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A SHAPE DESIGN SUPPORT SYSTEM FOR SELF-EXPANDABLE STENTS

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Abstract

This paper describes the frame of a computer-aided shape design of self-expandable stent, namely, a medical device of mesh-shaped tubular structure which is used to expand the constriction of a blood vessel. The stent has the structure of longitudinal repetition of wavy wire parts and strut parts. The stent should be just the right rigidity in radial direction to maintain enough blood stream without damaging the vessel wall, while it has to be as flexible as possible to fit various anatomical bends. The rigidity and flexibility are mainly determined by the shape of wire and construction of the strut. To design the self-expandable stents efficiently, a design support system is proposed by combining a three-dimensional CAD system and numerical simulation methods, and its effectiveness is discussed.

Keywords: Shape design, Design support system, Self-expandable stents, Mechanical properties

1. Introduction

A medical device of thin spiral or mesh-shaped tubular structure called stent is used to expand the constriction of a blood vessel. It has been widely accepted as effective for the treatment of iliac arterial stenoses and occlusions. Stents are usually made by weaving thin metal wires or slotting a thin tube, and they are coiled stent and slotted tube stent, respectively. They are also classified into two types based on expansion method, namely, balloon-expandable stent and self-expandable stent. Palmaz-Schatz stent which has been used world-wide is a balloon-expandable slotted tube stent, while Wallstent is a self-expandable coil stent. In any case, second-generation stents normally have the structure of longitudinal repetition of wavy wire parts and strut parts. Every wire part consists of ten or more pieces of wavy wire and the strut part connects them by several bridge wires.

The stent should be just the right rigidity in radial direction to maintain enough blood stream without damaging the vessel wall, while it has to be as flexible as possible to fit various anatomical bends. The rigidity and flexibility are mainly determined by the shapes of wavy wire (zigzag pattern) and strut. The stent must satisfy other clinical demands, of course.

Schmitz et al.[1] summarized the measurement of the most relevant mechanical and dimensional parameters for a given stent design. They measured longitudinal flexibility, radial stiffness, foreshortening due to expansion and so on. Duda et al.[2] measured physical properties such as weight, hoop strength for balloon-expandable stents, radial resistive force and chronic outward force for self-expanding stents as well as pushability and Radiopacity of various endovascular stents. Based on the experimental comparison, they concluded that there was no stent with ideal physical properties but the most appropriate stent could be chosen depending on the characteristics of the arterial lesion to be treated. Mori et al.[3] developed a test apparatus by use of four points bending and measured the bending stiffness of stents. The result showed that the stiffness was influenced by the stent structure and the flexible stent deformed smoothly, while the low flexible stents deformed with buckling. Whitcher[4] presented a simulation analysis of stents to provide designers with estimates of their in vivo structural behaviour and fatigue properties. He aimed a cost-effective source of information on design constraints as part of the product development process. Several studies of stent materials were also reported[5].

Though many studies have been performed, the influence of stent shape on its mechanical properties such as rigidity and flexibility has not been fully studied. As a result, the design of stent shape and its improvement often depend on trial and error tests or designers' experience. It needs much time and cost as well. From the background, it is obviously desirable that we should have an efficient method for both design of stent shape and evaluation of its mechanical properties. A design support system for self-expandable stents is framed in this paper by combining a three-dimensional CAD system and numerical simulation methods, and its effectiveness is discussed.

2. Self-expandable stents

2.1 Clinical demands in regard to stents

First we survey the clinical demands to clarify mechanical properties required for the stent. The survey is very important to reasonably translate doctor's words to engineering requirements in design task. The main demands are as follows:

a) Sufficient radial force to ensure vessel patency

b) Conform smoothly to the anatomy and not injure the arterial wall

c) Track-ability and push-ability to reach and cross target lesions

d) Small risk of restricture and occlusions in use

The demand a), namely, scaffolding property relates to the rigidity in radial direction after expanding, and the demands b) and c) can be realized in case the stent is as flexible as possible. Flexibility of stent mounted in a catheter also influences the demand c). However, the rigidity and flexibility are not quantitatively clarified unfortunately, probably because their ideal values should be determined based on the condition of patient. What we have to do is, therefore, to estimate the mechanical properties at the design stage and to clarify their sensitivities which are indispensable in design improvement. The demand d) is rather complicated, and the microscopic condition of blood stream may affect the restricture in use.

