Provisio Medical Sonic Lumen Tomography Intravascular Ultrasound (SLT IVUS™) System

Emerging Technologies Session

UIP - Miami, FL

09/18/23

Conflict of interest disclosure

- Dr. Carl Fastabend has a financial interest, arrangement, or affiliation with:

• Philips (Koninklijke Philips N.V.)	Consultant
• Provisio Medical, Inc.	Consultant, stockholder

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Current tools to assess vessel sizing for endovascular interventions are often inaccurate, difficult and costly

- Over 3.5 million endovascular procedures in the U.S. are performed annually (8 million globally)
- Physicians rely on fluoroscopy/angiogram to assess vessel sizing in approximately 85%[1] of these procedures, often underestimating vessel size[2]
- A minority of these procedures (15%) are informed by imaging catheters such as IVUS, adding an average of 22 minutes to the procedure[3]
- Imaging modalities require significant physician interpretation

1. Company estimate
2. Pliagas G, Saab F, Stavroulakis K, Bisdas T, Finton S, Heaney C, McGoff T, Hardy K, Adams G, Mustapha JA. Intravascular Ultrasound Imaging Versus Digital Subtraction Angiography in Patients with Peripheral Vascular Disease. J Invasive Cardiol. 2020 Mar;32(3):99-103.
3. American Medical Association RBRVS Datamanager

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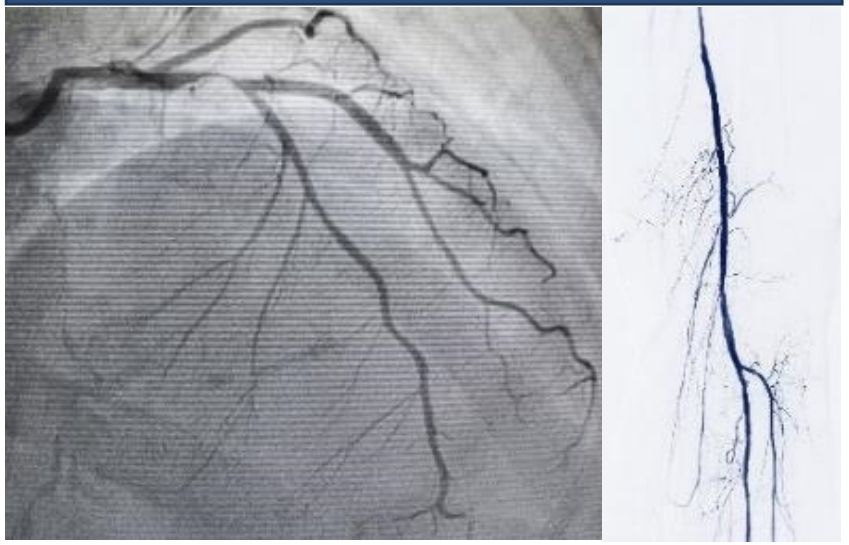
Current Vessel Sizing Methods:

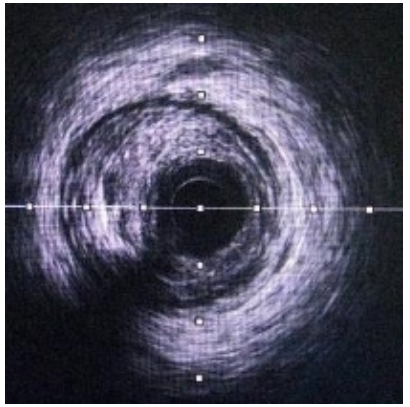
Fluoroscopy / Angiogram / Venogram



- Current predominant standard of care (85%+ exclusive utilization)
- Low-resolution 2D image
- Uses radiation, kidney-toxic media
- Often inaccurate measurements[1]

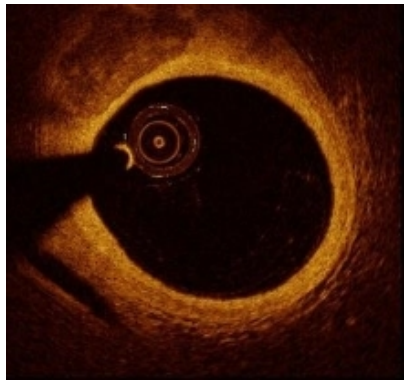
Traditional IVUS

- Vessel sizing gold-standard
- Requires time-consuming separate diagnostic procedure
- Complex image interpretation
- 5%-15% penetration depending on market



