

TEMPERATURE CHARACTERISTICS OF NITINOL SPIRAL STENTS

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Received after revision August 2005

Abstract

Attention is focused on problems of Nitinol spiral stent rigidity change in dependence on temperature change, especially in the usual range of temperature in which the stents are used. Simple methods of measuring temperature characteristics of Nitinol spiral stents are described and compared with our “exact” mathematical model. The results are shown in graphs.

Key words

Nitinol spiral stent, Temperature characteristics, Mathematical model

INTRODUCTION

Interventional radiology is one of the trends in modern medicine. As in other growing branches it possesses plenty of problems and unanswered questions which exceed the physician’s field of activity. Therefore we focused on the physical part of the problem, in particular on the mechanical behaviour of Nitinol spiral stents depending on temperature change. We used two methods of measuring the temperature characteristics of a Nitinol spiral stent, and compared them using the mathematical formula following from the stent geometry. Finally, we compared these two methods and data with our mathematical model of the stent and we validated the results against the expected value of the Young’s modulus of elasticity of the stent material acquired from the stress-strain test (*I*).

MATERIALS AND METHODS

The mechanical properties of Nitinol spiral stent result from the geometrical structure and material of the stent. We used the SX ELLA stent made by ELLA – CS. It is a self-expandable spiral stent with atraumatic edges made of Nitinol wire. The parameters of the stent are the following: length $L_s = 72$ mm; diameter $D = 14$ mm; pitch of spring $S = 29$ mm; wire diameter $d = 0.18$ mm; number of legs = 24; Young’s modulus of elasticity $E_{(40^\circ\text{C} - \text{Austenite})} \approx 60$ GPa (expected value acquired from stress-strain test); Poisson’s ratio $\mu = 0.3$ (according to product specifications given by producer). The geometry of the stent is a structure of a contrarotating spring connected together on its ends with consequent block

uncoiling of the springs (*Fig. 1*). There is mutual dependence in this structure between the length and diameter of the stent described by (*form. 1*), where l is the length of one coil. We know that in Nitinol for medical use the Young's modulus of elasticity is set on purpose to have a change within the range of (15–30) °C. This change is large. We also know that the rigidity of the spring is connected with the Young's modulus of elasticity. Because the temperatures are in the interval of (15–30) °C, which is a typical range in which the stents are applied in the body, we focused on the determination of the dependence of E on temperature. The rigidity of the stent depends on temperature in the same way.

$$D = \frac{\sqrt{l^2 - S^2}}{\pi} \quad (\text{form. 1})$$



Fig. 1
SX ELLA stent

An approximate model which we used for measuring the stent is described by a simple (*form. 2*), where Φ_i^0 are initial parameters of the geometry of the stent. We neglected the deformation of the material. We measured the dependence of the force of the stent on the length of the stent for each temperature we set as stable. Then we used only the initial parts of these characteristics that are approximately linear for small deformations. We applied linear regression on the data from these parts and for each temperature we obtained a typical slope. This slope is equal to the rigidity of the stent (!) and corresponds to the Young's modulus of the material of the stent. An advantage of this model is simple data processing (for example in Excel); it provides initial approach approximation. It is proved and normally used for small deformations. We used two methods for our measurement: (a) measurement

of the dependence of the axial force of stent F_A on the relative position of the free end of stent L (" F_A on L ") (Fig. 2), and (b) measurement of the dependence of the axial force of the stent on the change of the diameter of stent (" F_A on $D_{\%}$ ") or (" F_A on D ") after recalculation. It does not depend principally on the initial value of the measurement of the relative position of the free end of stent L . Using the (form. 1) we can easily transform the data obtained by method (a) to make them comparable with the data obtained by method (b), and vice versa. This enables us to compare these methods and eliminate errors of measurement.

