Optical Coherence Tomography (OCT)

OCT analysis of:

Devices

Metal
stents

Self-expandable
stents

Drug-eluting
balloons

Bioabsorbable
stents
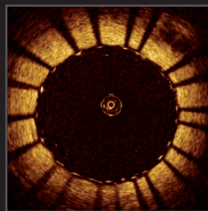
Atherosclerosis

Plaque type
assessment

Fibrous cap
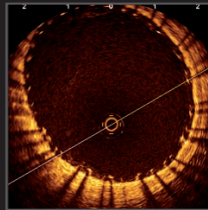thickness

Macrophages

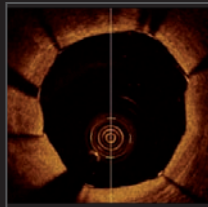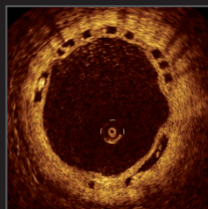**Anti-Xa, antiplatelets**

Thrombus

Flow area

Metal stents

Self-expandable stents

Drug-eluting balloons

Bioabsorbable stents

Cardialysis is an innovative leader in the field of image analysis. Continually researching new and emerging imaging modalities. Such an approach ensures that the evaluation of a novel device/drug will be carried out using cutting edge technology to maximise the information gained from a clinical study. Closely guided by clinical experts in the specific field, Cardialysis serves as a Core Laboratory for a variety of these imaging techniques.

CARDIALYSIS
Clinical Trial Management - Core Laboratories

fostering
discoveries

Optical Coherence Tomography and Statistics

A recent example is the successful implementation of a state-of-the-art intra-vascular imaging research technique: Optical Coherence Tomography (OCT). OCT is an innovative imaging technology with extremely high resolution that offers many novel image analysis possibilities and creates an overwhelming abundance of data points. This unique capability has resulted in OCT being rapidly adopted and accepted in stent studies with the ability to provide accurate assessment of both stent apposition and tissue coverage over individual stent struts. Other exciting applications include the detailed assessment of the vessel wall and its structural changes over time together with the characterisation of atherosclerotic plaque components.

The amount of data points created per analysed pullback is enormous and requires multilevel statistical approaches. The statistical challenge is to summarise these data, without losing the wealth of information. One single number is not able to express the results. Therefore, Cardialysis has developed different complementary ways for both descriptive and comparative analyses, including graphical and complex multilevel statistical methods.

Multi-level regression analysis methods are essential to compare in a valid manner different stenting methods, correcting for patient, vessel, lesion and stent correlations.

The OCT Core Lab is the example of Cardialysis' strength, where image analysis, statistical expertise, and clinical interpretation meet.

Key publication of Cardialysis in the field of OCT

1. Reproducibility of quantitative optical coherence tomography for stent analysis. Gonzalo N, Garcia-Garcia HM, Serruys PW, Commissaris KH, Bezerra H, Gobbens P, Costa M, Regar E. **EuroIntervention** 2009; 5(2): 224-32.

2. An optical coherence tomography study of a biodegradable vs. durable polymer-coated limus-eluting stent: a LEADERS trial sub-study. Barlis P, Regar E, Serruys PW, Dimopoulos K, van der Giessen WJ, van Geuns RJ, Ferrante G, Wandel S, Windecker S, van Es GA, Eerdmans P, Jüni P, di Mario C. **Eur Heart J** 2010; 31(2): 165-76.

3. A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial. Ormiston JA, Serruys PW, Regar E, Dudek D, Thuesen L, Webster MW, Onuma Y, Garcia-Garcia HM, McGreevy R, Veldhof S. **Lancet** 2008; 15;371(9616): 899-907.

4. A bioabsorbable everolimus-eluting coronary stent system (ABSORB): 2-year outcomes and results from multiple imaging methods. Serruys PW, Ormiston JA, Onuma Y, Regar E, Gonzalo N, Garcia-Garcia HM, Nieman K, Bruining N, Dorange C, Miquel-Hébert K, Veldhof S, Webster M, Thuesen L, Dudek D. **Lancet** 2009; 373(9667): 897-910.

5. Optical Coherence Tomography in Cardiovascular Research. Edited by: Regar E, van Leeuwen TG, Serruys PW, **Informa Healthcare** 2007.

References 6-26 are available at Cardialysis.

www.cardialysis.nl