2.2 Design and processing of Sendai Stent

Nashihara has developed a new self-expandable stent[6]. It is called Sendai Stent after the name of city where he was studying. He drew a sketch of stent on a paper, and cut out the pattern to make a tubular paper model. It was bent or pressed to approximately estimate mechanical performances, then he modified the shape. Based on this trial and error experiments, he obtained a final shape. It is shown in Figure 1.

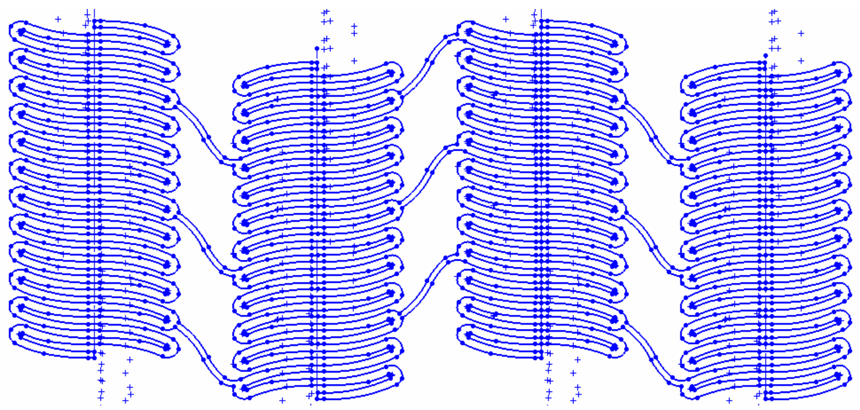

Figure 1 Drawing of self-expandable Sendai Stent

The stent is made of thin Nitinol (a shape memory alloy of nickel and titanium) tube, 2 mm in diameter, 30-40 mm long and about 0.2 mm thick. Many slits are processed on the tube by a laser beam then it is polished electrically. It has the structure of longitudinal repetition of wavy wire parts and strut parts as shown in Figure 2. Every wire part consists of 24 pieces of wavy wire and the strut part connects them by 3 bridge wires. Based on clinical demands, the laser-processed tube is expanded from 2 mm to 6-12 mm in diameter step by step. The shape-memory effect is expressed in this process. Figure 2 also shows typical expansion process to obtain the Sendai Stent of 12 mm in diameter. The biological effects of the stent have been examined in experiments with animals, and it shows good effects available for clinical use.

