

A Possible Product Design for Minute Medical Parts

Development of Self-Expanding Stent Made of Memory Alloy

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Abstract: This report describes a possible product design in the field of medical engineering, clarifying the constructive design performance of minute medical parts. It is known as a stent, and is a mesh-shaped tube made of a shape memory alloy of nickel and titanium (Nitinol), 2 mm in diameter, 30-40 mm long, wire width 0.15 mm and wire thickness 0.15-0.2 mm. Watching X-ray pictures, a doctor pushes out a stent which is built into a catheter (2 mm in diameter), into the lesion where flow through a blood vessel or ureter is blocked. The stent self-expands its diameter from 2 mm to 6-12mm (3- 6 times). As a result, the diameter of vessel expands and is maintained. The stent must satisfy the following design demands. When bent 180 degrees, its cylindrical shape must be maintained. The mesh-shaped tube must flexibly follow the bending vessel without injuring the arterial wall. When it expands 3-6 times, the mechanical strength must be kept and it must not lose its expanding force. If built in a catheter (2 mm in diameter), it must also bend. We researched the deformation mechanism and the relation between the construction and shape of the wire. After many of experimental designs and trial productions over 4 years, an original product model was obtained that has conspicuous flexibility, expansion properties and bending properties compared with other overseas stents. From several mechanical testing experiments, it was found that an organic design using a free curved line and a low angle of inclination provides flexibility and expansion properties, and eases stress. We believe that the role of design in the field of medical engineering is important.

Keywords: *Medical Engineering, Minute medical part, Constructive Design, Organic Design, Memory Alloy*

1.0 Introduction

Metallic stent placement has been widely accepted as safe and effective for the treatment of iliac arterial stenoses and occlusions[1]. Stent implantation is a minimally invasive technique for restoring the luminal patency of stenosed or occluded arteries. The stent itself is an intravascular scaffolding, most commonly composed of a thin spiral or mesh-shaped tube which supports the arterial wall from the inside. It is 30-40 mm long and the wire width is 0.15 mm. Watching X-ray pictures, a doctor pushes out a stent, which is built into a catheter (2 mm in diameter), into the lesion where the flow through the blood vessel or ureter is blocked. The stent self-expands its diameter from 2mm to 6-12 mm (3-6 times). As a result, the diameter of vessel expands and is maintained. To access the lesion and achieve optimal stent expansion, high flexibility and conformability of the stent are required. Due to the variety of designs and materials, there are large differences

in mechanical performance. The mechanical properties of stents are important parameters in the consideration of stent design, where resistance to pressures and forces generated by elastic arterial recoil and vascular spasm.

Nitinol is a shape memory alloy of nickel and titanium, and a good material for use in a self-expanding stent [2]. It is flexible and suitable for trans-luminal placement below its transient temperature, and above this temperature resumes its original annealed shape. Products from Strecker, Memotherm and Cragg are examples of nitinol stents which have recently become available overseas but are not yet available in Japan. The advantages of such stents for intravascular application are easy delivery, a high expansion rate and low metal to tissue ration.

We designed and developed a nitinol, tube type, vascular stent, to meet the highest demands of flexibility, strength and precise positioning for availability in Japan. We examined the mechanical properties compared with available other stents. The stent is manufactured from a solid nitinol tube (2.0 mm in diameter and about 0.2 mm thick). The internal structure of the stent is 10-15 pieces of wavy wire put side by side and connected by bridges to several spots on the circumference. It is processed numerically using a laser beam and is polished electrically. There are no welding points or filament crossings.

In this report, we show a possible product design in the field of medical engineering, and clarify constructive design performance of minute medical parts (stents) that have highly elastic properties and conform smoothly to the anatomy [3,4].

2.0 Design Demands

The stent must satisfy the following design demands.

2.1 Clinical Demands

- a) Sufficient radial force from each strut to ensure vessel patency.
- b) Regain its initial shape after compression due to the super-elastic property of the nitinol material
- c) Conform smoothly to the anatomy and not injure the arterial wall
- d) Track-ability and push-ability to reach and cross target lesions

2.2 Mechanical Demands to Satisfy Clinical Demands

- a) Must maintain its cylindrical shape when bent 180 degrees.
- b) Have flexibility to smoothly follow various anatomical bends
- c) Have a smooth surface that does not injure the arterial wall
- d) Must not lose its expanding force to ensure vessel patency when it expands 3-6 times.
- e) Have substantial axial length when it expands 3-6 times.
- f) Must also bend smoothly and follow various bending vessels if built into a catheter (2 mm in diameter)..

