BUDAPEST UNIVERSITY OF TECHNOLOGY AND ECONOMICS
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Booklet of PhD Theses

The functional properties of endovascular devices used in coronary angioplasty and their materials

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Prelude of the research

The leading cause of mortality in Hungary is heart disease. The onset of cardiovascular disease is related to the way of life, social standing, eating habits, and to a number of other factors. Researches around the world place emphasis into finding the cause of the atherosclerosis. Today they are able to treat the symptoms with medication but coronary stent implantation remains one of the most effective treatments of ischemic cardiovascular disease. The development of the stent has been made possible by a multidisciplinary collaboration between engineers and medical doctors.

The stent is a complicated engineering product of materials science and technology research. It contains technical characteristics, which can be understood only with combined knowledge from several specialties not just those within the classic technical or other natural science fields. The previously organized professional system allows for the objective evaluation and comparison of properties of stent and stent systems based on quantitative parameters. The major part of the functional properties till now have remained on the level of subjective definition, or possibly in the categories that benefit the manufacturer's own interest

Literature review

In the literature review part of my dissertation I describe the following: types, materials and manufacturing processes of the stents. The methods employed to determine the flexibility and the trackability criterion are described in detail as this is the foundation of my experimental work.

During my main research period the MSZ EN 14299:2004 and MSZ EN ISO 25539-2:2009 standards were used to provide prescriptive text on the topics: properties of stents under the topic of preclinical trials, specific requirements of artery stents. Nowadays, the MSZ EN ISO 25539-2:2013 standard is in place. This document contains some characteristics under which the manufacturers have to classify their implants. However, only in a few cases does it define and provide the methodology for the examination.

The stent system consists of a balloon catheter and a crimped stent. The stent system must be flexible to pass through tortuous, narrowed blood vessels. The specialists have been developing many different test methods to determine the stent flexibility and the results of the different tests are very often not comparable to each other. The tests based on force measurement are much more precise and reproducible.

After studying the literature, I have concluded that a flexibility testing method shall be made in a way that can be used for stents, stent systems and balloon catheters. It is important that method remains non-destructive throughout the entire measuring process.

Another field of my research is the trackability of stents. There is no specific standard measurement for trackability nor is there a specific description or set of determined parameters for modelling the coronary blood vessels. This is why a lot of different coronary models exist.

With regard to the literature on the trackability, it can be stated that I have not found any such measuring method for the trackability of the stents that satisfies all the following criteria: ob-

jective classification of the parameter, provides a numeric result, suitability to compare different stents (i.e. size and type).

Objectives

With giving attention to the facts associated with this subject and problems that evolved while defining my targets, I took into account the importance of answering the open questions and the demands of modern industry. Therefore my aims are as follows:

1. To develop a new testing method, which gives quantitative results to the flexibility of the stent and stent system. The different stents and stent systems can be compared with this new method.
2. To determine the factors, especially the effect of the stent geometry, which influence the results received by the flexibility test.
3. To develop a new testing method, which gives numerical results to the trackability of the stent system. The different stent systems can be compared by the new method.
4. To determine the relationship between the stent system's trackability and the stent system's flexibility.
5. To critically analyze the previously developed professional stent test methodology at the Budapest University of Technology and Economics and to supplement it with the measurements of flexibility and trackability.

Theses - New scientific results

Results concerning the testing of flexibility of the stent and the stent system:

I have made a new test method for the measurement of stents and stent system flexibility. The new test method measures in the same way the flexibility of the stent, the stent system and the balloon catheter. The stent flexibility as a functional property of the stent can be characterized with the „ flexibility factor". The determination of flexibility factor is based on the measurement of stent bending stiffness. I have determined the relationship between the flexibility factor and the main geometrical data of stent by the new test method. I proved that the stent and the balloon catheter should have a dominant role in the flexibility of stent system.

Thesis 1 [1] [3] [7] [8]

A new method was invented for the quantitative determination of stent, stent system and balloon catheter flexibility. The new method measures the flexibility of the stent, the stent system and the balloon catheter in the same way.

Thesis 2 [1] [3] [7] [8]

There are linear relationships between the flexibility factors (H_s, H_{sr}) and the nominal lengths and diameters of different states of the stents. The stent flexibility deteriorates as the length or the diameter of the stent increases.

Thesis 3 [1] [3] [7] [8]

To determine the flexibility of Sanocor stent, it is enough to carry out the measurement at any random position of the stent.

Results concerning the testing of the stent system trackability:

I have developed a test method for measuring trackability, which is based on force measurement in a simulated vessel model during the introduction of stent system. I have made a new coronary vessel model, based on X-Ray images from the coronary arteries to define the vessel model parameters. The new test method is simple and easy to repeat. The stent trackability as the functional property of the stent and can be characterized with the „trackability factor".

Thesis 4 [1] [6]

A new method was developed for the measurement of stent system trackability, which is based on force measurement. A new factor was determined for characterizing quantitatively the stent trackability.

The development of my new expertise stent testing methodology:

I have critically analysed the previously developed professional stent test methodology at the Budapest University of Technology and Economics, which allows the objective rating as well as the comparison with quantitative parameters. I have supplemented the test methodology with new modules and two new test procedures that were developed by me.

Thesis 5 [1] [2] [3] [4] [5]

The previously developed professional system was renewed to qualify the stent properties. New key elements were added to the professional system to create an upgraded professional system.

To sum up my research I can say that I tried to meet the practical needs of medical doctors with tangible results. In the interest of doing so, on one hand, I formulated qualification procedures for both flexibility and the trackability – both are basic properties of stent and stent systems – with defined comparable metrics. On the other hand I placed the properties of stents and stent systems into a well-organized and easy to use professional system. Both the qualification rating and the comparable metrics, as well as the systematic tabular summary is of great help to doctors and specialists engaged in research today.

Publication of the results

1. Szabadíts P., Puskás Zs., Dobránszky J.: Flexibility and Trackability of Laser Cut Coronary Stent System. Acta of Bioengeneering and Biomechanics 11,(2009:3)11-18.
2. Robák B., Szabadíts P., Bognár E., Puskás Zs., Toldy A.: Analysis of the Polimer Coating of Coronary Stents System from the Aspect of Drug Absorbing and Eluting. Materials Science Forum Vol. 659 (2010) 245-250
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4. Szabadíts P., Dobránszky J.: Aktív koronáriasztentek bevonatainak összehasonlítása gyógyszerfelvevő és -leadó képességük alapján. Biomechanica Hungarica 3,(2010:1) 224-230

5. Szabadíts P., Balázs T., Bognár E., Dobránszky J.: Examination method of uncoated Coronary Stents. Periodica Politechnica Mech. Eng. 54, (2010:2) 77-82
6. Szabadíts P., Dobránszky J.: Trackability Measurement of Coronary Stent in a Coronary Vessel Modell. Penninger A, Váradi K, Vörös G (szerk.) Gépészet 2008: Proceedings of Sixth Conference on Mechanical Engineering. Budapest, 2008.05.29-30. 1-5. Paper n13.pdf
7. Szabadíts P., Bagi I., Dobránszky J.: Comparison the Flexibility of Ballon-expandable Coronary Stents. Third Hungarian Conference on Biomechanic. Budapest, 2008.07.04-05. 315-319
8. Szabadíts P., Puskás Zs., Dobránszky J.: Flexibility and Trackability of Laser Cut Coronary Stent System. 25th Danubia–Adria Symposium on Advances in Experimental Mechanics. Ceske Budajovice, 2008.09.24-27. 245-250.