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

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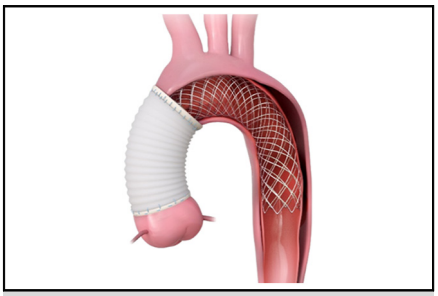
ABSTRACT

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 ≥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.

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ADULT

Patients with acute DeBakey type I dissection (ADTI) and a primary entry tear in the ascending aorta are treated with a hemiarch repair, currently a class I recommendation.[1,2] Patients who present with preoperative malperfusion have the highest incidences of morbidity and mortality.[3] Although hemiarch repair addresses the primary entry tear, any remaining dissection in the arch and descending aorta is left untreated. The presence of residual dissection

Abbreviations and Acronyms

ADTI = acute DeBakey type I dissection
CTA = computed tomography angiography
DANE = distal anastomotic new entry
FL = false lumen
FLD = false lumen diameter
IRAD = International Registry of Acute Aortic Dissection
MAE = major adverse event
TAD = total aortic diameter
TL = true lumen
TLD = true lumen diameter

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is associated with an elevated risk for early major adverse events (MAEs) and negative distal aortic remodeling.[4-8] Furthermore, the occurrence of distal anastomotic new entry (DANE) tears after hemiarch repair has been reported as high as 70%, which predisposes patients to continued antegrade pulsatile flow into the false lumen (FL).[9-12]

The AMDS Hybrid Prosthesis (Artivion) is a novel self-expanding, braided Nitinol stent (Figure 1) that is deployed antegrade into the arch and descending aorta during circulatory arrest as an adjunct to proximal aortic reconstruction. The device is designed to stabilize and expand the true lumen, avoid DANE tears, and enhance aortic remodeling in the arch.

The safety and effectiveness of the AMDS device is currently under investigation in the United States in an investigational device exemption study, PERSEVERE. The study enrolled patients with ADTI and preoperative malperfusion. Reported 30-day results include the primary results, rates of MAEs and DANE, and early aortic remodeling outcomes. The DARTS trial previously reported on safety and efficacy of AMDS in 46 patients presenting with ADTI, of which 26 patients (56.5%) had malperfusion.[13] PERSEVERE enrolled only patients with preoperative malperfusion, making it the largest prospective study in this patient population.

METHODS

Study Design and Endpoints

The PERSEVERE study (NCT05174767) is a prospective, single-arm, nonblinded, investigational trial conducted at 26 sites. A total of 93 patients were enrolled. A 5-year follow-up is planned for 5 years. There are 2 co-primary endpoints at 30 days. The first co-primary endpoint is a composite based on the incidence of the following MAEs: all-cause mortality, new disabling stroke, new renal failure requiring ≥1 dialysis treatment(s), and myocardial infarction. For the reference cohort, as agreed to with the Food and Drug Administration, individual MAE rates were considered from 5 publications reporting results in applicable patients with malperfusion; a composite rate was estimated from each publication, and the average (58%) was considered the performance goal (Table E1).[4-8] The second co-primary endpoint is incidence of DANE tears based on a Core Lab evaluation of computed tomography angiograms (CTAs). The average rate of DANE tears from 4 publications was used to set the performance goal (45%) for the reference cohort.[9-12] The study objective is to demonstrate a clinically meaningful reduction in patients who experience primary MAEs and DANE within 30 days.

The secondary endpoints include technical success, aortic remodeling parameters, and unanticipated aortic reoperations. Data analysis included changes in maximal total aortic diameter (TAD), true lumen diameter (TLD), false lumen diameter (FLD), and FL thrombosis status in the target treatment zones (1-3). An increase or decrease in diameter of ≥5 mm was considered significant; change from baseline was considered as a change between follow-up CTA and the preoperative CTA. Malperfusion resolution has not been widely defined or reported in the literature and was not originally included as an endpoint; future analyses will assess malperfusion.

Inclusion and Exclusion Criteria

Eligible patients were between 18 and 80 year old, diagnosed with ADTI, and presenting with clinical and/or radiographic malperfusion.

