A Post-market, Multi-vessel Evaluation of the Imaging of Peripheral Arteries for Diagnostic Purposes Comparing Optical Coherence Tomography and Intravascular Ultrasound Imaging (SCAN)

**CURRENT STATUS:** ACCEPTED

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*intravascular imaging, IVUS, OCT, plaque, diagnosis, treatment strategy*
Abstract
Background: Intravascular imaging plays an important part in diagnosis of vascular conditions and providing insight for treatment strategy. Two main imaging modalities are intravascular ultrasound (IVUS) and optical coherence tomography (OCT). The objective of this study was to prove non-inferiority of OCT imaging to IVUS images in matched segments of peripheral vessels in patients with suspected peripheral vascular disease.

Methods: The SCAN study was a prospective, non-inferiority clinical study of matched IVUS and OCT images collected along defined segments of peripheral vessels from twelve subjects (mean age 68 10.3 years; 10 men) displaying symptoms of vascular disease. Luminal diameters were measured by both imaging systems at the distal, middle, and proximal points of the defined segments. Three blinded interventional radiologists evaluated the quality of both imaging modalities in identifying Mann-Whitney-Wilcoxon testing. Intrareader reproducibility was calculated by intraclass correlation (ICC) analysis. Results: The mean scoring of plaque, calcification, and vascular stent struts by the three readers was significant better in terms of image quality for OCT than IVUS (p<0.001, p=0.001, p=0.004, respectively). The mean scores of vessel wall component visibility and artifacts generated by the two imaging systems were not significantly different (p=0.19, p=0.07, respectively). Mean vessel luminal diameter and area at three specific locations within the vessels were not significantly different between the two imaging modalities. No patient injury, adverse effect or device malfunction were noted during the study.

Conclusions: Imaging by OCT provides the physician with better visualization of some vessel and plaque characteristics, but both IVUS and OCT imaging are safe and effective methods of examining peripheral vessels in order to perform diagnostic assessment of peripheral vessels and provide information necessary for the treatment strategy of peripheral artery disease.

Full-text
Due to technical limitations, full-text HTML conversion of this manuscript could not be completed. However, the manuscript can be downloaded and accessed as a PDF.

Tables
Table 1. Patient and vessel characteristics.
|                      |        |
|----------------------|--------|
| **No. of patients**  | 12     |
| **Mean age, years (range)** | 68 (55 – 87) |
| **Sex**              | Male 10 (83%).  Female 2 (17%) |
| **Race**             | Caucasian 92%.  African-American (8%) |
| **Mean weight, kg (range)** | 82 (69 – 92) |
| **Mean height, cm (range)** | 176.8 (167.6 – 187.9) |
| **Leg of the vessel accessed** | Left 9 (75%).  Right (25%) |
| **Vessel imaged**    | SFA (64%)  Popliteal (36%) |
| **Mean length of target segment of vessel, cm (range)** | 24 (10 – 60) |
| **Number of images containing a specific vessel characteristic to be scored** | |
|                      |        |
| Layered structure    | 24     |
| Nonlayered structure | 104    |
| Calcification        | 40     |
| Stent                | 21     |
| Artifact             | 120    |

Table 2. Mean ranking of the image quality of layered structure, non-layered structure, calcification, stent structure, and artifacts as rated by three readers of matched images captured by OCT and IVUS systems.
| Vessel Characteristic | Mean score for IVUS images | Mean score for OCT images | Student’s t-Test | Mann-Whitney-Wilcoxon |
|-----------------------|---------------------------|--------------------------|------------------|-----------------------|
| Layered structure\(^a\) | 1.61                      | 1.49                     | \(p = 0.19\)     |                       |
| Non-layered structure\(^b\) | 2.70                      | 1.82                     | \(p < 0.001\)    |                       |
| Calcification\(^c\) | 2.45                      | 2.11                     | \(p = 0.001\)    |                       |
| Stent structure\(^d\) | 1.79                      | 1.43                     | \(p = 0.004\)    |                       |
| Artifacts\(^e\) | 1.87                      | 1.79                     | \(p = 0.07\)     |                       |

Scoring: \(^a\) Layered structure (1- clear differentiation of vessel wall layers, 2- differentiation of 3 wall layers, 3-differentiation of 2 wall layers, 4- no differentiation visible); \(^b\) Non-layered structure (1-excellent histology-like image quality to 5- unacceptably poor image quality); \(^c\) Calcification (1-excellent histology-like image quality to 5- unacceptably poor image quality); \(^d\) Stent structure (1 excellent image, 2 – acceptable image, 3 – unacceptably poor image); and \(^e\) Artifacts (1-none, 2-tolerable/not limiting, 3-is intense and limits image quality).

