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Biomechanical behaviour of coronary stent design with OCC technology

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Materials

ABSTRACT

Purpose: The work presents results of stresses and strains of three-layer vascular stent (Cr-Ni-Mo – Ta – Cr-Ni-Mo) and one-layer uniform one (Cr-Ni-Mo) used in operative cardiology.
Design/methodology/approach: On the basis of the geometrical model a finite element mesh was generated. The discretization process was realized with the use of the SOLID95 element. The set boundary conditions represented the phenomena which occur during balloon expanding.
Findings: The numerical analysis of the three-layer stent showed diverse distribution of stresses and strains in the individual layers. Minimum stresses in the analyzed range of expansion diameters ($d = 2.25 \div 3.50$ mm) were observed in the middle layer made of tantalum. Maximum stresses were observed in the layer made of the stainless steel.
Research limitations/implications: Values of stresses and strains in different stents' regions caused by applied displacements are valuable information for appropriate design of the geometry, hardening of the metallic biomaterial and forming of physio-chemical properties of surface layer.
Originality/value: The obtained results are valuable for selection of surface layer which is mainly responsible for ensuring proper hemocompatibility of the stent. The deformable surface layer is an effective way to reduce the surface reactivity of the stent in blood environment and in consequence coagulation.
Keywords: Metallic alloys; Biomaterials; Mechanical properties; Computational mechanics

1. Introduction

Intravascular implants, called stents, are among the most important achievements of last years in the area of the vascular cardiology in treatment of the ischaemic heart disease. Stents are a kind of metal elastic frames with spatial cylindrical structure and of millimetre sizes that are implanted into a critically stenosed section of the coronary vessel to support its walls and to dilate its lumen. They are used for the percutaneous treatment of the ischaemic heart disease in all haemodynamic laboratories being engaged in the percutaneous transluminal coronary angioplasty (PTCA) [1-11].

Stents have currently found their well founded position in the cardiological practice. Many types of stents are manufactured nowadays, differing with their manufacturing technology, shape, and expansion technique in the stenosed coronary vessel [12-13]. Nevertheless, there are research projects still on-going in many research centres, dedicated to development of a stent with better visibility in fluoroscopy, which is connected with improvement of the material of the stent with a required geometrical shape, decreased contact surface with vessel's walls, increased flexibility, and also coated with the relevant antithrombotic substances and covered with polymers that would decrease trombogenicity.

As there is no possibility to investigate the interaction of stents and coronary vessels in vivo, more and more publications are dedicated to model research using the finite elements method [1, 14-17]. Having the 3D model of stent implanted into the coronary vessel with its mechanical parameters we are able to evaluate interaction of these structures. Analyses carried out refer most often to distributions of stresses and strains of the particular elements of the modeled system and to blood flow problem. The research results are also verified in practice, which makes it possible to develop the approximation of the physiologic conditions of the environment [17]. This information is very useful for optimization of geometrical and material structures of the stent, and simultaneously makes it possible selection of such implants for their specific conditions of use.

2. Materials and methods

A geometrical model of a three-layer Trimaxx type (AbbotVascular® Devices – Fig. 1) coronary stent was worked out. The length of the stent was constant and equal to l = 13 mm, the initial outer diameter was equal to d_0 = 2,0 mm. The thickness of the individual layers of the stent was g = 0,025 mm.

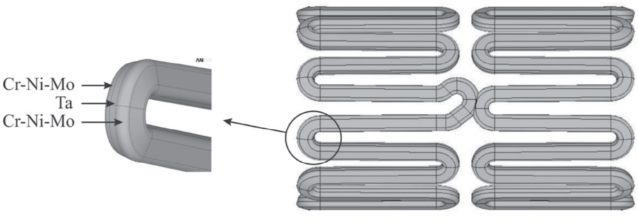

Fig. 1. A geometrical model of a three-layer coronary stent

The following material properties were set: a) Cr-Ni-Mo steel (316L): E = 190 000 MPa, υ = 0,33, R_m = 470 MPa, $R_{p0,2}$ = 195 MPa, b) tantalum: E = 185 000 MPa, υ = 0,30, R_m = 276 MPa, $R_{p0,2}$ = 172 MPa.

For each biomaterial, bilinear characteristics of elastic-plastic material of isotropic hardening were worked out. On the basis of the geometrical model a finite element mesh was generated. The discretization process was realized with the use of the SOLID95 element. This element allows for physical nonlinearities and large displacements and rotations. Due to the rapeatability of the system, the calculations were carried out for the single segments consisting of two arms with the connector and two arm without. The aim of the analysis was determination of stresses in the stent expanded radially in the displacement manner from the initial value d_0 = 1,0 up to d_1 = 3,5 mm – Fig. 2.

