Different Properties of Coronary Stents

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Abstract. Stents are mesh structured implants which are used to support the vessel wall in the balloon expanded vessel part. Several methods were developed and applied for the determination of mechanical properties of coronary stents, as a part of a complex pre-clinical in vitro diagnostic system: radiopacity, flaring, metallic surface area and fatigue tests. Three pieces of equipment were assembled for the examination of fatigue properties. The first method simulates the bending stress in the coronary arteries; the second method simulates the effect of the cylindrical mechanical strain which is equivalent to the systolic and diastolic pulse in the coronary arteries; and the third method is using the energy of the ultrasound concentrating to the stent. After fatigue tests stereomicroscopy, optical microscopy, scanning electron microscopy were used for the determination of surface quality and condition. The most frequent failures were scratches, pits and small shrinkage of materials originated from the manufacturing and finishing processes. Because of fatigue tests slip lines occurred in the critical curves, grain boundaries were outlined, the surface of the struts become rough, but these mutations do not affect the functionality of the stents.

Introduction

Nowadays in the highly developed Western European countries cardiac and circulatory diseases belong to the leading causes of death. 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 is heart catheterizing besides the open-heart bypass surgery and stenting within that field.

The mostly used stents these days are balloon expandable stents. During 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 the way of the blood open 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.

The base materials of the stents are biocompatible and haemocompatible alloys. The most widely used materials are AISI 316L and 316LVM types of stainless steel, which proved to be the most reliable in clinical applications [1]. In the last few years the stents manufactured of cobalt-chromium alloys (L605, MP35N, Phynox, Elgiloy) appeared in the market. These materials are more dense than 316L and provides higher strength, which allows the stents to be fabricated with thinner struts [2]. As for the semi-products 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 [1].

Methods

The aim of the examination program 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.

Flaring describes how the rings of the stent stick out in the vessel curves. Being aware of 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 that could be. The models prepared to examine this property are bended glass pipes [3]. The model we prepared is made of a 2.4 mm inner diameter glass pipe with 1 mm wall thickness. Its curves resemble the characteristic curvatures of vessels, which are: R_1 = 10 mm, R_2 = 8 mm.

The metallic surface area (MSA) parameter means metal to artery ratio. More precisely it is the percentage of the surface of the stent to covered surface of the artery and it has to be examined in expanded condition (Eq. 1).

$$MSA = \frac{external\ surface\ of\ stent}{surface\ of\ artery} \cdot 100 \qquad \text{(Eq. 1)}$$

It is difficult to calculate MSA because the laser cutting technology yields sophisticated stent designs. MSA was determined with digital image processing. Photos of the surface of the stents were taken while rotating them around then joined these pictures together. After making a greyscale photo of the whole surface, we got a picture of 1 bit colour depth applying a threshold filter (Fig. 1). The Eq. 2 shows the relation between MSA and the number of pixels of the picture.

$$MSA = \frac{number\ of\ black\ pixels}{all\ pixels} \cdot 100 \qquad \text{(Eq. 2)}$$

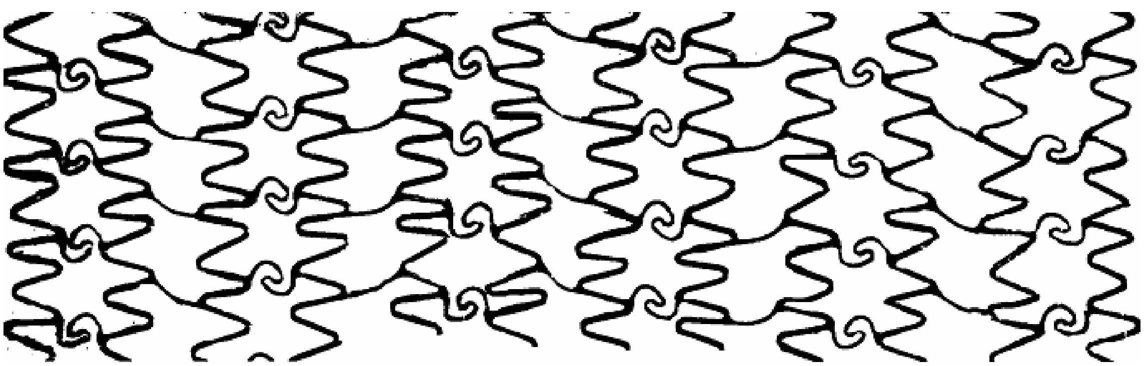


Figure 1 A stent design after digital image processing

The stents shall be seen by validated imaging technologies applied in the clinical practice. During implantation it is important that the physician can control the position of the stent and its positioning in the stenosed vessel part. The stents shall be clearly seen under X-ray to reach that. The implants shall be made of special materials or markers shall be placed on them to assure this feature. The visibility of the stent is determined by the material the stent or its density, the thickness and wideness of the strut and the design of the stent.