3.0 Design Process

We collaborated with NEC TOKIN Corporation (Tokyo, Japan), PIOLAX MEDICAL DEVICES, INC., (Tokyo, Japan) and MARUKI IKA Corporation (Sendai, Japan). We researched the deformation mechanism and the relationship between the construction and shape of the wavy wire. Nashihara and his assistant took part in creating a new construction and design shape. Ishibashi and another medical worker experimented with the mechanical properties and biological effects of the new design stent. NEC TOKIN Corporation took part

in manufacturing and experiments for mechanical properties. PIOLAX MEDICAL DEVICES, INC. was involved in medical engineering and mechanical properties experiments. MARUKI IKA Corporation took part in marketing and planning the project. Various trial models were created and examined. After many experimental designs and trial productions over 4 years from 1999, the original product model (Sendai Stent) was obtained in 2002. The design process was as follows.

- Step 1: Drew the idea sketch
- Step 2: CAD drawing
- Step 3: Made a paper model and examined it experimentally
- Step 4: Produced trail stent models using Nitinol tubing
- Step 5: Examined the mechanical properties compared with available other stents
- Step 6: Examined the biological effects compared with available other stents.
- Step 7: Achieved the original product model (Sendai Stent)
- Step 8: Applied for a patent
- Step 9: Obtained a license under the Pharmaceutical Affairs Law
- Step 10: Renewed design performance

4.0 Design Specification

(1) Material

A tube of nickel and titanium alloy (Nitinol) (2 mm in diameter, 30-40 mm long and about 0.15 mm-0.25 mm thick) was used. The size specification depends on clinical needs.

(2) Manufacture

The tube was processed numerically to make the stent using a laser beam and was polished electrically. It was annealed step by step from 2 mm in diameter to 6-12 mm in diameter for shape memory. The alloy of nickel and titanium did not extend yield points.

(3) Self-expand

It is 2 mm in diameter below its transient temperature (non-expanded state), and it self-expands to 6-12 mm in diameter (3-6 times) above this temperature, resuming its original annealed shape. The expanded diameter is determined by clinical needs.

(4) Wavy wire width and wire interval for processing

The minimum wire width is about 0.10 mm. The minimum wire interval is 0.08 mm and permits processing the width by the size of the laser beam (about 0.05 mm)

5.0 Result of Design

We designed some stents that can be applied to individual self-expanding demands (6, 8, 10, 12 mm in diameter). We pursued the design shape by applying organic curves and basic arts.

5.1 Drawing

A schematic drawing of the original stent is shown in Figure 1. It can self-expand from 2 mm to 10 mm in diameter. The wavy wire length from the top to bottom is 2.7 mm, and the interval of two waves is 0.8 mm. Minimum wire width is 0.12 mm and the wire interval is 0.10 mm. The size specification depends on the self-expanding demand.

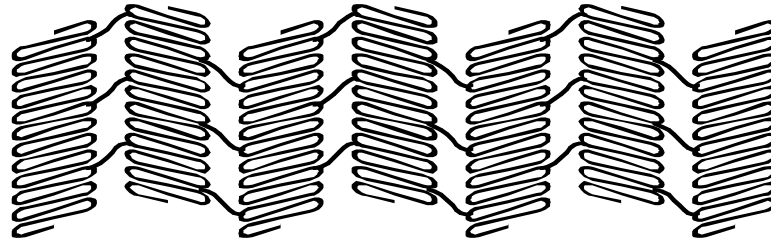
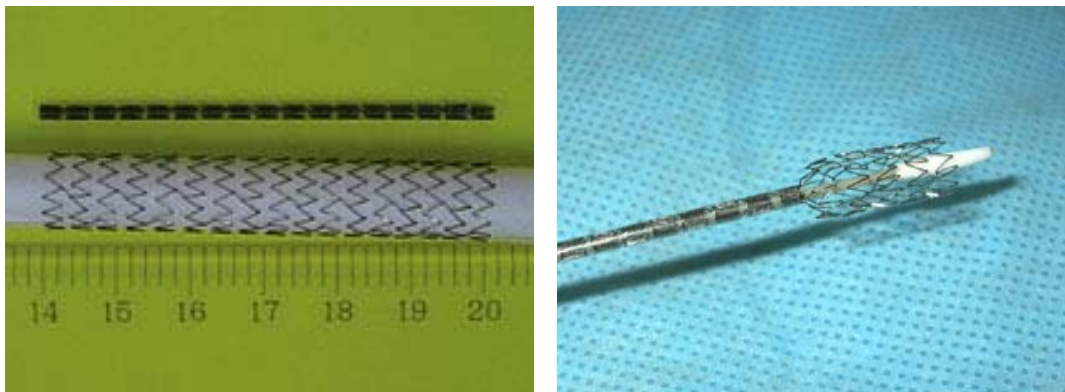


