7.001
EVS-4	139.710	7.001
EVS-5	136.445	7.001
EVS-6	200.993	7.001
Kyphon balloon	123.247	5.001

spherical surface, extruding destructing vertebral cancellous bone by its own pressure, making a cavity in the vertebral body. EVS has a structure of arch valves and the interface between valves are a small arc.Stress per unit area will be greater than the spherical contact balloon (just theoretically analysis, without finite element observation). The smaller the area is, the greater the stress is. Thus, when the EVS vertebral cancellous bone implanted, expanding valve leaflets compresses the cancellous bone, leading to cancellous bone fracture in contact surface subsidence, following with the expansion of EVS. The local compressive stress of EVS ensure the vertebrae fracture squeeze the destructive force of cancellous bone, making its own expansion. Besides, it is the arc instead of EVS body that contact with the vertebral cancellous bone, and vertebral body, combing with the power of the cortical bone and fiber ring around, the EVS eventually chelate with vertebral cancellous bone, fixed in the vertebral cancellous bone. And the height designing of the EVS ensure that EVS disc would not be prominent in the vertebral body [2, 5, 11].

When we designed the stents, we considered the shape of vertebral body that the peripheral vertebra, named upper and lower end plate, is relatively compact bone. After the EVS was implanted into vertebral body, cancellous bone expansion should be gained, namely the design of "cutting". By pushing the cancellous bone to promote restoration of vertebral endplate, the cavity was made in the SMA-EVS at the same time. For the height of EVS was comparable to that of cancellous bone space, the over-expansion of stent or vertebral endplate open will not happen.

When we study the spine fracture, two questions should be considered: reset of the collapsed vertebral body and the recovery of spinal mechanics. When the patients keep horizontal, vertebral body is not affected by the gravity of the vertical direction with the exception of pulling tension of ligament around. Therefore, the collapsed vertebral bodies can be reset to some content due to the tension force of peripheral ligament. That is position have effects on reset of fracture vertebral body, while can't provide the vertical stress of the spine. Vertebroplasty and keratoplastyis to fill bone cement to stabilize the vertebral body and spine based on the position reset. The vertebral pedicle screws could fix the adjacent vertebral body, and it stabilize the whole spine through the nail bar system. On the other hand, the SMA-EVS maintained the vertebral body shape through its expansion in the vertebral body due to its activity. And then, different bone filler materials were chosen to achieve the vertebral body bone healing and spinal stability according to the age of different patients [9, 10].

The main principle of SMA-EVS system is that direct expansion of the fracture vertebral body to get initial repositioning, followed by perfusion different bone filler materials in different patients to achieve the restoration of vertebral body and the spine function. For example, absorbable bone glue mixture is suitable for young vertebral fracture adults, while common PMMA bone cement is suitable for patients with bone tumor and osteoporosis.

Based on the results of stents expansion in vertebral body, this study determined the preliminary biomechanics of the stents, which provide some theory for research of suitable biological filler material for treatment of vertebral fracture. Further comprehensive biomechanical evaluation is needed after improvement of the stent technology. How to choose the filler material to achieve the initial stability of the fracture vertebral body will be a new research focus.

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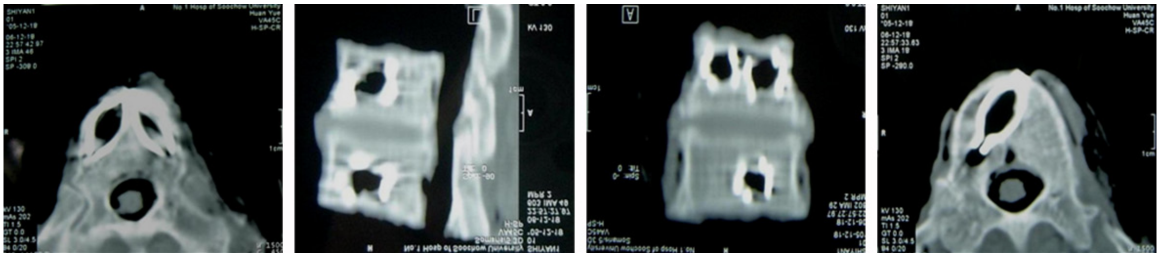

Figure 7. The Digital Orthophoto Map of vertebral body expansion of EVS.

Disclosure of conflict of interest

None.

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