

Measurement of Volumetric Blood Flow in Peripheral Vessels

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Peripheral Artery Disease / Chronic Limb Threatening Ischemia

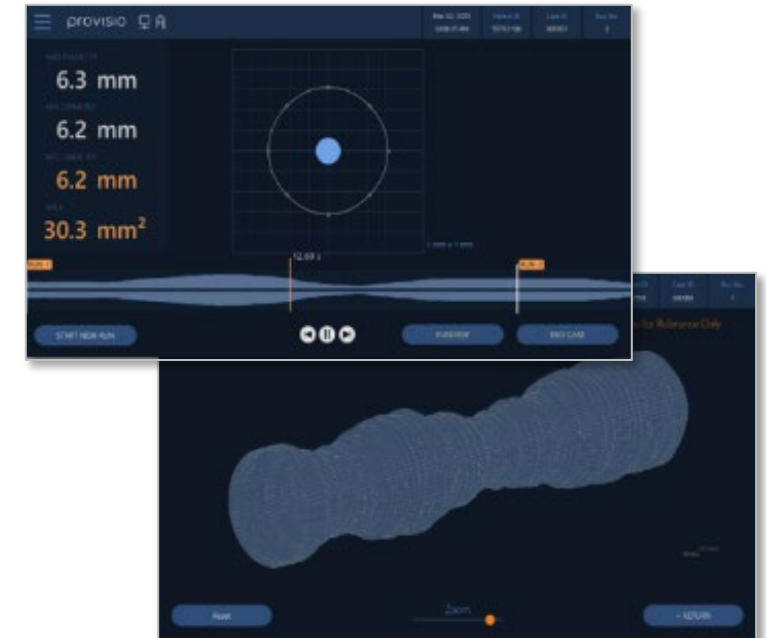
- **Peripheral artery disease (PAD)** is a prevalent atherosclerotic condition affecting over 200 million people globally
 - Causes arterial narrowing in the lower limbs that impairs blood flow and leads to tissue ischemia
 - Prevalence reaches nearly 30% in those over age 80
- **Chronic limb-threatening ischemia (CLTI)** is the most severe manifestation of PAD
 - Presents with ischemic rest pain, non-healing wounds, or gangrene
 - Requires urgent revascularization to prevent amputation
- Despite endovascular revascularization being the primary treatment, outcomes in CLTI remain poor:
 - 44% amputation-free survival at 36 months
 - Approximately 36% incidence of major limb events and all-cause mortality
- Although restoring blood flow is the core goal of treatment and the central feature of the disease, directly measuring volumetric blood flow in peripheral arteries during endovascular procedures has only recently become possible with Provisio Medical's SLT FLOW™ technology.

PAD and CLTI Current Limited Diagnostic Options

- Current diagnostic methods for PAD include:
 - angiography
 - ankle-brachial index (ABI)
 - toe-brachial index (TBI)
 - Doppler ultrasound
 - computed tomography angiography (CTA)
 - magnetic resonance angiography (MRA)
- Notable limitations
 - Angiography provides low-resolution anatomical visualization but lacks quantitative assessment of blood flow
 - ABI and TBI can yield falsely elevated readings in patients with diabetes or calcified vessels, while also failing to account for collateral circulation
 - Doppler ultrasound is operator-dependent and time-consuming
 - CTA and MRA involve radiation exposure, contrast agents with potential nephrotoxicity, and high costs, limiting their accessibility in routine clinical settings

Provisio Medical Sonic Lumen Tomography (SLT) Technology

- Utilizes intravascular ultrasound signals to perform multi-directional sonar measurements, not produce images
- Produces a virtual rendering of the cross-section of the vessel lumen along with luminal diameters and area measurements
- Unlike traditional IVUS systems that perform ultrasonography to produce an image that is then measured, SLT uses its sonar measurements to:
 - Graphically illustrate the vessel lumen and provide automated, real-time measurements without any interpretation of the physician
 - Uniquely enable SLT to provide luminal scans along the length of a vessel



