Design and Manufacture of an Innovative Vertebral Dilator with Ni-Ti Shape Memory Alloy

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Abstract: The knitted gridding vertebral dilator with Ni-Ti shape memory alloy is designed which is to be used in the treatment of osteoporosis vertebral compressed fracture. The knitted gridding vertebral dilators with different parameters are knitted and their radial force and elastic modulus are tested; then the best knitted parameter is obtained. Taking into consideration the practical application of the vertebral dilator, the structure of both ends of the dilator is improved and an innovative vertebral dilator is obtained which can meet the clinical application needs.

1. Introduction

With the increase of the elderly population in China, many women over 60 and men over 75 suffer from osteoporosis. The use of drugs to treat vertebral compression fractures is not effective. Although vertebroplasty and balloon kyphoplasty can get better early clinical results, the former cannot solve the problem of vertebral height loss and kyphosis. [1,2] The latter is very expensive, which is difficult for domestic patients.

Because Ni-Ti shape memory alloy has good shape memory effect and super elasticity, high mechanical properties, and good biocompatibility[3,4], and its elastic modulus is close to human bones, it becomes an ideal biomedical materials which have been used in many aspects of the medical field, including various shapes of spreaders in the lumen of the trachea, esophagus, prostate, etc. [5,6,7] The trachea, esophagus, and prostate are all soft cavities composed of soft tissues. Ni-Ti memory alloy spreaders, which have been used in hard tissues such as the spinal vertebrae and have a spreading effect, have not been reported. Therefore, using the shape memory function and super elasticity of Ni-Ti shape memory alloy to develop a new vertebral expander used in clinical medicine is a new attempt. After the new vertebral expander is permanently implanted in the vertebral body, it acts as a stent for osteoporotic fracture vertebral bodies and is filled with a bone cement which can induce bone
growth. It can reduce re-fracture of the fractured vertebral body and adjacent vertebral bodies and increase the height of the anterior column of the vertebral body. It reaches the effect of balloon kyphoplasty, and its low price can make up for the lack of cost of balloon kyphoplasty.

2. Materials and Method

The Ni-Ti shape memory alloy used in this experiment is a drawn Ti-51.1at.% Ni alloy wire purchased from Beijing Youyanyijin Co., Ltd. After aging at 500℃ for 15-30 minutes, the phase transition point $A_f$ is about 32℃ and $M_f$ is about 25℃. Using the shape memory effect of the alloy with this phase transition temperature as a function of temperature, it can satisfy medical surgery requirements.[8]

The vertebral expander is prepared by Ni-Ti memory alloy wire mesh weaving process. For the specific weaving process, see the process description below.

The braided vertebral expander was used to measure the radial force on the Instron 5567 electronic universal material testing machine. The minimum loading capacity of the universal material testing machine is 500N, the loading speed is 1mm/min, and the room temperature (20℃) and heating state (Over 37℃). Place the dilator between two parallel plates, and use a pressure tester to gradually flatten the dilator. When the circular cross section of the dilator becomes oval, and the short axis of the ellipse is equal to the cross section of the dilator design at half the diameter, the load shown by the pressure testing machine is the radial support force of the expander. The unit of measurement of the support force is Newton (N).

Vertebral kyphoplasty is a minimally invasive operation with a wound diameter of no more than 5mm. Therefore, after the dilator is shaped, it must be able to be rolled into a tube with a diameter of less than 5mm. The measurement method of the minimum curl diameter in this experiment is as follows: After placing the vertebral dilator in 4℃ physiological saline for 2 to 3 minutes, after the Ni-Ti shape memory alloy wire is in the martensitic state and becomes softer, prepare a series of non-toxic plastic pipes with different inner diameters. The inner diameter of plastic pipes is 3 ~ 5mm. Extend the tested dilator to the maximum extent in the axial direction, and then try it into the plastic tube, plug it by hand or pull it by wire.

