

Gépészet 2008
Budapest, 29-30.May 2008.

G-2008-N-04

TESTING METHOD OF STENT'S RADIAL FORCE

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Abstract. *In case of coronary arteriosclerosis and heart attack balloon-expandable stents are used. These balloon crimped implants are placed to the occluded vessel part and the balloons are pumped with big pressure (4-20 bar). The opened stents ensure the continuously flow of the blood in the opened lumen. The implants have to sustain the outer load from the vessel wall and have to keep the lumen open. In this study a method was worked out which valuating the radial force of the balloon expandable coronary stents. In an experimental program many types of methods were tested to find the best one.*

Keywords: *coronary stent, crush resistance, radial strain, radial force*

1 INTRODUCTION

Nowadays one of the most frequent health problems are the cardiovascular diseases principally the arteriosclerosis and the myocardial infarction. Angioplasty and stent implantation are widely used therapy of these illnesses. In this case an expandable balloon is used wherewith the artery narrowing plaque is pressed to the wall of the artery and a mesh structured vessel implant, which is crimped to the balloon, is placed to the artery [1,2].

Several materials were tested as vessel implants or coatings; however, the stainless steel (316L, 316LVM) is the most frequently used material which is proved to be the most reliable, based in clinical trials. Nowadays, cobalt-chromium alloys (L605, MP35N) are more and more frequently used (Fig. 1). The peripheral stents are made of nickel-titanium alloys (nitinol). The biodegradable stents made of magnesium are in trial phase [3,4,5,6].

Coronary stents are commonly manufactured from tube by laser cutting. Other manufacturing processes are coiling, spinning or looping from wire. The precision laser cutting leaves burrs and sharp edges which have to be remove by etching, electro-polishing and other post-processing technologies [7,8,9].

Mechanical and functional properties of stents primary describe the in vivo behaviour of coronary stents, therefore our experiments simulate the in vivo strains and stresses. In most cases there are connections between the different properties. One of them is crush resistance. The implant has to resist to the concentric, pulsating strain induced by heart and coronary arteries and furthermore, the implant has to keep its geometry. Currently, there is no generally accepted method to examine this resistance.

The European Standard for the specific requirements for arterial stents is the EN 14299. This standard defines the evaluation of crush resistance: for each nominal diameter and each implant configuration, the change in implant diameter shall be measured as a function of circumferential applied pressure or radial force until permanent deformation or full collapse occurs [10].

2 TESTING METHODS

In most cases crush resistance of coronary stents has force dimension (N „Newton”, £ „pound”), sometimes has tension dimension (Pa „Pascal”, £/in² „pound per square inch”). Accordingly crush resistance consists of two main parts, radial force and radial strength. Radial force is valuating the crushing caused by multifocal strain, and radial strength is valuating crushing caused by the hydrostatic strain. In case of radial force testing, the change in diameter caused by the outer radial strain has to be measured. It is necessary to determine the values causing permanent structure change and the total crushing of the stent [11,12]. Within the frameworks of our experimental program the testing of radial force of coronary stents was studied.

To start with the experiments and investigations the required materials were produced and connected to the precision tensile equipment. These materials serve as support for the stents (Fig. 1). Several support types were tested to work out the final testing methodology: crushing between two parallel plates; support with prismatic materials and crushing, and support on four edges to select the suitable ones. In case of support with prismatic materials and crushing, a prism with three different angles was used as lower support, and a pushing plate and a pushing edge were used as upper support (Fig. 2). With combination is them there were several support opportunities available. It is important that the stents get uniform strain, so all of the prisms were designed for testing of stents with the diameter of 3 mm. In the first section of the experimental program we tested stents cut from a tube made of 316LVM material by laser beam. The diameter of the stents was uniformly 3 mm and the length was 15 mm.

