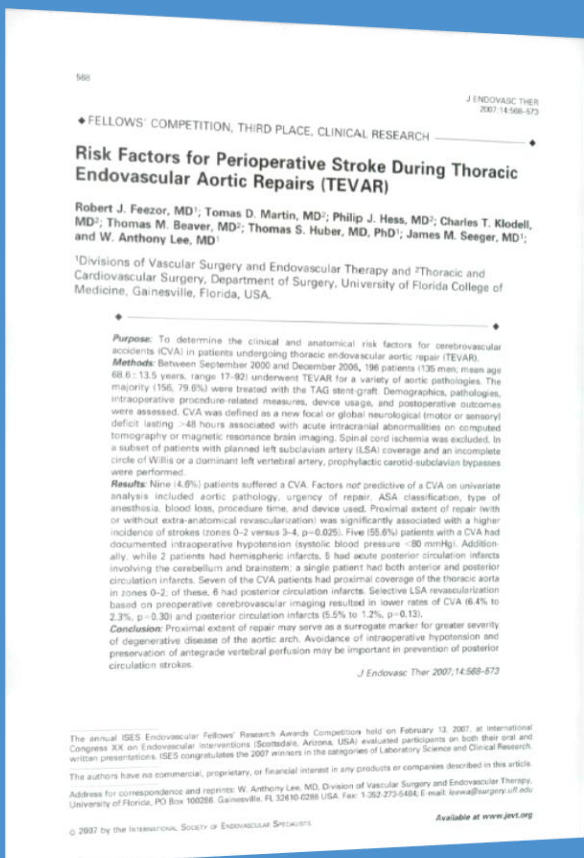
Development of a Branched LSA Endograft
&
Ascending Aorta Endograft

Frank R. Arko III, MD
Sanger Heart & Vascular Institute
Carolinas Medical Center
Charlotte, North Carolina, USA

20TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
in aortic endografting 2016
May 20 & 21 - LILLE - FRANCE

Disclosures

Proximal Landing Zone in TEVAR is Crucial



568

J ENDOVASC THER
2007;14:568–573

◆ FELLOWS' COMPETITION, THIRD PLACE, CLINICAL RESEARCH

Risk Factors for Perioperative Stroke During Thoracic Endovascular Aortic Repairs (TEVAR)

Robert J. Feezor, MD[1]; Tomas D. Martin, MD[2]; Philip J. Hess, MD[2]; Charles T. Klodell, MD[2]; Thomas M. Beaver, MD[2]; Thomas S. Huber, MD, PhD[1]; James M. Seeger, MD[1]; and W. Anthony Lee, MD[1]

[1]Divisions of Vascular Surgery and Endovascular Therapy and [2]Thoracic and Cardiovascular Surgery, Department of Surgery, University of Florida College of Medicine, Gainesville, Florida, USA.

Purpose: To determine the clinical and anatomical risk factors for cerebrovascular accidents (CVA) in patients undergoing thoracic endovascular aortic repair (TEVAR).
Methods: Between September 2000 and December 2006, 196 patients (135 men; mean age 68.6±13.5 years, range 17–92) underwent TEVAR for a variety of aortic pathologies. The majority (156, 79.6%) were treated with the TAG stent-graft. Demographics, pathologies, intraoperative procedure-related measures, device usage, and postoperative outcomes were assessed. CVA was defined as a new focal or global neurological (motor or sensory) deficit lasting >48 hours associated with acute intracranial abnormalities on computed tomography or magnetic resonance brain imaging. Spinal cord ischemia was excluded. In a subset of patients with planned left subclavian artery (LSA) coverage and an incomplete circle of Willis or a dominant left vertebral artery, prophylactic carotid-subclavian bypasses were performed.
Results: Nine (4.6%) patients suffered a CVA. Factors *not* predictive of a CVA on univariate analysis included aortic pathology, urgency of repair, ASA classification, type of anesthesia, blood loss, procedure time, and device used. Proximal extent of repair (with or without extra-anatomical revascularization) was significantly associated with a higher incidence of strokes (zones 0–2 versus 3–4, p=0.025). Five (55.6%) patients with a CVA had documented intraoperative hypotension (systolic blood pressure <80 mmHg). Additionally, while 2 patients had hemispheric infarcts, 5 had acute posterior circulation infarcts involving the cerebellum and brainstem; a single patient had both anterior and posterior circulation infarcts. Seven of the CVA patients had proximal coverage of the thoracic aorta in zones 0–2; of these, 6 had posterior circulation infarcts. Selective LSA revascularization based on preoperative cerebrovascular imaging resulted in lower rates of CVA (6.4% to 2.3%, p=0.30) and posterior circulation infarcts (5.5% to 1.2%, p=0.13).
Conclusion: Proximal extent of repair may serve as a surrogate marker for greater severity of degenerative disease of the aortic arch. Avoidance of intraoperative hypotension and preservation of antegrade vertebral perfusion may be important in prevention of posterior circulation strokes.

J Endovasc Ther 2007;14:568–573

The annual ISES Endovascular Fellows' Research Awards Competition held on February 13, 2007, at International Congress XX on Endovascular Interventions (Scottsdale, Arizona, USA) evaluated participants on both their oral and written presentations. ISES congratulates the 2007 winners in the categories of Laboratory Science and Clinical Research.

The authors have no commercial, proprietary, or financial interest in any products or companies described in this article.

Address for correspondence and reprints: W. Anthony Lee, MD, Division of Vascular Surgery and Endovascular Therapy, University of Florida, PO Box 100286, Gainesville, FL 32610-0286 USA. Fax: 1-352-273-5484; E-mail: *leewa@surgery.ufl.edu*

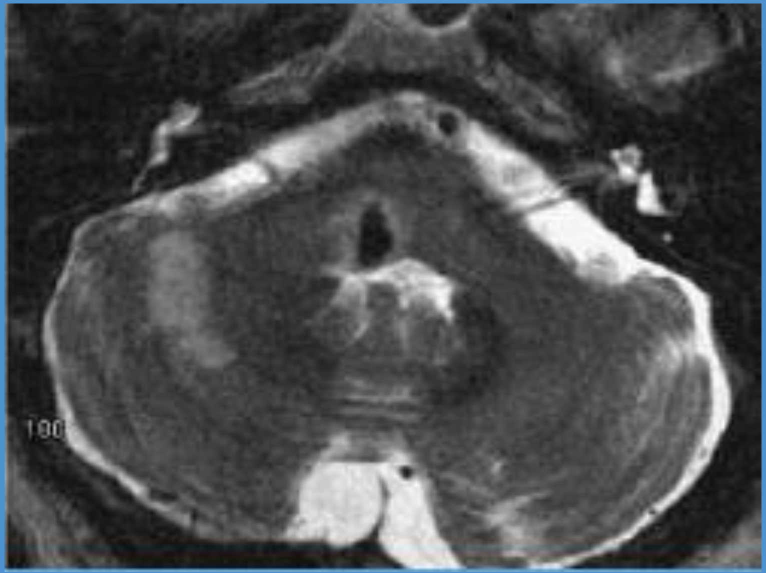
Available at www.jevt.org

- **Up to 40% of patients undergoing TEVAR have planned coverage of LSA to achieve an adequate proximal seal**
- **Surgeons revascularize the LSA either:**
  - **Routinely**
  - **Selectively**
  - **Not unless symptomatic**

