Angle–Torque Transmission Characteristics of Ti–Ta–Sn Alloy Guidewire

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As a simulated blood vessel circuit, a silicone tube was introduced into the groove of a circuit constituted by a curved line of 90° combined with a radius of curvature of R20 mm. The rotational angle trackability and torque transmission performance in this simulated blood vessel circuit were compared for core material bases of stainless steel and Ni–Ti alloy commercial guidewires and of a Ti–Ta–Sn alloy. According to the load–deflection curve, on protruding by 2 mm, the highest load was measured for stainless steel; however, plastic deformation was observed after unloading. The Ni–Ti alloy exhibited higher load values than the Ti–Ta–Sn alloy, the latter showing a load as small as 2.2 N; however, after unloading, the displacement was fully recovered in both cases. The best and worst rotational angle trackabilities were observed for Ti–Ta–Sn and Ni–Ti alloys, respectively. The proximal tip side torque was large in the stainless steel and Ni–Ti alloy, whereas the Ti–Ta–Sn alloy exhibited a small value. The distal tip side torque was the largest in stainless steel, whereas Ni–Ti and Ti–Ta–Sn alloys showed almost similar values. Comparing the results of torque loss, Ni–Ti and Ti–Ta–Sn alloys exhibited the largest and smallest torque losses, respectively. The results indicated that the rotational angle trackability of the Ti–Ta–Sn alloy is higher than that of a commercially available guidewire core, while showing the smallest torque.

1. Introduction

Currently, intravascular treatments using guidewires, catheters, and stents represent widespread means for treating cardiovascular diseases. A guidewire plays an important role when inducing a catheter to the site of the treatment. Therefore, it is important to understand the mechanical characteristics of a guidewire.1,2 There are various requirements concerning a guidewire, namely, tip flexibility and shape retention are required to permit passage through a tortuous blood vessel, protrusibility is necessary to introduce a guidewire inside a blood vessel, and torque controllability is needed to smoothly transmit the rotation of a proximal portion to the distal end.3 At present, stainless steel or Ni–Ti alloys are used as guidewires, both having advantages and disadvantages. When using a substance with a high elastic modulus and plastic deformability, such as stainless steel, as a core material, the vessel walls may be damaged in the intricately curved portions of the blood vessel. Because of plastic deformation, there is the additional problem that the operability such as the transmission of a rotational force and vascular selectivity deteriorates. However, the Ni–Ti alloy guidewire exhibits superelastic characteristics and thus excellent flexibility and shape recovery; however, because of its low rigidity, poor protrusibility, and torque controllability, its application is difficult in small affected sites. There is a further concern related to the allergic effect of Ni in the alloy.4

The Ti–23Ta–3Sn (at%) (Ti–Ta–Sn) alloy developed by the authors is a Ni-free β-type titanium shape memory alloy. The temperature of transformation is as high as 423 K, and superelasticity is not observed at room temperature. However, it is possible to obtain high strength (1360 MPa), low Young’s modulus (43 GPa), and high elastic strain limit (2.6%) by an optimized heat treatment (723 K, 1 h). In addition, the material exhibits high corrosion resistance3 and a non-magnetic property. The visibility confirmation using transmission X-rays is slightly less sharp than that with Pt-8W but sharper than that with the Ni–Ti alloy, demonstrating the excellent characteristics in X-ray visibility.6

In this study, we compared the rotational angle trackability and torque transmission performance in a simulated blood vessel for stainless steel and Ni–Ti alloy commercial guidewires as well as for the Ti–Ta–Sn alloy in the core material base.