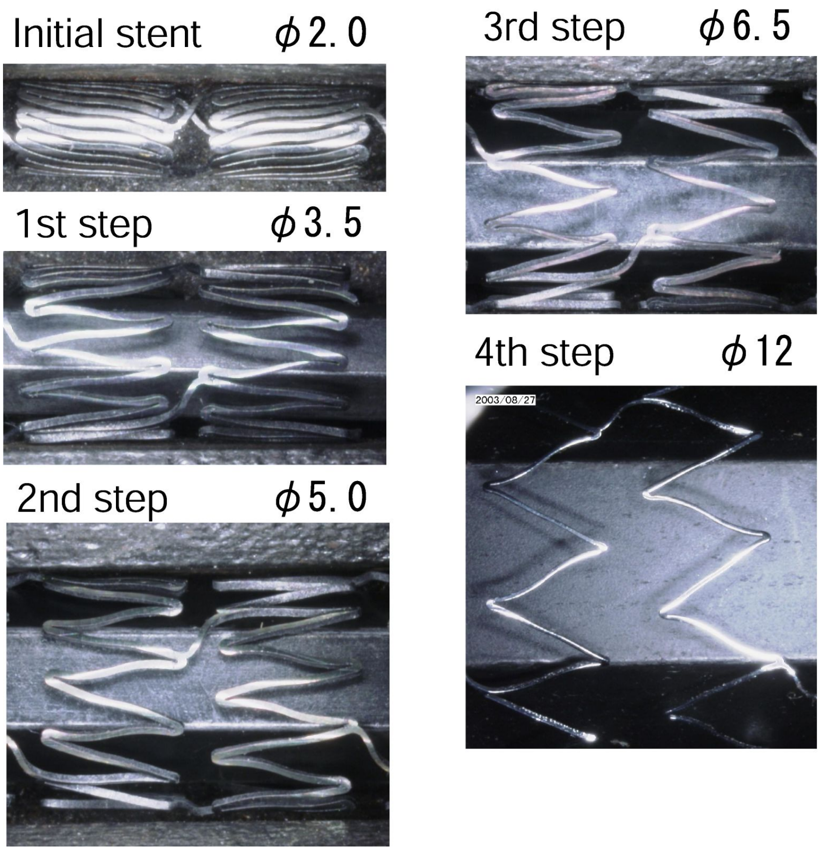

Figure 2 Expansion of laser-processed initial stent to obtain Sendai Stent

3. Design support system for self-expandable stents

3.1 Frame of design support system

Here, we propose a shape design support system for self-expandable stents considering well the production process of stents. Figure 3 illustrates the frame of the design support system. The left half shows manufacture and evaluation processes which are actually adopted in the production of Sendai Stent. As described above, the development, namely, two-dimensional drawing of developed shape of stent is given first, and NC data for laser cutting of Nitinol tube is generated. The laser-processed tube is expanded step by step by repeating insertion of a thick rod and annealing. This is the shape memory processing. Expanded stents are bent and pressed to evaluate their performances in the next step, and the self-expandable stents are completed. Of course, this step is usually omitted after the trial manufacture is finished and the production of stents is made a good start.

The right half of Figure 3 is the flow of proposed design support system which simulates above-mentioned manufacture and evaluation processes. We aim at the system with the following functions; modeling of initial stent processed by a laser, prediction of the shape of self-expanded stent, and evaluation of mechanical properties. The support system consists of three main parts corresponding to these functions, and they are indicated by the rectangles of broken lines.

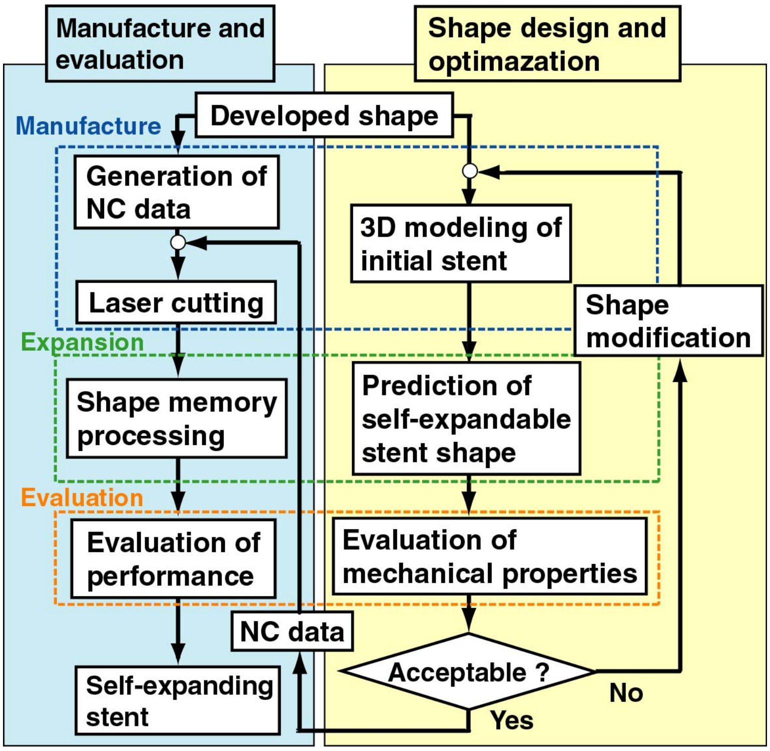

Figure 3 Design support system for self-expandable stents

3.2 Modeling of initial stent

In the first stage, the initial stent, or laser-processed tube is modeled in a three-dimensional CAD system from the development of stent shape. This modeling is very important and complicated process. It depends on the functions of CAD system as well. Therefore, it is explained in detail in the following. Figure 4 indicates several possible methods of modeling examined in this study.

