EXAMINATIONS OF COATED CORONARY STENTS' EXPANSION FEATURES AND STABILITY OF THE COATINGS

E. Bognár, Gy. Ring and J. Dobránszky

Budapest University of Technology and Economics, Department of Materials Science and Engineering, Budapest, Hungary

eszter@eik.bme.hu

Abstract: In this study the main features of coated coronary stents such as foreshortening, recoil are shown. Types of active and passive coats and their main effects are introduced. Test results show the different between coatings, obtained by stereomicroscope, Raman-spectroscope scanning electron microscope and energy dispersive x-ray microscope are also shown.

Introduction

In our days the disease of the cardiovascular system is one of the biggest problems of the people and medicine. The treatment of these illnesses is a developing section, so it gives a lot of possibilities to the engineers as well. The arteries often grow narrow, because of a fatty deposit called plaque. As a result of this stenosis, less blood can flow in the arteries, which can lead to heart attack. Therefore more and more new equipments are developed. Stents are net structure implants which are used to support the vessel wall in the in the balloon expanded vessel part. Their role is to prevent the restenosis.

This disease can be prevented or if it is evolved, the progress of it could be slowed down. The results show that the changing only of the culinary habits can reduce the early mortality by 30 %. The risk factors can divide into three groups: lifestyle, idiosyncrasy and physiological specialties. These risk factors have important function of the maturation of this illness.

Nowadays the key area of experiments is to develop drug eluted stents. In order to efficiently prevent restenosis, the effect and the dose of different pharmaceuticals are examined. Polymer coated stents can serve as a reservoir for local drug delivery. Preclinical studies have demonstrated the feasibility and efficacy of this approach, and preliminary results of on-going clinical trials are very promising. Future researches will probably concentrate on the interaction of the implant with the vessel wall and the blood.

Materials and Methods

Stents' preproduct may be tube or wire. They are very precisely manufactured and therefore the price is very high. The design is manufactured from a tube by laser cut. Stents are made of wires and are prepared by weaving, threading or reeling. The materials of stents are usually stainless steel, cobalt-chromium alloys or nitinol. There exist coated and uncoated stents as well. In this study the coated stents are shown, especially the types of the coatings. In general, passive coatings, which only serve as a barrier between the stainless steel and the tissue, and active coatings, which directly interfere with the process of intima proliferation have been identified.

The main respect at passive coated stents is that being invisible for the ambient tissues. Passive coatings have to assure the optimal interaction with blood and the wall of the artery. It has to inhibit the alluvium of the cells on the surface. For the sake of the complexity of blood, it is really difficult to construct reliable passive coatings.

Precious metals, e.g. gold is a highly radiopaque and biocompatible material. Coating with gold intensifies radio visibility and helps to positioning. Unfortunately, in contrast to the expected effect, the rate of restenosis has grown at gold coated stents.

Nowadays the oxide, nitride and carbide coatings (e.g. SiO_2, TiO_2, TiN, SiC) are very prevalent, especially the Diamond Like Coating (DLC). DLC is a really lasting coating and has increased haemo- and biocompatibility.

The chemical, material and mechanical properties of the synthetic polymers (silicone and other polymers (PE, PP))are variable on a wide range and they are easy to shape, but not biocompatible enough.

A special part of passive coatings are the human polymers (e.g. phosphorylcholine, fibrin, elastin, hyalurons acid). PC is the name of the chemical head group found in the inner and outer layers of lipids forming the cell membranes. PC contains both positive and negative charges and is overall, electrically neutral over a wide pH range. PC coatings are no allergenic because they are normal components of human cell membranes: more than 90 % of the phospholipids contains PC. They have a remarkable biocompatibility.

Active coatings obstruct the activation of the platelets. This is very important, because in the expanded part of the artery the chance of thrombosis is bigger without stent as well. There are two types of active coatings: binded drugs and radioactive coatings. The drugs were binded with the help of some kind of matrix on the surface of the stent. Their main role is to obstruct the platelet-activation and to raise antithrombotic effect. The bind of the drugs can be incorporation into a polymer, direct drug loading onto the stent, nanoporosical ceramics or PC-coatings. The other method, called brachytherapy, is an intravascular solution. The best way is to implant emitter stents, but there is a big problem, called edge effect. Edge effect means that restenosis is bigger, near to the edge of the emitter stent. Probably, the reason of this is that the dose of emitting intensifies the intimal hyperplasia. Therefore, the so-called “cold”, not radioactive stent-edge and the so-called “warm”, radioactive stent-edge were tested, but they didn’t work.

