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# First-in-Human Experience With a Novel Multimodality DeepOCT-NIRS Intracoronary Imaging System

Ziad A. Ali, MD, DPhil [a,*], Antonio Dager, MD [b], Mauricio Zúñiga, MD [b], Jaime Fonseca, MD [b], Camilo Arana, MD [b], Daniel Chamié, MD, PhD [c], Jonathan M. Hill, MA, MBChB, MRCP [d], Ryan D. Madder, MD [e], James E. Muller, MD [f], Charles A. Simonton, MD [g], Guillermo J. Tearney, MD, PhD [h,i,j,†], Gregg W. Stone, MD [k,†]

[a] *DeMatteis Cardiovascular Institute, St Francis Hospital & Heart Center, Roslyn, New York;* [b] *Angiografia De Occidente S.A., Cali, Colombia;* [c] *Section of Cardiovascular Medicine, Department of Internal Medicine, Yale School of Medicine, New Haven, Connecticut;* [d] *Cardiovascular Division, Royal Brompton Hospital, London, United Kingdom;* [e] *Frederik Meijer Heart & Vascular Institute, Corewell Health, Grand Rapids, Michigan;* [f] *Division of Cardiovascular Medicine, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts;* [g] *Abiomed Inc., Danvers, Massachusetts;* [h] *Wellman Center for Photomedicine, Massachusetts General Hospital, Boston, Massachusetts;* [i] *Department of Pathology, Massachusetts General Hospital, Boston, Massachusetts;* [j] *Harvard-MIT Division of Health Science and Technology, Cambridge, Massachusetts;* [k] *Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, New York*

Data continue to accumulate demonstrating the benefits of intravascular imaging guidance to improve patient outcomes after percutaneous coronary intervention (PCI)[1] and the potential of intravascular imaging to identify high-risk vulnerable plaques.[2] Optical coherence tomography (OCT) and near-infrared spectroscopy (NIRS) have been established as useful modalities for intravascular imaging in the catheterization laboratory. While the high resolution of OCT enables accurate identification of many plaque morphologies[3] and precise quantitative measurements of plaque and stent dimensions, limited penetration remains a limitation. Similarly, although NIRS has been extensively validated for detection of lipid-rich vulnerable plaques,[4] to date it has been paired with intravascular ultrasound with suboptimal resolution. Herein we demonstrate selected images from the first-in-human experience with a novel Food and Drug Administration-cleared combined multimodality next-generation OCT (DeepOCT) and NIRS coronary imaging system (HyperVue Imaging System, SpectraWAVE, Inc) which combines higher resolution imaging with enhanced depth penetration and NIRS co-registration for lipid detection.

Intracoronary imaging with the SpectraWAVE system was performed on 25 patients at Angiografia de Occidente S.A. in Cali, Colombia. Figure 1 (with link to Supplemental Video 1) demonstrates different morphologic features visualized by the HyperVue Imaging System including fibrotic, layered, calcific, lipidic, and mixed plaques, a ruptured plaque cavity, and thrombi. In 21 of the 25 patients, images were obtained in the same coronary artery with the HyperVue system and other contemporary intravascular imaging systems (Abbott OPTIS with Dragonfly OPTIS OCT Catheter and Boston Scientific iLab with POLARIS Software - OPTICROSS Intravascular Ultrasound Coronary Imaging Catheter). Figure 2 provides representative coregistered coronary artery images, demonstrating enhanced resolution, depth penetration, and morphologic clarity with the HyperVue system.

Compared with standard OCT technology, the greater depth penetration afforded by DeepOCT provides more complete visualization of the entire arterial wall, including the external elastic lamina, which is critical for PCI guidance[5] and vulnerable plaque detection. Increased resolution imparts greater clarity to interpret complex vascular structures and pathobiology. The integration of NIRS allows for identification of lipid-containing plaques with high specificity, circumventing artifacts and eliminating ambiguity from OCT interpretation alone. Other attributes of the HyperVue Imaging System include a no-flush catheter prep, rapid 100 mm pullback length, and artificial intelligence-enabled automated system identification of vessel lumen, external elastic lamina, plaque burden, lipid, calcium, stent struts, and malapposition, coregistered in real-time with the coronary angiogram (Figure 1M, N). Rapid pullback and high resolution imaging enable the performance of OCT with saline flush only, eliminating the risk of contrast nephropathy. The combination of DeepOCT and NIRS integrated into a single, ready-to-use catheter offers the potential for improved characterization of atherosclerotic coronary plaque and may enhance PCI procedural guidance.

