A Novel Characterisation Technique For Medical Device Coatings

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Introduction

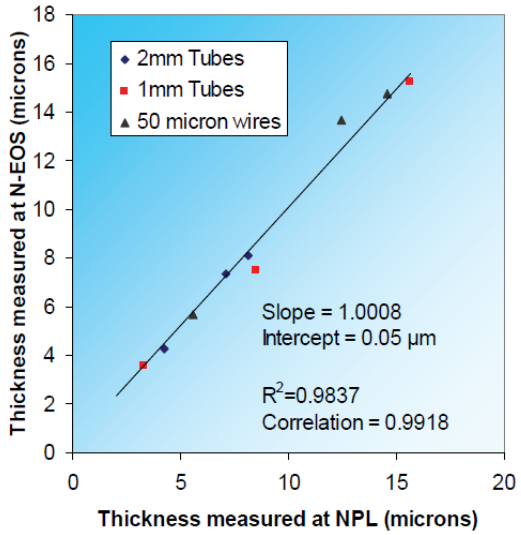
We describe the use of Beam Profile Reflectometry (BPR) to measure coating thicknesses on small, highly curved devices such as cardiac stents. The method uses a diffraction-limited focused laser beam to provide light at multiple angles of- incidence simultaneously within a submicron measurement area.

Validation measurements on stent-like reference samples, performed at the National Physical Laboratory and comparing results from BPR with destructive measurements on the same samples, show correlation of better than 99% over a range of coating thicknesses and sample morphologies down to curvature radii of ~50µm.

The method is intrinsically scalable to other, larger medical devices, such as catheters or orthopaedic prostheses.

Background

BPR was originally developed in the semiconductor industry for use in the characterisation of thin films such as SiO_2 on Silicon substrates [1]. Compared to established techniques such as spectrophotometry or spectroscopic ellipsometry, its use of a laser beam results in a significant benefit: no prior knowledge of the coating's optical properties is required. The refractive index (*n*) and extinction coefficient (*k*) can be measured directly. Techniques which depend on spectral data all require at least some prior assumptions, because the optical dispersion of the film (variation of *n* and *k* with wavelength) ensures that



there are never as many independent data points as there are unknown parameters. In contrast, at a single laser wavelength, the independent data points greatly outnumber the unknown parameters, enabling a deterministic measurement to be made. The result is a significant improvement in absolute accuracy.

Applications

By adapting the technology for use on devices with complex form-factors, Nightingale-EOS has shown that the BPR technology is a promising candidate for characterising coatings on medical implants, in the short term as a laboratory technique and in the medium term as an enabler of in-line process control for device manufacturers.

References

[1] J.T. Fanton, J. Opsal, D. L. Willenborg, S.M. Kelso and A. Rosencwaig, J. Appl. Phys. 73 (11) 7035 (1993).