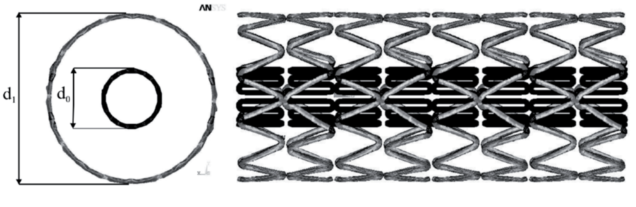

Fig. 2. A geometrical model of a three-layer coronary stent before and after expanded

Furthermore, as the comparison, the numerical analysis of the same form stent but made entirely of stainless steel (316L) was carried out. Mechanical properties of the steel were set the same as for the three-layer stent.

3. Results

3.1. Results of biomechanical analysis of three-layer stent

The first stage of the work included the stresses and strains analysis of the stent' arms with the connector. The analysis of the obtained results showed diverse distribution of stresses in the individual stent' layers. Maximum stresses in the individual layers after the expansion of the stent up to diameter d = 2,25 mm reached the values which exceeded yield point for the individual biomaterials. The maximum stresses for the inner and the outer layer of the stainless steel (316L) stent were equal to σ_{max} = 199 MPa and σ_{max} = 207 MPa respectively and were located in the connector region. The maximum stresses for the middle layer of the stent made of tantalum were also located in the connector region and were equal σ_{max} = 177 MPa. Further increase of diameter up to d_1 = 3,5 mm caused insignificant increase of the maximum stresses and the plasticization region of the stent' material – Tab. 1, Fig. 3. The analysis for the stent' arms without the connector also showed diverse distribution of stresses in its geometry. Maximum stresses in the individual layers after the expansion of the stent up to diameter d = 2,25 mm reached the values which exceeded yield point of 316L stainless steel and tantalum. The maximum stresses for the inner and the outer layer of the stent were similar to the stresses in the connector region and were equal to σ_{max} = 199 MPa and σ_{max} = 207 MPa respectively. Further increase of the expansion diameter also caused insignificant increase of the maximum stresses and the plasticization region – Tab. 1. The analysis of strains in the individual stent' layers (the expansion diameter range d = 2,25 ÷ 3,50 mm) showed diversity of their values. Results of strains in maximum effort regions were presented in Table 1.

3.2. Results of biomechanical analysis of one-layer stent

The numerical analysis of the uniform stainless steel stent also revealed that the expansion to the diameter d = 2,25 mm caused that maximum stresses, in the arms regions with and without the connector, exceeded the yield point of the steel. The maximum stresses were insignificantly different and were equal σ_{max}, = 205 MPa and σ_{max}, = 202 MPa respectively. Gradual expansion of the stent up to the diameter d_1 = 3,5 mm caused insignificant increase of stresses up to σ_{max}, = 219 MPa and σ_{max}, = 211 MPa respectively. Furthermore, the gradual increase of the plasticization region was observed – Tab. 2. The strains analysis, in the arms regions with and without the connector, showed diversity of their values. After the expansion of the stent up to d = 2,25 mm, the maximum strains were equal ε_{max} = 49% and ε_{max} = 40,8% respectively – Tab. 2. The expansion of the stent up to diameter d_1 = 3,25 mm caused the increase of the strains up to ε_{max} = 113% i ε_{max} = 87,3% - respectively – Tab. 2.

Table 1.
Results of biomechanical analysis of three –layer stent

Diameter d, mm	Stress σ_{max}, MPa			Strain ε_{max}, %		
	Arms with connector					
	Cr-Ni-Mo		Tantalum	Cr-Ni-Mo		Tantalum
	inner layer	outer layer		inner layer	outer layer	
2,25	207	199	177	55,3	20,8	29,1
2,50	209	199	179	66,2	24,3	34,7
2,75	211	200	180	75,9	27,3	39,6
3,00	213	201	181	88,0	31,1	45,7
3,50	217	202	186	102,0	36,9	53,7
	Arms without connector					
2,25	202	199	183	39,4	25,4	57,3
2,50	203	200	185	45,9	30,4	67,9
2,75	205	201	187	52,5	35,5	78,9
3,00	206	202	189	58,8	40,5	89,4
3,50	208	203	193	70,3	49,7	109,0

