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Biomechanical characteristics of the stent–coronary vessel system

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The paper presents the biomechanical characteristics of the stent–coronary vessel system defined using the finite element method. Within the framework of the project the stress and strain distributions in the elements of the modelled system were determined for various stent form features, taking into account stent implementation stage and also its operation with the changing blood pressure. The results obtained may be a basis for optimization of the coronary stent shape and its form features, as well as of the properties of metallic material from which stents are made.

Key words: biomechanics, coronary stent, finite element method

1. Introduction

Intravascular implants, called *stents*, are among the most important achievements of last years in the field 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]–[5].

First experiences connected with implantation of stents were not very encouraging. The year 1993, in which Antonio Colombo introduced the high-pressure expansion of tents, has been the turning-point [2]. This resulted in the widespread use of stents and after several years' long investigations they turned out to be a nearly ideal solution, suitable for treatment of the ischaemic heart disease.

Stents have currently found their well founded position in the cardiological practice. Many types of stents, differing in their manufacturing technology, shape, and expansion technique in the stenosed coronary vessel, are manufactured nowadays [6], [7]. Nevertheless, there are research projects still ongoing in many research centres and dedicated to the development of a stent with better visibility in fluoroscopy. This feature is connected with the improvement of the stent material which allows us to obtain a required geometrical shape of a stent, to decrease its contact surface with vessel's walls, to increase its flexibility, and also to coate it with the relevant antithrombotic substances and to cover it with polymers that would decrease trombogenicity.

As there is no possibility to investigate the interaction between stents and coronary vessels *in vivo*, more and more publications are dedicated to model research using the finite-elements method [8]–[10]. 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 the distributions of stresses and strains of the particular elements of the system being modelled and to the 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 [11], [12]. This information is very useful for optimization of geometrical and material structures of the stent, and simultaneously allows selection of such implants for their specific conditions of use.

2. Methods

The main goal of the project being presented was to determine the biomechanical characteristics of a stent for its various form features and to analyse of the influence of human blood pressure changes on the interaction between the stent and coronary vessel. The project scope included:

- development of the geometrical model of the coronary stent,
- development of the geometrical model of the coronary vessel,
- development of the discrete stent–coronary vessel model,
- development of the numerical model of stent and coronary vessel using the finite element method,
- carrying out calculations in the nonlinear range.

Development of the numerical model of stent and coronary vessel is a difficult task due to complexity of phenomena occurring in such an object. Significant changes in the stent geometrical configuration take place during its implantation, resulting in strengthening of the stent's material. Therefore, it is necessary to take into account both its physical and geometrical nonlinearities. The stent–coronary vessel interaction and load variability caused by blood pressure changes are an important problem.

2.1. Numerical model of the stent

Models of the coronary stent with various form features (figure 1) developed by Prof. Poloński's team from the Silesian Centre for Cardiac Diseases in Zabrze were analyzed within the framework of the project. Stent's wire diameter was the geometrical parameter that varied. It was assumed to be 0.12 mm and 0.16 mm. The stent's length l was constant and equal to 15 mm. The stent with the initial diameter d_{4F} (diameter of the cylinder with the perimeter equal to 4 mm) was expanded on a balloon with the 3 mm diameter. Mesh of elements for finite-element calculations was generated based on the geometrical models developed. It was generated using the parametrical methods to obtain a mesh ensuring high accuracy of object representation. Parametrical solid elements with three degrees of freedom in a SOLID type node were assumed as the finite elements. These elements make it possible to take into account the physical nonlinearity and large displacements and turns. The developed discrete model of the stent is presented in figure 2. The model developed in this way has about 400 000 degrees of freedom and it is not possible to undertake its multistep nonlinear analysis guaranteeing the required accuracy of calculations. Because of the repeating object's structure, the calculations were done for stent's material made of a single convolution consisting of four segments.