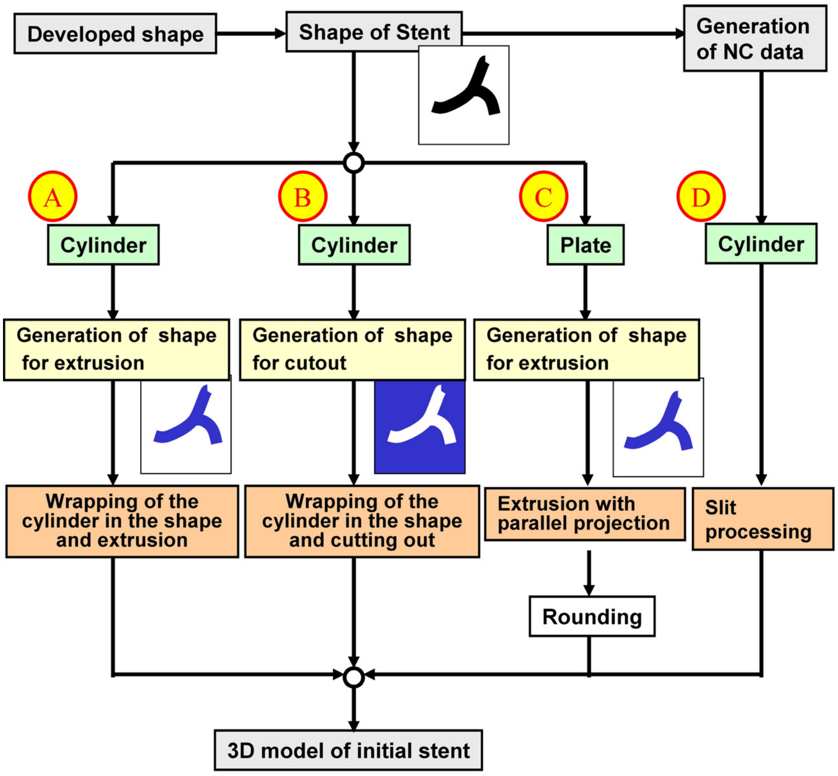

Figure 4 Possible methods of modeling of initial stent

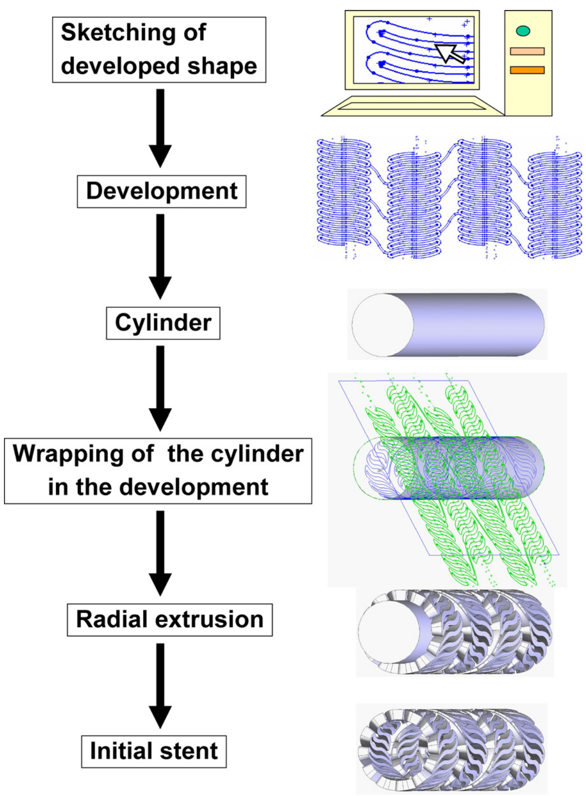

Figure 5 Flow of modeling of initial stent in three-dimensional CAD system

In method A, the shape of stent is drawn on the surface of a tube, and the initial stent model is generated on the tube by using the function of radial extrusion in a three-dimensional CAD system. Cutout pattern for stent is used instead in method B, and the initial stent is modeled by cutting it out. The initial stent is obtained by rounding the plane model extruded on a plate in the same way as sheet metal processing in method C, while a method like the laser cutting is considered in method D. However method C and D involve some difficulties such as seaming after rounding and numerical data creation for representing the profile of stent wires, so they are not selected. Method A and B are much the same, but the former is better since it generates the shape of stent directly. Consequently, method A is adopted for modeling the initial stent in this study. The flow of modeling is shown in Figure 5 with the solid models displayed at each process. Solid Works is used for the modeling in this study.

Several design variables which can parametrically modify the stent shape are introduced in this stage in expectation of the shape optimization. Main design variables are as follows; length of wavy wire part l_w, length of inclined part of wavy wire l_i and its angle θ_w, radii of curvature at the end of wavy wire r_o and r_i, length of strut part l_b, angle of bridge wire θ_b, thickness of wavy wire t_w, thickness of bridge wire t_b, gap of facing ends of wavy wire g, number of slits or wires at wire part n_w, number of bridge wires n_b. Most of them are shown in Figure 6.

