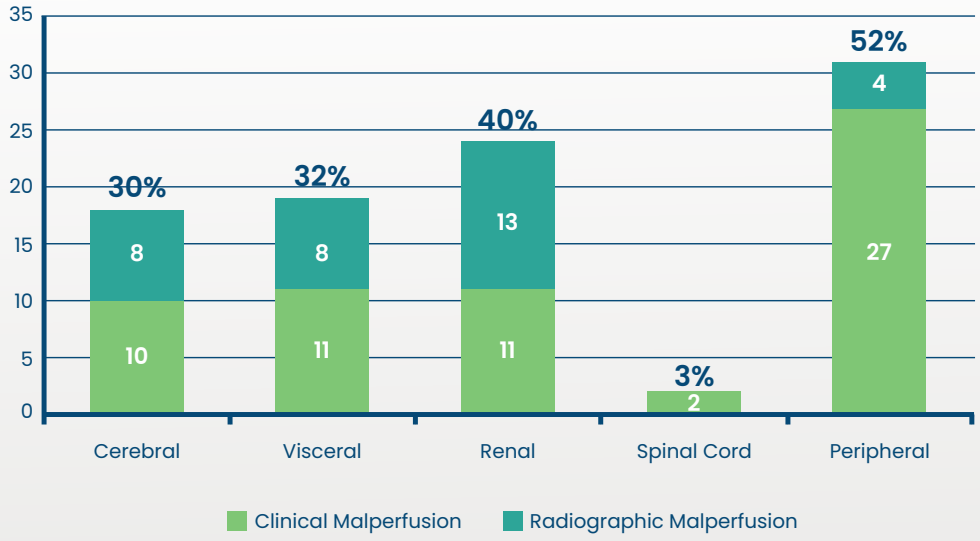
# PERSEVERE US IDE Study Interim Results

## A Prospective, Multi-Center Clinical Investigation to Evaluate the Safety and Effectiveness of AMDS in the Treatment of Acute DeBakey Type I Dissection

## Patients

- **Inclusion criteria:** Eligible patients were 18-80 years old and had an acute DeBakey type I (ADTI) dissection, presented with clinical and/or radiographic malperfusion, and were treated with ascending replacement plus AMDS.
- **Main exclusionary criteria:** Primary entry tear in the arch or other need for total arch repair or connective tissue disorder.
- **Enrollment:** 60 patients (of 93 total) enrolled at time of pre-planned interim analysis with a median age of 60.5 years.
- **Number of patients with clinical malperfusion:** 46 (77%)
- **Number of patients with only radiographic malperfusion:** 14 (23%)

**Pre-op Malperfusion Status**




Note: Patients with radiographic and clinical malperfusion in one anatomical area are considered "clinical" for the purposes of this bar graph. Some patients have >1 type of anatomical malperfusion.

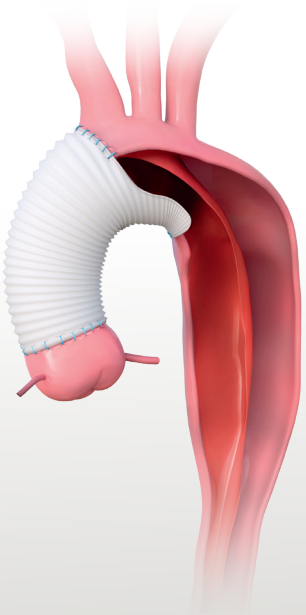
## Peri-Operative Data

| | Median |
|---|---|
| AMDS Deployment Time (mins) | 4.5 |
| Total AMDS Implant Time (mins)* | 17 |
| Total Hypothermic Circulatory Arrest (mins) | 30.0 |
| Time in ICU (days) | 5 |
| Time in Hospital (days) | 12.5 |

| | % |
|---|---|
| Guidewire Use | 3.3% |
| Fluoroscopy Use | 10.0% |
| Concomitant Procedure | 88.3% |

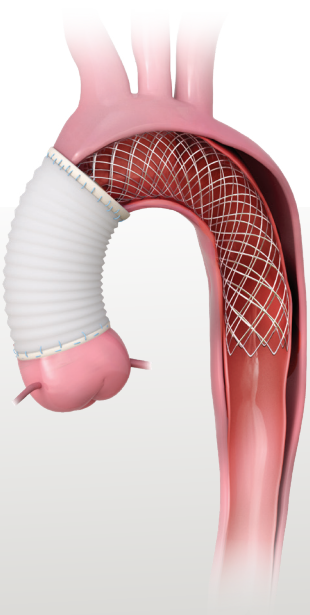
*Total time from AMDS insertion in aorta to last running suture

# Results: Primary 30-day MAE Endpoint



**ATDI with Malperfusion**

| Hemiarch Reference Cohort[1] (n=790 combined) | | PERSEVERE[2] (n=52) |
|---|---|---|
| 29-44% | All Cause Mortality | 13.5% |
| 12-35% | Stroke | 9.6% (new disabling) |
| 12-43% | New Onset Renal Failure Requiring Dialysis | 7.7% |
| 7-15% | Myocardial Infarction | 0% |



## Secondary Endpoints

| Secondary Endpoints | Total # of Patients (N=60) | Percentage |
|---|---|---|
| Technical Success | 59 | 98.3% |
| Unanticipated Aortic Reoperations | 1 | 1.7% |
| Distal Anastomotic New Entry (DANE) Tear | 0 | 0.0% |
| Distal Stent-Induced New Entry (d-SINE) Tear | 0 | 0.0% |
| Occlusion in Supra-Aortic Vessels | 0 | 0.0% |
| New Post-op Paraplegia or Paraparesis (SCI)* | 0 | 0.0% |

*Spinal Cord Injury

## Conclusions

The interim data from the PERSEVERE study suggests that AMDS use lowers 30-day MAEs in ADTI patients presenting with malperfusion compared to hemiarch alone. The PERSEVERE study is unique, as there are limited prospective studies of this size evaluating devices to treat and elevate the standard of care for ADTI dissection. Further follow-up of the entire 93 patient population will provide key data analyzing patient survival, occurrence of DANE, malperfusion resolution, and aortic remodeling.

**References:**

1. Zindovic I, 2019. Pacini D, 2013. Girdauskas E, 2009. Geirsson A, 2007. and Bossone E, 2002. 2. Adjudicated data as presented at EACTS Oct 2023 by Dr. Fernando Fleischman on behalf of corresponding authors, Interim results of AMDS Hybrid Prosthesis in acute DeBakey I Dissection with malperfusion (PERSEVERE Investigational Device Exemption Study)/Thursday 5 October 2023/17:30-18:30. Manuscript pending publication



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