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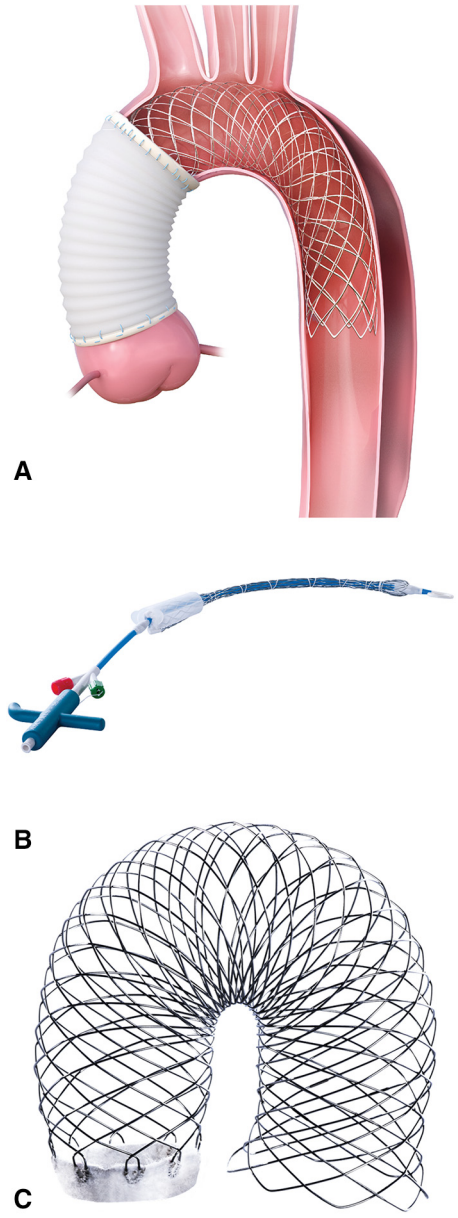


FIGURE 1. A, Illustration of the AMDS deployed into the arch, B, AMDS delivery system. C, AMDS stent.

TABLE 1. Baseline patient characteristics (N = 93)

Characteristic	Values
Age, y	
Mean ± SD	58.6 ± 9.45
Median (range)	60.0 (33-78)
<65 y, n (%)	71 (76.3)
Sex, n (%)	
Male	73 (78.5)
Female	20 (21.5)
Body mass index, kg/m^2	
Mean ± SD	29.7 ± 7.18
Median (range)	28.1 (18.0-63.2)
Race, n (%)	
Asian	1 (1.1)
Black or African American	21 (22.6)
White	56 (60.2)
Not reported or other	15 (16.1)
Ethnicity, n (%)	
Hispanic	10 (10.8)
Non-Hispanic	73 (78.5)
Not reported	10 (10.8)
Medical history, n (%)	
Arterial hypertension	45 (48.4)
Hyperlipidemia	28 (30.1)
Chronic kidney disease	28 (30.2)
Type II diabetes	13 (14.0)
Coronary artery disease	11 (11.8)
Cancer	11 (11.8)
Sinus bradycardia	9 (9.7)
Social history, n (%)	
Tobacco use	49 (52.7)
Illicit drug use	19 (20.4)
Aorta anatomy and disease, n (%)	
Normal aortic anatomy	67 (72.0)
Bovine arch	21 (22.6)
Isolated vertebral	5 (5.4)
Secondary entry tears (all)	80 (86.0)
Innominate artery	24 (25.8)
Left common carotid artery	5 (5.4)
Left subclavian artery	11 (11.8)
Malperfusion, n (%)	
Clinical	76 (81.7)
Radiographic only	17 (18.3)

General exclusion criteria included life expectancy <2 years due to another medical condition, pregnant/breastfeeding, and unwillingness to accept blood transfusions. Medical exclusion criteria included coronary malperfusion, circulatory shock, extreme hemodynamic compromise, and connective tissue disorder. While malperfusion is an inclusion requirement, AMDS is not intended to treat coronary malperfusion. Anatomic exclusion criteria included a primary entry tear in the arch or distal to the arch and/or the need for a partial or total arch replacement. The trial is designed to enroll patients with a primary entry tear in zone 0.

Each site was approved by the overseeing Institutional Review Board (central IRB reference number 20216348; initial approval on December 17, 2021). Between July 2022 and November 2023, 118 patients were prospectively consented for the study. In 25 of these 118 cases, a legally authorized representative was required because the patient was unable to provide written consent. Ultimately, 25 patients (21%) failed screening due to the need for a total arch replacement, primary entry tear in or distal to the arch, or a connective tissue disorder (Figure E1).

