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INTRACORONARY STENTS USED IN ISCHAEMIC HEART DISEASE – NUMERICAL CALCULATIONS OF MECHANICAL PROPERTIES OF NEW IMPLANTS.

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Abstract. Stents implanted with the use of a balloon have been situated in the centre of our interests. A very interesting fact during the implanting is that during the expanding the boundary of plasticity is exceeded, the material is hardened and the whole construction still works in the expanding state. The Finite Element Method (ANSYS)was used to create the numerical model.

Keywords: FEM, Stents, Non-linear Plasticity.

1. INTRODUCTION

Heart is the organ the work of which can be compared with the mechanism of the pump. Its task is to deliver blood to all parts of the body. Blood is delivered to myocardium through blood vessels called coronary arteries. In case of coronary arteries disease which is caused by cholesterol deposition the arteries can be narrowed or there may occur artery occlusion. The decrease of blood flow causes the myocardial hypoxia. It results in the sharp pain in the thorax. Many tests are conducted in order to discover the illness. Myocardial catheterization - coronaro-graphy – is the most important diagnostic method [4]. The method is based on introducing a thin tube called catheter to the outlet of coronary vessels by puncturing the skin and the vessel in the groin or in the forearm. The catheter enables the doctor to inject a special liquid (contrast) to a sick vessel, and to observe the shape and size of coronary vessels by means of X-ray apparatus [5]. Based on this examination the doctor can estimate the flow in the vessel, and whether there are occlusions which might cause coronary disease occurring in people at different ages. The flow occlusion in the vessels leads to necrosis of a certain area of myocardium called myocardial infarct. Then the sick person feels sharp pain in the thorax. Coronary disease can occur in people at different ages. Its symptoms considerably decrease life activity. There are many ways of curing myocardial ischemia. One of these is the implantation of one or a few stents into the coronary vessel (Figure 1). A stent is a kind of scaffolding which is implanted in the critically narrowed section in order to support the walls of the vessel and to broaden its light [4]. The aim of the following study is to create a numerical model showing the stage of stent expansion, interaction of blood vessel upon the stent, what will allow to determine the value of straining and stress, and the fatigue resistance of the stent.

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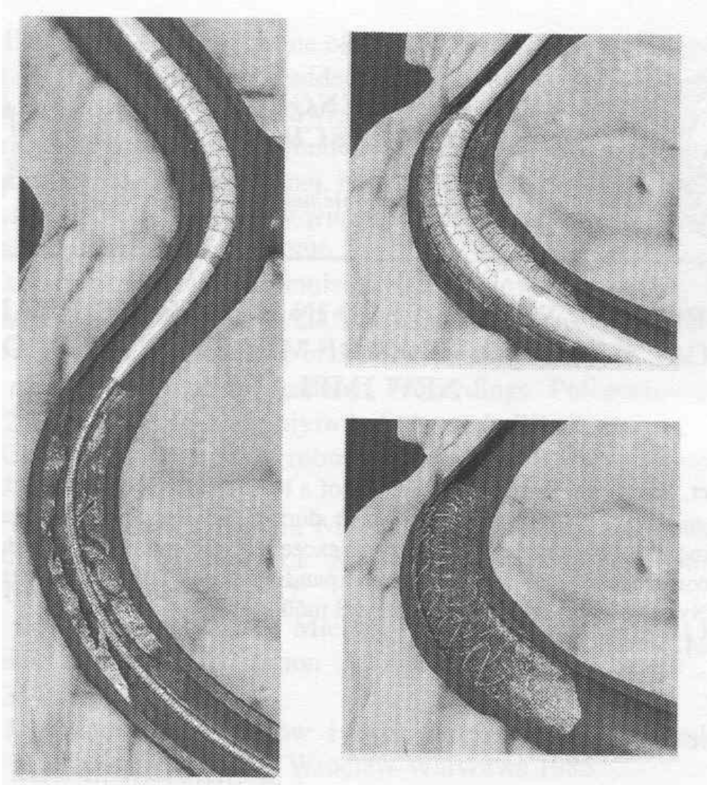

Figure 1. FLEX-STENT™ [6], [7].

