INVESTIGATION OF DESIGN PARAMETERS AFFECTING ON MECHANICAL PROPERTIES OF CORONARY ARTERY STENT MADE BY SHAPE MEMORY ALLOYS

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ABSTRACT

This research aims to fabricate prototype of coronary artery stent made from NiTi shape memory alloys by braiding method. The design parameters are number of wires and braiding angle, effects of such parameter is investigated. NiTi wire with diameter of 0.2 mm was prepared. The length and diameter of braiding stent were fixed at 30 mm and 4 mm, respectively. In order to obtain the optimum force, the number of wire was varied ranging from 12 to 36 wires, while braiding angle was varies between 35.43 to 85.01 degree. Heat-treatment was carried out at 823 K for 10 minutes in order to obtain shape setting and transformation temperature below body temperature. Mechanical properties were evaluated by three point bending test and radial compression test under temperature of 37 degree. It is found that with increasing braiding angle and the number of wire, both bending force and radial compression force increase. However, it is noted that the number of wire have greater effect on both bending force and radial resistive force under high braiding angle range above 60 degree. It is found that 36 wires stent with braiding angle of 75.03 degree shows the maximum value of bending force and radial resistive force which is equaled to 4.30 N and 2.76 N, respectively. So, ideal stent needs to have high radial resistive force to resist the load from artery wall and low stiffness to bend in the blood vessel during the delivery process. Then, more investigation and comparison with commercial stent will be required.

INTRODUCTION

At present the cardiovascular disease is the main cause of death of population around the world. This disease causes vessel closing by plague thus resulting in heart attack. To avoid tissue damage from heart attack, stent can help to treat patient. It expands the narrowed vessel and allows blood to flow [1]. Nickel-Titanium based Shape memory alloy(nitinol) are widely used to created self-expanding stent for treat Atherosclerosis patients. Nitinol Stent can be produced by laser-cutting process and braiding process. Laser cutting has disadvantage since the cost is expensive and heat effect from laser can change properties of shape memory effect which is very sensitive to heat-treatment [1]. So, braiding process has benefit when manufacturing in a large scale and easy to control the property of stent itself. [2]. There are many researches making comparison between braiding stent and other types of stent, however, the systematic experiment data was not published because of the confidential [3].

The aim of this study is to investigate the effect of design parameters in braiding process such as number of wires and braiding angle on mechanical properties of self-expanding nitinol stent. Moreover, radial resistive force and three-point bending force were observed.

MATERIALS AND METHOD

The raw material used to produce the stent is commercial Nickel-Titanium wire with diameter of 0.2 mm. The atomic ratio of Nickel per Titanium is 50.81:49.19 %at. The stents were made by braiding machine with condition shown in Table 1. The braiding angle was observed using optical microscope (Olympus NX-510). The stents were annealed at 823 K for 10 minutes. Heat-treatment was carried out in a furnace under Ar atmosphere. Transformation temperatures were detected by Differential Scanning Calorimeter (DSC). During the DSC test, temperature varied in range -50 °C to 100 °C with cooling and heating rate of 10 °C/min. The radial resistive force was determined by using Mylar loop [4]. The stent were loaded to reduce diameter to 60% of nominal diameter and the force recovery was measured. To study load-deflection behavior when the bending moment is applied, three-point bending tests were performed. Three-point bending tests were performed under ASTM F-2507 standard [5]. The span of the bending test was 21 mm. Specimens were loaded to a maximum deflection of 4.2 mm. All the tests were performed with texture analyzer machine (Stable Micro System Co., Ltd.) in water chamber at temperature of 37 °C.

Table 1. Conditions of stent fabrication

	Number of wires	Picking up speed (mm/s)
Wire diameter 0.2 mm	12 wires	1.01
		2.16
	24 wires	3.24
		4.32
	36 wires	5.40
		6.48

*Stent Length 30 mm. Stent diameter 4 mm.

