Design Investigation on Applicable Mesh Structures for Medical Stent Applications

Shoji Asano1*, Jianmei He1

1Dept. of Mechanical Engineering, Kogakuin Univ. 1-24-2, Nishi-shinjuku, Shinjuku-ku, Tokyo, 163-8677 Japan

Abstract. In recent years, utilization of medical stents is one of effective treatments for stenosis and occlusion occurring in a living body’s lumen indispensable for maintenance of human life such as superficial femoral artery (SFA) occlusion. However, there are concerns about the occurrence of fatigue fractures caused by stress concentrations, neointimal hyperplasia and the like due to the shape structure and the manufacturing method in the conventional stents, and a stent having high strength and high flexibility is required. Therefore, in this research, applicable mesh structures for medical stents based on the design concepts of high strength, high flexibility are interested to solve various problem of conventional stent. According to the shape and dimensions of SFA occlusion therapy stent and indwelling delivery catheter, shape design of the meshed stent are performed using 3-dimensional CAD software Solid Works first. Then analytical examination on storage characteristics and compression characteristics of such mesh structure applied stent models were carried out through finite element analysis software ANSYS Workbench. Meshed stent models with higher strength and higher flexibility with integral molding are investigated analytically. It was found that the storage characteristics and compression characteristics of meshed stent models are highly dependent on the basic mesh shapes with same surface void ratio. Trade-off relationship between flexibility and storage characteristics is found exited, it is required to provide appropriate curvatures during basic mesh shape design.

1. Introduction
In recent years, stenosis and obstruction have occurred in body lumen such as blood vessels, bile ducts, trachea and other like indispensable for maintenance of human life as in the superficial femoral artery (SFA) occlusion, which is caused by disease. As an effective treatment for such stenosis and occlusion, indwelling of medical stents is performed. On the other hand, the inside of the living body lumen where the stents are placed is a corrosive environment with complicated structure. The difficult environment may cause a rejection reaction when foreign matter intrudes. Therefore, it is required that the stent placed in the living body lumen has high flexibility, excellent biocompatibility, high strength and durability etc.

However, ready-made conventional stents have concerns that the design and manufacturing method of the shape structure causes stress concentration, and then fatigue fractures due to pulsation, or causes neointimal hyperplasia due to strong radial forces generated on the inner wall of the stents [1-9]. Therefore, there is the need for medical stents having high strength and high flexibility capable of following severe movements such as bending, torsion, expansion and contraction in the femoral artery.

Therefore, the purpose of this research is to design applicable mesh structures [10] for medical stent application to solve the problems of conventional stents. Meshed stent models with higher strength and higher flexibility with integral molding are design and investigated analytically. The storage
characteristics and compression characteristics of meshed stent models are examined through finite element analysis.

2. Design of meshed stent models with mesh structures

2.1. Evaluation of surface void contents of meshed stent models.

Based on the design concepts for mesh structures [10] of high strength and high flexibility, the meshed stent models are obtained as shown in figure 1 according to the shape and dimensions of the SFA occlusion treatment stents shown in table 1. For the five types of mesh basic shapes as shown in figure 1, the basic mesh shape number arranged in the stent circumferential direction (hereinafter referred to as “N”) is changed from 5 to 8, and the mesh line width is changed from 0.1 mm to 0.2 mm. Total of 40 kinds of meshed stent models are designed for all combinations between mesh type, basic mesh shape number and mesh line width. These basic mesh shapes are composed only with a tangent circular arc, and the S-shape curve bending is provided to achieve high strength and high flexibility.

![Figure 1. Basic mesh shapes and three-dimensional meshed stent models.](image)

**Table 1.** Dimensions of desired stents.

| Material         | Nickel-titanium alloy |
|------------------|-----------------------|
| Stent Length [mm]| ~100.0                |
| Mesh Line Width [mm]| 0.1, 0.2              |
| Strut Thickness [mm]| 0.18                 |
| Pre-storage Diameter [mm]| 6.0                  |
| Post-storage Diameter [mm]| ~2.0                |
| Surface Void Content [%]| around 80          |

For the designed 40 meshed stent models, surface void contents were evaluated. Surface void content is defined as the surface area removed before and after mesh structure’s application. It is desirable to have around 80% from medical point of view. Surface void content can be calculated by equation (1), and meshed stent models with surface void content around 80% are shown in Table 2 for further analytical investigations.

\[
\alpha = 100 - \frac{b}{c} \times 100
\]

where  
\( \alpha \): Surface void content of meshed stent models [%]  
\( b \): Cylindrical surface area after application of mesh structure [mm²]  
\( c \): Cylindrical surface area before application of mesh structure [mm²]

3. Evaluation of Storage Characteristics of Meshed Stent Models

The storage characteristics were analyzed and evaluated using finite element analysis software ANSYS Workbench 14.5 for meshed stent models having surface void content of around 80% shown in table 2. Material properties of nickel titanium alloy shown in table 3 were applied and constraint conditions were applied as 2.0 mm storage diameter of meshed stent model. Figure 2 shows typical finite element mesh
of meshed stent model for analysis. Figure 3 shows examples of the storage characteristic evaluation results of designed meshed stent models.

