

## Mechanical Performance of Cup-spherical-shaped and Straight Form Braided Esophageal Stent

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### Abstract

*This article introduces the application background and research overview of esophageal stent. The finite element models of two different forms of braided esophageal stent, such as cup-spherical-shaped and straight shaped, are created. Based on the configuration of material model selection and boundary condition, the stress and axial elongation of the stent with different wire numbers, different wire diameters and different leads are compared. The analysis results show that the maximum stress increases with the increase of the wire diameter and head, but decreases with the increase of the lead in straight stent while the maximal stress has a positive relationship with the wire diameter in cup-spherical-shaped stent. In the case the other parameters are the same, it is shown that the cup-spherical-shaped stent has the minimal stress when the crown number is 24. Meanwhile, the analysis results show that the lead has a great impact on the axial elongation of braided stent. In the case all parameters are the same, the axial elongation of cup-spherical-shaped stent is less than that of straight stent, which conclusively proves that the performance of cup-spherical-shaped stent is superior to that of the straight stent.*

**Keywords:** braided esophageal stent, the cup-spherical-shaped form stent, the straight form stent, finite element method

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### 1. Introduction

Medical stents following the catheter interventional techniques are widely used in clinical high-tech biomedical engineering technology, generally, divided into endovascular stent and non-vascular stent. The stent products have thin tubular structures, and they can be placed in the lumen in order to recover the function of the diseased lumen by providing mechanical supports [1]. The main application of the stent in the esophagus is to relieve esophageal strictures and plug up the fistula. The majority of the metal materials used includes nitinol wire, medical stainless steel wire, stainless steel alloy wire, etc.; the generally-used structures are screw type, mesh type, "Z" type, etc. [2]. Braided esophageal stents have a lot of features because of their special woven pattern. For example, braided esophageal stent structure can suit the shape of the human lumen and bending deformation. The stents are made from a single wire weaving; the nitinol wires of the final products still maintain the original surface condition and uniform cross section of wire size, and are less prone to fatigue fracture. Coated stent can inhibit tumor growth and seal fistula. Figure 1 shows the braided esophageal stent consisted of cross-cutting spiral wire with clockwise and counterclockwise directions, which can be divided into straight form, cup-spherical-shaped form, double spherical-shaped form, double horn-shaped form and other forms.

The finite element method is widely used in a variety of areas: machining, automotive, biomedical, electronic product etc. The finite element method was applied to different fields in the literature [3-5]. Many scholars at home and abroad used the finite element method and experimental method to study the mechanical performance of the endovascular stent structure. But the research on non-vascular stent such as esophageal stent, cystic stent, etc. is relatively few. Wei Wu et al. [6] studied the interaction between the stent expansion process and the cavity by the finite element method, built the models of bending cavity and linear cavity. The mechanical performances of the two models were studied and compared. By the comparison

result, the cavity can be straightened by stent in the curved cavity model that is very obvious at both ends of the stent. W. Kajzer et al. [7] analyzed the stress and strain of esophageal stent and esophageal cavity when the esophageal stent (Z-type) and esophagus were regarded as a whole system, and provided a reference for the design and optimization of the esophageal stent. Axerlad et al. [8] thought that the spiral coil shape esophageal stents that were easy to be removed and to prevent tumor ingrowth had advantages than other braided esophageal stents. Ni Xiaoyu et al. [9-10] calculated the fatigue life of the esophageal stent based on the finite element simulation method. The analysis results showed that the more the crown number was, the longer the fatigue life of the stent was. Ni Xiaoyu et al. [11] analyzed the relationship between the structural parameters and the radial stiffness of the braided stent to understand the stress distribution law of the wires inside braided stent. WangGuo et al. [12] calculated the radial force of the esophageal stent based on the finite element simulation method, and obtained the parameter ranges for excellent radial force of esophagus stent.

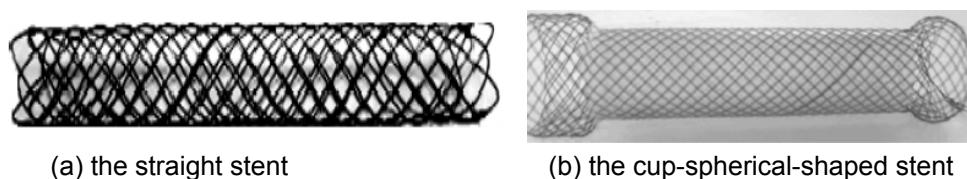


Figure 1. The Braided Esophageal Stent

Medical units at home and abroad have a growing demand for esophageal stent but the design of present stents cannot fully meet the clinical needs, and there are many complications such as chest pain, perforation, bleeding, stent migration, restenosis and so on [13-14]. Thereby it is very significant to improve the mechanical properties of braided esophageal stent to meet the clinical requirements through theoretical research, experimental method and computer simulation.

