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DEPENDENCE OF MECHANICAL PROPERTIES OF MITRAL VALVE ANNULOPLASTY RINGS ON ANNEALING MODES

K.Yu. Klyshnikov[1], T.V. Glushkova[1], N.A. Shcheglova[2], A.V. Kostelcev[2], E.A. Ovcharenko[1]

[1] Research Institute for Complex Problems of Cardiovascular Diseases, Kemerovo, Russian Federation
[2] NeoCor JSC, Kemerovo, Russian Federation

Objective: to investigate dependence of the mechanical properties of mitral annuloplasty rings on heat annealing modes. **Materials and methods.** The study evaluates the nature of change in stress–strain curves under uniaxial compression of experimental samples processed at varying annealing temperature, duration and pressure. **Results.** It was noted that higher exposure, temperature, and lower pressure led to increased structural rigidity and strength for small strains. Moreover, the extent of influence of annealing temperature and duration was comparable. A 40% (500–700 °C) change in temperature altered the mechanical properties of the ring – 20% increase in strength. A similar change in heat treatment time (4.5–6.5 min) resulted in a 27% increase in the force required for a 15% compression. **Conclusion.** The experimental dependences presented in the work allow recommending main parameters for heat treatment mode: temperature range 600–700 °C, 10.5 minutes exposure time, and 0.1–0.5 atm air pressure in the furnace chamber.

Keywords: nitinol, annealing, mitral regurgitation, annuloplasty, prosthetic ring.

INTRODUCTION

Chronic ischemic mitral regurgitation (IMR) is quite common and significant complication of myocardial infarction accompanying it in 20–30% of cases [1, 2]. The pathophysiological mechanism of IMR includes adverse remodeling of the left ventricle, dilatation of the fibrous ring and restriction of leaflet mobility, due to, among other reasons, changes in the geometry and properties of the chordal-papillary apparatus [3]. Such conditions require correction, both of ischemia as the root cause, by the technique of myocardial revascularization, and directly of morpho-functional disorders of the mitral valve by prosthetics or annuloplasty [4]. Modern publications and meta-analyzes of large studies comparing prosthetics and mitral valve reconstruction cannot definitely recommend this or that approach [5–7]. In general, most of these studies conclude that there are no significant differences in survival rate, the frequency of deaths associated with the intervention, or the frequency of serious adverse cardiac or cerebrovascular events, focusing on the benefits only for individual groups or for individual indicators [6, 7]. Thus, the choice of optimal surgical tactics for the correction of severe IMR in routine practice depends on a number of clinical and subjective indicators.

Modern trends in the development of rings for mitral annuloplasty are aimed at providing a compromise biomechanics of the fibrous ring with minimizing the stress-strain state in the relaxation phase to minimize the risk of mismatch between the characteristics of the product and surrounding tissues. Such an approach can maximally preserve the three-dimensional architectonics and mobility of the mitral fibrous ring with the possibility of natural deformations during the cardiac cycle and positively effect reduced risk of complications in the form of detachment of the implanted ring and subsequent fistula formation [8–10]. Three types of rings are distinguished by their stiffness: semi-rigid, rigid, and band. Current studies show that in the early postoperative period, semi-rigid rings have advantages over rigid rings; however, long-term clinical observation results show these advantages become less noticeable [6]. Nevertheless, further improvement of approaches and the introduction of new materials in the construction of semi-rigid rings aimed at maintaining the mobility of the fibrous ring can increase their efficiency in the correction of IMR and affect the clinical results of application [11–13]. In this connection we, in the FGBNU (Federal State Budgetary Scientific Institution) Research Institute of Complex Problems of Cardiovascular Diseases, are developing our own design of the mitral valve ring for IMR cases based on a semi-rigid support frame of a material with super elastic properties (nitinol).

MATERIALS AND METHODS

Target of research

The study was targeted at the supporting frames of the designed ring, closed three-dimensional ellipsoidal

Corresponding author: Kirill Klyshnikov. Address: 6, Sosnoviy blvd, Kemerovo, 650002, Russian Federation.
Tel. (923) 516-68-66. E-mail: KlyshnikovK@gmail.com

wire structure of medical titanium nickelide (SE508L-VM). The initial concept of the support ring involves semi-rigid execution in a compartment with a closed loop, which, on the one hand, will ensure its mobility in the systole-diastole cycle, and on the other hand, will reliably maintain the shape of the fibrous ring. All experimental ring frames were made in 30 mm size defined as a longitudinal length. The final form of the supporting frames was given by heat treatment in a metal matrix-mandrel, fixing the three-dimensional geometry of the product. The heat treatment as such was performed in TVF1200X43 (Aktan Vacuum LLC, Russia) tube muffle furnace able to create reduced pressure in the modes shown in Table.

