CASE STUDY · MEDICAL DEVICE

Four-Year Venous Stent Trial for Symptomatic Venous Outflow Obstruction

4,000+ venogram, x-ray and ultrasound exams · Venography, duplex ultrasound, radiographs · Primary patency and stent integrity

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 four-year clinical trial of an interventional device for symptomatic venous outflow obstruction required radiological review of more than 4,000 venograms, radiographs and ultrasound examinations. Venous patency assessment combines duplex ultrasound flow and diameter measurements with venographic stenosis grading, and the two modalities can disagree; stent integrity and migration must be assessed on radiographs against a post-deployment baseline.

Across a long follow-up, the sponsor needed consistent patency definitions, consistent measurement across readers and years, and a process that kept the longitudinal record intact as patients moved through annual follow-up visits. Longitudinal venous assessment requires continuity of meaning as well as continuity of follow-up. A patent lumen, a flow abnormality and an intact stent describe different aspects of the treated segment. Discordance between these observations therefore requires interpretation within the endpoint definitions rather than an assumption that any abnormal examination represents the same type of device failure.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter with definitions for primary, assisted primary and secondary patency, stenosis thresholds on venography, duplex flow and diameter criteria, and radiographic stent integrity assessment. Sites were qualified and trained on acquisition across all three modalities, including standardized duplex protocols for the iliofemoral segments. Distinguishing patency categories is important because the categories represent different clinical courses rather than interchangeable labels for an open vessel. Modality-specific criteria provide a basis for interpreting venographic anatomy alongside duplex findings. Radiographic integrity assessment addresses the implant itself, preserving the distinction between structural device observations and the vascular status that the device is intended to maintain.

Full-time interventional radiologists performed blinded reads of each examination against the patient's baseline, with the charter governing how discordant duplex and venographic findings would be reconciled. A second reader reviewed every examination with a patency failure or integrity finding, and adjudication resolved discordance. Baseline comparison provides a consistent reference for longitudinal assessment, while interpretation of migration or structural change depends on the available examinations and the definitions specified in the imaging charter. Focused additional review of failures and integrity findings places interpretive scrutiny on observations with direct endpoint significance. Adjudication resolves the classification under the charter, but does not imply that venographic and duplex evidence must become physiologically identical.

Centralized image transfer, quality control and processing linked each patient's serial examinations, and project managers tracked the four-year follow-up schedule against protocol windows. Linking serial examinations preserves the sequence needed to distinguish a newly observed finding from an established appearance. Schedule tracking supports that sequence, although attendance at a visit and interpretability of an examination remain distinct considerations. The reported follow-up compliance consequently describes retention of scheduled imaging evidence, not proof that later unobserved outcomes would resemble those already documented in the available record.

Intrinsic Imaging’s Results

- More than 4,000 venographic, radiographic and ultrasound examinations reviewed over four years by a dedicated interventional radiology team
- Patency definitions and stenosis thresholds applied uniformly across 28 sites with reader agreement on patency status above 90%
- Every patency failure and stent integrity finding double-read and adjudicated with documented rationale
- Follow-up imaging compliance maintained above 88% through the 36-month visit via active schedule tracking

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Read the full study online: https://intrinsicimaging.com/case-studies/device-venous-outflow

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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