2. Stents – Characterization, Kinds and Construction.

Stents are made of metal rustless net. The stent looks like a thin tube before it is introduced into the vessel. Once there, it is expanded to the size of the vessel in which it has to be placed. The flexibility enables leading the stent through the bends of proximate sections of coronary vessels, and implanting it into the occluded part. The lack of crushing susceptibility of the open stent diminishes the cycling stretching of the vessel wall. Materials used for stent construction differ in thrombus properties. Biologically indifferent rustless steel marked 316L is most frequently used for stent production. It is very important to minimize the surface thickness and porosity of metal. Rustless steel is characterized by long durability – and this is why only a small amount of steel is sufficient for the production of a stent. Small weight of a steel, however, is hardly visible in fluoroscopy, it hinders on the one hand precise location of a stent, on the other hand its recognition in case of displacement. Carefully chosen size of a stent (the ratio of the diameter to the diameter of the vessel is from 1 to 1,1) determines the success of the implantation. On the one hand the stent narrower than the size of the vessel tends to migrate, on the other hand the excessive expansion of the walls causes the damage of the inner and central layer of the artery. At present there are 3 basic types of stents as regards the method of implanting and the material used:

- Stents implanted by the use of the balloon – they were introduced by J. Palmaz in 1984. The use of the balloon makes the advantage of the plastic properties of rustless steel and enables precise installation of a stent. A low profile and a small surface of the metal is the advantage of this kind of the stent. The stent once expanded above the plastic properties of the steel does not change its shape. Palmaz-Schatz, Gianturco-Rubin, Wiktor and

Strecker are of this type. New models are the stents: Crown, Cross, Flex, XT, Freedom, NIR, Angiostent and Multi-Link [4].

Self expanding stents - built from elastic spiral of nitinol, which, having self expanded, can take different shapes, preserving all the time centrifugal expanding force, e.g. Wallstent. Flexibility at introducing and stability after implanting are the advantages of Wallstent. In spite of these advantages and results presented by U. Sigwort multicenter clinical testing showed that Wallstent is characterized by higher risk of thrombosis.

Stents expanding under the influence of heat. A stent of this kind built of nitinol spiral (the alloy of nickel and titanium) is placed on the catheter of low profile. The stent being introduced into the occluded place and heated, the metal spiral expands to the required dimension. The complicated process of introduction, and hard to foresee degree of expansion of nitinol stent restrict its clinical interest.

3. Construction of nonlinear numerical modelling.

Stents implanted with the use of a balloon have been situated in the centre of our interests. A very interesting fact during the implanting is that during the expanding the boundary of plasticity is exceeded, the material is hardened and the whole construction still works in the expanding state. Special software – the programme of the Method of Finite Elements ANSYS was used to create the numerical model (Figure 2).

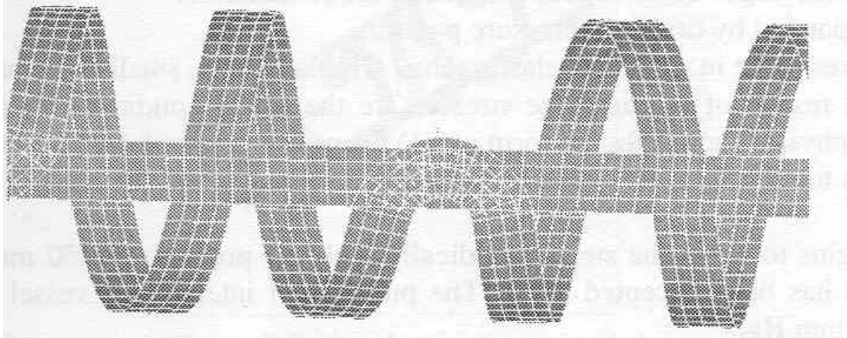

Figure 2. Numerical model of the stent divide into finite elements.