For the expansion of the five passive coated stents two in vitro methods were tried. Especially, their expansion features and the stability of their coatings were examined. Three of them were expanded in mid-air and two of them were expanded in an in vitro system. The stents in the in vitro system were flown through with physiological tincture and blood. The balloons were expanded above their nominal pressure (to 20 bars), simulated the clinical use of them. During the expansion and after expansion the examination of the stent’s surface and the coating were analyzed by stereomicroscope, Raman-spectroscope, scanning electron microscope and energy dispersive x-ray microscope.

Results and Discussion

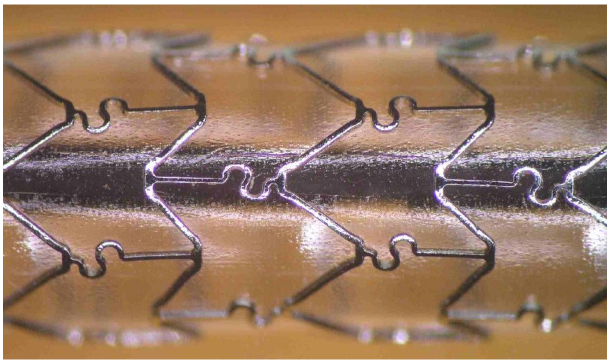
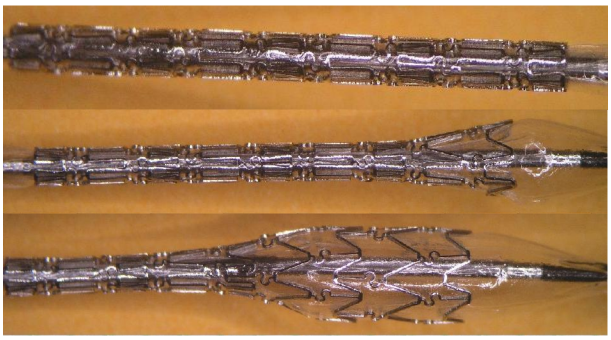


Figure 1: BiodivYsio phosphorilcoline-coated stent

The material of BiodivYsio^{TM} stent (Biocompatibles Ltd.) is stainless steel, 316L, coated with phosphorilcoline. The struts have rectangle shape and they are rounded. The nominal diameter of this stent is 3 mm and the nominal length is 15 mm. The foreshortening (4,13 %) and recoil (3,63 %) were measured and have correct values. Mid-air expansion was used (Fig. 2).



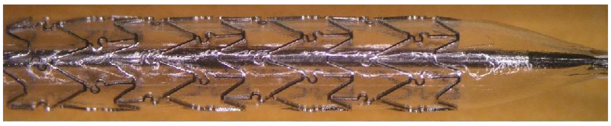


Figure 2: Expansion

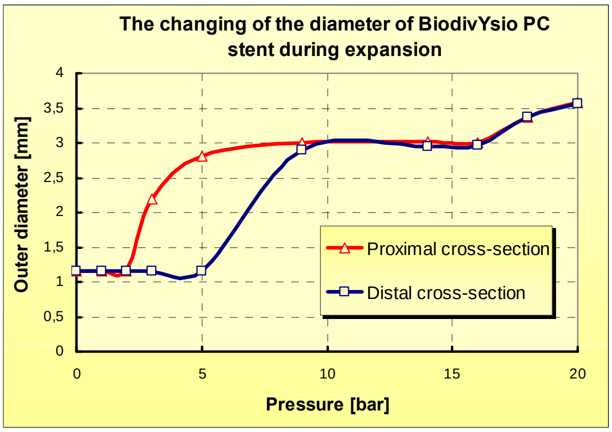


Table 1: The changing of the diameter

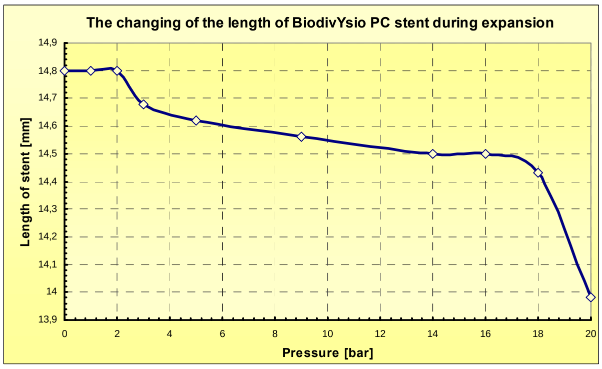


Table 2: The changing of the length

The coating of this stent had a good quality, the whole was uniform before expansion (Fig. 3). There were some grain boundaries.