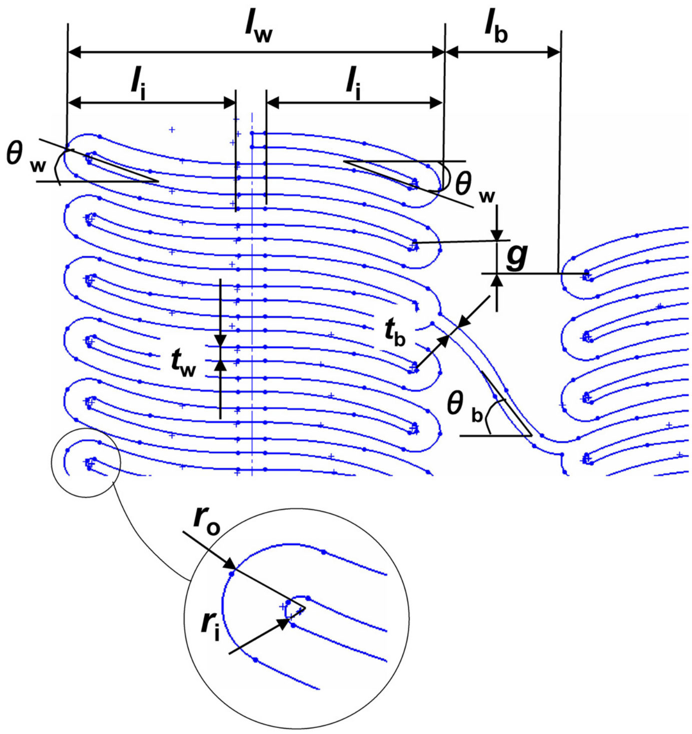

Figure 6 Main design variables for stent

3.3 Prediction of self-expanded stent shape

In the second stage, the expansion of the initial stent is simulated by the finite element method. The threee-dimensional CAD data of the initial model is output by using the data transformation format Parasolid and sent to the pre-processor of solver to generate the finite element mesh. Patran is used for this purpose. Then, the computation model is expanded to a diameter of the stent to predict the stent shape. We use non-linear finite element method in Marc for this simulation.

In case of mounting a self-expandable stent in a thin sheath, or catheter, the stent is iced to shrink in diameter. When the stent is pushed out into the lesion of the blood vessel, it must regain its initial shape due to the super-elastic property of the shape-memory alloy. Therefore, the shrinkage and expansion in diameter have to be reversible. This means the following; even if we are able to obtain better shape of stent by modifying the expanded stent shape, we have to get its initial shape not only for production but for confirmation of the mounting. In this sense, this simulation is the key to the design of self-expandable stent.

3.4 Evaluation of mechanical properties

The mechanical properties of stents should satisfy the clinical demands such as scaffolding property, flexibility, maintenance of cylindrical shape. They are evaluated in the third stage.

In the case that the expanded shape of stent is successfully predicted by the simulation described above, the finite element mesh used for the prediction is deformed and it forms the expanded shape as the result. Consequently, we can evaluate the mechanical properties using this mesh, if things go well.

The scaffolding property, namely, ensuring of vessel patency against the constriction is evaluated from how much a stent expands in the vessel. This is a statically indeterminate problem, and it needs the degree of constriction and the mechanical behavior of vessel as well as other cellular texture around the vessel. Therefore, the precise evaluation is not easy. The rigidity of stent in radial direction, or the reduction of diameter due to radial pressure may be used as a measure of the scaffolding property instead. Similarly, the flexibility of stent in vessel is considerably hard to estimate, though the flexibility of stent itself may be used for the evaluation. Flexibility of stent mounted in a catheter is estimated as well for the track-ability and push-ability into target lesions.

The maintenance of cylindrical shape of stent, which is experimentally determined by winding the stent around a cylinder and bending 180 degrees, is also an important property. So, the flattening of cylindrical shape is computed.

These mechanical properties and their sensitivities are evaluated in this stage by the finite element simulation. If the evaluated mechanical properties are acceptable, the design is completed and the process is advanced to production. If they are not acceptable, the shape of stent is modified based on the sensitivities, and the design task is repeated.

4. Performance of design support system

Since above-mentioned Sendai Stent has good clinical performances, it can be used as a prototype to modify its shape and obtain a better stent. In the preliminary stage, the design of this stent is traced by the proposed method, and the concept of the design support system as well as the functions are discussed in this section. Table 1 shows the main design variables for Sendai Stent indicated in Figure 6. n_w is number of wires at the wire part, and n_b is number of bridge wires.