JEVT 2007;14:568-73

Potential Consequences of LSA Coverage without Revascularization

- Upper limb ischemia
- Subclavian steal syndrome
- Type II endoleak
- Spinal cord ischemia
- Stroke (ant. & post. circulation)

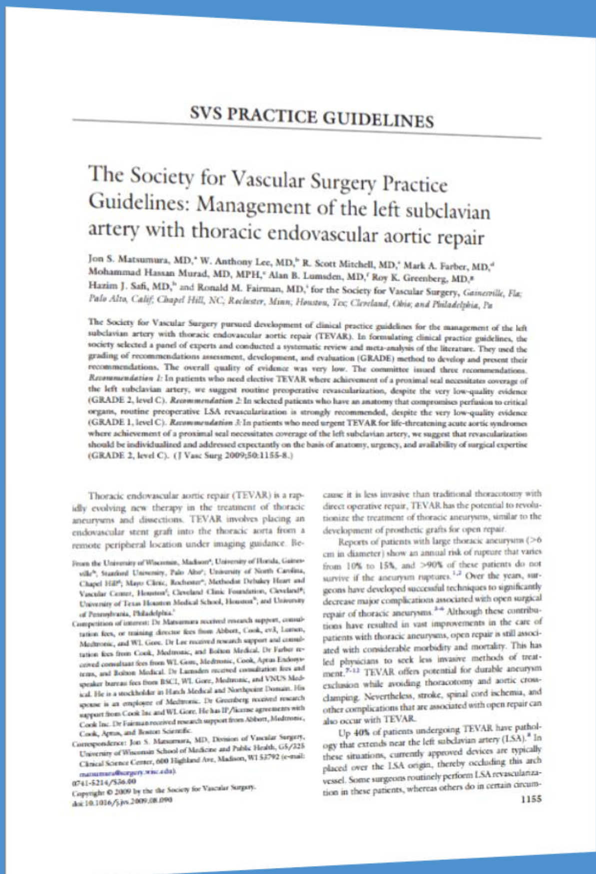


Coverage of LSA without revascularization is the single most important predictor of post-TEVAR stroke[1]

(OR, 3.8; 95% CI, 1.8-7.8; p<0.001)

[1] *J Vasc Surg 2014;60:1491-8*

SVS Guideline Recommendations on Management of LSA


SVS PRACTICE GUIDELINES

The Society for Vascular Surgery Practice Guidelines: Management of the left subclavian artery with thoracic endovascular aortic repair

Jon S. Matsumura, MD,[a] W. Anthony Lee, MD,[b] R. Scott Mitchell, MD,[c] Mark A. Farber, MD,[d] Mohammad Hassan Murad, MD, MPH,[e] Alan B. Lumsden, MD,[f] Roy K. Greenberg, MD,[g] Hazim J. Safi, MD,[h] and Ronald M. Fairman, MD,[i] for the Society for Vascular Surgery, *Gainesville, Fla; Palo Alto, Calif; Chapel Hill, NC; Rochester, Minn; Houston, Tex; Cleveland, Ohio; and Philadelphia, Pa*

The Society for Vascular Surgery pursued development of clinical practice guidelines for the management of the left subclavian artery with thoracic endovascular aortic repair (TEVAR). In formulating clinical practice guidelines, the society selected a panel of experts and conducted a systematic review and meta-analysis of the literature. They used the grading of recommendations assessment, development, and evaluation (GRADE) method to develop and present their recommendations. The overall quality of evidence was very low. The committee issued three recommendations. *Recommendation 1:* In patients who need elective TEVAR where achievement of a proximal seal necessitates coverage of the left subclavian artery, we suggest routine preoperative revascularization, despite the very low-quality evidence (GRADE 2, level C). *Recommendation 2:* In selected patients who have an anatomy that compromises perfusion to critical organs, routine preoperative LSA revascularization is strongly recommended, despite the very low-quality evidence (GRADE 1, level C). *Recommendation 3:* In patients who need urgent TEVAR for life-threatening acute aortic syndromes where achievement of a proximal seal necessitates coverage of the left subclavian artery, we suggest that revascularization should be individualized and addressed expectantly on the basis of anatomy, urgency, and availability of surgical expertise (GRADE 2, level C). (J Vasc Surg 2009;50:1155-8.)

Thoracic endovascular aortic repair (TEVAR) is a rapidly evolving new therapy in the treatment of thoracic aneurysms and dissections. TEVAR involves placing an endovascular stent graft into the thoracic aorta from a remote peripheral location under imaging guidance. Because it is less invasive than traditional thoracotomy with direct operative repair, TEVAR has the potential to revolutionize the treatment of thoracic aneurysms, similar to the development of prosthetic grafts for open repair.

Reports of patients with large thoracic aneurysms (>6 cm in diameter) show an annual risk of rupture that varies from 10% to 15%, and >90% of these patients do not survive if the aneurysm ruptures.[1,2] Over the years, surgeons have developed successful techniques to significantly decrease major complications associated with open surgical repair of thoracic aneurysms.[3-6] Although these contributions have resulted in vast improvements in the care of patients with thoracic aneurysms, open repair is still associated with considerable morbidity and mortality. This has led physicians to seek less invasive methods of treatment.[7-12] TEVAR offers potential for durable aneurysm exclusion while avoiding thoracotomy and aortic cross-clamping. Nevertheless, stroke, spinal cord ischemia, and other complications that are associated with open repair can also occur with TEVAR.

Up 40% of patients undergoing TEVAR have pathology that extends near the left subclavian artery (LSA).[8] In these situations, currently approved devices are typically placed over the LSA origin, thereby occluding this arch vessel. Some surgeons routinely perform LSA revascularization in these patients, whereas others do in certain circum-

From the University of Wisconsin, Madison[a]; University of Florida, Gainesville[b]; Stanford University, Palo Alto[c]; University of North Carolina, Chapel Hill[d]; Mayo Clinic, Rochester[e]; Methodist DeBakey Heart and Vascular Center, Houston[f]; Cleveland Clinic Foundation, Cleveland[g]; University of Texas Houston Medical School, Houston[h]; and University of Pennsylvania, Philadelphia.[i]

Competition of interest: Dr Matsumura received research support, consultation fees, or training director fees from Abbott, Cook, ev3, Lumen, Medtronic, and WL Gore. Dr Lee received research support and consultation fees from Cook, Medtronic, and Bolton Medical. Dr Farber received consultant fees from WL Gore, Medtronic, Cook, Aptus Endosystems, and Bolton Medical. Dr Lumsden received consultation fees and speaker bureau fees from BSCI, WL Gore, Medtronic, and VNUS Medical. He is a stockholder in Hatch Medical and Northpoint Domain. His spouse is an employee of Medtronic. Dr Greenberg received research support from Cook Inc and WL Gore. He has IP/license agreements with Cook Inc. Dr Fairman received research support from Abbott, Medtronic, Cook, Aptus, and Boston Scientific.

