Optical Profiling Enables High Volume Stent Manufacturing

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Stents have revolutionized treatment for atherosclerosis by reducing the possibility of narrowing of the artery after it is treated. These small stainless steel mesh tubes are designed for insertion into diseased arteries, typically of patients receiving angioplasty or an atherectomy. This application note discusses how optical profiling provides non-contact, 3D, measurement of stent shape, defects and coatings, to enable high-volume production measurement of these life-critical devices.

Critical Measurements

Figure 1 shows a three-dimensional view of one typical stent design. When spread open with an inflatable balloon these scaffolds remain in their enlarged shape and permanently maintain a large open cavity to enable blood flow. Stents can range in size from just over a millimeter in diameter unopened, to up to about a centimeter when inserted into larger blood vessels. Lengths range from a few millimeters to several centimeters.

Initially bare metal stents were used in stenting procedures. However, arteries implanted with these stents had high rates of restenosis, or re-closing of the artery. Stents coated in anti-coagulant drugs, called drug eluting stents, were found to greatly reduce the rate of restenosis. These are currently the most common type of stent in use.

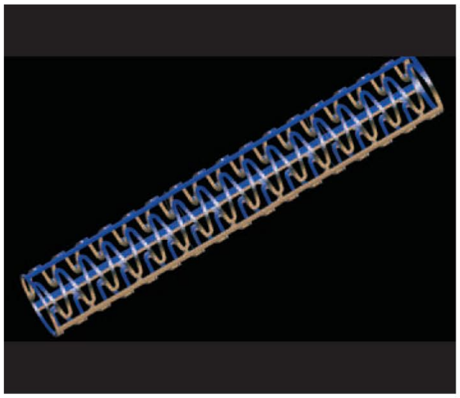

Figure 1. CAD representation of an arterial stent.

Because heart stents are implanted medical devices crucial to the long-term health of the patient, quality control must be extremely high. Typically the entire interior and exterior stent surfaces must be inspected, sometimes with multiple human and machine inspections. Critical parameters include roughness, feature shape, and radius of curvature. Potential defects include broken struts, scratches, pits and contamination. Additionally, the drug coating uniformity and thickness must be ensured to guarantee the proper duration and coverage area of the drug delivery.

Optical Profiling for 3D Stent Measurement

With over ten million stents currently being produced each year worldwide, inspection process throughput must be high without sacrificing quality. The most common technique to this point has been visual inspection through bright field microscopes, using a combination of human operators and sophisticated software to spot defects. One critical shortcoming of this method, however, is that it does not provide quantitative, 3D height or roughness information about the stent surface or the drug coating thickness. Therefore, many critical parameters are not measurable using bright field imaging alone.

Three -dimensional, optical profiling (white-light interferometry), is increasingly being used for quality control of both coated and uncoated stents, providing both lateral information and nanometer-resolution height information. An optical profiler typically requires only a few seconds to measure each field-of-view. This speed, combined with automation routines, ensure that the entire stent surface can be characterized efficiently, with full surface maps recallable for additional human review as required.

Optical profiling lets manufacturers accurately calculate surface roughness parameters of both the inside and outside of the stent in a non-contact, non-destructive fashion. Voids in the stent structure allow examination of the inside surface through the opposing wall. In addition, manufacturers can measure radius of curvature on a global and local level, and to map out any large-scale shape variations along the stent such as could occur through mishandling. Specialized pattern recognition software, included with each system, calculates feature widths and relative positions, and identifies deviations from the ideal shape.

