

INVESTIGATION OF FUNCTIONAL PROPERTIES OF CORONARY STENT SYSTEMS

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Abstract: This article introduces five measurement methods for investigation of functional properties of coronary stent systems. The properties were analysed in the ory, and then several stents were measured and evaluated. Crossing profile, flexibility of the stent system, foreshortening, metallic surface area, the largest and the smallest cell sizes, the maximum achievable cell diameter and side branch access were measured. Four types of coronary stents were examined, two pieces from each type. The results show that the properties mostly depend on geometry, stent pattern and material. These investigations can help the physics to select the appropriate stent.

Key words: coronary stent, crossing profile, examination method, flexibility, foreshortening, metallic surface area, side branch access

1. Introduction

The heart is the engine of the body, so it is important to protect and support the functions of this organ. If a large part of it dies, the rest is unable to take over the work of the casualty part and unable to supply the body with sufficient amount of oxygen [6].

In the European Union the most common reason of death is the disease of the cardiovascular system, amongst these the most significant is coronary artery disease. Currently the cardiac catheterization procedure is the most advanced treatment, which can restore the coronary circulation. The stent is a biocompatible mesh, which is

inserted into the narrowed section of the artery to dilate and prop it up; hereby it ensures continuous flow of blood [1].

2. Materials and methods

Functional properties of 8 uncoated stent systems were measured. Table 1 shows the investigated stent systems' nominal properties. (A-B) and (C-D) stents have the same geometry. The measurements began with the non-destructive tests and continued with the destructive ones, so the functional properties are described in chronological order.

The investigated stents

Table 1

Stent	Nominal diameter [mm]	Nominal length [mm]	Nominal pressure [bar]	Material
(A1) (A2)	3	19	9	CoCr (L-605)
(B1) (B2)	3	24	9	CoCr (L-605)
(C1) (C2)	3	20	11	PtCr
(D1) (D2)	3	24	11	PtCr

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The stents were expanded at nominal pressure. (A1), (B1), (C1), (D1) stents were expanded in air, (A2), (B2), (C2), (D2) stents were expanded in $37\pm 2^\circ\text{C}$ water. The water modelled the blood, and the differences between the two methods were also investigated.

The investigations were performed with stereo microscopy, scanning electron microscopy, metallographic microscopy, and tensile tests. The areas were determined with evaluating the digital images by image analysis software. Evaluation was performed by using JMicroVision measure software.

All measurements correspond to the MSZ EN ISO 25539-2 standard [5].

2.1. Crossing profile

Crossing profile is the maximum outer diameter of the crimped stent. This property provides information about the inner diameter of the vessel, which fits the stent in without causing injury to the endothelium [2].

To ease the understanding the stents' rings were numbered. The highest diameter was given to each ring. To determine the crossing profile (CP_{\max}) all rings were measured with a metallographic microscope and an image analysing software. The pictures were taken from 3 directions, each stent were rotated by 120° .

2.2. Flexibility of the stent system

Flexibility is a feature which can be defined to the stent, the balloon catheter or the stent system. Good flexibility is essential to get ahead in the convoluted blood vessel [4].

Several methods exist to do this, but there is no standardized solution. The measurement was performed in the crimped state of the stents and does not have any effect of other properties of the stents [4].

To measure the flexibility of stents and their delivery systems, tensile machine was used. The measurement was performed with a one-point bending test. The load cell automatically detected the force (F) and the bending deflection (f). One end of stent system was gripped and the other end was pressed with a plate which moved at a constant speed of 10 mm/minute. The maximum deflection (f_{\max}) was 5 mm to avoid the stent damage. All stents were tested three times in three different positions. The three rotational positions were at 0° , 120° and 240° . The highest measured data was chosen to describe the flexibility.

2.3. Foreshortening

The foreshortening mechanism describes the longitudinal contraction of the stent under dilation. Foreshortening is essential for the selection of the appropriate stent for the narrowed vessel's length [3]. Numerical values were determined by this equation [3]:

$$FS = \frac{L_0 - L_D}{L_0} \cdot 100 \quad [\%] \quad (1)$$

L_0 : length of the crimped stent [mm]

L_D : length of the dilated stent [mm]

FS: foreshortening of the stent [%]

The stents were dilated at nominal pressure. The pictures were taken with stereo microscope and the attached image analyser.