Correspondence: Jon S. Matsumura, MD, Division of Vascular Surgery, University of Wisconsin School of Medicine and Public Health, G5/325 Clinical Science Center, 600 Highland Ave, Madison, WI 53792 (e-mail: matsumura@surgery.wisc.edu).

0741-5214/$36.00

doi:10.1016/j.jvs.2009.08.090

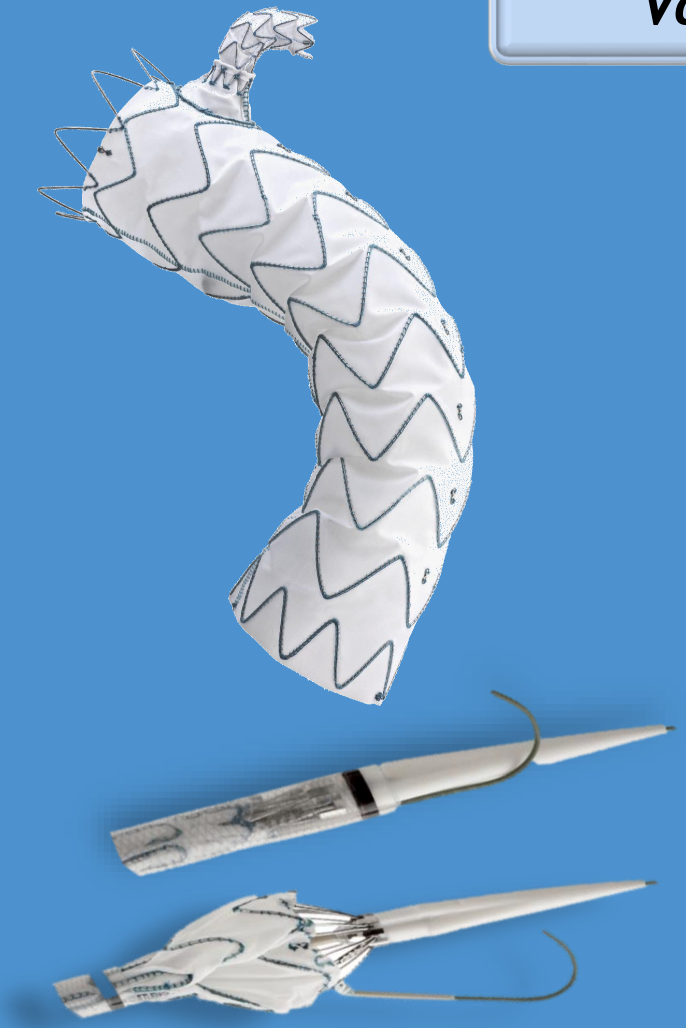
1155

- Based on systematic review of the literature, SVS recommends:
  - Routine revascularization
    - In elective cases
    - In those with compromised perfusion to critical organs
  - Selective revascularization
    - After urgent scenarios

J Vasc Surg 2009;50:1155-8

Endovascular Revascularization of LSA

Valiant Mona LSA



- Modified Valiant Captivia
- Flexible LSA Cuff
- Dedicated Branch Stent Graft
- Dual Wire System
  - Pre-cannulated LSA Cuff
  - Snaring of LSA wire

CAUTION: Investigational device, limited by law (US) to investigational use only.

Emergency and Compassionate Use Cases

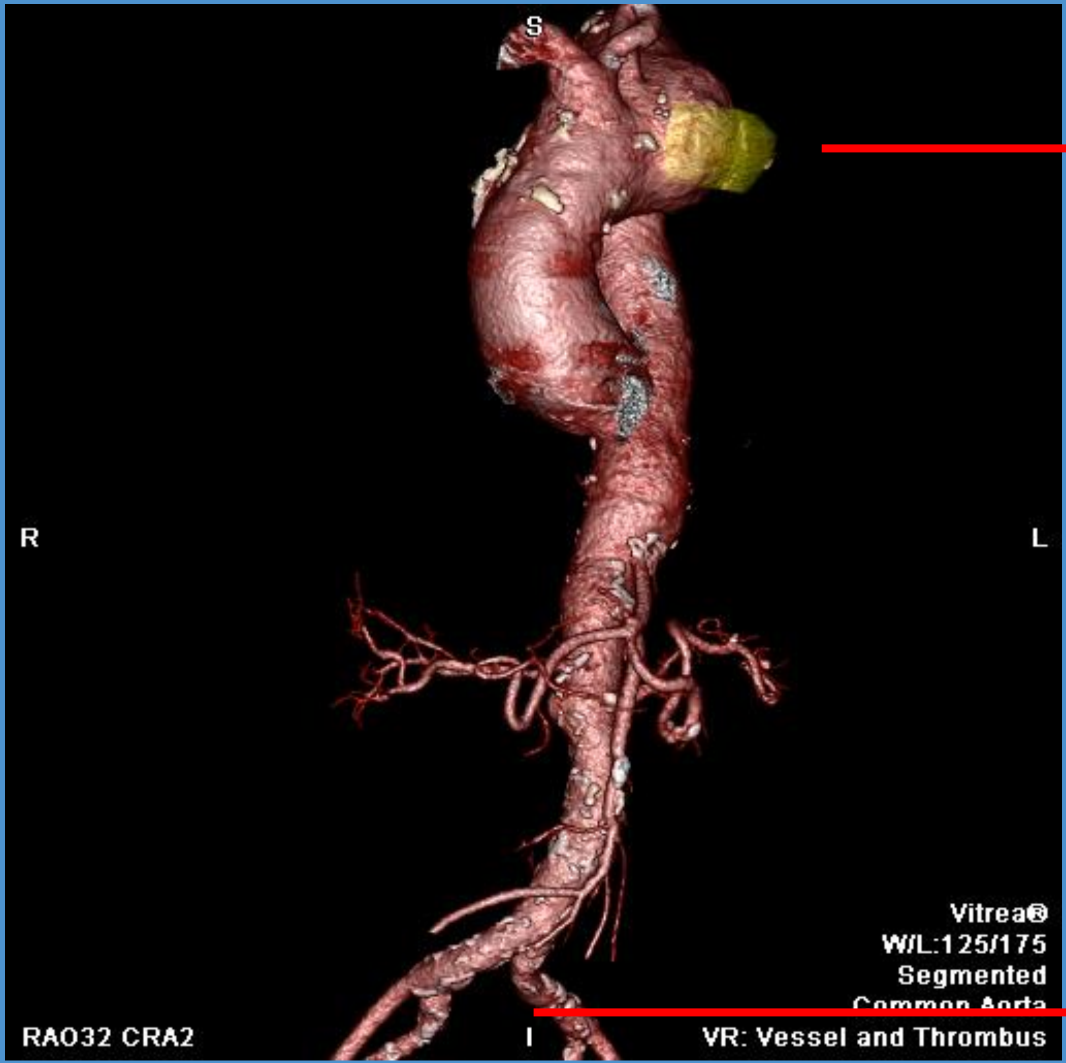
Sanger Heart and Vascular Institute
Carolinas Medical Center

