

# PERSEVERE Trial: Update on Hybrid (Bare Metal) Arch Graft for Type A Aortic Dissection

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Houston Aortic Symposium

March 6, 2026



## Disclosure Statement of Financial Interest

### Affiliation/Financial Relationship

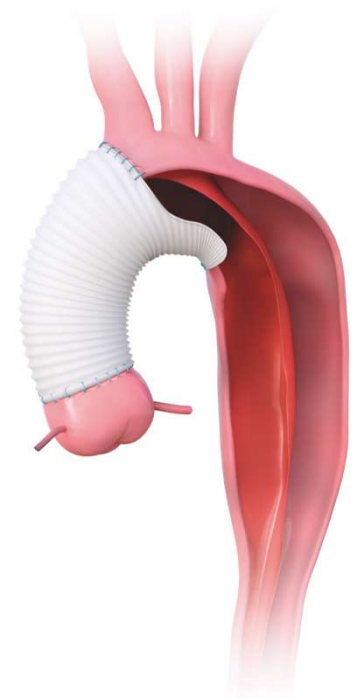
- Grant/Research Support
- Consulting Fees/Honoraria

### Company

- Abbott, Artivion, Edwards Lifesciences, Medtronic, Terumo Aortic

# Outcomes in the Current Era

- Hemiarch repair is a Class I recommendation for the treatment of acute DeBakey type I (ADTI) dissection with a primary entry tear in the ascending aorta<sup>1</sup>
- Rates of early major adverse events (MAEs) are especially high in patients who present with **malperfusion**<sup>2</sup>:
  - **Mortality:** 29 - 44%
  - **Stroke:** 12 - 35%
  - **Renal Failure:** 12 - 43%
  - **Myocardial Infarction:** 7 - 15%
- In addition, **distal anastomotic new entry tears (DANE)** are observed in 25 – 70%<sup>3</sup> of patients, which is a significant cause of continued false lumen patency, leading to aortic growth and reoperation



## References:

<sup>1</sup>Isselbacher EM et al. Circulation 2022

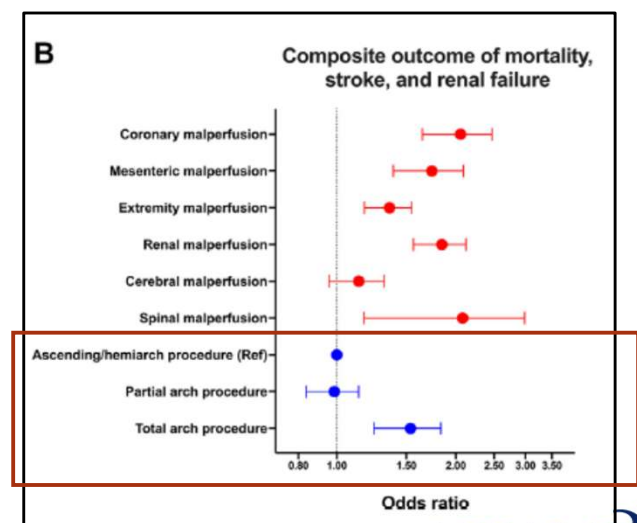
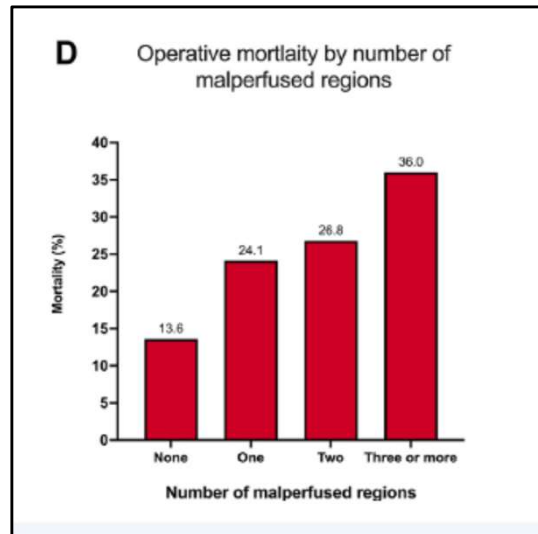
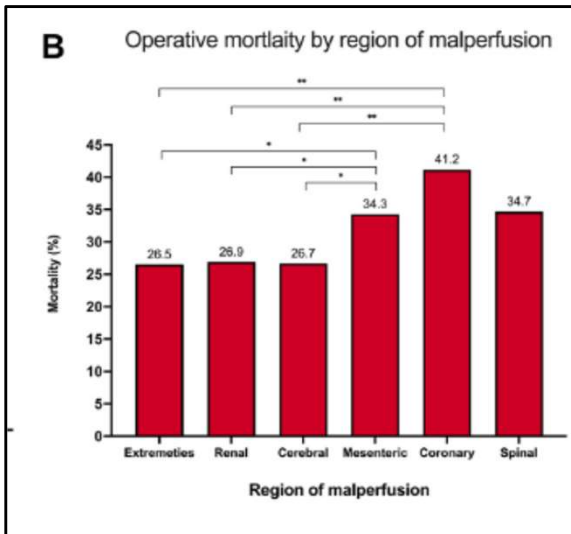
<sup>2</sup>Zindovic I et al. J Thorac Cardiovasc Surg 2019; Pacini D et al. Eur J Cardiothorac Surg 2013; Girdauskas E. et al. J Thorac Cardiovasc Surg 2009; Geirsson A. et al J Thorac Cardiovasc Surg 2007; Bossone E. et al Am J Cardiol 2002

<sup>3</sup>Bing F et al. Vasc and Endovasc Surg 2014; Ergin MA et al. Ann Thorac Surg 1994; Rylski B et al. Euro J Cardiothorac Surg 2017; Tamura K et al. Euro J Cardiothorac Surg 2017

## Malperfusion in Patients With Acute Type A Aortic Dissection: A Nationwide Analysis

Nicholas J. Goel, MD,<sup>1,2,3</sup> John J. Kelly, MD,<sup>1,2,3</sup> William L. Patrick, MD,<sup>1,2,3</sup> Yu Zhao, MS,<sup>1,2</sup> Joseph E. Bavaria, MD,<sup>3</sup> Maral Ouzounian, MD, PhD,<sup>4</sup> Anthony L. Estrera, MD,<sup>5</sup> Hiroo Takayama, MD, PhD,<sup>6</sup> Edward P. Chen, MD,<sup>7</sup> T. Brett Reece, MD,<sup>8</sup> G. Chad Hughes, MD,<sup>7</sup> Eric E. Roselli, MD,<sup>9</sup> Karen M. Kim, MD,<sup>10</sup> Himanshu J. Patel, MD,<sup>11</sup> Michael E. Bowdish, MD, MS,<sup>12</sup> Jason S. Sperling, MD,<sup>13</sup> Bradley G. Leshnowar, MD,<sup>14</sup> Ourania Preventza, MD,<sup>15</sup> William T. Brinkman, MD,<sup>16</sup> and Nimesh D. Desai, MD, PhD<sup>1,2,3</sup>

- From 2017-2020; N = 9958 ATAAD with 2748 (27%) malperfusion
- 30-D Mortality: Malperfusion **higher** mortality **26.8%** vs **13.6%**



# EACTS/STS Guidelines for Diagnosing and Treating Acute and Chronic Syndromes of the Aortic Organ

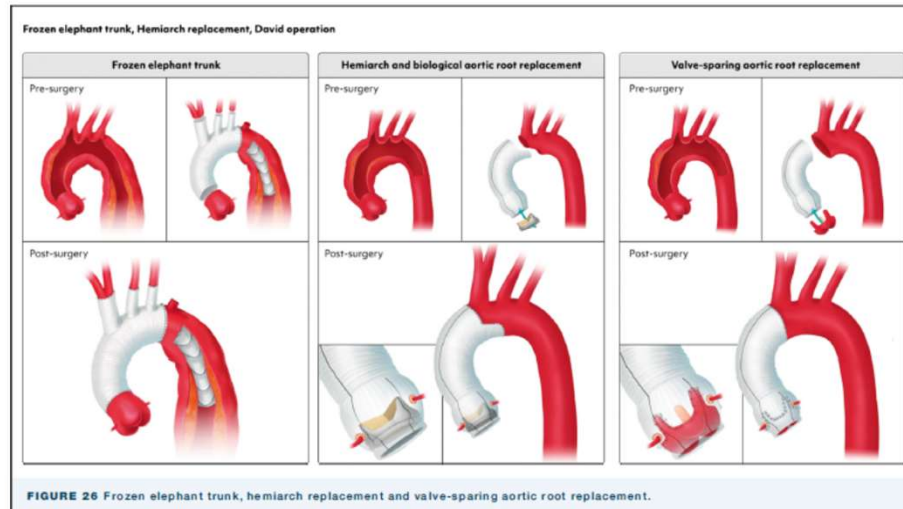


Authors/Task Force Members: Martin Czerny<sup>1,2,\*</sup> (Co-Chairperson) (Germany), Martin Grabenwöger<sup>3,4,\*</sup> (Co-Chairperson) (Austria), Tim Berger<sup>1,2</sup> (Task Force Coordinator), Victor Aboyans<sup>5,6</sup> (France), Alessandro Della Corte<sup>7,8</sup> (Italy), Edward P. Chen<sup>9</sup> (USA), Nimesh D. Desai<sup>10</sup> (USA), Julia Dumfarth<sup>11</sup> (Austria), John A. Elefteriades<sup>12</sup> (USA), Christian D. Etz<sup>13</sup> (Germany), Karen M. Kim<sup>14</sup> (USA), Maximilian Kreibich<sup>1,2</sup> (Germany), Mario Lescan<sup>15</sup> (Germany), Luca Di Marco<sup>16</sup> (Italy), Andreas Martens<sup>17,18</sup> (Germany), Carlos A. Mestres<sup>19</sup> (South Africa), Milan Milojevic<sup>20</sup> (Serbia), Christoph A. Nienaber<sup>21,22</sup> (UK), Gabriele Piffaretti<sup>23</sup> (Italy), Ourania Preventza<sup>24</sup> (USA), Eduard Quintana<sup>25</sup> (Spain), Bartosz Rylski<sup>1,2</sup> (Germany), Christopher L. Schlett<sup>2,26</sup> (Germany), Florian Schoenhoff<sup>27</sup> (Switzerland), Santi Trimarchi<sup>28</sup> (Italy), and Konstantinos Tsagakis<sup>29</sup> (Germany), EACTS/STS Scientific Document Group

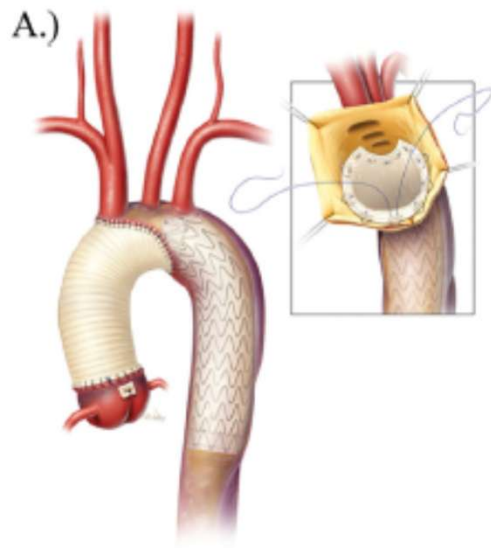
## AORTIC ARCH.