2.4. Metallic surface area, the largest and the smallest cell sizes and the maximum achievable cell diameter

Metallic surface area (MSA) is a rate which describes the ratio in percentage between the stent's cylindrical surface and the covered surface of the vessel [5].

Technically the too high ratio is not good, because the contact area with the vessel wall is too large and in this case the risk of foreign body mechanism increase, thereby the chance of restenosis increases too. Also the too small ratio can lead to static problems.

The evaluation based on the 2D projection of the stent pattern. High-resolution digital images were taken of each segments of the stents' mantle. The pictures were taken with stereo microscope attached with the image analysis software and a precision rotary unit. The stents were

rotated with 15° from the starting 0°

position to 360° . The pictures were joined

to each other to create the layout.

The largest and the smallest cell area and the maximum achievable cell diameter in them can be easily determined by an image analysis program. This feature is useful when the stent need to be placed into a side branch of a vessel and the physic has to get through one of the stent cells with another stent or a balloon catheter.

2.5. Side branch access

Side branch access is useful when another stent has to place in a vessel side branch beside the stent in the main vessel. In this case a predetermined balloon is dilated in one of the main stent's cell and then the largest cell area or the maximum achievable cell diameter is measured. This feature is destructive so in our case, it was the last test on the stents [2].

The stents were dilated at nominal pressure with their own balloon (so the balloons' diameters are 3 mm). Dilatations were made in a silicone tube with a rectangular hole on it. The tube prevented the stent from displacement. The pictures

were taken with scanning electron microscope and the attached image analyser.

3. Results

The stents are shown in Fig. 1-4., the crimped state above and the dilated state below.



Fig. 1. Image of (A1) stent

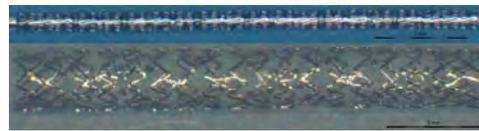


Fig. 2. Image of (B1) stent



Fig. 3. Image of (C1) stent



Fig. 4. Image of (D1) stent

3.1. Crossing profile

Fig. 5. shows the ring with the largest diameter of (A1). The measured values are shown in Table 2. The first ring is the proximal end of the stent systems, and the last ring is the distal end.

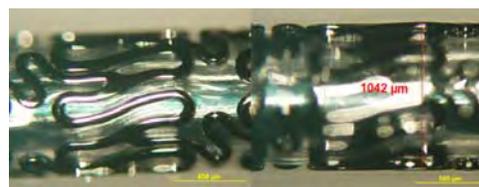


Fig. 5. Image of the 12th ring of (A1); left: middle-focused, right: focused to the measured diameter

Crossing profile Table 2

Stent	CP _{max} [μm]	Ring
(A1)	1,042	12 th
(A2)	1,018	9 th
(B1)	0,978	16 th
(B2)	0,981	12 th
(C1)	1,031	2 nd
(C2)	1,028	3 rd
(D1)	1,024	1 st
(D2)	1,027	1 st

The default manufacturing data of crossing profile is 1 mm, the average deviation is 0,024.

3.2. Flexibility of the stent system

The flexibility was determined by the force-deflection curves in N/mm. The lower numerical result means higher flexibility.

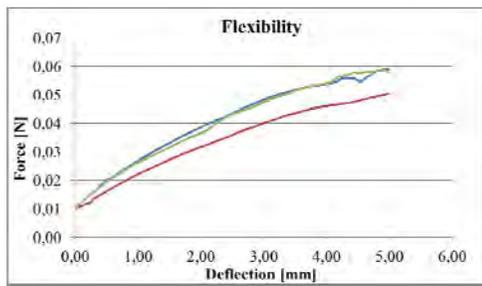


Fig. 6. Force-deflection curves of (A1)

One stent was measured from each type. The flexibility depends on for example the pattern, the size, the material and the geometry of the stent. As we can see in Table 3 longer stents have better flexibility. PtCr alloy has a higher modulus of elasticity so the stents (C-D) which made from it have a higher flexibility too.