OCT

- Requires saline flushing of blood from vessel during imaging
- Involves separate, high-cost procedure
- Limited clinical utilization
- (Currently only coronary indication and integrated into an atherectomy device)



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[1] J Invasive Cardiology, 2020;32(3)):99-103

Accurate Vessel Sizing Matters

"The most critical advantage of IVUS for clinical work derives from its unequivocally superior capability to define luminal dimensions, particularly cross-sectional area. The limitations of angiography in evaluating luminal dimensions have been well documented."

Jeffrey Isner & Kenneth Rosenfield– Mass General Hospital
Catheterization and Cardiovascular Diagnosis 26: 192-199 (1992)
Restated: VIVA Conference 2021

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Reliance on angiography significantly underestimates vessel size in peripheral vasculature

JOURNAL OF Invasive Cardiology [1]

Anatomic Location	DSA (mm)	IVUS (mm)	P-Value
Proximal SFA	5.5 (1.0-6.5)	6.1 (4.1-7.8)	<.001
Mid SFA	5.0 (1.0-6.0)	5.9 (3.8-7.9)	<.001
Distal SFA	4.8 (0.0-6.0)	5.9 (4.2-7.7)	<.001
Proximal POP	5.0 (3.0-6.0)	5.8 (3.7-7.2)	<.001
Mid POP	4.5 (2.5-5.0)	5.6 (3.6-8.6)	<.001
Distal POP	4.0 (0.0-5.0)	5.3 (3.5-7.5)	<.001
Proximal Anterior Tibial	2.5 (1.0-4.0)	3.6 (3.0-4.0)	<.001
Mid Anterior Tibial	2.0 (0.0-3.0)	n/a	n/a
Distal Anterior Tibial	2.0 (0.0-2.5)	3.0 (2.7-3.6)	<.01
Tibioperoneal Trunk	3.0 (1.5-3.5)	4.0 (2.3-5.5)	<.001
Proximal Posterior Tibial	2.5 (0.0-3.0)	3.4 (2.5-4.4)	<.001
Mid Posterior Tibial	2.0 (0.0-2.5)	n/a	n/a
Distal Posterior Tibial	2.0 (0.0-2.5)	3.2 (2.5-4.4)	<.001
Proximal Peroneal	2.0 (1.0-2.5)	3.3 (2.6-3.4)	.03
Mid Peroneal	1.5 (0.0-3.0)	n/a	n/a
Distal Peroneal	1.0 (0.0-2.8)	n/a	n/a
Dorsalis Pedis	0.5 (0.0-2.0)	n/a	n/a

- Digital subtraction angiography (DSA) was used to measure peripheral vessels and compared to measurements taken with IVUS (N=43 patients)
- Conclusion. IVUS appears to offer a greater degree of accuracy in measuring arterial lumen diameter. As measurements obtained from angiographic imaging consistently under-estimated vessel size, utilization of IVUS may aid in the determination of treatment algorithms and lead to improved endovascular outcomes.[1]
- Accurate vessel sizing is necessary to optimize biologic delivery to the adventitia with drug-eluting devices.[1]
- As a significant number of PAD patients have chronic kidney disease, the amount of contrast that can be safely utilized for DSA imaging is often limited.[1]

1 - Pliagas G, Saab F, Stavroulakis K, Bisdas T, Finton S, Heaney C, McGoff T, Hardy K, Adams G, Mustapha JA. Intravascular Ultrasound Imaging Versus Digital Subtraction Angiography in Patients with Peripheral Vascular Disease. J Invasive Cardiol. 2020 Mar;32(3):99-103.

