Comparative examination of the functional properties of coronary stents

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Abstract. This article introduces measurement methods for investigating functional properties of coronary stent systems. The properties were analysed in theory first, then several different coronary stents were investigated. The object of the measurements were functional stent properties (e.g. recoil, foreshortening) which can be applied to the stent itself; and functional stent-system properties (e.g. crossing profile, overhang), which can be applied to the joint behaviour of the balloon catheter and the attached stent. Each measurement corresponds to the MSZ EN ISO 25539-2 standard. The collected experience and examination results during this work can provide a basis for further research. The examination of any vasoactive properties of coronary stents gives results that can be used in practice. These investigations can help physicians to select the appropriate stent.

Introduction

The heart can be compared to a muscular pump, which maintains the blood circulation with sixty to eighty contractions per minute. That means nearly 2.5 billion contractions during the life. Understanding this huge number is not easy, but more important that this process should be performed without intermission. A cardiac arrest leads to death within a very short period of time. The continued contraction of the heart also means the continuous use of the coronary arteries, so the streamline in them is very important [1,2].

In Europe, most of the deaths are due to cardiovascular diseases. During the disease a fatty, calcariferous subsidence, called plaque formation, evolve in the inner wall of the blood vessel. The stenosis, formed thereby, blocks the free flow of blood, which can cause long-term myocardial infarction. The stent is a biocompatible tubular mesh, which is inserted to the narrowed vessel segment. It compresses the plaque so extends and supports the vessel (Fig. 1). Stents are made generally by laser beam cutting of high-precision tubes of 90-120 micrometer thickness. Tube materials usually are 316L stainless steel, L605 type cobalt-chromium alloy or platinum-chromium alloy [3,4,5].

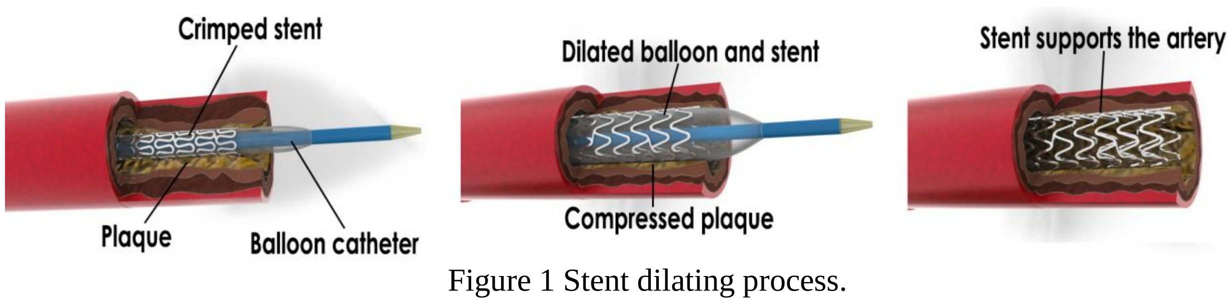

Figure 1 Stent dilating process.

The functional properties of stents are important technical parameters in the aspect of the deployment, the dilation and the long-term efficacy of the stent. In clinical practice, the operator must decide which stent is the most appropriate for the patient. Physicians' choice depends on (among others) the coronary condition, the location and the curvature of the stenosis. After

measuring and comparing the numerical value of functional properties of stents, physicians can choose the appropriate stent for patients more easily with the results [6].
The stent manufacturers give little information about the functional properties of the stent systems. The given values are usually only geometric dimensions (e.g. diameter, strut thickness) and no tolerance is assigned. The other properties (e.g. flexibility, radial force) are given in different units by different manufacturers and the measurement method is not presented. Our aim is to evolve an objective examination method to each property therefore the stents can be compared.

Materials and methods

Functional properties of six stent systems were measured. Table 1 shows the investigated stent systems' nominal properties. (A1)-(A2) and (B1)-(B2) stents are the same. (C) and (D) stents have the same pattern but different length. A research plan was made, so the measurements began with the non-destructive tests and continued with the destructive ones, so the functional properties are described in chronological order. Destructive tests can be divided into two groups; primary and secondary destructive tests. During primary destructive tests the stents are only dilated, during secondary destructive tests the stents undergo permanent deformation, so further examinations are limited. In our work we use non-destructive and primary destructive tests, the stents were dilated at nominal pressure. The investigations were performed with stereo microscopy (Olympus SZX16 stereomicroscope) and reflected light microscopy (Olympus PG 3). The areas were determined with evaluating the digital images by image analysis software. All measurements correspond to the MSZ EN ISO 25539-2 standard [7]. The investigated stents are shown in Fig. 2-4, the crimped state above and the dilated state below.

Table 1 The investigated stents' nominal properties.