Several stages leading to full expansion of stent were taken into consideration during modelling. The constructed model has got as nonlinear character because of nonlinear straining as well as nonlinear formula (1) making use of plasticity criterion according to van Misses, and of kinematic strain hardening of the materials.

The equivalent plastic stress has the following form

$$\sigma_e = \left[\frac{3}{2}\left(\{s\}-\{\alpha\}^T\right)\cdot[M]\left(\{s\}-\{\alpha\}\right)\right]^{\frac{1}{2}}, \tag{1}$$

$$\{s\} = \{\sigma\} - \sigma_m[111000]^T, \tag{2}$$

where:

$\{s\}$ – vector of stress deviator,

$[M\}$ – matrix describing plastic stress changes,

$\{\alpha\}$ - translation vector of plastic deformation,

σ_m - hydrostatic stress = $^1/_3(\sigma_x + \sigma_y + \sigma_z)$.

The whole model vessel-stent (Figure 3) is built of 3.273 elements. The stent was modelled from elements of SHELL 93 type (spatial, 8 – nodal), and the vessel from the elements of CONTACT 170 and CONTACT 174 type (spatial, 8 – nodal).

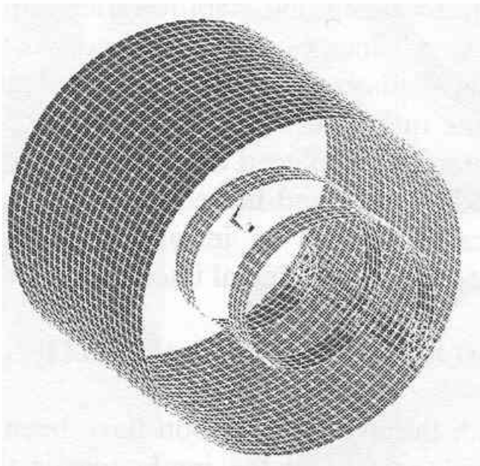

Figure 3. Numerical model vessel-stent with the division into the finite elements.

The following several stages of numerical simulation are remarkable:
- the stent is expanded by the inner pressure p=6atm,

the initial stage takes place in the linear elastic range (Hooke's law), small deformations,
- next the final results of elastic stage stresses are the initial conditions of the plastic stage and the physical law takes the form of (1) (large non-linear deformations),
- stent becomes totally expanded touches the surface of the vessel, the material becomes hardened,
- the vessel begins to press the stent periodically with the pressure p=250 mm Hg (the safety margin has been accepted as 3). The pressure of interaction vessel – stent is about p=83,9 mm Hg.

The above model aims at taking into consideration the history of deformations, what has an enormous influence upon the level of deformations and final stresses, caused by the vessel interaction upon the implant, and what follows is the definition of stent fatigue strength during the millions of cycles caused by heart action. Surgery steel 316L has been taken as the material from which the mentioned above stent has been made.

4. The results of numerical simulations.

The data concerning the level of deformations and stresses in particular stages of stent expansion have been obtained as a result of numerical calculations. The expansion the implant with the balloon and then application of load with the coronary vessel is a typical example of occurrence of the Bauschinger effect. The foregoing considerations lead to determination of the yield point of the material (316L) after the expansion of it with the balloon. The yield point of the unexpanded material is 170MPa and after the expansion – 100MPa. Figure 4 shows the exemplary results of reduced stress achieved for plastic stage.

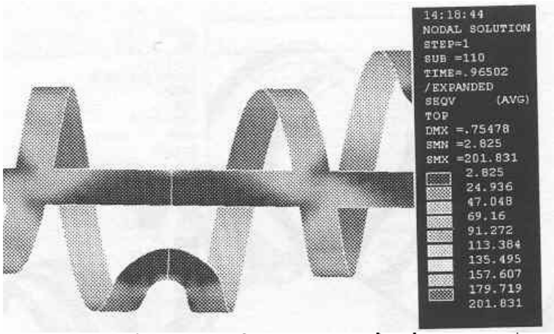

Figure 4 Reduced stresses – plastic stage.