*Keywords:* coronary artery disease; first-in-human clinical study; intravascular coronary imaging; near-infrared spectroscopy; optical coherence tomography; vulnerable plaque.

* Corresponding author: ziad.ali@dcvi.org (Z.A. Ali).

† Co-senior authors.

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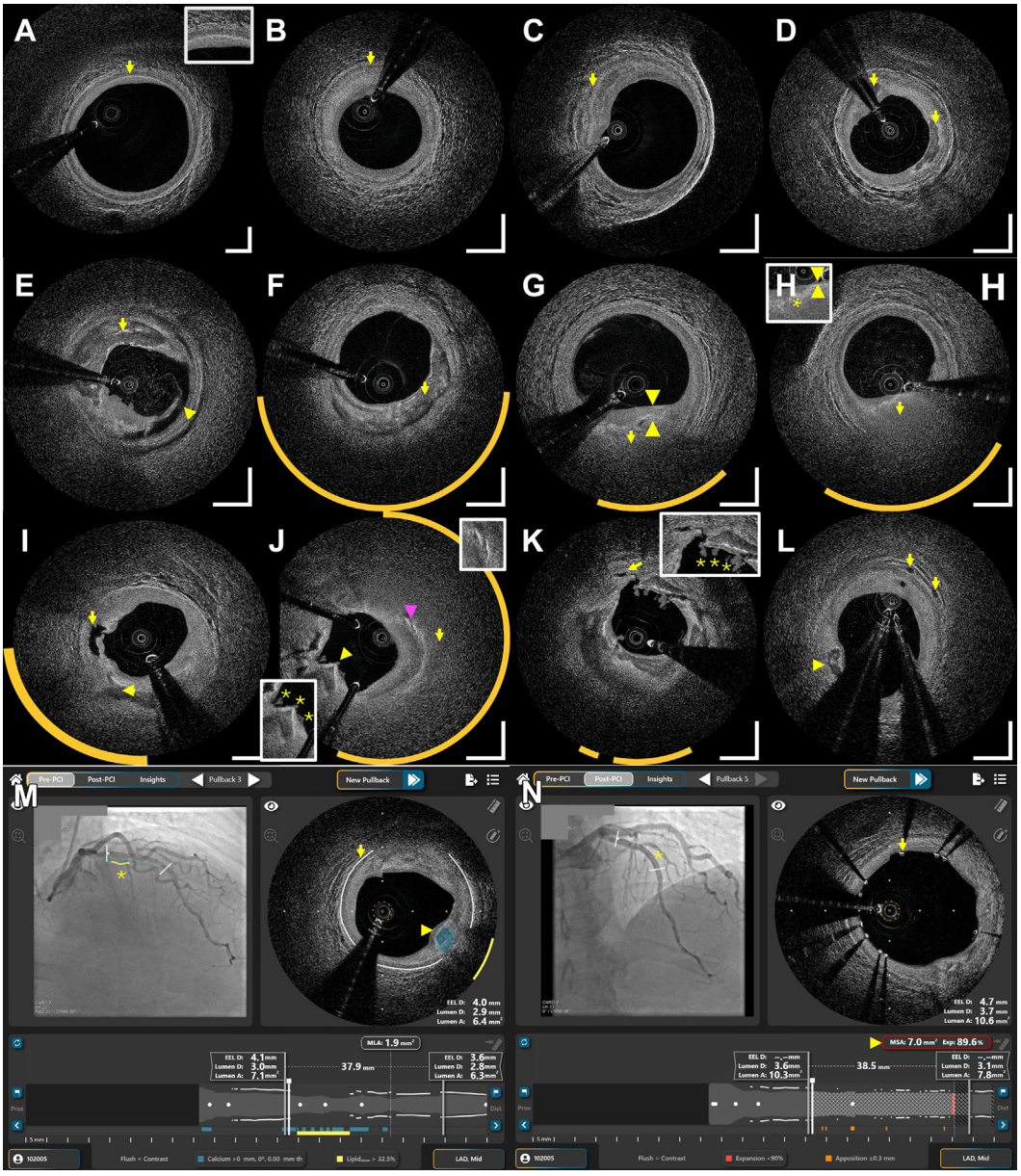