Stent	Nominal length [mm]	Nominal diameter [mm]	Nominal pressure [bar]	Material
(A1), (A2)	24	3	11	PtCr
(B1), (B2)	12	3	9	CoCr L605
(C)	12	3	9	CoCr L605
(D)	8	3	9	CoCr L605

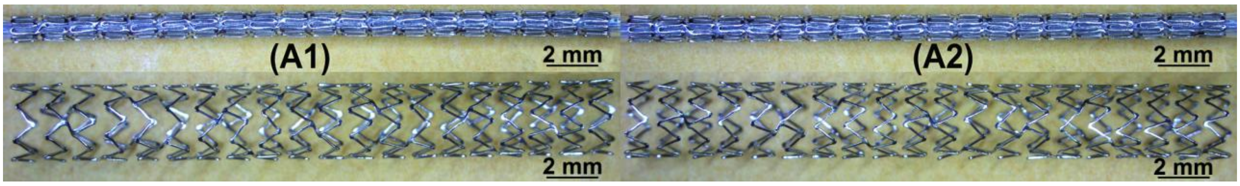

Figure2 Left: (A1) stent, right: (A2) stent.

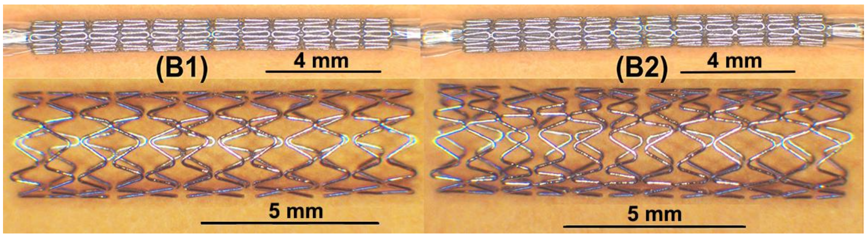

Figure 3 Left: (B1) stent, right: (B2) stent.

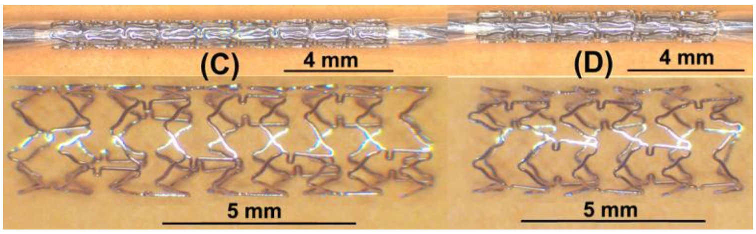

Figure 4 Left: (C) stent, right: (D) stent.

Crossing profile. Crossing profile is the maximum outer diameter of the crimped stent. The purpose of this test is to determine the maximum diameter along sections of the stent system in order to evaluate the dimensional compatibility between the stent system and the vasculature, including the lesion to be treated. This property is important for the stent system's ability to access [7,8]. To determine the crossing profile all rings were measured with a metallographic microscope and an image analysing software. The pictures were taken from 3 directions, each stent was rotated.

Overhang. This property describes the longitudinal overhang of the balloon to the stent. The value of overhang shows the exact location of the stent positioned between the balloon markers. Ideally, the stent is located centrally (equidistant from the two markers), so if the physician can't see the stent during the insertion, it can also be positioned appropriately [7].

Balloon diameter. Diameter of the balloon means the maximum outer diameter of the balloon on the distal and the proximal end of the balloon [7]. This value can be greater than the value of the crossing profile due to the so-called thermal balloon crimping, in which the crimping strength is increased by the heat during the process. Consequently, the balloon material slightly expands so it is pressed between the stent struts, and bulges at both ends. Overhang and balloon diameter are examined with stereomicroscope. During the measurement several images were taken of the balloon catheter distal and proximal end, while the stent system was repeatedly rotated.

Recoil. Recoil is the percent change of the stent outer diameter from the maximum outer diameter obtained with balloon inflation to the final outer diameter after balloon removal. This property is relevant in the fixation effectiveness (the ability of the stent to remain in its deployed position). Knowing the exact value of recoil is necessary to dilate the stent to a diameter that is appropriate after the deflation of the balloon. In the case of greater recoil value the stent may dislocate, which causes thrombosis [7,8,9]. Numerical values were determined by Eq. 1.

$$RE = \frac{D_0 - D_D}{D_0} \cdot 100 \ [\%] \tag{1}$$

D_0: diameter of the dilated stent on the balloon [mm]
D_D: diameter of the dilated stent [mm]
RE: recoil of the stent [%]

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 [7,9]. The stents were dilated at nominal pressure and pictures were taken of each segment with stereo microscope. Numerical values were determined by Eq. 2.

$$FS = \frac{L_0 - L_D}{L_0} \cdot 100 \ [\%] \tag{2}$$

L_0: length of the crimped stent [mm]
L_D: length of the dilated stent [mm]
FS: foreshortening of the stent [%]

Results

Crossing profile. To ease the understanding the stents' rings were numbered and the greatest diameter was given to each ring. The first ring is on the proximal end of the stent and the last ring is on the distal end of the stent. Fig. 5 shows the ring with the largest diameter of (D) stent. The measured values are shown in Table 2. Comparing the default manufacturing data and the measured values we can describe a difference which shows the diversion of the manufacturer data from the measured data. Negative difference value means that the stent profile is smaller than the manufacturer data, which is desirable.