Testing of radiopacity can be performed, among others, by an X-ray microscope under tube voltage (90 kV) and tube power (0,8-1,2 W) sets applied in the clinical practice. The stents can be tested in a porcine's heart or phantoms in order to simulate real circumstances better.

The fatigue tests are of high importance among in vitro pre-clinical testing. The evaluation has to show that the in vivo conditions which the stents are subject to do not damage the implant.

Three pieces of test equipment were assembled to test fatigue features with accelerated fatigue tests. The first piece of equipment is a bending machine simulating the bending stress, the second one is a vessel model simulating the effect of the pulsating mechanical strain, the third one is an ultrasonic resonator. The time of the examinations have to be equal with 10 years lifetime, so the testing time is 380 million cycles, as stated in the standard.

The aim of the test done by the bending machine is to simulate the bending stress in the coronary arteries. A plastic tube of 12-15 centimetres is attached to the equipment seen in Fig. 2. One end of the tube is steadily fixed, the other end is connected to an excentric disc. Turning away of the disc results in bending of the plastic tube in the consequence of which the stents placed in the tube are also bent. The movement of the tube simulates the movement of the coronary arteries in systolic and diastolic phases (Fig. 3).

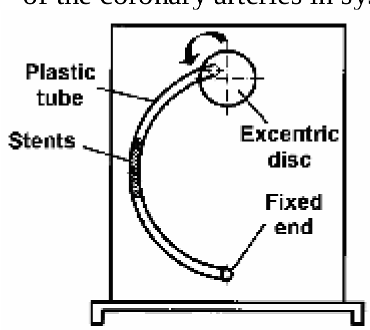


Figure 2 The equipment of the fatigue test to simulate bending stress

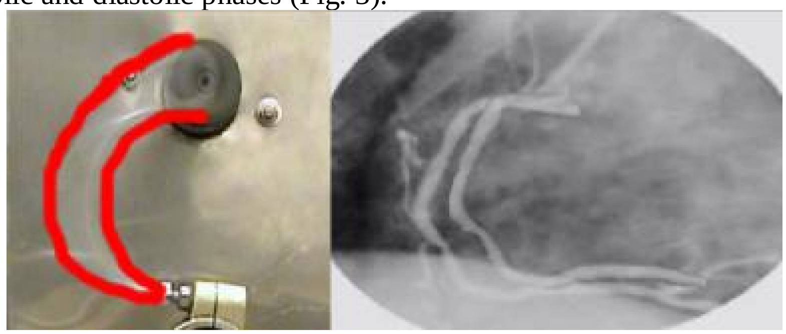


Figure 3 The similarity of the movement of the bending machine and the coronary arteries

The vessel model simulates the effect of the pulsating mechanical strain. The stents are placed into a silicon tube under pressure of a minimum 160 centimetre water column. This pressure is equal to the medial pressure of 120 Hgmm in the coronary arteries. At the bottom of the water-column a membrane pump is connected to the silicon tube, which provides a systolic-diastolic pulsation to the medial pressure at 50 Hz frequency (Fig. 4).

At the third kind of method the equipment is an ultrasonic cleaning device and a glass flare placed into it. There is water in the cleaning device and the flare placed into it concentrates the energy of the ultrasound as a resonator to the tube part of the flare where the stents are placed. The load of the equipment effects to the fixed stent by frequency of 35 kHz.

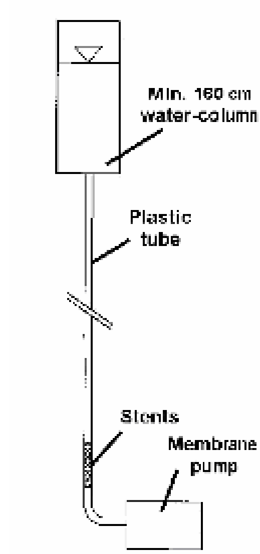


Figure 4 The equipment of the fatigue test to simulate the effect of the pulsating mechanical strain

Results

The motion of the stents was investigated and photographed under stereomicroscope to determine flaring. The implants tried to straighten the curves between the two ending points leant against the glass wall that is they showed the slightest possible bending (Fig. 5-6).