$$F = k(E, \phi_0) \cdot L \quad (\text{form. 2})$$

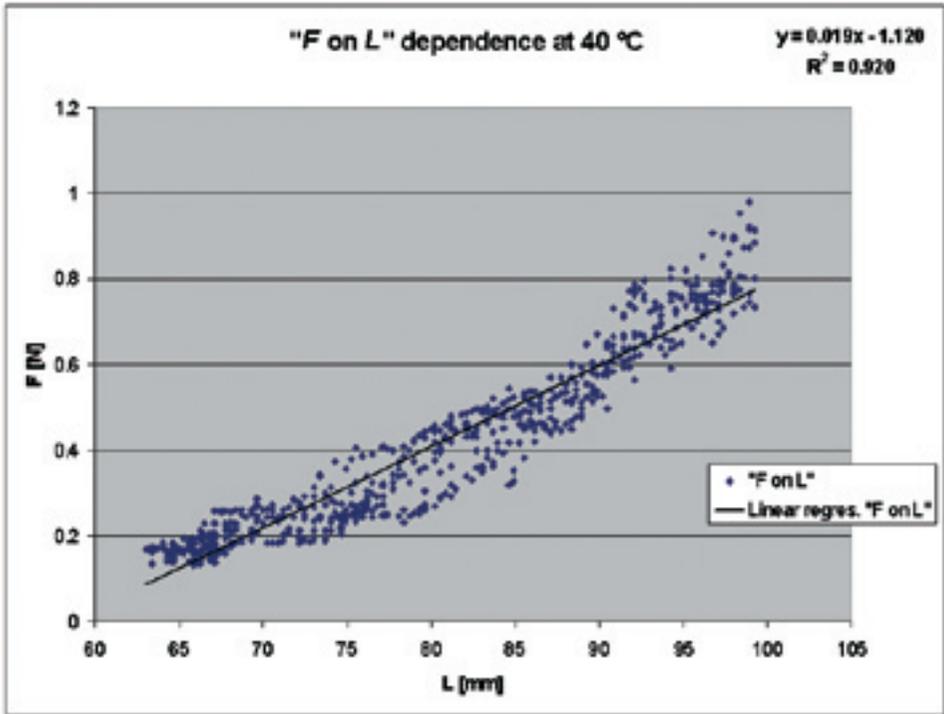


Fig. 2
Selected part of data with applied linear regression.
Measurement of "F on L" dependence at 40 °C

Our equipment (Fig. 3) consists of (2): measuring system ISES with a measuring card National Instruments, N/g meter, position meter, camera TOPICA; thermostat JULABO, lighting FOMEI, thermostatic bath of own design with distilled water, special fixtures of own design for holding the stent (stent was held at the ends under six bends on each end). The parameters measured were: temperature $T = [^{\circ}\text{C}]$ with an accuracy of $\pm 0.01^{\circ}\text{C}$ - JULABO and $\pm 0.075^{\circ}\text{C}$ - ISES; $L = [\text{mm}]$ position of the free end of the stent with an accuracy of ± 0.200 mm; change of diameter $D_{\%} = [\%]$ with an accuracy of ± 2.475 %; force of the stent $F = [\text{N}]$ with an accuracy of ± 0.030 N. We set the range of temperatures between (15-45) °C. At each temperature (Tab 1) we made 1000 measurements of each parameter with a sampling frequency of one measurement per 0.3 second. Filtration of data, approximation, recounting, statistical processing, graphs, and tables were processed in Excel.

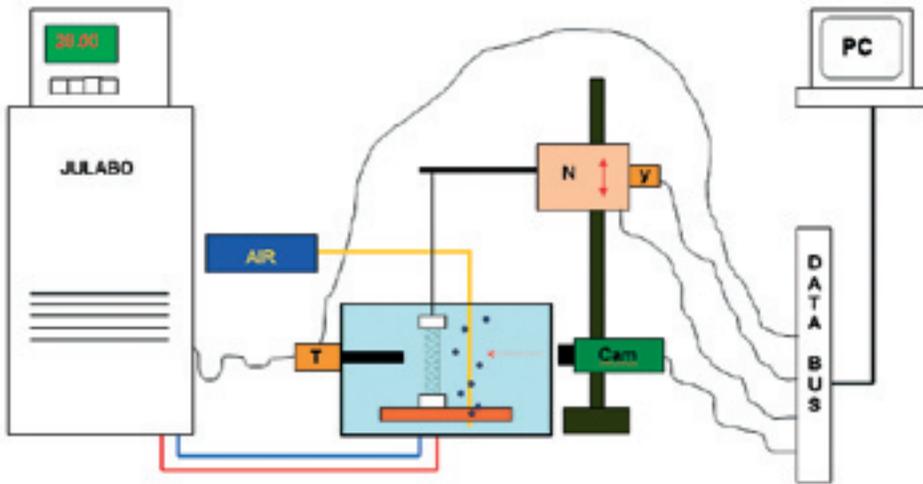


Fig. 3

Scheme of measuring equipment

JULABO - thermostat

AIR - system for continuous mixing of the bath

T - thermocouple for measuring temperature T

N - n/g meter for measuring axial force F_A

Y - position meter for measuring the position of the free end of stent L

Cam - Topica camera for measuring the change of the stent diameter $D_{\%}$

Table 1

k - axial rigidity; k_R - radial rigidity; S_x - standard error of the mean; R^2 - coefficient of determination