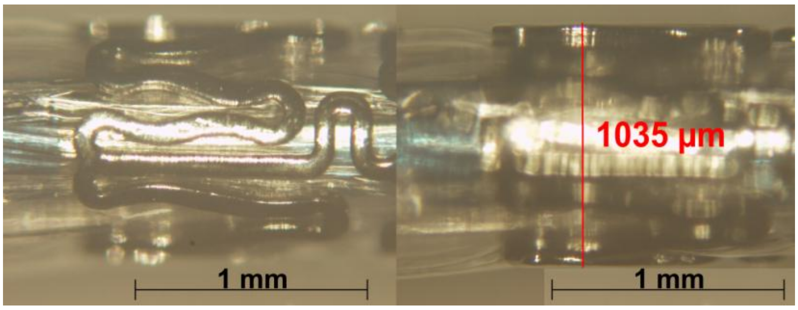

Figure. 5 Image of the first ring of (D) stent; left: middle-focused, right: focused to the measured diameter.

Table 2 Crossing profile values of the stent systems.

Stent	Crossing profile [mm] Manufacturer data	Crossing profile [mm] Measurement	Deviation [mm]	Difference [mm]
(A1)	1.020	1.117	0.011	-0.097
(A2)		1.100	0.009	-0.080
(B1)	1.190	1.170	0.009	0.020
(B2)		1.195	0.011	-0.005
(C)	1.067	1.027	0.010	0.040
(D)		1.035	0.021	0.032

Overhang. The overhang of the balloons show that the stents are not exactly equidistant from the two ends of the balloon (so the two markers). The difference between the distal and the proximal overhang is given in Table 3. Interesting that (A1) stent has the best values and (A2) stent has the worst, although they are same type.

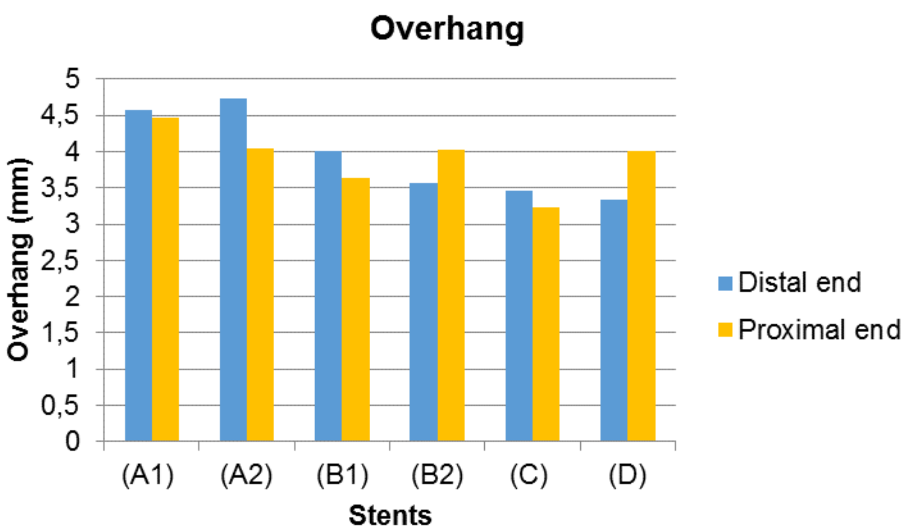

Figure 6 Overhang of the balloons.

Table 3 Overhang values of the stent systems.

Stent	Distal Overhang [mm]	Proximal Overhang [mm]	Difference [mm]
(A1)	4,57	4,48	0,09
(A2)	4,72	4,04	0,69
(B1)	4,01	3,64	0,37
(B2)	3,56	4,02	0,46
(C)	3,47	3,23	0,24
(D)	3,34	4,01	0,68

Balloon diameter. Fig. 7 shows the distal and the proximal balloon diameter compared to the crossing profile. We can see that the outer diameter of the stent is smaller than the outer diameter of the balloon in all cases.

