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NEW EXPERIMENTAL METHOD TO MEASURE THE METALLIC SURFACE AREA OF CORONARY STENTS

Abstract: Endovascular stents, such as coronary stents are widely used for the treatment of narrowed or blocked blood vessels. We developed a new experimental method to measure the metallic surface area (MSA) of stents. Our aim was to compare this method with the previously used. According to the results we could make a suggestion to use the new automatic method, because this gives the most and accurate information in the shortest time. The collected experience and results of this study can help physicians to choose an appropriate stent.

1. Introduction

The most common reason of death is the diseases of the cardiovascular system worldwide, amongst which the most significant is coronary artery disease. These numbers are still increasing, so preventing this disease is a high priority in public health policy. Stent implantation is the primary method of angioplasty to treat atherosclerosis. Cardiovascular stents are small expandable tubes that are inserted into the blood vessels to restore blood flow and prevent localised constriction [1,2]. The following explanatory 3D models show the dilating process (Fig. 1).

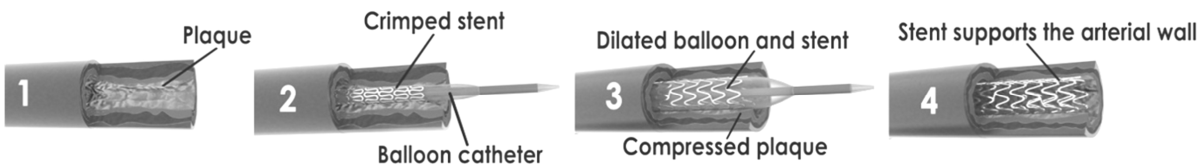

Fig. 1. The stent is mounted on a balloon and delivered to the constriction by a catheter system. When the balloon is inflated, pressure expands the stent. After the deflation of the balloon and the removal of the whole catheter system, the expanded stent holds the blood vessel open and compresses the plaque blockage to help restore normal blood flow

The re-narrowing of the previously expanded blood vessels is maybe the major complication associated with endovascular stent implantation. Amongst others restenosis is supposed to be caused by the inadequate metallic surface area (MSA) of stents. The metal to artery ratio is given as a percentage, of the stent's cylindrical surface to the covered surface of the blood vessel. For technical reasons a ratio too high is not recommended, because the contact area with the blood vessel wall is too large thus the risk of thrombus formation and restenosis increase. On the other hand, a ratio too small can lead to mechanical problems [3,4].

With the stent pattern, the largest and the smallest cell area and the maximum achievable cell diameter in them can be easily determined by an image analysis program. This feature is useful when the stent need to be placed into a side branch of a vessel and the physician has to get through one of the stent cells with another stent or a balloon catheter [5].

Most studies related to stent surface focus on stent coatings. They are looking for a stent material and coating material that meets mechanical requirements and generates an optimal biological response in the body. So knowing the exact size and geometry of the stent surface is very important. Furthermore, in the case of drug-eluting stents the stent pattern can also affect uniform dissolution [6,7].

2. Materials and methods

During our work four L605 CoCr coronary stents were investigated (Fig. 2). (A) stent (3.0×8 mm) and (B) stent (3.0×12 mm) have the same geometry, but different size. (C1) stent (3.0×12 mm) and (C2) stent (3.0×12 mm) have the same geometry and the same size too. The stents were expanded at nominal pressure.

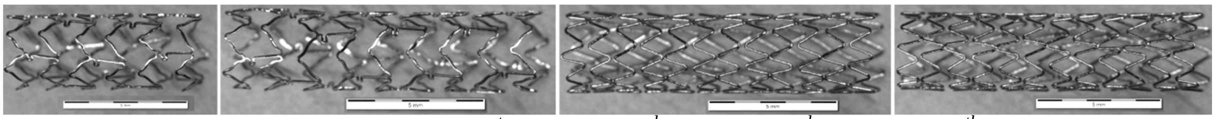

Fig. 2. The investigated stents: 1st (A) stent, 2nd (B) stent, 3rd (C1) stent, 4th (C2) stent

The aim of our work was to compare two different measurement methods to determine the MSA. Both of the methods were developed by us. The methods' efficiency was compared. Both methods aimed at converting the cylindrical stent into a flattened two dimensional image in order to analyse the stent pattern with imaging software. The MSA measurement methods correspond to the MSZ EN ISO 25539-2 standard [8].

2.1 The manual method

The first method was performed manually. High-resolution digital images were taken of each segment of the stents' mantle. The stent was fitted to a precision rotary unit and the pictures were taken with a stereomicroscope. The stent was rotated by increments of 15° from the starting 0° position to 360° then the 24 pictures were joined to each other.

2.2 The automatic method

The second method was done in an automated manner by a new configuration. The stents were pulled up to a shaft which is connected with a motor so the stents were rotating during the scanning process. In this case we get one whole picture of the stent pattern. The rotational speed and direction can be changed using the control panel buttons. Pictures were taken at a resolution of 4800 DPI. The Canon CanoScan LiDE 700F scanner, that we used, has a 9600 DPI resolution, so the images have far better quality than required.

3. Results

Our findings showed that the first and the second methods gave similar results (Fig. 3). The locations of the largest and smallest cells are the same with the manual and the automatic method, except in the case of (C1) stent, where the location of the largest cell was different. Since the difference between the largest and the second largest cell was negligibly small, the error might be due to inappropriate joining of images.

