CASE STUDY · MEDICAL DEVICE

Multi-Center Study of a Novel Vascular Device

Multi-center device study · Angiography, CT angiography, duplex ultrasound · Deployment success and surveillance

Challenge

Intrinsic Imaging supported this study's imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. A multi-center study of a novel vascular device required imaging assessment of deployment, device position and vessel response over follow-up. Vascular device surveillance combines angiographic measurements at the procedure with CT angiography and duplex ultrasound thereafter, and each modality measures vessel dimensions differently, which can produce apparent changes that reflect modality rather than device performance.

The sponsor needed consistent measurement conventions across modalities, a charter that defined deployment success and surveillance endpoints, and interventional radiologists with device experience to interpret findings such as apposition, endoleak-type phenomena, stenosis and thrombus. The interpretive problem was not simply whether a vessel measurement changed, but whether that change remained meaningful when the acquisition method changed. Deployment appearance, subsequent lumen caliber and flow findings address related but distinct aspects of device performance. A consistent framework was therefore important for separating anatomical observations from differences introduced by the modality used at a particular visit.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter defining acquisition for procedural angiography, CT angiography and duplex ultrasound, together with measurement conventions and endpoint definitions for deployment success, device position, vessel patency and device-related findings. Sites were qualified and trained on each modality with emphasis on reproducible duplex technique. Defining endpoints alongside acquisition requirements gives each measurement an explicit interpretive context rather than treating all vascular images as interchangeable evidence. In particular, reproducible duplex acquisition matters because a flow assessment and a reconstructed anatomical measurement do not describe precisely the same property. Their relationship must be understood within the documented conventions before either is interpreted as longitudinal change.

Board-certified interventional radiologists performed blinded reads of procedural and follow-up imaging under the charter, including 3D reconstruction of CT angiography for device and vessel measurement. Primary endpoint assessments were double-read with adjudication. Independent assessment and adjudication address reader variability without implying that agreement establishes biological truth. Reconstruction provides spatial context for device and vessel relationships, while the charter determines how that context contributes to an endpoint. These complementary elements are especially relevant when an apparent abnormality could reflect device configuration, vessel anatomy or the plane selected for measurement.

Image transfer, quality control and processing were centralized so that each patient's multimodal record was complete and co-registered before reading, and the longitudinal dataset was delivered with modality identified for every measurement. Keeping the modality attached to each measurement preserves information needed to interpret the longitudinal record. Co-registration supports anatomical comparison, but does not make measurements from different techniques inherently equivalent. Likewise, a complete multimodal record provides a stronger basis for review than isolated examinations, while remaining subject to the visibility and measurement limitations of its constituent images at each assessment.

Intrinsic Imaging’s Results

- Approximately 190 patients at 16 sites assessed across angiography, CT angiography and duplex ultrasound
- Cross-modality measurement conventions applied uniformly with modality recorded for every vessel measurement
- Primary endpoint reader agreement above 90% with adjudication documented for all discordant assessments
- 3D CT angiography reconstruction used for device and vessel measurement at every follow-up with CT

Read the full study online: https://intrinsicimaging.com/case-studies/device-vascular-multicenter

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 50 board-certified and fellowship-trained physicians, Intrinsic Imaging’s team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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