FATIGUE TESTING OF CORONARY STENTS

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Abstract: Stents are net structure implants used to support the vessel wall in the balloon expanded vessel part. Their role is to prevent the restenosis. In this study materials and manufacture technologies of coronary stents used nowadays are introduced. High cycle fatigue tests of coronary stents are described. Two different equipments were used for testing. The first method simulates the making bending stress in the vessel wall. 4 coronary stents (Terumo Tsunami, Guidant Multi-Link Cobalt Chromium, Boston Scientific LP, AVE GFX) were examined with this method for different durations. The second method simulates the effect of the pulsating mechanical strain which is equivalent to the pulse in the coronary arteries. 3 coronary stents (Boston Scientific Express², Phytis Diamond Sidebranch, Orbus R Evolution) were examined with this method for different durations. Surface features and failures of the coronary stents after the fatigue tests were examined by scanning electron microscope and energy dispersive analysis.

Introduction

In civilized societies atherosclerotic diseases are the leading causes of death, and heart attack is very crucial. Calcification of coronary arteries first leads to stenosis then to heart attack. Messes are concerned by this disease, mainly if thrombus formation is also taken into account.

In these cases cardiologists approach the plaque and press it to the vessel wall by using a balloon catheter, and then remove the thrombus. In order that new thrombus does not be formed in the injured vessel wall or new plaque formation does not evolve a mesh structured vessel prothesis, a stent, is deployed to the coronary artery using by a balloon catheter. However, intima proliferatio can start and restenosis can be developed on the place of expansion. The stents prevent the restenosis, but this intima proliferatio can quiet frequently lead to in-stent restenosis when penetrating into the stents.

Materials and Methods

In the revolution of the stents different kinds of materials were tested in order to get better mechanical features and physiological effects. Such a material was searched which is resistant to mechanical and biochemical effects, works for a long time in the body and does not cause any damage when deploying the vessel.

Many stent performance features are directly linked to the material. Biocompatibility, X-ray and MRI visibility, radial force, recoil, flexibility, transportability, profile and long term integrity are all depending on the mechanical and physical features of the material.

Holding capacity and plasticity stand opposite as physical requirement of the materials. The aim is to apply materials where the same holding capacity can be reached by using the thinnest struts. At the same time plasticity of the material is also important to better position into the vessel wall.

Several materials were tested as vessel implants or coatings; however the stainless steel (316 L, 316 LVM) is the most frequently used material which is proved to be the most reliable, based in clinical trials. Nowadays, stent are also made of nickel-titanium alloys (nitinol) and cobalt-chromium alloys (L605, MP35N).

In case of bio- and haemocompatibility of 316 austenic steels clinical trials prove that the body accommodate them and there is no irritation leading to restenosis in the damaged vessel part.

Cobalt-chromium alloys have been used for a long time as a material of dental, orthopedic and cardiovascular implants. These are very dense which is advantageous to X-ray opacity, the huge elasticity modulus limits the recoil and the huge tension makes possible to design thinner stent struts. Therefore, smaller stents with better flexibility my be produced to be better deployed into the vessels. All these development became possible because cobalt-chromium alloys were used to produce new generation stents.

Nitinol is used for peripherial stents and not for coronary stents. Self-expanding stents are made of austenic nitinol and balloon-expanding stents are made of martensic nitinol.

Stent preproducts can be either tubes or wires. Produced by any techniques they are very precise and have very high price. The mesh structure is produced from a thin wall tube by laser cut. Stents made from wires are produced by weaving, sewing or reeling. Crossings are fixed by welding. Nowadays, stents are produced only by laser cut.

After precision laser cut there are burrs and sticking edges which have to be removed to reach better haemocompatibility and adhesion of coatings. These can be done by post finishing. Electro polishing is the typical procedure but it can be done by polishing and chemical processes as well. Coating is critical to the performance of the stents: coating process can be deep in, sprinkling or chemical vapour deposition.