Device Sizing and Implantation

The AMDS is manufactured in 4 sizes (40 mm, 40-30 mm tapered, 55 mm, and 55-40 mm tapered) and supplied preloaded over the delivery system catheter (Figure 1, *B*). Device sizing is based primarily on TAD in zone 1, between the innominate and left common carotid, with an allowable range between 20 and 45 mm. A secondary TAD,

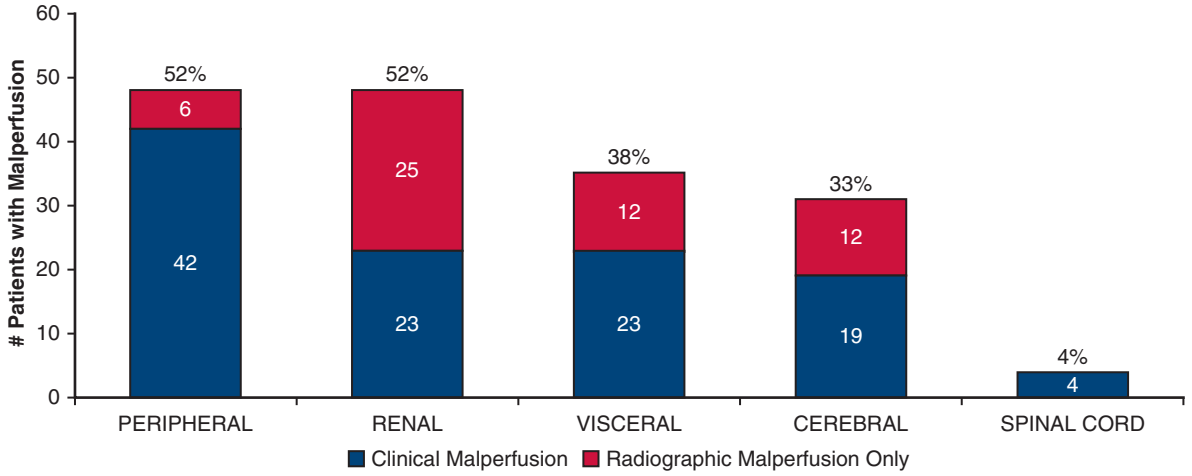


FIGURE 2. Summary of preoperative malperfusion status.

at the level of the pulmonary artery bifurcation, is needed to select between the straight and tapered configurations. The AMDS was configured with a latticed structure for potential use in a wide range of aortic sizes and to exert lower radial force on a dissected aorta. Oversizing is not recommended.

During circulatory arrest, AMDS implantation is performed concomitantly with resection of the ascending aorta. A notable distinction from the standard hemiarch repair is that ≥1 cm of aortic tissue proximal to the innominate artery is required to accommodate the cuff. The AMDS device is introduced into the true lumen of the distal aorta in an antegrade fashion, and an external felt strip is applied to the outside of the aorta/cuff. The stent is deployed, and the delivery system is then removed. The anastomotic site is secured with a running suture circumferentially. A polyester Dacron graft is used for the ascending aortic replacement and the graft to the distal aorta anastomosis is performed with a second continuous suture.

TABLE 2. Operative and hospital summary (N = 93)

Characteristic	Value
AMDS deployment time (min), mean ± SD; median	4.5 ± 2.74; 4.0
AMDS total implant time (min), mean ± SD; median	18.7 ± 28.36; 15.0
Hypothermic circulatory arrest time (min), mean ± SD; median	30.1 ± 21.40; 28.0
Type of cerebral perfusion, n (%)	
Antegrade	43 (46.2)
Retrograde	45 (48.4)
None	4 (4.3)
Cardiopulmonary bypass time (min), mean ± SD; median	190.8 ± 66.47; 176.0
Concomitant procedures, n (%)	
Yes	78 (83.9)
Aortic root intervention	36 (38.7)
Aortic valve resuspension	34 (36.6)
Valve intervention	21 (22.6)
Coronary artery bypass surgery	5 (5.4)
Other	22 (23.7)
Guidewire use, n (%)	9 (9.7)
Fluoroscopy use, n (%)	8 (8.6)
Method to identify the true lumen, n (%)	
Transesophageal echocardiography	62 (66.7)
Intravascular ultrasound	3 (3.2)
Visual inspection	58 (62.4)
Time in ICU, d, mean ± SD; median	10.2 ± 13.25; 6.0
Time in hospital, d, mean ± SD; median	16.7 ± 16.15; 12.0

ICU, Intensive care unit.