Fig.1. A Schematic Drawing of the Original Stent

5.2 Appearance

Non-expanded (2 mm in diameter) and expanded states (10 mm in diameter) are shown in Figure 2.



The stent is not bult into catheter.

The stent is pushed out from a catheter.

Fig.2. Non-Expanded and Expanded States

5.3 Post electro polishing

The shape memory alloy pipe (2 mm in diameter and about 0.2 mm thick) is processed numerically to make the stent using a laser beam and is polished electrically. An electron micrographic photograph of a 6 mm ϕ stent is shown in Figure 3.

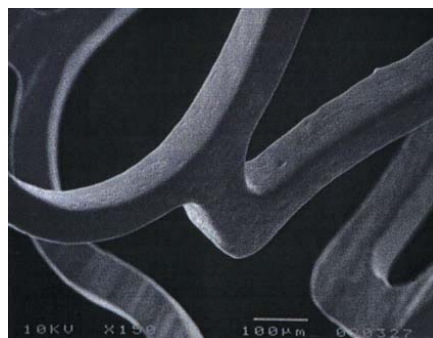


Fig.3. Micrographic Photograph of Post Electric Polishing

5.4 Design Shape

The design shape items made use of organic curves and basic arts as follows.

(1) Wave cycle on circumference is short (12 cycles).

If the wave cycle on the circumference is not short (e.g. 6), the wave length must be long to keep expandability and flexibility to comply smoothly to various anatomical bends is lost.

(2) Few struts on the circumference (3 struts, intervals of 120 degrees on the circumference).

If there are many struts the bending characteristic is lost. Three struts are the minimum number for a stent.

(3) Continuous construction using free curved lines

The wave-profile and strut-profile are constructed by free curved lines, not by straight lines. When it is bent, a thrust component would be generated to alleviate the resistance of bending stress. It would have flexibility and pressure on the arterial wall is alleviated

(4) Top of the wave-profile has a circular shape.

It should have a smooth surface to prevent injury to the vessel.

(5) Wave-profile articulation has about a 15 degree inclination angle

If built into a catheter (2 mm in diameter), it should have flexibility and bend smoothly and follow various bends in the vessel. Track-ability should be good.

(6) Wavy wire width varies continuously

The wavy wire width is wide at the top and narrow at the middle. When it expands, it should have good strength and alleviate concentrated stress.

(7) A strut connection spot should be kept slightly away from the top of the wave

When the stent expands, extension will be not strongly affected by struts.

(8) A wave connection spot by a strut should be separated by a 1.5-2 pitch from the next wave connection spot.

When the stent expands, one wave should be in phase with the next wave. When it is bent, the top of the wave wires should not contact (Fig.4).

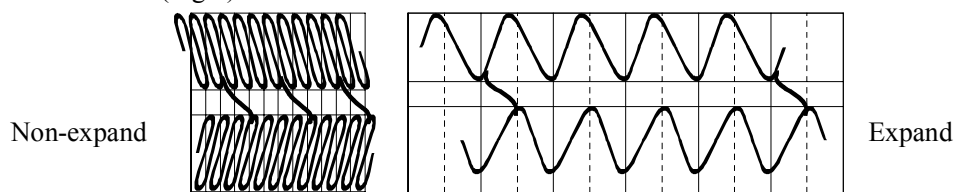


Fig.4. A Wave Connection Spot by a Strut

6.0 Evaluation

We examined the mechanical properties of the new stent (Sendai Stent) compared with available other stents.

