

**SASCI STATEMENT ON USE OF OPTICAL COHERENCE TOMOGRAPHY, INTRA-VASCULAR ULTRA SOUND AND FRACTIONAL FLOW RESERVE IN IMPROVING OUTCOMES AND COST EFFICIENT MANAGEMENT IN PATIENTS UNDERGOING CORONARY ANGIOGRAPHY**

**23 January 2015**

The Executive Committee of the South African Society for Coronary Intervention has reviewed the data on the appropriate use of Optical Coherence Tomography (OCT), Intra-Vascular Ultrasound (IVUS) (aka ICUS) and Fractional Flow Reserve (FFR) and strongly recommends that the cost pertaining to the use of these devices is routinely covered by the medical aid fund, and that this payment is pre-authorized prior to the coronary angiogram being done.

Currently some - medical aids still exclude the use of OCT, IVUS or FFR and, if used in such patients during coronary angiography, payment for the devices is often withheld by the medical aid despite subsequent motivation of appropriate use by the cardiologist. This cost (of approximately R7000 for FFR and R9000 for OCT or IVUS) is therefore passed onto the patient. We believe that this is unfair on the patient as the appropriate use of OCT, IVUS and FFR have been shown to improve patient outcomes in the short and long term<sup>1,2,3,4</sup>, reduce number of stents implanted by approximately 30%<sup>4</sup> and are cost effective. Therefore by not guaranteeing to cover the cost of these devices, stents (usually drug eluting stents at R14000 each) may be inserted in non-significant lesions. Patient outcomes in the short and long term may be worse, resulting in more repeat hospital admissions and possible coronary interventions. The net result of which is higher cost to the funders in the long term.

FFR is used to determine whether a coronary artery stenosis (narrowing) is of functional significance or not<sup>5</sup>. It is very difficult to determine this on angiography alone especially if the angiographic stenosis is 50-70%. FFR is performed in the cardiac catheterization laboratory after coronary angiography and takes about 5-10 minutes to do. Where FFR is not available, cardiologists are likely to stent these lesions routinely, as they are thought to be flow significant and the cause of the patients symptoms, FFR assessment of the lesion in question is likely to show that approximately 30% are in fact NOT flow significant and therefore do not require an intervention – be that a stent or bypass surgery.

In fact it has been shown that inappropriate stenting worsens the 1year outcome<sup>2</sup>. On the other hand, appropriate FFR guided stenting results in a better outcome than best medical therapy alone in patients with stable coronary disease<sup>3</sup>. Appropriate FFR use would be in approximately 20-30% coronary angiography cases. FFR is a technology that reduces cost and improves outcomes – the best case scenario for any technology.

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IVUS allows for accurate measurement of vessel diameter (rather than relying on angiographic measurement alone which often underestimates true lumen diameter) and therefore correct stent size choice. Its other main use is to determine whether a stent is well deployed with good stent expansion and apposition to the vessel wall. These 2 factors result in better short and long term outcomes following stent deployment due to a lower incidence of stent thrombosis and less in stent restenosis respectively<sup>6,7,8</sup>. Appropriate IVUS use would be in approximately 5-10% of cases.

OCT (Optical Coherence Tomography) is an imaging modality that uses fibre optic technology with optical imaging catheters that emit near-infrared light to produce high-resolution real-time images, providing a visual look inside the arteries. OCT provides detailed views inside the coronary arteries to help assess the anatomical characteristics of the vessel and plaque. As a result of its high resolution and speed, OCT produces clear, easy-to-understand views of vessel anatomy and plaque composition for planning and optimizing treatment. The Consensus Standards for Acquisition, Measurement, and Reporting of Intravascular Optical Coherence Tomography Studies<sup>9</sup>, provide a standard reference regarding the current state of the IVOCT imaging modality. OCT is further used as a clinical tool to guide interventional procedures as it provides accurate luminal measurements of lesion severity due to a better delineation of the lumen-wall interface. The OPUS-CLASS Study<sup>10</sup> compared the performance of OCT and IVUS in making lumen measurements and in guiding PCI procedures. The results indicate that OCT provides reliable quantitative measurements of coronary dimensions in the clinical setting. The CLI-OPCI study<sup>11</sup> concluded that OCT plus angiography can improve clinical outcomes of patients undergoing PCI, specifically a reduction in the 1-year rate of cardiac death or MI.

Both IVUS and OCT can be used to visualize minimum lumen diameter (MLD), MLA, lesion length, calcium, fibrosis and lipids. However, when it comes to evaluation of strut apposition, stent coverage, and cap fibroatheroma evaluations, thrombus and macrophages, OCT tends to be better by virtue of the higher resolution. Post-intervention findings such as dissection, tissue prolapse and apposition tend to be seen better with OCT.

With its unique high image resolution capabilities, OCT can be used to reliably evaluate vessel and lesion-characteristics both pre- and directly after BVS (Bioresorbable vascular scaffold) implantation, as well as during long-term follow-up. This information can help to improve BVS implantation and to better understand the potential advantages and limitations of these devices.

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**6. Impact of Intravascular Ultrasound Imaging on Early and Late Clinical Outcomes Following Percutaneous Coronary Intervention with Drug-Eluting Stents**

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A Report from the International Working Group for Intravascular Optical Coherence Tomography Standardization and Validation

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