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Mechanical characteristics of nitinol stent elements

Andrey Savchenko, PhD (Engineering)*[1], Pavel Bogdan, PhD (Engineering)[2], Vladimir Minchenya, PhD (Engineering)[3], Heorgiy Viarshyna, PhD (Engineering)[4], Alexandr Ulasevich, MSc (Engineering)[5], Sunnat Sattorov, MSc (Engineering)[6].

[1] Head of Department, Belarusian National Technical University, Instrumentation, alsavchenko@bntu.by.

[2] Associate Professor, Belarusian National Technical University, Biomedical Engiheering, pbogdan@bntu.by.

[3] Chief Researcher, State enterprise"Science and technology park of BNTU Polytechnic", Instrumentation, v.minchenya@bntu.by.

[4] CEO, State enterprise"Science and technology park of BNTU Polytechnic", Engineering, dvs_vershina@bntu.by.

[5] Junior Researcher, State enterprise"Science and technology park of BNTU Polytechnic", Biomedical Engiheering, ulasevich.aleksandr@park.bntu.by.

[6] Postgraduate, Belarusian National Technical University, Biomedical Engiheering, limitsunat@mail.ru.

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Abstract:

The article examines the influence of heat treatment conditions, such as device design and wire tension force, on the mechanical characteristics of nitinol wire stent elements. Stent elements are components of an aortic stentgraft for the surgical treatment of aortic aneurysms. It has been shown that with increasing wire tension force, the radial stiffness of the finished heat-treated stent elements decreases. Therefore, it is necessary to fix the wire on the device, providing a minimum tensile force. For experimental studies, samples of Ti-44.48 wire were taken; Ni-49.16; Cu-6.02 from Fukarawa (Japan) with a diameter of 0.45 mm, used for the manufacture of wire frames of stentgrafts. The results obtained will be proposed for implementation in the technological process of manufacturing medical products from nitinol in the Scientific and Technological Park of BNTU "Polytechnic". After production tests, conclusions will be drawn about the advisability of using them in production conditions.

Keywords: Stentgraft, Heat treatment, Mechanical characteristics

1. Introduction:

Innovative technologies that make it possible to improve the results of operations in patients with various types of aneurysms of the thoracic aorta and arch are associated today with intra-aortic stentgrafts. A tubular stentgraft is a tubular cylindrical structure, the basis of which is an elastic metal frame attached to a tissue covering. Self-expanding stentgrafts, when installed in an artery, independently acquire the desired shape, moving into it from the compressed state in which they are located in the introducer of the delivery system. They use the effect of thermal shape memory, that is, they expand when released from the delivery system into an area with a temperature above 30 °C. They are made from nitinol (titanium nickelide), which, depending on heat treatment, can have various properties, including shape memory and unique elastic properties. To form spatial structures from nitinol wire, heat treatment is needed to fix the required shape. The heat treatment mode determines the temperature at which nitinol is in a state of superelasticity, that is, it recreates the shape specified during heat treatment. The Science and technology park of BNTU "Polytechnic" has established serial production of stentgrafts, the design of which contains zigzag elements made of nitinol (Figure 1).

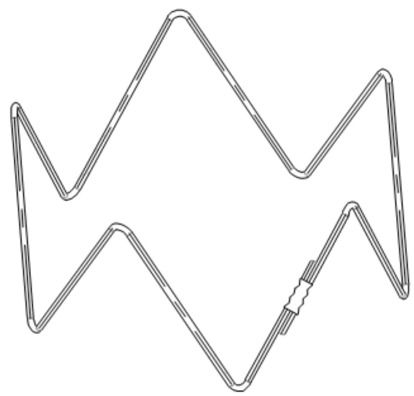

Figure 1 – Nitinol stent element.

While developing the technology for forming the shape of elements, postoperative control of zigzag elements for stentgrafts was carried out at a given temperature. It was found that zigzag elements created on the same device and under the same thermal conditions can have different bending stiffness and in a number of cases it turns out that the rigidity is insufficient for use in stentgrafts.

The purpose of the study is to find ways to solve this problem.

2. Literature Review:

Previously, the authors developed technological processes for the manufacture of stent elements from nitinol wire, and they are known from literature sources (Rubanik, 2018). It is known that for structures obtained from flexible wire, the following work is required: preparation (cutting) of nitinol wire, connecting the ends of the wire by crimping a stainless steel tube or welding, forming the wire in a device (to facilitate forming, the wire is cooled to a temperature of approximately 5...15 °C), heat treatment (holding in an furnace at a given temperature for a given time), assessment of the mechanical characteristics of the obtained samples at fixed temperatures, installation in a delivery system. The individual stages of the technological process are described in various published works. In particular, forming processes are described in (Utela et al., 2007), (Hodgson, 2000), processes for joining wire ends by laser welding (Kush & Kapil, 2019), and heat treatment processes in (Ming, 2001). The authors carried out a number of studies (Minchenya, Savchenko & Gitkovich, 2010; Savchenko, Minchenya V. & Minchenya N., 2012; Khrustalyov et al., 2013; Minchenya & Savchenko, 2014; Minchenya et al., 2015, 2016, 2017, Ulasevich, Savchenko & Minchenya, 2022; Savchenko et al., 2022), which resulted in the production of zigzag elements for stentgrafts and other medical products from nitinol wire.