In this paper, according to the clinical applications and working conditions of the braided esophageal stent, two typical structures: the straight form stent (Figure 1(a)) and the cup-spherical-shaped form stent (Figure 1(b)) are taken as the object of analysis. By comparing the stress results of these two different stents in the same deformation, the structural performances of the two different stents can be analyzed under different parameters and the structure of the esophageal stent can be optimized.

## 2. Materials and methods

### 2.1 Geometric Model

The structure of the double helix braided esophageal stent is chosen in this paper. The entity models of two different forms of the stent are built; one is cup-spherical-shaped form, another is straight form. The deformation and stress of wires in their work process are analyzed.

The diameter and the total length of the straight stent are 20mm and 80mm respectively. The entity model is shown in Figure 1(a). The diameter in the middle of the cup-spherical-shaped form stent is 20mm, too, and the total length is 80mm. But its structure is different on both ends. The diameter of cup head is 28mm and the length of cup head end is 15mm; the diameter of spherical head is 26mm and the length of spherical head end is 10mm. The entity model is shown in Figure 1(b). The wire diameter of stent is set to  $d$ ; the head of stent is set to  $n$  and the lead of stent is set to  $s$ .

Due to the geometric parameters of the braided esophageal stent including the head of stent, the lead of stent, the wire diameter and so on, the parametric models of the stents can be built using the APDL (ANSYS Parameter Design Language). The parametric model can facilitate the optimization of stent and the simulation of the mechanical properties for series products. Mesh structure of the stent is composed of overlapping metal wires. When the stent is under load, the relative rotation will occur between the contact points of crossing-wires but no slippage or dislocation. To establish the finite element model of stent, the three-dimensional beam element is selected to simulate the wire structure and the contact points between the crossing

wires are taken as the beam element nodes. The finite element models of the straight form stent and the cup-spherical-shaped form stent are shown in Figure 2.

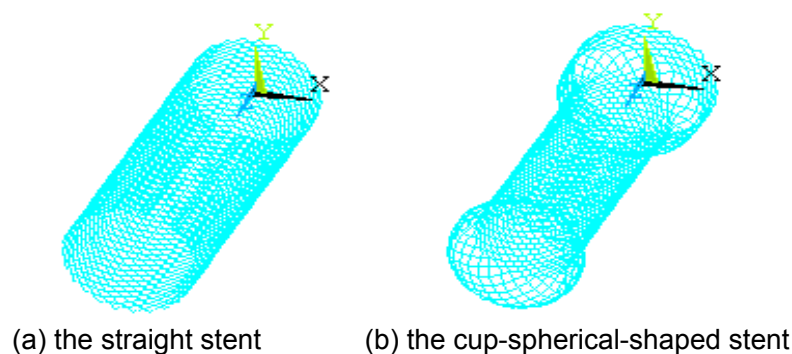


Figure 2. Finite Element Model of Braided Esophageal Stent

## 2.2. Material Properties

The material studied of the braided esophageal stent is nitinol, containing 55% nickel and 45% titanium. It has shape memory effect and superelasticity. Nitinol is widely applied in medical for its good biocompatibility, radiopacity and no impact in nuclear magnetic resonance. The super-elastic under body temperature provides the alloy stent by a good longitudinal flexibility, thus easily being bonded well with the soft complex lumen. Because of its excellent capability of expansion, it can provide a radical force to recover the function of diseased lumen.

The mechanical properties of the material are shown in Table 1.

Table 1. Material Parameters of Ni-Ti alloy [15]

Melting point/ $^{\circ}\text{C}$	1300
Density/( $\text{g}/\text{cm}^3$ )	6.45
Young's modulus/GPa	83
Yield strength /MPa	195~690
Tensile strength/MPa	895
Poisson ratio	0.33
Elongation /%	25~50

## 2.3. Boundary Conditions Setting

In expansion and service stages of stents, given to the interaction of esophageal stents and the esophageal wall, the stents will be affected by esophageal motility, the pressure of esophageal wall, the pressure of esophageal cancer, the thrust of food and other composite loads. This article, which focuses on the comparison of the maximum stress and axial elongation of the straight form stent and the cup-spherical-shaped form stent, therefore will not discuss about esophageal peristalsis wave and the thrust of the food. The stent boundary conditions are established in the cylindrical coordinates, which sets the axial direction of the stent as Z-direction, sets the radial direction of the stent as X- direction, sets the circumferential direction of the stent as Y-direction, as shown in Figure 2.

1) Z-direction constraints. Based on the clinical selection standards and situations, stents in human's lumen are compressed 10% to 15%. That is, the stent with 20mm diameter will be compressed to a diameter of 18 to 17mm in the human body. Because the radial size of stent is greater than the radial size of the esophagus, the stent will not move longitudinally or rotate around the z-axis after its implantation into the esophagus. The z degree of freedom of one end of stent is constrained and the z degree of freedom of the other end of stent is free. The stent can stretch axially under load.