Table 1 Design variables for Sendai Stent

Variables	l_w	l_b	l_i	t_w	t_b	g	r_o	r_i	θ_w	θ_b	n_w	n_b
Value	3.6	0.8	1.1	0.09	0.08	0.26	0.14	0.03	20deg	53deg	24	3

4.1 Generation of initial stent model

An initial stent model is generated in the three-dimensional CAD system Solid Works following the flow illustrated in Figure 5. The CAD data of the model is send to Patran using the data format Parasolid. This format is better than IGES format in our trial. The model is divided into 12114 10-nodes tetrahedron elements as shown in Figure 7.

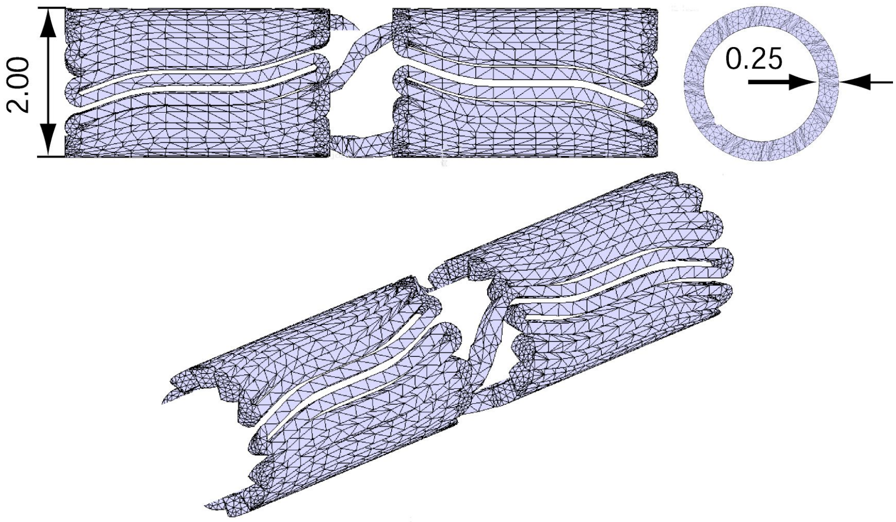

Figure 7 Finite element mesh for initial stent

4.2 Simulation of self-expansion of stent

We assume that the self-expansion of stent is simulated by the forced displacement problem in this study. The initial stent is expanded to the diameter of 4mm which is equal to the outer diameter of the first step of expansion shown in Figure 2. Assuming an elastic-perfectly plastic material, we use non-linear finite element method in Marc for this simulation. The modulus of longitudinal elasticity, Poisson's ratio and the yielding stress are approximated to be 17.5 MPa, 0.3 and 172 MPa, respectively. The axial and circumferential displacements at a circular edge are fixed, and the inner surface of the stent is forced to displace 0.75mm outward. The increment of displacement is 0.01mm. The computed shape is shown in Figure 8.

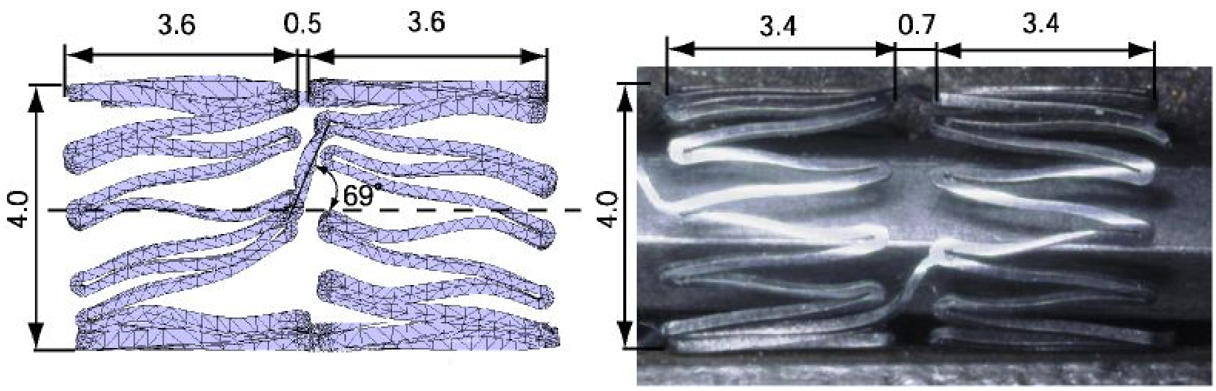

Figure 8 Simulated shape of stent at the first step of expansion

The axial length of wavy wire part is about 0.2mm longer than the one of expanded stent, while the axial length of bridge wire is about 0.2mm shorter than that of the stent. The latter difference is mainly caused from the difference of deformation of the wires to which the bridge wires are connected. This causes about 18 degrees larger inclination angle of the bridge wire. On the other hand, the shapes of other wires are close to the stent wires. The reason of the simulation error remains unsolved, though we find out imperfections of condition of simulation; the assumption of elastic-perfectly plastic material, the neglect of insertion of a rod for expansion and induced friction force, stress relaxation by the heat treatment in the expansion process. We may predict the expanded shape of stent if these imperfections are corrected.