On gaining this information, a new, identical, stent was modelled but expanded and loaded with the pressure caused by the coronary vessel (p=250mmHg = 33330Pa). The margin of safety was assumed as 3. Elements of the type 'Shell 93 Special' (shell with 8 kinematic pairs). The load was applied to the centers of those elements (Figure 6).

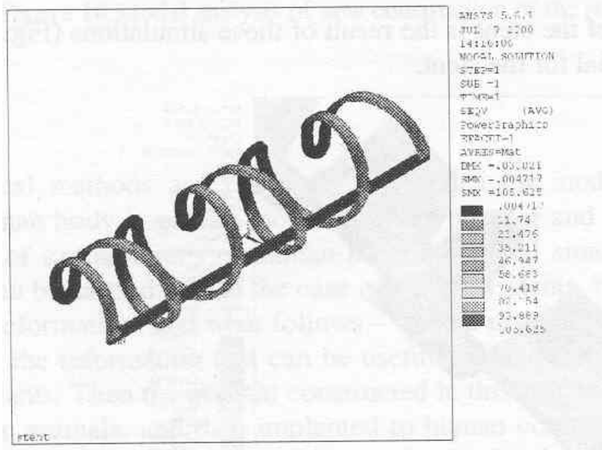

Figure 5 Reduced stresses in expanded stent GR II

The static boundary conditions are presented in the Figure 6.

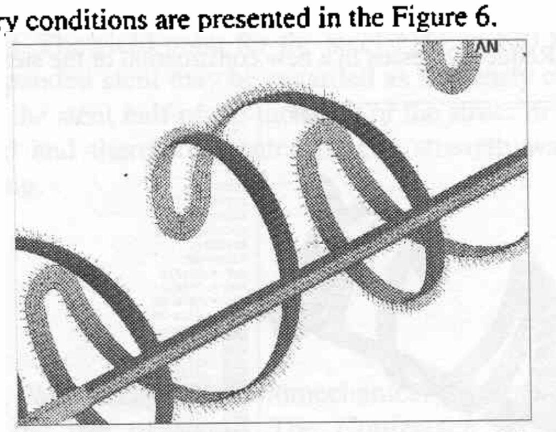

Figure 6 The static boundary conditions

The results of numeric calculations with the appliance of dynamic loads were also presented (Figure 7).

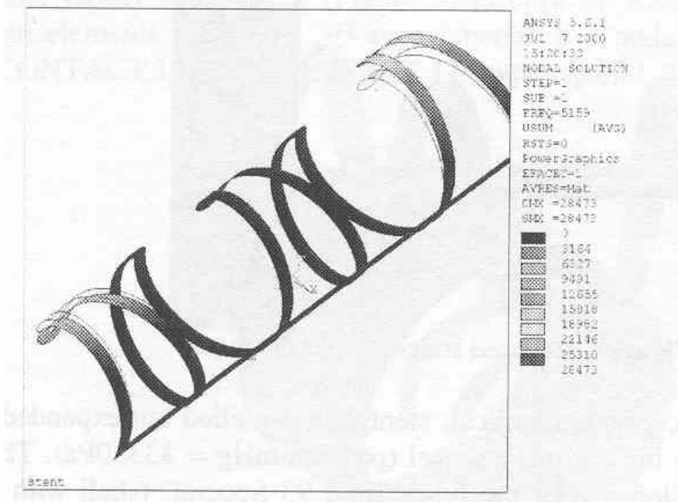

Figure 7 Model analysis in stent GR II

The new construction of the stent is the result of those simulations (Figure 8). The steel 316 L were used as a material for the stent.

