

## FLEXIBILITY TEST OF THE TOOLS OF ANGIOPLASTY

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**ABSTRACT.** Coronary angioplasty is a procedure used to treat the narrowed coronary arteries. Physicians operate with many different tools during the intervention, the main devices are the following: guidewires, guiding catheters, balloon catheters and stents.

One of the most important properties of the tools of angioplasty is flexibility. This article introduces a flexibility measuring device and a testing method. With the help of this the flexibility of the tools of angioplasty can be compared easily.

**KEYWORDS:** angioplasty, coronary stent, balloon catheter, flexibility.

### 1. INTRODUCTION

Coronary artery disease (CAD) is a leading cause of morbidity and mortality in both developing and developed countries [1]. During life fat and cholesterol deposits (called plaques) emerge inevitably in the coronary vessel walls. They gradually increase over time, first they cause coronary stenosis, then complete blockage of the coronary vessels.

Percutaneous transluminal coronary angioplasty (PTCA) is an invasive procedure performed to reduce blockages in coronary arteries [2]. During the process a balloon catheter is guided into the narrowed section of the coronary artery. Physicians expand this at the place of the stenosis, thereby the balloon compresses the plaque and ensures continuous flow of blood.

Usually, a metal mesh is also expanded with the balloon, called stent (Fig. 1). Stents are commonly made of CoCr, PtCr or stainless steel. The most important requirements for stent materials are biocompatibility and hemocompatibility. The stent should not produce a toxic, injurious or immunologic response in living tissue. It is also important for physicians to see the stent during the intervention, therefore it should be visible under X-rays. MRI compatibility is another main property of stents, that is why these devices are made from non-magnetic metals (for example austenitic stainless steel). The stent should be flexible to follow the curves of the vessel during the pulsation of the heart, but it should be rigid to compress the plaque [2, 3].

Sometimes arteries will still become clogged and narrowed again even with a stent. This phenomenon is called restenosis [4]. Low endothelial shear stress can affect the emergence of atherosclerosis and restenosis. Stent design, strut thickness and so flexibility have a main role in this field [5].

Stent and stent-system properties are mechanical parameters which are important during the deployment, dilation and long term use of the devices. We

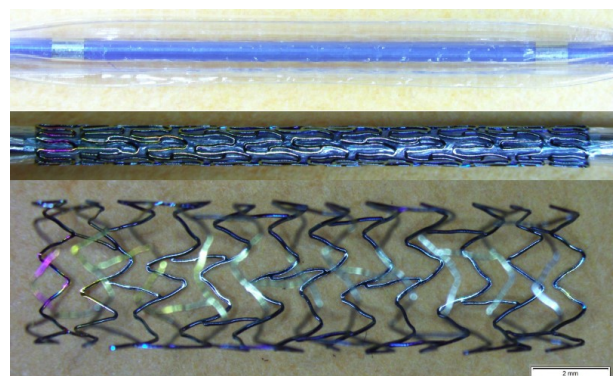


FIGURE 1. Balloon catheter, stent-system and stent.

can say that flexibility is one of the most important properties of the tools of angioplasty. The catheter and with it the stent have to follow the curves of the vascular network without damaging or losing their function during deployment, and the stent has to follow the curves of the vessel after dilation at the place of the stenosis.

There are many methods to measure the flexibility of the tools of angioplasty, for example the company Certiga Engineering Solutions developed a special equipment. They push the tested tool into a spiral tube as long as it breaks. Then they measure the radius at the place of the breaking; they characterize the flexibility with this value [6].

In the study of Mori and Saito the four-points bending test was utilized. Acryl resin bars were attached to both ends of the stent prior to bending measurements, thereby allowing for application of a constant moment to the specimen. Through contact with the punch on the acryl resin bars, stent bending with a constant moment and without radial deformation can be achieved [7].

Another method is based on the mechanical model of a loaded beam. Dr. Péter Szabadits characterize the flexibility with the flexural strength of the beam.

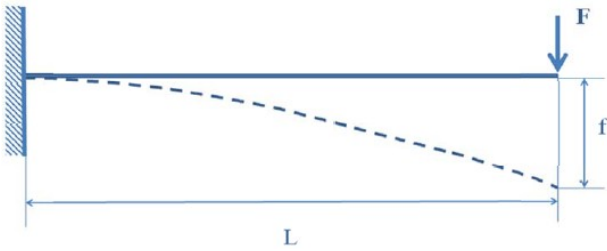


FIGURE 2. The used mechanical model.

We also used this model, but by us to the characterization of flexibility the reciprocal of the flexural strength was used [8].