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

To test fatigue features two test equipments were assembled. The first 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 aim of test done by bending machine is to simulate the bending stress in the coronary arteries. As seen in Figure 1 a 12-15 centimetre long plastic tube is attached to the equipment. One end of the tube is steadily fixed; the other end is connected to an excentric disc. Turning away of the disc results the bending of the plastic tube, and therefore stents placed in the tube are also bent. The movement of the tube simulates the movement of the coronary arteries in systolic phase (Figure 2).

Figure 1: The bending machine

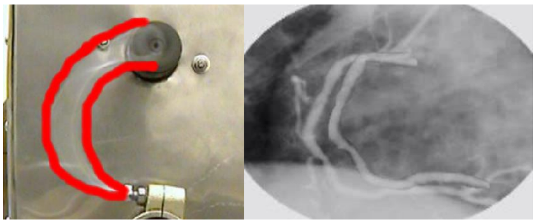

Figure 2: The similarity of the movement of the bending machine and the coronary arteries

Using by this equipment 4 coronary stents (Terumo Tsunami – 5 hours, 900000 cycles; Guidant Multi-Link Cobalt Chromium and Boston Scientific LP – 120 hours, 21,6 million cycles; AVE GFX – 1488 hours, 267,84 million cycles) were tested.

The vessel model simulates the effect of the pulsating mechanical strain. Stents are placed into a silicon tube under pressure of a minimum 160 centimetres water-column. This pressure is equal to the 120 Hgmm medial pressures in the coronary arteries. At the bottom of the water-column a membrane pump is connected to the tube, which provides a systolic-diastolic pulsation to the medial pressure at 50 Hz frequency (Figure 3).

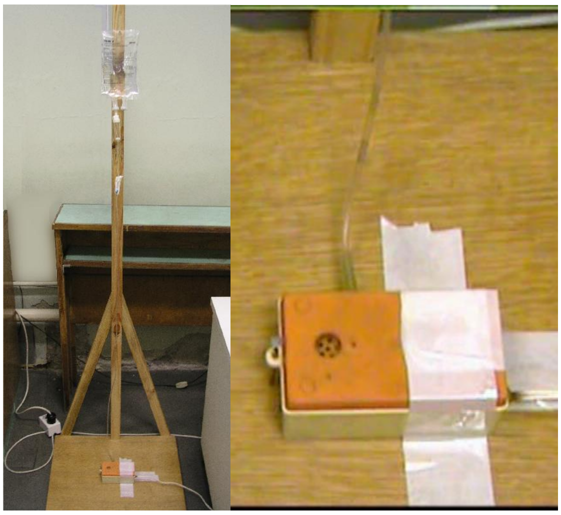

Figure 3: The vessel model

Using by this equipment 3 coronary stents (Boston Scientific Express[2] and Phytis Diamond Sidebranch – 120 hours, 21,6 million cycles; Orbus R Evolution – 1488 hours, 267,84 million cycles) were tested.

Having finished the tests, changes and traces of fatigue on the stents were examined.

Results and Discussion

After the fatigue test performed by the bending machine fatigue traces were detected by scanning electron microscope on the surface of the Terumo Tsunami stent. Grain boundaries were outlined and slip lines were observed on the surface. These processes were happened in the most active systems of metamorphosis.

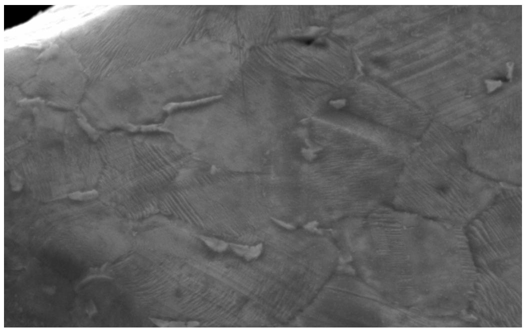

Figure 4: Scanning electron microscopic image of Terumo Tsunami stent's surface after the fatigue test at 1677 times magnifying

Grain boundaries could also be well observed (Figure 4). The reason could be that the stress was rather concentrated at grain boundaries compared to the inner part, and the grains were better deformed there. Smaller holes frequently occurred on the surface (Figure 5). These were inclusions in the material milled into the surface by electro polishing and managed to show by the fatigue test. Due to the big metamorphosis several parts of the stent surface became rough and pitted.