6.1 Flexibility

We tested the flexibility of an expanded stent (10 mm ϕ). A plastic tube was inserted into the inside wall of the stent and was bent in various ways. The results are shown in Figure 5. Good flexibility was shown. We then tested the flexibility of non-expanded stents (2 mm ϕ) by hand. It bent smoothly in various directions.



Fig.5. Test of Flexibility of Expanded Stent

6.2 Bore holding

We examined the holding property of the bore of a stent (10 mm ϕ) when bent 180 degrees compared with 3 overseas products (Memotherm, Smart Stent, JO Stent). The internal diameter was changed step by step to bend and the bore diameter measured. The results are shown in Figure 6. When the interval diameter was 25 mm, the diameter of all of stents was about 9-10 mm. When the internal diameter was 2 mm, the Sendai Stent kept 9 mm in diameter. Other stents were 4-8 mm in diameter, and did not hold the original diameter. The developed stent has superior bore holding properties and good flexibility.

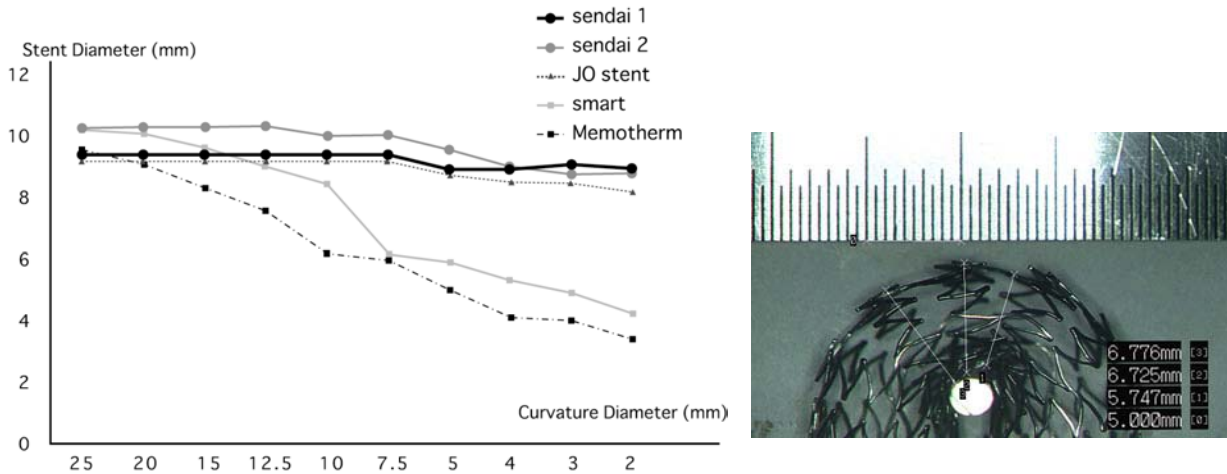


Fig.6. Holding Property of the Bore of a Stent When Bent 180 degrees

6.3 Radial Strength

The hydrostatic pressure was measured with a pressure gauge to find the radial strength compared with 3 overseas products (Memotherm, Smart Stent, JO Stent). The radial strength was measured when the external diameter shortened in steps from 10 mm to about 4 mm in diameter. It was, then, measured when the diameter was extended from about 4 mm to 10 mm. The results are shown in Figure 7. The radial strength of the Sendai Stent was comparable to other stents. There is sufficient radial force from each strut to ensure vessel patency, and it does not lose its expanding force.

