

TESTING OF PSEUDOELASTIC CARDIOLOGY IMPLANTS

ТЕСТИРОВАНИЕ КАРДИОИМПЛАНТАТОВ С ЭФФЕКТОМ СВЕРХУПРУГОСТИ

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Abstract

A method of testing and stabilization of physical and mechanical properties for TiNi alloy prepared implants used for low-invasive correction of mitral regurgitation is proposed. The method allows to forecast the change of critical points of phase transformations in the material of the implant in the conditions of loading. A special scheme of testing the device by strain cycling has been developed.

KEYWORDS: Ti–Ni, shape memory effect, scheme of testing, strain cycling

1. Introduction

Currently the low-invasive method transcatheter implantation is used for correction of mitral regurgitation [1]. The method is based on the placement of a special mitral annuloplasty device made of alloys with the shape memory effect between the great cardiac vein and the coronary sinus to correct the diameter of the mitral valve and reduce regurgitation.

Before the operation the implantable device is placed in a delivery catheter, resulting device is subjected to plastic deformation. It is very important that plastic deformation is not caused to change the complex of physical & mechanical properties, in particular the emergence of residual deformation which can radically alter the form of the implant [2].

The presented research has a purpose to develop a scheme of thermo-mechanical tests of the implant material in order to guarantee full recovery of the implant shape after installation.

2. Experimental Procedure

The wire of Ti_{49.4}Ni_{50.6} alloy with the shape memory effect and pseudo elasticity, which is applied in medicine [3], was investigated. Temperatures of the martensitic transformation were studied by using the differential scanning calorimetry measurement (DSC) (Tabl.1).

Table 1. Transformation Temperatures for Ti_{49.4}Ni_{50.6} Alloy (by DSC)

Number of deformation cycle	Temperature Rs (B2→R start), ±2°C	Temperature Ms (R→B19' start), ±2°C	Temperature M _f (R→B19' finish), ±2°C
1	+4	-56	<-110
50	+1	-58	<-110
	Temperature As (B19'→B2 start), ±2°C	Temperature A _f (B19'→B2 finish), ±2°C	Temperature A _f ¹ (R→B2 finish), ±2°C
1	-33	-9	+1
50	-35	-8	+1

