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Biomechanical characterization of the balloon-expandable slotted tube stents

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Materials

ABSTRACT

Purpose: The aim of the presented work was determination of the biomechanical characteristics of the vascular stent made of stainless steel (Cr-Ni-Mo) and Co-Cr-W-Ni alloy. Additionally, in order to compare obtained results, an experimental analysis of the stent made of stainless steel was carried out.

Design/methodology/approach: In order to determine the strength characteristics of the analyzed stent the finite element method was applied. Geometrical model of the vascular stent, which was meshed with the use of the SOLID95 element, was worked out. Selection of the finite element was conditioned by large strains that occur during angioplastic procedure. The established boundary conditions imitated the phenomena during the balloon expansion in real conditions.

Findings: The result of the analysis was determination of relationship between equivalent stresses and strains in the individual regions the stent in the function of the diameter's change (d = 1.20 - 4.00 mm) caused by expanding pressure. Analysis of the obtained results indicates diverse distribution of stresses and strains in the stent depending on the applied biomaterial.

Research limitations/implications: The obtained results of the biomechanical analysis of the coronary stent are valuable information for correct design of the geometry and mechanical properties of the applied metallic biomaterials. Strain analysis of the stent indicates that in order to limit a surface reactivity of the stent in blood environment, a deformable surface layer must be applied.

Originality/value: Results of the numerical analysis indicate that mechanical properties of the metallic biomaterials used to manufacture the analyzed vascular stent were selected correctly. The correctness of the selection (mechanical properties of the metallic biomaterials) should be confirmed in in vitro tests realized with the use of the coronary angioplasty set.

Keywords: Metallic alloys; Biomaterials; Mechanical properties; Computational mechanics

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1. Introduction

Atherosclerosis is a systemic disease that develops for years and shows different clinical syndromes. If we realize that such diseases as ischaemic heart disease – cardiac infarction, brain ischaemia – stroke or acroischaemia are the result of an atherosclerosis then we become convinced that atherosclerosis is social disease, not less important than tumors for example. Even

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though progress in medical sciences, no effective solution preventing an atherosclerosis was found.

In recent years a dynamic development in diagnostics of vascular diseases, as well as in operational procedures, was observed. Even though, this should be clearly mentioned that operational procedures on arteries are palliative procedure operations only. Application of stents was one of the most important achievements of nineties of twentieth century in treatment of ischaemic heart disease. Currently over 80% of coronary angioplasty procedures in Poland are done with application of a stent. The coronary stents are mainly made of metallic biomaterials (stainless steel, Co-Cr-W-Ni and Ni-Ti alloys). A stent is a small mesh tube that's used to treat narrowed or weakened arteries in the body in order to improve blood flow and to help prevent the artery from bursting [3-5].

For many years different kind of stents have been used. Construction of the stents was continuously improved. Implantation of stent is a minimally invasive procedure. During the angioplasty procedure, a thin tube called a catheter is placed through the groin or arm and passed through an artery to the site of the blockage. There is a small balloon located on the tip of the catheter which is then slowly inflated to open the blockage. After opening the blockage with a balloon catheter, a stent may be placed to help keep the blockage open. The stent is delivered on a balloon catheter to the site of the blockage. Once in place, the balloon on the tip of the catheter is inflated to expand the stent to the size of the vessel. Once expanded, the balloon catheter is removed and the stent remains in the vessel to hold the artery open [6].

Long-term clinical experiences allowed to determine geometric features of different kind of stents – Fig. 1.

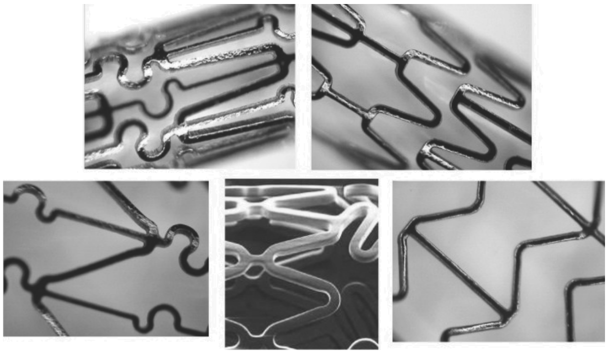

Fig. 1. Different constructions of coronary stents

It is rare that geometrical solutions as well as suggestions worked out on the basis of the appropriate implantation technique are verified with the use of biomechanical analyses. Basic data that characterize the applied biomaterial which determines application properties of the sent is often missing. Also, so far presented quality criteria of biomaterials do not specify the requirements for stents. Furthermore, the significance of surface treatment of the applied metallic biomaterial is not emphasized in many works. Determination of the mentioned problems allows to work out optimal geometrical features of stents as well as their mechanical properties [5, 6].