2) Y-direction constraints. To prevent stents from axial rotating, the y degrees of freedom of all nodes are constrained.

3) X-direction constraints. The x degree of freedom of the stent is free, so the stent can distort in z- and x-axis. The article supposes the stents in the lumen is compressed 15% in longitude.

The stent material is super-elastic material and the stress-strain relation of the material has a high non-linear. Newton-Raphson iterative method is used in the nonlinearly solving process, with the large deformation options opening, reducing the load step, and enlarging the convergence criteria.

### 3. Results and Discussion

There are some complications after implantation of esophageal stents, such as pain, bleeding, esophageal perforation, migration slippage of stents, and restenosis and so on. Structural strength of the esophageal stent has an important impact on these complications. Because the strength and stiffness of the support structure mainly depend on the crown number, wire diameter and lead of the stent, it is necessary to evaluate and compare the stress of the stent in different sets of parameters.

In this paper, stress and axial elongation of straight stent and cup-spherical-shaped stent are analyzed and compared by parametric finite element analyses. The values of wire diameter, head and lead of the stent are based on the structural parameters from actual production, that wire diameter of the stent ( $d$ ) changes from 0.18mm to 0.24mm, the crown number ( $n$ ) varies from 22 to 28, and lead ( $s$ ) changes from 55mm to 70mm. In this paper, only one parameter of the stent is changed in every analysis.

Figure 3 shows the deformation of two types of braided stents.

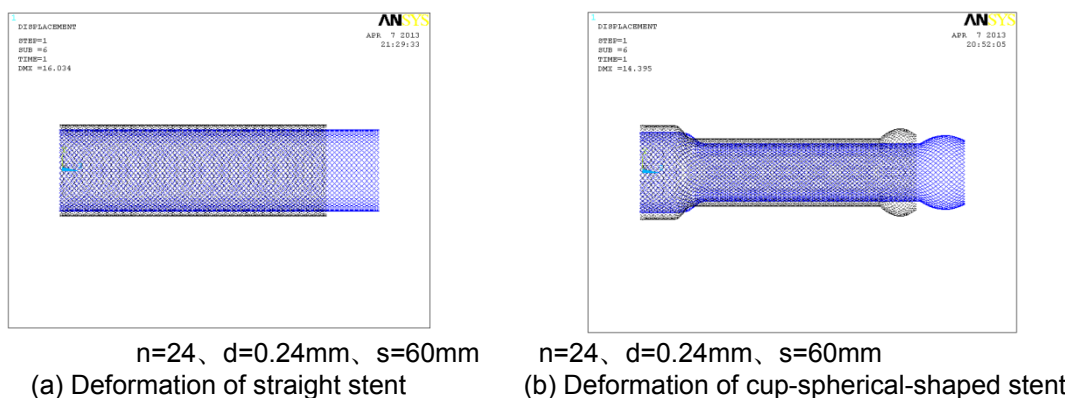


Figure 3. Deformation of Stents on a Set of Parameters

#### 3.1. Effect of Parameters on Stress of Wires Inside Stents

Through analyzing the stress distribution of the stent with various wire diameters, number of head and lead of both straight stent and cup-spherical-shaped stent, the stress concentrations occur at the positions of two ends and the neck junction of cup-spherical-shaped stent. However, the stresses in the rest parts of the stents are evenly distributed. The parts of the stents with uniform stress distribution should be compared. Table 2~4 list the maximum stress in those stress distribution positions, when the wire diameter, the crown number and the lead vary, hereinafter referred to as the stent stress.

From Table 2 to 4, for the straight form, the maximum stress increases with the wire diameter and the crown number increasing, but decreases with the lead increasing. The stress in straight stent with wire diameter of 0.24mm increases by 133.6% compared to the wire diameter of 0.18mm; while stress in straight stent with the number of head of 28 than the number of 22 only increases 108.4%. So the changing of wire diameter than the changing of the head has much more impacts on the stress.

The maximum stress increases with the increase of the wire diameter in cup-spherical-shaped stent. Stress in cup-spherical-shaped stent with wire diameter of 0.24mm than the wire

diameter of 0.18mm increases 137.2%. When the crown number and the lead are changed, the cup-spherical-shaped stent shows different performance and characteristics. Through analyzing and calculating, it is known that the stress in cup-spherical-shaped stent with the crown number of 24 is the minimum, which is consistent with the conclusion in reference [11]; when lead is 65mm, stress in cup-spherical-shaped stent is the maximum, and it is greater than that of the straight stent.