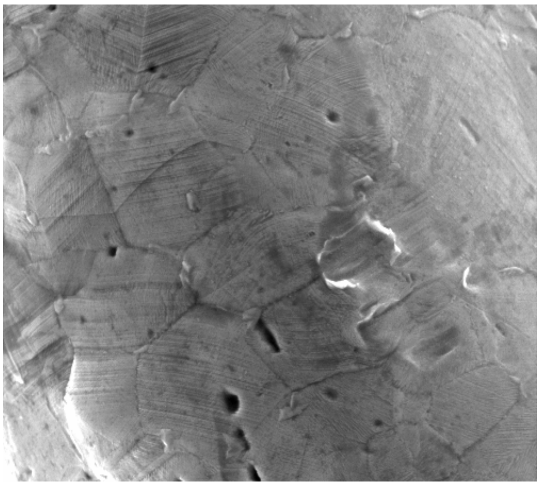

Figure 5: Small holes, slip lines and grain boundaries on the Terumo Tsunami stent's surface at 1000 times magnifying

Using scanning electron microscope after the fatigue test it was found that the Guidant Multi-Link Cobalt Chromium stent had much smaller metamorphosis then the Terumo Tsunami stent under shorter fatigue test. Metamorphosis and slip lines could also be seen on the surface of this stent, however, these were much smaller, because the cobalt-chromium alloy is of a higher flexibility, better tolerating the load, and therefore having smaller metamorphosis. Presence of slip lines and grain boundaries mainly occurred in the strut bends. These traces were more intense in the inner bend, so they could be proven to have had bigger use (Figures 6 and 7). Inclusions were also seen on the surface (Figure 8).

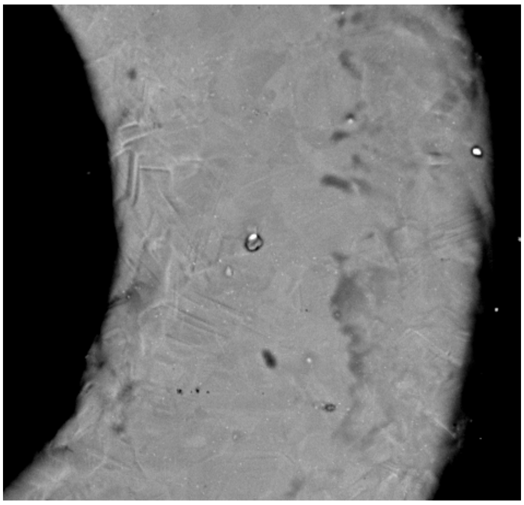

Figure 6: The Guidant Multi-Link Zeta Cobalt-Chromium stent's surface after fatigue test at 582 times magnifying

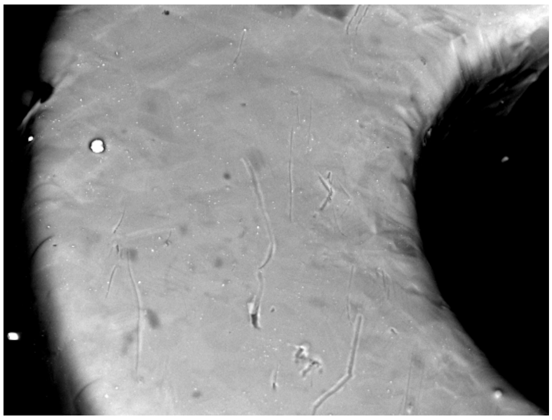

Figure 7: The Guidant Multi-Link Zeta Cobalt-Chromium stent's surface after fatigue test at 708 times magnifying

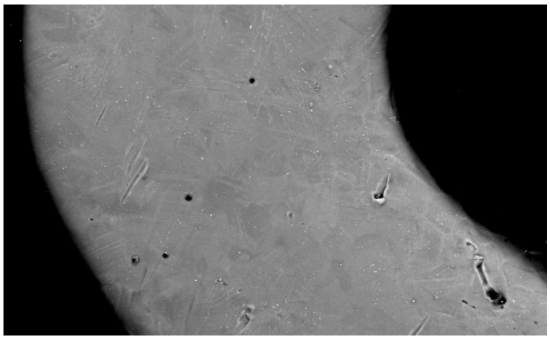

Figure 8: Inclusions on the Guidant Multi-Link Zeta Cobalt-Chromium stent's surface at 582 times magnifying

Some grains were observed on the surface. The stent was laser cut out of the tube which was probably rather produced by powder metallurgy process then by alloying. Material failures caused by the process were observed after the fatigue test (Figure 9). Investigated by energy dispersive analysis separated parts were detected to be wolfram grains.