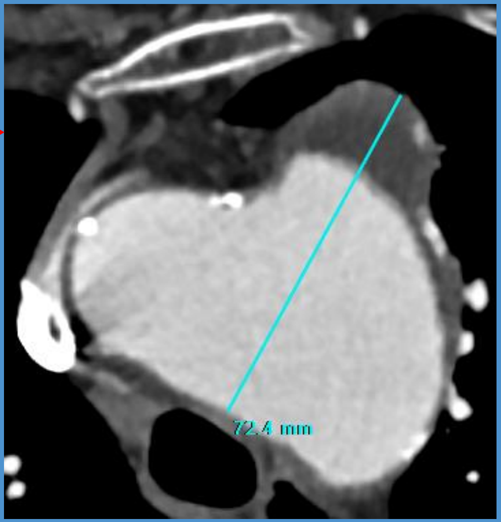
Emergency Use Case

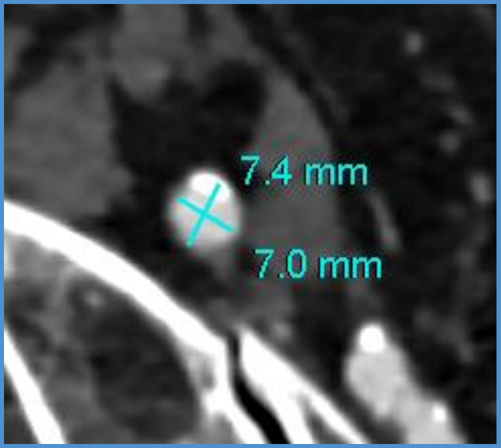
- 84 y/o female with transverse arch aneurysm
- Conservatively managed for 2 years post-diagnosis
- Presented symptomatic with worsening upper back/scapula pain
- CTA indicated rapidly expanding TAA with asymmetric expansion of anterior wall
- Bovine arch with patent LSA
- Marginal access vessels (7.0 – 7.4mm)

Initial CTA

3D Reconstruction

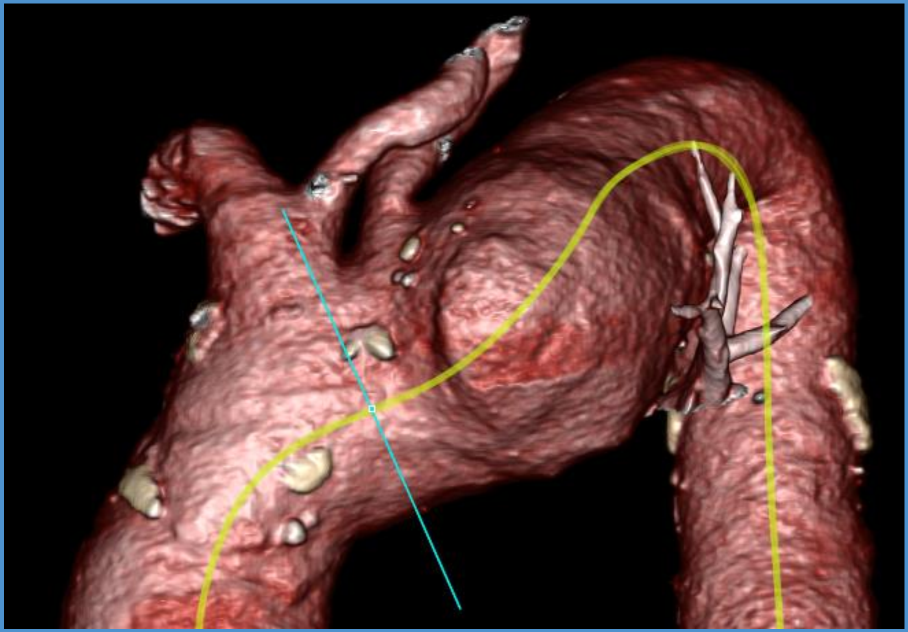




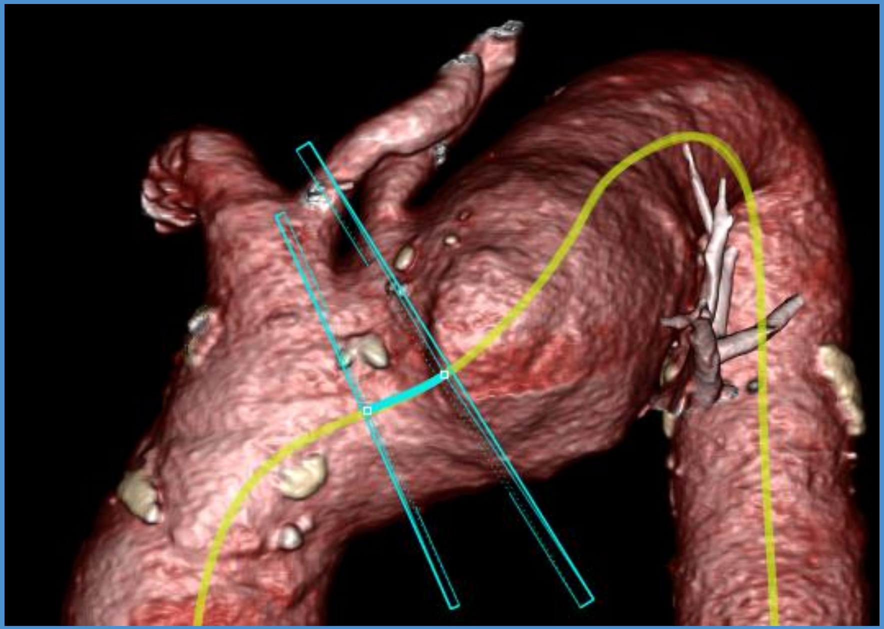


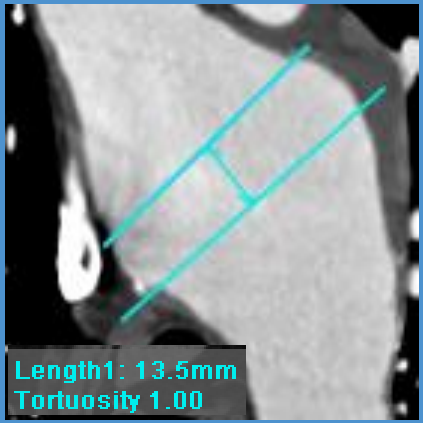
Proximal Target Landing Zone

Diameter – 40mm



Length – 13.5mm



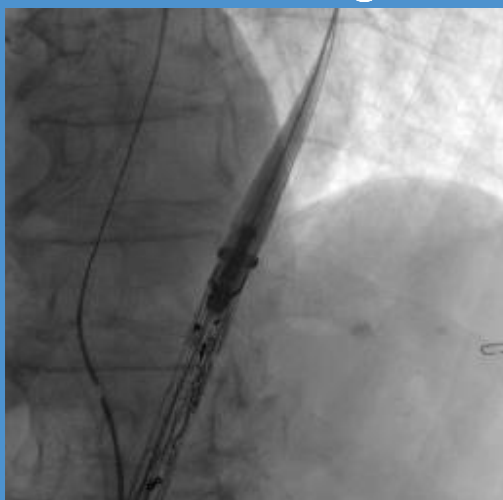


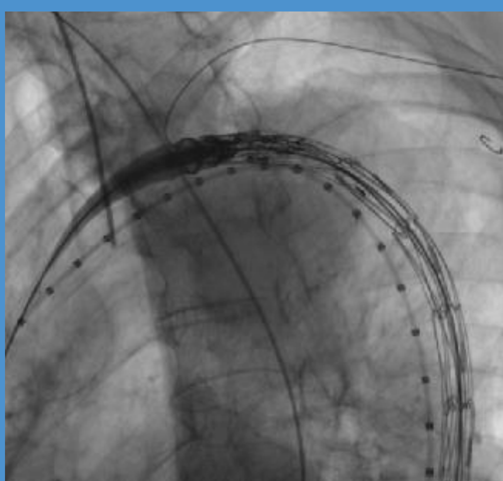
Addressing Access

- A right-sided retroperitoneal exposure was performed in standard fashion
- A 10x30 Dacron was sewn onto the right mid-common iliac to ensure safe delivery and removal of the delivery system (25F)