RESULTS AND DISCUSSION

Transformation temperature

Transformation temperatures of fabricated NiTi stent were detected by DSC. Fig. 1 shows the heat-flow under cooling and heating obtained from NiTi wire heat-treated at 823 K for 10 min. In order to obtain superelasticity, NiTi alloy with transformation temperature range below body temperature is required. From the DSC curves, it is confirmed that specimen shows transformation temperature range lower than the body temperature.

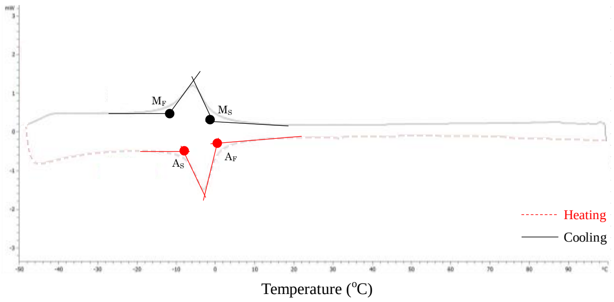

Fig. 1 DSC curves of NiTi alloy wires used for fabricating stent

Braiding angle

Braiding angle was observed with optical microscope. Table 2 shows the braiding angle of stent after shape setting process. With increasing of pick up speed, the braiding angle decreases until pick up speed of 5.40 mm/s. After this speed, the structure of stent cannot hold itself and the wires detach out. It is noted from this experiment that the minimum braiding angle is limited around pick up speed of 5.40 mm/s.

Table 2. Braiding angle of the specimens after shape setting process

Number of wires	Picking up speed (mm/s)	Average Braiding angle (degree)	SD
12 wires	1.08	85.01	3.06
	2.16	75.52	3.67
	3.24	66.03	2.95
	4.32	55.80	3.14
	5.40	46.30	3.18
	6.48	-	-
24 wires	1.08	80.23	3.50
	2.16	69.65	2.78
	3.24	59.85	3.68
	4.32	48.84	2.84
	5.40	37.89	4.01
	6.48	-	-
36 wires	1.08	75.03	2.53
	2.16	65.43	2.98
	3.24	54.13	2.29
	4.32	44.53	2.09
	5.40	35.41	2.56
	6.48	-	-

Radial resistive force

Fig.2 shows the radial resistive forces of 12 wired-stent with various braiding angle obtained during circumferential compression load. This force is very important in order to evaluate the stability of stent under compression load from movement of blood vessel. Fig.3 and 4 show those values of 24 and 36 wired-stent, respectively. It is seen that with increasing braiding angle, the resistive force increases. Moreover, with increasing the number of wires, the resistive force also increases. The effect of number of wire on resistive force seems to be greater than those of braiding angle. It found that highest value of radial resistive force is 2.76 N from 36 wires stent with angle 75.03 degree which is shown in Fig. 5.