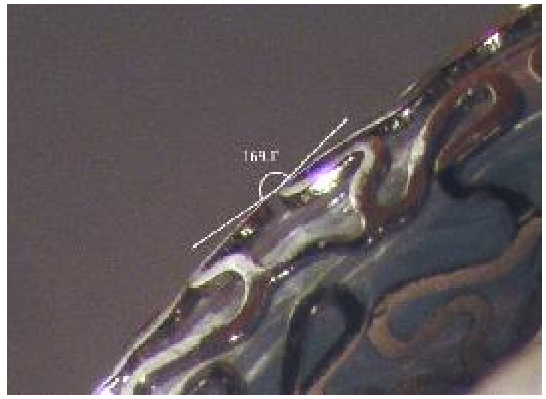


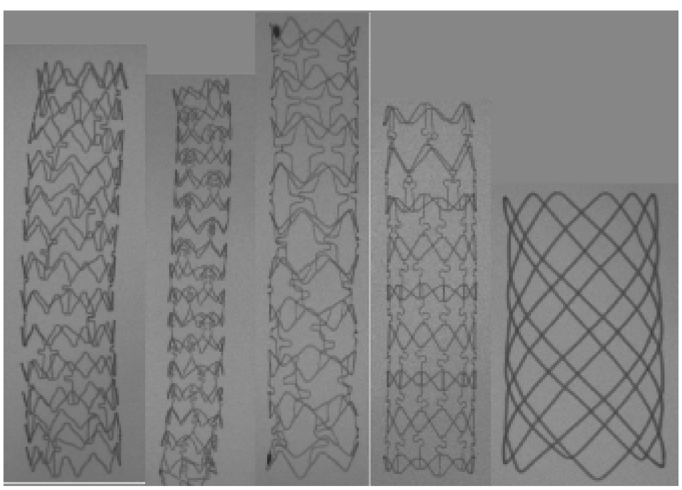
Figure 5 Stent in the tube

Figure 6 Deflecting rings

The stents can be divided into three MSA categories: low (MSA < 15 %), medium cover (15 % < MSA < 20 %) and high cover (MSA > 20 %).

The ratability of radiopacity depends on the visibility of the stents under X-ray image. Radiopacity is determined by two important parameters, one is the visibility of the markers placed on the stent system, which helps to define the position of the stent during implantation and the other one is the visibility of the expanded stent, which can be important in further stenting and observing in-stent restenosis. The degree of radiopacity can be low, moderate) or high based on these parameters.

Using radiopacity tests it can be stated that 316 L and cobalt-chromium stents are adequately visible on the X-ray images. The stents made of stainless steel can be seen better than the stents made of cobalt-chromium. The main reason for that is that the strut thickness of the cobalt-chromium stents is smaller than the strut thickness of the stainless steel stents (Fig. 7-8).



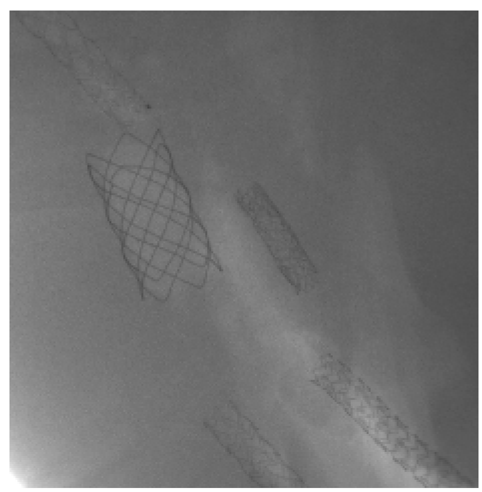


Figure 7 X-ray image of different material's coronary stents

Figure 8 X-ray image of coronary stents in a porcine's heart

After the fatigue test performed by the bending machine fatigue traces were detected on the surface of the 316L stents by a scanning electron microscope. Grain boundaries were outlined and slip lines could also be observed on the surface. These processes happened in the most active systems of metamorphosis. The reason for that may be that the stress was more concentrated at grain boundaries comparing to the inner part and the grains were deformed there in a greater extent [4]. Smaller holes occur on the surface rather frequently. They are the inclusions in the material milled into the surface by electro polishing and produced by the fatigue test. Due to the metamorphosis, several parts of the stent surface became rough and pitted (Fig. 9-11).