Data and Follow-up

Data were collected prospectively, and the mean follow-up at the time of analysis was 5.6 months (interquartile range [IQR], 2.9-9.3 months). All available CTAs were collected and analyzed by an independent imaging core lab (Cleveland Clinic's Vascular Core Laboratory) using TeraRecon analysis software. Core lab analysis included more than 100 data points per scan, including the presence of false lumen communications documented as primary or secondary tears. The aortic zones were defined based on the Society for Vascular Surgery and Society of Thoracic Surgeons reporting standards for type B aortic dissection.[14,15]

Statistical Analyses

Analyses and summary outputs were generated using SAS version 9.4 (SAS Institute). Supplemental analyses were performed using Microsoft Excel version 2308. Continuous variables were summarized using the number of observations, mean ± standard deviation, and median and range. For categorical variables, frequency count and percentage of patients were recorded. A 2-sided Fisher exact test was used to compare primary MAE outcomes to the average rates reported in the reference cohort.

RESULTS

Baseline Patient Characteristics

The baseline patient characteristics are presented in Table 1. The mean patient age was 59 ± 9.45 years. A majority of the cohort was male (79%), white (60%), and

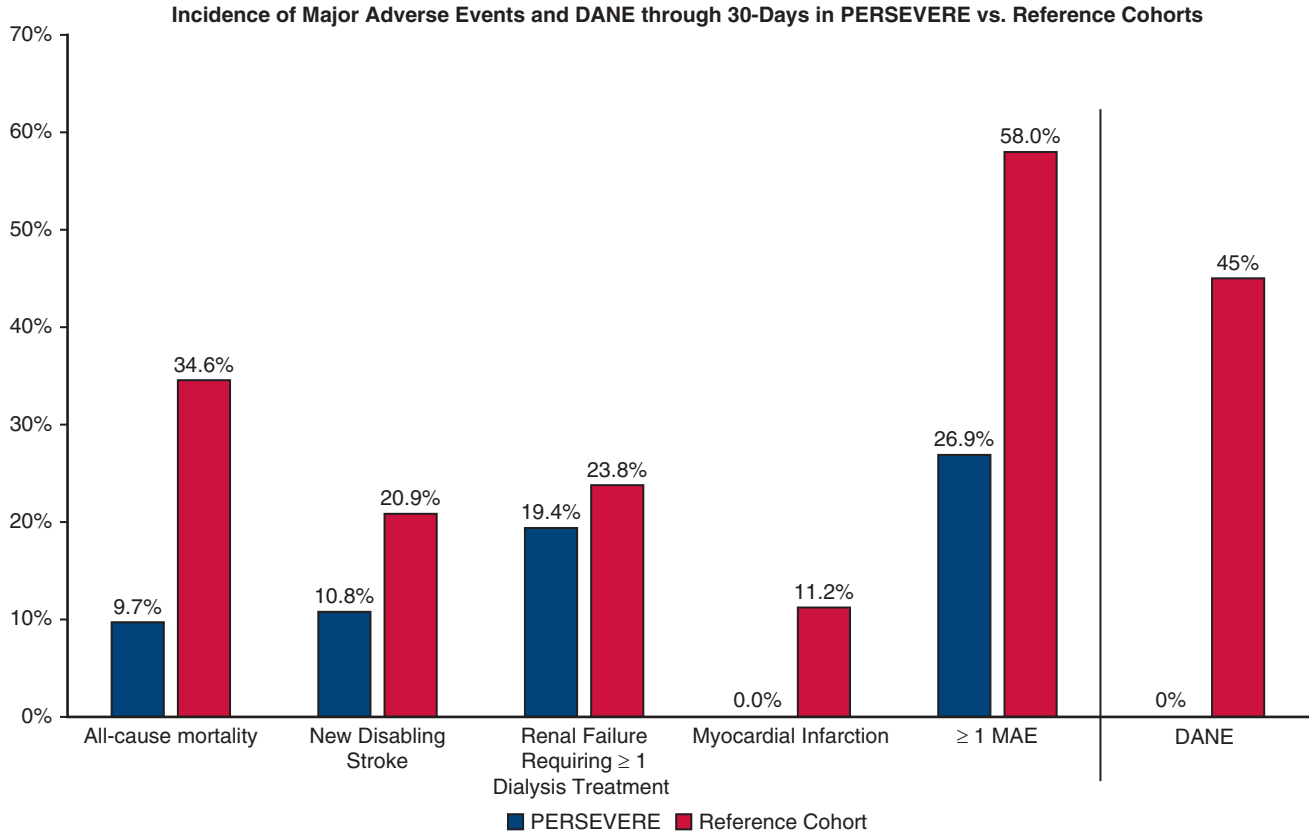


FIGURE 3. 30-day MAE and DANE rates compared with reference cohorts. *MAE*, Major adverse event; *DANE*, distal anastomotic new entry.

non-Hispanic (79%). Most patients (82%) presented with clinical malperfusion. The anatomies affected by malperfusion are displayed in Figure 2. At baseline, most patients (97%; 90 of 93) had a primary entry tear documented by the core lab in zone 0. Patient eligibility was determined by perioperative assessment by the treating surgeon, and in all cases the primary tear was described in zone 0. Forty-two percent (35 of 83) of patients with available data had ≥1 secondary entry tear(s) in zones 1 to 3 (Figure E2); 37% (31 of 83) had a secondary entry tear in at least 1 of the supra-aortic vessels.