Flexibility Table 3

Stent	Max. flexibility [N/mm]	Average flexibility [N/mm]
(A1)	0,0121	0,0114
(B1)	0,0082	0,0079
(C1)	0,0077	0,0076
(D1)	0,0056	0,0055

3.3. Foreshortening

The previous markings were used in Table 4 to show the foreshortening. The negative numbers mean that the stents were not shortened but elongated. That is probably because of the special pattern of the stents. Therefore the stent surely covers the narrowed section of the vessel.

Foreshortening Table 4

Stent	L ₀ [mm]	L _D [mm]	FS [%]
(A1)	19,51	19,96	-2,30
(A2)	19,47	19,92	-2,31
(B1)	24,85	24,82	0,12
(B2)	24,78	24,89	-0,44
(C1)	20,66	21,20	-2,60
(C2)	20,63	21,45	-3,97
(D1)	24,20	24,85	-2,69
(D2)	24,24	25,31	-4,40

3.4. Metallic surface area, the largest and the smallest cell sizes and the maximum achievable cell diameter

The measurement results are given with the following markings (Table 5):

- largest cell area (marked in yellow in Fig. 7.): A_{LC} [mm²]
- maximum diameter of the circle in the largest cell (marked in red in Fig. 7.): D_{LCmax} [mm]
- smallest cell area (marked in blue in Fig. 7.): A_{SC} [mm²]
- maximum diameter of the circle in the smallest cell (marked in red in Fig. 7.): D_{SCmax} [mm]
- average cell area: A_{AC} [mm²]

MSA only depends on the stent pattern. (A-B) and (C-D) stent have similar values because of the same pattern. Fig. 7. shows that (A-B) stents have 2 different cell types while (C-D) stents have similar cells. To ease the understanding the stents' cells were numbered; (A1) has 76 cells, (B1) has 92 cells, (C1) has 32 cells, (D1) has 38 cells.

MSA and the according properties of stents

Table 5

Stent	MSA [%]	A _{LC} [mm ²]	D _{LCmax} [mm]	A _{SC} [mm ²]	D _{SCmax} [mm]	A _{AC} [mm ²]
(A1)	16,72	3,41	1,14	0,58	0,63	1,96
(B1)	17,61	3,36	1,14	0,49	0,48	2,09
(C1)	14,02	6,64	1,14	4,57	0,82	5,84
(D1)	13,40	6,05	1,08	4,44	0,81	5,42

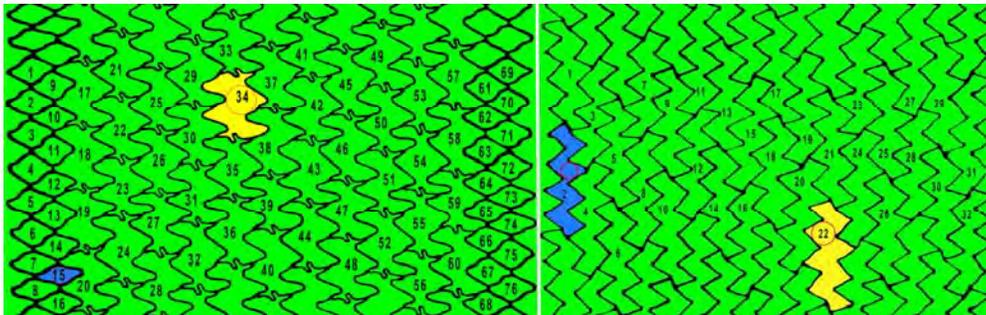


Fig. 7. Image of stent patterns; left: (A1), right: (C1)

3.5. Side branch access

To ease the understanding the side branch measurement's steps are shown in Fig. 8. and 9.