In general, the mode selection for final shaping the support ring included a variation in the temperature (500–700 degrees) and time (4.5–12.5 min), and pressure (0.1–1.0 atm) indicators of heat annealing. In addition, in order to establish the basic dependences of the strength and elastic strain properties on the wire diameter, the supporting frames were made of 0.48 and 1.00 mm wire.

As a control, commercial size 30 semi-rigid rings were used: Physio (Edwards LifeScience, USA), CG Future™ (Medtronic, USA), Memo 3D™ (LivaNova, UK), widely used in surgical practice [14–16].

Table

Characteristics of the annealing modes of the studied annuloplasty rings

Nos.	t, °C	T, min	P, atm	D, mm
1	700	6.5	0.1	0.48
2	600	6.5	0.1	0.48
3	500	6.5	0.1	0.48
4	700	12.5	0.1	0.48
5	700	10.5	0.1	0.48
6	700	8.5	0.1	0.48
7	700	6.5	0.1	0.48
8	700	4.5	0.1	0.48
9	700	6.5	1.0	0.48
10	700	6.5	0.5	0.48
11	700	6.5	0.1	0.48
12	700	6.5	0.1	1.00
13	700	6.5	0.1	0.48

Test procedure

The selection criteria criterion for the optimal mechanical parameters was the physical and mechanical properties of the ring frameworks under uniaxial (longitudinal and transverse) compression. The mechanical properties were measured on a Z-series universal testing machine (Zwick/Roell, Germany) with a 50N nominal force sensor. The test samples were mounted between flat plate holders with subsequent application of a load until 15% strain was achieved (Fig. 1). The load range was chosen empirically as the elastic strain area. Loading and unloading were performed at 50 mm/min. meanwhile, the data on the "force-offset" ratio were obtained, serving to analyze the key mechanical property, i.e. rigidity of the frames.

RESULTS

Assessment of physical and mechanical properties

The main dependences of the mechanical properties of the samples under study on pressure, temperature, and heat treatment time are presented in Fig. 2.

The results of the study show that an increase in exposure, temperature, as well as decrease in pressure led to an increase in structural rigidity and strength in the range of small strains. Similar trends were shown for the transverse direction, however, to a lesser extent as the applied strain was lower, 3.2 mm versus 4.9 mm for longitudinal direction.

The dependence of the mechanical properties of the samples on the wire diameter of 0.48 compared to 1.00 for the same conditions showed the expected increased stiffness for the second option; however, the increase in

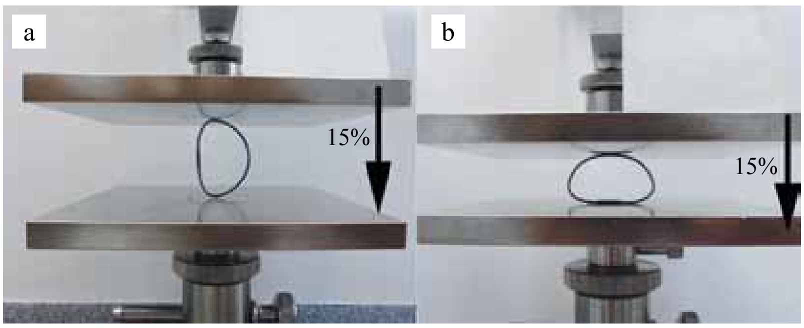

Fig. 1. Mechanical testing of the annuloplasty rings: a – mitral annuloplasty ring mounted between grips of the universal testing machine; b – a similar ring tested in the transverse compression (baseline)