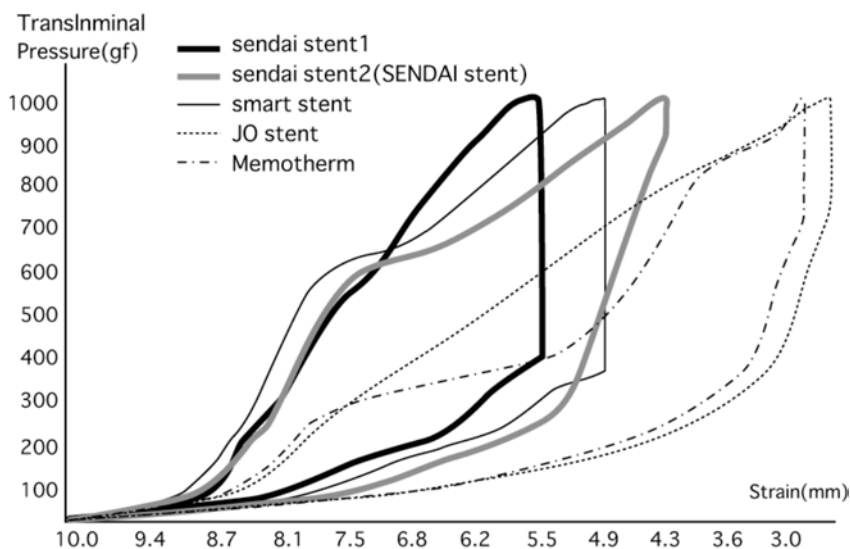


Fig.7. Radial Strength measurements (Hysteresis curve)

6.4 Axial length

When expanded 4-5 times, the change of axial length was slight (about 90% of the original length).

6.5 Biological effects

The mechanical properties of stents are important parameters in stent design. There must be resistance to pressures and forces generated by elastic arterial recoil and vascular spasms. We are examining the biological effects of the new stent in experiments with animals and comparing them with overseas stents. We feel that the new stent has good biological effects compared with other stents and should be available for clinical use.

7.0 Discussion

The new product model has conspicuous flexibility, expansion and bending properties compared with other stents in the world. When bent 180 degrees, the cylindrical mesh-shape is maintained. The cylindrical mesh-shape flexibly follows the bending vessel. When expanded 3-6 times, radial strength is kept and it does not lose its expanding force. If built into a catheter (2 mm in diameter), it bends easily. Its superior flexibility complies smoothly to the anatomy, minimizing the straightening force to the artery without kinking. It satisfies clinical demands. It is estimated that the shape design applying organic curve and basic arts (8 items) was valuable, and comfortable to anatomy. Especially, the free curved line and a little angle of inclination was available. The design shape has Oriental features that are different from Western features.

The mechanical properties of stents for clinical use are diverse and more construction and design procedures need to be developed. Establishing the most suitable design method for stent models according to various clinical demands is needed. It is thought that the role of product design in the field of medical engineering is important and has many possibilities.

8.0 Conclusion

- (1) The original product model has conspicuous flexibility, expansion and bending properties compared with other stents in the world. It will be comfortable to the anatomy.
- (2) It satisfied the following clinical design demands.
 - a) Must maintain its cylindrical shape when bent 180 degrees.
 - b) Be flexible and comply smoothly with various anatomical bends.
 - c) Have a smooth surface and not injure the arterial wall.
 - d) Must not lose its expanding force when expanded 3-6 times.
 - e) Only a slight change in axial length when expanded 3-6 times.
 - f) Must also bend easily when it is 2 mm in diameter.
- (3) The design shape applying organic curve and basic were valuable. Especially, the free curved line and a little angle of inclination were available.
- (4) We are examining the biological effects of the new stent .We feel that the new stent shows good biological effects compared with other stents and should be available for clinical use.
- (5) The most suitable design method for stent models according to various clinical demands must be established.
- (6) The role of product design in the field of medical engineering is important and has many possibilities.

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References

- 1) Stephan H. Duda, Jakub Wiskirchen, Gunnar Tepe, Michael Bitzer, Theodor W. Kaulich, Dieter Stoeckel, Claus D. Claussen. Physical Properties of Endovascular Stents: An Experimental Comparison. *JVIR* 2000; 11, pp. 645-654(2000)
- 2) Piolax Medical Devices, INC. Special Quality and Application of Shape Memory Alloys. pp64(2002)
- 3) Tadashi Ishibashi, Hiroshi Nashihara. Development of Self-Expanding Nitinol Stent with Conspicuous Bending Properties(12557073). The Report of Research which was Supported by Grants-Aid for Scientific Research in Japan (2000~2002) (2003)
- 4) Tadashi Ishibashi, Takayuki Yamada, Akihiro Satoh, Hiroshi Nashihara. The Sendai Stent, A New Self-Expanding Nitinol Stent :The Experimental Results and Early Clinical Experiences. 22 International Congress of Radiology 2002 July Mexico (2002)