2. Materials and methods

Biomechanical study was carried out on JOSONICS Flex, a single-layer, slotted tube coronary stent currently used in operative cardiology. The stent was totally made of stainless steel. Chemical composition of the steel applied for the stent was presented in Table 1. On the basis of the literature review, an alternative Co-Cr-W-Ni alloy was also proposed for the stent. Physiochemical properties of the cobalt alloy are more favorable than the properties of the commonly used stainless steel. Length of the stent was equal to l = 19 mm, wall thickness g = 0.1 mm, initial diameter d = 1.2 mm – Fig. 2.

Fig. 2. The JOSONICS Flex coronary stent

Table 1.
Chemical composition of biomaterials used for the JOSONICS Flex stent

Element	Co-Cr-W-Ni alloy		Stainless steel	
	ISO standard	The sample	ISO standard	The sample
	% mas.	% mas.	% mas.	% mas.
C	<0.15	0.08	<0.03	0.01
Co	reszta	50.56	-	-
Cr	19.0-21.0	20.45	17.0-19.0	17.49
Fe	<3.0	1.88	reszta	reszta
Mn	<2.0	1.24	<2.0	1.68
N	-	0.019	0.1-0.2	0.087
Ni	9.0-11.0	10.16	14.0-16.0	14.49
P	<0.04	0.002	<0.025	0.017
S	<0.03	< 0.001	<0.01	0.003
Si	<1.0	0.01	<1.0	0.21
W	14.0-16.0	15.14	-	-
Mo	-	-	2.35-4.2	2.76
Cu	-	-	<0.5	0.05

2.1. Experimental study

In experimental part of the study, radial displacements caused by the applied expansion pressure were determined. In order to carry out the experimental study on real models, a testing stand was prepared. The stand allowed for fully controlled expansion of the stent. The stand consisted of a light microscope with measuring system and original set for the stent's expansion. Change of the stent's diameter was recorded with accuracy equal to ±0.01mm. Appropriate immobilization of the stent during expansion was assured by application of the proper fixation. The aim of the experiment was determination of relation between the applied expansion pressure and the increase of the stent's diameter (1).

$$\Delta r = f(p) \tag{1}$$

where:
Δr – increase of the stent's diameter, mm; p – expansion pressure, atm

The expansion pressure was applied with increment equal to 0.5 atm until the stent reached its nominal diameter. Changes of diameter were recorded in 3 planes – Fig. 3.

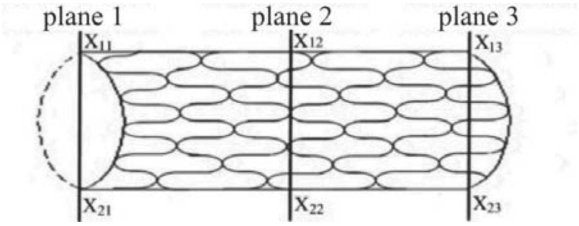

Fig. 3. Planes, in which changes of the stent's diameter during the expansion were recorded

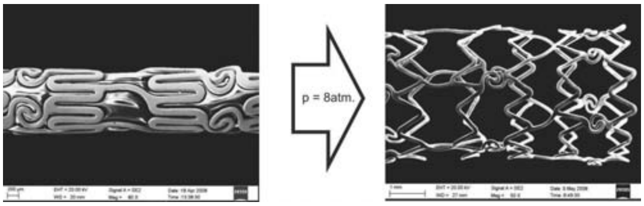

Fig. 4. The JONSONIC Flex stent in the initial state and after the expansion with the pressure p = 8 atm

The experimental study was carried out in order to determine the expansion curve of the JONSONIC Flex stent. Figure 4 presents the stent in the initial state and after the expansion with the pressure p = 8 atm.