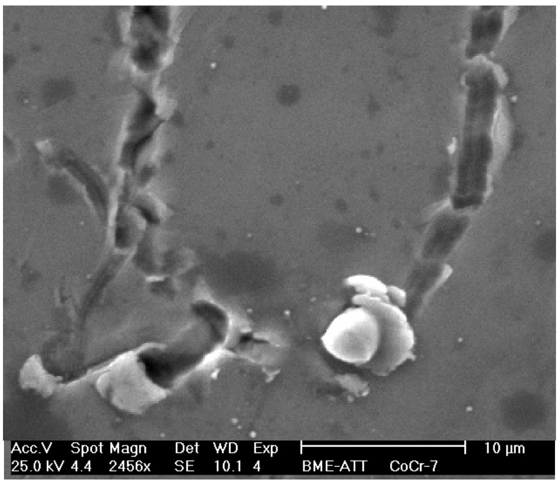

Figure 9: Separated wolfram grain on the Guidant Multi-Link Zeta Cobalt-Chromium stent's surface

Also due to the process failure some parts of the surface were split. Small balls of a diameter of 2-3 micrometre were also seen in turns on the surface (Figure 10). The tube preproduct was produced from the dust of this grain size. Material composition of it is the same as the composition of the intact parts of the stent.

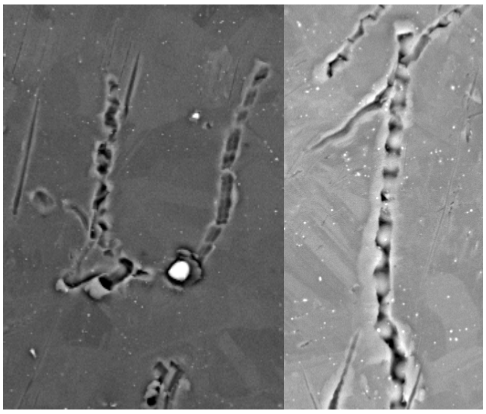

Figure 10: Small balls seen in turns on the surface of Guidant Multi-Link Zeta Cobalt-Chromium stent at 969 and 1417 times magnifying

Only some traces of fatigue were occurred on the Boston Scientific LP stent. Damages mainly caused during the production were seen on the surface. Fatigue features of the stent were quite good, the surface was rough and pitted only in the bends, on the side parts of the struts. These parts can hardly be done flat by post finishing, and fatigue stress can cause metamorphosis (Figure 11).

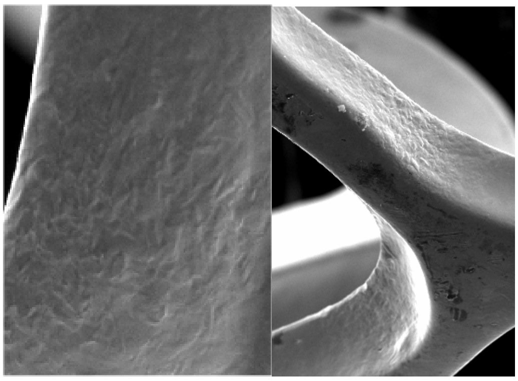

Figure 11: The fatigue stress caused metamorphosis on the Boston Scientific LP stent's surface

There were no important fatigue traces on the AVE GFX stent. Using by scanning electron microscope the same failures could be observed on the surface as is case of the other stents. Slip lines, grain boundaries were outlined and the surface became rough (Figures 12 and 13).