2. Experimental Procedure

2.1 Tested materials

As for the Ti–Ta–Sn alloy test material, after melting three 25 g button ingots using an arc melting furnace, they were minutely cut, the oxide film on the cut surface was removed, and 75 g of a rod-shaped ingot was formed by double melting. After a homogenizing treatment of the ingot was performed in vacuum at 1127 K, cold forging was used to fabricate a wire of φ3.5 mm. Subsequently, wire drawing was achieved in a die wire-drawing machine with the intermission of intermediary annealing (723 K) to produce a core material of φ0.34 mm. As a result of having performed phase identification by the X-ray diffraction (XRD), α aspect and Ti3Sn aspect were detected from heat-treated Ti-Ta-Sn.6 For comparison, by removing the resin coating of the core material of commercially available guidewires, φ0.34 mm stainless steel (SUS304) and the Ni–Ti alloy (Ni-49Ti) were used as the core material.

2.2 Simulated blood vessel circuit

As illustrated in Fig. 1, the simulated blood vessel circuit used in the experiment was prepared by forming a groove 2.2 mm wide and 2.2 mm deep in a polycrystalline resin of 100 mm × 100 mm constituted by a curved line of 90° combined with a radius of curvature of R20 mm.7 A silicon tube (Helix Medical) with inner and outer diameters of 1.0 and 2.2 mm, respectively, was inserted into this groove to configure the simulated blood vessel circuit.
2.3 Three-point bending test

The distance between two supporting members was 14 mm, and the radius of curvature was R2.5 mm. The load was measured when pressing to 2 mm to obtain the load–deflection curve. The experiments were performed at a pressing rate of 0.125 mm/s.

2.4 Rotational angle trackability and torque transmission performance

Figure 1 presents a schematic of the experimental apparatus. To measure the rotational angle trackability and torque transmission performance, a PT-8000G guidewire transmission measuring instrument (Pro-Tech Co., Ltd.) was used. The proximal end (proximal tip) with the distal end (distal tip) of the guidewire were fixed to the pin vise of the measuring instrument. The proximal end side sensor consisted of an AC servo motor and rotary torque sensor, and the sensor shaft was automatically rotated by the servo motor to measure the load torque. To the distal end side sensor, a non-contact type encoder for transmission angle measurement and a torque detection load cell for distal end torque measurement were mounted. The support of the rotational axis of the distal end measuring sensor had an air bearing to eliminate measurement loss due to friction. The resolution of the torque-measuring instrument was 0.1 and 0.01 mN·m. at the proximal and distal end sides, respectively. Three values of 3, 6, and 9 rpm were selected for the rotational speed of the proximal end side, and the experiments were conducted by rotating the proximal end side by 360°.

3. Results and Discussions

3.1 Three-point bending test

The load–deflection curve when pressing to 2 mm is shown in Fig. 2. For stainless steel, which has the highest modulus, the load was as small as 2.2 N. Moreover, as the Ti-Ta–Sn alloy exhibits a high elastic strain limit, after unloading, the displacement was completely recovered. Owing to its high modulus, stainless steel has excellent protrusibility; however, unlike Ti alloys, it is easily susceptible to plastic deformation, and on application of a load above the elastic limit, plastic deformation occurs, whereby the operability is extremely deteriorated. The Ni-Ti alloy exhibits superelasticity and the Ti-Ta–Sn alloy has a high elastic strain limit; hence, these alloys show high flexibility, which is considered suitable for a breakthrough in stenosis.