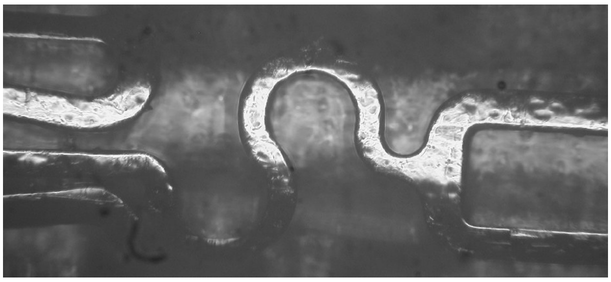


Figure 3: Before expansion

After expansion the coating of the stent peeled off (Fig. 3, 4). It is for sure that if the stent had expanded in some kind of a liquid, the coating would not have peeled off. The expansion in liquid weren’t realized, because there were no other PC-coated stent.

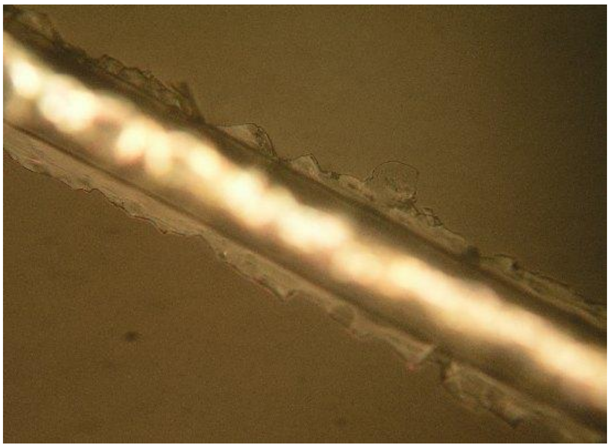


Figure 4: The peeled off coating after mid-air balloon expansion

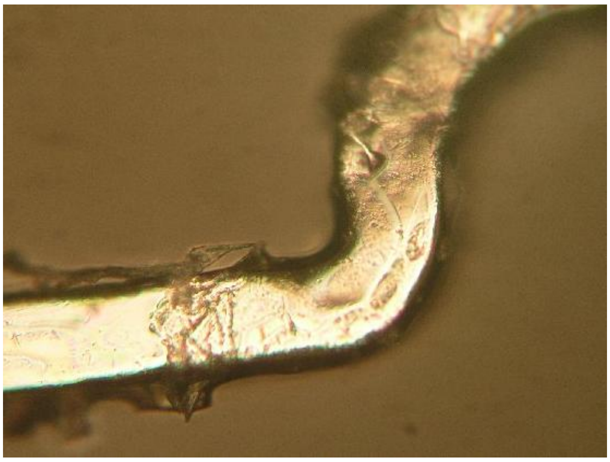


Figure 5: A strut with the peeled off coating

The material of Tecnic Carbostent^{TM} is stainless steel, 316LVM, coated with carbofilm. The struts have rectangle shape and they are rounded. The nominal diameter of this stent is 3,5 mm and the nominal length is 25 mm. The foreshortening (0,4 %) and recoil (2,1 %) were measured and have correct values. Mid-air expansion was used (Fig. 6).

Figure 6: Mid-air expansion

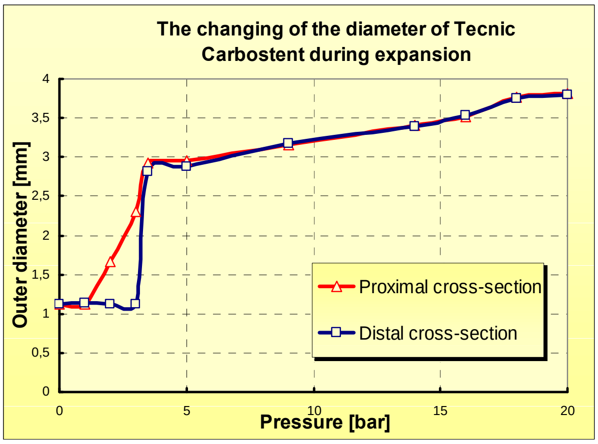


Table 3: The changing of the diameter

The carbofilm coating was perfect before expansion, there were not any lesions.

After expansion the coating was not changed: nice, clean and uniform. The surface remained intact and smooth (Fig. 7,8).