temperature [°C]	rigidity k [mN/mm]	S_x	R^2_x	rigidity k_R [mN%	S_{xR}	R^2_{xR}
15.00	4.093	0.172	0.629	9.052	0.134	0.612
16.00	6.625	0.229	0.613	9.626	0.126	0.904
17.00	7.275	0.161	0.786	10.176	0.125	0.904
18.00	8.765	0.145	0.832	10.748	0.138	0.924
19.00	9.152	0.142	0.868	11.608	0.128	0.912
20.00	10.547	0.103	0.629	13.023	0.136	0.917
21.00	12.043	0.166	0.894	14.679	0.098	0.966
22.00	13.338	0.166	0.911	17.233	0.126	0.966
23.00	17.441	0.188	0.932	23.761	0.140	0.971
24.00	19.085	0.245	0.896	27.802	0.150	0.971
25.00	19.165	0.252	0.904	28.342	0.175	0.970
26.00	19.144	0.267	0.904	28.296	0.187	0.966
27.00	19.153	0.274	0.889	28.365	0.207	0.960
28.00	19.161	0.275	0.919	28.514	0.189	0.964
29.00	19.150	0.226	0.920	28.276	0.152	0.970
30.00	19.163	0.234	0.932	28.426	0.146	0.969

Finally, we applied our “exact” mathematical model (*Fig. 4*) to the measured and transformed data from “ F on D ” dependence to “ F on L ” dependence. The values of the Young’s modulus of elasticity of the stent material were obtained by the least-squares method ($E = 60.36$ GPa for $40\text{ }^{\circ}\text{C}$; $E = 62.69$ GPa for $45\text{ }^{\circ}\text{C}$). We used an analytical approach. We compared these values with the expected value of the Young’s modulus of elasticity obtained from the stress-strain test ($E_{\text{AUSTENITE}} = 60$ GPa).

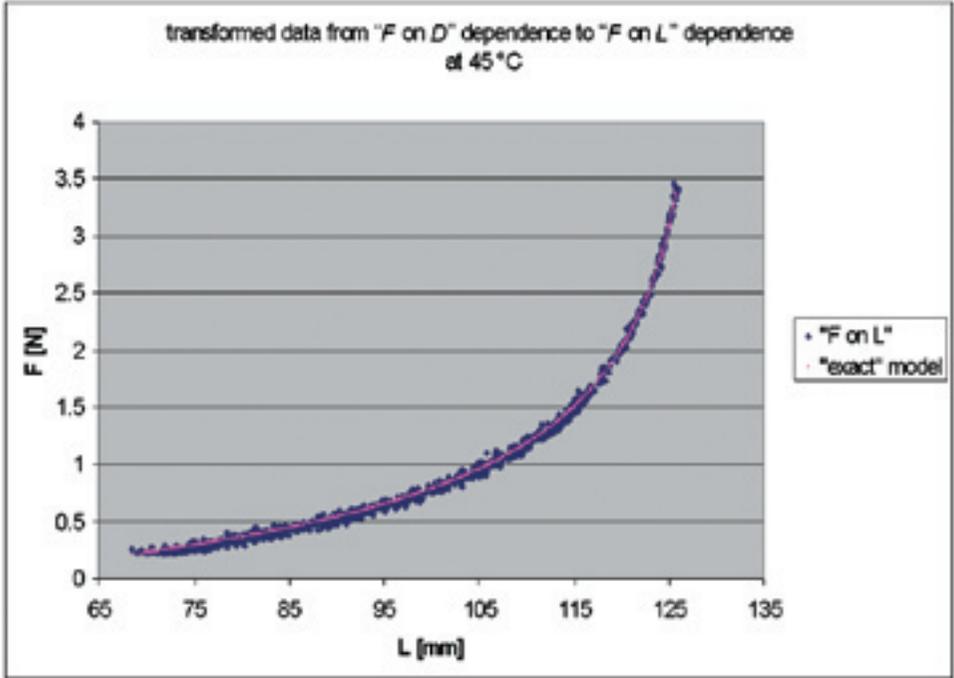


Fig. 4
Application of our developed “exact” model on the data at $45\text{ }^{\circ}\text{C}$