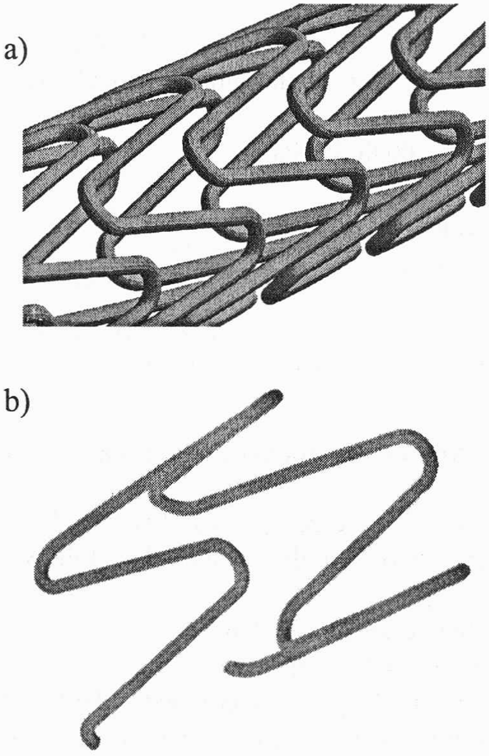

Fig. 1. Geometrical models: a – coronary stent, b – single pitch of the stent

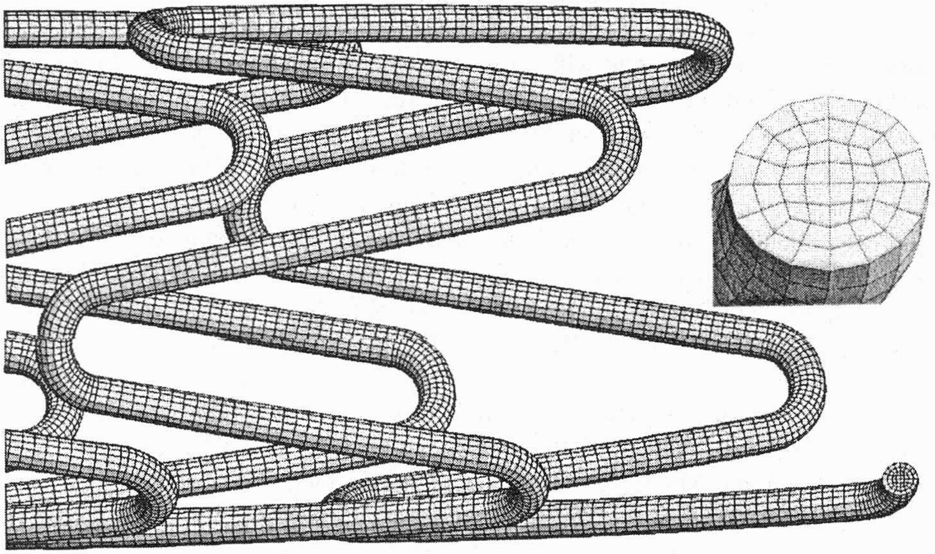

Fig. 2. Discrete model of the coronary stent

The following data for the Cr-Ni-Mo steel of the AISI 316L type, as the stent's material, were used for evaluation of the biomechanical characteristics of the coronary stent:

- Young's modulus $E = 200\,000$ MPa,
- the Poisson ratio $\nu = 0.33$,
- ultimate tensile strength $R_m = 470$ MPa,
- yield point $R_e = 195$ MPa,
- deformation $A_5 = 40\%$.

For the above material data the bi-linear characteristics of the elastic-plastic material with the isotropic strengthening was worked out.

2.2. Numerical model of the coronary vessel

The geometrical model of the coronary vessel with a thin-walled tube shape was developed within the framework of the project. The following form features were assumed for this model [13]:

- inside diameter of the vessel $d = 2.90$ mm,
- vessel wall thickness $g = 0.90$ mm.

The coronary vessel model length was assumed to be the stent's length increased by its triple pitch on both ends (figure 3). Young's modulus $E = 0.75 \times 10^7$ Pa [13] was used for calculations.