Graft Orientation

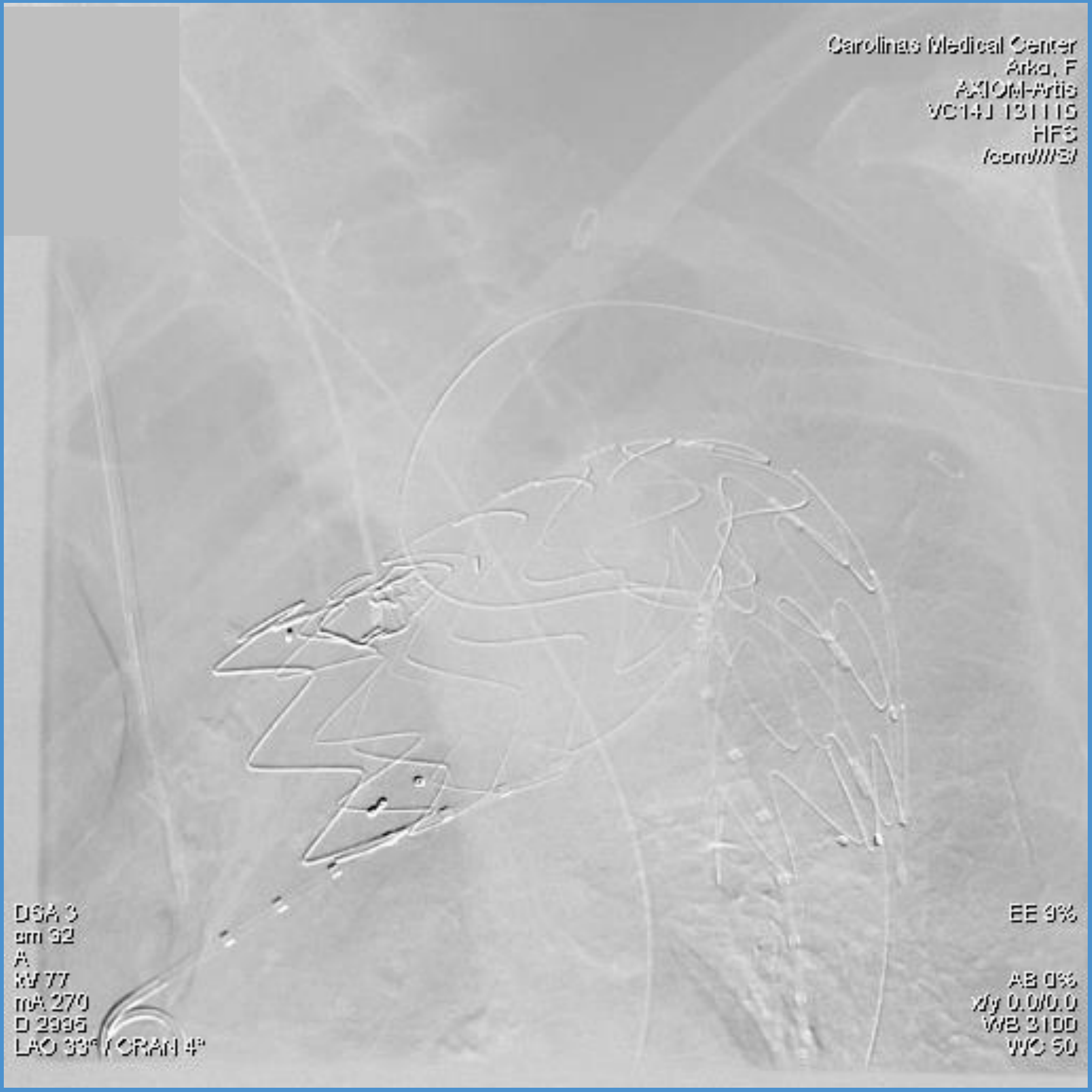
Snaring and Positioning





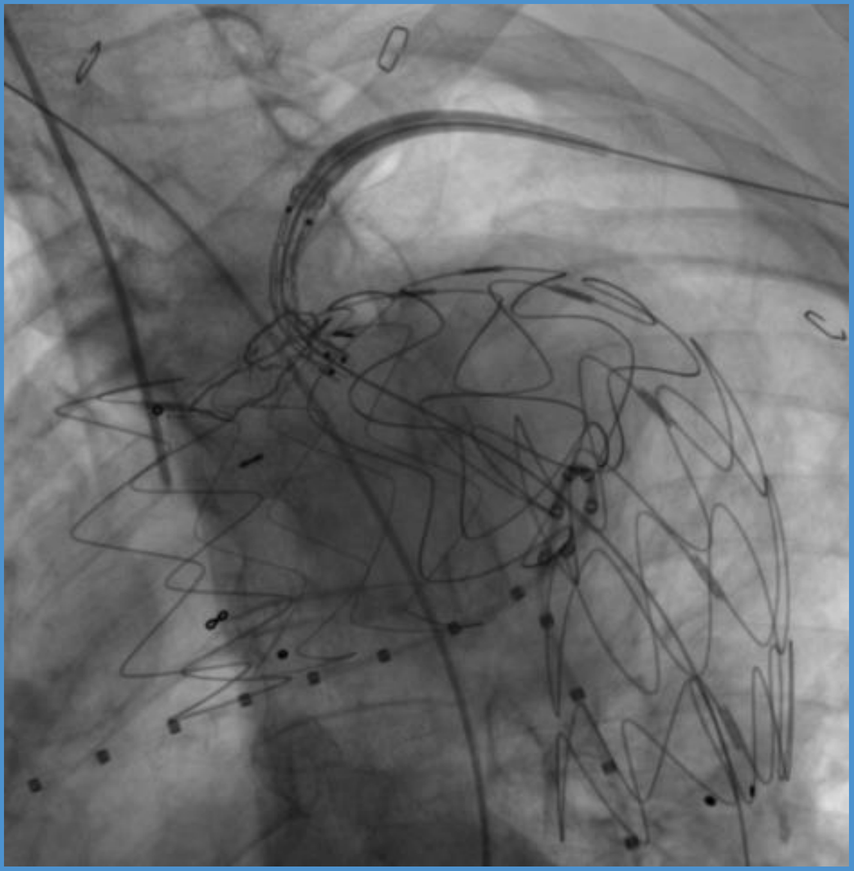
Angiogram

Deployment of 46 x 46 x 150 Valiant Mona LSA

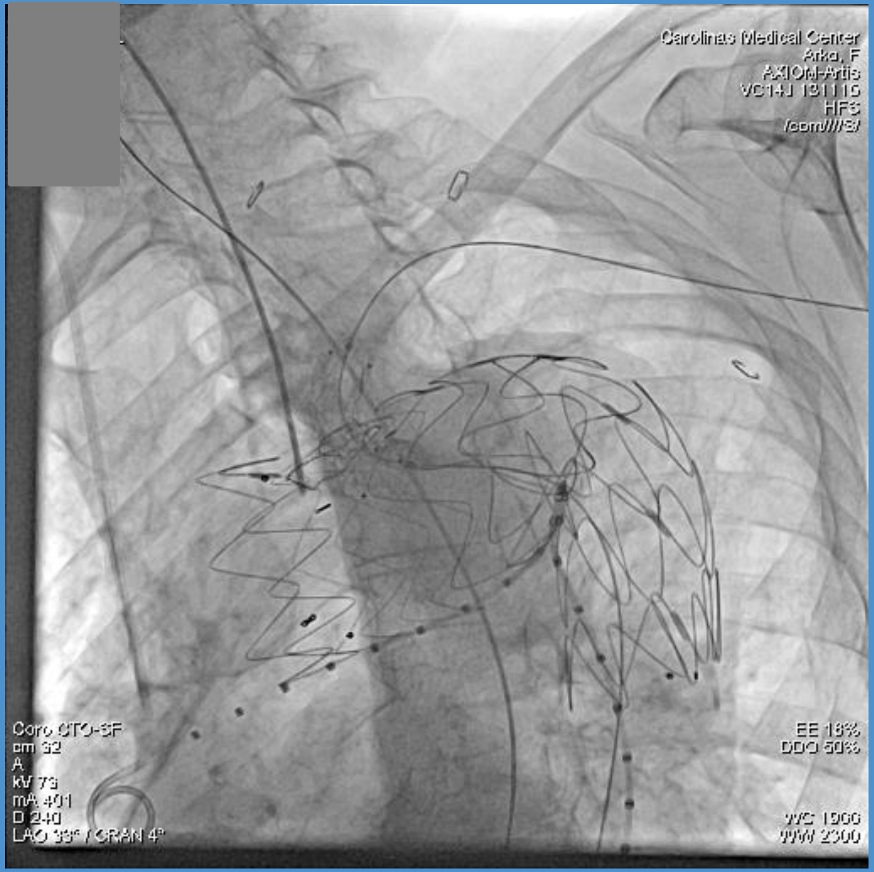


Placement of LSA Branch

Positioning of 10x40 LSA Branch Graft



Ballooning of 10x40 LSA Branch Graft