3.2 Rotational angle trackability

Measured with the PT-8000G guidewire transmission measuring instrument, the results of the rotational angle trackability of the stainless steel and Ni-Ti and Ti-Ta–Sn alloys are presented in Figs. 3, 4, and 5, respectively. At a rotational speed of 3 rpm, the best rotational angle trackability was observed for the Ti-Ta–Sn alloy; however, because of its high elastic strain limit, when the driving angle was small, the angle gradient of tracking was small. However, the angle gradient of tracking increased with the driving angle. The worst rotational angle trackability was observed for the Ni-Ti alloy. Because of the superelastic property of the Ni-Ti alloy, a sudden whipping phenomenon of tracking occurred at the distal end side near 310°. Almost the same results were obtained at rotational speeds of 6 and 3 rpm; however, when all the materials started with an increased angle gradient of tracking, the angle decreased at the proximal end side. Moreover, in the Ni-Ti alloy, the whipping phenomenon was not observed at 6 rpm. At a rotational speed of 9 rpm, the stainless steel and Ni-Ti alloy exhibited almost the same behavior as that at 6 rpm; however, the tracking angle gradient of the Ti-Ta–Sn alloy was slightly larger. The effect of the rotational speed was small in stainless steel; on the other hand, for the Ni-Ti alloy, lower rotational speeds resulted in larger tracking angle gradients. In the Ti-Ta–Sn alloy, in contrast to the Ni-Ti alloy, the angle gradient of tracking increased with rotational speed. According to these results, it may be inferred that because of the high rigidity of stainless steel, the effect of the rotational speed is small. The best rotational angle trackability was observed for the Ti-Ta–Sn alloy, which is attributable to the reduced frictional resistance to the simulated blood vessel wall of the
curve part resulting from this material exhibiting the lowest stiffness. The low rotational angle trackability of the Ni–Ti alloy is ascribable to superelasticity.

### 3.3 Torque transmission

The measurement was performed with the PT-8000G guidewire transmission measuring instrument, and the torques at the proximal and distal end sides of the stainless steel and Ni–Ti and Ti–Ta–Sn alloys are shown in Figs. 6, 7, and 8, respectively. The difference between the torque of the proximal and distal end sides was considered as the torque loss, and the results are presented in Figs. 9, 10, and 11, respectively.

The torque did not have the big change by the difference in rotational number. The proximal end side torque was large in the stainless steel and Ni–Ti alloy, whereas the Ti–Ta–Sn alloy exhibited a small value. The distal end torque in the stainless steel was the largest. The results for Ni–Ti and Ti–Ta–Sn alloys were almost the same. In comparison, the Ni–Ti alloy exhibited the largest torque loss, whereas the Ti–Ta–Sn alloy exhibited the smallest torque loss. Since stainless steel exhibits high rigidity, it shows the largest distal end torque; however, because of its easy plastic deformation, torque loss...
is large. The Ni–Ti alloy exhibits a higher elastic modulus than the Ti–Ta–Sn alloy; however, the proximal end side torque is large, and as it shows a superelastic behavior, the torque is less likely to be transmitted to the distal end side. Even though the proximal end torque for the Ti–Ta–Sn alloy was the smallest owing to its low elastic modulus, because of the absence of a yield point in the stress–strain curve as for the Ni–Ti alloy, it is believed that despite the small torque at the proximal end side, the torque loss at the distal end side is almost the same as that in the Ni–Ti alloy.

4. Conclusion

On the basis of tests comparing a Ti–Ta–Sn alloy with stainless steel and Ni–Ti alloy commercial guidewire core bases, the following conclusions were drawn.

(1) According to the load–deflection curve, the stainless steel exhibited the highest load when protruded by 2 mm; however, the wire underwent plastic deformation after unloading. The Ni–Ti alloy exhibited a higher value on the order of 0.7 N than the load of the Ti–Ta–Sn alloy, which exhibited a small load of 2.2 N; however, in both cases, the displacement was completely restored after unloading.

(2) The rotational angle trackability was the best for the Ti–Ta–Sn alloy and the worst for the Ni–Ti alloy.

(3) The proximal end torque was large in the stainless steel and Ni–Ti alloy, whereas the Ti–Ta–Sn alloy exhibited a smaller value. The distal end torque was the largest in the stainless steel; Ni–Ti and Ti–Ta–Sn alloys exhibited almost similar values. The torque loss of the Ni–Ti alloy was the largest and that of the Ti–Ta–Sn alloy was the smallest.

According to the above results, it has been confirmed that the Ti–Ta–Sn alloy is superior in rotational angle trackability than commercially available guidewire cores, with the smallest torque loss.

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