RECOMMENDATION TABLE 24 Therapeutic Options: Aortic Arch			
Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
In patients with an intended one-stage aortic arch treatment, the FET technique should be considered.	IIa	B	576-581
Aortic arch replacement, including the creation of a sufficient landing zone, is recommended in the treatment of multisegmental aneurysms of the thoracic aorta in order to facilitate the further downstream repair.	I	C	-
When performing the frozen and conventional elephant trunk techniques, a distal anastomosis in arch zone 2 should be considered.	IIa	C	-
In the case of an elephant trunk implant, the polyester trunk component should be considered to be accessible in zone 4.	IIa	C	-
Hybrid procedures may be considered for aortic arch repair.	IIb	C	-
In any TEVAR involving zone 2, left subclavian artery revascularization is recommended to reduce the risk of neurologic complications such as stroke and spinal cord ischemia.	I	B	582-584

<sup>a</sup>Class of recommendation; <sup>b</sup>Level of evidence; <sup>c</sup>References. FET, frozen elephant trunk; TEVAR, thoracic endovascular aortic repair.



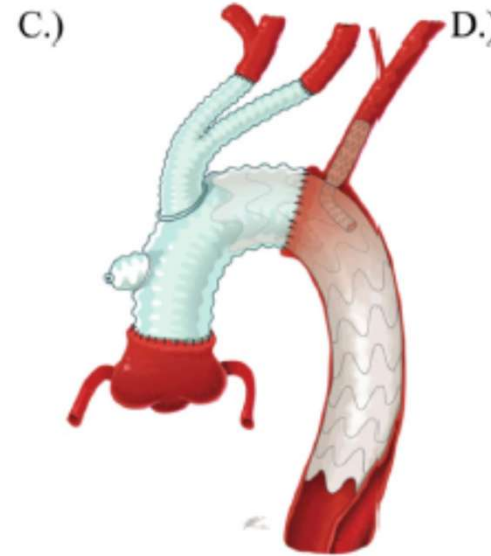
# Extended Arch Reconstruction



Hybrid  
Antegrade  
TEVAR



Zone 3 FET



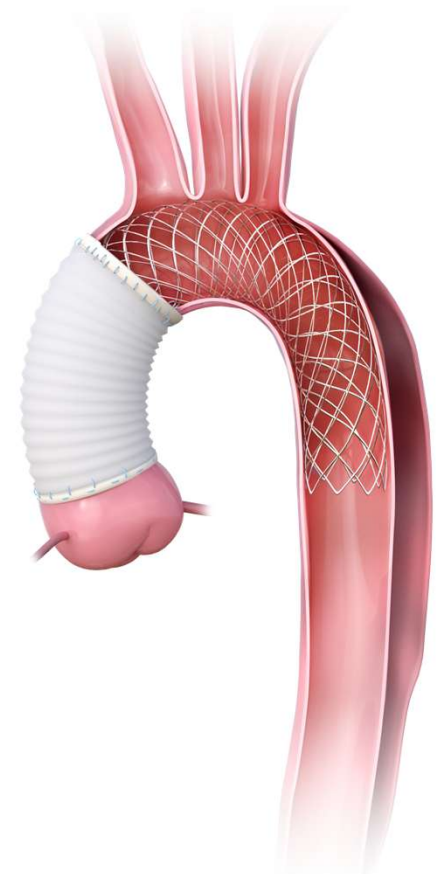
Zone 2 + TBE



Zone 0 +  
AMDS

# Hemiarch + AMDS

- AMDS Hybrid Prosthesis (AMDS) is a novel bare metal stent, with proximal PTFE cuff, designed to stabilize the true lumen, avoid distal anastomotic new entry (DANE) tears and enhance aortic remodeling in the arch.
- AMDS requires minimal change to the conventional surgical approach of replacing the ascending aorta.



Artivion Granted FDA Humanitarian  
Device Exemption for the AMDS Hybrid  
Prosthesis

**ARTIVION**

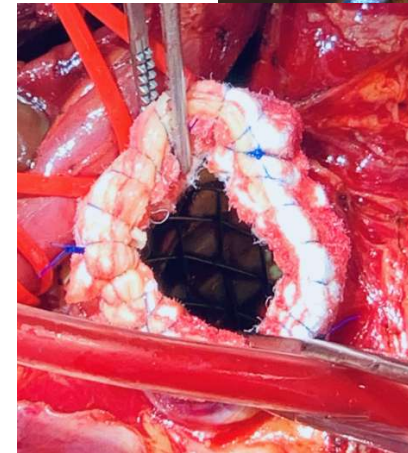
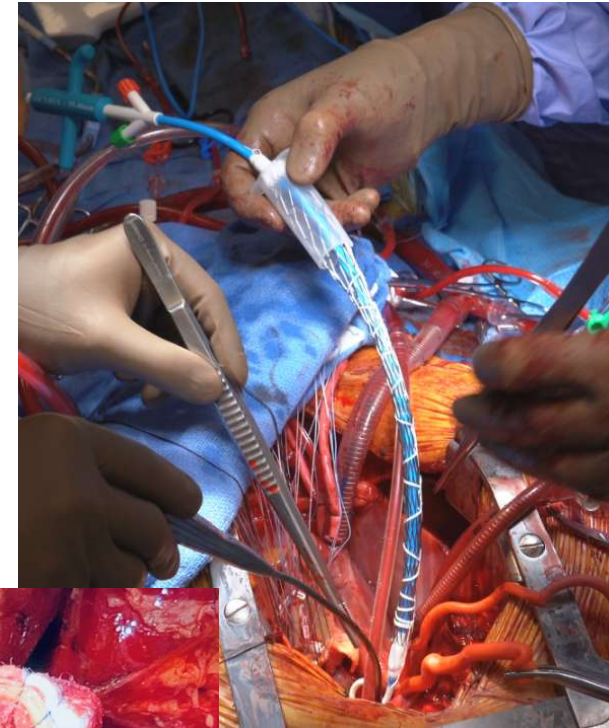
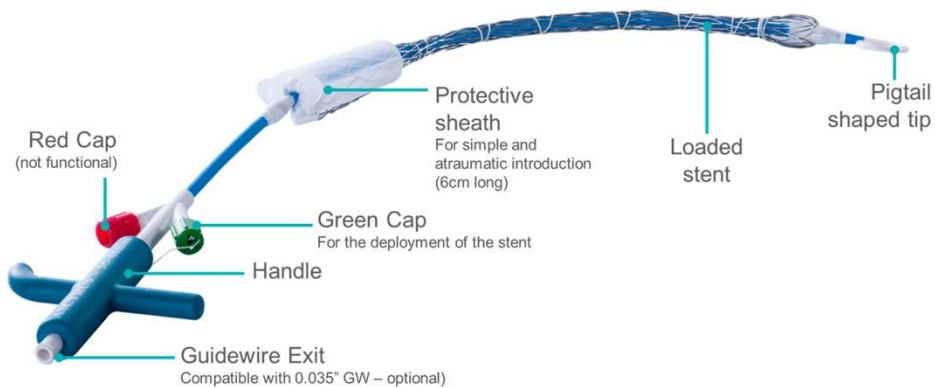
NEWS PROVIDED BY  
Artivion, Inc. →  
Dec 09, 2024, 08:00 ET

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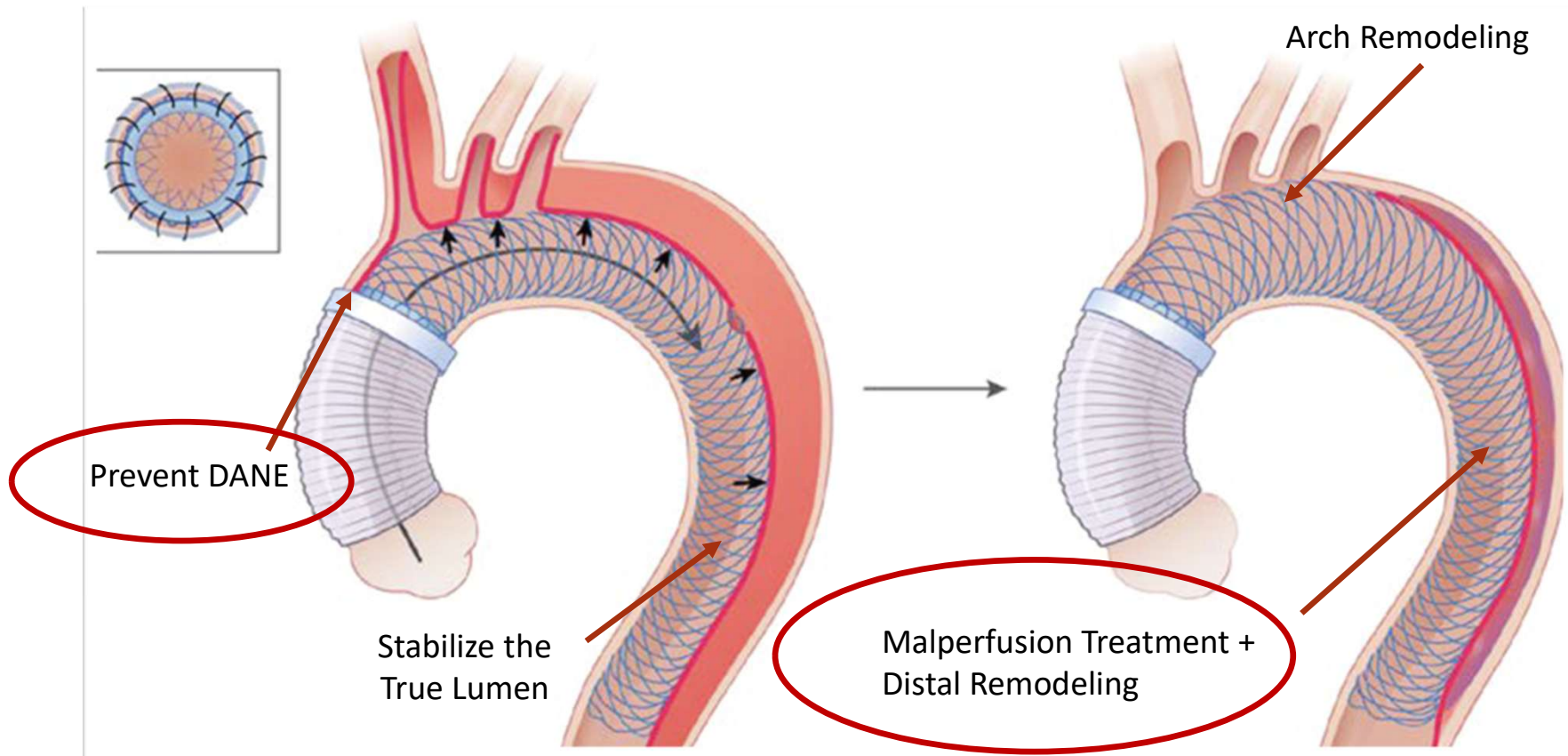
# AMDS Hybrid Stent: Device Description