Table 2. Effect of Changes of Wire Diameter on the Stress (n=24 , s=60mm)

Wire diameter d(mm)	Stress of straight stent(MPa)	Stress of cup-spherical-shaped stent (MPa)
0.18	38.64	38.326
0.20	42.95	43.018
0.22	47.28	47.773
0.24	51.628	52.579

Table 3. Effect of Changes of Number of Head on the Stress (d=0.18 s=60mm)

The crown number n	Stress of straight stent(MPa)	Stress of cup-spherical-shaped stent(MPa)
22	36.867	51.222
24	38.64	38.326
26	39.141	45.697
28	39.96	42.279

Table 4. Effect of Changes of Lead on the Stress (d=0.18 n=24)

Lead s(mm)	Stress of straight stent(MPa)	Stress of cup-spherical-shaped stent(MPa)
55	40.204	36.193
60	38.64	38.326
65	36.635	51.842
70	33.45	24.215

Through above comparison and analysis, it is known that straight stent and cup-spherical-shaped stent show the same performance and characteristics when wire diameter is changed; but they show different characteristics when the crown number and the lead are changed. In the same deformation conditions, the stent more easily crack if the greater stress exists. So considering the using life of the stent, stent with less stress should be selected.

### 3.2. Effect of Parameters on Axial Elongation of Stents

The changes of axial elongation in both straight stent and cup-spherical-shaped stent with various wire diameters, crown number and lead are shown in Table 5, 6 and 7. According to Table 5 and Table 6, there are no significant change of the axial elongation in the two types stent with various crown number and wire diameter; however, axial elongation in the stent significantly increases when lead decreases. Elongation in straight stent with lead of 55mm is 1.55 times longer than that of lead of 70mm; elongation in cup-spherical-shaped stent with lead of 55mm is 1.51 times longer than that of lead of 70mm. Table 5, 6 and 7 indicate that in the cases of different parameters, the ratio of axial elongation in cup-spherical-shaped stent and straight stent is about 89%, it is stable. Axial elongation in stent will cause friction between the stent and the esophageal wall, which results in tissue hyperplasia and restenosis [12]. Therefore, axial stretching should be as small as possible. Elongation in the stent is very small when the crown number and wire diameter are changed, so it is necessary to pay attention to the axial elongation when the lead of the stent is chosen. Bigger lead is a good choice as long as the strength of stent is enough. According to the analytical results, in the case of the same parameters, the axial elongation in cup-spherical-shaped stent is less than that of straight stent, which can prove that the performance of cup-spherical-shaped stent is superior to the straight stent.

Table 5. Effect of changes of wire diameter on the axial elongation (n=24 s=60mm)

Wire diameter d(mm)	Axial elongation of straight stent(mm)	Axial elongation of cup- spherical-shaped stent(mm)	Axial elongation of cup-spherical- shaped stent /Axial elongation of straight stent
0.18	16.034	14.396	89.78%
0.20	16.034	14.396	89.78%
0.22	16.034	14.395	89.77%
0.24	16.034	14.395	89.78%

Table 6. Effect of Changes of Number of Head on the Axial Elongation (d=0.18mm s=60mm)

The crown number n	Axial elongation of straight stent(mm)	Axial elongation of cup- spherical-shaped stent(mm)	Axial elongation of cup-spherical- shaped stent /Axial elongation of straight stent
22	16.088	14.459	89.87%
24	16.034	14.396	89.78%
26	15.989	14.365	89.84%
28	16.059	14.431	89.86%

Table 7. Effect of Changes of Lead on the Axial Elongation (d=0.18mm n=24)

Lead s(mm)	Axial elongation of straight stent(mm)	Axial elongation of cup- spherical-shaped stent(mm)	Axial elongation of cup-spherical- shaped stent /Axial elongation of straight stent
55	18.782	16.729	89.07%
60	16.034	14.396	89.78%
65	13.854	12.563	90.68%
70	12.123	11.09	91.48%

#### 4. Conclusion

In this paper, the finite element method is used to calculate and analyze stress and axial elongation of straight and cup-spherical-shaped braided stents under the same radial compression, and then a comparison of the results is made. It is concluded that the strength of the structural in different types of esophageal stent is relative to the crown number, the wire diameter and the lead. The conclusion of this work is as same as the relevant conclusions of references [9-12]. Axial elongation in different types of esophageal stent is mainly relative to the lead of the stent. The axial elongation in cup-spherical-shaped stent is less than that of in straight stent, which is better for the application of the stent.

However, as previous mentioned, there are many different forms for the end portions of stent, such as double cup-spherical-shaped, double-honk. Moreover, the peristaltic waves, as well as the friction between the crossing wires inside of bare stent, setting of tumor and so on, are not considered in the analysis. Therefore, in our further research, taking into account all factors is very necessary to understand the overall mechanical properties of braided stents.

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