# Novel Stent Optical Inspection System

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**Abstract:** Stent quality control is a critical process. Coronary stents have to be inspected 100% so no defective stent is implanted into a human body. Skilled operators currently perform the quality process control visually, and every stent could need tens of minutes to be inspected. In this paper, a novel stent optical inspection system is presented. By the combination of a high numerical aperture microscope, a triple illumination optical system, a rotational stage, and a line-scan camera, unrolled sections of the outer and inner surfaces of the stent are obtained with high resolution at high speed. We expect with this new approach to make the stent inspection task more objective and to dramatically reduce the time and the overall cost of the stent quality control process.
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## 1. Introduction

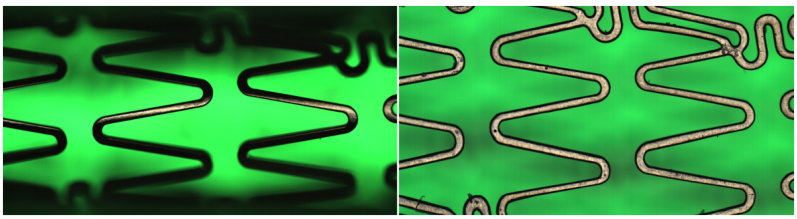
In recent times, stent manufacturing has grown exponentially. Stents are miniature hollow cylinders that are implanted into the human body in order to remove a stenotic lesion or to facilitate access for surgery. They are manufactured from raw tubes, which are laser-cut. Some of the most important processes during the manufacturing of a stent are dimensional control and visual inspection. Defects and shape deviations from the nominal design are affecting its performance, lifetime, and even cause a hazard to the patient. Stent quality assurance processes are tremendously strict. Inspection of a stent is today an extremely labor-intensive, time-consuming and expensive process, executed visually by skilled operators equipped with optical microscopes. Human errors can eventually yield samples out of specifications, and increase the stent rejection, which ends with higher manufacturing costs.

Few automated inspection systems (with contact and non-contact techniques) have been proposed in the recent years to provide objectivity, repeatability and speed to the inspection process. One of the first developments is based on a stent inserted onto a mandrel, which is rotating, illuminated with a backlight and imaged with a line-scan camera [1]. Another approach to avoid some of the limitations of the mandrel is the use of two rollers with dual illumination [2]. However, those systems are using telecentric optics to form the image of the surface of the stent, using low numerical aperture, and thus recovering images with low resolution. Another disadvantage is that they don't measure the inner surface of the stent [3].

In this paper a new optical, high-resolution inspection system is presented. Our approach uses a high numerical aperture imaging optics, a triple-light illumination arrangement (back, front and side), and a high-precision rotational stage aimed to obtain unrolled images of all stent surfaces [4]. We provide well-focused and high contrast images of the outer, inner and side surfaces with up to 1µm lateral resolution. The obtained images are used for measuring strut dimensions, roundness quality of the edges after polishing stage, and also for detection and classification of defects.

## 2. Experimental setup

In order to perform accurate stent dimensional metrology it is essential to acquire well focused and high contrast images. Our approach to acquire such images is based in three steps: a microscope arrangement with the use of low magnification optics, a triple illumination system, and a rotational stage. In a bright field microscope, the image of stent-like samples decreases in light gathering and focus for those regions far from the apex (Figure 1a). With the use of a line scan camera and a rotational stage, the final image is composed only from the regions of the apex of the stent (Figure 1b).



a b

**Figure 1** Images taken with a 5X 0.15NA lens. (a) Bright Field image, (b) part of a line-scan acquired section.

Figure 2 shows the optical and mechanical arrangement of our approach. A white light LED illuminates the field diaphragm of a microscope and is imaged onto the pupil of a microscope objective in a Köhler type illumination scheme. The light reflected from the stent surface is going back to the objective, which is forming an image onto an area scan camera. A couple of additional light sources are located at one side and under the roller stage to provide diffuse back and side illumination. The resulting image can be seen in Figure 1a. We used microscope objective magnifications ranging from 2.5X to 20X with numerical apertures from 0.075 to 0.45. This provides the possibility to acquire images with a very large field of view while keeping an optical resolution below 1 µm.

