APPLICATION NOTE

Characterization of coatings on drug-eluting stents

Introduction

The introduction of drug-eluting stents (DES) has, over the past decade, revolutionized the field of interventional cardiology. The DES-type of stent is coated with a thin layer of drug-eluting material that dramatically reduces stent restenosis. In most cases this prevents vessel revascularization.

DES usually comprise three main components:

- A metallic stent structure, the **stent platform**, usually made of stainless steel, cobalt-chromium, or other metallic alloys.
- A **drug carrier**, usually polymer-based, that is used as a coating for the metallic stent and that contains and delivers the drug to the artery over time.
- A **drug** embedded in the polymer-based coating, that suppresses the formation of excess tissue.

Insertion, balloon inflation, stent in position, in-stent restenosis (from left)

Manufacturing approaches for DES comprise various types of materials (drugs and polymers) together with different coating processes. Despite the variations, most of the coating methods effectively consist of spraying the drug-eluting coating over the metallic stent structure.

The characterization of coating uniformity – with thicknesses typically between 5 and 15 µm – has undeniably become an essential necessity in order to reduce therapeutic risks, but this step also doubles as an effective control of the coating process and its stability. Nonetheless, the characterization of such coatings is still a challenging application, due in part to the need to perform high-throughput and non-destructive measurements on structures with very complex morphologies.

It has been common in the industry in recent years to test equipment such as Confocal Laser Scanning Microscopy (CLSM), Chromatic Confocal Distance Sensors (CCDS), Spectroscopic Reflectometry or Total Coating Mass as non-destructive techniques for coating characterization. The three former approaches each exhibit different limitations when used for coating characterization on DES, e.g. low working distance, point vs. areal measurements and low light efficiency. Although Total Mass Coating is the approach most frequently used to streamline stent production, it does rely on a qualitative assumption, i.e. on the homogeneity of the coating.

None of these technologies has proven to be ideal for a fast and reliable characterization of DES coatings at the rate required for production, due in part to the fact that they require a different measurement platform to characterize coatings than the one used to inspect the rest of the stent.

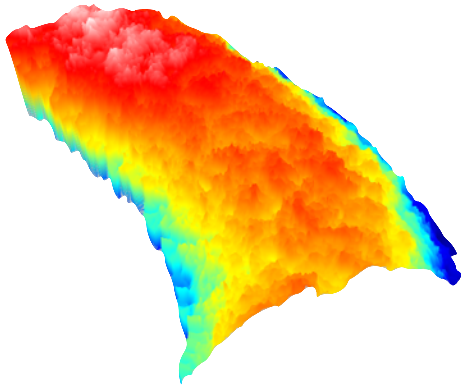
Coating characterization using the Q six

Q six uses Vertical Scanning Interferometry (VSI) as an embedded technology for the characterization of coating thickness and coating uniformity on DES. This technology provides a thickness map of the stent surface with a **lateral resolution of 0.5 µm** and a **vertical resolution of 2 nm**.

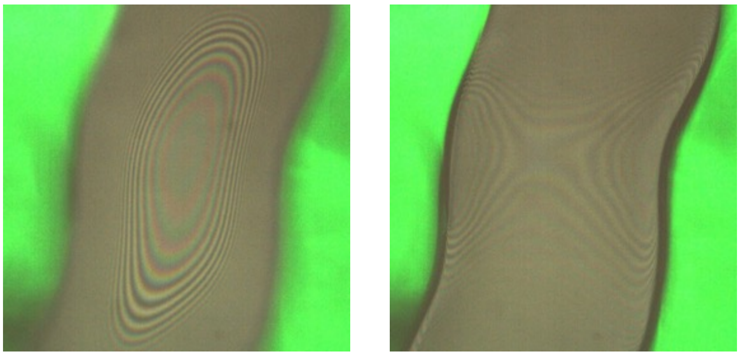
The main advantage provided by Q six is the fact that coating characterization is performed in just few seconds and on the same platform where dimensional and visual inspection of the stent is performed. This allows use of the same platform for inspection of all critical characteristics of the stent in production.

In order to obtain a three-dimensional map of a surface, Q six performs a vertical scan that locates the best contrast of an interferometry signal at every point in the field-of-view (FOV) acquired through an appropriate objective. The maximum contrast position determines the exact height of every point on the surface within the FOV.

In the case of coating measurements, two interference signals are acquired: one corresponding to the air/coating interface, and a second signal corresponding to the coating/stent interface. By applying correction models based on the index of refraction of the coating, a thickness map of the coating is obtained with nanometer accuracy by simply subtracting one interface plane from the other.