Operative Characteristics

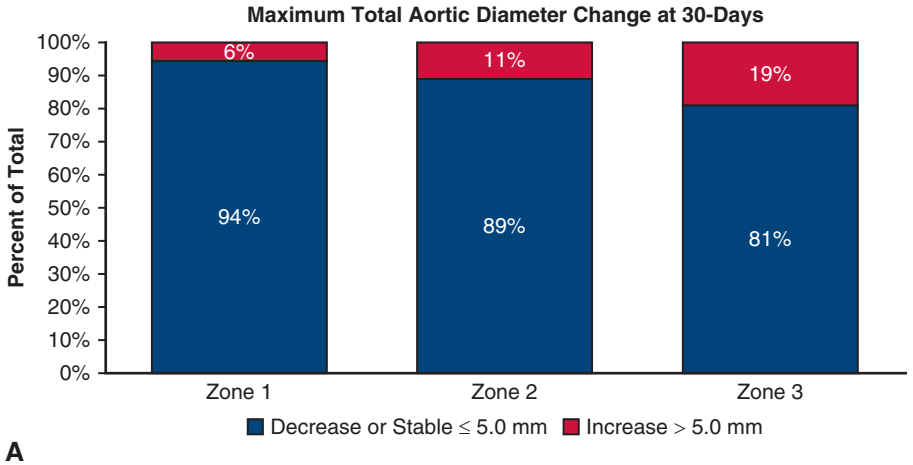
Intraoperative characteristics are shown in Table 2. Thirty-four surgeons performed the 93 procedures. The median time to deploy the AMDS device was 4 minutes, and the median time to complete the implantation was 15 minutes. Cerebral perfusion was used in 95% of procedures (antegrade, 46%; retrograde, 48%). The median hypothermic circulatory arrest time was 28 minutes, and the median cardiopulmonary bypass time was 176 minutes. In all cases, the AMDS anastomosis was performed proximal to the innominate artery. Seventy-eight patients (84%) underwent concomitant procedures, including 36 with aortic root interventions, 34 with aortic valve resuspensions, 21 with valve interventions, and 5 coronary artery bypass surgeries. The median time in the intensive care unit was 6 days, and the median hospital length of stay was 12 days.

Primary Endpoints

The incidence of MAEs within 30 days of the index procedure is shown in Figure 3. All primary events were adjudicated. Thirty-day mortality was 9.7% (n = 9); causes of death are listed in Table E2. Ten patients (11%) experienced new disabling stroke. Eighteen patients (19%) had new renal failure that required dialysis at least once. No myocardial infarctions were reported. In total, 25 patients (27%) experienced ≥1 MAE(s) within 30 days, which is a lower rate than seen in the reference cohort (58%) and met the study goal. The second co-primary endpoint was the incidence of DANE within 30 days. Based on the core lab review, no DANE was observed, below the rate seen in the reference cohort (45%), which met the study goal.

Secondary Endpoints

A summary of the secondary endpoints is provided in Table E3. Technical success was achieved in 92 patients (99%). In 1 patient, the majority of the AMDS was implanted into the true lumen, but the distal end of the



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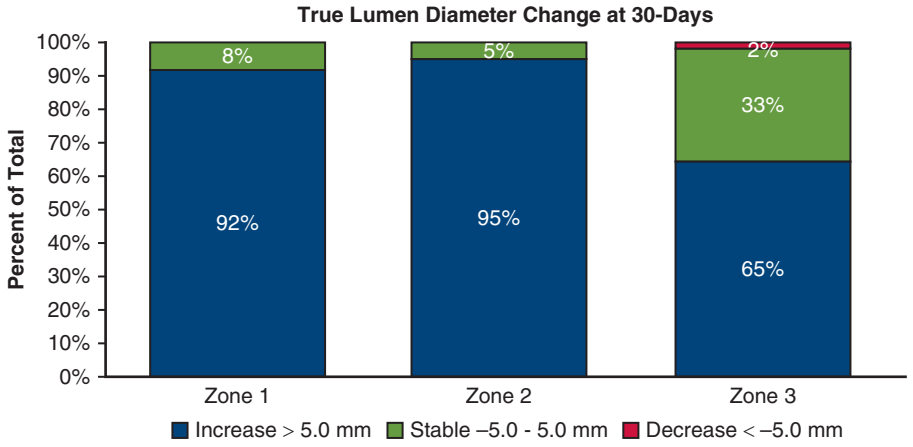

