MEASUREMENT OF COATING THICKNESS ON STENTS

There are several types of stents used for different medical conditions. One class of vascular stent is drug-eluting stents (DES) that are designed to minimize in-stent restenosis that was a main disadvantage of bare-metal stents. DES consists of a standard metallic stent, a polymer coating, and an antiproliferative drug that is embedded within a polymer and released over time. Nonuniform coating can result in unpredictable drug distribution and release. Quality control of coating thickness and uniformity is one of the critical tasks during DES manufacturing.

Another class is covered stents that are used for clot extraction, restriction of the blood flow in cases of aneurism or cancer. Stent encapsulation is also used in vascular application to deploy the stent. The covering of the stent is made from polyurethane, PTFE or similar polymer materials. It is important to test the thickness of covering membrane between and on the struts of the stent.

In both cases, MProbe VisHR-MSP system offers a reliable, non-destructive measurement solution for quality control.

I. Vascular DES stents coating

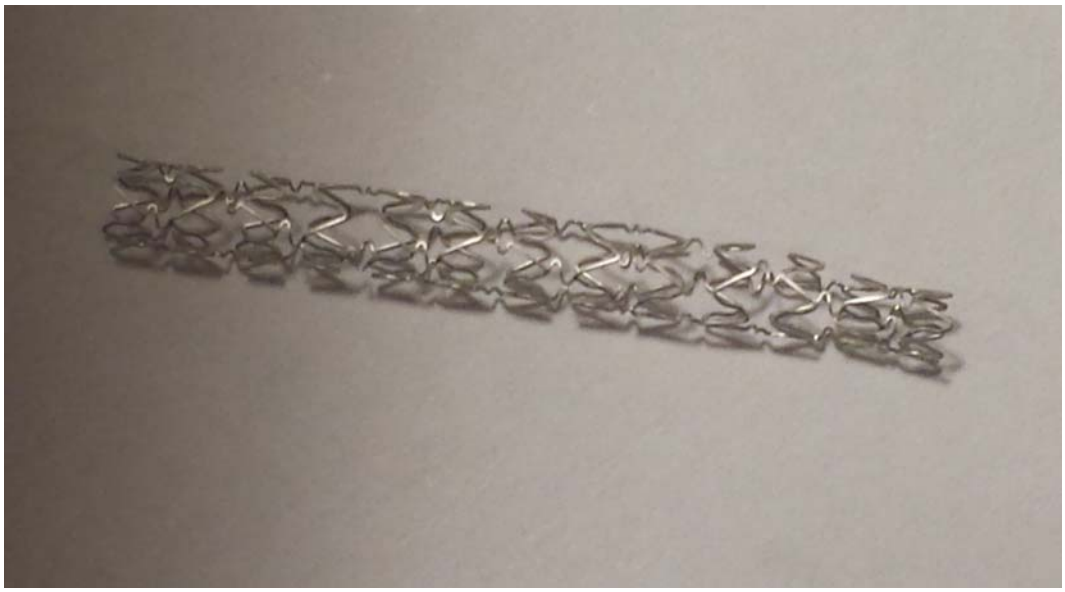

Fig. 1 DES vascular stent

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The coating was measured directly on the product. DES mesh was formed by ~80-120µm Co-Cr wire that is coated with the Sirolumus eluting polymer. Small spot size (~8 µm) was used to do the measurements. Results were correlated/verified with the SEM measurement.

Measurements were done during several production runs to adjust the production line settings to a target thickness of ~ 4.5 µm.

