Achievements in Mechanical and Materials Engineering

COMMENT Worldwide Congress on Materials and Manufacturing Engineering and Technology
16th - 19th May 2005 Gliwice-Wisła, Poland

COMMITTEE OF MATERIALS SCIENCE OF THE POLISH ACADEMY OF SCIENCES, KATOWICE, POLAND
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13th INTERNATIONAL SCIENTIFIC CONFERENCE ON ACHIEVEMENTS IN MECHANICAL AND MATERIALS ENGINEERING

Experimental and numerical biomechanical analysis of vascular stent

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Abstract: The paper presents results of the experimental and numerical research of a vascular stent used in a treatment of blood vessel stenosis. In particular, the biomechanical characteristic of the stent was determined. The characteristic presents changes of the outer diameter of the stent as a function of an expanding pressure. The analysis of the obtained results confirms the usefulness of numerical methods in analyzing phenomena occurring while expansion process of implants used in an interventional cardiology.

Keywords: Vessel stents; Finite elements method; Austenitic steel;

1. INTRODUCTION

One of the most important achievements of the last years in the area of the interventional cardiology in treatment of the ischaemic heart disease is employment of the intravascular implants, called stents. Stents are a kind of metal elastic frames with spatial cylindrical structure and of millimeter sizes that are implanted into a crytically stenosed section of the coronary vessel to support its walls and to dilate its lumen. The initial experiences connected with implanting of stents were not too encouraging, as blood thrombosis used used to occur often, closing the artery lumen and causing severe complications, leading in consequence to cardiac infarction or death of the patient. Year 1993 was the turning point when Antonio Colombo introduced the high-pressure method of stent deployment. It was the high-pressure deployment and introducing the antithrombotic treatment that significantly lowered the frequency of thrombosis incidences. This led to wide use of stents and after several years long investigation they turned out to be the nearly ideal solution for the ischaemic heart disease [1].

While determining the biomechanical characteristic of the stent it should be remembered that during the implantation large changes of the geometrical configuration occur [2,3]. The changes cause hardening of the material the stent is made of. Therefore physical as well as geometrical nonlinearities should be taken into consideration. Some authors assume material properties only by giving the Young's modulus E but it doesn't take into consideration nonlinear phenomena during implantation [4].

2. METHODS

The basic aim of the presented work was a determination of the biomechanical characteristic of the vascular stent in experimental conditions and with the use of the finite element method. The characteristic presents changes of the outer diameter d_z of the stent as a function of an expanding pressure p. Tests were performed with the use of the GENESIS^{TM} vascular stent intended for the treatment of large blood vessel stenosis (Johnson & Johnson Company – fig. 1) [5].

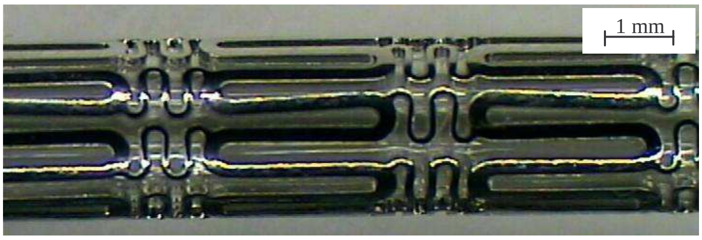

Figure 1. The GENESIS^{TM} vascular stent [5]

In order to determine the dz = f(p) relation in the experimental conditions the stent was fixed on the specially designed laboratory stand ensuring the possibility of the observation and recording of the stent geometry changes. To fix the stent a polyethylene pipe was used. The fixation ensured a free expansion of the central segments of the stent. The pressure in the balloon was changed incrementally (0,1 MPa) in the range of p = 0 – 0,5 MPa. The expansion process was realized with the use of the original implantation set.

In order to calculate the analyzed relation with the use of the finite element method a geometrical model of the stent was worked out – fig. 2a. The next step was meshing carried out with the use of the SOLID95 finite elements. Appropriate initial and boundary conditions were set. The expansion process of the stent was reflecting real conditions. The pressure was uniformly applied to the inner surface of the stent. The expanding pressure value was incrementally applied (0,002 MPa) in the range 0 ÷ 0,5 MPa.