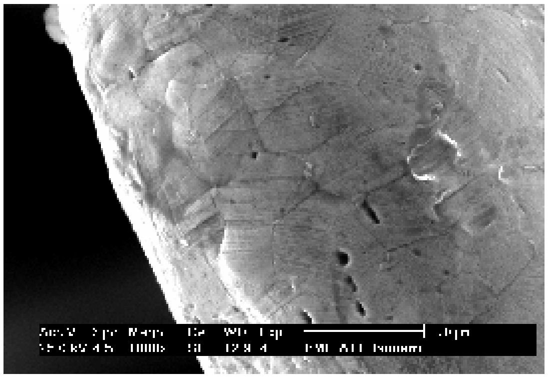


Figure 9 Small holes, slip lines and grain boundaries on the Terumo Tsunami stent’s surface at 1000 times magnifying

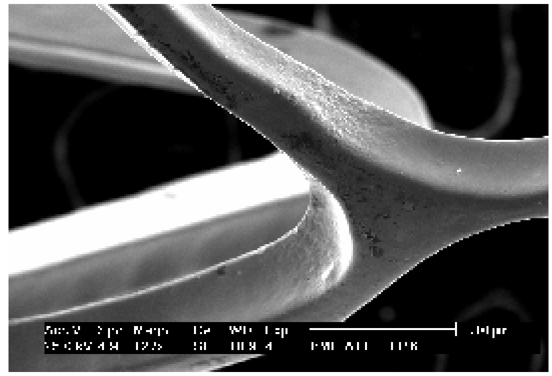


Figure 10 The fatigue stress caused metamorphosis on the Boston Scientific LP stent’s surface at 127 times magnifying

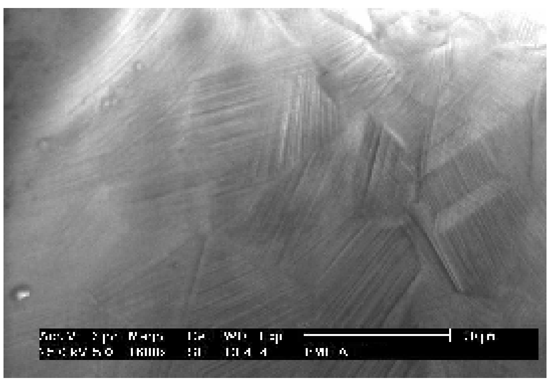


Figure 11 Slip lines and grain boundaries on the AVE GFX stent’s surface after fatigue test at 1600 times magnifying

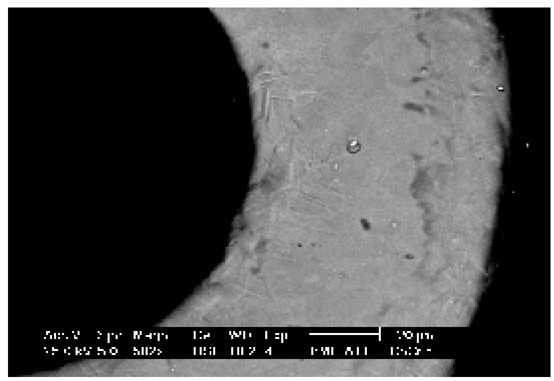


Figure 12 The Guidant Multi-Link Zeta Cobalt-Chromium stent’s surface after fatigue test at 582 times magnifying

Metamorphosis and slip lines can also be seen on the surface of the cobalt-chromium stents, however, these are smaller because the cobalt-chromium alloy is of higher flexibility, it tolerates the same load better, therefore it suffers a smaller metamorphosis than the 316L stents. Presence of slip lines and grain boundaries mainly occurred in the strut bends. These traces are more intense in the inner bend, so it can be determined that they are exposed to bigger stress there (Fig. 12).

Fatigue traces could not really be observed on the surface of bare metal stents after the fatigue tests in the vessel model. The stents suffered a small metamorphosis, slip lines and grain boundaries became visible but supposedly they were caused by the expansion and not by the fatigue test. These traces could be seen on the inner parts of the bends of the struts (Fig. 13-15).