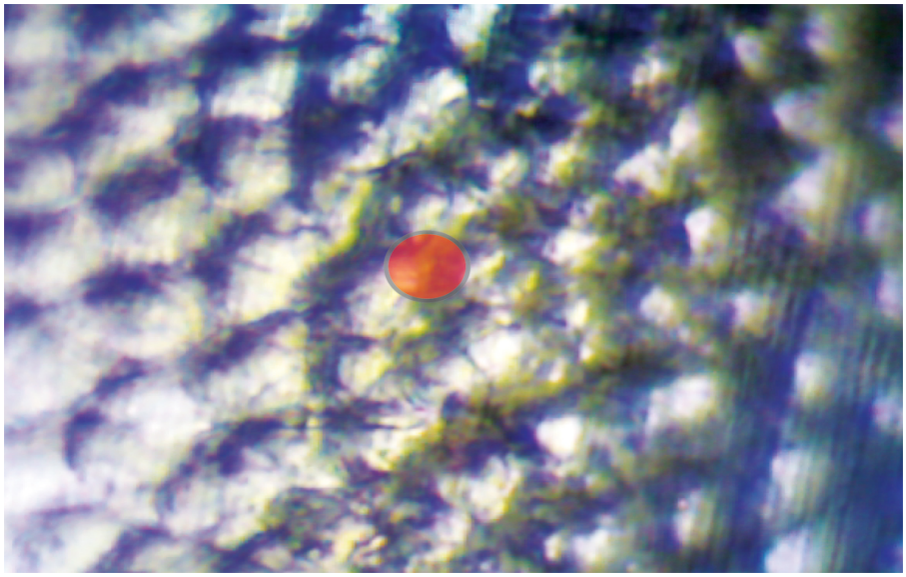

Fig. 2 Measurement location – red circle indicates the measurement spot area. The surface is ablated to increase the retention of the medicated polymer

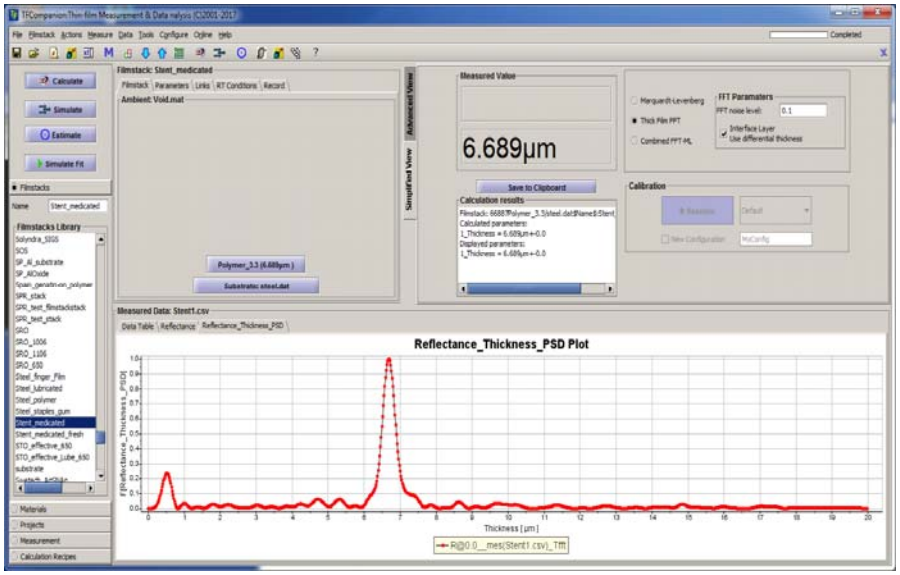

Fig. 3. Measurement of stent from the 1st production run – thickness 6.69µm (coating is too thick)

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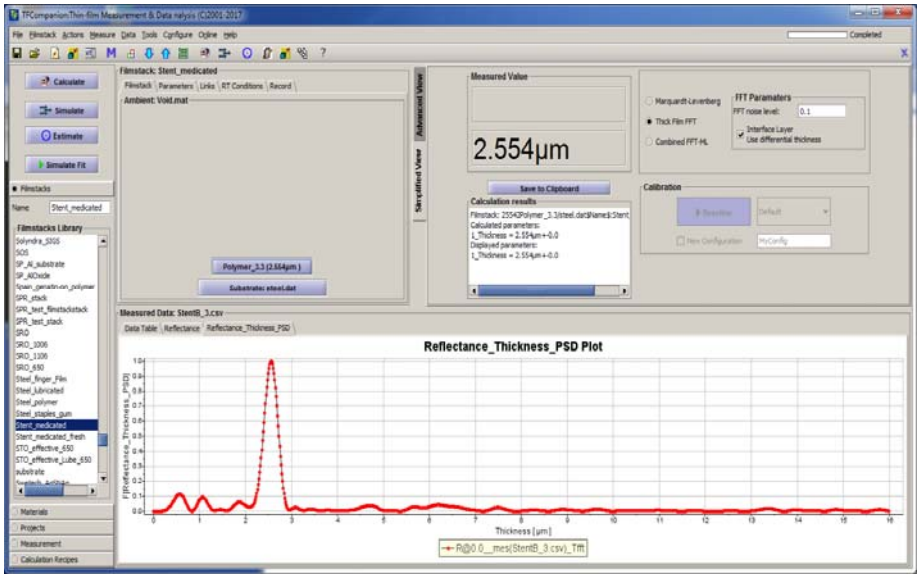