When the temperature rises from the softened state during cooling to a certain critical temperature, the expander returns to its original design shape. This temperature is called the recovery point of the expander. The measurement method of the dilation recovery point in this experiment is as follows: The dilator to be tested is placed in a thermostatic water tank containing 4℃ physiological saline, and pressure is applied to soften and deform it. The degree of deformation is controlled after the cross section of the dilator is deformed when its short axis length is approximately equal to half the diameter of the original cross section. Then heat the water, stir while heating the water, measure the temperature of the water with a thermometer, and observe the deformation of the expander at the same time, recording the temperature that the expander has fully recovered. Each dilator was measured three times and taken the arithmetic average value. This temperature was the recovery point of the dilator.

The measurement method of the maximum spread height is as follows: The dilator to be tested is placed in a thermostatic water tank containing 4℃ physiological saline, and pressure is applied to soften and deform the deformation. Set the maximum temperature when the thermostatic water tank is heated to 37℃, then heat the water in the thermostatic water tank, stir while heating, measure the water temperature with a thermometer, and observe the deformation of the expander. When the water temperature reached 37℃, the cross-sectional diameter of the expander at this time was measured.

3. Experimental results and discussion

3.1. Design and manufacture of grid-type vertebral dilator

The technical requirements of vertebral expanders used clinically in hospitals are as follows:

① In vitro molding: refers to the expansion device material that is implanted into the body after prefabrication in vitro, and expands in the body due to changes in temperature difference, so as to achieve the purpose of treating the vertebral compression fracture.
Original size: The working channel of the dilator is only 5mm in diameter (minimally invasive surgery), so the size of the vertebral dilator pre-formed outside the body cannot exceed 5mm.

Dilated size: The dilated size reaches 10 ~ 20mm.

Expansion force: The expansion force of the dilator formed in vitro reaches 100 ~ 150N and the elastic modulus is about 45MPa; the expansion force of the in vivo shaping reaches 170 ~ 200N and the elastic modulus is about 53MPa.

Shape requirements: both cylindrical and circular, but must be hollow, and the pores must not be too dense to avoid difficulty in filling other materials.

According to the medical clinical requirements, a dilator formed by mesh weaving was designed. According to the manufacturing process of woven mesh type vertebral expander, 13 kinds of Ni-Ti memory alloy wire mesh type vertebral expander with different diameters, different warps, different weaving heads, and different pitches are prepared. As follows:

(1) Weaving a woven mesh-type vertebral expander with a thread diameter of 0.3mm and a thread diameter of 6mm, a pitch of 3mm, and a cross-sectional diameter of 15mm and 20mm;

(2) Braided mesh-shaped vertebral body expansion with 0.5-mm Ni-Ti memory alloy wire with thread heads of 6, 8, 10, 3 mm, 5 mm, and 6 mm pitch and 20 mm cross-section diameter One for each device, a total of nine;

(3) Weaving woven mesh-type vertebral dilators with a thread diameter of 0.5mm and a thread diameter of 6mm, a pitch of 3mm, and a cross-sectional diameter of 13mm and 16mm.

Figures 1 and 2 show the macro morphology of two vertebral expanders with different specifications as examples of woven mesh-type vertebral expanders.

3.2. Mechanical properties of grid-type vertebral expander

The design of Ni-Ti memory alloy wire braided mesh vertebral expander is based on the design of spring.

The axial support force of the dilator is equivalent to the spring force of the spring. The elastic force of the spring is related to the characteristic parameters of the material and the geometric size of the spring. The characteristic parameters of the material include the maximum shear stress \( \tau_{\text{max}} \), the shear modulus \( G \), and the shear strain \( \gamma \); the geometric dimensions of the spring include the coil cross-sectional diameter \( D \), the wire diameter \( d \), and the effective coil turns \( N \). The spring output load \( P \) is affected by the cross-sectional diameter \( D \) and wire diameter \( d \) of the coil, and the output displacement \( \delta \) is affected by the number of effective coil turns \( N \). Have equations:

\[
P = \frac{\delta G d^4}{8D^3 N}
\]

\[
G = \frac{\tau}{\gamma}
\]

It can be known from Eq.1 that under the condition that the displacement and the number of effective coil turns are the same, the load on the spring is proportional to the wire diameter and inversely proportional to the average diameter of the spring. It can be known from this that the smaller
the cross-sectional diameter of the dilator, the greater the axial supporting force, and the smaller the wire diameter, the smaller the axial supporting force.