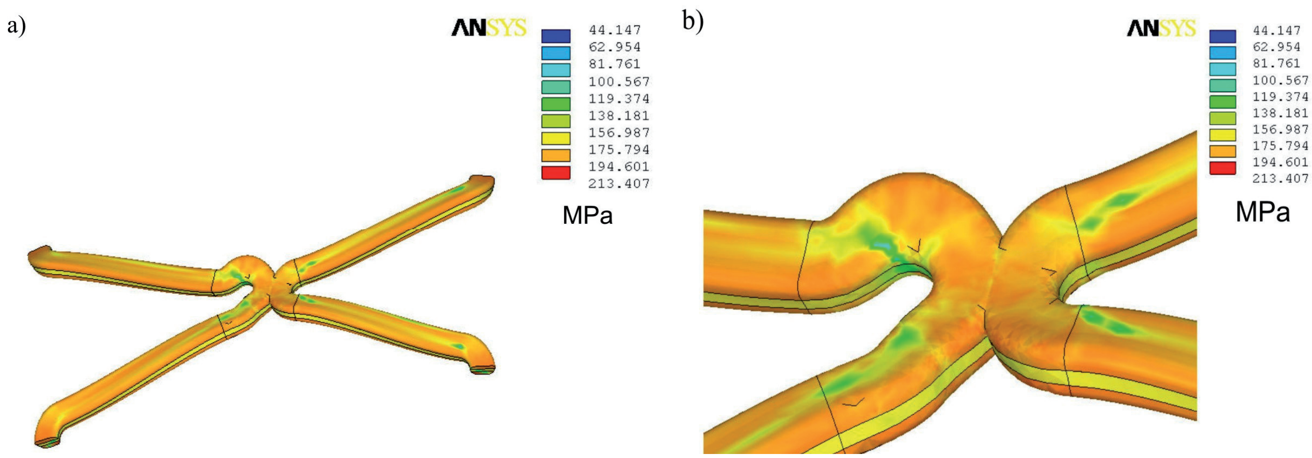

Fig. 3. Results of the analysis of the three-layer coronary stent after expansion to d_1 = 3,5 mm a), b) stresses in arms with the connector

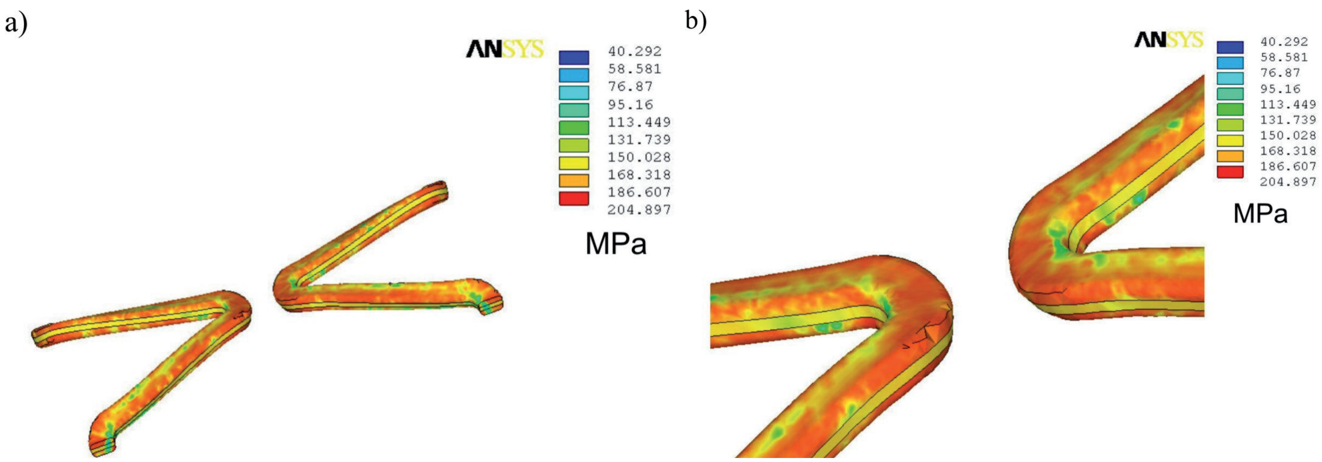

Fig. 4. Results of the analysis of the three-layer coronary stent after expansion to d_1 = 3,5 mm a), b) stresses in arms without the connector

Table 2.
Results of biomechanical analysis of one – layer stent

Diameter d, mm	Stress σ_{max}, MPa	Strain ε_{max}, %
Arms with connector		
2,25	205	49,0
2,50	208	60,3
2,75	212	82,1
3,00	214	92,6
3,50	219	113,0
Arms without connector		
2,25	202	40,8
2,50	205	54,0
2,75	207	65,4
3,00	208	75,6
3,50	211	87,3

4. Conclusions

The work presents results of the numerical analysis of the three-layer coronary stent. Basic features of proper coronary stent are as follows: good radiopaque and good elasticity. To improve a radiopaque of the analyzed stent a middle layer made of tantalum was proposed. Therefore, the main aim of the work was the influence evaluation of the proposed solution on the biomechanical characteristics of the stent. Furthermore, a comparison numerical analysis, for the same form of the stent made entirely of stainless steel (316L), was carried out.

The numerical analysis of the three-layer stent showed diverse stress distribution in the individual layers of the stent. Minimum stress values, in the analyzed range of expansion diameters (d = 2,25÷3,50 mm), were observed in the middle layer, made of tantalum. Maximum stresses were observed in the inner layer of the stent, made of stainless steel – Table 1, Fig. 3 and 4. Stresses in different regions of the stent depending on displacements are very important for the appropriate design and hardening of suggested metallic biomaterials.

The numerical analysis also revealed diverse strains in the individual layers of the stent – Tab. 1. These data are valuable for selection of surface layer which is mainly responsible for ensuring proper hemocompatibility of the stent. The deformable surface layer is an effective way to reduce the surface reactivity of the stent in blood environment and in consequence, coagulation.

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