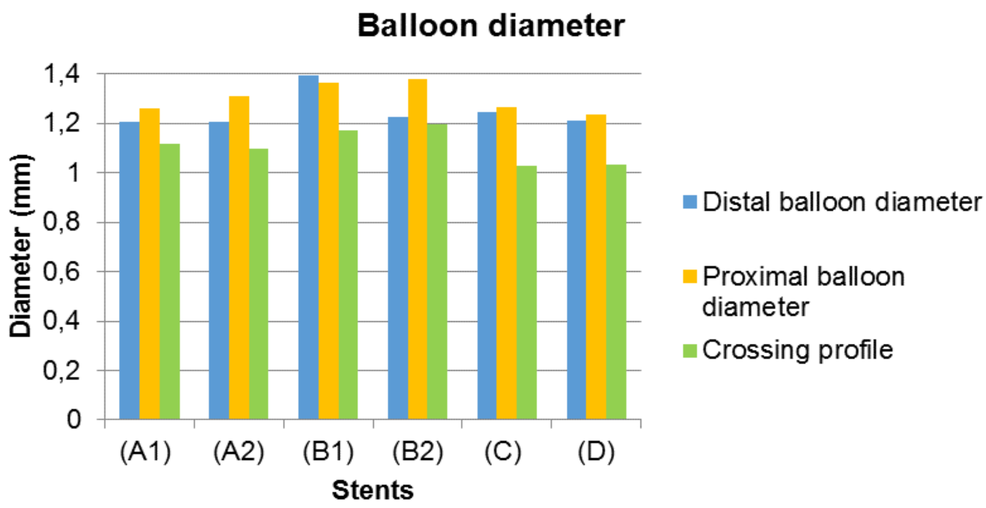

Figure 7 Balloon diameters of the stent systems.

Recoil. All stents have nearly the same recoil values, between 3-5%. The measured values are shown in Table 4.

Table 4 Recoil values of the stents.

Stent	Outer diameter [mm] (on balloon)	Outer diameter [mm] (stent)	Recoil [%]
(A1)	3.06	2.94	3.88
(A2)	3.03	2.93	3.11
(B1)	3.09	2.99	3.14
(B2)	3.14	2.98	5.07
(C)	2.99	2.87	3.98
(D)	3.03	2.93	3.27

Foreshortening. The negative numbers mean that the stents were not shortened but elongated, therefore the stent surely covers the narrowed section of the vessel. That can be caused by the special pattern of the stent or the crimping technique. On Fig. 8 we can see that (A1) and (A2) stents were elongated, and the other stents were shortened. The measured values are shown in Table 4. After comparing the measured length of the stents after dilation (Table 5) with the nominal length of the stents (Table 1), we can say that all stents are shorter than the length given by the manufacturers.

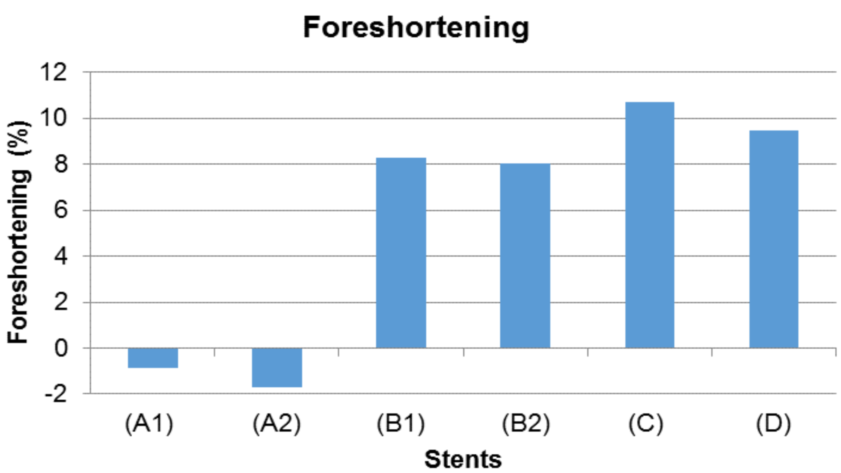

Figure 8 Foreshortening of the stents.

Table 5 Foreshortening values of the stents.

Stent	Length before dilation [mm]	Length after dilation [mm]	Foreshortening [%]
(A1)	23.294	23.501	-0.89
(A2)	23.225	23.616	-1.68
(B1)	12.526	11.487	8.29
(B2)	12.531	11.522	8.05
(C)	12.305	10.987	10.71
(D)	8.250	7.468	9.48

Summary

Some properties of the stents are important during the implantation as crossing profile, and others are important for the long-term effect of stents after the implantation as foreshortening or recoil. In this case each stent has almost the same crossing profile, the largest deviation was 0.021. Except (A1) and (A2) all stents were shortened after dilatation.

During this work the collected experience and examination results can provide a basis for further research. The examination of any vasoactive properties of coronary stents gives results that can be used in practice. Physicians usually decide what size and kind of stent they use during stenting by many years observations and just a look. These objective tests can help them to select the appropriate stent.

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