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Real world evidence shows significant improvement in clinical outcomes using IVUS for peripheral vascular interventions

Beth Israel Deaconess Medical Center | Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology | HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

- Independent large-scale, real-world analysis of Centers for Medicare and Medicaid Services (CMS) data from 697,794 peripheral artery and 20,984 venous intervention patients[1]
- **32% reduction in major adverse limb events**, such as amputation, with use of IVUS in arterial cases[1]
  - Findings were consistent across disease states, including critical limb ischemia and non-critical limb ischemia; as well as arterial segments such as iliac (hip area), femoropopliteal (upper leg area), and tibial (lower leg area)[2]
- **31% reduction in repeat intervention**, hospitalization or death in venous stenting with IVUS[1]

"We know that IVUS can be critical for understanding how to size vessels, so when we have therapies like a stent implant or drug-coated devices, they're not going to be nearly as effective if they're not sized appropriately"[3]

– Dr. Eric Secemsky, MD

Director of Vascular Intervention and Interventional Cardiologist at Beth Israel Deaconess Medical Center and assistant professor of medicine at Harvard Medical School

1 - TCT 2021, Eric A. Secemsky, MD
2 - https://www.dicardiology.com/content/ivus-improved-outcomes-largest-real-world-analysis-lower-extremity-peripheral-vascular, November 9, 2021
3 - https://evtoday.com/news/ivus-guidance-associated-with-improved-outcomes-in-lower-extremity-pvd-interventions-in-medicare-data-analysis

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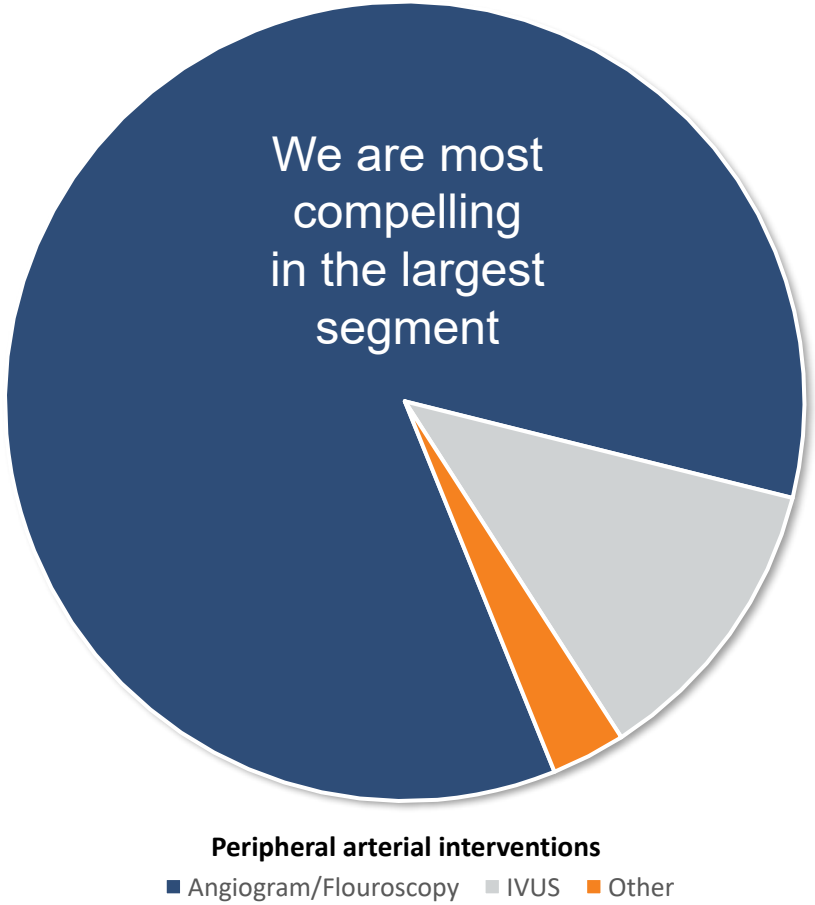
Our largest competitor is non-use