DISCUSSION AND CONCLUSION

The approximate model is clear, well known, simple for data processing, and provides an initial approach approximation. Using this model we can obtain temperature characteristics (*Fig. 5*), which are important data for production and quality control of the stents and no less important information for physicians. Such information gives us the picture about the behaviour of the stent in the conditions of the human body! Our “exact” model possesses all advantages of the approximate model and much more. It allows prediction of stent behaviour in the conditions of the human body and in this way it enables designing of “customised” Nitinol spiral stents. The “exact” model expresses explicit dependence between the axial F_A and the radial F_R force (= also, radial pressure) independent of the material of the stent and of the temperature (!) (*Form. 3 and 4*). That is why it allows us, by measuring

the dependence of the axial force on the length of the stent and applying the transformation (form. 3), to determine the dependence of the radial force (and so the radial pressure) on the diameter of the stent. This radial force (radial pressure) will permanently affect the tissue (e.g. vessel wall).

$$F_R = f(F_A) \quad (\text{form. 3})$$

$$\frac{dF_R}{dT} = \frac{df(F_A)}{dT} = 0 \quad (\text{form. 4})$$

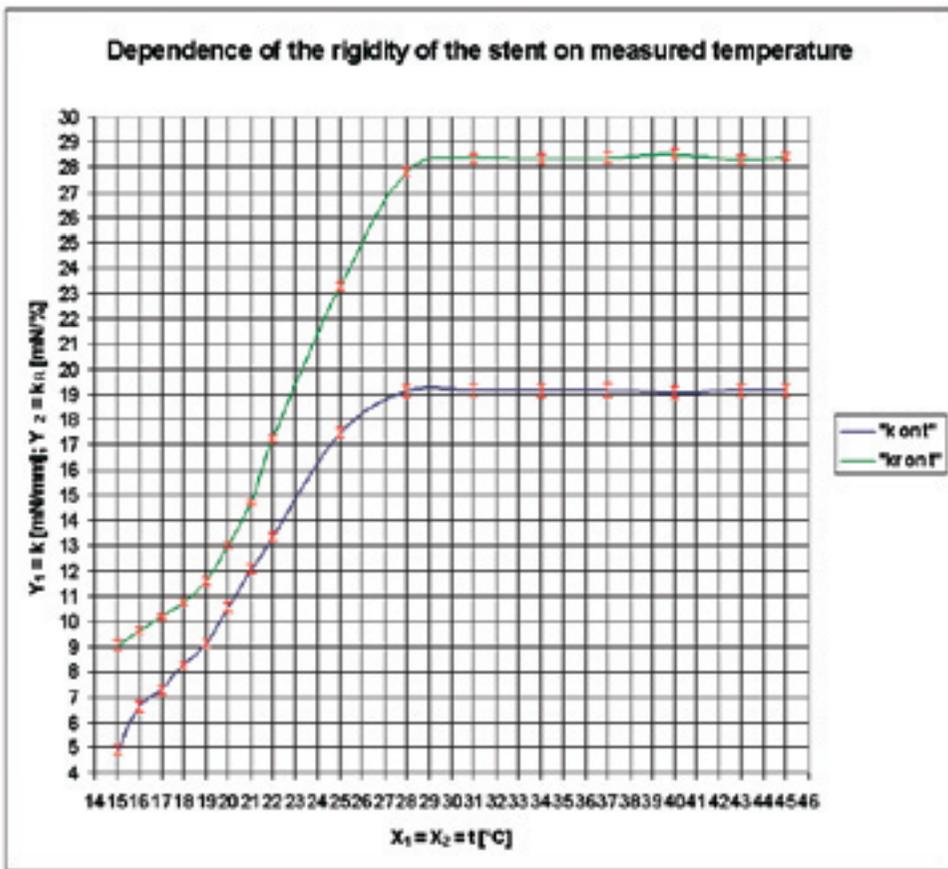


Fig. 5

Temperature characteristics of the Nitinol spiral stent showing standard errors of means (k - axial rigidity; k_R - radial rigidity)

Acknowledgement

The approximate model and the measurements were supported by FT – TA/097.

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TEPLOTNÍ CHARAKTERISTIKY NITINOLOVÝCH SPIRÁLNÍCH STENTŮ

Souhrn

Práce je zaměřena na studii změny tuhosti nitinolových spirálních stentů v závislosti na změně teploty, zvláště pak v běžné oblasti teplot jejich použití. Popisuje jednoduché metody měření teplotních charakteristik nitinolových spirálních stentů a porovnává je s námi vyvinutým “přesným” matematickým modelem. Výsledky jsou zobrazeny v grafech.

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