However, in real production conditions, the undesirable effect described above appeared, this is a change in rigidity in a separate part of the zigzag element, which can be caused by the following reasons:

– uneven heating and cooling of the wire during heat treatment due to multilayer winding;

– uneven wire tension when winding a zigzag element on a tubular device for the same reason;

– change in dimensions and, accordingly, a decrease in rigidity due to the transition to a new layer of winding;

– change in tension due to the difference in the coefficients of thermal linear expansion of nitinol and the material of the device.

For heat treatment, stent elements are placed on multi-site devices in the form of tubes with pins to give the wire a zigzag shape. To increase productivity, the wire is wound in several rows (e. g., 2 rows), each row in several layers (the number of layers reaches ten). The appearance of such a device is shown in Figure 2., the location of the wire on the pins is in Figure 3.

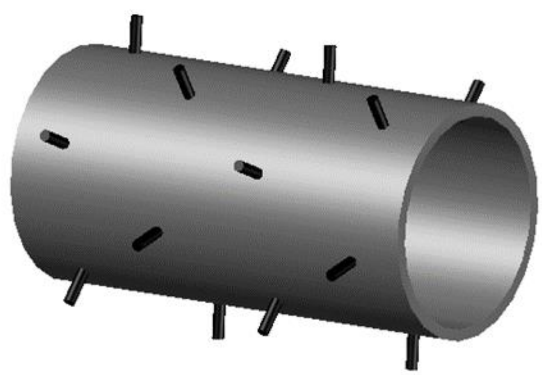

Figure 2 – Wire winding mandrel.

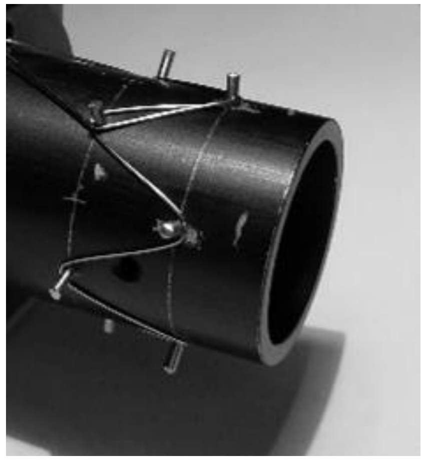

Figure 3 – Winding wire onto a mandrel.

The wire is wound under tension and placed in the furnace directly on the fixture.

However, in real production conditions, the undesirable effect described above appeared, which can be caused by the following reasons:

– uneven heating and cooling of the wire during heat treatment due to multilayer winding;

– uneven tension of the wire during winding for the same reason;

– change in dimensions and, accordingly, a decrease in rigidity due to the transition to a new layer of winding;

– change in tension due to the difference in the coefficients of thermal linear expansion of nitinol and the steel of the fixture.

3. Material and Methods:

For experimental studies, samples of Ti-44.48 wire were taken; Ni-49.16; Cu-6.02 from Fukarawa (Japan) with a diameter of 0.45 mm, used for the manufacture of wire frames of stentgrafts.

Checking the uneven heating and cooling of the wire in the winding layers requires complex research, however, the heat treatment conditions in a special furnace can significantly reduce the manifestation of this factor.

A device was developed (Figure 4), in which the wire was wound onto pins and fixed after setting the tension with a dynamometer. The result was Λ-shaped elements of the same size.

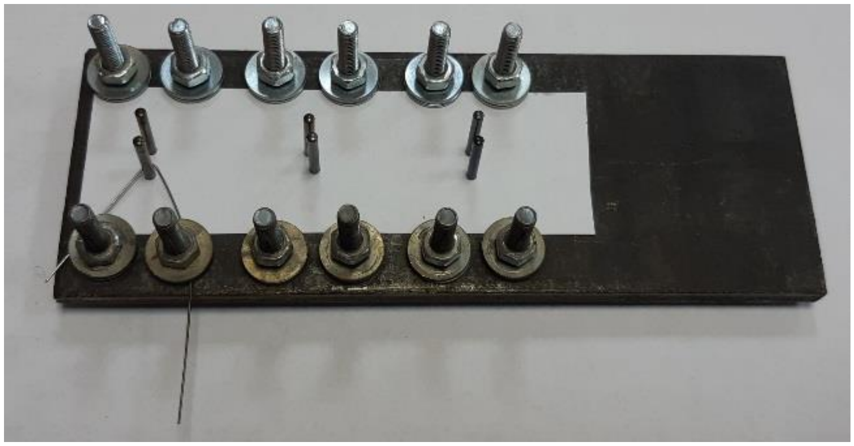

Figure 4 – Heat treatment device.