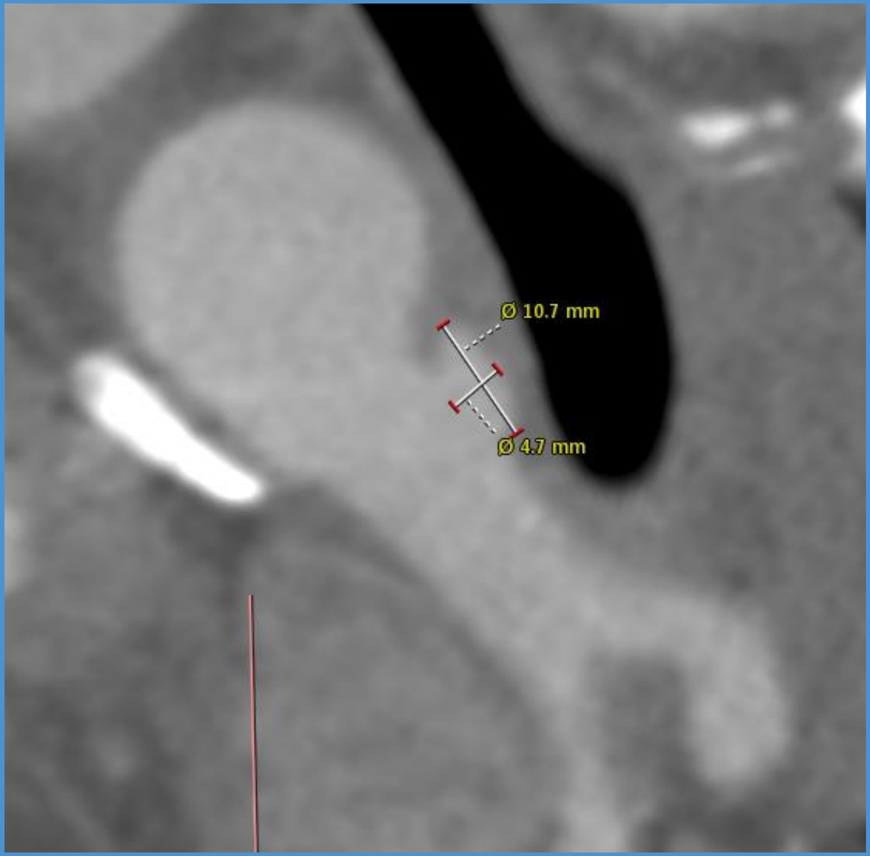
Final Angiogram

Compassionate Use Case

- 61 y/o female with traumatic pseudoaneurysm at base of Innominate post-MVA
- Poly-trauma:
    - Small left pneumothorax
    - Multiple cervical fractures
    - Bilateral subdural hematoma
    - Subarachnoid hemorrhage
    - C5/C6 cord injury resulting in bilateral lower extremity paralysis