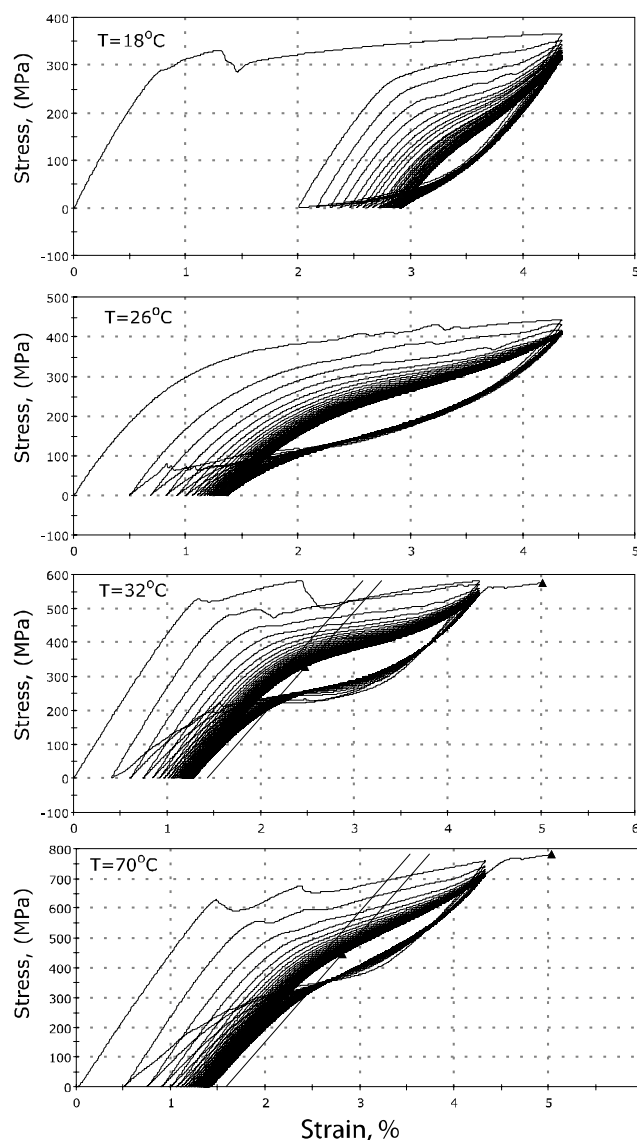


Fig. 1. Stress/Strain Curves at Various Temperatures

While being implanted, the device is exposed to periodic loading in the 20-37 temperature range. It is known that cycling

accompanied with the change of the deformation temperature affects mechanical properties of Ti-Ni alloys [4, 5] for the first 20 cycles and then this influence decreases. The strain cycling with the deformation degree equal to 4.3% and the number of strain cycles equal to 50 was performed in the temperature range from +18 to +32°C. The studied samples were obtained by warmly drawing hot-rolled TiNi bars till they become 0.7 mm in diameter. The deformation cycling was performed using Instron 3365. The length of samples was 70 mm, deformation rate was 0.0017 s^{-1} .

3. Results

Figure 1 shows a series of stress-strain curves at various temperatures. It is shown that the strain recovered on unloading increases with deformation cycling. Deformation cycling in the +26...+70°C interval leads to the formation of predominantly thermoelastic martensite, but at +18°C the martensitic transformation is partly irreversible. Additional peaks on the deformation curves can be resulted from the partial realization of intermediate steps transformation, which are initiated by deformation. The same effect can be traced on changes of the whole complex of mechanical properties. In particular, the deformation cycling in the mentioned temperature interval affected all parameters determined from deformation curves. Complex of mechanical properties with the increase the number of cycles is stabilized after the first 10-15 cycles as it was showed earlier [6].

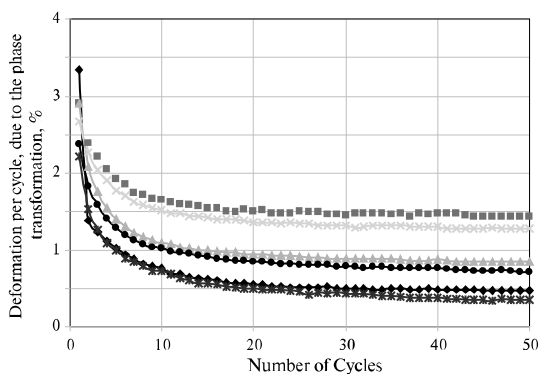


Fig.2. Change of the Deformation per Cycle, Due to the Phase Transformation at Various Temperatures

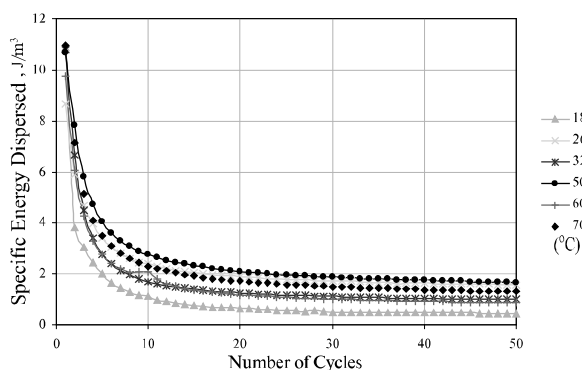


Fig.3. Change of the Specific Dissipated Energy per Stress-Induced Transformation Cycle at Various Temperatures

Figures 2 and 3 shows deformation per cycle, due to the phase transformation and change of the specific energy disseminated per stress-induced transformation cycle at various temperatures. Specific dissipation of energy per cycle is asymptotically aspires to some constant value at various deformation cycles, which indicates a possible direct or reverse transformation $B2 \leftrightarrow B19'$ without formation a large number of structural defects.