Table 3. Mean ranking of the image quality of layered structure, non-layered structure, calcification, stent structure, and artifacts as rated by three readers of matched images captured by OCT and IVUS systems.

| Reader | Layered Structure\(^a\) | Non-Layered Structure\(^b\) | Calcification\(^c\) | Stent Structure\(^d\) |
|--------|--------------------------|-----------------------------|---------------------|-----------------------|
| 1      | IVUS 1.58, OCT 1.12, \(p = 0.002\) | IVUS 2.97, OCT 2.08, \(p < 0.001\) | IVUS 2.28, OCT 2.05, \(p < 0.001\) | IVUS 2.00, OCT 1.48, \(p < 0.001\) |
| ICC intrareader | 0.82, 0.91 | 0.89, 0.91 | 0.77, 0.83 | 0.82, 0.93 |
| 2      | IVUS 1.42, OCT 1.04, \(p = 0.02\) | IVUS 2.55, OCT 1.54, \(p < 0.001\) | IVUS 2.15, OCT 1.60, \(p < 0.001\) | IVUS 1.81, OCT 1.14, \(p < 0.001\) |
| ICC intrareader | 0.70, 0.83 | 0.73, 0.81 | 0.91, 0.85 | 0.84, 0.88 |
| 3      | IVUS 1.83, OCT 2.29, \(p = 0.005\) | IVUS 2.58, OCT 1.84, \(p < 0.001\) | IVUS 2.95, OCT 2.68, \(p = 0.19\) | IVUS 1.52, OCT 1.67, \(p = 0.52\) |
| ICC intrareader | 0.84, 0.75 | 0.89, 0.77 | 0.92, 0.87 | 0.83, 0.86 |
Scoring: \(a\) Layered structure (1- clear differentiation of vessel wall layers, 2- differentiation of 3 wall layers, 3-differentiation of 2 wall layers, 4- no differentiation visible); \(b\) Non-layered structure (1- excellent histology-like image quality to 5- unacceptably poor image quality); \(c\) Calcification (1-excellent histology-like image quality to 5- unacceptably poor image quality); \(d\) Stent structure (1 excellent image, 2 – acceptable image, 3 – unacceptably poor image); and \(e\) Artifacts (1-none, 2-tolerable/not limiting, 3-is intense and limits image quality)

Table 4. The longest and shortest luminal diameter of vessels at the distal, middle, and proximal portions of the target segments of vessels and the resultant luminal area as measured by the Pantheris OCT or Visions PV IVUS systems.

| Patient | Imaging Modality | Longest Diameter (mm) | Shortest Diameter (mm) | Luminal Area from Longest Diameter (sq mm) | Longest Diameter (mm) | Shortest Diameter (mm) |
|---------|------------------|-----------------------|------------------------|--------------------------------------------|-----------------------|------------------------|
| P1      | IVUS             | 5.4                   | 4.3                    | 22.9                                       | 5.1                   | 4.6                    |
|         | OCT              | 6.1                   | 3.9                    | 29.22                                      | 5.7                   | 4.2                    |
| P2      | IVUS             | 4.3                   | 4                      | 14.52                                      | 3.8                   | 3.2                    |
|         | OCT              | 3.9                   | 3.3                    | 11.95                                      | 4.2                   | 3                      |
| P3      | IVUS             | 3.9                   | 3                      | 11.95                                      | 4.4                   | 4                      |
|         | OCT              | 4.2                   | 2.9                    | 13.85                                      | 4.6                   | 4.3                    |
| P4      | IVUS             | 6.4                   | 5.9                    | 32.17                                      | 5.2                   | 4.7                    |
|         | OCT              | 5.7                   | 5.3                    | 25.52                                      | 4.8                   | 4.4                    |
| P5      | IVUS             | 6.7                   | 5.8                    | 35.26                                      | 5.9                   | 5.1                    |
|         | OCT              | 5.7                   | 5                      | 25.52                                      | 5.5                   | 4.8                    |
| P6      | IVUS             | 4.8                   | 4.1                    | 18.09                                      | 3.8                   | 3.1                    |
|         | OCT              | 5.4                   | 4.1                    | 22.9                                       | 3.6                   | 2.8                    |
| P7      | IVUS             | 5.3                   | 4.3                    | 22.06                                      | 4.6                   | 4                      |
|         | OCT              | 4.6                   | 4                      | 16.62                                      | 4.2                   | 3.5                    |
| P8      | IVUS             | 5.3                   | 4.3                    | 22.06                                      | 5.4                   | 4.8                    |
|     | OCT | IVUS | OCT | IVUS | OCT | IVUS |
|-----|-----|------|-----|------|-----|------|
| S1  | 5.6 | 3.5  | 4.7 | 3    | 24.63 | 9.62 |
|     | 3.8 | 3.8  | 3.2 | 3.2  | 11.34 | 2.5  |
| S2  | 2.9 | 2.9  | 2   | 2    | 6.6   | 6.6  |
|     | 2.8 | 2.8  | 2.5 | 2.5  | 6.16  | 2    |
| S3  | 3.7 | 3.7  | 2.9 | 2.9  | 10.75 | 10.75|
|     | 4.1 | 4.1  | 2.4 | 2.4  | 13.2  | 13.2 |
| S4  | 4.6 | 4.6  | 4.2 | 4.2  | 16.62 | 16.62|
|     | 4.3 | 4.3  | 3.9 | 3.9  | 14.52 | 14.52|
| MEANS | IVUS | 4.7  | 3.9 | 3.9  | 18.55 | 18.55|
|      | OCT  | 4.7  | 3.8 | 3.8  | 17.28 | 17.28|

\[ p = 0.80 \quad p = 0.10 \quad p = 0.39 \quad p = 0.54 \quad p = 0.02 \]

Figures

![Figure 1](image1.png)

Figure 1
Figure 2