EXAMINATION OF MECHANICAL AND MEDICAL APPLICATION PROPERTIES OF CORONARY STENTS

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ABSTRACT

The medical application properties of coronary stents describe their behaviour in the human vascular system from planting to functioning. However these properties have great importance to surgeons, not all of them have standardized examination methods. In our study we demonstrate three procedures, which can be used to examine stents, considering the referred properties, like flaring, trackability and MSA (metallic surface area). In the course of our research four stents were investigated, three made of tube and one made of wire, and the results were promising about the application of these methods described in the followings.

KEYWORDS
Stent, trackability, metallic surface area

1 INTRODUCTION

Nowadays in Hungary – just like in other highly developed countries – cardiac and circulatory diseases belong to the leading causes of death. There are 200.000 new patients registered a year fallen ill by these problems. According to the Hungarian Society of Cardiology the number of deaths caused by cardiovascular disorders increased to 39.000 from the former 25.000 in the last 1-2 years [1].

The most serious type of cardiovascular disorders is heart attack. Due to this the tissues in the blood supply area of the closed coronary artery get short of oxygen and die. The basic treatment of heart attack besides the open-heart surgery is heart catheterizing with stent. The mostly used stents these days are balloon expandable stents. During the stenting procedure the mesh structured implant mounted on a balloon – the stent – is placed into the closure through a catheter with a guidewire. After the balloon is inflated at high pressure (8-20 bar) the expanded stent keeps open the blood’s way through the artery. The base material of these implants has to be capable of plastic deformation, which takes place during the expansion of the balloon. After the balloon is deflated the stent keeps its expanded form despite a little recoil. These base materials are biocompatible and haemocompatible alloys. The widely used materials are AISI 316L and 316LVM type stainless steels, which proved to be most trustworthy in clinical applications [2]. In the last few years there have appeared stents manufactured of cobalt-chromium alloys (L605, MP35N, Phynox, Elgiloy) in the market. This material is more dense than 316L and provides higher strength, which allows the stents to be fabricated with thinner struts [3].

As for the semiproducts of stents, they can be tube or wire. The tubular stent design is usually fabricated by laser cutting, the ones made of wire are prepared by threading [2].

2 EXAMINATION OF STENTS

The goal of the examination was to assess the application properties of coronary stents. These properties describe the ability of placing them into the lesion, their geometric changes during the expansion and their functional behaviour.

In the examination program we tested four different balloon expandable stents (Fig. 1, Tab. 1). The performed tests were tended to compare the values of the application properties with the ones provided by the manufacturer, and to classify and compare the stents by getting familiar with their published or not published features.

a) c) b) d)

Figure 1. a) Invastent Volo, b) Jostent Flxmaster, c) Multi-Link Vision, d) HorusS

	Invastent Volo (Invatec)	Jostent Flexmaster (Abbott)	Multi-Link Vision (Guidant)	HorusS (IBS)
Base material	316L	316L	L-605	316L
Coating	None	None	None	None
Semiproduct	Tube	Tube	Tube	Wire
Fabrication method	Laser cutting	Laser cutting	Laser cutting	Threading

Table 1. Production data of examined stents

3 STRUCTURE

Apart from the base material the mesh geometry is what determines the application properties of stents. The design aims the balance between strength and flexibility and through these it has influence on expansion characteristics and determines the metallic surface area (MSA) as well. To understand the properties detailed in the followings is necessary to get to know these definitions:

Strut: The struts make up the stent's metal surface left of the tube after laser cutting. The struts form rings.

Bridge: Connecting elements, which join the rings [2].

4 FLARING

Flaring describes how the rings of the stent stick out in the vessel curves. Knowing this it can be ascertained whether the stent can cause injuries during the placement in the vascular system and if it does, what type of injury could that be. The models prepared to examine this property are bended glass or polymer pipes [4].