4.3 Estimation of mechanical properties

The expanded shape of stent is not precisely predicted by the simulation, so we can not use the deformed shape of stent directly for the estimation of mechanical properties of the stent. Therefore, several models for simulation are anew formed in the CAD system and they are divided into the finite elements. In these models, the number of wires at the wire part n_w and the ratio of length of wavy wire part to length of strut part $\alpha = l_w / l_b$ are selected as design variables. Here, the sum of l_w and l_b is constant, 4.0mm. The influence of α on the shape of stent is schematically shown in Figure 9. $\alpha = 3.7$ indicates Sendai Stent.

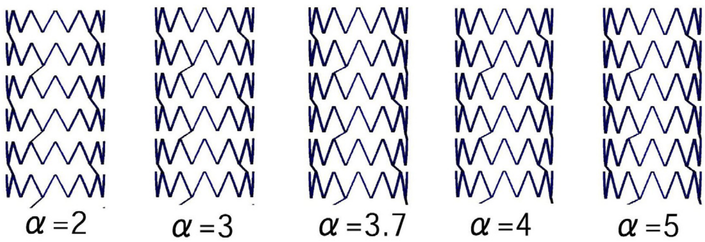

Figure 9 Schematic view of stent shapes with various ratio of wire and strut lengths

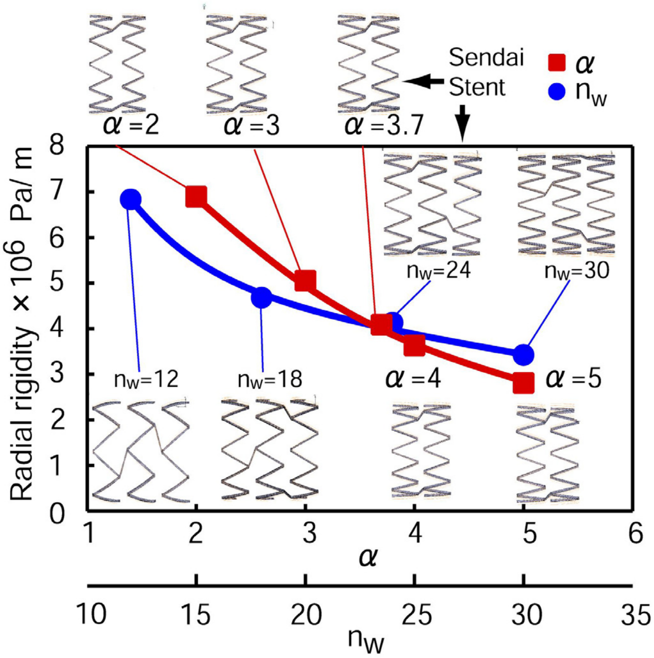

Figure 10 Rigidity of stents in radial direction due to uniform pressure

In the first place, the rigidity of the stents in radial direction, or the reduction of diameter due to radial pressure is evaluated. The objective of this evaluation is to know the influences of n_w and α on the rigidity, therefore, it is evaluated as a linear problem. The result is indicated in Figure 10. The rigidity reduces with the increase of n_w and α. The induced stress at the straight part of wire is smaller than the stress at the corner of wire. This means the corner exceeds in deformation. The more the number of corners, the larger the deformation. This may be the reason of the rigidity reduction with the increase of n_w. Similarly, the influence of α on the rigidity may be understood that the length of moment arm is increases with the increase of α and this causes the reduction of the rigidity.