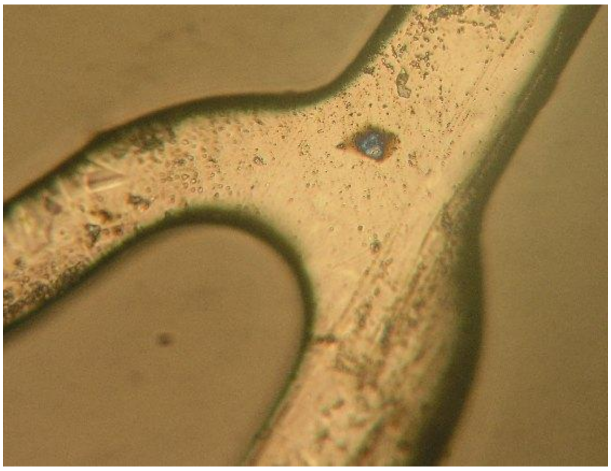


Figure 7: After expansion

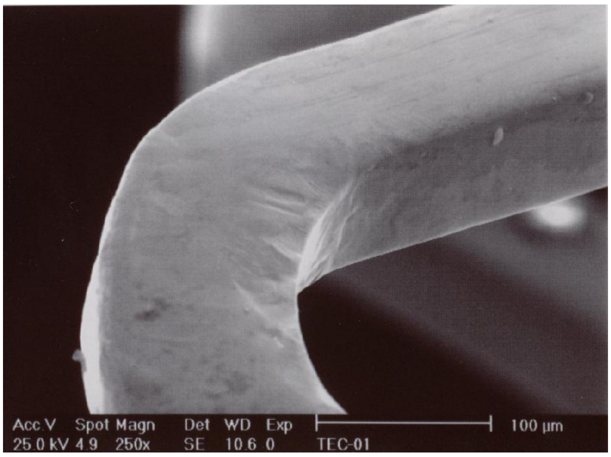


Figure 8: Electron microscopic image at 250 times magnifying

There is a wide and complex zone in the Raman-spectrum of DLC at 1000-1900 cm^{-1} of wavelength area. This can be divided into two component peaks by the help of Gauss-curve, G and D zones. G zone can subscribe with the C-C tensile-oscillation of sp2 hybridization carbon atom. D can subscribe with the breathing oscillation of the hexagonal rings of sp2 carbon atom. The name of the zones became by the Raman-spectrum of the graphite (G: 1580 cm^{-1} and D: 1360 cm^{-1} The only relevant difference is that in the graphite there are only ring carbon atoms and in DLC there are chains as well. Figure 9 shows a typical Raman spectrum of a DLC coated stent. The other curve, measured in different places, does not diverge too much. The decomposition showed that the D and G peaks were at 1410 and 1574 cm^{-1}. The position of 1574 cm^{-1} is near to graphite which shows that most of the coating's sp2 hybridisated carbon atom settled into rings and makes small graphite character clusters. The high intensity of D zone supports this, too. The position of D zone differs from the value of graphite. This means that the size of sp2 clusters is small in this zone.

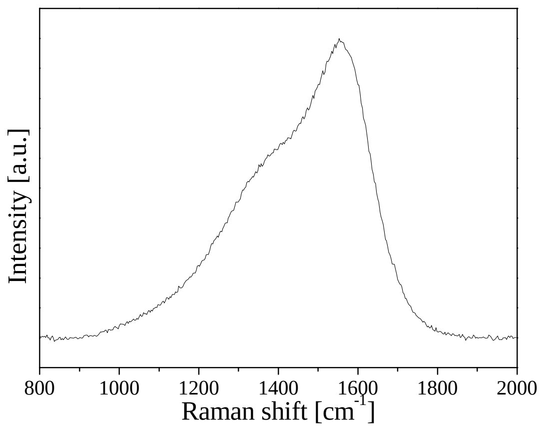


Figure 9: Typical Raman-spectrum

Figure 10: A strut of Tecnic Carbostent

The material of Tecnic Carbostent™ is stainless steel, 316LVM, coated with carbofilm. The struts have rectangle shape and they are rounded. The nominal diameter of this stent is 3,5 mm and the nominal length is 25 mm, like the mid-air expanded stent. The expansion features were not imponderable about the silicone tube.

An in vitro system was used during expansion, flown through with physiological tincture in a silicone tube (Fig. 11). The rate of flow was about 200 ml/min. The stent stayed there for 24 hours. After this test the coating were examined and it was not changed.

The in vitro system, flown through with blood did not worked, because there was coagulation, in contempt of using heparin, so the examination of Phytis Diamond Sidebranch was not possible.