The model we prepared is made of a 2,4 mm diameter (D) glass pipe with 1 mm wall thickness. Its curves resemble the characteristic curvatures of vessels, which are:

- R_1 = 10 mm, α_1 = 180°
- R_2 = 8 mm, α_2 = 90°

We investigated and photographed the motion of the stents under stereo-microscope. The implants tried to straighten the curves, between the two ending points leant against the wall they showed the possibly slightest bending (Fig. 2, Tab. 2). Further tests were performed using a force-measuring device. With this the force exerted to press the stent onto disks with different diameters in a 2 mm (d) distance was measured (Fig. 3). The curves were:

- R_3= 10 mm, α_3 = 90°
- R_4= 7,5 mm, α_4 = 90°

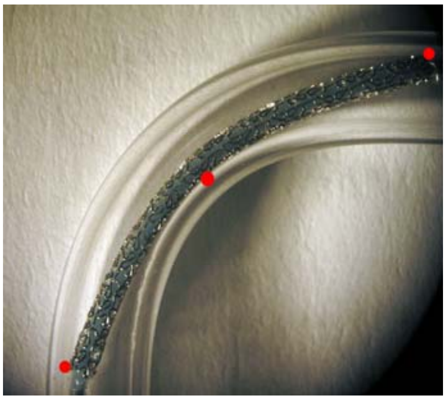
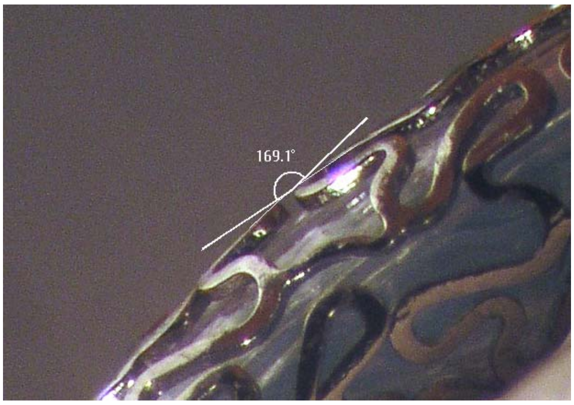
a)  *b)* 

Figure 2. a) Stent in the pipe, b) Deflecting rings

	Invastent Volo	Multi-Link Vision	HorusS
D= 2,4 mm R_1=10 mm , α_1= 180° [°]	5,2	8,5	17,5
D=2,4 mm R_2=8 mm, α_2= 90°-os [°]	7,1	10	21,9
d= 2 mm R_3=10 mm , α_3= 180° [°]	9,3	9,6	18,9
d= 2mm R_4=7,5 mm , α_4= 180° [°]	10,7	11,9	23,6

Table 2. Deflection of rings of different coronary stents

5 TRACKABILITY

The push force during the stenting process characterizes trackability. This tracking force determines the handling properties and the deliverability of the stent system, but there are not standardized methods for measuring it yet. This force also depends on many other properties, just like surface features, the friction factor between the vessel wall and the stent and flaring [4].

The method of measuring the tracking force is based on the stent’s behaviour in the glass pipe. In a 90° curve the push force can be calculated. In this simplified case the stent leans against the wall in three points. This is where the stent pushes the vessel wall, so here exerts friction force, which needs to be surmounted (Fig. 3a).