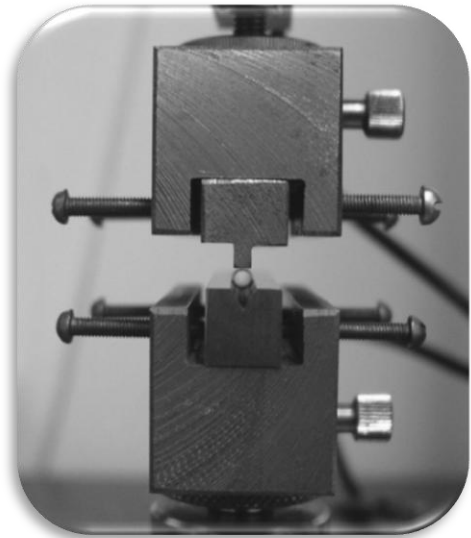


Fig. 1 The clamps with the supports attached to the tensile equipment

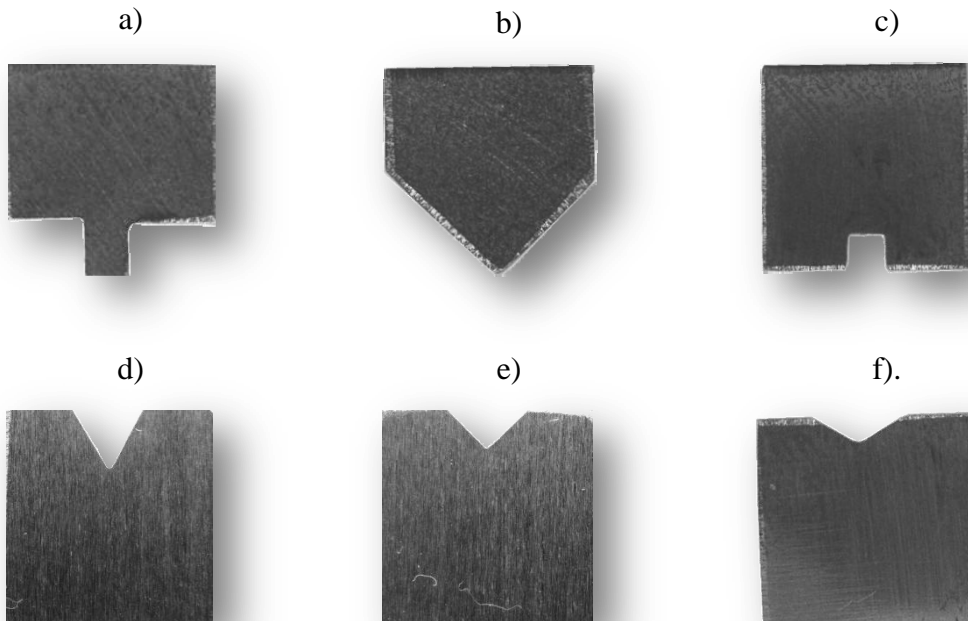


Fig. 2 The used supports: pushing plate (a), pushing edge (b), four edges equipment (c), the prisms with 60° (d), with 90° (e) and with 120° (f)

After the pilot measurements the best supports were chosen. The support on four edges did not give the expected results because during the experiment the stents were pushed together but took elliptic forms and laid between the four edged. After this the shape of the stents did not changed. Therefore, the support with four edges was excluded from the program. During the pilot measurements the pushing speed were changed also but as a result of this there were no difference in the character of the diagrams so a constant pushing speed of 1 mm/min were used.

In case of prismatic shoulders we tried to achieve the greatest possible uniformity of force distribution. Provided that stents have round cross-section the prism with 60° is the best. This way we ensured that the stent get uniform strain from both sides. Besides the prism with 60° we kept the prism with 90° as well but the prism with 120° was excluded from the further experiments.

From the upper shoulders pushing plate was chosen also to ensure uniform force distribution. So finally the pushing edge was excluded too.

Accordingly in further measurements we applied only the following supporting methods:

- Pushing between two plates
- Pushing between prism with 60° and pushing plate
- Pushing between prism with 90° and pushing plate

The last step of the experimental program was to select one of the three supports we considered to be the best. It was still an important aspect that stents could get as symmetrical strain as possible. Having compared the methods the prismatic support had a big disadvantage, the stents skulked into the V-shape prism when pushed together, and therefore, the distribution of the strain was not ideal (Fig. 3). The additional disadvantage of the prismatic supports was that prisms of different sizes had to be used for different stent diameters in order to get proper seats. The pushing between two plates can eliminate all these disadvantages, and provides a well manageable, generally applicable support independent from the stent size.



Fig. 3 Crushed stent in the prism

At the evaluation of results, two force values were defined: the first one belongs to the pushing in of the stent (F_P) and the second one belongs to the collapsing (F_C) of the stent. Three sections can be differentiated on the pushing diagram due to its character. The desired force values can be determined by using these sections. The force related to the pushing in of the stent, was determined by line regression to the first and second sections of the curve. The intersection of the lines projected perpendicularly to the curve give the value of this force of the pushing in of the stent. At the force value related to the collapsing of the stent the character and rise of the curve change; no specific plotting is needed for the determination of this point and the related force value (Fig. 4).

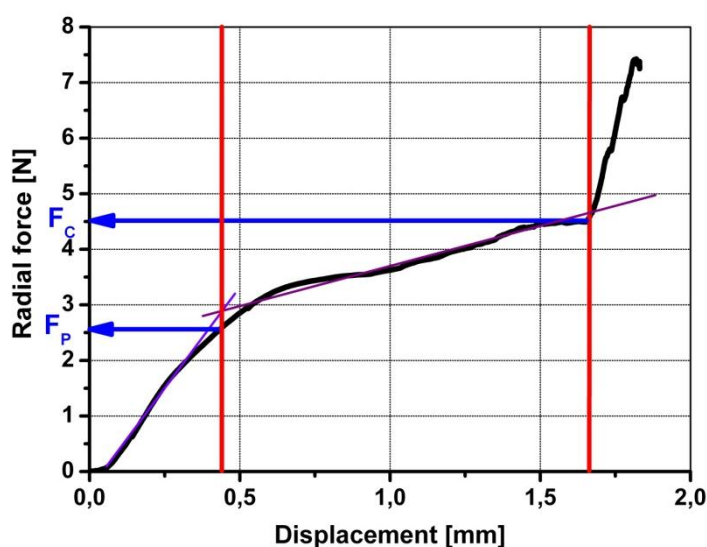


Fig. 4 The determination of the two radial force values

3 CONCLUSIONS

Taking into account our experience so far, the following methodology has been developed to examine the radial force of the balloon expandable stents: pushing between two plates using a precision tensile equipment with 1 mm/min constant pushing speed.