**Figure 1.**

**Representative coronary artery DeepOCT-NIRS images.** Scale bars in the bottom right of each image are all 1 mm unless otherwise noted. (**A**) Minimal intimal hyperplasia (inset is 1.5× magnification) and (**B**) a thicker neointima/fibrous plaque, both demonstrating clear visualization of the external elastic lamina (EEL) (arrows) and surrounding adventitia. (**C**) Fibrous plaque showing collagen layering (arrow). (**D**) Fibrocalcific plaque with calcific plates (arrows). (**E**) Postballoon angioplasty of a nonlipidic fibrocalcific plaque with a calcific plate (arrow). An intimal dissection is present (arrowhead). (**F**) Fibrocalcific plaque demonstrating a large calcific plate (arrow). Note that the yellow NIRS arc indicates the coexistence of lipid with calcium that would otherwise be difficult to discern from the optical coherence tomography (OCT) image alone. (**G**) A thick-cap fibroatheroma showing a thick fibrous cap (arrowheads) overlying a lipid core (arrow). The minimum cap thickness measurement is 332 μm. (**H**) A thin-cap fibroatheroma demonstrating a large protruding necrotic core (arrow) with a thin fibrous cap (arrowheads in inset) and infiltrating macrophages (the white pinpoint inclusions as noted by the asterisk in the inset; inset is 1.5× magnification). The minimum cap thickness measurement is 39 μm. (**I**) An empty cavity following plaque rupture (arrow) with calcium (arrowhead) with coexisting lipid. (**J**) A mixed plaque with a fibroatheroma containing lipid (arrow) and cholesterol crystals (magenta arrowhead and upper right inset box) and features consistent with a superficial eruptive calcified nodule (diamond and lower left inset box), implicated in plaque instability, with overlying microthrombi (asterisks in inset). Both insets are at 2× magnification. (**K**) An intimal tear (arrow) and thrombi (asterisks in inset). (**L**) A fibrocalcific plaque showing vasa vasorum (arrows) and a calcium plate (arrowhead). K-inset is 2× magnification. (**M**) Pre-PCI user interface of the HyperVue Imaging System including artificial intelligence (AI)-enabled automated calcium (arrowhead), EEL (arrow), and angiographic coregistration (asterisk). (**N**) Post-PCI user interface of the HyperVue Imaging System including AI-enabled stent detection (arrow), stent expansion (arrowhead), and angiographic coregistration (asterisk). Images in Figure 1 (**F**, **G**, **H**, **I**, **J**, **K**, and **M**) contain lipid, as evidenced by the presence of a NIRS arc. Conversely, images in Figure 1 (**A**, **B**, **C**, **D**, **E**, **L**, and **N**) do not contain lipid, as evidenced by the absence of a NIRS arc. NIRS, near-infrared spectroscopy; PCI, percutaneous coronary intervention.

## Declaration of competing interest

Ziad A. Ali has institutional grant support from Abbott, Abiomed, Acist Medical, Boston Scientific, Cardiovascular Systems Inc, Medtronic Inc, National Institute of Health, Opsens Medical, Philips, Teleflex, consulting fees from Astra Zeneca, Philips, Shockwave, and equity in Elucid, SpectraWAVE, Shockwave, and VitalConnect. Antonio Dager is a proctor for Medtronic. Jonathan M. Hill has institutional grant support from Abbott, Abiomed, Boston Scientific, Medtronic Inc, Shockwave, and equity in Shockwave. Ryan D. Madder has received speaker honoraria from Abbott Vascular, Corindus, and Infraredx; has served as a consultant to Abbott Vascular, Corindus, Infraredx, and SpectraWAVE; has received research support from Corindus and Infraredx; and serves on the advisory boards of Medtronic and SpectraWAVE. James E. Muller