2.2. FEM analysis

In order to calculate stresses and strains of the stent, for different radial displacements caused by the expansion pressure, a numerical analysis was carried out. The obtained results are important for selection of structure and mechanical properties of the metallic biomaterials applied for stents. Due to the implantation process, stresses caused by displacements have a significant influence on permanent deformation of the stent, in consequence the change of the stent's geometry. The stresses in different parts of the stent, depending on the induced displacements, are very important for appropriate design of stent's geometry, strain hardening of the biomaterial and physiochemical properties of surface. The numerical analysis was carried out by mean of the finite element method with the use of ANSYS V. 11 software.

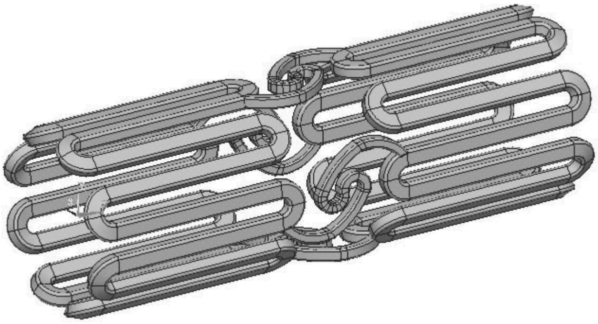

Fig. 5. Numerical model of the single segment of the JOSONICS Flex stent

In the first step of the analysis a numerical model of the stent was worked out. The model was based on the JOSONICS Flex solution. The stent consisted of three segments. The geometry of the analyzed stent was presented in Fig. 5.

The meshing was carried out with the use of the SOLID95 finite element. This type of element is characterized by 20 nodes and 3 degrees of freedom in each node (displacements in x, y and z direction) – Fig. 6. Selection of such element allows to take into consideration physical nonlinearities as well as large displacements and rotation.

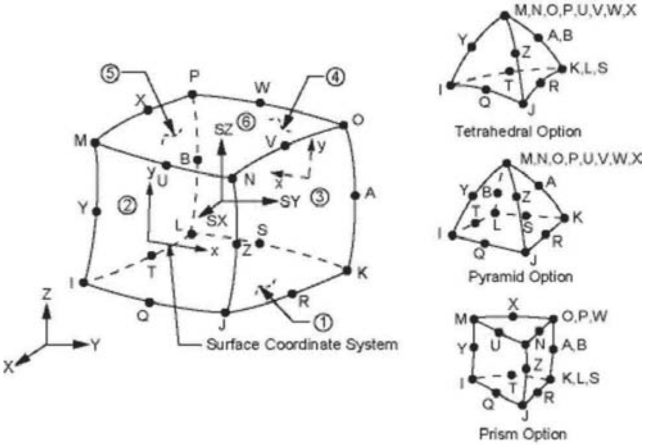

Fig. 6. SOLID95 geometry and stress output

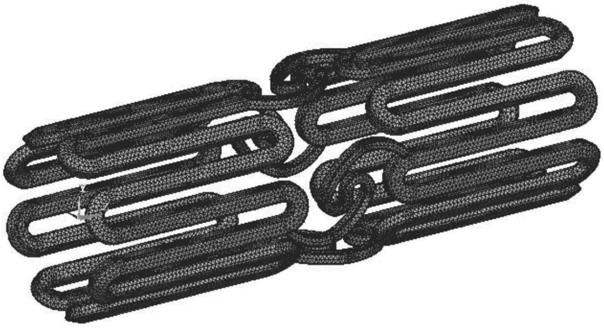

Fig. 7. Meshed model of the single segment of the JOSONICS Flex stent

The numerical model of the stent consisted of 450 thousand elements – Fig. 7. For such high number of elements it is impossible to carry out multi-step nonlinear calculations with required accuracy. Thus, with regard to repeatability of the geometry, the calculations were carried out for the segment consisting of two struts and one connector – Fig. 8.

In order to carry out the finite element analysis the geometrical model was meshed – Fig. 9.

For the analyzed geometry of the stent the following material properties, corresponding to stainless steel and cobalt alloy, were taken into consideration:

a) Stainless steel
- Young modulus $E_{(316L)} = 190\,000$ MPa,
- Poisson's ratio $\upsilon_{(316L)} = 0.33$,
- tensile strength = 470 MPa,
- yield point = 195 MPa
- elongation = 40 %,

b) Co-Cr-W-Ni alloy
- Young modulus $E_{(L605)} = 243\,000$ MPa,
- Poisson's ratio $\upsilon_{(L605)} = 0.30$,
- tensile strength = 917 MPa,
- yield point = 476 MPa,
- elongation = 65 %.

