SENSOFAR MEDICAL

Qvix

APPLICATION NOTE

Stent wall thickness measurement

Stents must be extremely well manufactured and free of critical defects. Inspection of such devices, leading to their acceptance or rejection, is a critical step in the overall manufacturing process. One of the most tricky inspection tasks is the wall thickness measurement. Such thickness is a critical dimension that has to fit into a tight tolerance for an acceptable stent that will be implanted into a human body.

There are two methods that have been used so far to measure the wall thickness of the stents. The most widely used method consists of imaging the sidewall with a low magnification microscope. Ideally, the sidewalls must be placed perpendicularly to the optical axis so that the entire wall thickness can be displayed within the field of view. However, this technique has two drawbacks. The main one is that it is difficult to determine precisely where are located the limits of the sidewalls of a polished stent, because they correspond to the rounded edges of the struts. The second disadvantage is that, because of the cylindrical shape of the stents, there are many positions in which the upper struts hide the sidewalls that should be measured.

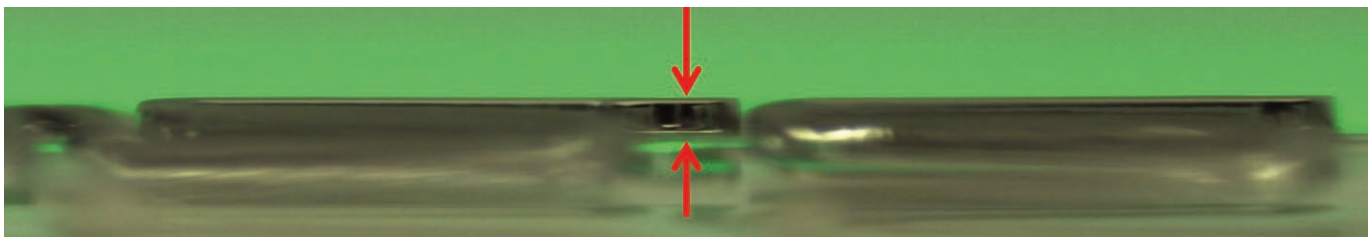

Figure 1. Standard optical method used so far to measure the wall thickness of a stent.

The second method consists of inserting the stent in a mandrel that fits to its inner surface. Then a sensor is used to measure the wall thickness as the height difference between the surface of the mandrel and the outer surface of a contiguous strut. Such sensor may be either a contact tip or a single-point optical probe. This second method has also two drawbacks. The main one is the gap that may arise between the mandrel and the inner surface of the stent due to a bad fitting of the mandrel size or a local bending of the strut whose wall thickness is being measured. This effect always leads to an overestimation of the wall thickness. The second disadvantage of this method is that it is very slow since the measurements are point-to-point and, as a result, only very few positions can be measured within a reasonable inspection time slot.

Sensofar Medical has developed a new optical technique for the measurement of wall thickness of stents based on the acquisition and analysis of unrolled images of the sidewalls. These images are obtained by focusing the optical head at a laterally displaced position in which it is possible to image a certain amount of the cross section of the sidewalls, as it is shown in Fig. 2. The illumination system is a proprietary setup that combines back and side light sources. We have also developed a new geometrical model that takes into account the effect of the rounded edges of the polished struts on the wall thickness measurement.

This new method makes it possible to obtain wall thickness results along continuous regions of the sidewalls acquired in the unrolled images. In addition, it is not necessary to use a mandrel for acquiring the unrolled images, but even if a mandrel were used, the wall thickness results would be insensitive to the existence of gaps between the mandrel and the inner surface of the stent. The new method has been tested with different models of stents currently available in the market.