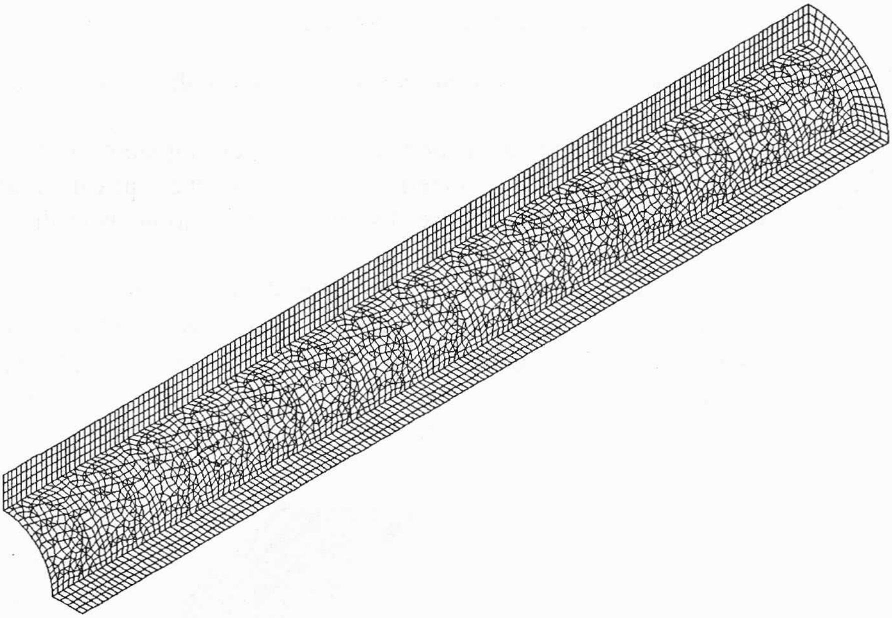

Fig. 3. Discrete model of the coronary vessel (1/4 of the longitudinal cross-section)

2.3. Boundary conditions

The following assumptions were accepted in the calculations:

- stent's inner surface is loaded uniformly during its expansion,
- friction forces during balloon expansion result in stent's diameter change due to wire deflection and not because of unwinding the coiled stent,
- stent's diameter change during expansion from d_{4F} to d_3 (balloon's diameter after expansion) was preliminarily assumed,
- the degrees of freedom were restricted in a way reflecting the real object's deformation,
- blood pressure loads uniformly the entire side-wall surface of the coronary vessel.

3. Results

The numerical analysis of the coronary stent was carried out using the COSMOS/M$^{\text{TM}}$ system ver. 2.5 of Structural Research and Analysis Corp. in Santa Monica, California, USA. Because of the main goal of the calculations, the control of the incremental mesh node displacement in the radial direction was used. The variable problem solution step was applied:

$$\Delta u_r = (1 \times 10^{-8} \div 0.02)\, u_{r\max},$$

in which use was made of step iterations carried out with the Newton–Raphson method.

In the first stage of the project, stress and strain fields during stent expansion on the balloon and during unloading were determined, and also the equivalent stresses were evaluated according to the Huber–Mises hypothesis in locations with the largest stent effort.

Analysis of the results obtained indicates that for the stent made from the wire with the diameter of 0.12 mm the reduced stresses' value is equal to $\sigma_1 = 257$ MPa, and for the stent made from wire with the diameter of 0.16 mm this value is $\sigma_2 = 275$ MPa. In both cases, the maximum stress values occur at the inner side of particular stent segments' bends. Stress distribution in a single stent coil is presented in figure 4.

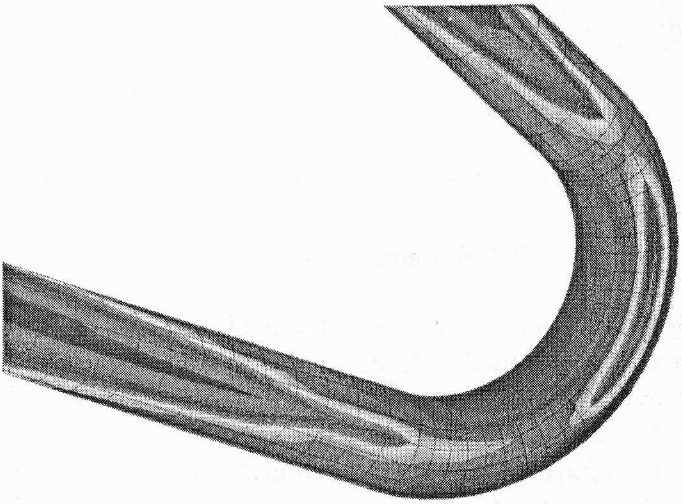

Fig. 4. Stress distribution in a single segment of the stent made from wire with the 0.12 mm diameter

The model developed allowed also evaluation of the possible stent characteristics, presenting the dependence of the radial force F upon one stent coil as a function of radial displacement (figure 5). The characteristics obtained includes both the stent expansion on the balloon stage and its unloading. Stiffness of one stent coil was evaluated based on the characteristics obtained in the project, separately for expansion with the balloon $k_{(+)}$ and for tightening by the coronary vessel $k_{(-)}$. The stiffness values determined were $k_{(+)} = 0.2416$ N/mm and $k_{(-)} = 10.92$ N/mm for the stent made from wire with the diameter of 0.12 mm and $k_{(+)} = 0.4961$ N/mm and $k_{(-)} = 24.50$ N/mm for the stent from wire with the diameter of 0.16 mm. Deformations of the coronary vessel in a scale of 5:1 developed by stent expansion are presented in figure 6.