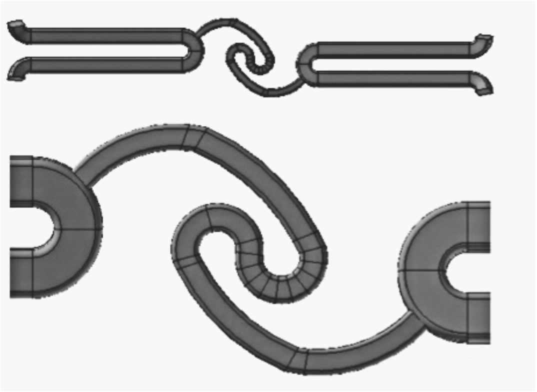

Fig. 8. Geometrical model of the single segment selected for the analysis

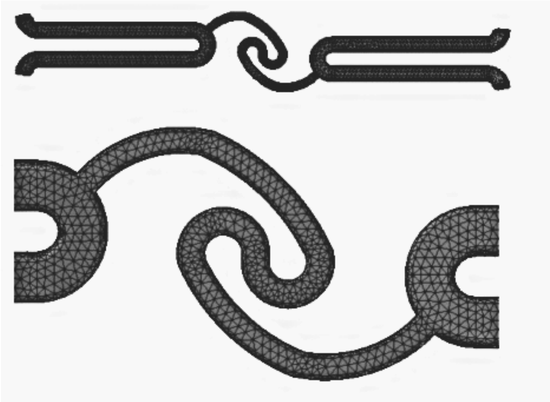

Fig. 9. The meshed model of the analyzed segment

For the individual types of biomaterials, bilinear characteristics of an elastic and plastic isotropic material were worked out – Fig. 10.

The analysis was carried out in order to calculate displacements, strains and stresses, depending on the applied mechanical properties of the selected biomaterial. In order to carry out the calculations it was necessary to evaluate and establish initial and boundary conditions which imitate phenomena in real system with appropriate accuracy. The following assumptions were established:

1. inner surface of the stent was loaded with pressure on its whole length (during expansion),
2. appropriate determination of degrees of freedom allowed for free radial expansion of the stent without shortening,
3. the applied degrees of freedom reflected real conditions in the vessel,
4. the analysis was carried out in the full range of expansion pressures (the pressure was increased until the external diameter reached d = 8.00 mm).

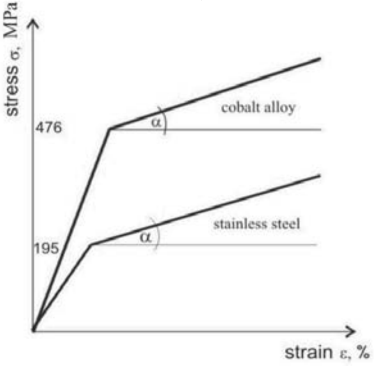

Fig. 10. Bilinear characteristics of the stent material: stainless steel - $\alpha = 19°$, cobalt alloy - $\alpha = 25°$

Stresses and strains obtained in the analysis are equivalent values according to the Huber – Misses hypothesis.

3. Results

3.1. Results of experimental analysis

The analysis of the experimental results showed that increase of the stent's diameter was not proportional in accordance to the applied pressure in the balloon – Fig. 11 and Table 2.

Sudden increase of the stent's diameter was observed in planes I and III (begining and ending of the stent – dogboneing effect) for the pressure exceeding the value of p = 2.5 atm. Increase of the pressure up to p = 4 atm caused the increase of the diameter measured in plane II (in the middle part of the stent). Increase of the pressure up to p = 5 atm caused that the stent of reached the nominal diameter d = 4 mm. Further increase of the pressure up to the nominal value p = 8 atm caused uniform, inconsiderable increase of the implant's diameter on its whole length (Δd = 0.1 mm) – Table 2 and Fig. 11. Application of the admissible pressure p = 16 atm caused the change of the stent's diameter from the value of 4.09 mm up to 4.27 mm. After deflation of the balloon the diameter of the stent decreased to the minimal value equal to d = 4.01 mm.