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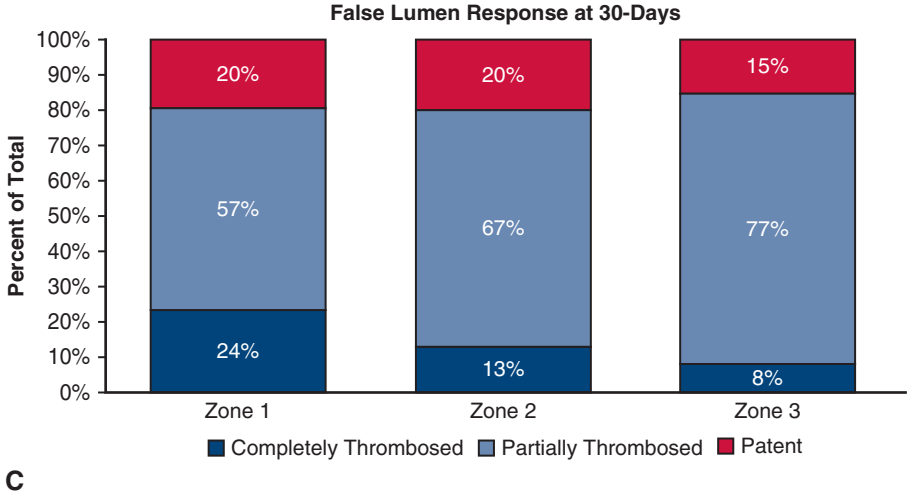
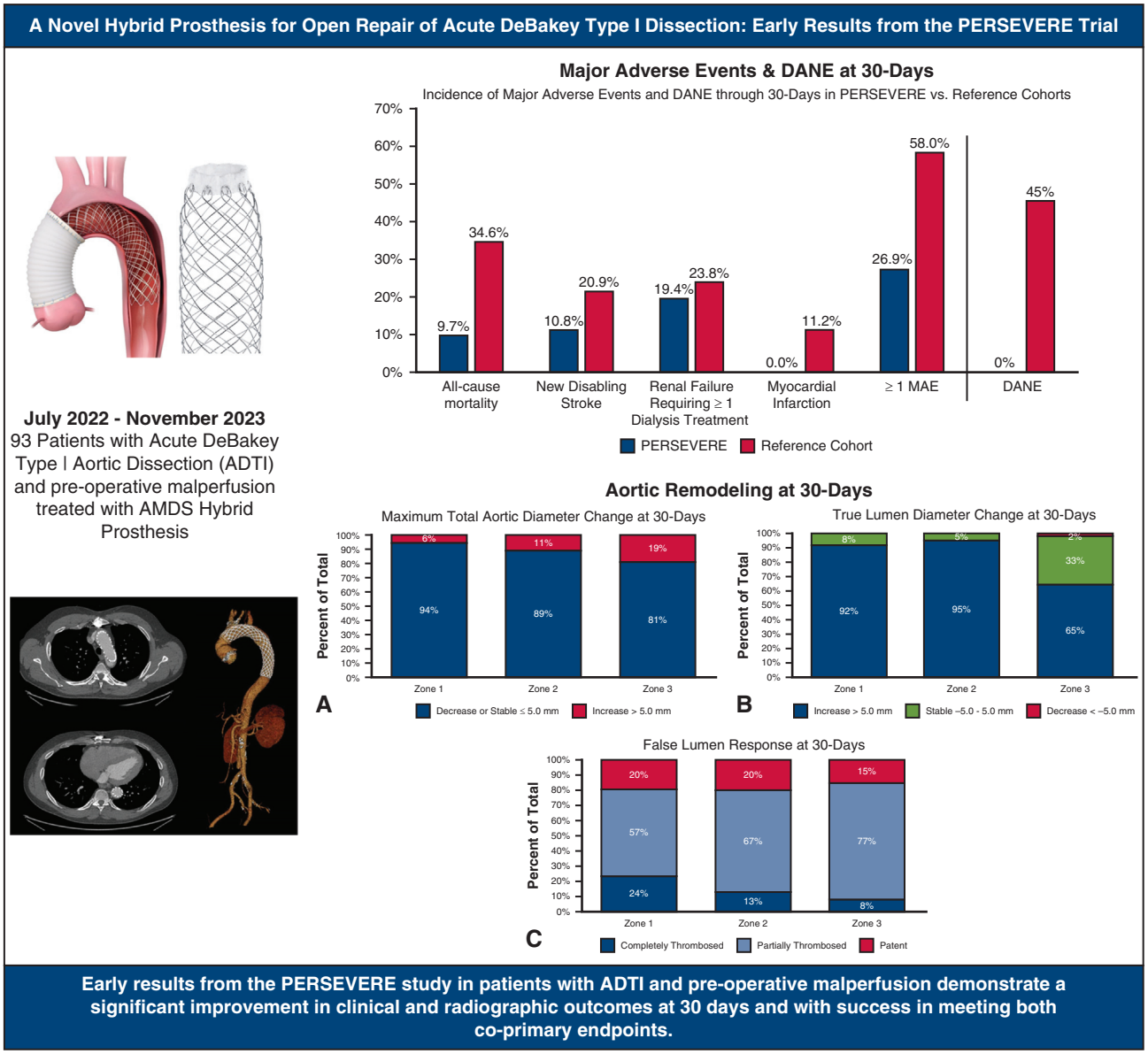