Due to the evaluation process of the test diagram two radial force values can be given for the characterisation of the stents, the first one belongs to the pushing in of the stent (F_P) and the second one belongs to the collapsing (F_C) of the stent. At the same time the method also allows that a force belonging to a concrete displacement may be determined as stent's radial force (Fig. 5).

This final methodology developed during the experimental program is uniformly applicable for balloon expandable stents of different length and diameter. The method allows not only the comparison of radial force of stents having the same size and different markings, but different sizes of the same stent types can also be well tested.

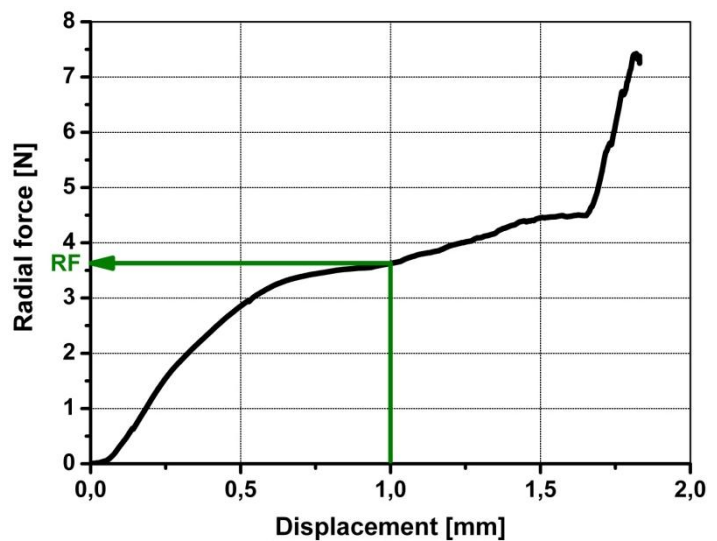


Fig. 5 The determination of radial force belonging to a concrete displacement

REFERENCES

- [1] M Keltai.: Coronaria angioplastica, Medicina Kiadó, Klinikai bizonyítékok, Budapest (2006)
- [2] I Karádi: Infarktusz és koleszterin, <http://www.mindentudas.hu/karadi/20050502karadi.html> (14/03/2007).
- [3] Gy Ring, E Bognár, J Dobránszky: Fatigue testing of coronary stents. EMBEC'05 Conference, Prague, IFMBE Proceedings Vol. 11, ISSN: 1727-1983, 1921F.pdf
- [4] Zs Puskás, L Major: Ausztenites acélból készült sztent érprotézisek felületi jellemzőinek és bevonatainak vizsgálata, BKL Kohászat, 134. (2001:5) 191-196
- [5] P Poncin, C Millet et al: Comparing and Optimizing Co-Cr Tubing for Stent Applications, Materials & Processes for Medical Devices Conference, St. Paul, Minnesota, 2004.
- [6] B Rapp: Nitinol for stents, Materials Today 7. (2004:5) 13
- [7] Zs Bálint-Pataki, E Bognár, Gy Ring, B Szabó, J Ginsztler: Koszorúersztentek vizsgálata, GÉP 58 (2006:11) 3-7
- [8] B Szabó, J Dobránszky, L Major, Zs Nyitrai: Development and Micro Manufacturing of Coronary Stents in Hungary. Multi Material Micro Manufacturing (4M) 2006 Budapest, Workshop and Conference focusing on: Metal Processing and Metrology
- [9] P Poncin, C Millet et al: Materials & Processes for Medical Devices Conference, <http://www.minitubes.com/images/brochure/asm04.pdf> (21/03/2007)
- [10] European Standard EN 14299 nonactive surgical implants – Particular requirements for cardiac and vascular implants – Specific requirements for arterial stents, CEN, 2 February 2004
- [11] A Severini, S Mantero et al.: Polyurethane-Coated, Self-Expandable Biliary Stent: An Experimental Study, Association of University Radiologists, 2 (1995) 1078-1081
- [12] R Rieu, P Barragan et al: Radial Force of Coronary Stents: A Comparative Analysis, Catheterization and Cardiovascular Interventions 46. (1999) 380-391

ACKNOWLEDGEMENT

Authors wish to thank Istvánné Hrotkó, Tamás Kranauer.

The authors also express their sincere gratitude to Zoltán Simon, Márk Hatala, BUTE Department of Polymer Engineering.

This work was supported by the National Research and Development Programs (NKPF-304/042-04) and by the Hungarian Research Fund (OTKA K69122).

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