The European Standard (EN) does not contain any method for the test of the flexibility. The U.S. Food and Drug Administration recommends to wrap the catheter around a series of mandrels with successively smaller radius until the catheter kinks or the lumen collapses. But there is no standard for the stents flexibility measurement [9].

Our aim was to design and manufacture a device which is appropriate for the measurement of the flexibility. The method should be fast and easy and adaptable to all kind of tools of angioplasty.

## 2. MATERIALS AND METHODS

For the flexibility tests a mechanical model of a loaded beam was used (one end of the cantilever beam was clamped and the other end was loaded; Fig. 2).

The following equation was used to describe the model:

$$EI = \frac{FL^3}{3f} \quad (1)$$

With the help of this equation, the flexibility can be easily calculated:

$$Flexibility = \frac{1}{EI} \quad (2)$$

For the tests a measuring device was needed (Fig. 3), which can be impacted into the testing machine (Instron 5965). After designing the device it was fabricated with PolyJet and FFF rapid prototyping technologies. This device consist of a bottom and a top holder, 33 guide bushes, 2 bolts and 5 spacers. All of the guide bushes had a mortise in their centers with different diameters from 0,4 to 4,7 millimeters. The spacers have the following length: 1, 2, 4, 8 and 16 millimeters; with these between 1 and 31 millimeters all discrete quantities can be assembled. Several stents, balloon catheters and stent-systems were investigated as a loaded beam in the model.

The investigated devices were the following: 3 balloon catheters with different diameters; 10 stent-systems, from these 6 were the same type, they had difference just in the size of the diameter; and 5 stents

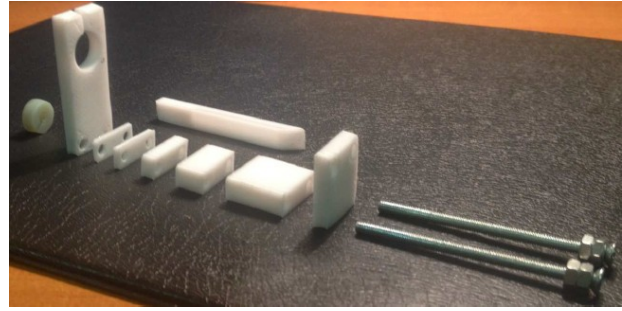


FIGURE 3. Flexibility measuring device.



FIGURE 4. The investigated stents.

with different diameters and strut widths (Fig. 4). The investigated stents were made from platinum chromium (PtCr) or cobalt chromium (CoCr) alloys.

The investigations were performed by stereo microscope and testing machine. First, the diameter of the tools was measured with the help of the stereo microscope. Then it was impacted into the right size guide bush, which was embed to the top holder. The guide bushes had a bigger outside diameter as the diameter of the mortise on the top holder, so they were fitting tight. After that, the required length was adjusted with the spacers and the whole measuring device with the tested tool was impacted into the testing machine. The tested tools were loaded with a perpendicular force at the end.

The load force, the length and deflection of the beam was measured. After the tests the flexibility was calculated with the help of equation (2).

Every device was loaded five times, between the measurements each was rotated about its axis with the same angles.

	Marking	Diameter x length	Clamping length	Max. deflection	Max. force	Material	Strut width	Flexibility
	[-]	[mm]	[mm]	[mm]	[mN]	[-]	[ $\mu\text{m}$ ]	[ $1/\text{Nmm}^2$ ]
Balloon catheters	B1	2,5x9	5	1	17,00	-	-	1,342
	B2	3x9	5	1	19,53	-	-	1,151
	B3	3,5x9	5	1	31,51	-	-	0,646
Stent-systems	A1	2,5x15	8	1,6	42,18	Pt-Cr	73,89	0,216
	A2	3x15	8	1,6	73,85	Pt-Cr	81,32	0,121
	A3	4x15	8	1,6	90,02	Pt-Cr	84,95	0,096
	G1	2,75x25	8	1,6	183,30	Co-Cr	96,66	0,045
	C1	2,25x24	18	3	9,68	Pt-Cr	58,71	0,159
	C2	2,5x24	18	3	14,54	Pt-Cr	60,15	0,106
	C3	2,75x24	18	3	16,18	Pt-Cr	64,81	0,095
	C4	3,5x24	18	3	24,01	Pt-Cr	80,02	0,064
	C5	4x24	18	3	31,33	Pt-Cr	86,15	0,049
C6	4,5x24	12	2,4	39,42	Pt-Cr	85,52	0,039	
Stents	D1	2,25x24	12	2,4	2,81	Pt-Cr	58,71	1,839
	D2	2,5x24	12	2,4	3,34	Pt-Cr	60,15	1,241
	D3	2,75x24	12	2,4	2,96	Pt-Cr	64,81	1,399
	D4	3,5x24	12	2,4	4,52	Pt-Cr	80,02	0,916
	D5	4x24	12	2,4	6,86	Pt-Cr	86,15	0,605

TABLE 1. The results.