Provisio® SLT IVUS FLOW™ System – SLT FLOW™

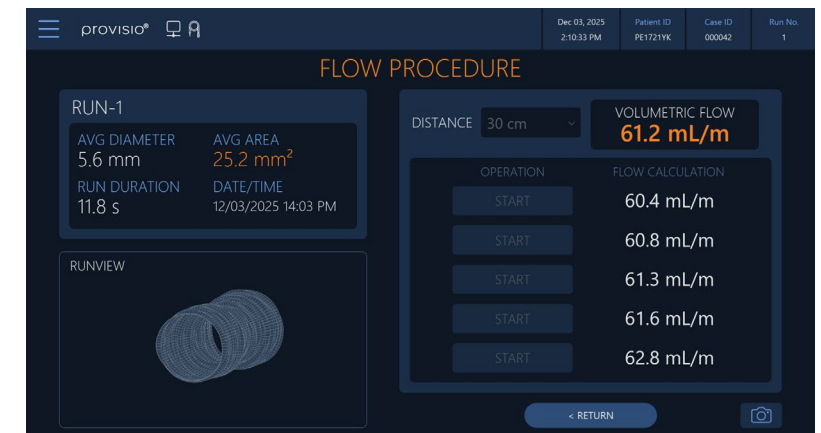
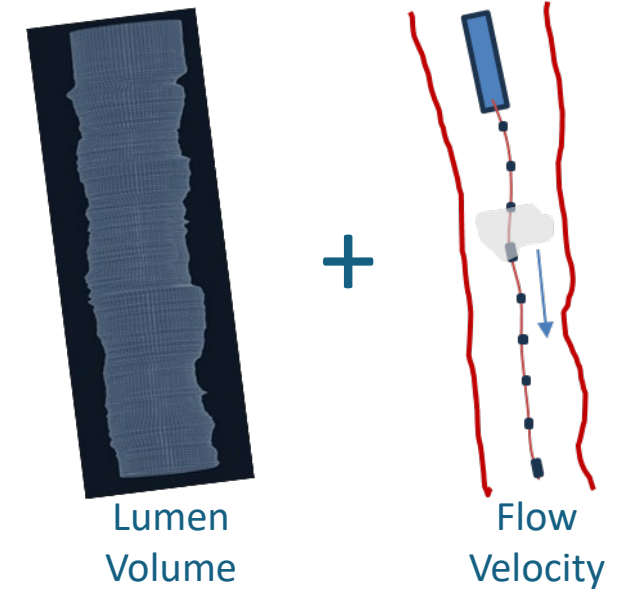
- Utilized during peripheral vascular procedures to provide real-time assessment of vessel flow lumen dimensions, while simultaneously functioning as a support crossing catheter
- Delivers numerical measurements of cross-sectional diameter and area, with the cross-section also represented graphically to visualize the flow lumen
- As the operator advances the catheter through the vessel, cross-sectional area data is continuously captured and displayed along a timeline
 - These sequential measurements can be compiled to generate an orthogonal graphical representation of the vessel lumen
 - Uniquely enables volumetric blood flow measurement within peripheral arteries



SLT FLOW™ Volume Measurement Procedure

To perform a volumetric blood flow measurement:

- Position catheter distal tip 20-30cm from the distal tip of the guide catheter or introducer
- Retract catheter over that same length as sequential lumen measurements are captured, facilitating a volume measurement over that length of vessel
- Reposition catheter tip to the same distal length
- Inject 3-5 boluses of 1-2cc of saline or contrast media, when instructed by the Provisio® SLT P1 System, through the guide catheter or introducer
- Volumetric blood flow is then calculated from the measured lumen volume and flow velocity and displayed on the Provisio® SLT P1 System



Medical Record Identification

Documentation of the SLT IVUS FLOW™ System volume measurement procedure will be included in the operative report

Procedure Terms:

- Endovascular volumetric flow measurement

- Flow volume measurement

- Peripheral vascular volumetric flow measurement

- SLT FLOW™

Device Identification:

- Provisio® SLT IVUS FLOW™ System

- including Provisio® SLT IVUS FLOW™ Support Crossing Catheter