Table 2.
Results of the experimental analysis

Expansion pressure p, atm	Stent's diameter d, mm		
	Plane 1	Plane 2	Plane 3
0	1.27	1.17	1.27
0.5	1.27	1.27	1.27
1.0	1.28	1.19	1.28
1.5	1.28	1.19	1.34
2.0	1.55	1.21	1.39
2.5	1.57	1.21	1.40
3.0	2.45	1.22	2.38
3.5	2.84	1.23	2.74
4.0	3.13	1.24	3.49
4.5	4.00	3.90	4.00
5.0	4.02	4.00	4.02
5.5	4.03	4.00	4.03
6.0	4.05	4.01	4.05
6.5	4.06	4.01	4.05
7.0	4.08	4.02	4.07
7.5	4.08	4.02	4.08
8.0	4.09	4.03	4.09

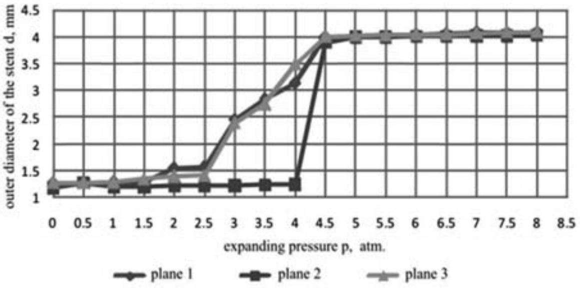

Fig. 11. The relation between the stent's diameter and the expansion pressure

3.2. Results of FEA

Results of the numerical analysis showed that stresses obtained in result of change of the diameter caused by application of the expansion pressure in the stent made of stainless steel are diverse and reached values from the range σ = 36 - 209 MPa.

Maximum stresses were localized in the inner region of bends and were equal to Maximum stresses were localized in the inner region of bends and were equal to σ_{max} = 209 MPa for the arms – Fig. 12a and σ_{max} = 202 MPa for the connectors – Fig. 12b.

The stent was expanded to the value d = 4.00 mm, e.i. till the stent reached the inner diameter of healthy coronary vessel. Examples of stress distribution in the XY, YZ and ZX planes for the maximum diameter d = 4 mm in the single arm were presented in Fig. 13. The obtained equivalent stresses exceeded the yield point of the stainless steel (195 MPa) causing plastic deformation of the stent, essential for proper implantation in the vessel. Furthermore, the relationship between the expansion pressure and the change of the stent's diameter (radial displacements of the stent's elements) was determined – Fig. 14.

a)

b)

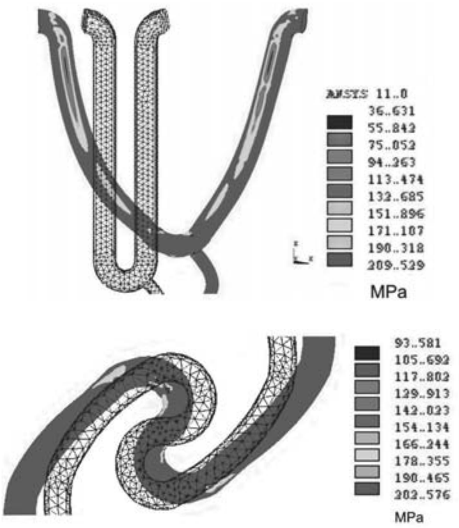

Fig. 12. Results of the numerical analysis of the stainless steel stent: a) stress distribution in the single arm, b) stress distribution in the connector

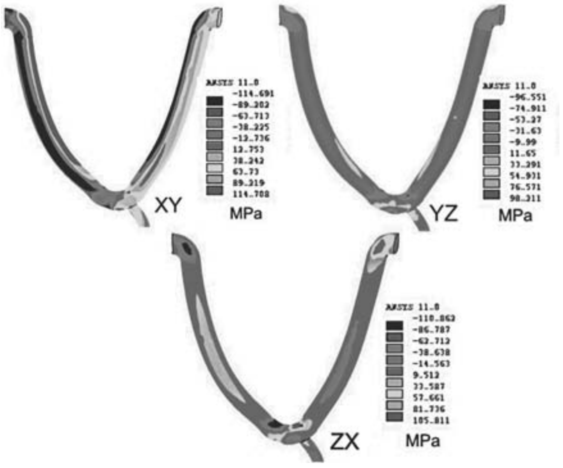

Fig. 13. Stress distribution in the single arm in the XY, YZ and ZX planes

Application of small increment of the expansion pressure allowed to determine the crucial stage of the stent's expansion which was realized over the expansion pressure p = 2.52 atm gradually – Fig. 15. The numerical analysis allowed also to calculate shortening of the stent – Table 3. Shortening rate of the stent after the expansion was adequate to the one obtained in clinical practice for stents of different manufacturers. The maximum strains equal to ε = 83 % were observed in the regions of maximum deformation – Fig. 16.