Fig. 4. Measurement of stent after production line adjustment – thickness 2.55µm (coating is too thin)

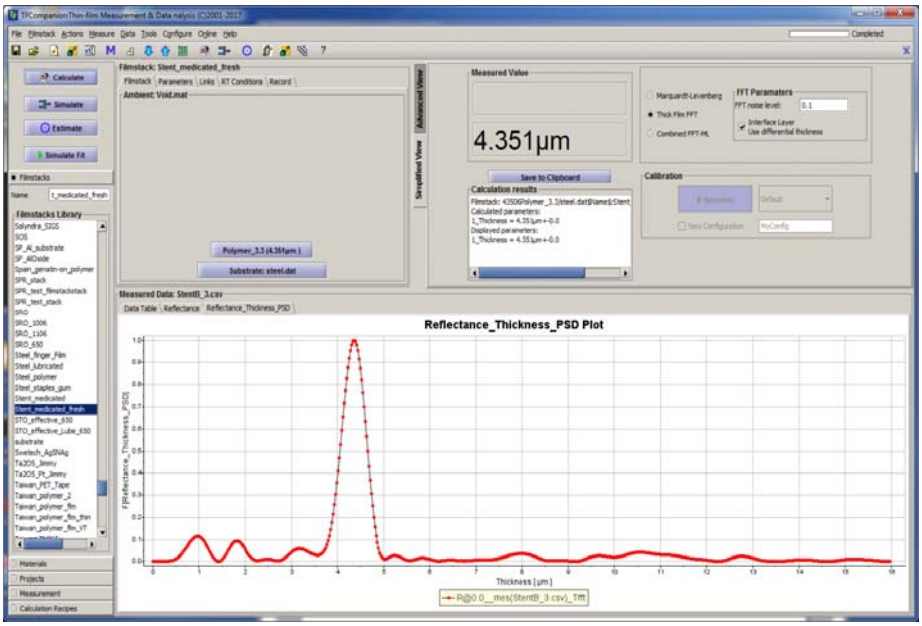

Fig. 5. Measurement of the stent coating after second adjustment of production line – thickness 4.35µm (coating thickness is on-target)

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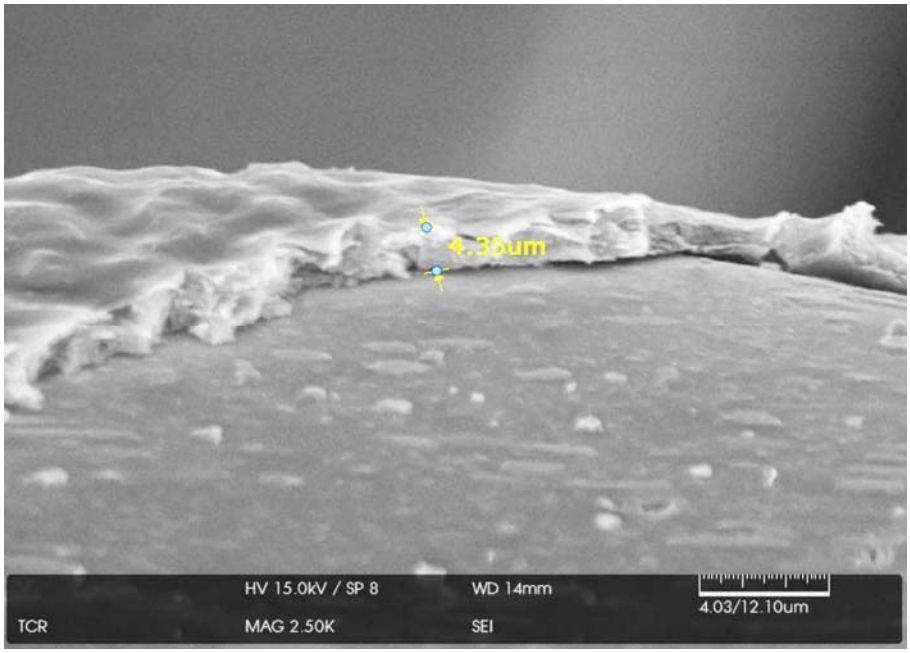