Table 2. Surface void content results of meshed stent models.

| Mesh shape - Mesh line width | N Number (Surface void content [%]) |
|-----------------------------|------------------------------------|
| Model 1-0.2mm               | N5(82.65), N6(80.21), N7(77.77)   |
| Model 2-0.2mm               | N7(81.58), N8(79.84)               |
| Model 3-0.1mm               | N8(82.55)                           |
| Model 3-0.2mm               | N5(79.23)                           |
| Model 4-0.1mm               | N5(82.25), N6(81.01), N7(78.81)    |
| Model 5-0.1mm               | N6(81.59), N7(80.51), N8(78.77)    |

Table 3. Material properties of nickel-titanium, number of nodes and number of elements.

| Density [g/cm³] | 6.45 |
|-----------------|------|
| Poisson’s ratio | 0.3  |
| Modulus of longitudinal elasticity [GPa] | 75   |
| Number of nodes | 130260–176620 |
| Number of elements | 79827–103362 |

Figure 2. Finite element mesh for meshed stent model 1-N5.

Figure 3. Sample analytical results of storage meshed stent models.

From these analytical results,

1. Stents having basic mesh shapes with deep S-shaped curve (Model 5) can be expected to greatly reduced stress concentration during storage, but the mesh lines tend to come into contact during storage and tend to be inferior.

2. Stents composed of basic mesh shapes with a shallow S-shape curve (Model 1, 2) can be expected to have higher storability.

3. The storage characteristics are not necessarily dependent on surface void contents. In the case of same surface void contents of meshed stent models, the storage characteristics are highly dependent on basic mesh shapes.

4. Evaluation of compression characteristics of meshed stent models

Similarly to the storage characteristic analysis, compression characteristics were analyzed and evaluated using finite element analysis software ANSYS Workbench 14.5 for meshed stent models having surface void contents of around 80% shown in table 2. Meshed stent models are sandwiched between flat jigs.
and applied by compressive load of 10 N in the direction perpendicular to stent cylinder axis. Table 4 shows the number of nodes and elements of meshed stent model for analysis. Figure 4 shows the image of typical finite element mesh of meshed stent model including compressive fixtures.

Table 4. Number of nodes and elements in analysis of cylindrical axis vertical direction.

| Number of nodes       | 186090–251505 |
|-----------------------|---------------|
| Number of elements    | 94578–125192  |

Figure 4. Finite element mesh of meshed stent model with compressive fixtures (Model 1-N5).

Figure 5 shows sample un-deformed and deformed results of meshed stent model under compressive loads. Compressive stiffness $k$ is then calculated by fitting the deformation amount $\delta$ with compressive load $P$ applied to the meshed stent models to equation (2). Figure 6 shows the relationship between compressive stiffness and surface void content of different meshed stent models.

![Figure 5](image)

**Figure 5.** Un-deformed and deformed results of meshed stent model with compressive fixtures.

(2)

$$k = \frac{P}{\delta}$$

where

- $k$: Compressive stiffness [N/mm]
- $P$: Compressive load [N]
- $\delta$: Displacement [mm]

(1) Stents having longitudinally elongated basic mesh shapes tend to have lower compressive stiffness than elongated basic mesh shapes in lateral direction.

(2) Similarly to the storage characteristic evaluations, the compression characteristics of meshed stent models are not necessarily dependent on their surface void contents. With same surface void contents, the compressive stiffness of meshed stent models is highly dependent on basic mesh shapes.

(3) Compressive stiffness of a ready-made conventional stent with a diameter of 10.0 mm is to be about 0.3 N / mm, and the compressive stiffness of the meshed stent models designed in this research tend to be considerably higher overall. Improvement on the meshed stent models need to be executed.
Figure 6. Relevance between compressive stiffness and surface void content of meshed stent models from these analytical results.

5. Summary
Meshed stent models with higher strength and higher flexibility with integral molding are investigated analytically. It was found that the storage characteristics and compression characteristics of meshed stent models are highly dependent on the basic mesh shapes with same surface void content. Trade-off relationship between flexibility and storage characteristics is found exited, it is required to provide appropriate curvatures during basic mesh shape design.

6. References
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