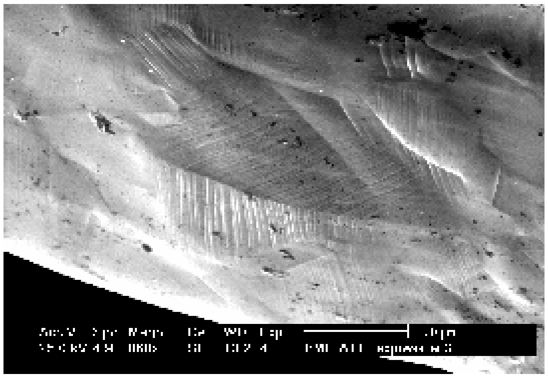


Figure 13: Slip lines and grain boundaries on the Boston Scientific Express^2 stent's surface after fatigue test at 860 times magnifying

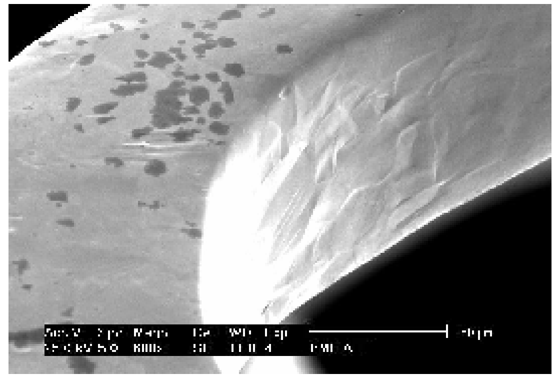


Figure 14: Rough surface on the inner parts of the bends on the Orbus R Evolution stent after fatigue test at 600 times magnifying

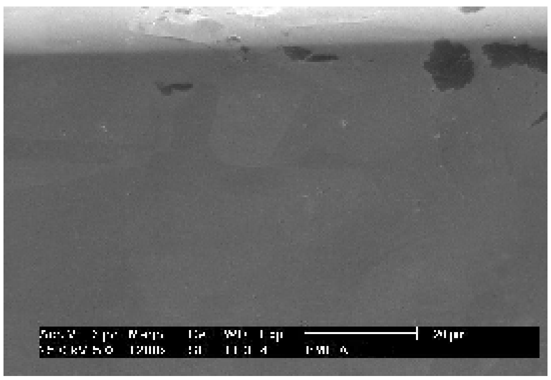


Figure 15: The smooth and intact part of Orbus R Evolution stent's surface after fatigue test at 1200 times magnifying

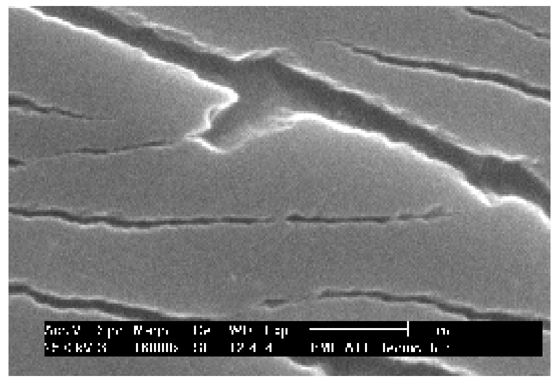


Figure 16 Parallel splittings on the carbon coating at 16000 times magnifying

When using the third kind of fatigue test method changes on the surface of the uncoated coronary stents fatigued by ultrasonic energy could not or only in small amount could be caused by the test itself. Comparing to the status before the fatigue test, slip lines and grain boundaries occurred more frequently. On the places of the carbon-coated coronary stents tested by this method which were exposed to the biggest metamorphosis, parallel splittings occurred, the coating cracked and did not remain uniform (Fig. 16).

Conclusions

Apart from the base material it is the stent geometry what significantly influences the application properties of the stents. The design aims at the balance between strength and flexibility in the first place and through these it has influence on the expansion characteristics and also determines the metallic surface area.

The examination method for assessing flaring properties of coronary stents is usable. However, the disadvantage of the model is stiffness. The vascular system embedded in the tissues is flexible, so it can suffer smaller deformations without injuries. At flaring tests the deflection of the rings depends on the strut thickness and the designs, the bent struts assist the expansion and the flexibility as well.

The favourable effects of MSA values are not clearly defined yet. Considering strength, the high ratio is the best because in this case the stent can support the vessel wall more securely. On the other hand, the high ratio is bad because the large metallic surface raises the possibility of thrombosis and restenosis.

The fatigue properties were tested by three pieces of equipment. Macroscopic damages did not appear on the stents and the implants were not broken. Only small traces of fatigue occurred on the surface, which became rough, slip lines and grain boundaries were outlined. However, these changes do not influence the functionality of the stents. After examining the fatigue tests, it is important to see that changes of the stents were not significantly different considering the period of time during which they were tested. We can come up to the conclusion that most of the metamorphosis was caused by the production, crimping to the balloon or during the expansion of the stent.

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