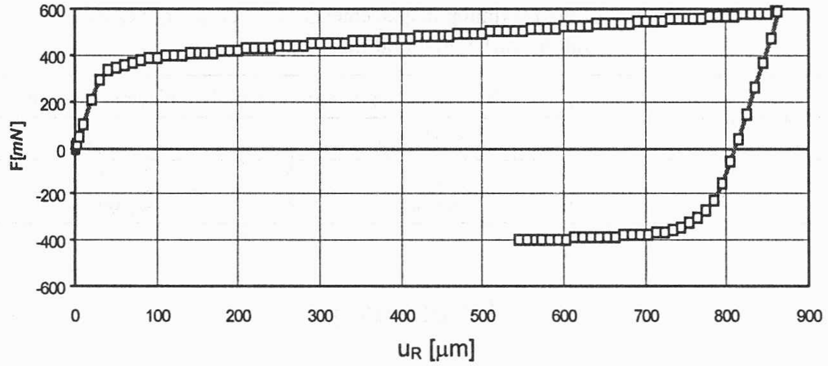

Fig. 5. Dependence of the radial force *F* exerted on one pitch as a function of radial displacement u_R for stent from wire with the diameter of 0.12 mm

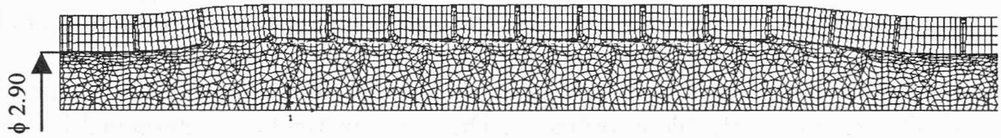

Fig. 6. Deformation form of the coronary vessel expanded with the stent on the balloon with the 3 mm diameter

Next, the stent–coronary vessel system behaviour was studied for two blood flow pressure values ($p_1 = 10$ kPa and $p_2 = 16$ kPa) with a particular attention paid to displacements of the coronary vessel elements. The maximum radial displacement values of the coronary vessel walls are presented in the table and in figure 7.

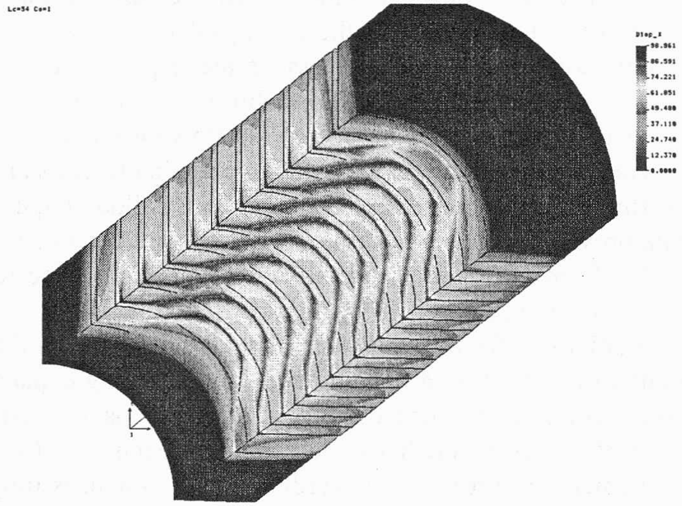

Fig. 7. Contour lines of the radian displacements of the coronary vessel, stent from wire with diameter of 0.12 mm, blood pressure of 10 kPa

Table. Values of the maximum displacements of the coronary vessel wall for different blood flow pressures

Stent wire diameter d, mm	Values of the maximum radial displacements, μm	
	$p_1 = 10$ kPa	$p_2 = 16$ kPa
0.12	51.61	53.14
0.16	98.96	99.98

4. Summary

The stent–coronary vessel model developed in the project is – due to the complexity of the problem – a model with the simplified design assumptions. The simplifications refer to the issues associated, among others, with modelling the coronary vessel shape, which in fact is not a rectilinear section of a thin-walled tube. Moreover, the varying geometry of the coronary vessel connected with the particular work phases of the cardiac muscle was not taken into account.

