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# X-ray examination of integrated stent markers

P. Nagy

*Budapest University of Technology and Economics, Faculty of Mechanical Engineering, Department of Materials Science and Engineering, 1111 Budapest, Bertalan Lajos utca 7, Hungary*

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**Abstract**

To treat coronary stenosis, balloon expandable stents can be used. To maximize X-ray absorption, the stent is issued with a marker which enhances its recognition while using X-ray and assists to better positioning of the stent in the required vessel segment.

Objectives: The aim of this research was to improve the cardiovascular stents' X-ray visibility using a unique marker placed in the stent strut.

Materials and Methods: For the experiments, austenitic stainless steel tubes with 1.81 mm outside diameter and tantalum powder with grain size 3–10 μm diameter (98% purity) were used. On the X-ray microscopic images, the area outlined by markers was manually separated. A calibration diagram was used to describe the relation between the pixels' level of grayness on the images and their material thickness.

Results: A new type of manufacturing technology was worked out to integrate markers into stent struts. $2.4 \times 10^{-5}$ mm$^3$ volume of tantalum powder used as a marker, integrated into the stent strut increased its local X-ray visibility by 0.44% with 0.03 coefficient of variation (visibility was greater when seen with naked eyes).

Conclusion: Using laser micro-manufactured markers integrated in the stent struts, the stent's X-ray visibility can be increased. By examining the X-ray microscopic images, a calibration diagram describing the relation between the individual pixels' level of grayness and their material thickness can be concluded. The volume of the individual markers can be determined using this diagram that describes the marker area separated on the images and the material thickness.


## 1. Introduction

One of the methods to treat coronary stenosis is to use balloon expandable stents. There are many stents and stent manufacturing companies around the world [1]. There are various types of stents produced depending on their metallic base-materials, coatings and geometries. In Europe, currently, the most commonly used stent materials are the austenitic stainless steel, cobalt chromium and platinum chromium alloys [2, 3]. These days, it is becoming more popular to use markers integrated into stent struts to which assists physicians during the implantation procedure. These markers improve the X-ray visibility and the precision of implantation [4,5].

*E-mail address:* npeter@eik.bme.hu.

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### *1.1. Markers*

One of the methods to position markers is to use cold-forming technology. In a patent, it was shown that markers could be suitably fixed into the stent's proximal and distal rings by extruding cladding. The advantage of this was that it did not limit the stent during expansion. Its shapes may vary from ring to disc and its material may be gold or platinum [6]. Disc shaped markers were placed in an irregular reservoir formed on the stent strut. The edges of the reservoirs' inner sides provided the markers with secured positioning and fixture was executed by extrusion [7]. A research group created markers from strips made of tantalum. These strips were fixed on the stents' proximal and distal rings. The markers were formed parallel to the struts and were fixed by riveting or welding [8]. In another patent, a stent marker was placed in the tube wall (parallel to the tube's centerline), prior to cutting the stent using laser. The reservoir in the tube wall was created by laser micro-machining or by a miller and then, platinum, gold, tantalum, niobium or barium sulfate powder was placed inside and used as a marker. This process may also be used for stents made of stainless steel, nickel titanium, polymer or other bio-compatible materials. After implanting the marker, the reservoir was closed by laser beam welding [9]. Laser beam welding could be used to fix tantalum, gold and platinum markers into nickel titanium stents and these were placed in the reservoirs formed in the stent strut. It was determined that both the gold and platinum markers' X-ray absorption was excellent; however, it damaged the base material's anti-corrosive features [10].

There is another production technology for metal–matrix composite stent. The tube material of the stent is produced by powder-scattering technology, which consists of powder scattering units such as laser source, matrix, marker and in some cases, even a booster material. The metal–matrix composite tube is created in a cylindrical substrate, which at the end of the process is removed through chemical etching, heating or other mechanical ways. Then, the stent is formed from the tube by laser cutting. With this method, stents with increased X-ray absorption component can be produced. The component material used as a marker can be tantalum, niobium, gold, tungsten, hafnium, palladium or rhenium [11].