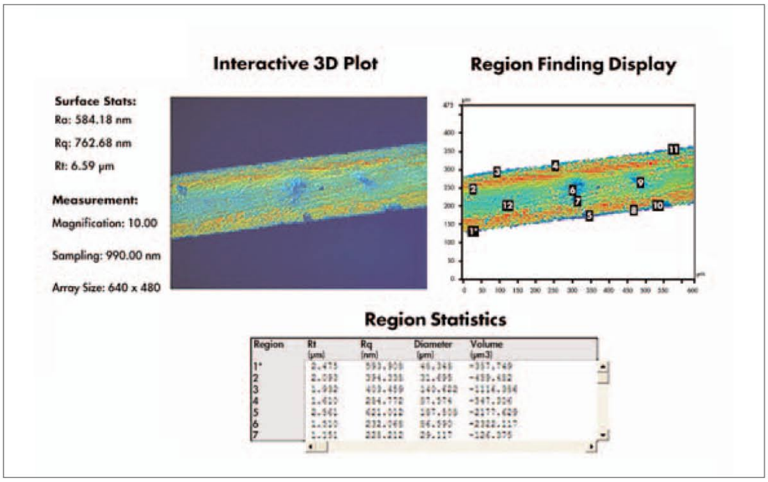

Figure 2. 3D surface profile of a defective stent. Pits are found automatically, and their dimensions, depths and volumes are logged to a database.

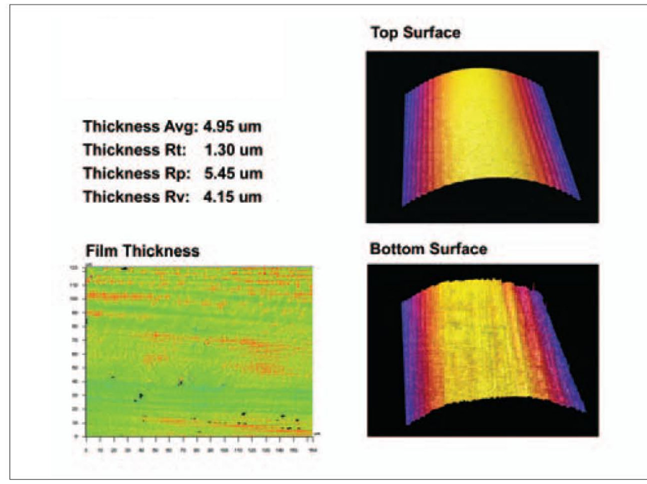

Figure 3. Measurement of coated part showing top and bottom surface as well as the coating thickness. Pits in the coating can be seen in the lower half of the image.

A user can also screen for defects, such as scratches and pits, at user-specified lateral and vertical thresholds, with automatic part rejection and reason logging for improved process control. Figure 2 shows a representative surface plot, showing a number of defects that have been located and quantified on the sample stent.

Measuring Film Thickness and Roughness

The thickness and uniformity of the drug coating determine the location and amount of the drug that will be applied to the surrounding artery. Uncoated or thinly coated areas may increase the risk of restenosis, while thickly coated areas may lead to other complications.

Recent advances in optical profiling now enable stent manufacturers to simultaneously measure the coating roughness and thickness, as well as the roughness of the stainless steel below the drug coating. This is a great improvement for stent manufacturing over point-wise film thickness measurement systems—for the first time the coating can be mapped with micron level lateral resolution across the entire stent surface, and defects can be readily identified for improved process uniformity.

Figure 3 gives an example of a coated part measured at high magnification, showing the film's outer roughness, the underlying steel roughness, and the film thickness. The data indicates several pits towards the bottom of the measurement area where the coating is thin or nonexistent which might have been missed through purely two-dimensional bright-field inspection, or single point thickness measurements. Acceptable ranges for the average thickness, standard deviation, and maximum and minimum acceptable levels can all be evaluated on the stent to screen for proper drug coverage.

Conclusion

Each year millions of life-saving arterial stents are implanted in patients worldwide. Inspection of these devices must be rapid, accurate, and non-damaging, performed not only on the outside surface of the stents but on the inside as well. Only optical profiling offers the required combination of flexibility, speed, and reliable results to enable high-volume measurement of both the stent and its outer drug coating. This method promises higher quality and lower cost as manufacturers refine their processes based on the metrology feedback, which in turn may enable even greater use of the devices.

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