- **PTFE felt graft** component made of a PTFE felt tube is used to buttress and strengthen the aortic tissue in preparation to perform the conventional polyester graft to aorta anastomosis
- **Uncovered nitinol wire braided stent** enables the stabilization of the dissection flap within aortic arch and descending aorta thereby stabilizing the structure of the aortic wall and promoting its healing



# Mode of Action



## A novel hybrid prosthesis for open repair of acute DeBakey type I dissection with malperfusion: Early results from the PERSEVERE trial

Wilson Y. Szeto, MD,<sup>a</sup> Shinichi Fukuhara, MD,<sup>b</sup> Fernando Fleischman, MD,<sup>c</sup> Ibrahim Sultan, MD,<sup>d</sup> William Brinkman, MD,<sup>e</sup> George Arnaoutakis, MD,<sup>f</sup> Hiroo Takayama, MD, PhD,<sup>g</sup> Kyle Eudailey, MD,<sup>h</sup> Derek Brinster, MD,<sup>i</sup> Arminder Jassar, MBBS,<sup>j</sup> Joseph DeRose, MD,<sup>k</sup> Chase Brown, MD,<sup>a</sup> Woodrow Farrington, MD,<sup>l</sup> and Michael C. Moon, MD<sup>m</sup>

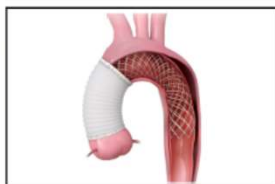
### ABSTRACT

**Background:** Outcomes after hemiarch repair for acute DeBakey type I aortic dissection (ADTI) remain unfavorable, with high rates of major adverse events and negative aortic remodeling. The PERSEVERE study evaluates the safety and effectiveness of the AMDS Hybrid prosthesis, a novel bare metal stent, in patients presenting with preoperative malperfusion.

**Methods:** PERSEVERE is a prospective single-arm investigational study conducted at 26 sites in the United States. Ninety-three patients underwent ADTI aortic dissection repair with AMDS implantation. The 30-day primary endpoints are a composite rate of 4 major adverse events and the rate of distal anastomotic new entry tears. The secondary endpoints include aortic remodeling.

**Results:** Clinical malperfusion was documented in 76 patients (82%); only radiographic malperfusion, in 17 (18%). The median follow-up in the 93 patients was 5.6 months. Within 30 days, 9 patients died (9.7%), 10 patients (10.8%) experienced new disabling stroke, and 18 patients (19.4%) had new-onset renal failure requiring  $\geq 1$  dialysis treatment. There were no cases of myocardial infarction. The composite rate of major adverse events (27%) was lower than that reported in the reference cohort (58%). There were no distal anastomotic new entry tears. Technical success was achieved in 99% of patients. Early remodeling indicated total aortic diameter stability, true lumen expansion, and false lumen reduction in the treated aortic segment.

**Conclusions:** Early results show significant reductions in major adverse events and distal anastomotic new entry tears, successfully meeting both primary endpoints. The technical success rate was high. AMDS can be used safely in patients with ADTI dissection with malperfusion. (J Thorac Cardiovasc Surg 2024; ■:1-13)



AMDS hybrid prosthesis deployed in the aortic arch.

### CENTRAL MESSAGE

The initial results from the PERSEVERE study in acute DeBakey type I dissection patients with preoperative malperfusion demonstrate improved clinical outcomes and a decreased incidence of distal anastomotic new entry tears compared to the literature.

### PERSPECTIVE

There are no prospective studies evaluating acute dissection patients with preoperative malperfusion. The PERSEVERE study is unique because of its prospective design and thorough collection of radiographic datapoints. In addition, the device under investigation aims to improve outcomes following ascending repair in high-risk patients, which includes improvement in mortality and a reduction of distal anastomotic new entry tears.

See Commentary on page XXX.  
See Discussion on page XXX.

# PERSEVERE

## Pivotal IDE Study

A Study Designed to Evaluate the Use of **AMDS Hybrid Prosthesis** to Treat Acute DeBakey Type I Aortic Dissections **with malperfusion**

**STS**  
**2024**

# Methods

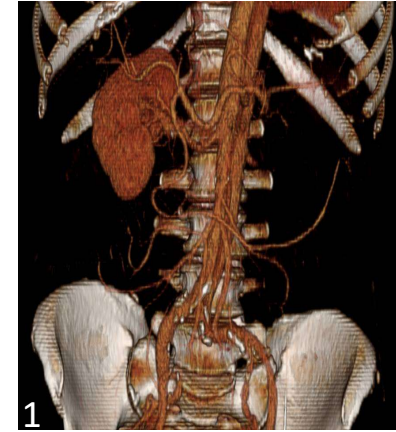
- **Design:** Prospective, single arm, IDE study
- **Sites:** 26 US sites
- **Follow-up Visits:** Pre-op, Procedure/Discharge, 30-days, 3-6 months, 1, 2, 3, 4, 5 yrs
- **Enrollment Period:** July 2022 - November 2023
- **30-day Co-Primary Endpoints:**
  - % patients with  $\geq 1$  MAE (mortality, new disabling stroke, renal failure requiring dialysis, MI)
  - % of patients with DANE
- **Performance Goals:**
  - MAE endpoint considered 5 reference publications (Average: 58%)
  - DANE endpoint considered 4 reference publications (Average: 45%)
- **Main Inclusionary Criteria:** 18-80 yrs old, ADTI, malperfusion
- **Sample Size:** 93 patients with 30-day follow-up
- **Maximum Follow-Up:** 1-year



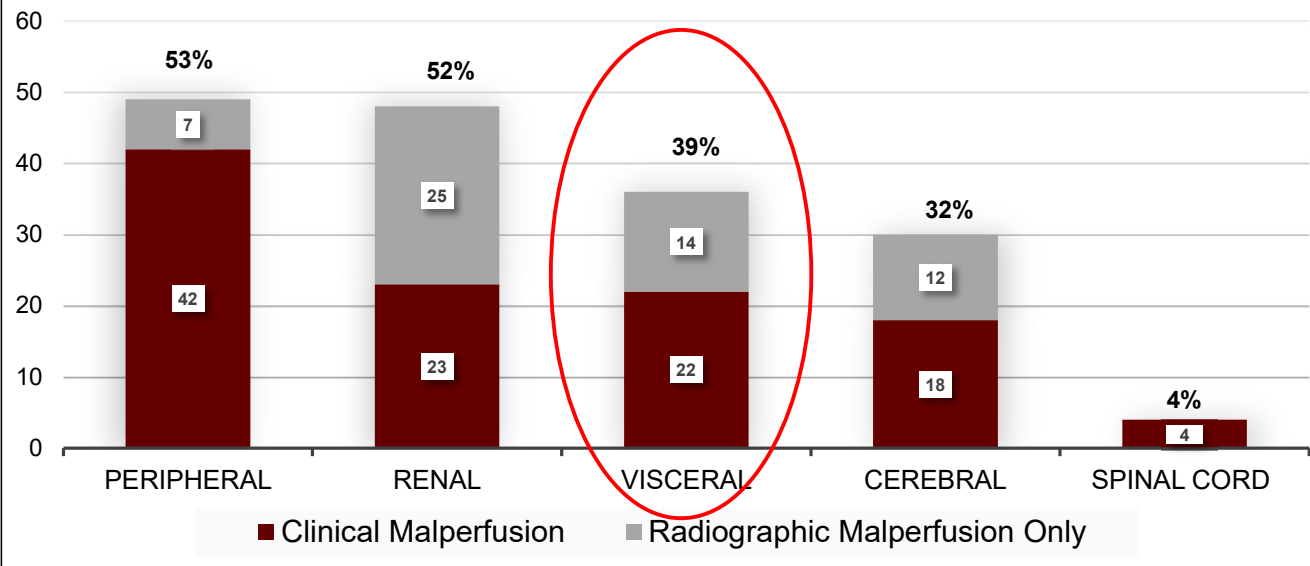
# Baseline Malperfusion

- 74 (79.6%) Patients had clinical malperfusion
- 19 (20.4%) Patients had only radiographic malperfusion<sup>1</sup>
- 52 (55.9%) Patients had >1 anatomical malperfusion

- (1) Renal Malperfusion
- (2) Peripheral Malperfusion



Pre-operative Malperfusion Summary



<sup>1</sup>Radiographic malperfusion defined as severe compression of true lumen with radiographic concern for compromised flow to distal aorta or end organs resulting in static and/or dynamic malperfusion.