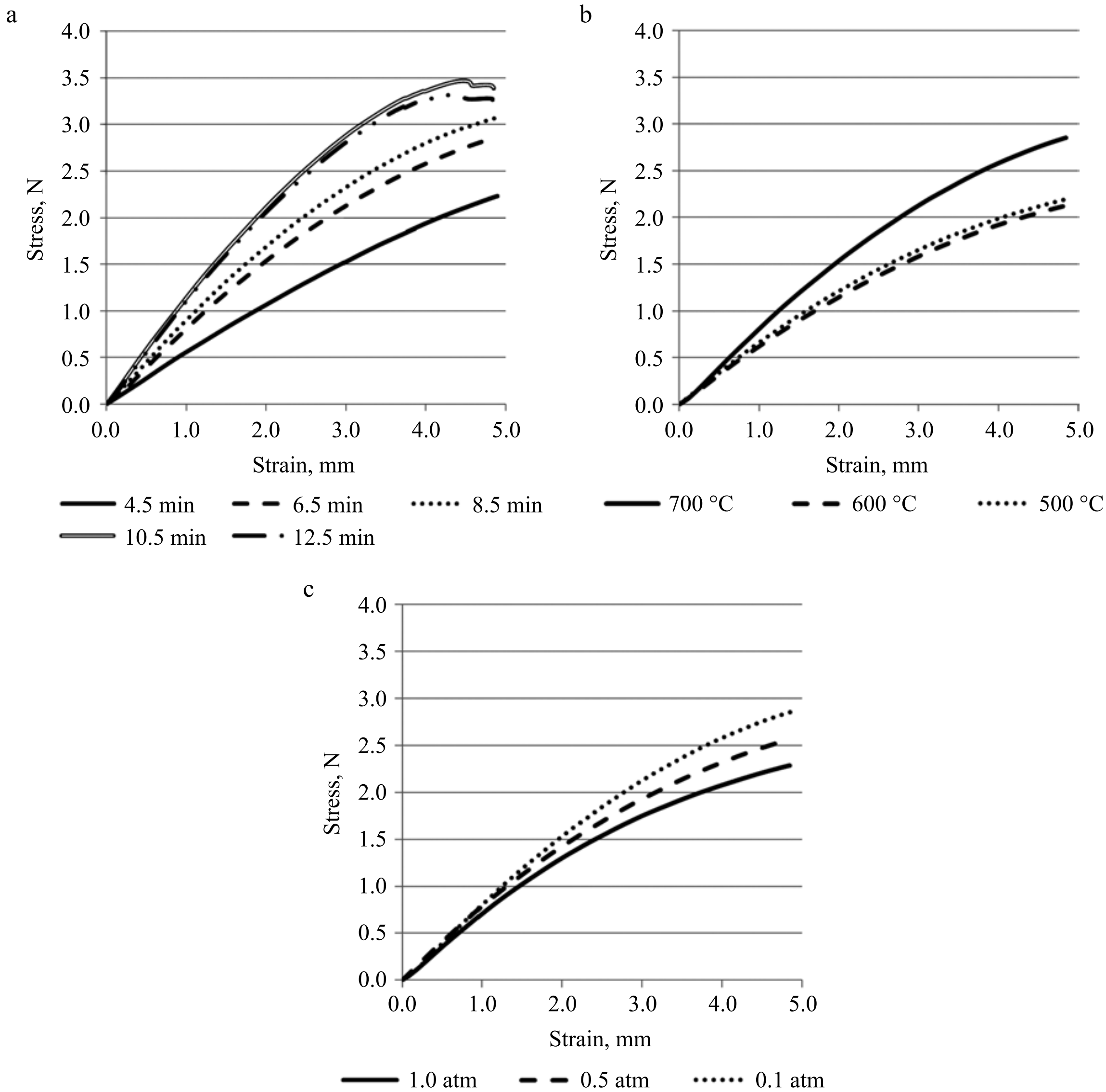

Fig. 2. Dependencies between the mechanical properties of the tested samples and the annealing modes, presented as the stress-strain curves under uniaxial compression in the longitudinal direction by 15%: a – processing time; b – annealing temperature; c – pressure, atm, in the furnace chamber

compression force was disproportionate to the increase in wire thickness. So, with an increase in diameter by 2.08 times, the force required for compression increased by 9.7 times, from 2.44 N to 25.9 N. A similar increase in strength was obtained for the transverse test – by 8.6 times. In this case, the plastic deformation of 38.5% was noted.

DISCUSSION

In general, the results of the study demonstrated a persistent dependence of the properties of the product on the heat annealing mode. Moreover, the degree of influence of temperature and time was comparable in terms of contribution. In the first case, a change in the parameter by 40% (500–700 degrees) caused a change in the mechanical properties of the ring in the form of strength increase by 20%. A similar change in annealing time (4.5–6.5 min) caused a 27% increase in the force required for compression by 15%.

