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A Study of the Mechanical Properties of a Real Coronary Stent – Dynamical Behaviour of an Optimal Stent

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Abstract. Due to different reasons the coronary stent become more and more popularity. There are different type of stents in the construction and inaterials.

For the reliability of stent the mechanical behaviour is of exclusive importance. The experimentally estimation of this behaviour is often impossible due to the expensive tests and need of specialized apparatus.

As an international standard for releasing a stent into production the "Guidance for Industry and FDA Stuff – Non-clinical Engineering Tests and Recommended Labeling for Intravaskular Stents and Associated Delivery Systems" is accepted.

In this work we show a Finite Element pre-clinical simulation of mechanical properties of the stent during expanding of the stent and following relaxation using the COMSOL software. The most important properties of a real stent, which is under review for admission are predicted: diameter of the stent, recoil, dogboning, critical stresses. These parameters are in conformation with other stents. The construction show ever better parameters in comparison with classical Palmaz-Scatz types.

1 Introduction

The lack of long time effectiveness of percutaneous transluminal coronary angioplasty (PTCA) and the *coronary bypass* (CABG) and the prize of the coronary surgery lead the researchers to search new technologies like laser angioplasty, atherectomy and implanted endovascular devices, called *stents*. The stents become more and more popular because of their high success rate, of minimal invasive nature and the continued improving of their effectiveness.

Every year over 1 million percutaneous interventions are performed in the world. This exceeds the number of coronary bypasses (CABG) in the year. The real use of coronary stents has been increased from 10% in 1994 up to 80% in the current praxis [1].

Since the first stent appeared, the technology progresses very rapidly. The flexibility of the stents has been improved. New materials and technologies for stent catheter systems have been developed, the coronary stenting found an use for different lesions [1,2]. Despite of the success, some problems like restenosis (18-32%) [3,4], migrations [5], recoil [6] or positioning [7] still exist. Restenosis was the main motive for development of the stent-techniques [8].

Up today, there are many publications, dedicated to typical medical problems which are in relation with stenting technique like biocompatibility of the material, thrombosis and neointimal pathology. New innovative stents appeared on the light, as example bioceramic and biopolymer, radioactive, bio-degradable stents, as well stent, which discharge medical preparates [1,8-10].

However, the connection between the stent and its equipment, especially of the ballon, the mechanical behaiour of the stent is not fully cleared [11-14].

2 Materials and Methods

2.1 Stent parameters studied

Following parameters of the expanded stent have been calculated as a function of the expanding balloon pressure: distal and central diameter in the stationary case, dogbonig, recoil, foreshortening.

Distal and central diameter

These parameters of the stent show the aperture in expanded state of the stent after removing the balloon pressure in both end and middle of the stent. It is in a connection with the diameter, which is needed for normal blood circulation.

Dogboning

The dogboning shows the difference in the distal and central diameter. It will be calculated as follows:

$$\mathrm{DB} = \frac{d_{\text{middle}} - d_{\text{distal}}}{d_{\text{middle}}} \times 100\% \,,$$

where DB is the dogboning calculated in percents. The dogboning can be positive, as well as negative.

Recoil

Recoil is defined as the ratio of diameter difference or the fully inflated and relaxed stent over the inflated diameter:

$$\text{SR} = \frac{d_{\text{inflated}} - d_{\text{relaxed}}}{d_{\text{inflated}}} \times 100\%\,,$$

where SR is the stent recoil.

Foreshortening

Foreshortening FS is the ratio of stent length difference at relaxed and initial states over initial length

$$\text{FS} = \frac{l_{\text{relaxed}} - l_{\text{initial}}}{l_{\text{initial}}} \times 100\%\,.$$

2.2 3D geometrical model

The studied real stent is a S-shaped stent with a repeated unit cell (RUC) which planar form is shown in Figure 1. RUC is repeated after rotation in 60° around the stent axis and translated an half RUC along the axis. Figure 1 shows the uncoiled form of a stent with initial diameter of 1.6 mm and a length of 10 mm and typical strut thickness of 100 μm.

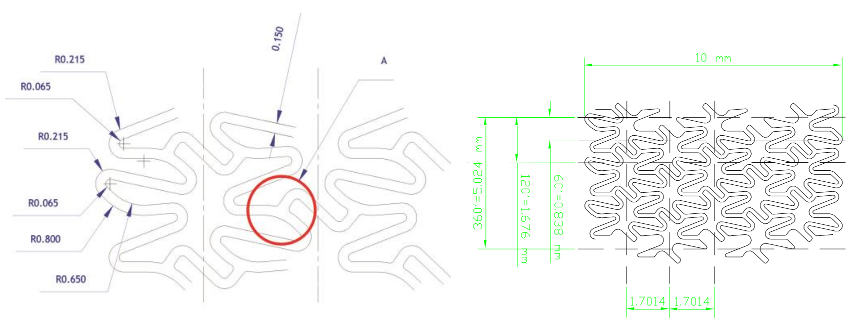

Figure 1: Repeated Unit Cell (RUC) of a real coronary stent.