C

FIGURE 4. Aortic Remodeling in Aortic Zones 1-3. A, Maximum total aortic diameter change at 30-days; B, True lumen diameter change at 30-days; C, False lumen thrombosis response at 30-days.

device was implanted into the FL. This patient had a severely angulated gothic arch and notable secondary arch entry tears. At the time of this report, the patient had no new device-related issues at 1 year after the procedure. The cumulative all-cause mortality through maximum follow-up was 20%; causes of death are listed



ADTI: Acute DeBakey Type I Aortic Dissection; DANE: distal anastomotic new entry tears

FIGURE 5. Graphical abstract illustrating early primary results from the PERSEVERE Study.

in Table E2. The cumulative incidence of secondary MAEs is presented in Table E3.

Most patients (98%) had at least 1 postoperative diagnostic image obtained. A 30-day CTA was available in 77% of patients (72 of 93); availability of data varied by zone and was dependent on CTA quality. At 30 days, most patients had a stable or decreased maximum TAD in zones 1, 2, and 3 (94%, 89%, and 81%, respectively) (Figure 4). Most patients demonstrated increased in TLD in zones 1, 2, and 3 (92%, 95%, and 65%, respectively). Most patients had a partially or completely thrombosed FL in zones 1, 2, and 3 (80%, 80%, and 85%, respectively). The mean FLD change from baseline was −11.6 ± 6.4 mm in zone 1, -10.8 ± 5.5 mm in zone 2, and -3.5 ± 6.0 mm in zone 3.

Unanticipated aortic reoperations are summarized in Table E4. There were 3 unanticipated aortic reoperations, occurring at a median of 125 days after the index procedure. Freedom from unanticipated aortic reoperation was 97%, and the reoperations were not device-related.

Considering all diagnostic imaging analyzed throughout the follow-up period, there was no incidence of the following: DANE, supra-aortic branch vessel occlusion,