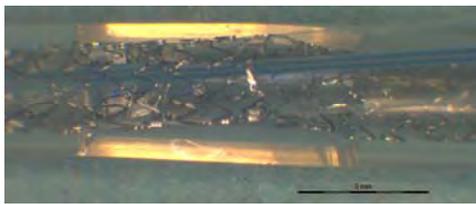


Fig. 8. The balloon was led through one of the stent's cells and dilated

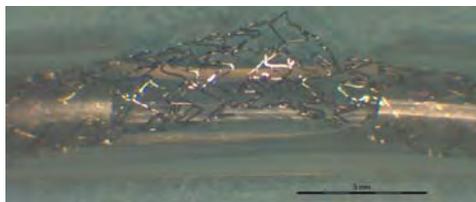


Fig. 9. The stent in the silicone tube after the balloon is removed

The stent were tipped to a suitable position so the surface stretched by the bordering strut of the cell lies on the horizontal plane. Fig. 10. shows that the dilated cell has not yet reached the

maximum circumference, so (A1) and so the other stents are suitable for side branch stenting. Fig. 11. shows the maximum achievable diameter circle in the cell. It is important when the physic first dilates with a balloon catheter and dilates the stent just after that.

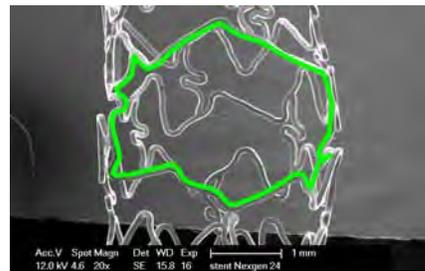


Fig. 10. Dilated cell in (A1) stent

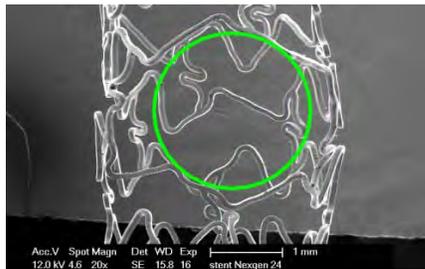


Fig. 11. Maximum achievable diameter circle in (A1) stent's cell

The measurement results are given with the following markings (Table 6):

- maximum circumference of the dilated cell (marked in green in Fig. 10.):

C_{max} [mm]

- maximum area of the dilated cell:

A_{max} [mm²]

- maximum diameter circle in the dilated cell (marked in green in Fig. 11.):

D_{max} [mm]

Side branch access Table 6

Stent	C_{max} [mm]	A_{max} [mm ²]	D_{max} [mm]
(A1)	10,368	4,934	1,750
(B2)	10,296	5,437	2,142
(C1)	13,450	7,352	2,125
(D2)	12,709	6,684	2,101

Side branch access depends on the stent pattern very much. For example if one of (A1) stent's outer cells is dilated, it can never reach as high cell diameter or area as one of the central cells.

4. Conclusions

Some properties of stent are important during the implantation as crossing profile or flexibility of the stent system, and others are important for the long term effect of stent after the implantation as foreshortening, metallic surface area, the largest and the smallest cell sizes, the maximum achievable cell diameter and side branch access.

Every stent have almost the same crossing profile, the largest deviation was 0,042. Except (B1) all the stents were elongated after dilatation. (C-D) stents have higher flexibility, lower MSA and better side branch access than (A-B) stents, because of the different material and stent pattern. The measurement results show that these properties are not influenced by whether the stents were dilated in air or in water.

The collected experience and examination results during this work can

provide a basis for further research. The examination of any properties, that have an effect on the vessel, can produce results in practise. Physics usually decide what size and kind of stent they use during stenting by many years observations and just a look. These tests can help them to select the appropriate stent.

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References

1. O.F. Bertrand et al, *Biocompatibility Aspects of New Stent Technology*, J Am Coll Cardiol Vol. 32 (1998), p. 562–571
2. A. Colombo et al, *Selection of Coronary Stents*, Journal of the American College of Cardiology Vol. 40, No. 6 (2002)
3. D.E. Kioussis et al, *Experimental Studies and Numerical Analysis of the Inflation and Interaction of Vascular Balloon Catheter-Stent Systems*, Annals of Biomedical Engineering, Vol. 37, No. 2, (2009), p. 315–330
4. K. Mori et al, *Effects of stent structure on stent flexibility measurements*, Annals of Biomedical Engineering 33, (2005), p. 733-742
5. MSZ EN ISO 25539-2: *Cardiovascular implants. Endovascular devices. Part 2: Vascular stents* (ISO 25539-2:2008)
6. E. Topol, *Coronary and Peripheral Angioplasty: Historic Perspective. Textbook of Interventional Cardiology*, Saunders, Philadelphia (2003)