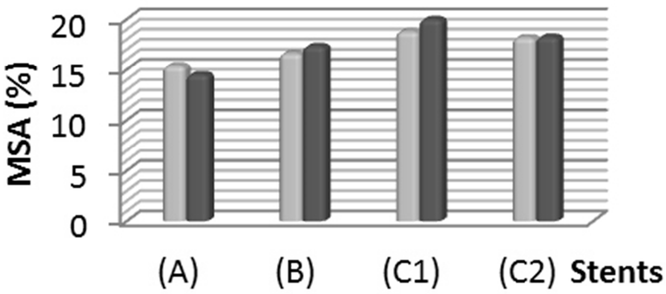

Fig. 3. MSA values are similar with the two methods.

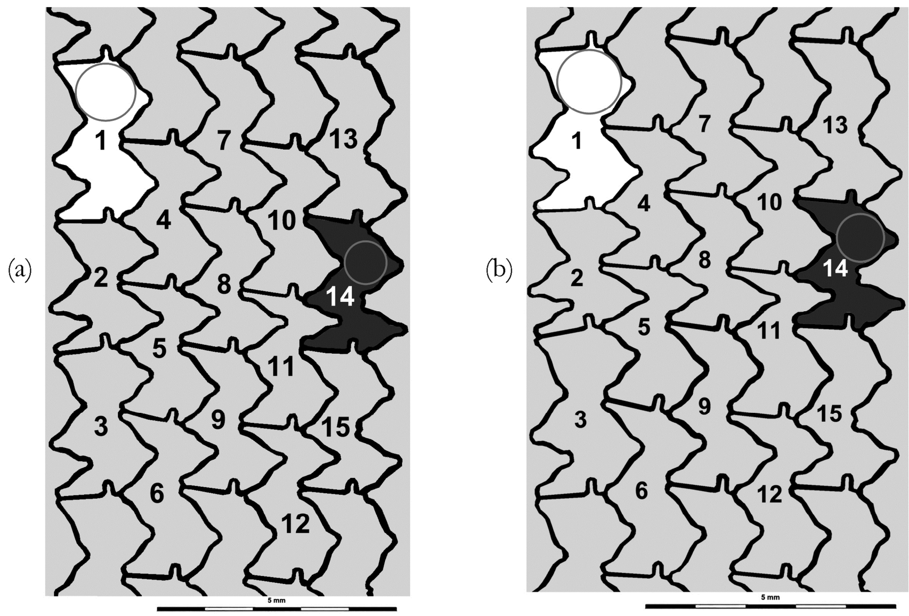

Fig. 4. The evaluated stent pattern of (A) stent (a) with the manual method (b) with the automatic method. The largest cells are white, the smallest cells are black, and the circles with the maximum achievable diameter are dark grey

Fig. 4 shows the evaluated stent pattern of 3.0×8 mm (A) stent. The largest differences between the methods were speed and accuracy. The automatic method needs less time (the difference is in hours), because the pictures did not need to be joined together. This is an important factor, especially, when the stent is too long to fit into the microscopic field. In that case separate images are taken of both ends of the stent, and then 48 images have to be joined up to create one big image. Resulting errors are multiplied during image editing, and time needed also increases.

In addition, Fig. 5 clearly shows that the metal struts reflect the light in the microscope pictures. Bright and dark parts seem to have different strut widths which need to be corrected during evaluation. This both takes more time and causes inaccuracy. In contrast, reflective glare is eliminated in the images taken by scanner.

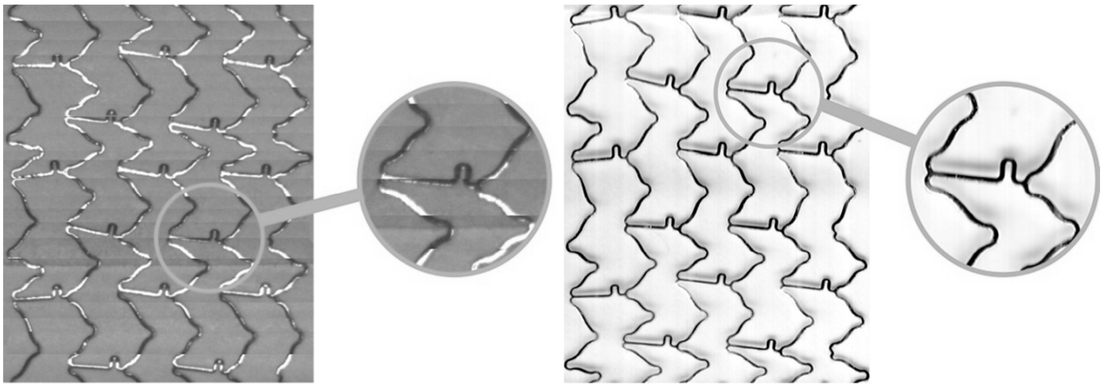

Fig. 5. Stent pattern (left) manual, (right) new automatic method. The automatic method gives a more accurate picture of the stent pattern

Metallic surface area, the largest and the smallest cell sizes, and the maximum achievable cell diameter are stent properties which are important for the long-term effectiveness of the stent after implantation. We used two methods to measure MSA values. These results favour the new automatic method, which on the basis of this study seems to give the most accuracy in the shortest time. The collected experience and results of this study provide a basis for further research.

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