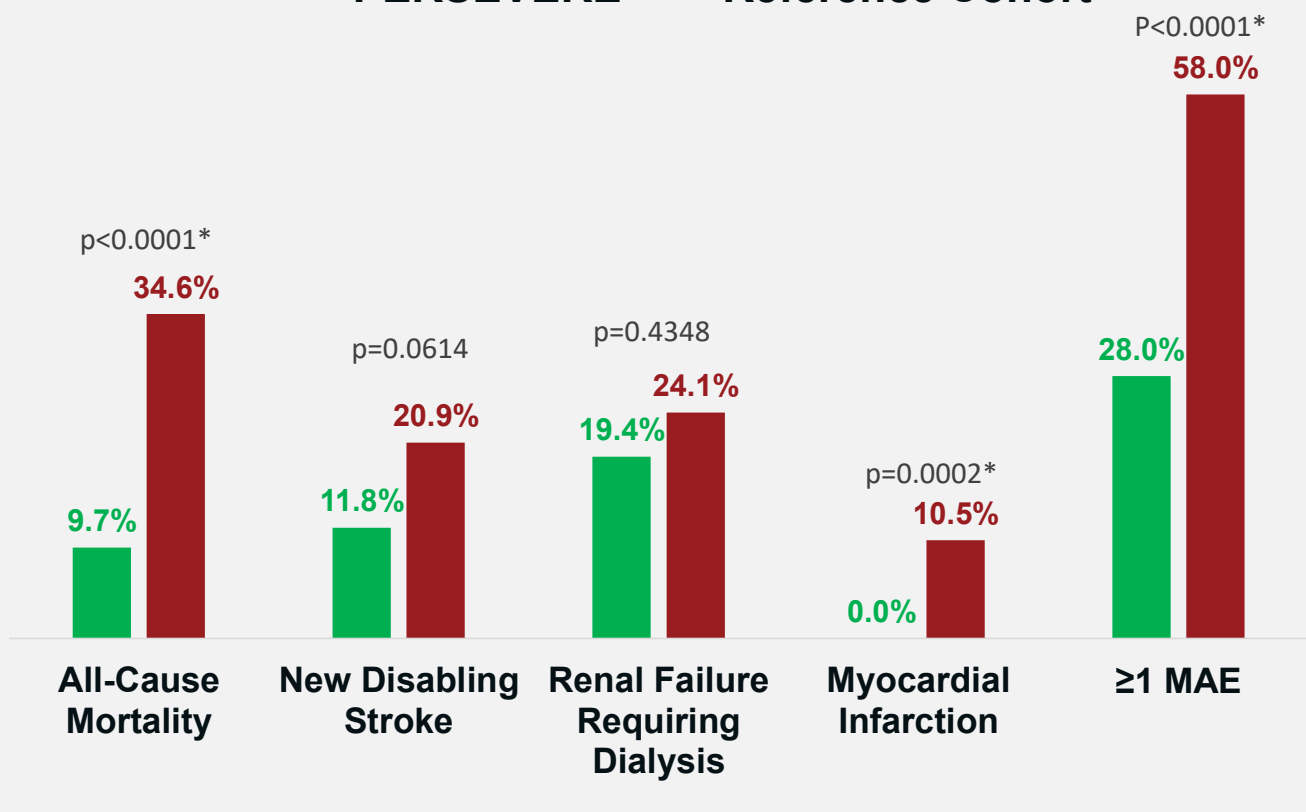
# Peri-Operative Data

Operative Summary	Total # Patients (n=93)	
	#	%
Concomitant Procedure	79	84.9%
Root Repair or Replacement	35	37.6%
Aortic Valve Resuspension	34	36.6%
Valve Repair or Replacement	21	22.6%
CABG	5	5.4%
Other	24	25.8%
Guidewire Use	10	10.8%
Fluoroscopy Use	8	8.6%
Antegrade Cerebral Perfusion	43	46.2%
Retrograde Cerebral Perfusion	45	48.4%
	Median	
AMDS Deployment Time (mins)	4	
Total AMDS Implantation Time (mins)	15	
Circulatory Arrest Time (mins)	28	
Lowest Core Temperature (deg C)	24.7	
Time in ICU (days)	5	
Time in Hospital (days)	11	



# Results: Primary Endpoints

■ PERSEVERE ■ Reference Cohort



Total # Patients with ≥ 1 MAE: **26 (28%)** **GOAL: < 40%**

Total # Patients with DANE: **0 (0%)** **GOAL: < 10%**

Primary 30-day Endpoint (Adjudicated)	Total # Patients (N=93)	%
All-cause mortality	9	9.7
New Disabling Stroke	11	11.8
New Onset Renal Failure Requiring Dialysis	18	19.4
Myocardial Infarction	0	0.0



# One-Year Results of a Novel Aortic Arch Hybrid Prosthesis for Open Repair of Acute DeBakey Type I Dissection with Malperfusion in the PERSEVERE Study

Wilson Y. Szeto, MD, Shinichi Fukuhara, MD, Fernando Fleischman, MD, Ibrahim Sultan, MD, William Brinkman, MD, George Arnaoutakis, MD, Hiroo Takayama, MD, PhD, Kyle Eudailey, MD, Arminder Jassar, MD, Anthony Estrera, MD, Michael C. Moon, MD, on behalf of the PERSEVERE Investigators

**STS 2025**





January 29 – February 1, 2026 | New Orleans, LA

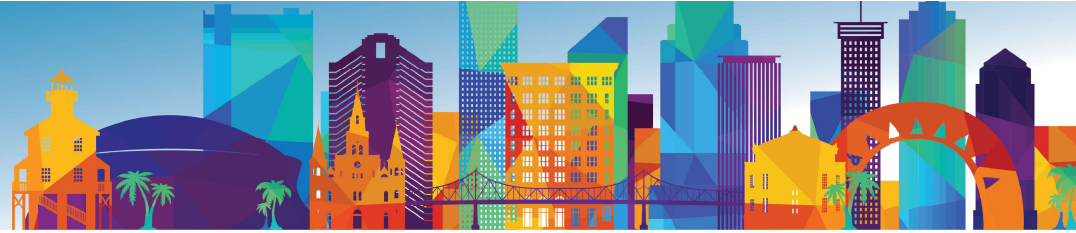
Teaching for Tomorrow Together

# Using a Novel Hybrid Aortic Arch Prosthesis for Open Repair of Acute DeBakey Type I Dissection with Malperfusion: Two-Year Results from the PERSEVERE Trial

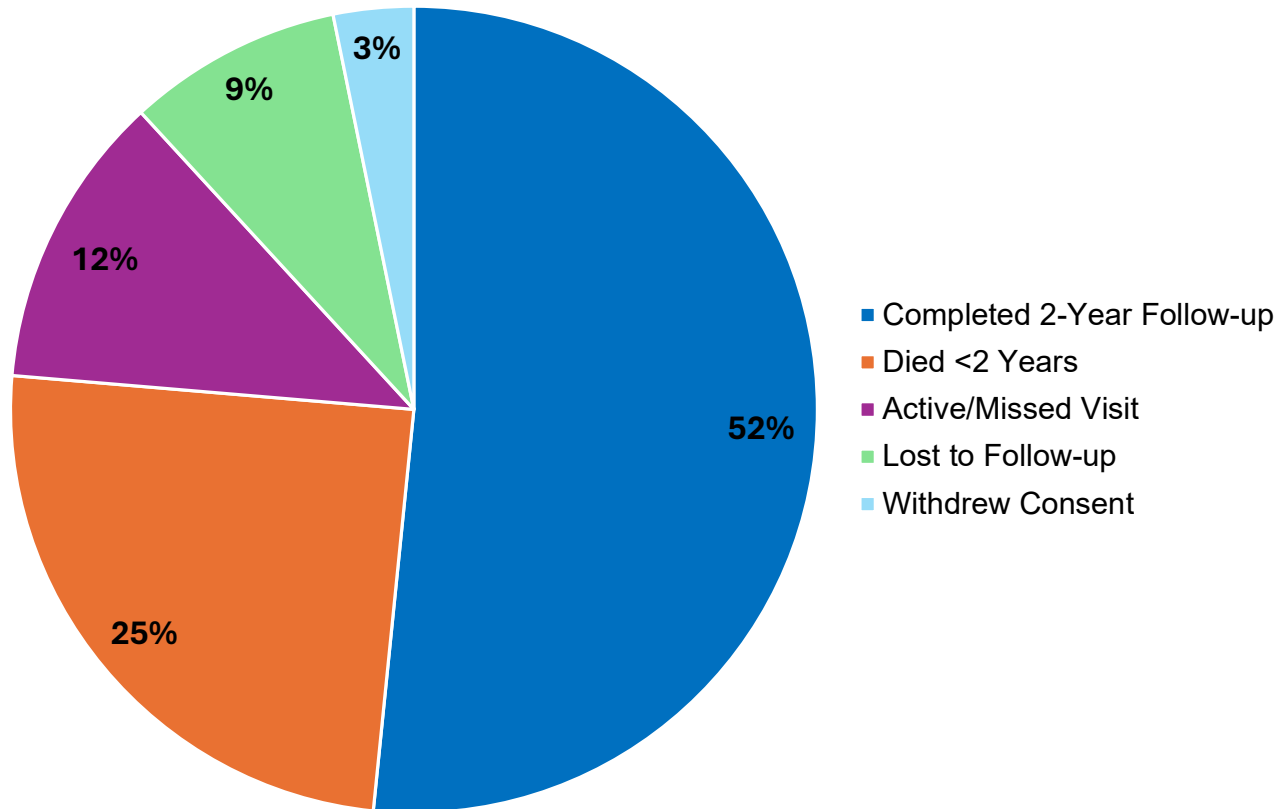
George J. Arnaoutakis, MD, Kyle Eudailey, MD, Shinichi Fukuhara, MD, Fernando Fleischman, MD, Ibrahim Sultan, MD, William Brinkman, MD, Hiroo Takayama, MD, PhD, Armand Jassar, MBBS, Anthony Estrera, MD, Michael C. Moon, MD, and Wilson Y. Szeto, MD

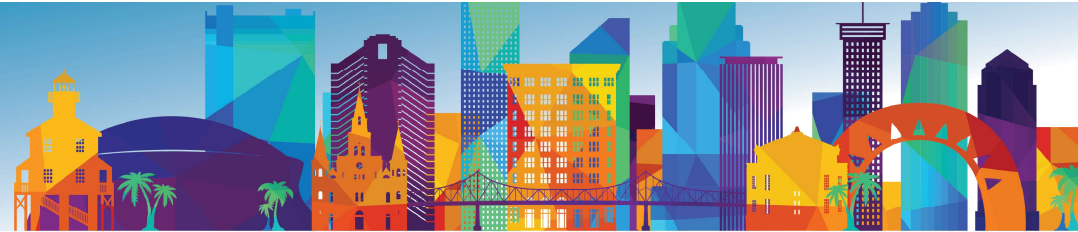
on behalf of the PERSEVERE Investigators