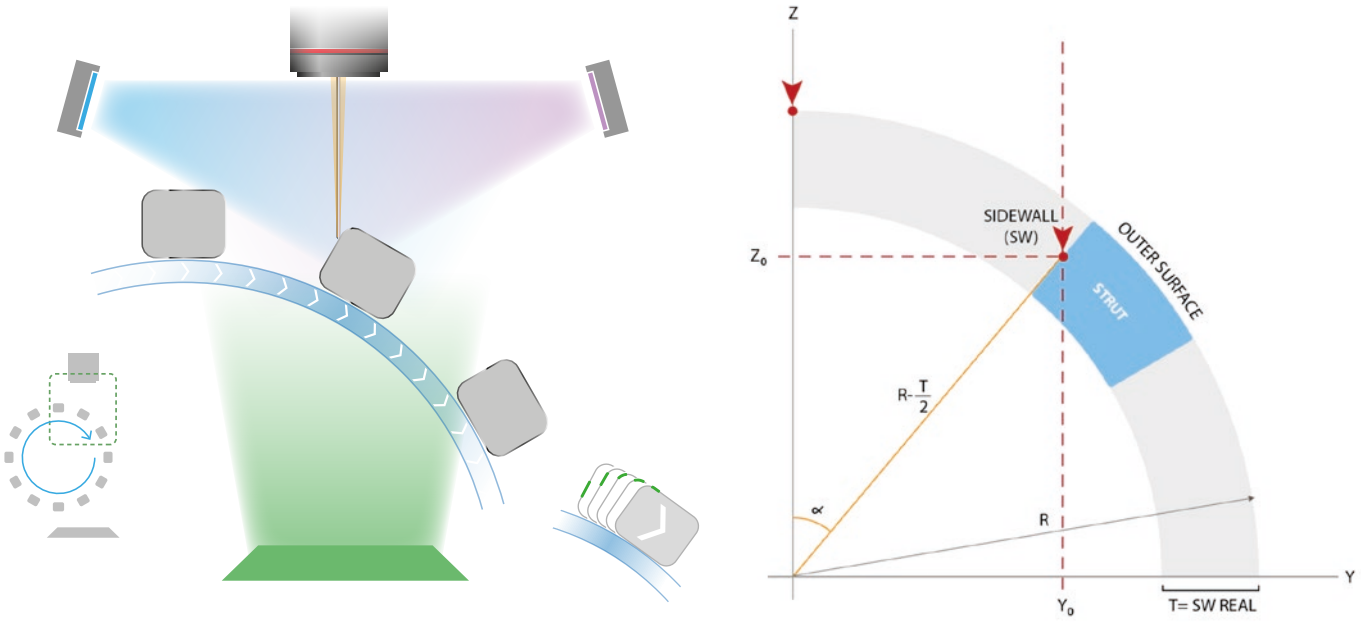

Figure 2. Diagram of the new optical technique for the acquisition of the unrolled sidewall images, showing the measurement position and the illumination setup

Measuring wall thickness and edge radius using Sensofar Medical Q vix system

The unrolled image of the sidewalls is acquired by focusing the optical head of the Q vix on a fixed measurement point in which the radius of the stent forms an angle α with the vertical axis z and at the midpoint of the sidewall, as shown in Figure 2.

The unrolled image of the sidewalls is obtained in the same way as the unrolled images of the outer and inner surfaces. The roller stage of the Q vix rotates the stent at a calibrated speed, while the camera is acquiring single-pixel lines at a fixed frame rate. The resulting unrolled images are built by setting all these lines top-bottom together.

These unrolled images show green pixels when there is no strut blocking the back illumination. The position A in the unrolled image is acquired when the outer surface of a strut reaches the position of the optical axis position. Continuing the rotation of the stent, position B is acquired when the edge between the outer surface and the sidewall crosses the optical axis. From that point, the acquisition of the sidewall begins. Stent rotation and line acquisition continue until the bottom part of the sidewall is reached. This position, where the edge between the sidewall and the inner surface of the stent reaches the optical axis, is defined as the C position. In addition, when the unrolled image of the sidewall of an electro-polished stent is acquired, a bright stripe appears in the sidewall region. We refer to this bright stripe as "Halo" and it is produced by a direct reflection of the side illumination on the rounded edge of the stent.