### 1.2. X-ray analysis

For those stents that are implanted, it is very important to be able to continuously monitor the position. Good X-ray visibility of the stent is a great help not only in a narrow vessel section but also to determine the stent's relative position [12–14]. The ASTM F640 (2012) regulation contains the criteria regarding medical implants' X-ray visibility and how the implant must be separated from the background on the X-ray images.

The EN 14299 regulation also says that the implant must be visible on the accepted medical imaging systems; however, this regulation was withdrawn in 2004. Currently, the ISO 25539-2:2013 regulation is in place which contains the previously mentioned regulation's main components, but it does not have further clarification on X-ray visibility [15–17]. A research group examined the images made by X-ray equipment used in clinical practice. They presented a uniquely designed digital imaging algorithm, which was used to evaluate the images of the guide wires and the markers on them. The algorithm calculated from the markers' segments on the guide wire completed the less visible parts of the catheter. The total time of the image quality repair process was only $16.6 \pm 3$ s. The algorithm is being further improved to follow the movement of stents and markers which, in the future, can assist doctors to perform the procedure. However, this method does not give numerical data regarding the X-ray's visibility [18].

Another group summarized the main features of the commercially available stents. The authors reviewed and ranked the combined stent and marker's X-ray visibility and created difficult, moderate and clearly visible groups. They did not provide any numerical data in relation to the stent's visibility [19]. Potential marker materials were chosen for nickel titanium stents. The research group correlated the applied marker material's X-ray visibility to nickel titanium reference discs. They did not backup the markers' and stents' X-ray visibility with any numerical values [10].

Computed tomography and magnetic resonance images taken from different positions of nickel titanium stents equipped with platinum markers were examined. It was concluded that both procedures could be used to examine nickel titanium stents using X-ray, however, the authors did not give numerical evaluation regarding the stent's X-ray visibility [20]. The X-ray visibility of nickel titanium and nickel titanium platinum stents was compared. It was seen that platinum improved the nickel titanium stent's X-ray visibility. It was demonstrated that the platinum alloy stent was more visible on the image, but numerical values were not provided [21]. A researcher examined the stents' X-ray visibility and worked out its objective factors. He took images of the stent and its background with an X-ray microscope using 100 kV beam voltage and 1 W cathode heating settings. He defined the so-called visibility windows, its visibility functions and from this, he created the relative visibility index ($XRV_{REL}$). The $XRV_{REL}$ parameter depicted how big the visibility window containing the stent's visibility function integral was compared to the background's visibility function integral [22].

The aim of this work was to increase the X-ray visibility of stents using unique tantalum marker placed in the stent strut. The highlight of this work was that, in addition to the visibility increasing, the marker was integrated (laser micro-welded) into the stent strut. This increase was verified by quantification of the visibility.

## 2. Materials and methods

In this study, Lasag KLS246 and Trumpf TruPulse103 impulse Nd:YAG laser equipment were used. Fig. 1 shows the production process of stents with markers integrated in the stent strut.

### 2.1. Laser ablation

The markers were placed in the stent struts of Sanocor Coronary stents [23]. The reservoirs were created by laser ablation and were suitable for storing. Reservoirs were produced on the distal and proximal ends of five stents. As similar method is followed in clinical practice too, this distribution was used the study.

On the stainless steel tube's pre-production surface, 1 mm long, 30–35 μm wide and 40–45 μm deep reservoirs were created. The optimal parameters of laser ablation were defined experimentally. On the laser equipment, the accelerator voltage, impulse time, impulse repetition frequency, the centerline movement's speed and acceleration and the gas pressure used for ablation were changed. The reservoirs were made (using a 20 μm diameter laser beam) suitable for storing markers with 365 V acceleration voltage (photoflash lamp), 0.02 ms impulse time, 2000 Hz impulse repetition frequency, 5 mm/s speed and a 10 bar ($O_2$) gas pressure (Fig. 2).