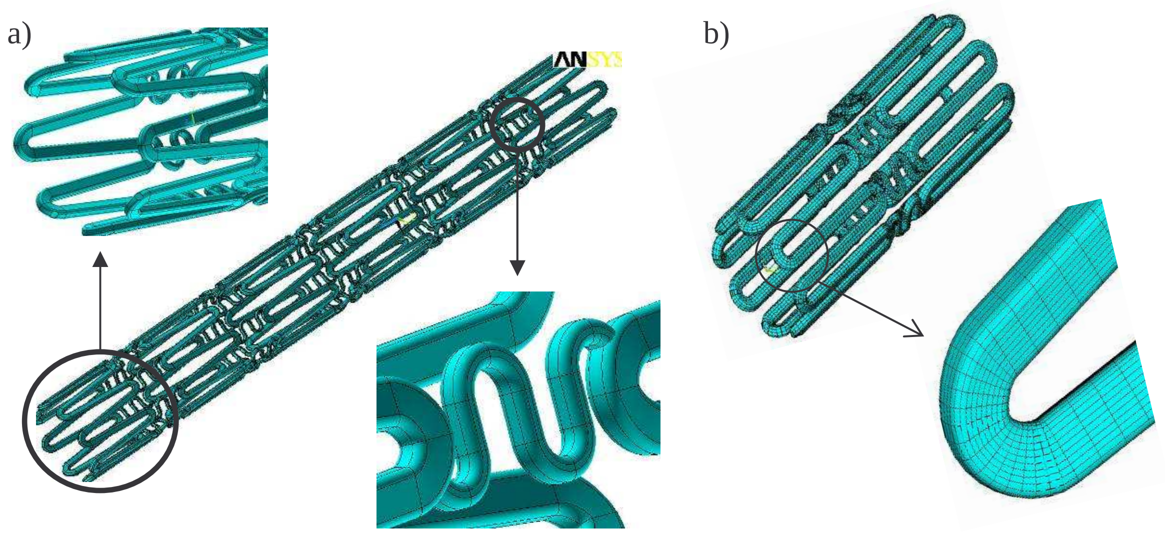

Figure 2. The model of the vascular stent used in the FEM analysis: a) geometrical, b) meshed

Due to the repeatability of the structure the calculations were carried out for the single segment taking a nonlinear strain phenomenon into consideration.

The following material data were assumed (316L stainless steel):

- Young's modulus E = 200 000 MPa,
- Poisson's ratio υ = 0,33,
- tensile strenght R_m = 470 MPa,
- yield stress $R_{p0,2}$ = 195 MPa.

3. RESULTS

The biomechanical characteristic of the stent analyzed in the experimental conditions and with the use of the finite element method was presented in fig. 3.

The analysis of the experimental results shows that the process of the stent diameter increase doesn't proceed proportionally to the given pressure value in the balloon. A sudden increase of the implant diameter was observed after exceeding the given critical value of the expanding pressure – fig. 3. The increment of the expanding pressure used in the test (0,1 MPa) was to high to precisely determine the value of the pressure causing, after exceeding its value, the sudden increase of the stent diameter. The further increase of the expanding pressure (above 0,3 MPa) didn't cause the increase of the outer diameter of the stent.