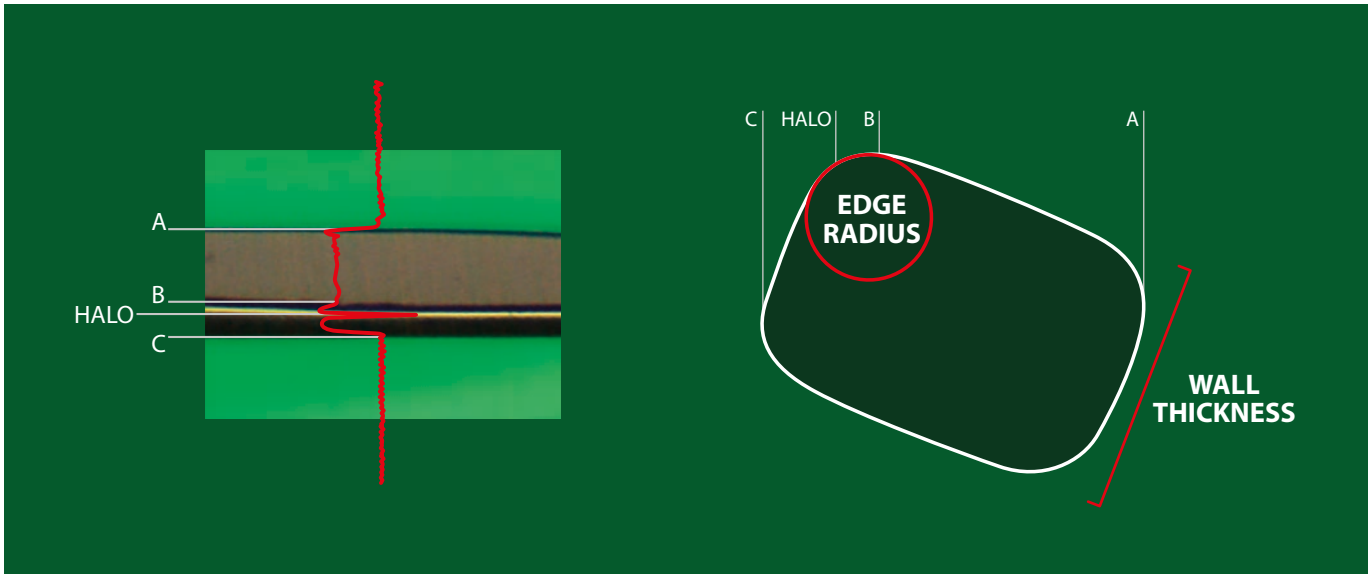

Figure 3. Unrolled sidewall image obtained with the Q vix. The analysis of the distribution of the grey levels in these images (red line in the left image) allows to determine the limits of the strut (points A and C), the transition between the outer surface and the sidewall (point B) and the position of the Halo, from which the radius of the edge can be obtained.

The unrolled images of the sidewall obtained from the lines acquired between positions B and C contain the information about the thickness of the strut. Therefore, the upper position B and the lower position C should appear well focused in that unrolled image. Figure 4 shows the depth of focus required in the optical system to obtain a well-focused unrolled sidewall image.

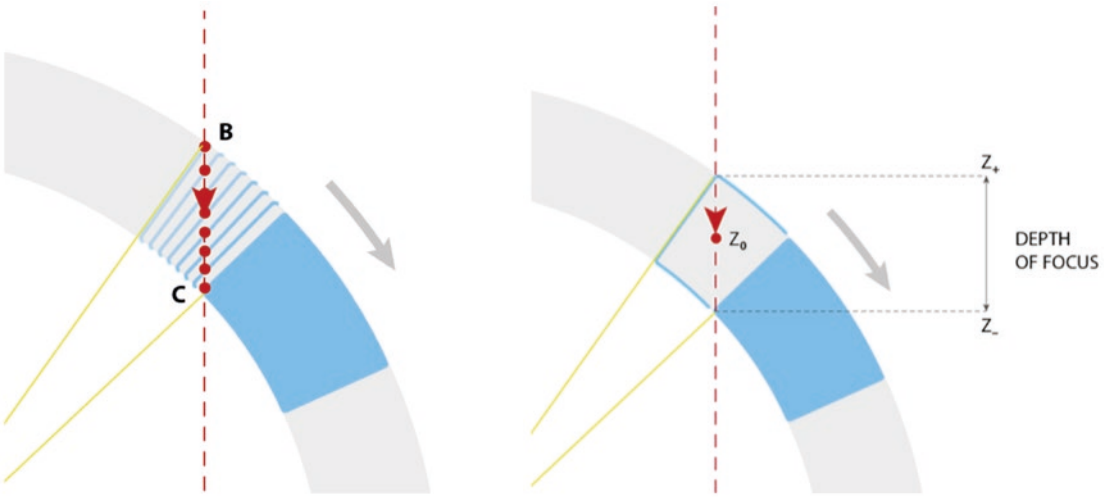

Figure 4: Acquisition of the sidewall (left image) and the required depth of focus (right image) of the optical system to obtain well focused B and C transitions

The unrolled images of the sidewalls are processed to detect the transitions that define the limits of the strut (points A & C), the transition from outer to lateral surface (point B), and the position of the Halo. The wall thickness and the edge radius are accurately determined from the relative positions of these points using a proprietary geometrical correction model that takes into account the effect of the rounded edges of the polished struts.

The results of wall thickness end edge radius are obtained and displayed in a few seconds all along the sidewalls or in predefined regions of interest, as it can be seen in Fig. 5. Automatic inspection routines are used to set the measurement positions. Summary tables with numerical results are always available for quick navigation through the inspection results, reducing the Acceptance/Rejection decision time and increasing inspection throughput.