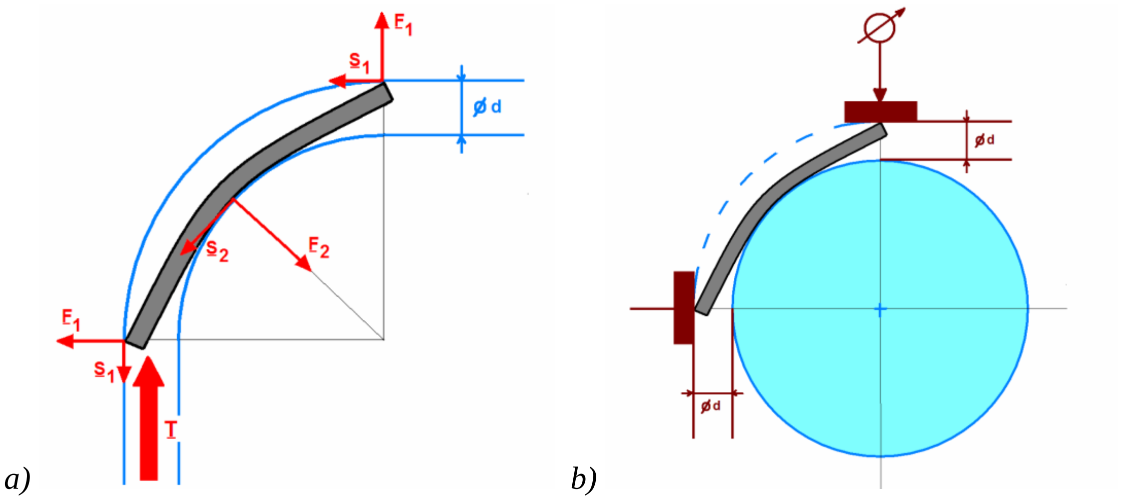


Figure 3. a) Force model in the pipe, b) Model of force-measuring device

Fixing one endpoint of the stent onto a disk of an appropriate diameter in an appropriate distance (d), the pressure force exerted to get the other endpoint into the same conditions can be measured (Fig. 3b).The force relations in a 90° curve are presented in *Eq.1*.

$$F_2 = \sqrt{2} \cdot F_1; \qquad S_1 = \mu \cdot F_1; \qquad S_2 = \mu \cdot F_2 = \mu \cdot \sqrt{2} \cdot F_1 \qquad \text{(Eq. 1)}$$

where F_1 : pressure force at endpoints
F_2 : pressure force at the middle of the curve
S_1 : friction force at endpoints
S_2 : friction force at the middle of the curve
μ : friction factor between vessel wall and stent

The tracking force (Eq. 2):

$$T = 2\,S_1 + S_2 = \mu \cdot F_1 \cdot (2 + \sqrt{2}) \qquad \text{(Eq. 2)}$$

In *Eq. 2* only the friction factor is unknown. We measured the pressure force (F_1) of three stents using the force-measuring device. The results of this test are shown in *Fig. 4.* diagram.