In spite of the simplifications being introduced, results of the calculations carried out yield a wealth of valuable information. The stress distributions determined for the particular elements of the modelled system may be the basis for optimisation both of their form features and also of the metallic material from which the stent will be made. Stresses occurring in the elements of the expanded stent should reach the values exceeding the yield point of the material from which the implant is made. This decides the effectiveness of the stent's implantation operation. Permanent deformation of an implant mounted on a balloon makes it possible to put it precisely in place and ensures supporting the walls of the previously contracted vessel. In addition, the determined strain distributions of the system elements feature a valuable information during assessment of the applicability of the coatings deposited on stents' surfaces to improve their hemo-compatibility. Usefulness of the deposited coatings should be evaluated, among others, based on their deformability. The analysis of the behaviour of the stent–coronary vessel for two values of the flowing blood ($p_1 = 10$ kPa and $p_2 = 16$ kPa) indicates that the strain values of the system's elements are clearly lower than those occurring during expansion of the stent on a balloon (figure 7, the table). This type of data provides valuable information about conditions of carrying out this type of coatings' deformability tests under *in vitro* conditions. The research results obtained indicate that the applicability of the deposited coatings should be verified under *in vitro* conditions, reflecting the stage of stent expansion on the balloon. It is just during mounting the stent on a balloon, and its succeeding expansion, when the maximum stresses occur, determining usefulness of the deposited coatings. It seems, therefore, that use of numerical methods and computer techniques for modelling and analyzing of phenomena occurring in the cardiovascular system is fully justified and is of a prospective importance.

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References

[1] SIGWART U., *Endoluminal Stenting*, W. B. Saunders Company Ltd., 1996.

[2] WITKOWSKI A., *Stent implantation operations into the coronary arteries and venose arterial-coronary bypasses: indications and results* (in Polish), Nowa Medycyna, 1997, 4, 17.

[3] RUŻYŁŁO W., *Żyjmy dłużej* (in Polish), 1999, 3, 22.

[4] BRZOSTEK T., *Stents in the ischaemic heart disease* (in Polish), Kardiologia Polska, 1996, 45, 541.

[5] BUSZMAN P., SIGWART U., ZEMBALA M., *Percutaneous revascularization of the cardiac muscle with patients after the arterial-coronary bypass implantation operation* (in Polish), Kardiologia Polska, 1996, 43.

[6] SERRUYS P., KUTRYK M. (ed.), *Handbook of coronary stents*, Martin Dunitz Ltd, 1998.

[7] PASZENDA Z., TYRLIK-HELD J., MARCINIAK J., *Corrosion resistance tests of the coronary stents made from the Cr-Ni-Mo steel coated with the passive layer* (in Polish), Acta of Bioengineering and Biomechanics, 2001, Vol. 3, Suppl. 1, 169.

[8] DUMOULIN C., COCHELIN B., *Mechanical behaviour modelling of balloon-expandable stents*, Journal of Biomechanics, 2000, 33, 1461–1470.

[9] WENTZEL J., WHELAN D. et al., *Coronary stent implantation changes 3-D vessel geometry and 3-D shear stress distribution*, Journal of Biomechanics, 2000, 33, 1287–1295.

[10] ETAVE F., FINET G., BOIVIN M., BOYER J., RIOUFOL G., THOLLET G., *Mechanical properties of coronary stents determined by using finite element analysis*, Journal of Biomechanics, 2001, 34, 1065–1075.

[11] BERTOLOTTI C., DEPLANO V., *Three-dimensional numerical simulations of flow through a stenosed coronary bypass*, Journal of Biomechanics, 2000, 33, 1011–1022.

[12] FABRUGUES S., BAIJENS K., RIEU R., BERGERON P., *Hemodynamics of endovascular prostheses*, Journal of Biomechanics, 1998, 31, 45–54.

[13] PURINIA B., KASJANOW W., *Biomechanicieskije swojstwa koronarnych arterii cieławieka* (in Russian), Kardiołogija, 1977, 108–111.