However, it is clear that the variability within each parameter is heterogeneous. An increase in the thermal exposure time by 2 min in the range from 4.5 to 10.5 min always led to an increase in the rigidity of the support ring (Fig. 2), while the transition of 10.5 to 12.5 minutes made no significant changes in the mechanical properties for either the longitudinal or transverse directions. Apparently, a change in the properties of the material with an increase in the heat annealing time is determined only by the metal volume that has time to warm up to the required temperature. Given the high heat capacity, with a short duration of heat treatment, the mandrel matrix did not have time to sufficiently heat up, which led to insufficient heating of the ring itself. The heat treatment process consists in giving the product a new "parent" form without changing the configuration of the crystal lattice [17]. It can be assumed that with a small exposure, an insignificant part of the material of the ring framework under study did not have time to fix the necessary "parent" shape, which, on the whole, did not visually express in the ring geometry but affected its physical and mechanical properties. Thus, for thy present study, it follows that a minimum of 10.5 minutes is sufficient to completely warm up the mandrel matrix and transfer heat energy to the ring itself to completely fix the "parent" geometry when using titanium nickelide wire with a diameter of 0.48 mm.

The features of the physicomechanical response of nitinol are determined by the transformation of the phases of the austenite-martensite crystal lattice and vice versa, providing a high percentage (up to 9–10%) of reversible strain [18]. The determining factor of this transformation is the transition point A_f (Austenite Finish – the final transition to austenite)б the temperature at which the material demonstrates its basic physical and mechanical properties when it is in the austenite phase, i.e. in working order. An important feature is an increase in the stiffness of the material depending on the difference between A_f and the current material testing temperature [19]. For example, at $A_f = 0$ °C and testing at room temperature of 22 °C, the alloy will exhibit greater rigidity than an alloy with $A_f = 17$ °C. It has been shown in the literature for nitinol that the A_f offset is affected primarily by the treatment temperature. Fig. 3 shows that the temperature of the heat annealing significantly shifts A_f, especially after 600 °C [20].

A similar result was obtained in the present study when the temperature changed from 500 to 600 degrees: the properties of the frames did not significantly change, and with an increase to 700 degrees a sharp increase in compression force and rigidity was observed. This effect is due to the characteristics of A_f which can be significantly shifted precisely by high temperature in the range of 600–700 degrees. The heat treatment process itself is also possible at lower temperatures, ranging from 450–550 degrees [17, 22]; however, for this range, on the contrary, an increase in A_f is shown to lead to decrease in stiffness.

Another factor influencing the parameter A_f is the molar composition of the alloy, namely, the nickel – titanium balance [17]. One per cent change in the concentration of free nickel or titanium leads to a shift in the temperature of transition to austenite by 100 °C [23]. At the same time, the air pressure in the furnace chamber which determines the oxygen content during heat treatment and, ultimately, the amount of nickel and titanium oxides formed, indirectly affects the change in the composition of the nickel-titanium alloy. The present study showed that during heat treatment under conditions of normal atmospheric air pressure, a weaker structure was obtained in comparison with the options under reduced pressure (0.1 and 0.5 MPa). The reason for this phenomenon is a decrease in the percentage composition of free nickel and titanium due to the formation of oxides NiO, Ni_2O_3, and TiO_2, i.e. in changing the equibalance state of nickel-titanium. In the initial alloy, the amount of nickel is 50.8% by mass [24] featuring its physicomechanical response, the effect of superelasticity [25]. In the process of oxidation, a change occurs, usually uncontrolled, of the nickel-titanium ratio, which changes the mechanical characteristics due to the offset of the A_f point. Thus, the