## Results: Patient Status at 2-Years

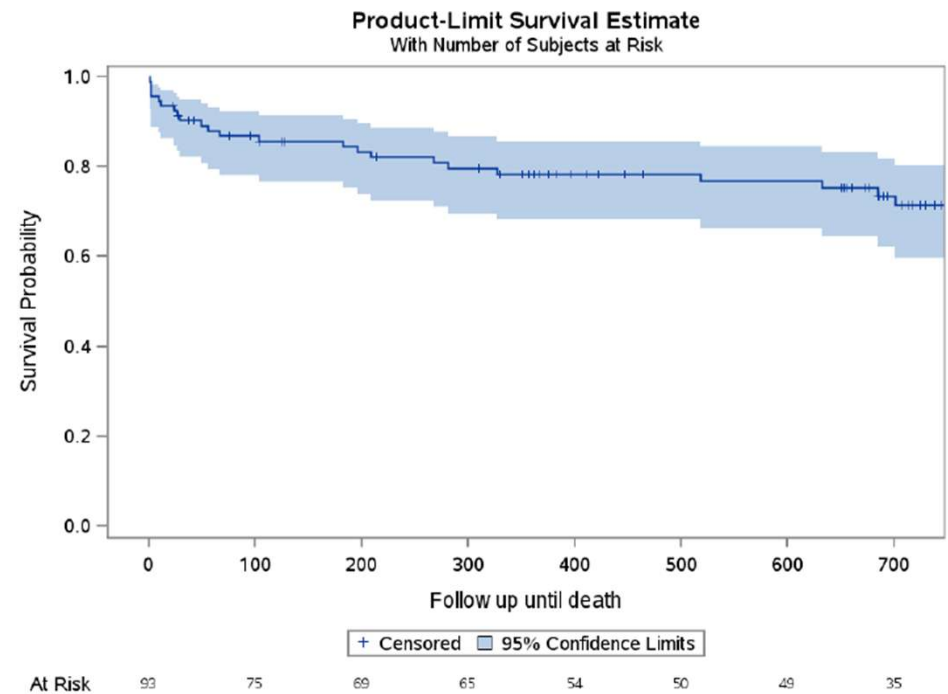


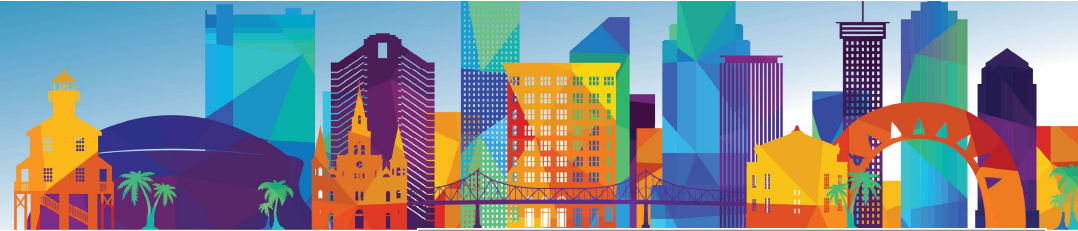


## Results: Survival and MAEs

- 23 patients died <2 years, post-procedure
  - 19 deaths < 1 year
  - 4 deaths between 1- and 2-years post-op
- Average time to death was 190 days (SD: +/-232)
- 7/23 (30.4%) deaths were cardiovascular-related
- Earlier causes of death have been published
- Cause of death after 1 year include:
  - MI
  - Bladder cancer
  - Intracranial hemorrhage post fall
  - Intraparenchymal brain bleed after TAAA repair
- There were no new disabling strokes and new renal failure / dialysis between 1- and 2-years post-op

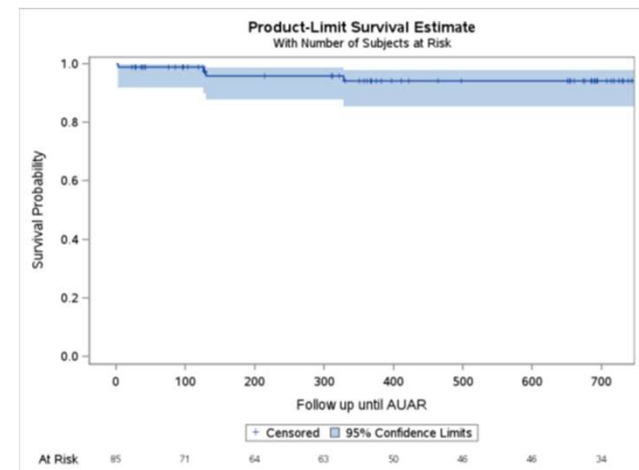
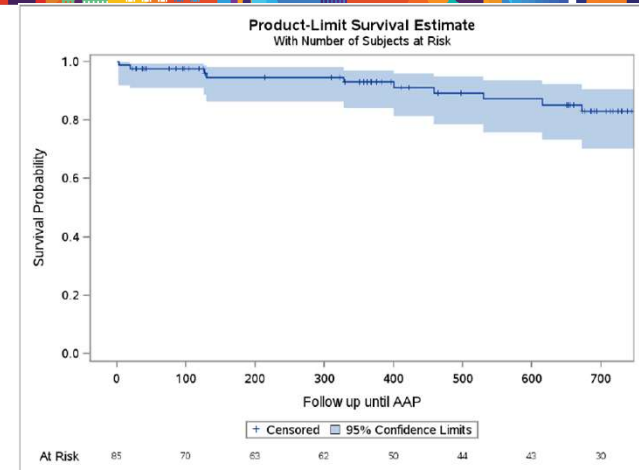
### KM Plot for Survival:

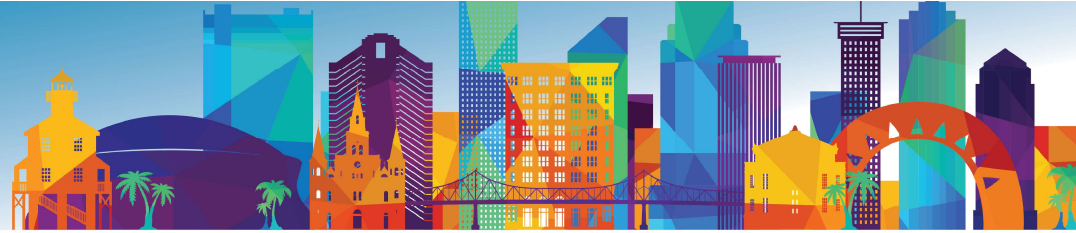




## Results: Additional Aortic Procedures

- **10 patients (10.8%) had 15 additional aortic procedures (AAP) < 2 yrs** post index procedure (see top KM plot to the right)
  - 6 endo procedures and 9 open procedures
  - Avg time to AAP is 333 days (SD: 237.8 days) post-op
  - 8 procedures < 1 year and 7 procedures between 1- and 2-years, post-op
- A minority of patients (4.3%) required additional unanticipated aortic reoperation (AUAR); indicated in blue below (see bottom KM plot to the right)
- Procedures include:
  - 4 Arch branch manipulations (stenting, bypass, embolization)
  - **3 Total arch repairs + FET**
  - 3 TEVAR
  - 2 TAAA repairs
  - 1 redo ascending/root
  - **1 distal anastomosis repair**
  - 1 iliac artery stent

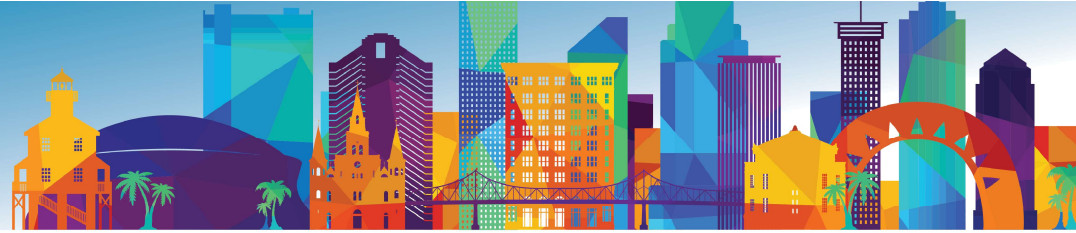




## Results: Device-Related Events and Aortic Remodeling

- 42/93 (45.2%) patients had a 2-year CTA [42/48 with a 2-year visit]
- The following are cumulative 2-year rates:
  - 0 patients had DANE, migration, stent fracture, kink, or twist
  - 2 patients had d-SINE (1 case documented after TEVAR)
  - 5 patients had stent narrowing with no known clinical impact
- Freedom from TAD growth  $\geq$  1cm between 1 and 2 years was 100% in aortic Zones 1-3