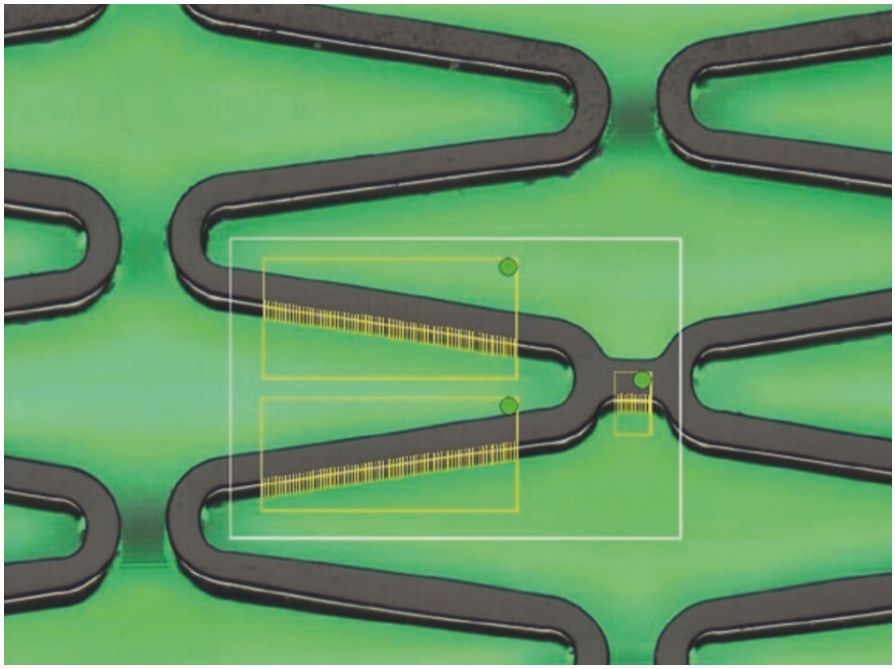

Figure 5. Wall thickness results obtained with the Q vix in predefined regions of interest

After proper calibration, the wall thickness results obtained with this new optical technique will be accurate, assuming that the following conditions are met:

- The sidewall is radial
- The shape of the edges is circular
- The radii of the outer and inner surface edges are very similar

Any deviation from the above conditions should be checked by measuring the "True Thickness" of the struts using the 3D topography measurement capability of the Q vix and setting a "Radius Factor" value that matches the wall thickness result to the true value within a maximum deviation of 1 micron.

Conclusions

The new optical technique developed by Sensofar Medical has been validated with different real stent models. The wall thickness results obtained have proven to be repeatable and accurate enough to meet the GR&R standard requirements of stent manufacturers. The new technique is extremely fast and reliable and clearly outperforms existing methods that have been used so far to measure the wall thickness of stents.

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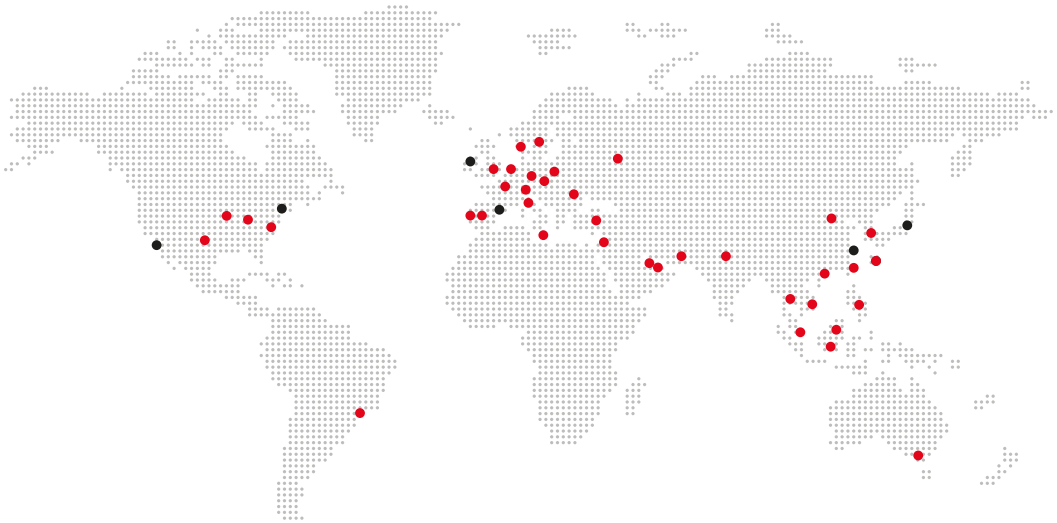

SENSOFAR is a leading-edge technology company that has the highest quality standards within the field of surface metrology

Sensofar Medical provides state-of-the-art technology for the inspection of implantable medical devices and components as well as leading-edge solutions for R&D worldwide, with each system designed to incorporate the highest quality standards within the field.

Sensofar Group's Headquarters is located in Barcelona, also known as a technology and innovation hub in Europe. The Group is represented in over 30 countries through a global network of partners and has its own offices in Asia, Germany and the United States.

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