Device Plan: 30x30x150 MSG with 14mm BSG

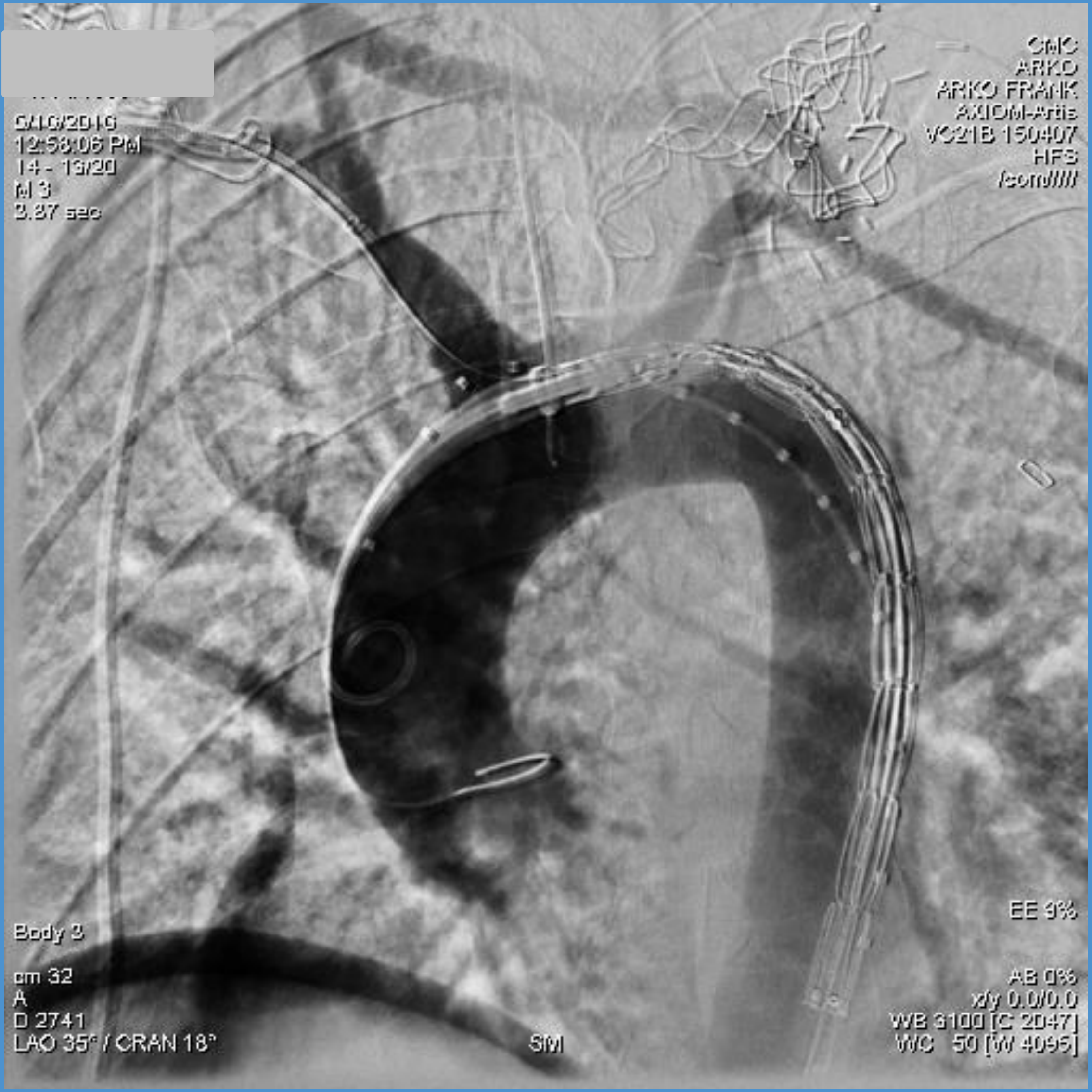
Initial CTA & 3D Rendering



Initial Angiogram

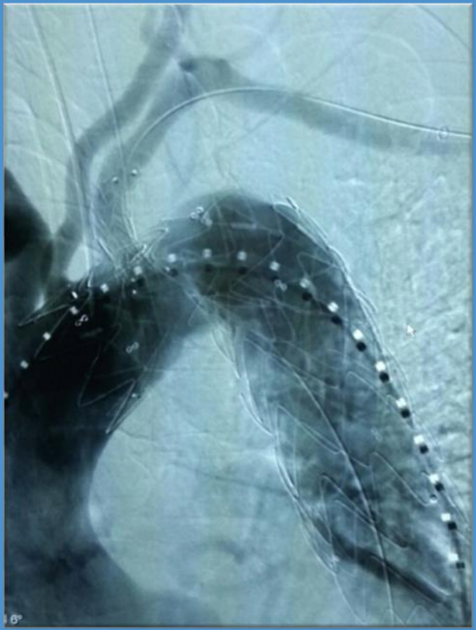
Positioning/Snaring of Wires for Graft Orientation

Confirmation of Alignment



Final Angiogram

Current Status with Valiant Mona LSA



Feasibility Study

- 7 sites in the USA and 24 additional patients
  - 15 patients currently enrolled

- Indication expansion received
  - Chronic Type B Aortic Dissection
    - 20 additional patients
    - 3 additional sites

Development of an Ascending Aorta Endograft

20TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
in aortic endografting 2016
May 20 & 21 - LILLE - FRANCE

Ascending Aortic TEVAR
PSIDE Feasibility Study

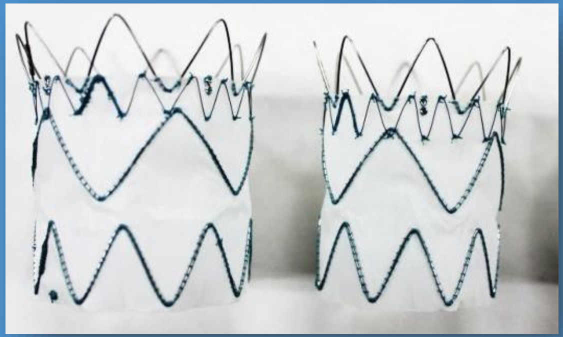
Evaluate Valiant thoracic endografts for treatment of ascending thoracic lesions with preserved "tubular" aortic anatomy (non-aneurysmal)

- **deployment accuracy**
- **stability of device in ascending aorta**
- **assess aortic remodeling**

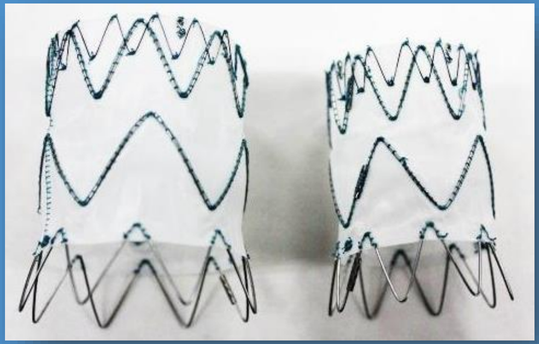
*CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.

Valiant Ascending is a modified Valiant Thoracic Stent Graft with Captivia Delivery System

Freeflo



Closed Web



*CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.

Valiant Ascending

PS-IDE Indications

- **Type A Aortic Dissection**
- **Retrograde Type A Aortic Dissection**
- **Intramural hematoma, Penetrating Athero Ulcer**
- **Pseudoaneurysm – between Sinus of Valsalva and Innominate orifice (with no involvement of the aortic valve)**
- **Proximal and Distal Landing Zones between 28-44 mm diameter**
- **Non-surgical or Very High-Risk Surgical Candidate**