**Positive aortic remodeling and stabilization**

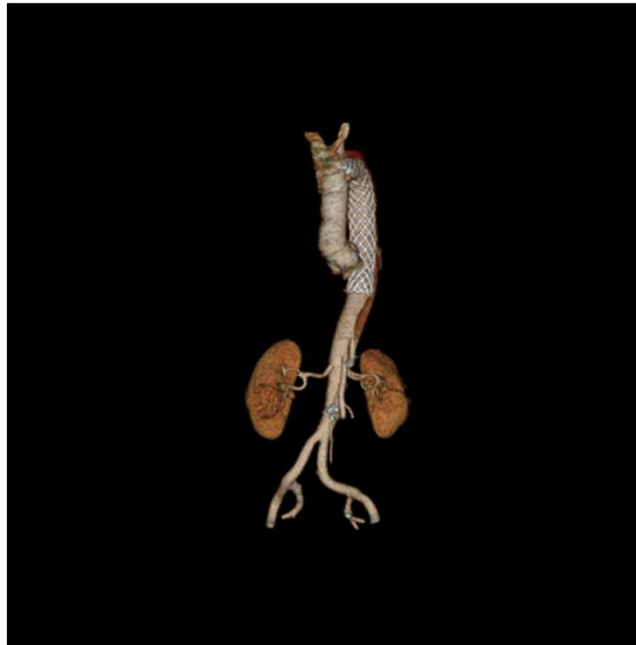


## Results: Example of Positive Aortic Remodeling

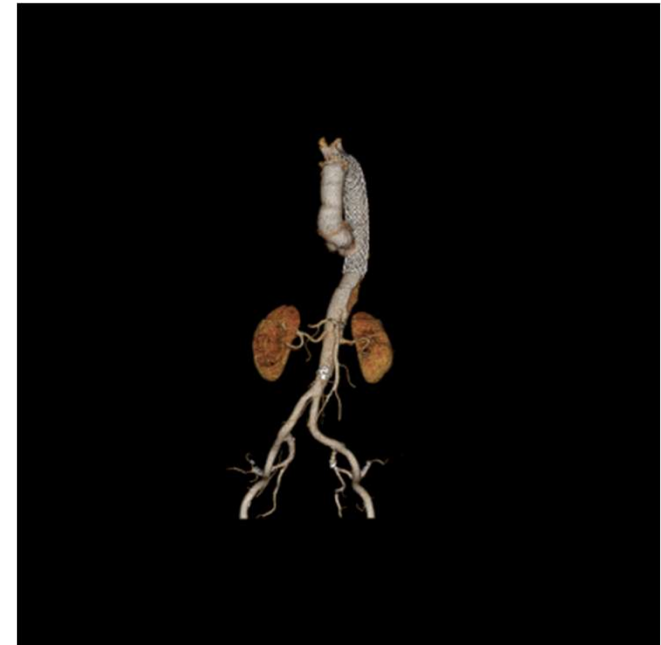
Pre-Procedure

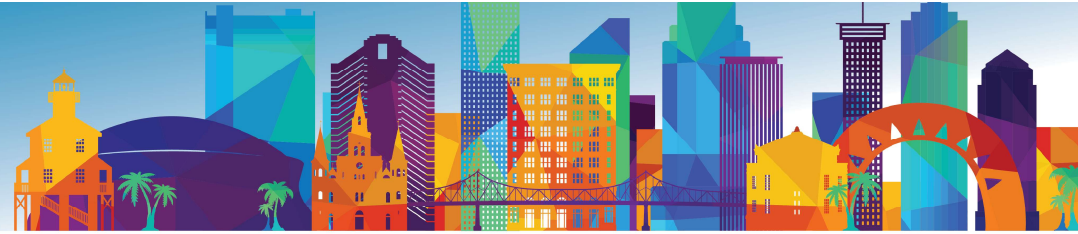


30-Days



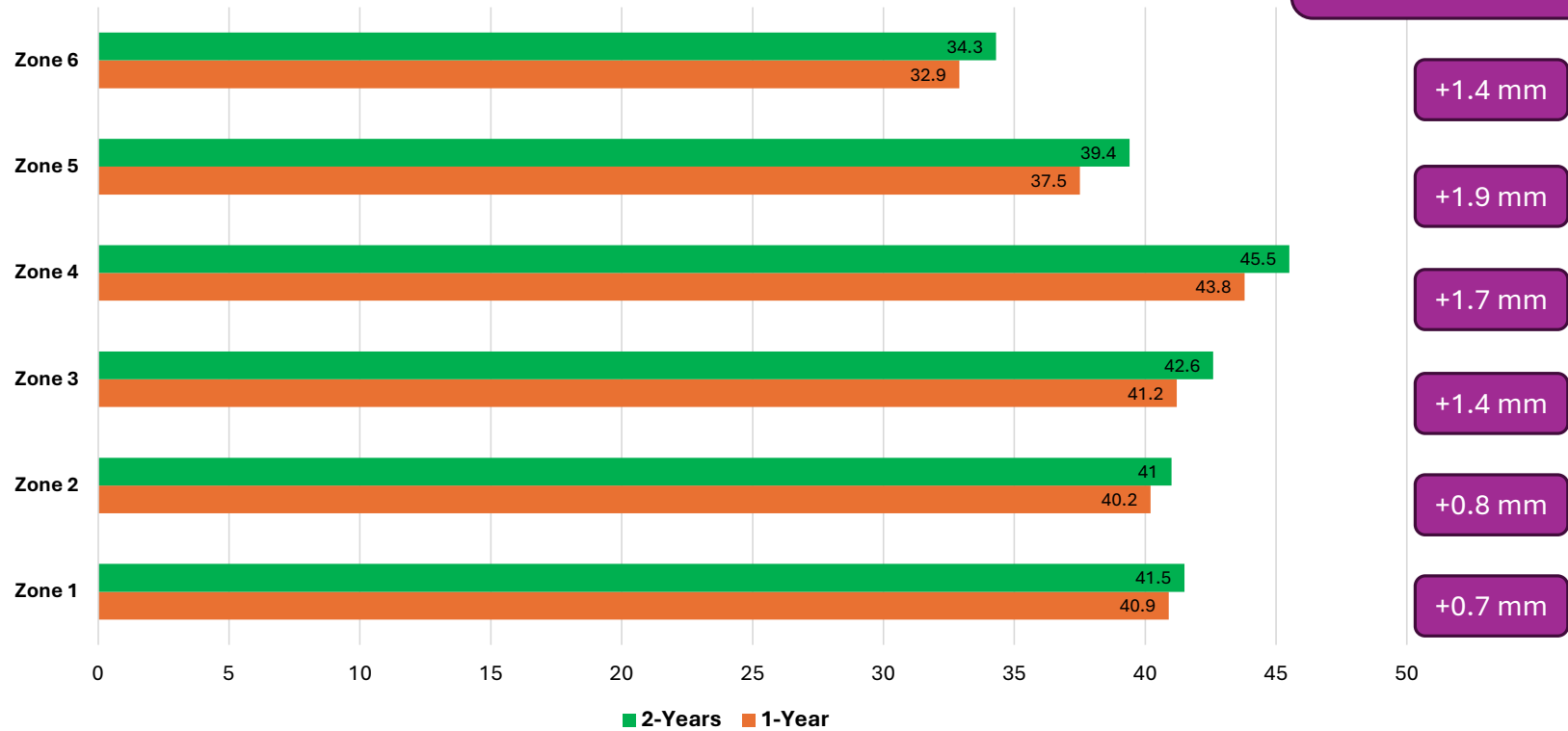
2-Years

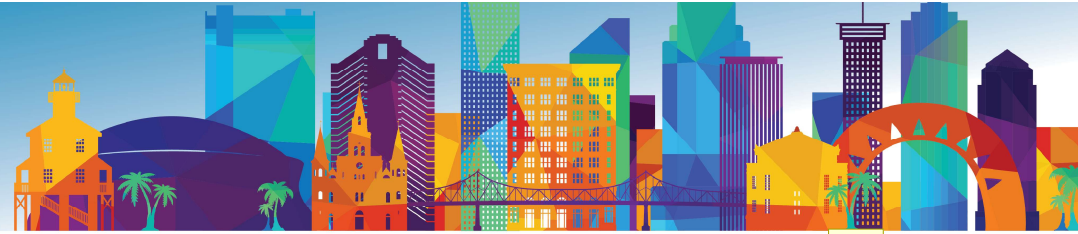




## Results: Aortic Remodeling (TAD)

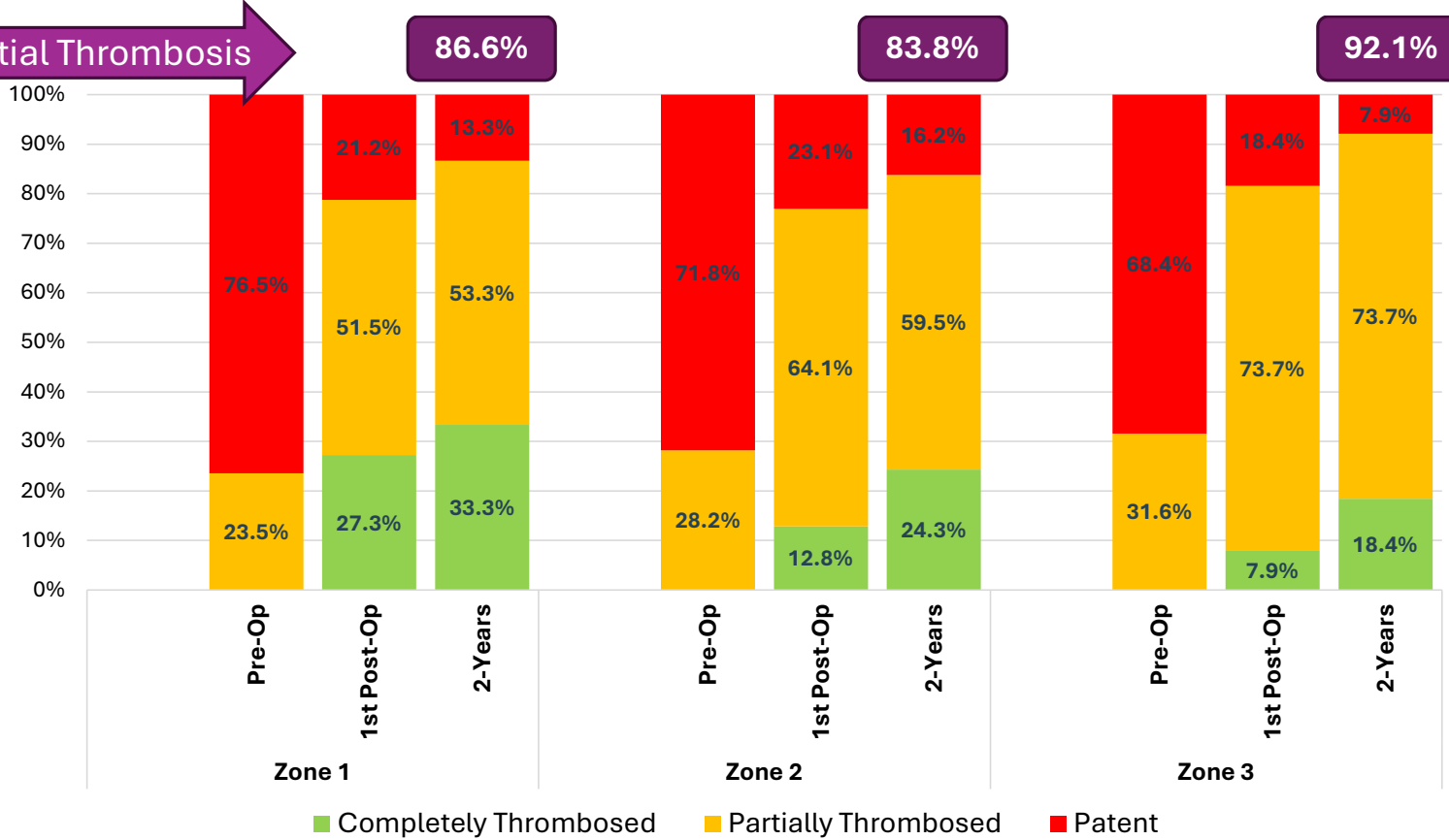
Mean TAD (mm) at 2 yrs vs. 1 yr





## Results: FL Thrombosis Status

Complete/Partial Thrombosis



## Slide 23

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**EA1** There were 39 patients who had a CTA with data for pre-op, 30-days (or pre-discharge) and 2-years. This bar graph only considers those with all 3 to try to include the same people in each bar.

Erin Adams, 2026-01-13T19:57:32.199

Cite this article as: Brinkman W, Squiers JJ, Jassar A, Fukuhara S, Fleischman F, Takayama H et al. Cerebral malperfusion resolution after repair of acute DeBakey type I dissection with a novel hybrid prosthesis: early results of the PERSEVERE Study<sup>†</sup>. Eur J Cardiothorac Surg 2025; doi:10.1093/ejcts/ezaf199.

## Cerebral malperfusion resolution after repair of acute DeBakey type I dissection with a novel hybrid prosthesis: early results of the PERSEVERE Study<sup>†</sup>

William Brinkman <sup>a,\*</sup>, John J. Squiers <sup>a,\*</sup>, Arminder Jassar <sup>b</sup>, Shinichi Fukuhara <sup>c</sup>,  
 Fernando Fleischman <sup>d</sup>, Hiroo Takayama <sup>e</sup>, Ibrahim Sultan <sup>f</sup>, George Arnaoutakis <sup>g</sup>,  
 Michael C. Moon <sup>h</sup> and Wilson Y. Szeto <sup>i</sup>, on behalf of all PERSEVERE Investigators

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CONVENTIONAL AORTIC SURGERY

### Cerebral Malperfusion Resolution after Repair of Acute DeBakey Type I Dissection with a Novel Hybrid Prosthesis: Early Results of the PERSEVERE Study

#### Summary

30 subjects presenting with acute DeBakey type I aortic dissection and cerebral malperfusion were prospectively enrolled in a clinical trial evaluating the AMDS Hybrid

Prosthesis. Among 18 with *clinical* cerebral malperfusion surviving the perioperative period, 11 (61%) experienced resolution of preoperative symptoms and 5 (28%) had no worsening of preoperative symptoms.