After the planar model by using AutoCAD has been created, a 3D model of stent has been prepared in SolidWorks, imitating the process of 3D laser cutting with a Nd^{3+}:YAG laser and the following chemical etching. Figure 2 presents the final 3D model of the stent.

Figure 2: 3D model of the stent.

The model has been imported in Comsol, a FEM modeling and simulation software.

Governing equations

As Physics Structural Mechanics model has been chosen. Linear elastic deformation has been calculated, as well as plastic deformation, following the material stress-strain curve (Linear elastic Material node with Plasticity subnode). The inflation and relaxing of the stent has been studied using a stationary solver. The balloon pressure has been change parametrically from 0 Pa to maximal pressure of 8 atm and backwards.

Material properties

As material medical stainless steel has been introduced. Table 1 shows the mechanical parameters of the steel. The steel has been accepted to nearly incompressible with small plastic strains model.

Table 1: Material constants of stainless steel 317L

Density (kg/m^3)	Young's modulus (GPa)	Poisson's ratio	Yield strength (MPa)	Isotropic tangent modulus (GPa)	UTS (MPa)
8027	200	0.276	170	2	627

In order to collect all data from different points around the peripheral in the middle and at the ends and to round the data, concerning the diameters, a MFC computer program has been developed.

Mesh

A modified Physics controller Normal mesh has been used to overcome small element, generated by the wrapping of stent pattern over the steel tube. The smallest size of an element has been selected to 1 μm.

3 Results

Balloon pressure

In order to estimate the working balloon pressure, a pre-simulation has been performed. In this simulation the stent has been expanded to a pressure of 8 atm (see Figure 3). The required diameter of approx. 2.53 mm is achieved at parameter 0.5, i.e. 4 atm.

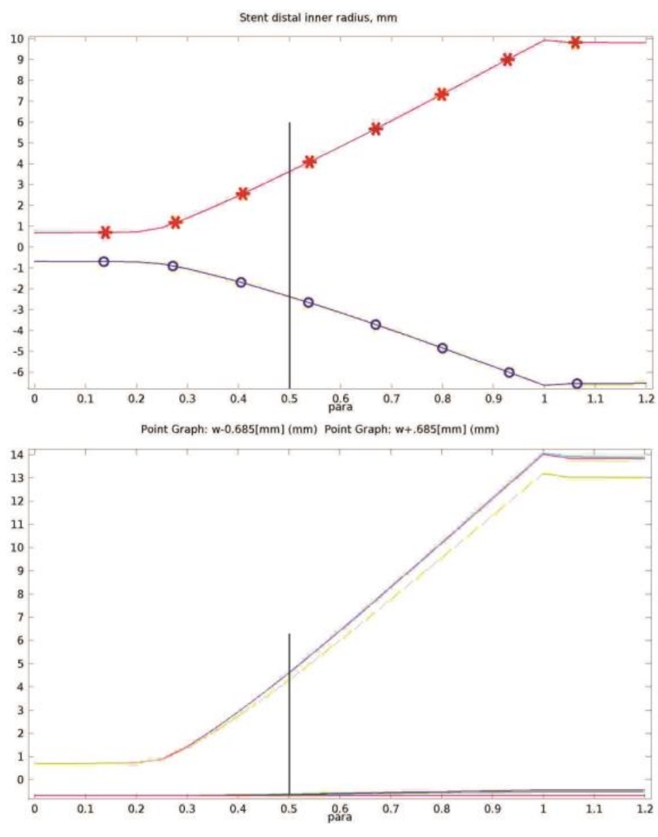

Figure 3: Diameters at 8 atm balloon pressure: top – at the end, bottom – in the middle.

Stent parameters

Table 2 shows the mechanical parameters of the real stent after inflation with maximal balloon pressure of 4 atm.

Table 2: Results of calculations

Distal diameter, mm	Middle diameter, mm	Recoil distal, %	Recoil middle, %	Fore-shortening, %	Dog-boning, %	Maximal von Mises stress MPa
2.6	2.8	1.5	1.6	-1.7	-26.3	400

4 Discussion

The simulation of a real S-shaped stent shows very good mechanical parameters. The construction allows a relatively low balloon pressure of approx. 4 atm to achieve the need inner diameter of 2.5–3 mm, which is preferable in order to avoid problems during inflation of the balloon.

The recoils have low values. This guarantees that the diameter of the inflated stent will not decrease significantly after it is mounted in the vessel an balloon is depleted. The negative foreshortening is neglectable.

A peculiarity of the stent is its negative dogboning. This type of construction allows a more better position of the stent, putting the stent middle in the point of minimal vessel diameter.

The von Mises stress lies under critical value of UTS (627 MPa). This should guarantee a long stent life.

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