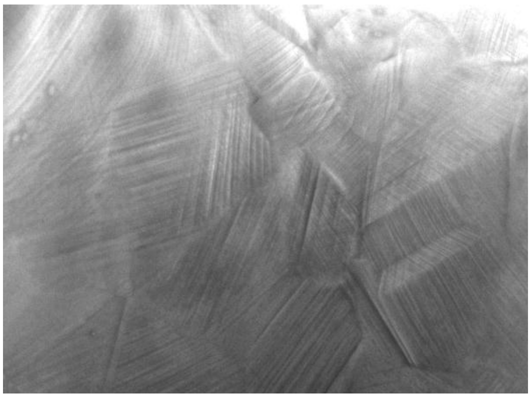

Figure 12: Slip lines and grain boundaries on the AVE GFX stent's surface after fatigue test at 1600 times magnifying

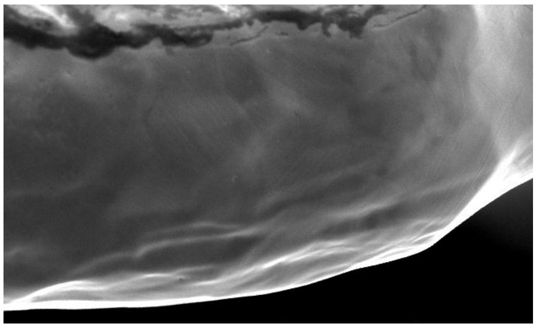

Figure 13: The rough surface of the AVE GFX stent after fatigue test at 600 times magnifying

Fatigue trace was not really observed on the surface of the Boston Scientific Express^2 stent after the fatigue test in the vessel model.

There was a small metamorphosis of the stent, slip lines and grain boundaries, but these were caused by expansion and not by the test (Figure 14). These were seen on the inner parts of the bends. The surface was smooth and intact, apart from small production failures (Figure 15).

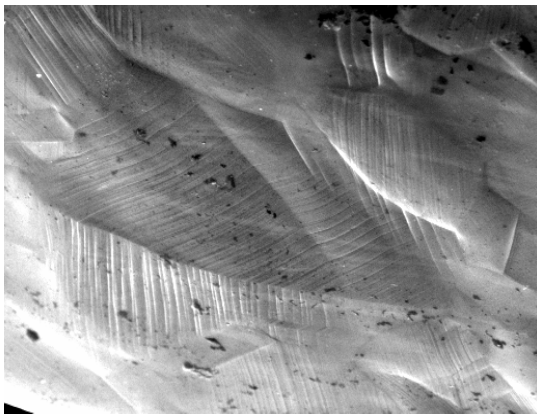

Figure 14: Slip lines and grain boundaries on the Boston Scientific Express^2 stent's surface after fatigue test at 860 times magnifying

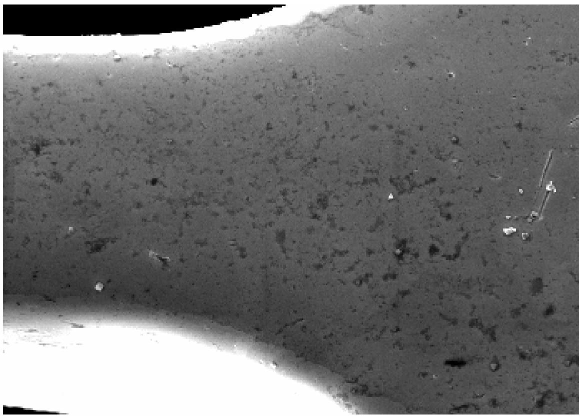

Figure 15: The smooth and intact part of Boston Scientific Express[2] stent's surface at 430 times magnifying

The Phytis Diamond Sidebranch is a coronary stent with diamond-like coating (DLC). After fatigue tested in the vessel model, examination performed by scanning electron microscope concentrated on the fatigue traces, and the changes and split of the layers of the coating.

After the fatigue test grain boundaries were outlined (Figure 16), slip lines occurred (Figure 17), but the coatings remained consistent.