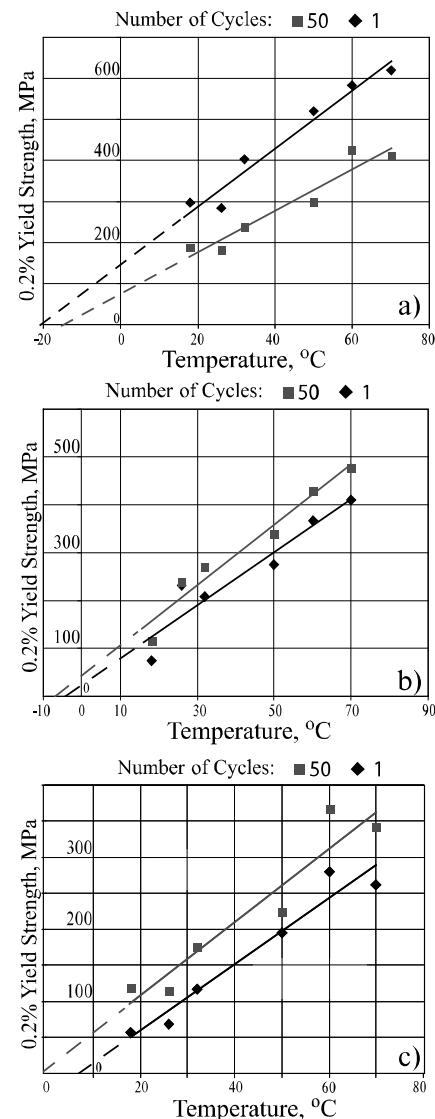


Fig.4. 0.2% Yield Strength vs. Temperature and Number of Cycles: a) at loading, b) at the start of unloading, c) at the end of unloading

4. Discussion

All mechanical properties in the studied temperature range were stabilized during cycling. The effective module of elasticity was measured by the tangent method during the strain cycling. The tangent of the rectilinear part was measured for the loading curve, in the area of discharge in the phase state when thermoelastic martensite is present, as well as on the segment corresponding to completion of the reverse martensitic transformation [7].

Additionally, the tensile yield strength treated as the beginning of the corresponding phase transformation and the area of the hysteresis of curves characterizing specific dissipation of energy of transformation (per a cycle) was calculated. The influence of the deformation cycling on the yield strength depending on temperature is shown in Fig.4 for the start of

direct $B2 \rightarrow B19'$, the start of reverse $B19' \rightarrow B2$ and the end of reverse $B19' \rightarrow B2$ martensitic transformation respectively. Processing of results with the extrapolation of dependencies to zero at the intersections with the horizontal axis allows obtaining the value of temperature corresponding transition temperature in the absence of an external load.

The results of the analysis of influence of deformation cycling on the 0.2% yield strength, depending on the temperature for the test at loading, for the beginning and completion of unloading was extrapolated on zero point of stress [6, 7]. The extrapolated values characterize the influence of the deformation cycling on the position of the critical points corresponding to different stages of $B2 \rightarrow B19'$ transformation. In table 2 shows the comparative results of the values of the temperatures at the beginning of $B2 \rightarrow B19'$, $B19' \rightarrow B2$, and the finish of $B19' \rightarrow B2$ transformations.

Table 2. Phase Transformations Temperatures after the Deformation Cycling Evaluated by Extrapolation of the Temperature-Stress Line

Number of cycles	1	50
Temperature M_s (start of $B2 \rightarrow B19'$), $\pm 2^\circ\text{C}$	-15	-20
Temperature A_s (start of $B19' \rightarrow B2$ transformation), $\pm 2^\circ\text{C}$	-5	-7
Temperature A_f (finish of $B19' \rightarrow B2$ transformation), $\pm 2^\circ\text{C}$	+7	0

Comparison of this value with temperatures of phase transitions obtained by DSC at start makes it possible to suggest that the strain cycling facilitates the direct $B2 \rightarrow B19'$ (which is consistent with [5, 8]) as well as the beginning of the reverse $B19' \rightarrow B2$ martensitic transformations. Study of the mechanical properties of the implant material showed that a preliminary deformation (10-15 cycles) stabilizes the complex of mechanical and temperature properties (Fig.2,3), which corresponds results [8-10]. Besides that, the property of pseudoelasticity is preserved at temperatures corresponding to implant operating and this fact provides the stable shape of the implant after installation.