Peripheral Vascular / Coronary / Vessel sizing intra-procedure

- Angiogram/Flouroscopy – Real time 2D x-ray based, requires contrast media (expensive and toxic), limited resolution, chronically mis-sizes vessels, used for vessel sizing in an estimated 85% of procedures
- Phased Array (Digital) and Rotational IVUS – Philips and Boston Scientific. IVUS is approximately 11.7%[1] penetrated in arterial cases and 72.4%[1] in venous cases. Adds an average of 22 minutes[2] to the procedure.
- Optical Coherence Tomography (OCT) – Higher resolution than IVUS. Continues to require interpretation and added time. Requires saline flushing of blood in order to capture image. Limited market penetration. Excellent for research. **Coronary only.**
- Near infrared spectroscopy (NIRS) – Lipid composition detection. Unclear what clinical interventions could be applied with this information. **Coronary only.**

Not-competitive coronary modalities / Pre-treatment diagnostics

- Heartflow – Diagnostic CT based visualization of coronary arteries. Requires up to 5 hours to generate. Limited to resolution of CT.
- Cathworks – Diagnostic visualization from FFR and angiography. Limited to resolution of angiography.



1 – Opportunities to Improve Outcomes: IVUS, TCT 2021, Secemsky EA, et al.
2 – American Medical Association RBRVS Datamanager

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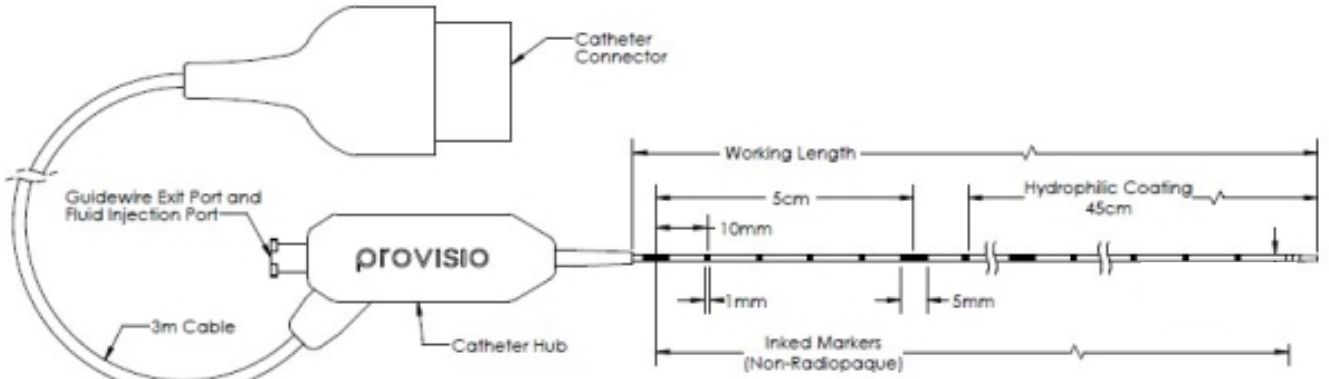
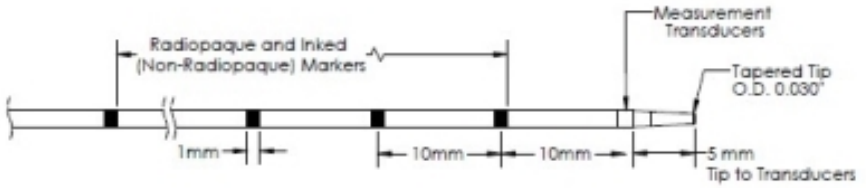
Provisio Medical SLT IVUS™ System