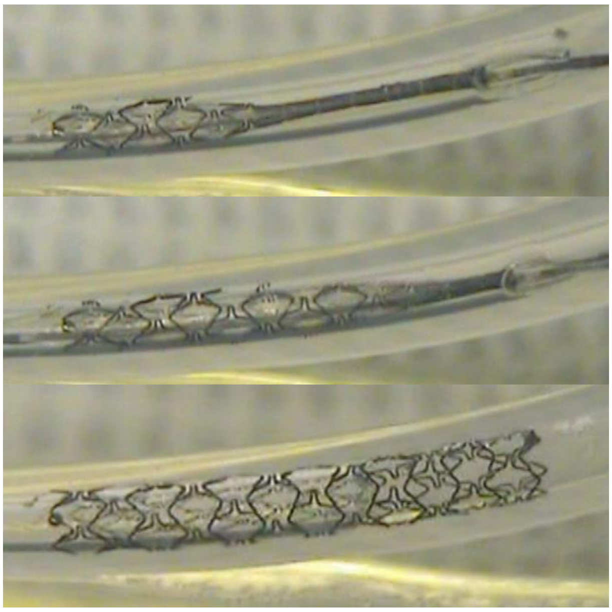


Figure 11: Expansion in the silicone tube

The Phytis Diamond Sidebranch stent has a diamond side branch. For 5 days (21,6 million cycles) it was put in a silicon tube which simulates the effect of the pulsating mechanical strain which is equivalent to the pulse in the coronary arteries. After this examination slip lines and grain boundaries occurred (Fig. 12), but the coating remained uniform (Fig. 13, 14).

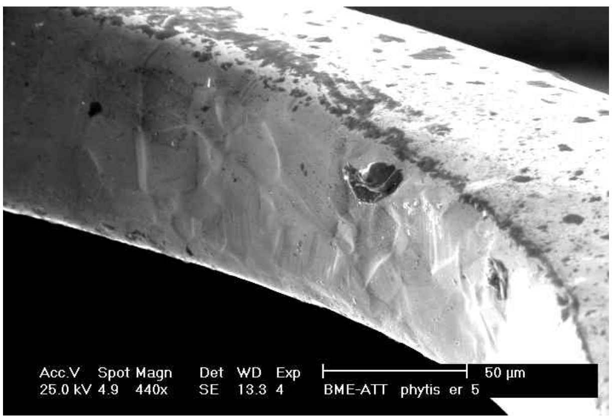


Figure 12: After pulsation mechanical strain, the grain boundaries

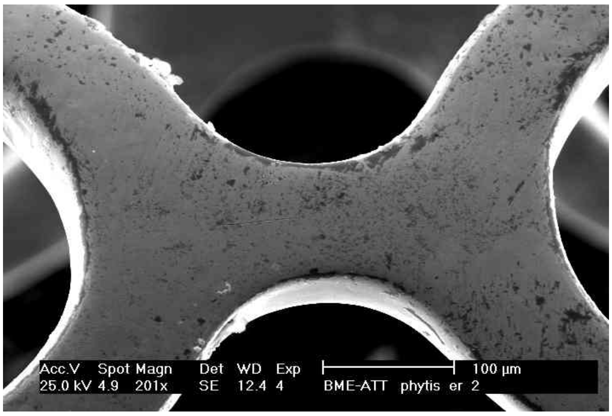


Figure 13: The slip lines

Figure 14: The grain boundaries

Conclusions

The aim of this study was to examine the expansion features of coronary stents and the stability of stents' coatings.

The most frequent failures before expansion are pits, scores, surface rubs, etc.

The expansion was done on mid-air and an vitro system. After expansion the coating strained mostly on the curves.

In vitro examinations are necessary; otherwise the result is not valuable. On the whole, all of the examined stents were met the requirements. The examinations of the expanding properties were genuine only at the mid-air studied stents.

References

[1] GYENES G.: 'A coronaria angiographia és angioplastica kézikönyve', Melania Kiadó, Budapest, 2001

[2] KUTRYK M. JB., SERRUYS P. W.: 'Coronary Stenting Current Perspectives – A Corporation to the Handbook of Coronary Stents', Martin Dunitz Ltd. 1999

[3] WIERSMA S.A., TAYLOR D.: 'A critical distance approach applied to microscopic 316L biomedical specimens under fatigue loading', Department of Mechanical and Manufacturing Engineering, Trinity College Dublin, Dublin

[4] KEAN-WAH LAU, KOON-HOU MAK, JUI-SUNG HUNG, SIGWART U.: 'Clinical impact of stent construction and design in percutaneous coronary intervention', Singapore

[5] Biocompatibles Ltd., Internet site address: http://www.biocompatibles.com

[6] BOGNÁR E., RING GY., DOBRÁNSZKY J.: 'Koszorúérsztentek anyagvizsgálata' Anyagvizsgálók Lapja, 14 (2004:4) p.127-132