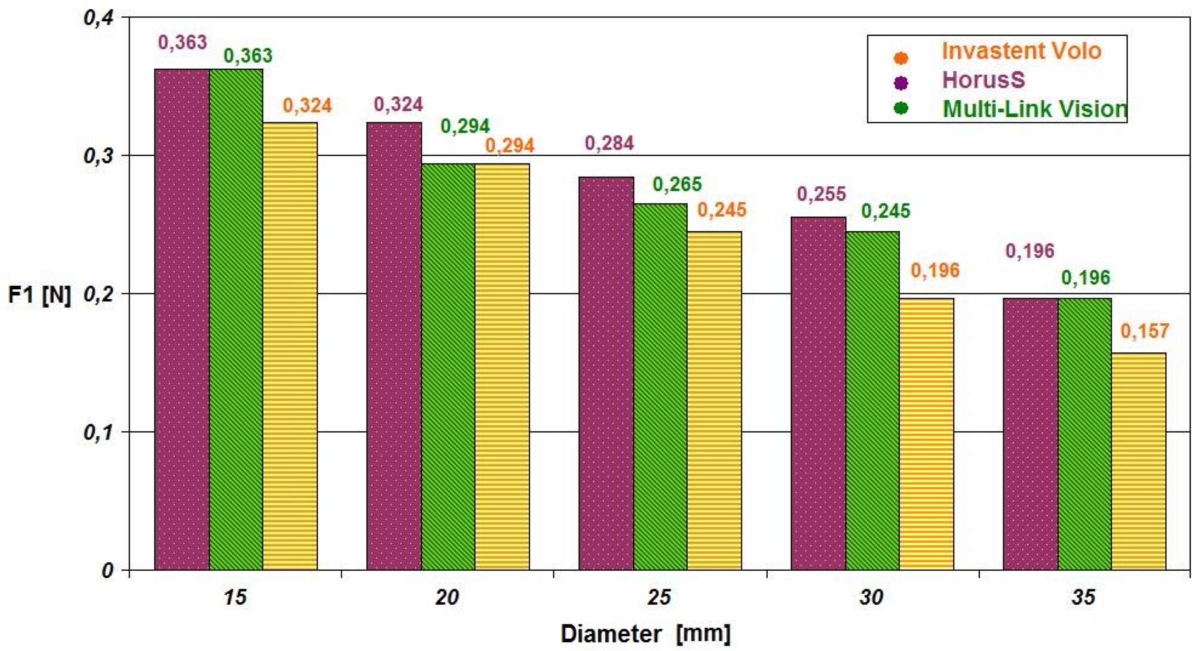


Figure 4. Pressure forces (F_1) for different stents

6 METALLIC SURFACE AREA (MSA)

The MSA parameter means metal to artery ratio. Precisely it is the percentage of stent surface to covered artery surface and it has to be examined in expanded condition (Eq. 3).

$$MSA = \frac{external\ surface\ of\ stent}{surface\ of\ artery} \cdot 100 \qquad \text{(Eq. 3)}$$

MSA categories:

- Low cover (MSA < 15 %)
- Medium cover (15 % < MSA < 20 %)
- High cover (MSA > 20 %)

MSA is hard to calculate because the laser cutting technology yields sophisticated stent designs. We determined the MSA with digital image processing. We took photos from the surface of the stents while rotating them around then joined these pictures together. After making a greyscale photo of the whole surface, with a threshold filter we got a picture of 1 bit colour depth. The *Eq. 4* shows the relation between MSA and the number of pixels of the picture [5].

$$MSA = \frac{number\ of\ black\ pixels}{all\ pixels} \cdot 100 \qquad \text{(Eq. 4)}$$

The results got from the performed tests are shown in *Tab. 3*.

	Invastent Volo	**Jostent Flexmaster**	**Multi-Link Vision**	**HorusS**
MSA [%]	13,3	20,51	10	11,4

Table 3. MSA values for stents

7 CONCLUSION

Regarding the deflection of the rings, flaring tests performed with force-measuring device resulted higher values. The reason of this is that the pressing distance was 0,4 mm smaller than the glass pipe's 2,4 mm diameter. Invastent Volo showed the slightest deflection, Multi-Link Vision showed bigger and HorusS showed the biggest. All of the three stents have almost the same strut thickness, so the causes of different attitudes must be in the different designs. The struts of Invastent Volo have no straight sections. The bent struts assist the expansion and the flexibility in any direction as well. This stent possesses the greatest number of bridges, which prevent the rings from deflection. Multi-Link Vision stent has some straight sections in its strutting, and also has fewer bridges. Corresponding to the fabrication method, HorusS stent has no bridges and its struts are straight. The ranking list is the same for trackability and the reason of that is the flexibility of the designs again.

The favorable effects of MSA values are not clearly defined yet. Considering strength, the highest ratio is the best, because in this case the stent can support the vessel wall securely. On the other hand, high ratio is bad, because the large metallic surface area raises the possibility of thrombosis and restenosis. The examined stents belong to the following MSA categories: Invastent Volo, Multi-Link Vision and HorusS to *low cover*; Jostent Flexmaster to *high cover* category.

The examination methods for assessing flaring and trackability properties of coronary stents are usable. The disadvantage of these models is stiffness, while the vascular system embedded in the tissues is flexible, so it can suffer smaller deformations without injuries.

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