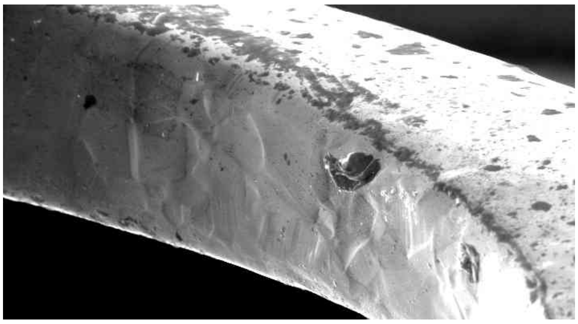

Figure 16: Grain boundaries on the Phytis Diamond Sidebranch stent's surface after fatigue test at 440 times magnifying

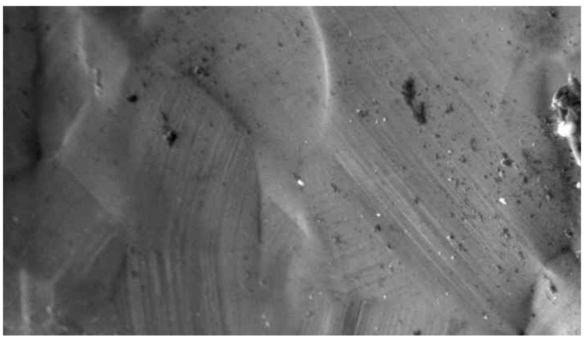

Figure 17: Slip lines on the Phytis Diamond Sidebranch stent's surface after fatigue test at 1622 times magnifying

After fatigue test there were no important traces of metamorphosis on the Orbus R Evolution stent either. Those ones seen by the scanning electron microscope were located on the side parts (Figure 18), but the surface of the inner and outer parts remained smooth and intact (Figure 19). It may be concluded that the metamorphosis not definitely caused by the pulsating mechanical strain.

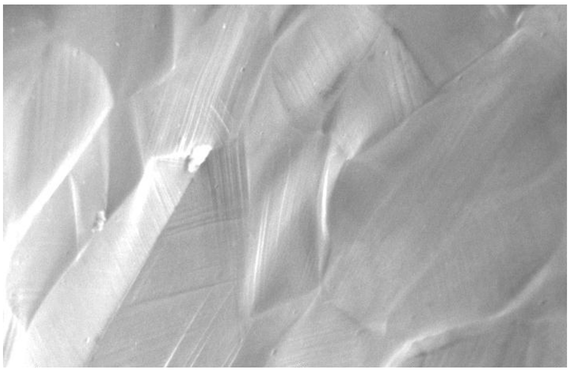

Figure 18: Slip lines and grain boundaries on the Orbus R Evolution stent's surface after fatigue test at 2400 times magnifying

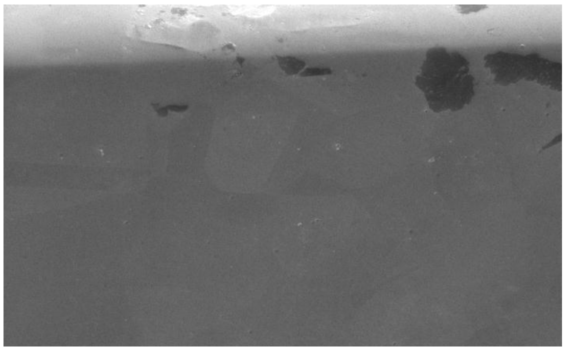

Figure 19: The smooth and intact part of Orbus R Evolution stent's surface at 1200 times magnifying

Conclusions

Four coronary stents were tested by the bending machine. Macroscopic damages were not originated on the stents, and the implants were not broken down. Only small traces of fatigue occurred on the surface, which became rough, slip lines and grain boundaries were outlined. The surface of the cobalt-chromium stent was partly split, and some grains (wolfram) were separated.

Three coronary stents (two uncoated and one coated) were tested by the vessel model. Uncoated stents had small metamorphosis, slip lines and grain boundaries were occurred, but most of them were rather caused by the expansion then definitely by the test. The surface remained smooth and intact. In case of the coated stent slip lines and grain boundaries could also be seen, but the coating remained consistent.

Having been examined by both tests (equal to more than 7 years of use) it was interesting to see that changes of the stents were not significantly different as if they have been tested in shorter period of time. It can be concluded that most parts of the metamorphosis were caused by the production, crimped to the balloon or during expansion of the stent.

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