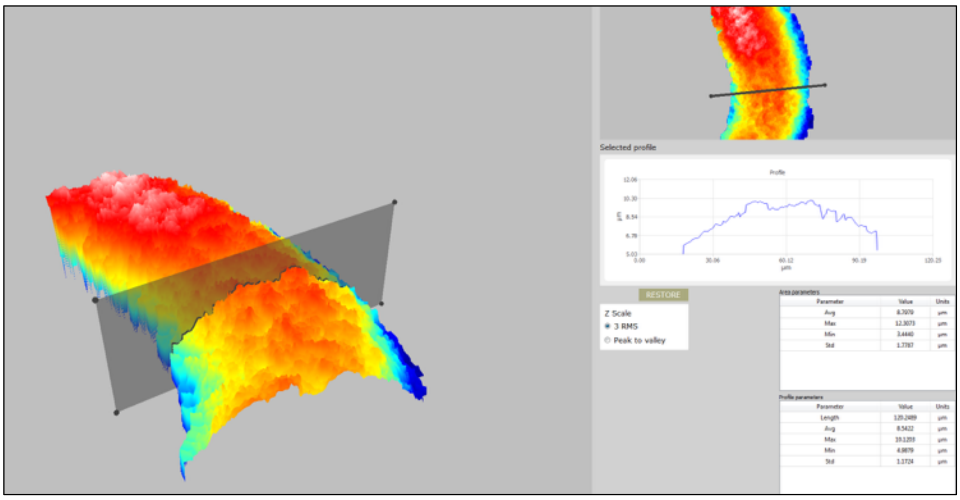


Coating measurement on a DES



Interference patterns for the upper (left) and lower (right) interfaces of the coating

Characterizing coatings on DES with the Q six is as easy as focusing on the strut surface, selecting the size of the area to be mapped and entering the index of refraction of the coating material into the *Coating* panel of the **SensoINSPECT** User Interface. A few seconds after starting the acquisition, **SensoINSPECT** will then show the thickness map of the coating inside the selected area on screen.



The results are shown as a 3D map of the coating thickness. The user can analyze any transversal section (profile) of the thickness map by simply manipulating the profile handles shown on screen with the mouse. It is also possible to evaluate the coating thickness of the selected profile, which provides a highly intuitive and quantitative characterization of coating thickness and uniformity.

Together with the quantitative results (3D thickness map and selected profile), a set of surface parameters and profile parameters to qualitatively complete the set of information is always displayed. The average value provides useful information for thickness characterization, while the maximum, minimum and standard deviation values provide the information needed for coating uniformity characterization.

Parameter	Value	Units
Avg	8.7979	µm
Max	12.3073	µm
Min	3.4440	µm
Std	1.7787	µm

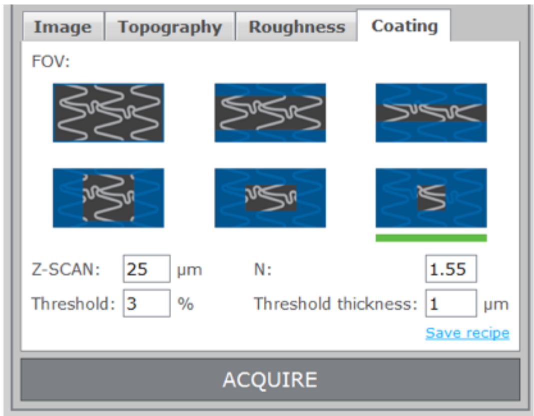
Parameter	Value	Units
Length	120.2489	µm
Avg	8.5422	µm
Max	10.1203	µm
Min	4.9879	µm
Std	1.1724	µm

Area (top) and profile (bottom) parameter tables

Conclusions

By using the technology embedded in the Q six stent inspection system, several gains are possible in a production environment:

- Coating characterization in production can be performed using the same measurement platform used during the device prototyping and development.
- The same platform can be used for dimensional measurements, visual inspection and coating characterization.
- Coating integrity assessment and coating characterization can be performed within a single measurement routine, facilitating streamlining of the process.
- Quantitative and reliable values for coating thickness are obtained within a few seconds with nanometer accuracy and repeatability.
- Coating measurements are performed optically with no contact with the sample, guaranteeing no sample manipulation.



Parameters panel in SensoINSPECT

Sensofar Medical provides state-of-the-art technology for the inspection of implantable medical devices.

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