Radiographic markers of malperfusion also improved postoperatively.

Legend: IA innominate artery; LCCA left common carotid artery; TAD total artery diameter; TL true lumen diameter

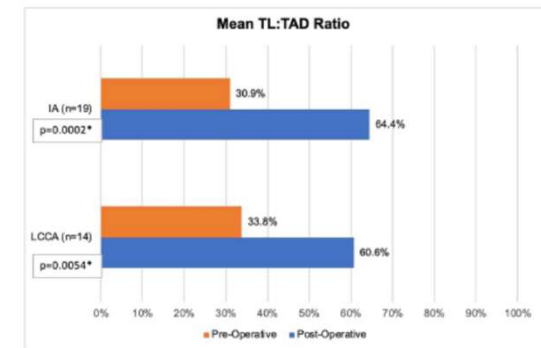
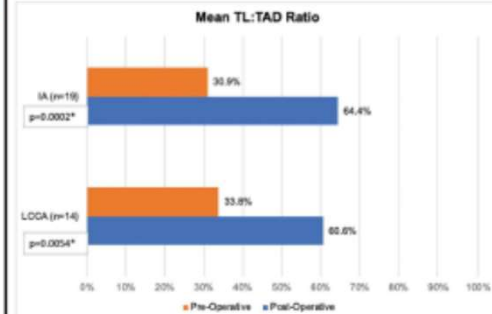


Figure 2: Mean true lumen to total arterial diameter (TL:TAD) ratio, expressed by percentage, as measured on computed tomography angiography at preoperative baseline and 30 days postoperatively in patients with acute DeBakey type I aortic dissection and radiographic cerebral malperfusion evident in the innominate artery (IA) or left common carotid artery (LCCA).

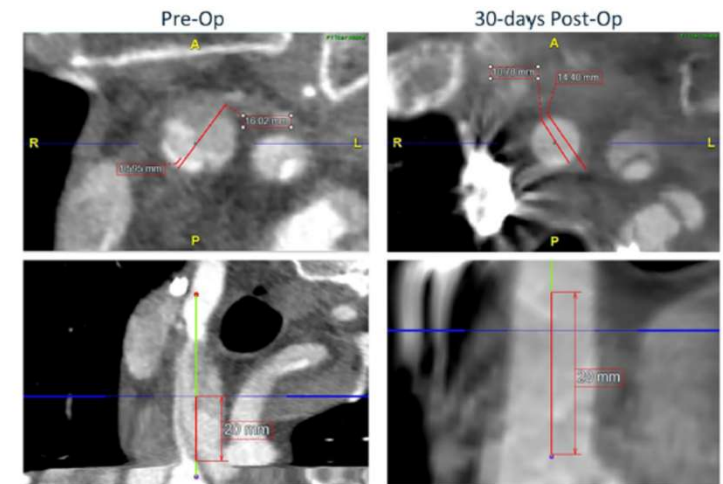


Figure 2: Representative core lab imaging measurements demonstrating improvement in true lumen to total arterial diameter ratio in the innominate artery from preoperative baseline to the 30-day postoperative timepoint.



# Effectiveness of AMDS Hybrid Prosthesis in Resolving Visceral and Renal Malperfusion in Acute DeBakey Type I Dissection-

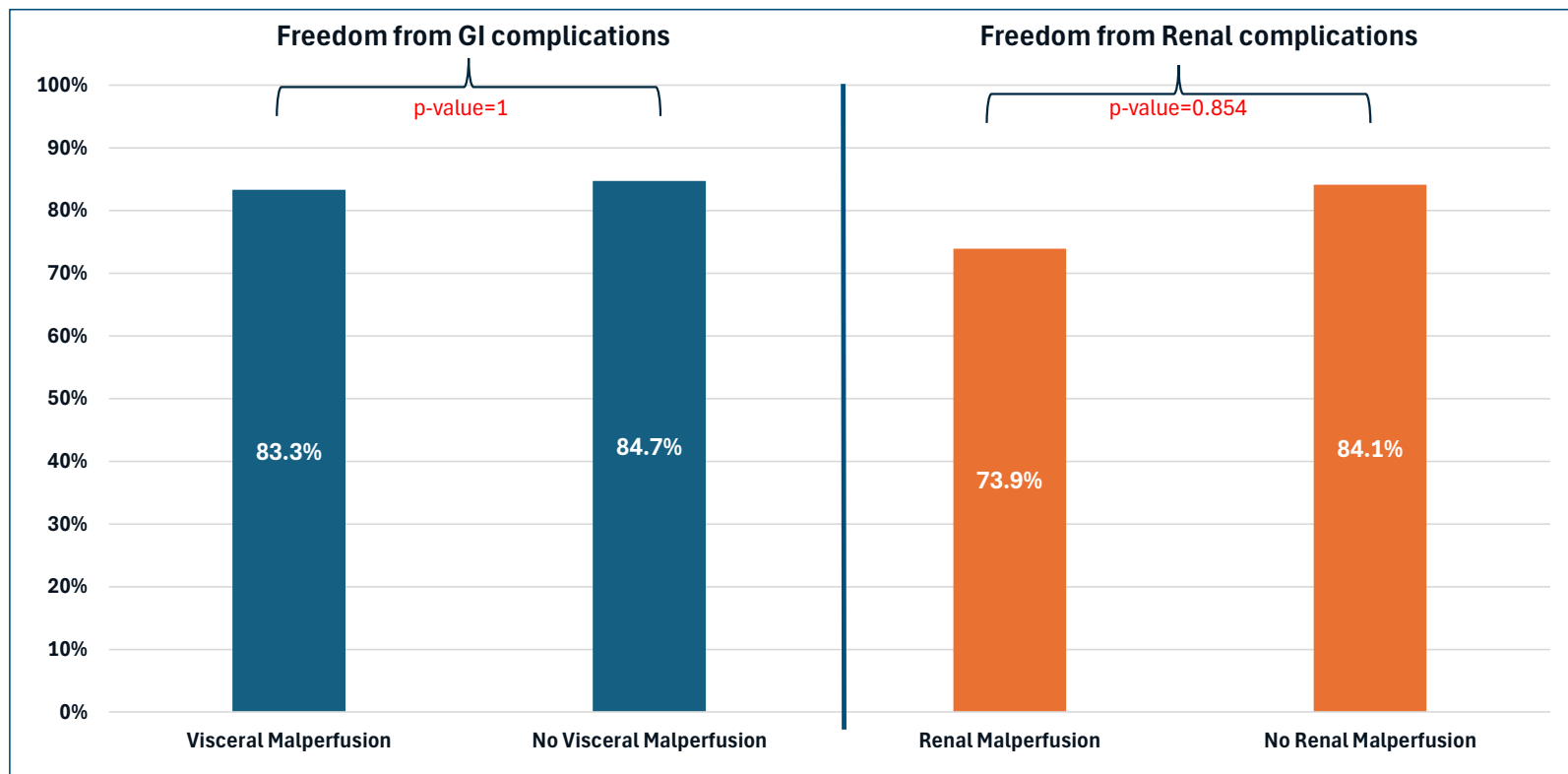
## Results from the PERSEVERE Study

A Jassar MD, et al.



## Clinical Malperfusion Results:

- No difference in post-op GI complications in patients with or without visceral malperfusion
- No significant difference in post-op Renal complications in patients with or without renal malperfusion





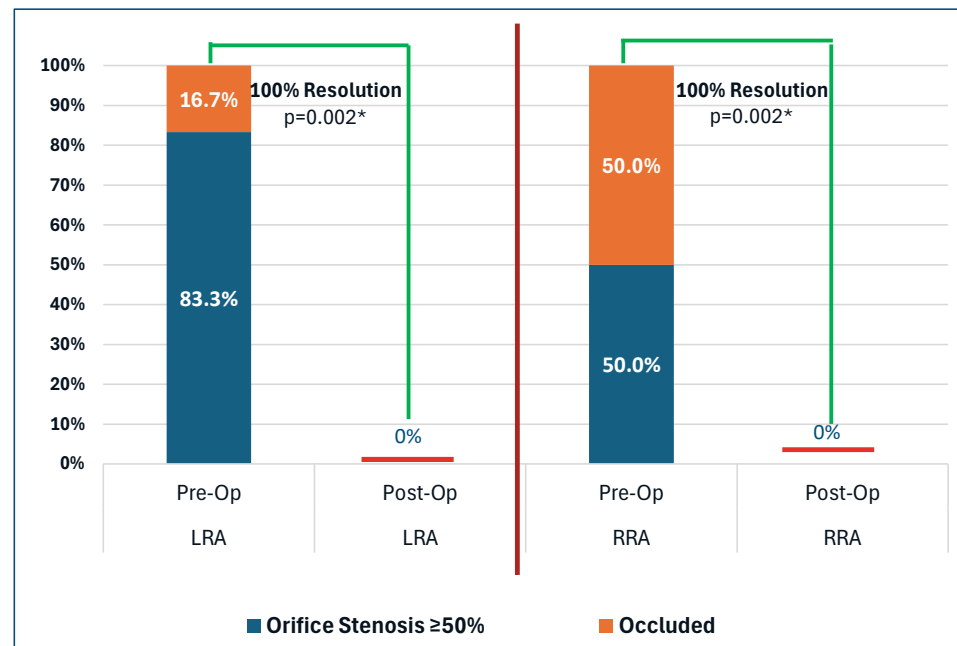
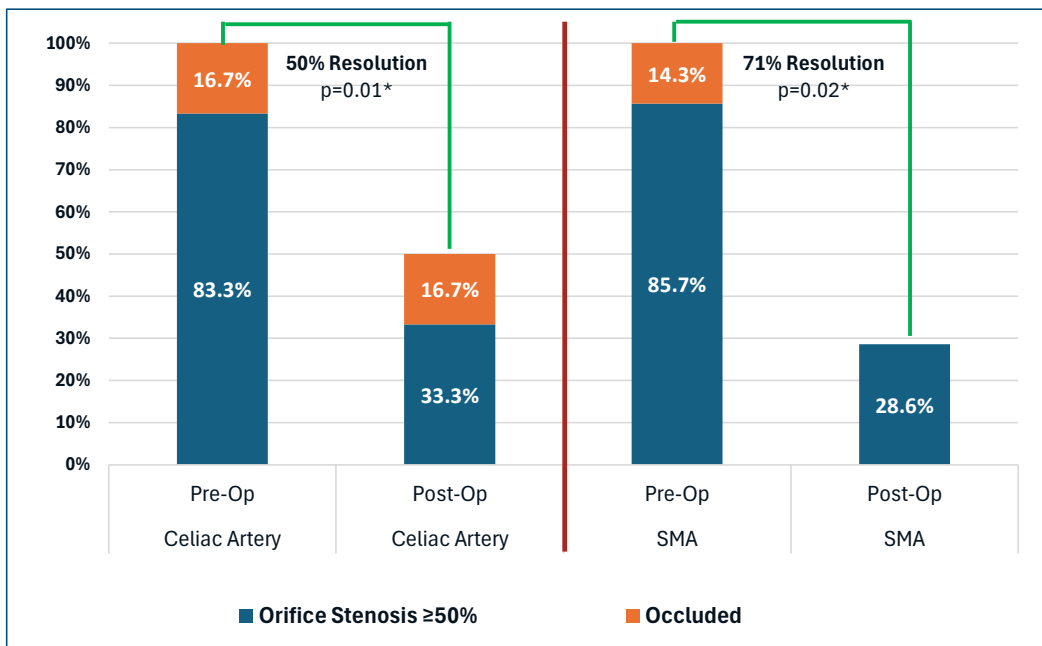
## Radiographic Malperfusion Results