a b

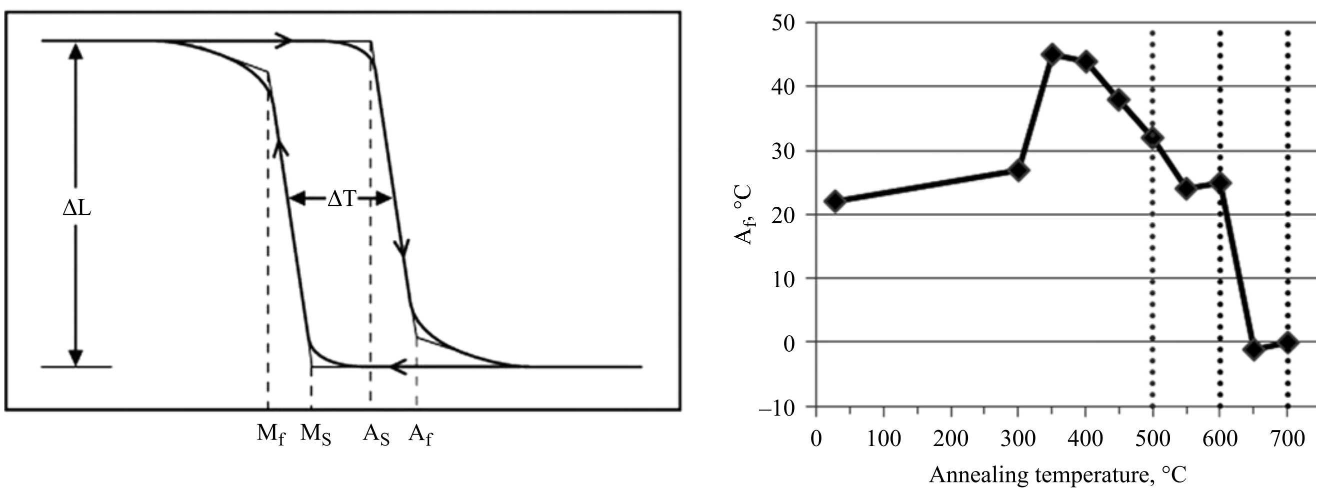

Fig. 3. Nitinol response to temperature: a – the dependence of the nitinol phase state on the temperature; A_s, the initial temperature of martensite to austenite transformation during heating; A_f, the final temperature of martensite-austenite transformation during heating; M_s, the initial temperature of austenite-martensite transformation upon cooling; M_f, the final temperature of austenite-martensite transformation upon cooling [20]; b – A_f offset under the annealing temperature of Ti-50.85 mol % Ni [21]. The dotted lines indicate the annealing modes used in this study: 500, 600 and 700 °C

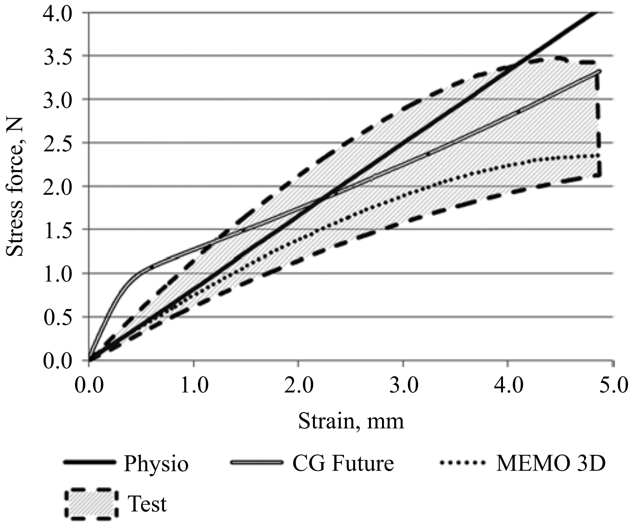

Fig. 4. Analysis of the variability of the mechanical properties of the study samples in comparison with the 30-mm commercial annuloplasty rings: Physio (Edwards LifeScience, USA), CG Future™ (Medtronic, USA), Memo 3D™ (LivaNova, UK)

occurrence of oxides can significantly distort the predicted properties of the final product, increase or decrease its rigidity, which is a negative factor in real production and most likely is leading to rejection of frames with properties altered due to oxidation. It is worth noting that the occurrence of oxides is confirmed visually, by changing color of the surface of the frames to gray, i.e. the formation of titanium oxide TiO_2 [26], which was seen on the frames under study at heat treatment under normal pressure.

Comparison of the physicomechanical properties of the support frames under study with foreign commercial prosthetic rings of similar diameters and purposes showed the similarity of physicomechanical properties at 15% compression (Fig. 4). The clinical results of commercial semi-rigid rings (Physio, CG Future, Memo 3D) [14–16], which are already well established in surgical practice, are presumably due to their elastic deformation properties similar to those of native tissues. With this in mind, it is possible to assume that the developed prosthetic rings will have similar biomechanics.

CONCLUSION

In general, the present study made it possible to determine promising heat treatment modes for further production, taking in mind the conformity with similar commercial devices, annuloplasty rings of world manufacturers. The obtained experimental dependences demonstrate the advantages of the following parameters of the heat treatment mode: temperature range of 600–700 degrees, exposure time from 10.5 minutes, air pressure in the furnace chamber of 0.1–0.5 atm.

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The authors declare no conflict of interest.

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