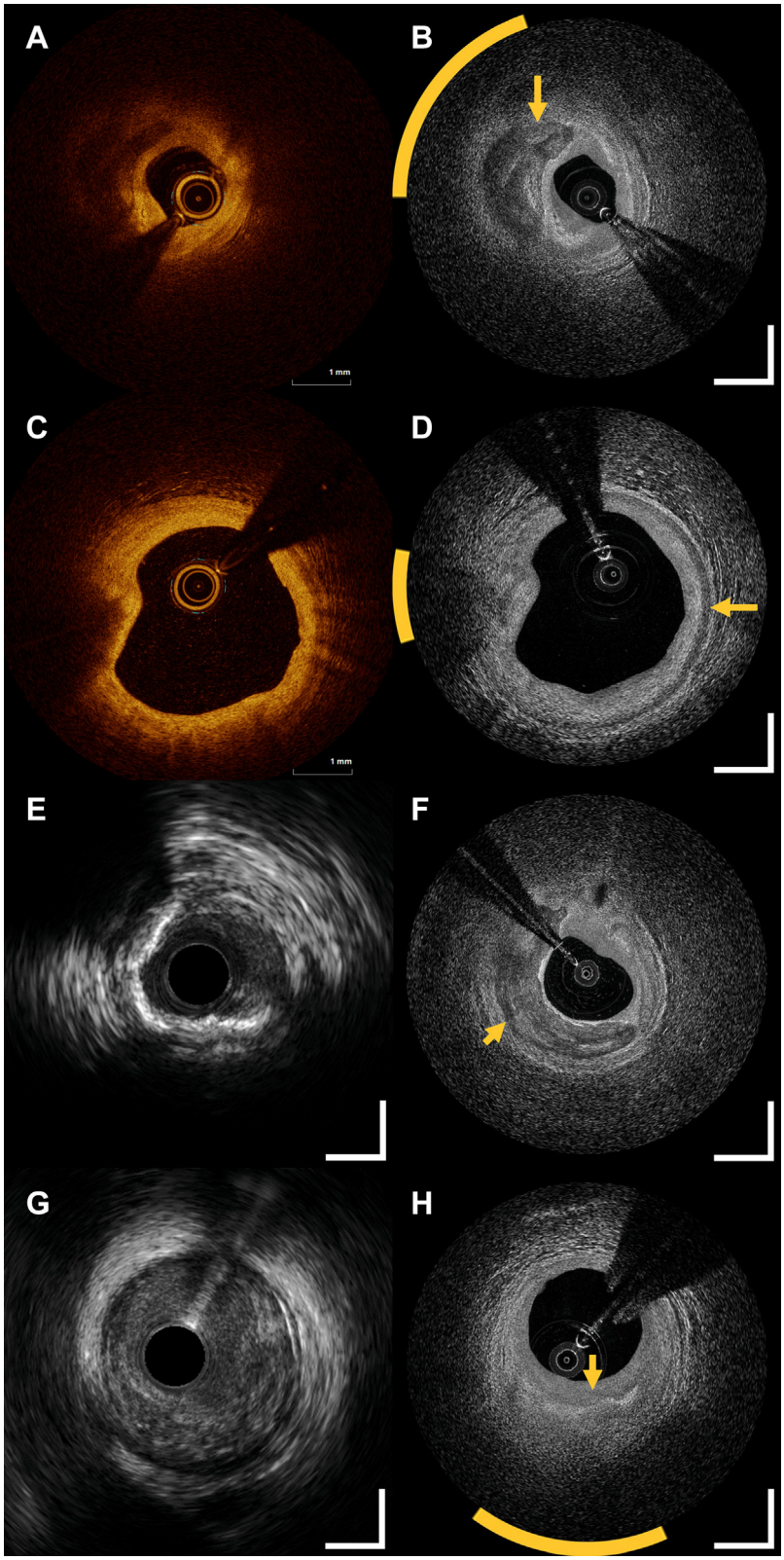


**Figure 2.**

**Representative coregistered comparisons with commercially available contemporary intravascular imaging systems (left column) and DeepOCT-NIRS imaging (right column).** Left panels **A** and **C** are from the Abbott OPTIS with Dragonfly OPTIS OCT Catheter. Left panels **E** and **G** are from Boston Scientific iLab with POLARIS Software - OPTICROSS Intravascular Ultrasound (IVUS) Coronary Imaging Catheter (E – 40 MHz and G – 60 MHz). All right panels are from the SpectraWAVE HyperVue integrated DeepOCT and NIRS coronary imaging system. Scale bars in the bottom right of each image are all 1 mm. (**A** and **B**): A calcified and lipidic plaque. The arrow demarks the deep border of the calcific plate that can be seen circumferentially surrounding the calcium only with DeepOCT. Microstructure in the calcium and in the fibrous cap overlying the calcium and lipid can also be seen. (**C** and **D**): A lipidic plaque. The yellow NIRS arc of the DeepOCT-NIRS image confirms the presence of lipid at 9 O'clock. The external elastic membrane (external elastic lamina [EEL], yellow arrow) is also most clearly visualized at 3-o'clock on the DeepOCT image. (**E** and **F**): A calcified plaque. Penetration of DeepOCT-NIRS enables visualization through the entire lesion, allowing the deep border of the calcific plate to be clearly seen (arrow). (**G** and **H**): A thick-capped fibroatheroma containing lipid confirmed by NIRS. The cap (arrow) can be clearly seen by DeepOCT-NIRS. NIRS, near-infrared spectroscopy; OCT, optical coherence tomography.

is an equity holder in SpectraWAVE, Inc, and CEO with salary and equity in ECHAS, LLC. Charles A. Simonton is an Abiomed employee, on the SpectraWAVE Inc. BOD, and equity interest in SpectraWAVE, Inc. Guillermo J. Tearney has received materials/sponsored research related to intracoronary imaging from Terumo Corporation, Verdure Biotech Holdings, Canon Medical, and has a financial/fiduciary interest in SpectraWAVE, a company developing an OCT-NIRS intracoronary imaging system and catheter. Guillermo J. Tearney's financial/fiduciary interest was reviewed and is managed by the Massachusetts General Brigham in accordance with their conflict-of-interest policies. Gregg W.