Fig. 6 SEM measurement of the stents coating shows a perfect match to MProbe thickness measurement: 4.35 µm

II. Encapsulated/covered stents.

Fig. 7 Polyurethane covered/encapsulated stent

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Stent scaffolding is build from the thin (~ 200 µm) nitinol wires. Polyurethane cover thickness target is ~40 µm to reduce recoil force. The measurement was done using 40 µm spot (from membrane between the struts) and 20 µm spot for the measurement on struts.

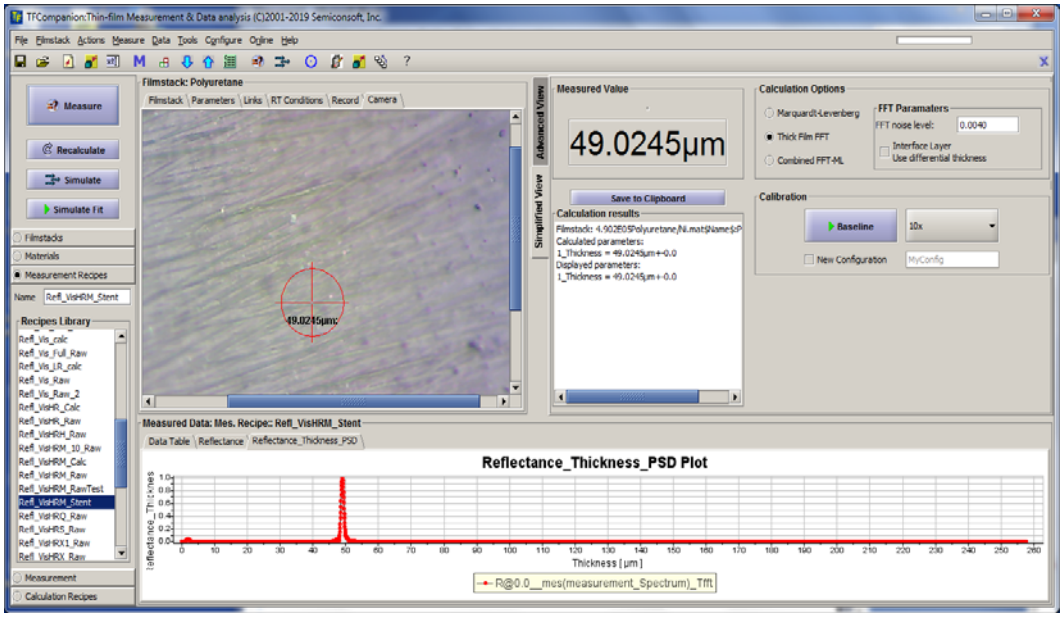

Fig. 8 Membrane thickness measurement

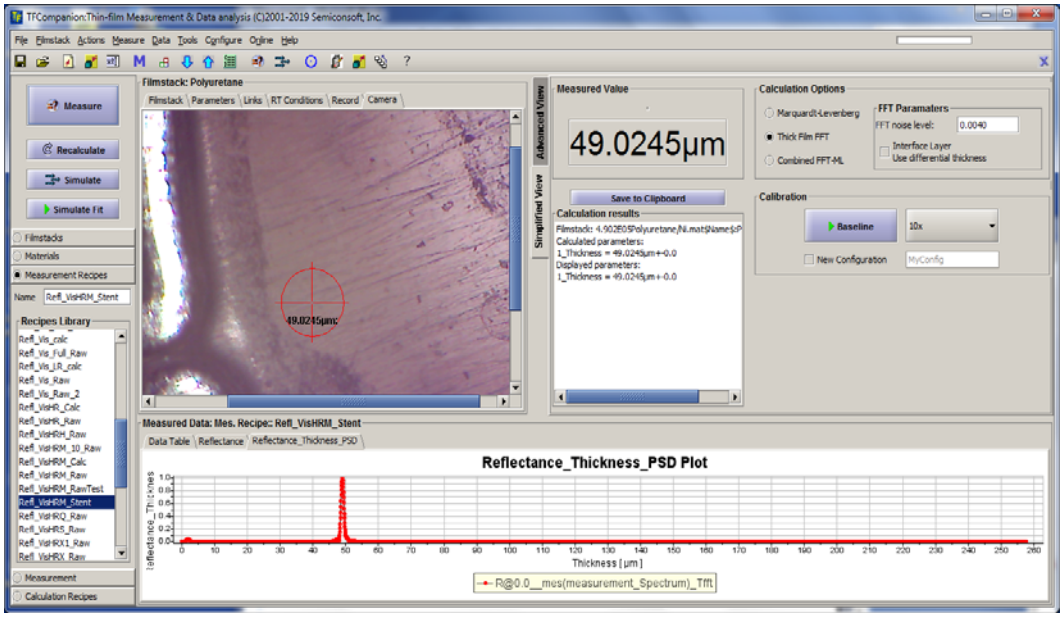

Fig. 9 Enlarged membrane measurement area (reticle indicates spot location)

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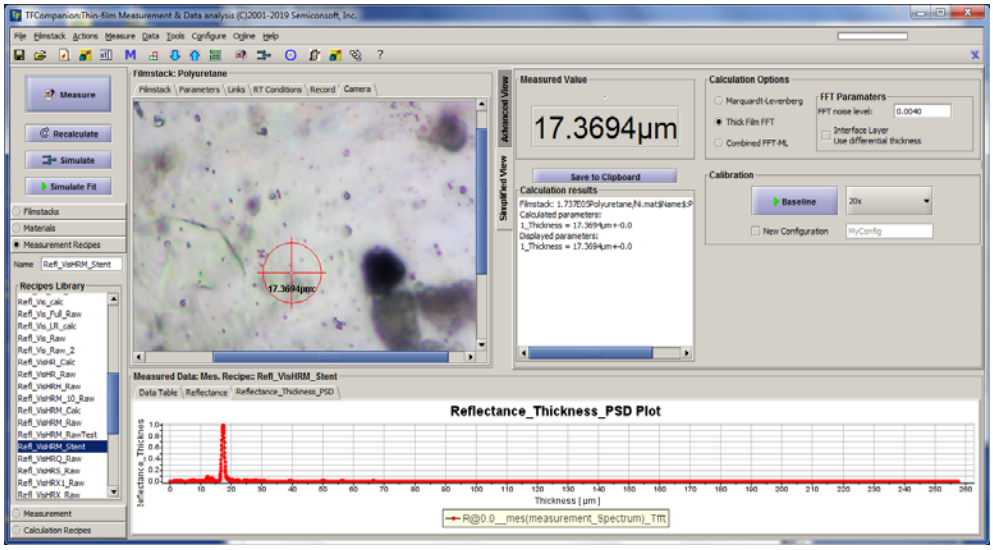

Fig. 10 Polyurethane thickness measurement on a strut. Thickness is reduced due to stretching.

