

ANALYSIS OF EXPLANTED CORONARY STENTS

Eszter Bognár

Budapest University of Technology and Economics, Faculty of Mechanical Engineering, Department of Materials Science and Engineering, Bertalan Lajos u. 7, 1111, Budapest, HUNGARY. E-mail: eszter@eik.bme.hu

MTA-BME Research Group for Composite Science and Technology, Műegyetem rkp. 3, 1111, Budapest, HUNGARY.

1. Introduction

Cardiovascular diseases globally cause serious problems. There are only a few tools and methods are available for physicians to restore the blood flow in patients' vessels. One of these tools is the so-called stent. Stent deployment became a routine in interventional cardiology to reduce the mortality and the effects of the disease.

Stent is a tubular, biocompatible implant for the dilatation of the narrowed vessel with the possible lowest vessel-stent contact surface. The manufacturers can achieve low contact surface with the meshing of the implant's wall.

Stent has numerous advantages against the traditional surgery; this is why stenting is wide spread applied nowadays. Stent development and analysis is critical to push forward the effectiveness of this technique. One possible way to obtain experience is that examining the explanted stent and their possible failures.

In this paper the author reveal a method to examine stent failures. This information can be useful in stent development.

2. Literature

There are only a few studies deals with the failures of the stents. From the aspect of long-life stent enhancement the implantation circumstances are very important influencing factors. Grewe et al. examined the effects of intravital and post-mortem stenting on coronary morphology in human hearts. The study was performed to correlate the histomorphologic changes of the vessel wall after coronary stenting with stent expansion pressure. They determined that postmortem stent implantation could serve as an adequate model to study the mechanical effects of coronary stenting. Their investigations showed that the plaque depending upon its location and content can hinder the stent's even expansion. They concluded that stent symmetry was not influenced by the applied

implantation pressure [1]. Nakazawa et al. analyzed 177 stent fractures with the help of high-contrast film-based radiographs. As a main result of their analysis, the stent fractures were classified into five different groups. The I. group contains the fracture of one strut; the II. group contains fractures of two or more struts, but without deformation; the III. group contains fractures of two or more struts with deformation; the IV. group contains multiple strut fractures with acquired transection without gap; finally the V. group contains multiple strut fractures with acquired transection with gap [2]. Chung et al. investigated stent strut fractures. They defined strut fractures as the angiographically visible strut intermission or the less visible struts on intravascular ultrasound (IVUS). The classification of the fractures of their model contains three groups: disruption, avulsion and displacement [3]. For the detection of stent under-expansion intravascular ultrasound (IVUS) is the most commonly applied method [4]. In his study, Ring quantifies the visibility of the stent by separating the stent from the background. His method is calculating a real visibility index by dividing the integral area of the grey scale including the stent by the integral area of the grey scale excluding the stent. This measure quantifies the visibility of the stent [5].

3. Materials and methods

Categorization of failures has to be composed also more detail in which the main aspect is the problem's seriousness and the character of the damage.

3.1 Non-destructive analysis

- To find the failures of the specimen with optical microscopic examinations (stereo- and reflected light microscopes). It contains the complex analysis of the fractured section, investigations for the causes of the fractures.

- Identify inner material failures by X-ray microscopic investigations (Fig. 1).

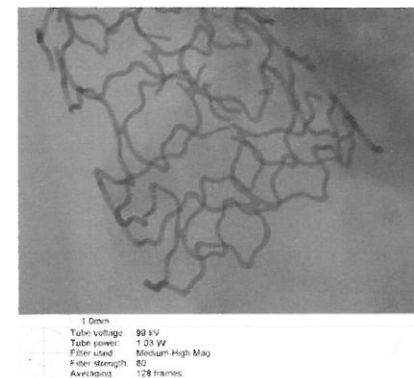


Fig. 1 Explanted coronary stent in a vessel.

- Smaller sized failures and the material contents' documentation by Scanning Electron Microscope (SEM) and EDS analysis (Fig. 2).

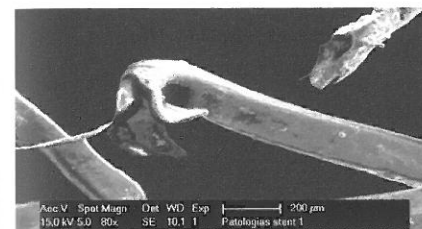


Fig. 2 Fractured strut of an explanted stent.

- Surface roughness determination with Atomic Force Microscope and Confocal Microscope.

These investigations can be carried out consecutively since do not cause damage the samples and afterwards all analyzed samples can also be used for destructive analysis.

3.2 Destructive analysis

- Drug elution analysis in case of drug-eluting stents to measure the remained active substance's elution.

- If the stent has coating, analysis of the remained coating's adhesion and its thickness.

- Preparation of metallographic cross-section: strut cross-section, grain size, hardness measurements (Fig. 3).

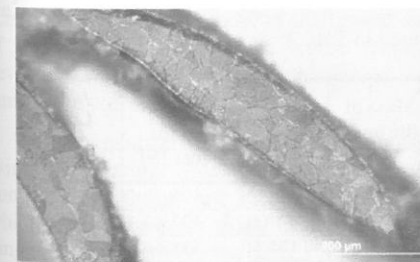


Fig. 3 Grains of an explanted stent.

- Measurement of radial force for the determination of the resistivity for the radial strain for unit length. By this method stent as a device, which is determined by its strength, raw material, geometry and manufacturing technology, can be well characterized.

4. Remarks

- It is important to explant the stents together with the vessel part to avoid from any damages.
- Using this method, the plaques and the deformation of the stent can be analyzed as well. On the basis of the investigations it is clearly visible if the stent has coating or not.
- The type of stent fracture can be determined with confidence.

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