Stone has received speaker honoraria from Medtronic, Pulnovo, Infraredx, Abiomed, Amgen, Boehringer Ingelheim; has served as a consultant to Abbott, Daiichi Sankyo, Ablative Solutions, CorFlow, Apollo Therapeutics, Cardiomech, Gore, Robocath, Miracor, Vectorious, Abiomed, Valfix, TherOx, HeartFlow, Neovasc, Ancora, Elucid Bio, Occlutech, Impulse Dynamics, Adona Medical, Millennia Biopharma, Oxitope, Cardiac Success, HighLife; and has equity/options from Ancora, Cagent, Applied Therapeutics, Biostar family of funds, SpectraWAVE, Orchestra Biomed, Aria, Cardiac Success, Valfix, Xenter. Gregg W. Stone's employer, Mount Sinai Hospital, receives research grants from Abbott, Abiomed, Bioventrix, Cardiovascular Systems Inc, Phillips, Biosense-Webster, Shockwave, Vascular Dynamics, Pulnovo and V-wave. Family disclosure: Gregg W. Stone's daughter is an employee at IQVIA. The other authors have no disclosures.

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## Ethics statement and patient consent

The research reported has adhered to the relevant ethical guidelines and patient consent has been obtained.

## Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2024.101344.

## References

1. Stone GW, Christiansen EH, Ali ZA, et al. Updated network meta-analysis of intravascular imaging-guided coronary drug-eluting stent implantation. *Lancet (London, England)*. 2024. https://doi.org/10.1016/S0140-6736(23)02454-6
2. Stone GW, Maehara A, Lansky AJ, et al. A prospective natural-history study of coronary atherosclerosis. *N Engl J Med*. 2011;364(3):226–235. https://doi.org/10.1056/NEJMoa1002358
3. Tearney GJ, Regar E, Akasaka T, et al. Consensus standards for acquisition, measurement, and reporting of intravascular optical coherence tomography studies: a report from the International Working Group for Intravascular Optical Coherence Tomography Standardization and Validation. *J Am Coll Cardiol*. 2012;59(12):1058–1072. https://doi.org/10.1016/j.jacc.2011.09.079
4. Erlinge D, Maehara A, Ben-Yehuda O, et al. Identification of vulnerable plaques and patients by intracoronary near-infrared spectroscopy and ultrasound (PROSPECT II): a prospective natural history study. *Lancet*. 2021;397(10278):985–995. https://doi.org/10.1016/S0140-6736(21)00249-X
5. Shlofmitz E, Jeremias A, Parviz Y, et al. External elastic lamina vs. luminal diameter measurement for determining stent diameter by optical coherence tomography: an ILUMIEN III substudy. *Eur Heart J Cardiovasc Imaging*. 2021;22(7):753–759. https://doi.org/10.1093/ehjci/jeaa276