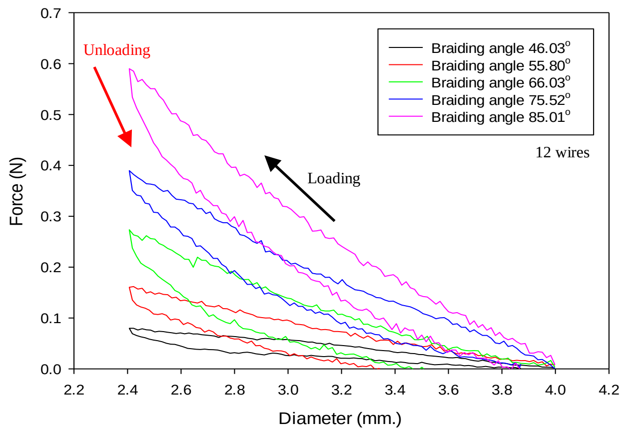

Fig. 2 Load-unloading curves obtained from 12 wired-stent under compression test

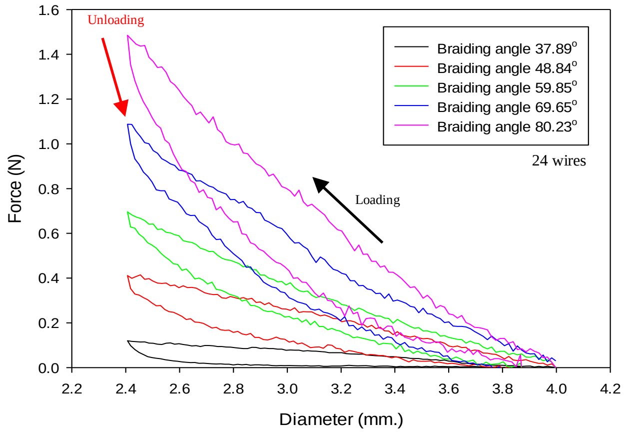

Fig. 3 Load-unloading curves obtained from 24 wired-stent under compression test

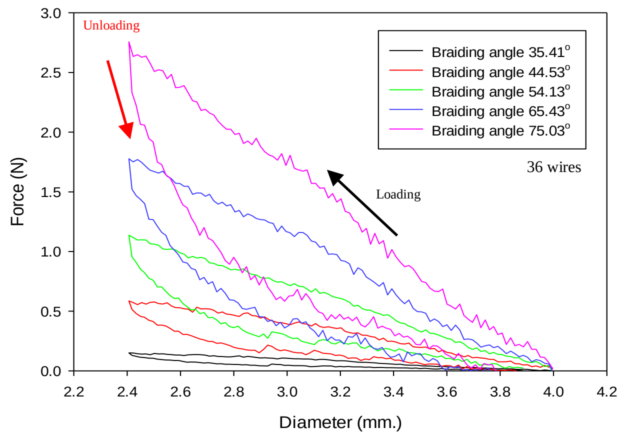

Fig. 4 Load-unloading curves obtained from 36 wired-stent under compression test

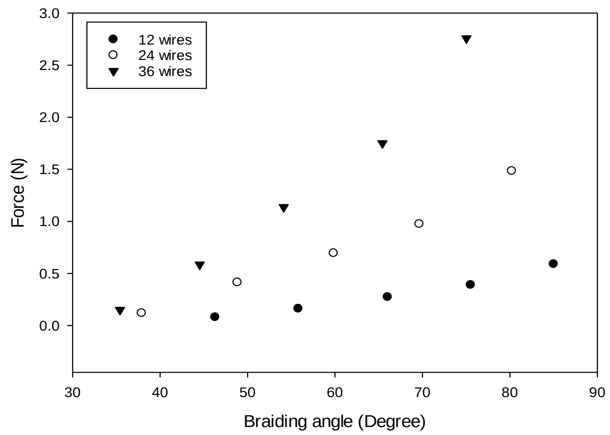

Fig. 5 Maximum radial resistive force of stent with various braiding angle

Three-point bending force

The load deflection curves of stent indicated the bending characteristics of stent during movement of blood vessel. Fig. 6 - 8 show the bending behavior of braiding stent with various braiding angles and number of wires obtained from three-point bending tests. It is obvious that with increasing the braiding angle and number of wire resulting in higher bending force. In the other hand, number of wire has greater effect at high braiding angle above 60 degree. It is able to see from Fig. 9 that stent with 36 wires and braiding angle of 75.03 degree reveals the highest bending force. It is noted that stents with low braiding angle shows relatively unusual curve since the slip between wire might be occurred.

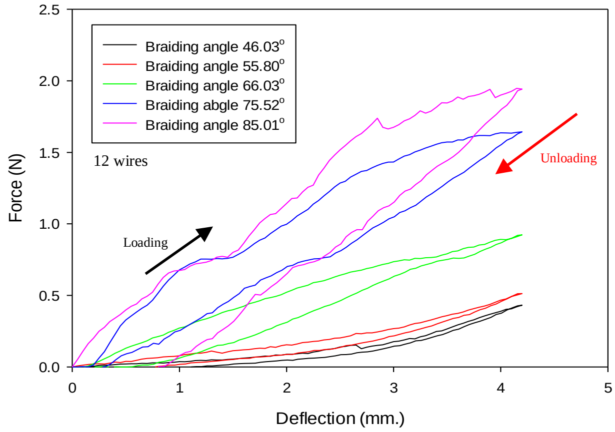

Fig. 6 Load-deflection curves of 12 wired-stent with various braiding angles under three point bending test