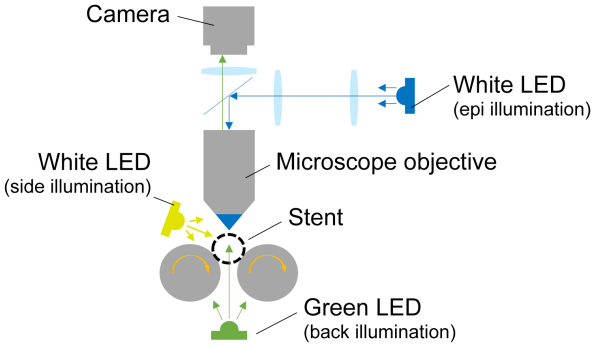
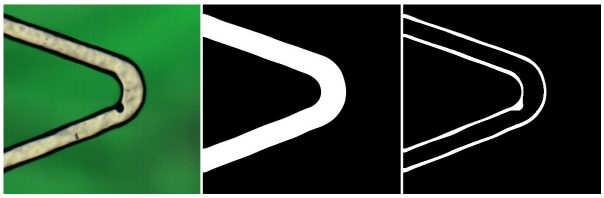



**Figure 2** Triple lighting system arrangement

The camera used in this study is capable to provide us with an area scan (2 million pixel) or single line at much higher frequency. Unrolled images as shown in Figure 1b are obtained with the line scan mode of the camera and a roller stage. The roller stage is a two-roller arrangement consisting of two stainless steel nuclei rollers enclosed with a white polyoxymethylene (POM) 2mm thick cover to provide enough stiffness and a smooth surface (Ra < 0,8µm). Light reflections are avoided thanks to the elevated diffusion capacity of the plastic. Roller diameter and distance between them is optimized to maintain enough back light aperture while providing the possibility to focus a shorter working distances objectives, such as a 20X 0.45NA with a working distance of 4.5mm, and at the same time able to focus in the inner surface of stents ranging from 1.5mm to 15mm in outer diameter (OD).

## 3. Critical dimensions

The most common dimensional analyses in stent inspection are strut width and edge roundness .We used segmentation algorithms to isolate stent struts from the background. We obtained binary masks from strut outer geometry of figure 3a, and edges with the use of morphological operations (Figure 3b and c). From the original image and said binary masks, critical dimension analysis, defect detection and classification and further metrology investigation can be performed.



a b c

**Figure 3** Stent with a crack defect, (a) unrolled image, (b) inverted surface mask, (c) edge mask.

We also analyzed the main difference when measuring critical dimensions with a bright field microscope in comparison to our unrolled images. Conventional microscope images measure the projected surface width, while unrolled images measure the arc section of the strut. The result is a larger measurement, which fits exactly to the nominal design, but not to what the inspection operators are used to measure. A correction method is proposed with the use of the geometrical information of the stent.

## 4. Calibration

Critical dimension measurement accuracy is achieved through a calibration process of the complete setup.

1. To ensure the proper focusing of the microscope objective onto the surface, the geometry and position of the rollers with respect to the sensor head has to be calibrated.
2. Real optical magnification of the microscope's objective. A magnification calibration specimen for microscopes was used for the X direction. The unrolled direction magnification is dependent on the acquisition framerate and the rotational speed. We developed a custom calibration specimen to calibrate the rotational speed at a given, fixed framerate. The specimen consists of a chromium coated rod lens and laser-engraved Ronchi grating parallel to the radial direction, with 50μm pitch.
3. To obtain images with different objectives, parfocal and parcentric misalignment between them have to be adjusted. Additionally, every objective could have different light efficiency due to different numerical apertures. A light factor between them needs is calibrated to take this effect into account.
4. Aliasing may appear owing to the coupling of framerate and illumination PWM frequency. Integration time of the frames of the camera is adjusted to minimize this effect.

## 5. Error sources

In order to accomplish the required image quality, the roller stage components require strict tolerance manufacturing. Few deviations of these parts are translated into focus errors, wrong magnification images, or even wrong positioning of the stent under the microscope. We have detected two types of errors that impose critical manufacturing tolerances: axis skewness and roller eccentricity.

### *6.1. Axis skewness*

When assembling the roller stage, the center-to-center line between the two rollers has to be perpendicular to the optical axis, and to the Z translation stage. If a skewness error is present between these two axes, different stents of different diameters will not focus onto its apex, but at a slightly lateral shift. To minimize this effect, the maximum angular error is the one that shifts the apex between the smallest and largest stent diameter that the system can measure by 1 pixel of a 5X objective. This skewness angular error is about 0.5 arc-minutes, and it can come from two sources: lack of perpendicularity between the vertical scanning stage and the rotational stage, and skewness due to different roller diameter. To characterize the skewness error we used a set of different glass rods with varying diameters from 2mm to 10 mm. For each rod, the height of the Z stage and the lateral shift of the apex are recorded. This characterization opens the possibility to shift the Y stage when loading a new stent into its correct position.

### *6.1. Roller eccentricity*

Each roller could have form deviations from the nominal cylindrical shape, and its rotational axis to be not totally parallel. During roller revolution, these deviations mean that the rollers locally separate or approach each other, making the stent to move up and down. The maximum eccentricity error allowed is the one that keeps the stent within the depth of field of the objective. For a 5X 0.15NA objective, this means to have a maximum eccentricity error of 10 micrometers.

## 7. References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