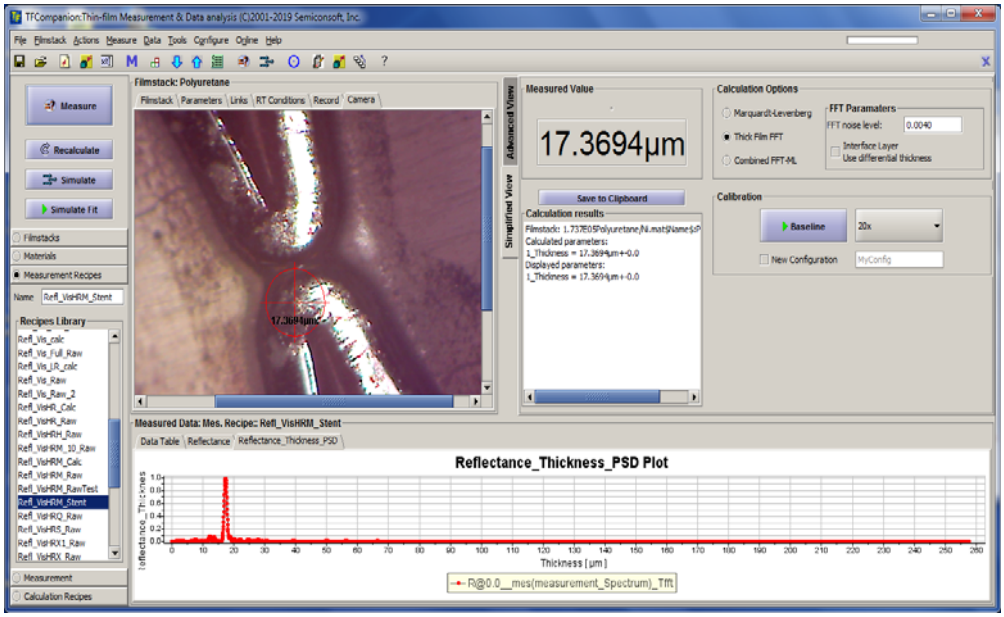

Fig. 11 Enlarged area – reticle indicates measurement location

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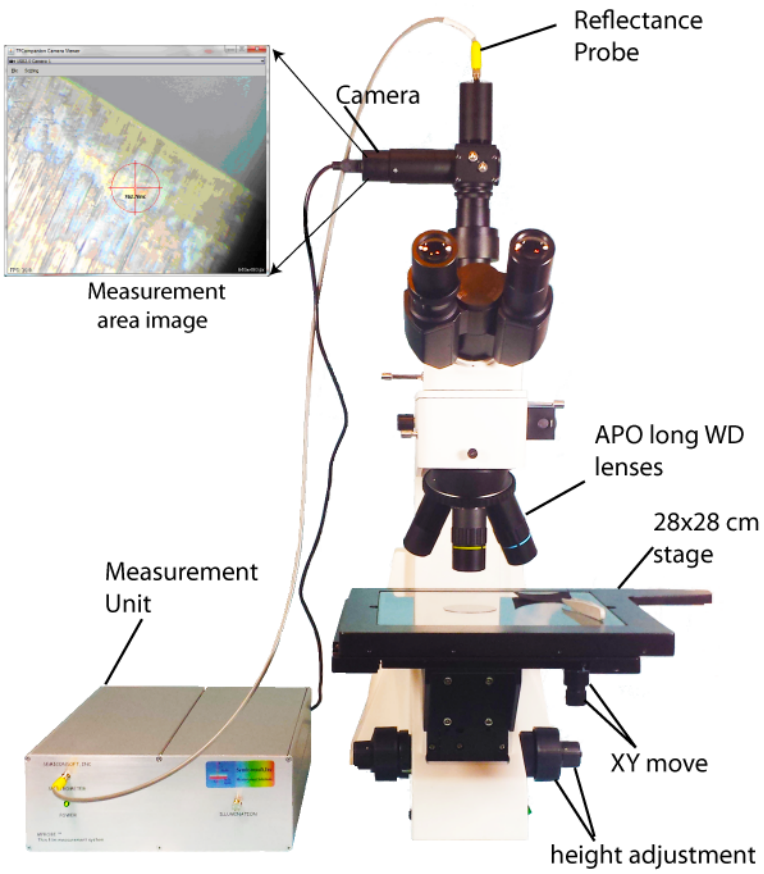

Fig. 12 MProbe MSP system used in the measurement

Conclusion.

A non-destructive, quick, accurate and affordable coating thickness measurement using MProbe MSP system makes it easy to check stent samples and verify that coating is within tolerances.

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