The factors that affect the radial support force of the grid-type vertebral expander are mainly two aspects of material factor and geometric factor. The material factors include the elastic modulus $E$, the shear modulus $G$, and the wire diameter $d$, and the geometric factors include the original diameter $D_0$, the original length $L$, the restraint diameter $D$, and the braided half-angle $\theta$ (direction and expansion of the wire) Angle between the axial direction of the actuator) and so on. The calculation of the radial support force of the grid-type vertebral expander is shown in the equation (3):

$$P = \frac{NGd^4}{2\pi^2 D_0^4} \cdot \frac{(\theta_0 - \theta) \sin^2 \theta_0}{\cos^2 \theta \sin \theta} + \frac{NGd^4}{2\pi^2 D_0^4} \cdot \frac{(\theta_0 - \theta) \sin^2 \theta_0}{\cos^2 \theta \sin \theta} + \frac{3Ed^4 \sin^2 \theta_0 \cos \theta_0 (tg \theta_0 - tg \theta)}{16L^2 D_0^2 \sin \theta \cos^3 \theta}$$  \hspace{1cm} (3)

According to Eq.3, the radial support force of the braided mesh-type vertebral expander is proportional to its elastic modulus. The larger the elastic modulus, the greater the radial support force; the larger the wire diameter, the mesh-shaped vertebral body. The greater the radial support force of the dilator, the greater the radial support force of the dilator. Under the condition that the cross-sectional diameter of the mesh-type vertebral expander and the wire parameters are constant, the braided half-angle $\theta_0$ of the expander is another important factor that affects the radial support force of the expander. As $\theta_0$ increases, the radial support force also increases significantly. The larger the weaving half angle $\theta_0$ is, the smaller the radial support force of the dilator. From this we can see that the pitch decreases and the radial support force of the braided mesh-type vertebral expander also increases. The significant effect of the pitch on the radial support force allows us to use this structural factor to adjust the radial support force of the expander in actual design. But unfortunately, while reducing the pitch, the axial ductility of the dilator increases, which increases the difficulty of designing the delivery device and brings difficulties to the accurate positioning of the dilator in clinical applications. Therefore, when designing the structure of the expander, the effects of these two aspects should be considered comprehensively.

Considering that the temperature of the vertebral dilator after it is implanted in the human body is the human body temperature (37 °C) and is in its parent phase state to ensure that it has super elasticity, we have heated some of the expanders with better mechanical properties in Table 1. The heating method is to fix the hair dryer next to the mechanical testing machine, and then continue to heat the dilator sample before loading measurement. The measurement results of the mechanical properties of the expander under heating are shown in Table 1.

Table 1 also shows the measurement results of the minimum crimp diameter, the maximum spread height and the recovery point.

| Thread heads | Wire diameter (mm) | Pitch (mm) | Cross-section diameter (mm) | Minimum crimp diameter (mm) | Maximum spread height (mm) | Recovery point (°C) | Radial support force (N) | Elastic Modulus (MPa) |
|--------------|-------------------|------------|-----------------------------|----------------------------|---------------------------|----------------------|------------------------|-----------------------|
| Room temperature | Heated | Room temperature | Heated |
| 6 | 0.3 | 3 | 14.82 | 3 | 14.79 | 26.8 | 13.58 | — | 2.67 | — |
| 6 | 0.3 | 3 | 19.46 | 3 | 18.98 | 32.3 | 7.52 | — | 1.05 | — |
| 6 | 0.5 | 3 | 13.68 | 5 | 13.60 | 32.1 | 67.80 | 136.89 | 26.14 | — | 46.23 |
| 6 | 0.5 | 3 | 16.48 | 5 | 16.32 | 27.9 | 36.67 | 84.02 | 16.46 | — | 5.41 |
| 6 | 0.5 | 3 | 20.02 | 5 | 20.00 | 28.3 | 44.60 | 88.74 | 8.12 | 14.47 |
| 6 | 0.5 | 5 | 19.22 | 5 | 19.20 | 27.6 | 23.22 | 43.04 | 3.72 | — | — |
| 6 | 0.5 | 6 | 21.40 | 5 | 21.36 | 24.6 | 15.20 | — | 3.62 | — |
| 8 | 0.5 | 3 | 21.64 | 5 | 21.48 | 27.7 | 47.67 | 66.20 | 10.21 | 17.47 |
| 8 | 0.5 | 5 | 20.30 | 5 | 20.20 | 29.6 | 24.17 | — | 2.92 | — |
| 8 | 0.5 | 6 | 20.44 | 5 | 20.44 | 30.1 | 20.51 | — | 3.05 | — |
| 10 | 0.5 | 3 | 21.44 | 5 | 21.42 | 29.1 | 47.43 | 86.91 | 9.00 | 13.91 |
| 10 | 0.5 | 5 | 20.78 | 5 | 20.68 | 30.7 | 31.39 | — | 3.62 | — |
| 10 | 0.5 | 6 | 21.60 | 5 | 21.54 | 31.2 | 23.08 | — | 3.14 | — |
There are four points can be seen from Table 1:

1. When the number of screw heads, wire diameter and cross-sectional diameter are the same, the smaller the pitch, the greater the radial support force of the expander, and the greater its elastic modulus.

2. When the number of thread heads, wire diameter and pitch are the same, the smaller the cross-sectional diameter, the greater the radial support force of the expander and the greater its elastic modulus.

3. When the number of screw heads, pitch and cross-sectional diameter are the same, the larger the wire diameter, the greater the radial support force of the expander, and the greater its elastic modulus.

4. The radial support force and elastic modulus of the expander measured during heating have significantly increased compared with that at room temperature, indicating that the support force of the expander in the parent phase is much higher than that in the martensite state support.

It can also be seen from Table 1 that the recovery temperatures of the dilators are all less than 37°C, and the Ni-Ti memory alloy wire can be in a complete parent phase state after being implanted in the human body. At 37°C, the expansion height of the dilator is relatively large, and it can almost reach the original height (original diameter). The minimum curl diameter of the 13 dilators is less than 5mm, which can meet the requirements of 5mm for the minimally invasive surgical working channel.

It can be seen from Table 1 that the largest supporting force is the expander with 6 thread heads, wire diameter of 0.5mm, pitch of 3mm, and cross-sectional diameter of 13mm. Its radial supporting force in the parent phase state is 136.89N, and the elastic modulus is 46.23MPa. This data can already meet the requirements of in vitro forming.

Considering the operability of minimally invasive surgery in the actual clinical application, we have made the following improvements to the design of the dilator: In order to allow the woven mesh vertebral expander to be placed in the vertebral body under contraction and retract, we add a small ring with internal thread to each end of the braided mesh vertebral dilator. At low temperature, the braided mesh-type vertebral expander with a small ring at both ends can be pulled into a sleeve with an inner diameter of 5mm through the auxiliary device of the vertebral expander. Inside the barrel, the entire releasing process is shown in Figure 3. When the dilator is heated to 37°C, it can completely return to its original shape. The entire contraction and expansion process of the vertebral expander can meet the clinical requirements of minimally invasive surgery.

4. Conclusion

1. The factors that affect the radial support force of the braided mesh vertebral expander are mainly material factors and geometric factors. Therefore, when designing the structure of the expander, the influence of various parameters of the expander should be considered comprehensively, and the appropriate pitch, number of threads, wire diameter, and diameter of the expander should be selected to meet the requirements of the support force and elastic modulus of the expander.

2. The knitting parameters of the expander with better mechanical properties are as follows: the number of thread heads 6, the wire diameter is 0.5mm, the pitch is 3mm, and the cross-sectional diameter is 13mm. Its radial support force in the parent phase state can reach 136.89N, elasticity modulus is 46.23MPa, which has great practical potential and can be used as a basic parameter for subsequent improvement of knitting parameters.

3. A small ring with an internal thread is added to each end of the mesh-type vertebral expander, so that the expander can be pulled into a sleeve with an inner diameter of 5 mm after being rolled and
shrunk at a low temperature. It is smoothly pushed into the vertebral body through the pedicle, and can be opened by itself at the normal human body temperature of 37°C, and restored to the original designed shape, and can be pulled out at any time when necessary, fully satisfying the minimally invasive vertebral expander clinical requirements for surgery.

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