**Celiac artery (occlusion or ≥50% stenosis):**

Pre-op 12 patients → Post-op 6 patients (50% resolution)

**SMA (occlusion or ≥50% stenosis):**

Pre-op 7 patients → Post-op 2 patients (71% resolution)





## Case Examples of Radiographic Malperfusion Resolution

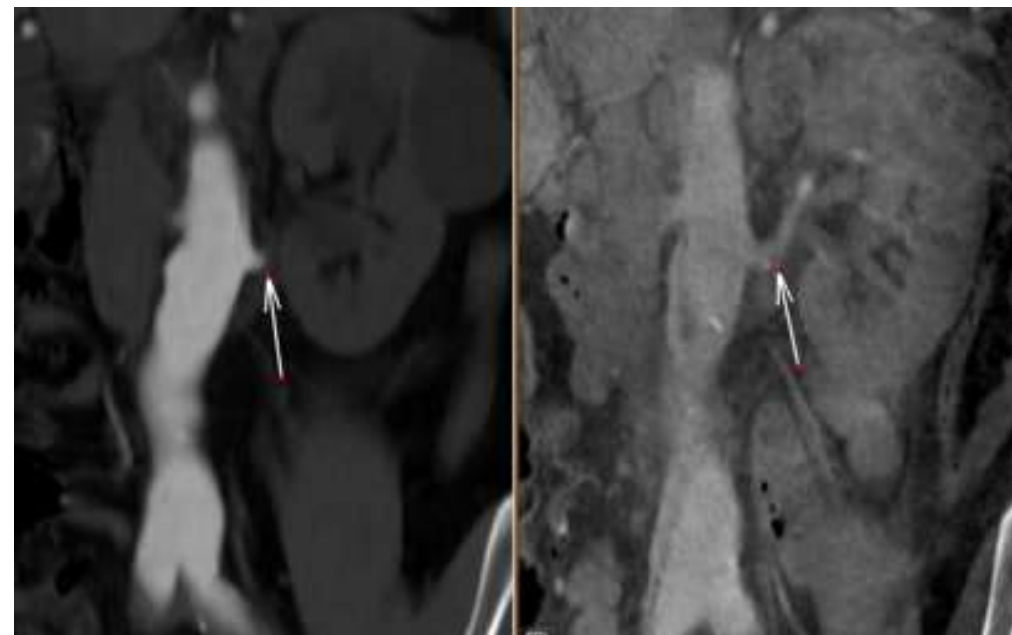
### Case 1 Details:

- Pre-Op (left): SMA with  $\geq 50\%$  stenosis
- Post-Op (right, 32 days): SMA is patent



### Case 2 Details:

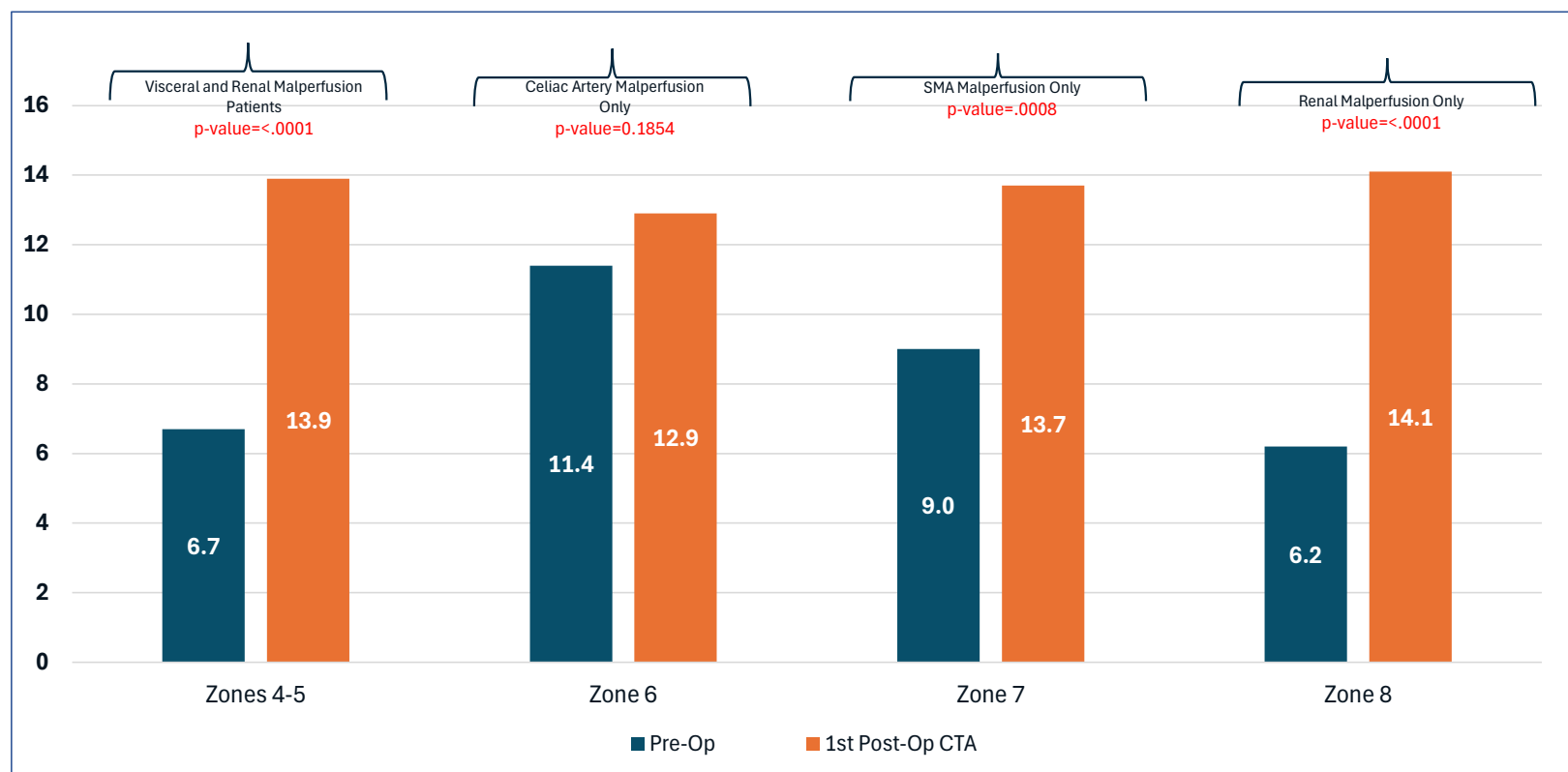
- Pre-op (Left): Left renal artery with  $\geq 50\%$  stenosis
- Post-op (Right, 2 days): Left renal artery is patent





Mean distance from distal end of AMDS to Celiac Artery= 72 mm (+/- 42.2 mm)

## Change in Narrowest TL Diameter



# 5 Key Benefits of AMDS

## 1) Reduction in Major Adverse Events (MAE's)

- At 30-days, AMDS significantly reduces MAE's such as; mortality, new disabling stroke, and new renal failure requiring dialysis, compared to hemiarch alone.<sup>14</sup>

## 2) Prevention of DANE

- The stent supported cuff of the AMDS and expansion of the device from the arch distally, elevates and supports the intimal flap. This reduces tension on the intima, media, and the suture line, avoiding the formation of DANEs in the friable anastomosis.<sup>13,14</sup>

## 3) Resolution of Malperfusion

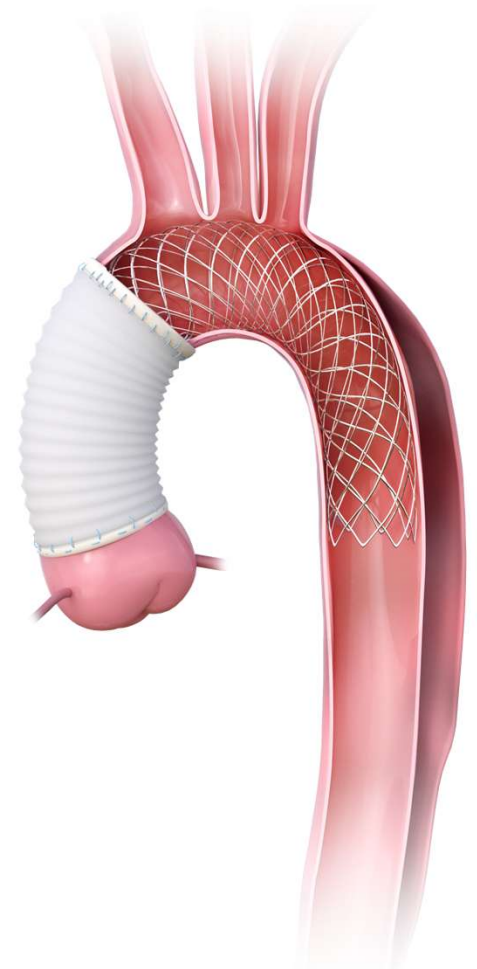
- AMDS-induced expansion of the true lumen demonstrates over 95% resolution of vessel malperfusion.<sup>13</sup>

## 4) Promotes Positive Aortic Remodeling

- By avoiding DANE and stabilizing the true lumen, AMDS induces positive aortic remodeling, defined by 3 key measures<sup>13</sup>:
  - 1) True Lumen Expansion
  - 2) False Lumen Reduction
  - 3) Total Aortic Diameter Stabilization

## 5) Ease of Use

- AMDS adds minimal time to the procedure without adding significant technical complexity.<sup>14</sup>





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