The results of this study was successfully used for the design of a special device for mitral annuloplasty implanted minimally invasive transcatheter method of correction of mitral regurgitation [11].

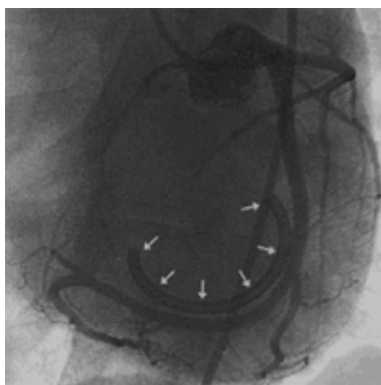


Fig. 5. The Device Inside the Coronary Sinus

5. Conclusions

1. The cyclic deformation with the number of cycles up to 10-15 facilitates the process of the direct $B2 \rightarrow B19'$ and reverse $B19' \rightarrow B2$ transformations, without affecting the transformations going with the emergence of the R-phase.
2. The cyclic deformation is required for reduction of the residual deformation when manufacturing medical device.
3. The results were used to design and produce an adjustment device for mitral annuloplasty.

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6. References

- [1] N. Chigogidze, J. Bilbao, M. Avaliani, et al., Intervascular Anastomoses Created by an Endovascular Approach: Technical Aspects and Initial Results in an Animal Study, Intervascular Anastomoses Created by an Endovascular Approach, v.7, №3, 2006.
- [2] V. G. Pushin, R.Z. Valiev, S.D.Prokoshkin, et al., Effect of Equal Channel Angular Pressing and Repeated Rolling on Structure, Phase Transformations and Properties of TiNi Shape Memory Alloys: Materials Science Forum, vol 503-504, 2006, pp 539-544
- [3] Shape Memory Materials, Ed. by K. Otsuka and C. M. Wayman, Cambridge University Press, Cambridge, 1998.
- [4] A.Yawny, M.Sade, G.Eggeler, "Pseudoelastic cycling of ultra-fine-grained NiTi shape-memory wires". Zeitschrift für Metallkunde 96 (2005) 6, p 608-618.
- [5] J. Olbricht, A. Yawny, A.M. Cond'ó, F.C. Lovey, G. Eggeler The influence of temperature on the evolution of functional properties during pseudoelastic cycling of ultra fine grained NiTi. J. Olbricht et al. Mat. Sci. Eng. A 481-421, 2008, p.142-145
- [6] D.E. Kaputkin, T.V.Morozova, E.V. Esina. Pseudo Elastic Cyclic Deformation of Ti-Ni Alloy Under Various Temperatures. Mater Sci.Forum - 2013, v.738- 739. - pp.332-337
- [7] D.Kaputkin, T.Morozova. The deformation cycling of the pseudoelastic TiNi alloy applied in cardiology. // Machines, Technologies, Materials. (ISSN 1313-0226) – 2012. Year VI. - #9 – p.15-18.
- [8] S.K. Wua, H.C. Lin b, Y.C. Yen a, J.C. Chen Wire drawing conducted in the R-phase of TiNi shape memory alloys. Materials Letters v. 46, 2000, pp.175–180
- [9] S.A. Egorov, M.E. Evard, N.N. Resnina, A.E. Volkov, Influence of stress on the temperature characteristics of martensitic transformation and on strain variation in Ti–Ni shape memory alloys, Materials Science and Engineering, A 462, 2007, pp 325–328
- [10] Tomohiro Nishiura and Minoru Nishida. Internal Defects of $B19'$ Martensite via R-Phase in Ti-Ni-Fe and Thermally Cycled Ti-Ni Alloys. Materials Transactions, Vol. 50, No. 5, 2009, pp. 1219 – 1224.
- [11] D. Kaputkin, T. Morozova, N. Chigogidze, M. Avaliani. Design of Pseudoelastic Implants to Apply to Cardiology. / In: Shape Memory & superelastic technologies conference & exposition. May 20-24, 2013, Prague, Czech Republic, p. 79