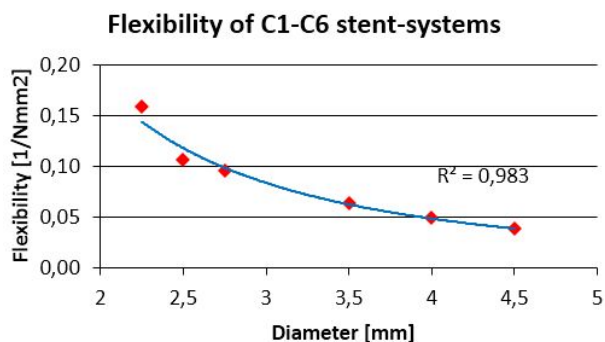


FIGURE 5. Correlation between flexibility and diameter in the case of stent-systems.

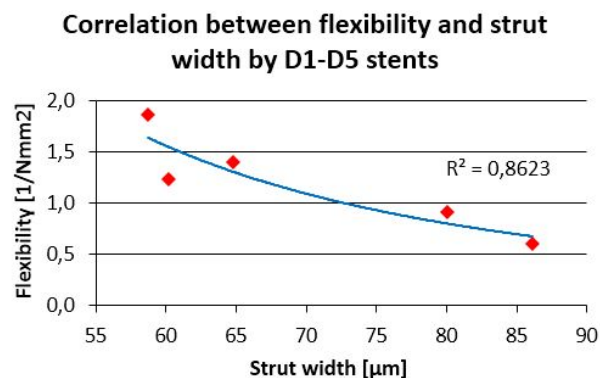


FIGURE 6. Correlation between flexibility and strut width in the case of stents.

### 3. RESULTS

Table 1. contains basic information and flexibility of the investigated devices. Diameter and length are the nominal sizes. The maximum deflection was 20% of the clamping length, but it was maximized in 3 millimeters. Strut width was measured with the help of stereo microscope.

Three main factors influences the flexibility of the tools of angioplasty, these are the followings: diameter, material and stent pattern. Primarily the relationship between the flexibility and diameter was investigated. The results show that between the flexibility and the diameter there is a power function dependence (Fig. 5).

In the case of stents the relationship between flexibility and strut width was also investigated; between

the flexibility and the strut width there is a power function dependence (Fig. 6).

Based on the measurement the flexibility of stents and balloon catheters are about with one order of magnitude greater than the flexibility of stent-systems (Fig. 7).

### 4. CONCLUSIONS

Based on the experiments the measuring device is adequate for the investigation of flexibility. In every case the relative standard deviation of the data is lower than 10% (in most cases it is lower than 1%), so the data is homogeneous, this means that it isn't needed to measure more times in different positions. The flexibility depends on the diameter, raw material,



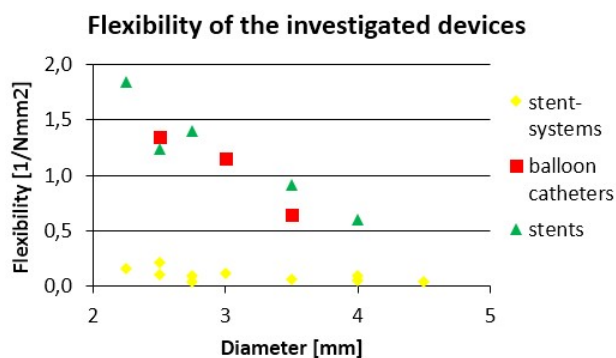


FIGURE 7. Correlation between flexibility and diameter of the investigated devices.

strut width and stent pattern.

The manufacturers don't give any concrete, numerical data about flexibility of the tools of angioplasty, that's why these investigations are important. With the help of these results, physicians can easily compare stents or stent-systems according to flexibility, and they can purposefully choose the most suitable tools for the intervention.

#### LIST OF SYMBOLS

$E$	Young's modulus [MPa]
$I$	Moment of inertia of beam [mm <sup>4</sup> ]
$F$	Force [N]
$L$	Length of beam [mm]
$f$	Deflection of beam [mm]

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