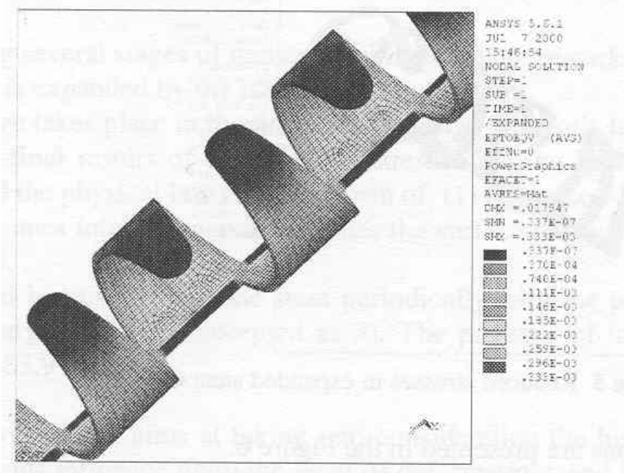

Figure 8 Reduced stresses in a new construction of the stent

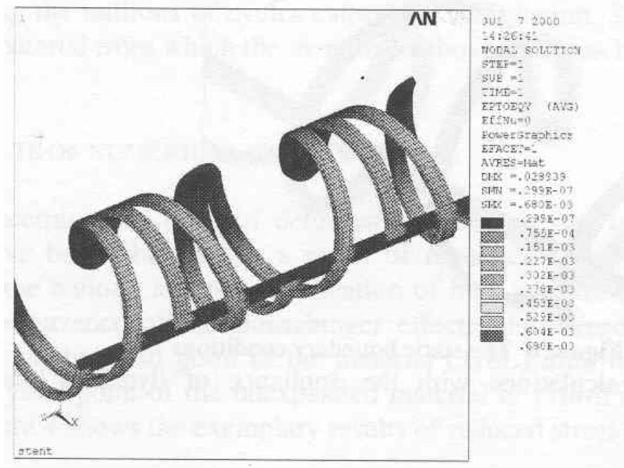

Figure 9 Reduced stresses in a new construction of the stent

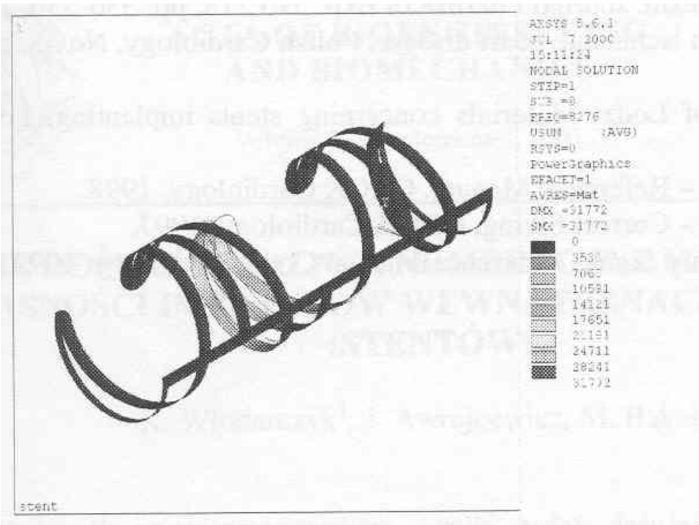

Figure 10 Modal analysis of new construction of the stent

5. SUMMARY

The use of numerical methods and computer techniques for modelling the phenomena occurring in the human body is getting more and more popular and gives better and better results. In the case of examinations of human heart numerical simulations are sometimes the only ones that can be carried out. In the case of coronary stents they allow to define the level of stress and deformation, and what follows – fatigue resistance. Computer simulation gives the scientists the information that can be useful while getting the optimal shape in construction of implants. Then the implant constructed in this way is subjected to testing on fatigue machines, on animals, and then implanted to human coronary vessels. The cost of numeric simulations, however, cannot be compared to other kinds of investigation.
Numeric model, in which the nonlinear physical relation and nonlinear deformations (expansion of the stent) were used, was applied to determine the new yield point, appearing in the expanded stent. The yield point for the steel 316L is 170 MPa. After the expansion it is 120 MPa. The expanded stent may be regarded as a linearly elastic object. Thanks to the new construction of the stent half of the intensity of the stress in it was achieved at the same quantity of the load and therefore greater fatigue strength was achieved as well as the reduction of detaching.

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