To create identical conditions in the process of forming shape memory, several zigzag samples with different tensions were simultaneously installed on the mandrel, which, together with the device, were subjected to heat treatment. After this, the samples were removed and subjected to stiffness measurements in a device that made it possible to measure the deformation force of the samples at a given angle, in this case 30° (Fig. 5).

Figure 5 – Measuring device.

4. Results and Discussion:

The results of measuring the hardness of heat-treated samples are given in Table 1.

Table 1 – Deformation force depending on the tension force, N

0	5	10	30	50	70	90
1,7	1,5	1,4	1,2	0,95	0,7	0,45

It can be seen that as the tension increases, the stiffness of the samples decreases. For clarity, this is shown in the graph (Figure 6).

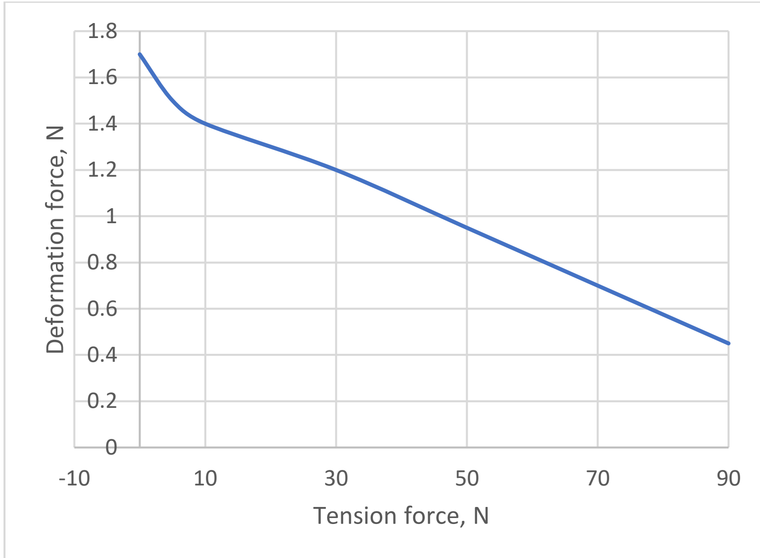

Figure 6 – Dependence of sample rigidity on tension during heat treatment.

The technological features of the heat treatment process do not allow it to be carried out with zero wire tension, since it is difficult to achieve the required shape. (Utela et al., 2007) suggest using special 3D-printed fasteners, but this can cause difficulties in ensuring uniform heating and cooling. When winding, it is necessary to ensure the same tension on all zigzag branches in order to ensure the same rigidity of the elements as a result. To achieve this, some changes to the design of the devices are proposed. In particular, it is proposed to use fewer layers of winding and change the mechanics of tension. These measures should lead to a reduction in friction between the wire and the elements of the fixture and, therefore, increase the uniformity of tension.

At the same time, the results obtained require clarification: whether the increase in the bending rigidity of the wire with a decrease in tension is the result of the nature of the heat treatment or an increase in the bending radius due to a decrease in effort. According to the calculation results, the determining factor is still the influence of heat treatment conditions.

In addition, the following factors should be considered.

The coefficient of thermal linear expansion of nitinol is from $6{,}6 \cdot 10^{-6}$ 1/°C in the martensitic phase to $11 \cdot 10^{-6}$ 1/°C in the austenitic phase. For stainless steel 40X13, the same figure is obviously higher - $12{,}5 \cdot 10^{-6}$ 1/°C. That is, when heated, the tension of the wire will increase due to temperature deformations. This should be taken into account when selecting pretension.

When switching to a new layer of winding, the diameter of the resulting workpiece will increase by double the diameter of the wire. For the study, wire samples with a diameter of 0.45 mm were taken, that is, the diameter from layer to layer will increase by 0.9 mm.

When moving to a new layer, each time the length of the inclined section of the zigzag will increase by approximately 1.3%, respectively, the bending rigidity of this section will decrease by the same amount. By the tenth layer the elongation will be 12%.

Even if you connect the ends of the stent element blank to obtain the same diameter, the zigzag geometry will still be different, which will lead to a difference in the stiffness of the finished stent element. Moreover, when using a blank from layer to layer, the unevenness of the rigidity of the finished stent element in different directions will increase. Therefore, it is necessary to maintain uniform tension of the zigzag around the circumference of the stent element.

5. Conclusion:

It is necessary to change the design of the heat treatment device to ensure wire fixation and uniform zigzag around the circumference of the stent element with minimal wire tension.

When choosing the wire tension force, it is necessary to take into account the coefficients of thermal linear expansion of nitinol and the mandrel material.

The results obtained will be proposed for implementation in the technological process of manufacturing medical products from nitinol in the Scientific and Technological Park of BNTU "Polytechnic". After production tests, conclusions will be drawn about the advisability of using them in production conditions.

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