SLT IVUS™ P1 System

SLT IVUS™ Support Crossing Catheter





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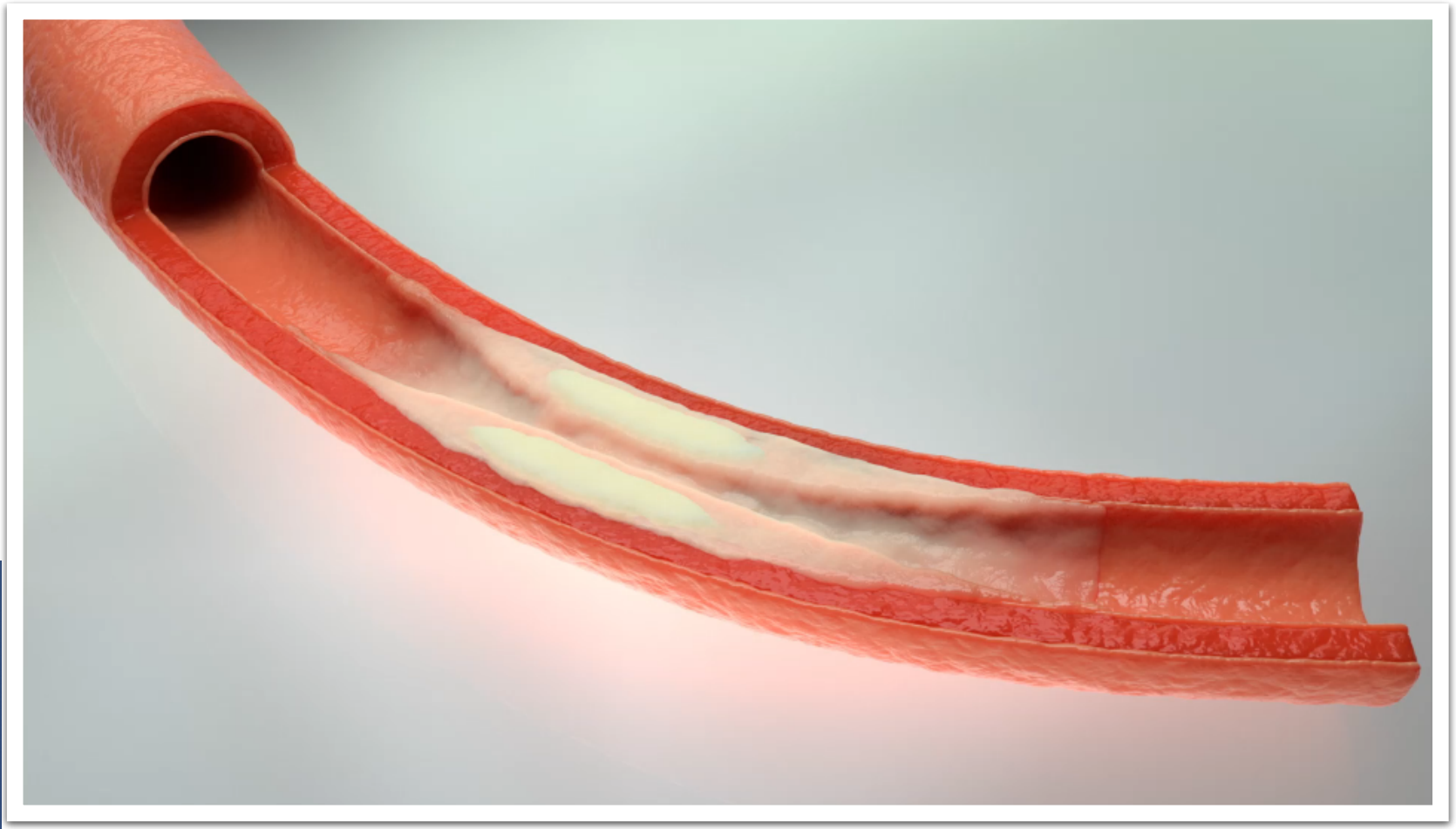
Indications For Use

- The Provisio SLT IVUS System is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature.
- The Provisio SLT IVUS System is designed for use as an adjunct to conventional angiographic procedures to evaluate the vessel lumen and provide dimensional measurements.
- The SLT IVUS Support Crossing Catheter also guides and supports a guidewire during access of the vasculature and provides a conduit for the delivery of saline solutions or radiopaque contrast agents.

Provisio Medical SLT IVUS™ System



Provisio Medical's devices are under development and are not available for investigational or commercial use