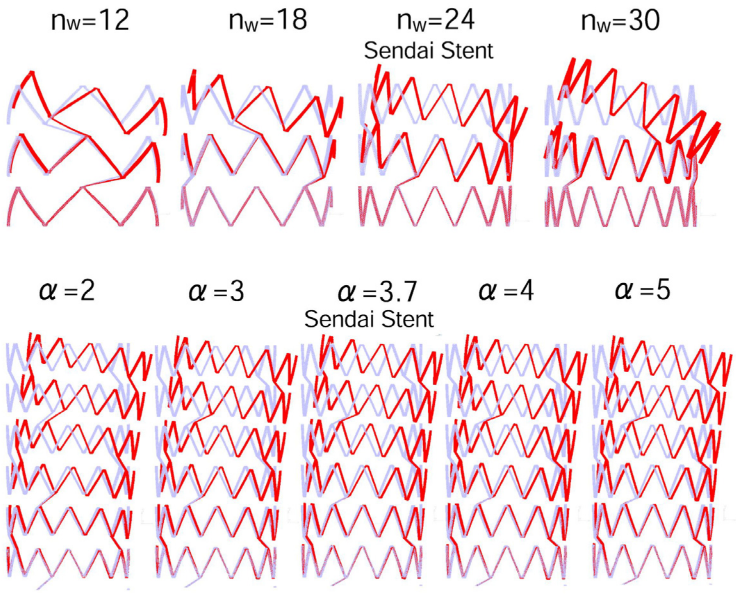

Figure 11 Deflection of stents due to bending moment

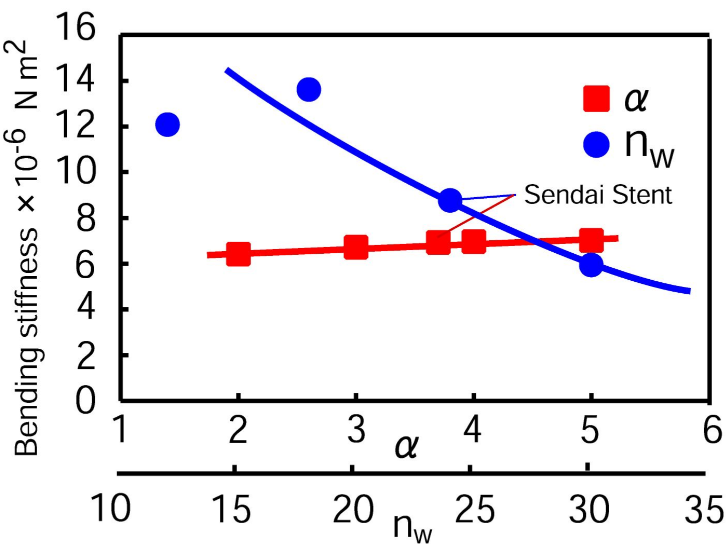

Figure 12 Bending stiffness of stents

Next, the flexibility due to bending moment is evaluated as a linear problem. The deflection of stents is illustrated in Figure 11. The deflection at the strut part is larger that the deflection at the wavy wire part as might be expected. The influence of n_w is noticeable in comparison with the influence of α. The former may be caused by the difference of inclination angle of the bridge wire θ_b.

As described in the previous section, the scaffolding property, namely, ensuring of vessel patency against the constriction and the flexibility of stent in vessel should be evaluated to answer the clinical demands. However, it needs the mechanical behavior of vessel and other cellular texture around the vessel, and the evaluation of the properties is not very easy. In addition, other properties such as the maintenance of cylindrical shape of stent, etc. have to be estimated. The authors will continue the evaluation of these mechanical properties in order to design suitable stents for patient. stent is modified based on the sensitivities, and the design task is repeated.

5. Conclusions

Ideal medical devices have to be designed by the collaboration of doctors and engineers to suit the condition of a patient. The stent, which is used to expand the constriction of a blood vessel, is one of them and realization of an efficient method for both design of stent shape and evaluation of its mechanical properties is highly expected. From the background, a frame of design support system for self-expandable stents was presented and discussed in this paper. The conclusions may be summarized as follows.

1. The clinical demands were surveyed first to clarify the mechanical properties required for the stent. This was very important to reasonably translate doctor's words to engineering requirements in design task.

2. A design support system for self-expandable stents was proposed considering well the actual production process of the stents. The system was based on functions of three-dimensional CAD system and non-linear finite element method.

3. The design support system functioned as modeling of initial stent processed by a laser, prediction of the shape of self-expanded stent, and evaluation of mechanical properties.

4. The system was applied to Sendai Stent and the functions were examined. The prediction of the self-expanded stent shape, which was computed by non-linear finite element method, was not perfect at the moment, and some corrections such as the introduction of stress-strain relation of stent material should be required.

5. The rigidity in radial direction and bending flexibility of stents were evaluated, and the influences of the number of wires at the wire part and the ratio of length of wavy wire part to length of strut part on the mechanical properties were discussed.

Acknowledgement

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