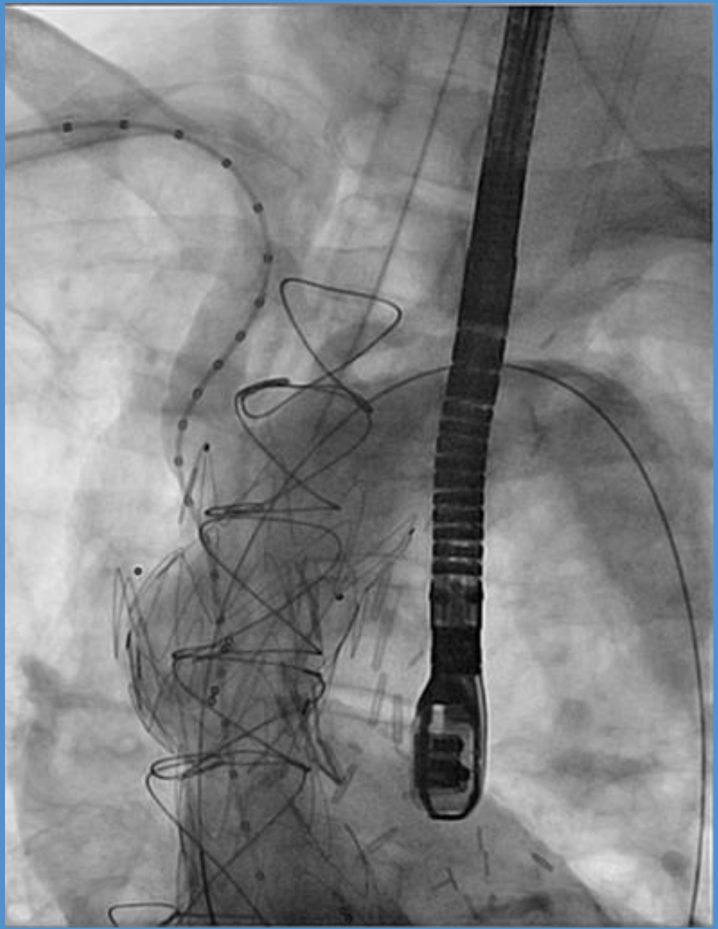
Valiant Ascending

PS-IDE Contra-Indications

- **Type A Dissection with Aortic Valve/Root Involvement**
- **Diffuse Ascending Aneurysm**
- **Annulo-Aortic Ectasia**
- **Pregnant or Pediatric Patients**
- **Infections, Allergies, No Consent**
- **Expected Survival Less Than 1 Year**

TEVAR for Ascending Aorta: Technical Considerations

- Hemodynamics, aortic regurg, coronary anatomy including CABG
- Access evaluation, transapical?
- Radial/brachial/carotid access
- Transfemoral RV pacing
- TEE, IVUS, Angio, CTA
- Bailout maneuvers
- HLM in standby
- Parallax and deployment accuracy

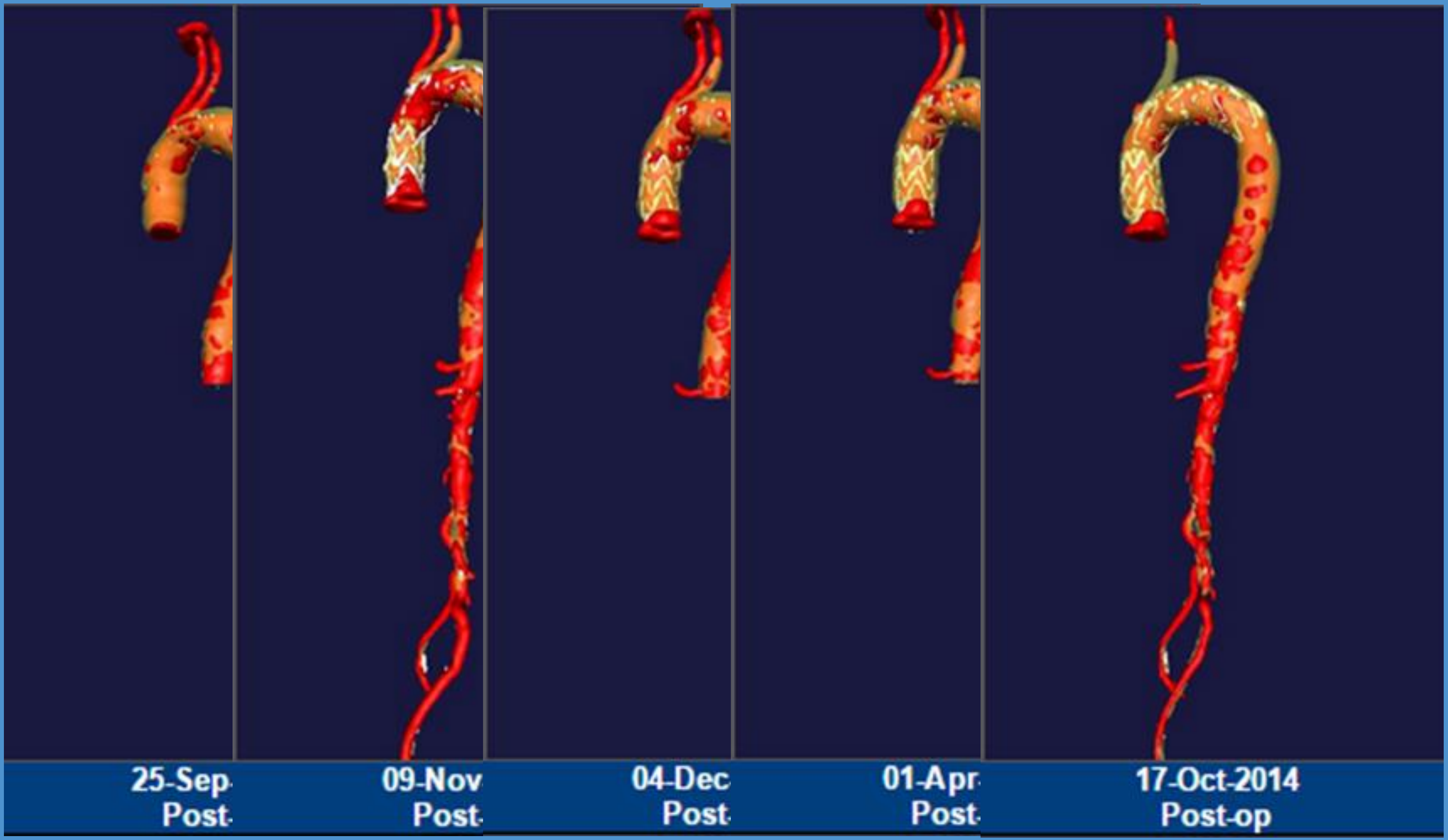


*CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.

Valiant Ascending: Case Example

*CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.

Valiant Ascending: Case Example



*CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.

Valiant Ascending
PS-IDE Current Experience

- 10 Patients Consented for PS-IDE Study
- Early Results
  - No Early Mortality or Early Open Conversion
  - 100% Technical Success (Delivery and Deployment)
  - 1/9 stroke, 1/9 Type Ia Endoleak (same patient)
    - Open repair (FET procedure) at 2 mo, death at 4 mo

Ascending TEVAR
Lessons Learned

Valiant Ascending provides durable treatment of lesions of the thoracic aorta with tubular aortic anatomy (non-aneurysmal)

- **No deployment or device stability issues**
- **Aortic remodeling of lesions similar to descending thoracic devices**

Conclusions

Preliminary evaluation of Valiant Ascending endografts demonstrates:

- **Accurate deployment**
- **Secure fixation**
- **No migration**

Longer-term follow-up required to demonstrate durable exclusion

Development of a Branched LSA Endograft
&
Ascending Aorta Endograft

Thank You

Frank R. Arko III, MD
Sanger Heart & Vascular Institute
Carolinas Medical Center
Charlotte, North Carolina, USA

20TH INTERNATIONAL EXPERTS SYMPOSIUM
CRITICAL ISSUES
in aortic endografting 2016
May 20 & 21 - LILLE - FRANCE