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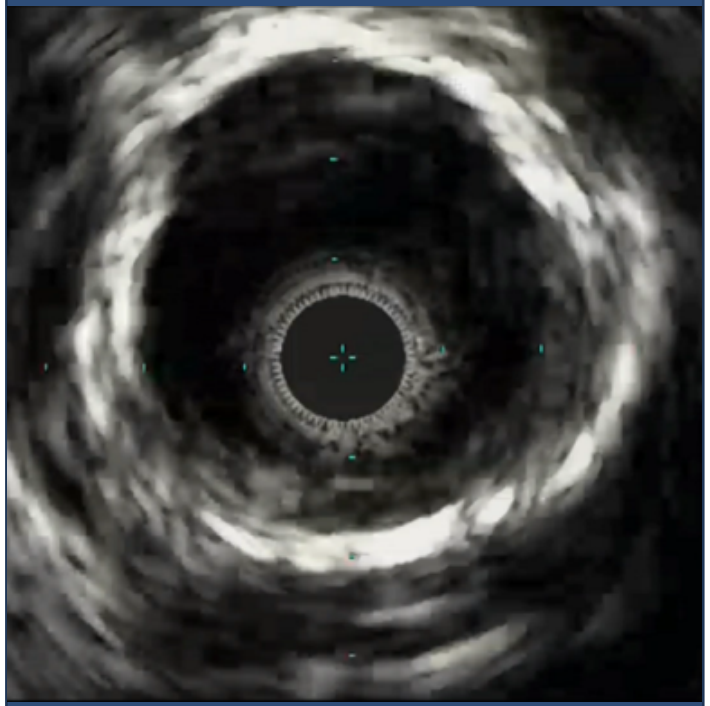
Accurate Vessel Sizing Matters….

Fluoroscopy / Angiogram

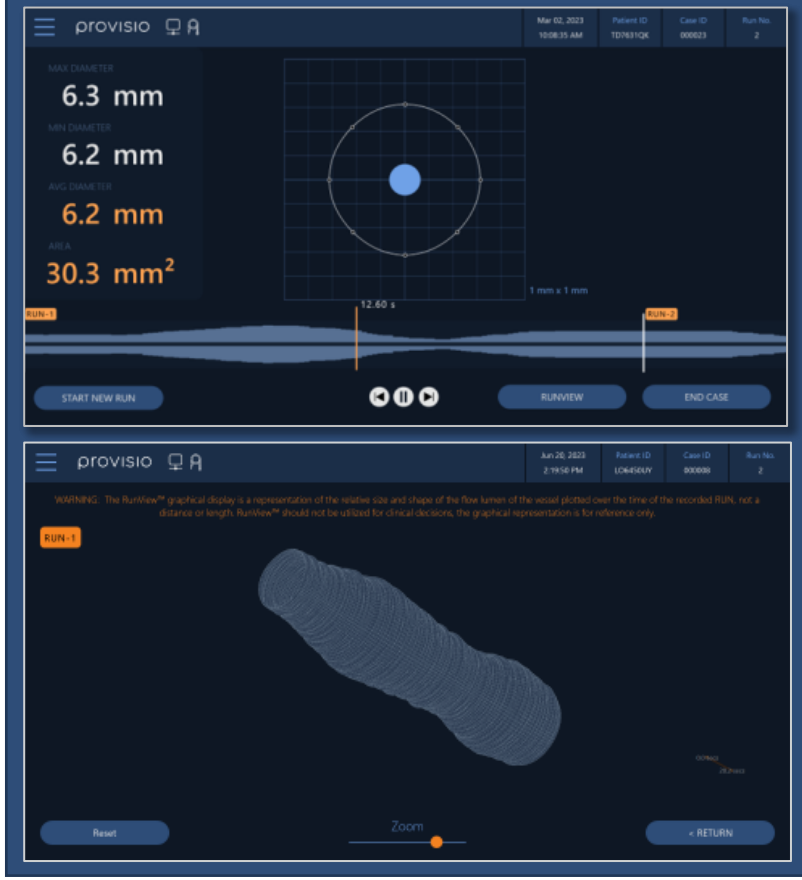
Exposes physician to radiation and patient to toxic injection of contrast media

Traditional IVUS



Difficult to use and interpret grayscale image, requires significant training and experience, adds catheter exchange and setup to workflow

Provisio Medical SLT IVUS™



SLT IVUS™ transducers are integrated into a Support Crossing Catheter

Activated with A-Mode Ultrasound

Provides automated answers without user input or interpretation

No additional procedure/change in workflow

SLT IVUS is integrated into catheters already used during the procedure

(Sample images from a below-the-knee artery)

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