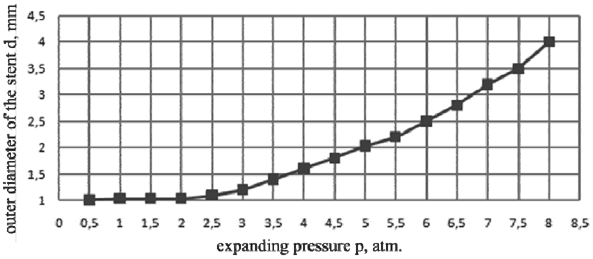

Fig. 14. The relation between the diameter of the coronary stent (Cr-Ni-Mo steel) and the expanding pressure (numerical analysis)

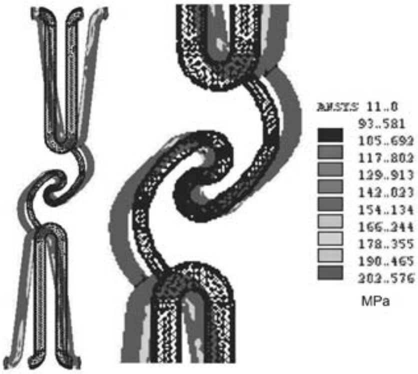

Fig. 15. Stress distribution in the stent's arms and the connector for the applied expansion pressure p = 2,52 atm

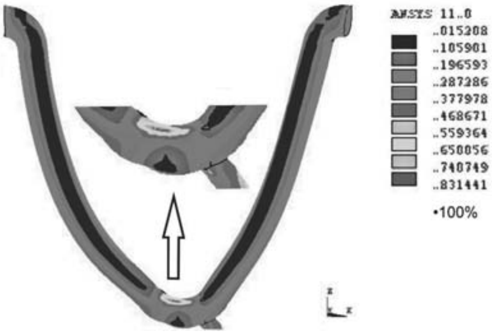

Fig. 16. Strains in the single arm of the stent made of stainless steel

The numerical analysis of the stainless steel stent carried out with the use of the finite element method was a basis for selection of the alternative metallic biomaterial - Co-Cr-W-Ni alloy. It was assumed that in order to manufacture the analyzed geometry of the stent, an annealed thin-walled tube made of the Co-Cr-W-Ni alloy (L605) should be used. The mechanical properties should be as follow: YS = 476 MPa and TS = 917 MPa. For the established material properties the stent was numerically analyzed.

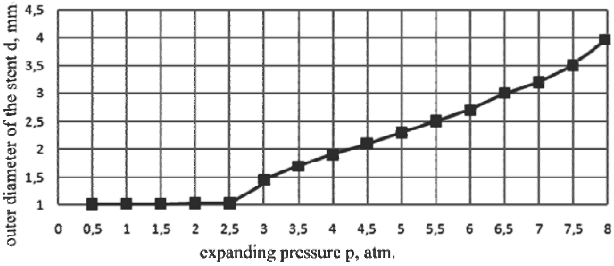

Fig. 17. The relation between the diameter of the coronary stent (Co-Cr-W-Ni alloy) and the expanding pressure (numerical analysis)

As the result of the analysis the maximum strains were calculated. The strain analysis allowed to determine regions prone to damage during the stent expansion or use. Moreover, a relationship between equivalent stresses in the function of the radial displacement was determined – Fig. 17.

The analysis of stress distribution caused by the radial displacement showed that maximum stresses were localized, like for the stainless steel stent, in the inner region of bends, exceeding the value of yield strength YS = 476 MPa – Fig. 18, causing plastic deformation of the stent. For the total expansion of the stent up to the diameter d = 4.00 mm maximum equivalent stresses did not exceed σ_{max} = 486 MPa, what ensured appropriate change of the stent geometry.