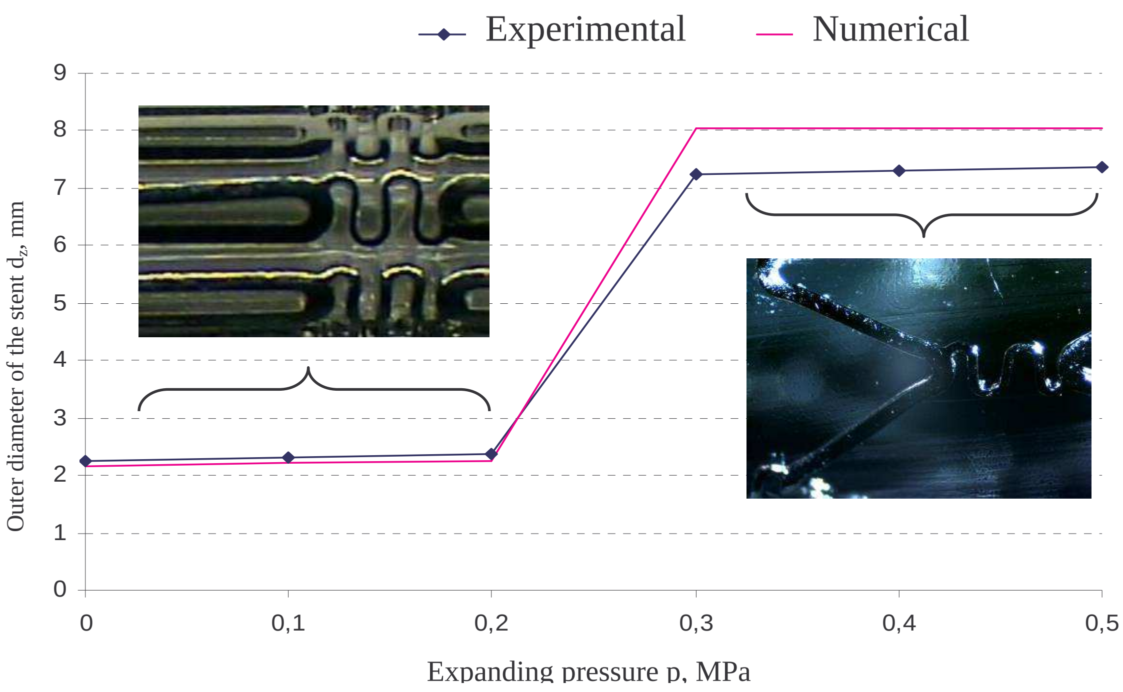

Figure 3. The relation between the outer diameter of the vascular stent and the expanding pressure

The biomechanical characteristic obtained with the use of the finite element method shows a very high correlation with results obtained in the experimental method – fig. 6. The decrease of the pressure increment up to 0,002 MPa allowed to calculate the pressure responsible for the sudden increase of the stent diameter. On the basis of the numerical simulation it was affirmed that the fundamental stage of the stent expansion was realized in the range of pressures p = 0,266 ÷ 0,280 MPa responding the increase of the diameter in the range d_z = 2,63 ÷ 8,05 mm. Also in this case the further increase of the expanding pressure didn't cause the change of the stent diameter.

On the basis of the numerical simulation it was affirmed that after the exceeding the pressure p = 0,280 MPa (the diameter d_z = 8,05 mm) the stress values didn't change and were equal to σ = 222 MPa – fig. 4.

4. SUMMARY

The paper presents the methodology for biomechanical characteristic of the vascular stent used in a treatment of blood vessel stenosis, for example carotid artery – fig. 1. The appropriate initial and boundary conditions set for the numerical models allowed to reflect the phenomena occurring in the real object during implantation. A high correlation between results obtained in the experiment and with the use of the finite element method proves that – fig. 4. Furthermore, the information obtained from the modeling considerations is very useful with respect to the optimization of the geometrical and material features of stents. It also can be used to predict a stability of the utilitarian features of this type of implants.

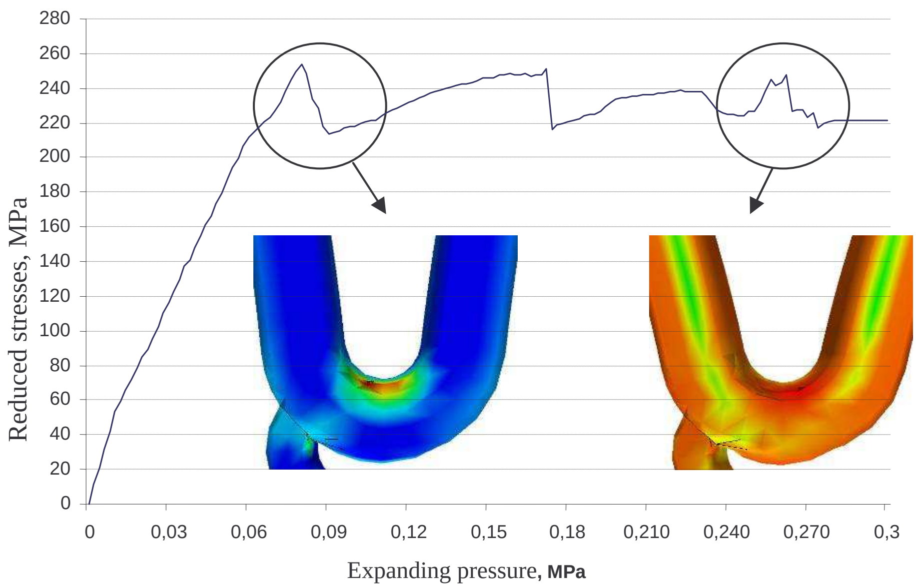

Figure 4. The relation between the outer diameter of the vascular stent and the expanding pressure

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