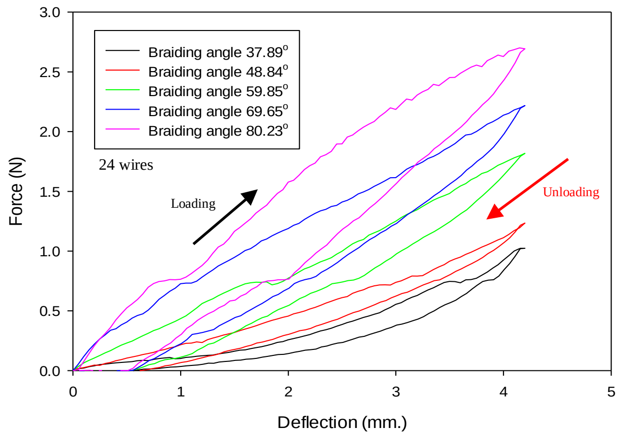

Fig. 7 Load-deflection curves of 24 wired-stent with various braiding angles under three point bending test.

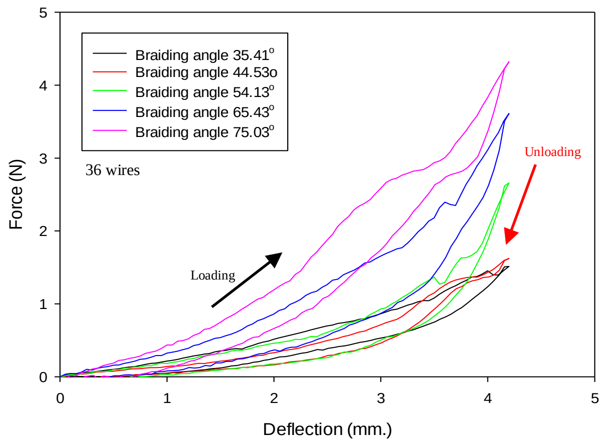

Fig. 8 Load-deflection curves of 36 wired-stent with various braiding angles under three point bending test.

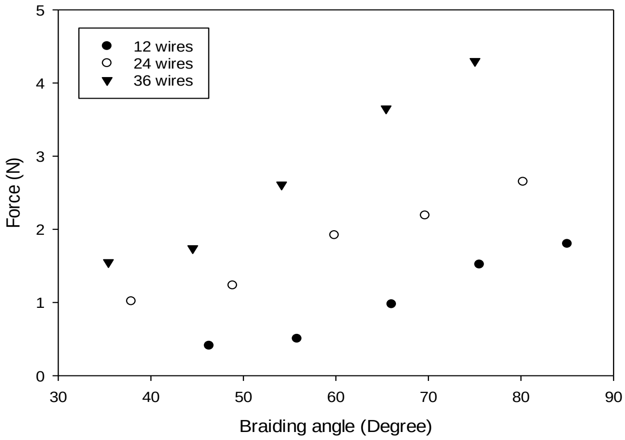

Fig. 9 Maximum bending force obtained from stent with various braiding angles and number of wire

CONCLUSION

In order to fabricate the nitinol braiding stent, two principle factors, (Braiding angle and number of wire) should be carefully determined to investigate their effect on mechanical properties. Increasing of braiding angle and number of wire result in increasing of both radial resistive force and three-point bending force but the number of wire has greater effect under high braiding angle range above 60 degree. Moreover, low braiding angles show the slip mechanism that causes structure of stent collapsed. It is found that 36 wired-stent with braiding angle of 75.03 degree shows the maximum value of bending force and radial resistive force which is equaled to 4.30 N and 2.76 N, respectively. So, ideal stent needs to have high radial resistive force to resist the load from artery wall and low stiffness to bend in the blood vessel during the delivery process. Then, more investigation and comparison with commercial stent will be required.

ACKNOWLEDGEMENT

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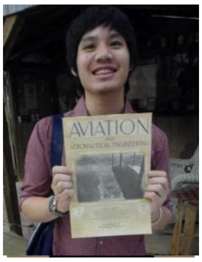

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