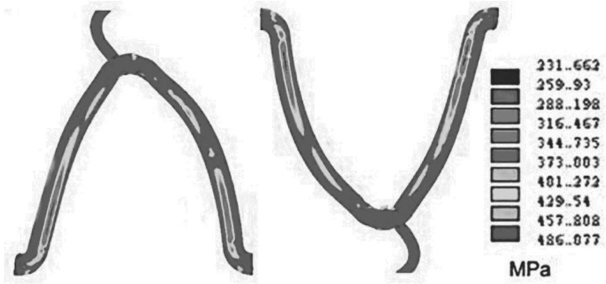

Fig. 18. Results of the numerical analysis of the cobalt alloy stent: a) stress distribution in the single arm, b) stress distribution in the connector

4. Conclusions

Selection of mechanical properties of metallic biomaterial as well as physio-chemical properties of stent are important issues when forming of application features is involved [12]. The forming is based on selection of proper biomechanical characteristics determined with an implantation procedure taken into account. This results from an expansion of a stent

Table 3.
Results of biomechanical analysis of stent

Diameter d, mm	Reduction %	Stress σ_{max}, MPa				Strain ε_{max}, %			
		XY Shear	YZ Shear	XZ Shear	von Mises	XY Shear	YZ Shear	XZ Shear	von Mises
Stainless steel									
1.50	1.5	112	112	111	198	8	11	19	20
2.00	2.1	112	109	110	200	13	15	27	28
2.50	2.7	112	109	109	201	17	18	32	33
3.00	3.4	112	110	108	202	22	21	36	38
3.50	4.3	113	111	109	205	54	52	59	72
4.00	5.2	114	108	105	209	71	72	67	83
Cobalt alloy									
1.50	1.5	274	273	271	479	0.3	0.3	0.3	0.2
2.00	2.1	274	270	265	481	13	13	28	28
2.50	2.7	274	268	265	483	18	18	36	35
3.00	3.4	274	266	265	484	24	24	40	42
3.50	4.3	273	261	264	485	29	30	44	49
4.00	5.2	273	253	262	486	34	38	49	56

in a treated blood vessel to required diameter. Permanent deformation of a stent must be the effect of stent's expansion. Due to difficulties connected with experimental determination of strength characteristic, for such small implants, research is focused on numerical studies with the use of finite element method mostly [13-15]. Usefulness of this methodology is connected with the established assumptions that should mimic anatomical and physiological conditions in blood vessels. Numerical analysis and experimental verification as well as determination of structure and physiochemical properties of metallic biomaterial and tissue are the basis for design of appropriate biomaterial which can be safely used in a living body [7-12].

The numerical analysis carried out in the first stage of the research allowed to calculate equivalent stresses in the coronary stent made of stainless steel, depending on the change of the diameter caused by the expansion pressure. On this basis, regions with maximum stresses were determined. The obtained values of the maximum stresses were higher than the yield strength of the stainless steel. This ensures permanent deformation of the analyzed stent necessary for correct embedment into narrowed vessel.

The obtained results showed that after the exceeding of the expansion pressure p = 2,96 atm, a sudden increase of the stent's diameter, up to d = 4 mm, took place. Good correlation of the results obtained from the numerical and the experimental analyses indicates that the boundary conditions were established correctly. The numerical analysis and the experimental verification of the results obtained for the stainless steel stent were a basis for selection of alternative metallic biomaterial of more favorable physiochemical properties.

Therefore, an annealed Co-Cr-W-Ni cobalt alloy was proposed for the stent. The selected cobalt alloy is characterized by better hemocompatibility in comparison with stainless steel. The obtained results showed that cobalt alloy has very good expansion characteristics. It was demonstrated that change of the stent's diameter (d = 1.50 mm), caused by the expansion pressure, resulted in exceeding of the yield strength and permanent deformation of the stent in consequence. Expansion of the stent up to the nominal diameter caused that the obtained maximum equivalent stresses did not exceed σ_{max} = 486 MPa. Taking into consideration that tensile strength of the Co-Cr-W-Ni cobalt alloy is about 900 MPa, such occurence should be considered as favorable. Maximum stresses were localized in the same regions as for the stainless steel stent. It was also observed that regardless of the applied biomaterial, the expansion of the stent is realized only by deformation (unbend) of the individual arms (no participation of the connectors).

The numerical analysis realized with the use of the finite element method of the stent made of the Co-Cr-W-Ni cobalt alloy showed that the maximum equivalent stresses exceeded the yield strength of the material (YS = = 476MPa) in the region of bending of the arms. This allows to deform the stent up to its nominal diameter d = 4 mm permanently and safely. The obtained results substantiate the acceptance of the analyzed biomaterial as the alternative solution for this type of implant.

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