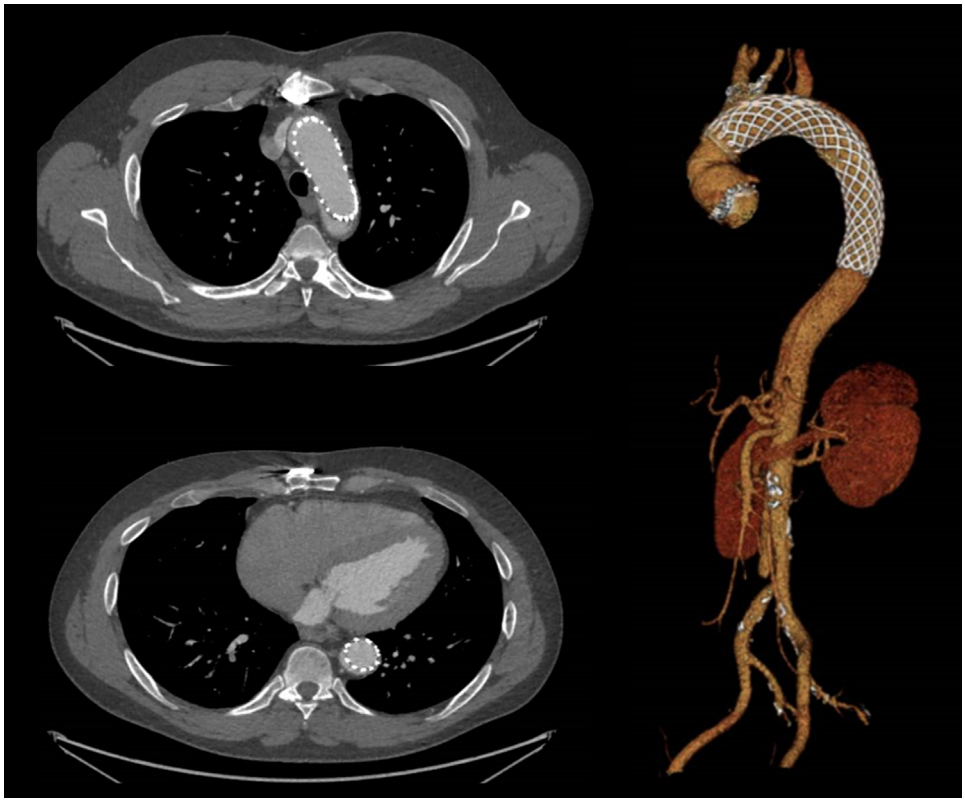


FIGURE 6. Example of positive aortic remodeling at 1-year, post-procedure at 1-year, post-procedure.

device migration, stent fracture, or stent kink/twist. There was 1 instance of d-SINE, which was observed at 1 year postprocedure. Five patients had documented stent narrowing, which had no clinical impact.

DISCUSSION

The PERSEVERE study demonstrates that AMDS is safe and effective in the treatment of ADTI patients who present with malperfusion (Figure 5). Both co-primary endpoints were met, with reduced rates of MAEs and DANE. All-cause mortality at 30 days was 9.7%, well below the reference cohort average of 34.6%. The cumulative all-cause mortality was 20%, as would be expected with associated comorbidities in ADTI patients. In addition, the early mortality rate compares favorably with the in-hospital mortality rate of 20% reported by the International Registry of Acute Aortic Dissection (IRAD) in a mixed cohort of patients surgically treated for acute Stanford type A dissection.[16] It has been demonstrated that malperfusion is correlated with higher mortality risk.[3-7]

Given that the PERSEVERE cohort comprises 82% of patients with preoperative clinical malperfusion, the mortality rate of patients treated with AMDS is encouraging. The new disabling stroke rate within 30 days of 10.8% is lower than the stroke rate range in the reference cohort of 12% to 35%. The stroke rate was expected in this high-risk group, which included 33% of patients presenting with cerebral malperfusion. The results also compare favorably with those in a mixed cohort reported by IRAD, which reported a stroke rate of 17.5% in patients surgically treated for acute type A dissection, along with a 15% rate of cerebral malperfusion.[17] The rate of new renal failure requiring $\geq$1 dialysis treatment(s) of 19.4% is below than the reference cohort average of 24.1%. The primary composite rate of patients with $\geq$1 MAEs was lower than the estimated rate in the reference cohort (27% vs 58%) and lower than the original sample size assumptions for the study design (Figure 3). The absence of DANE was equally encouraging and clinically significant. DANE has been observed in up to 70% of patients following hemiarch repair and has been associated with negative aortic remodeling and additional aortic reinterventions.[11]

An example of aortic remodeling in 1 patient through 1 year is provided in Figure 6, which demonstrates expansion of the TL with stabilization of TAD and complete thrombosis of FL in zones 0-3. Residual thoracoabdominal dissection distal to AMDS is expected and remains stable. Most patients demonstrated TAD stabilization or decrease, TL increase, and FL decrease in zones 1 to 3 when comparing 30-day CTAs to preoperative CTAs. All zones

are being assessed by the core lab, but the early focus remains on the critical zones 1 to 3 in the arch, as remodeling in this area is a key predictor of the need for future reoperations following hemiarch. The FL was completely or partially thrombosed in 82% of patients in zone 1, 85% of those in zone 2, and 90% of those in zone 3. FL thrombosis rates are anticipated to increase over time as the aorta stabilizes due to the prevention of DANE and expansion of the TL by the stent. Long-term aortic remodeling will be investigated in future analyses.

There was no evidence of migration, fracture, kink, or twist. There was only 1 incidence of d-SINE at 1 year. A low percentage of patients (5%) had documented device narrowing. In all cases, the stent cells remained open and did not impede blood flow through the aorta lumen or the aortic branch vessels. Luehr and colleagues[18] first reported on radiographic observations of device narrowing after implantation of the AMDS device, similarly noting no associated clinical sequalae. Following thorough case investigation, benchtop testing, and cadaver studies, 3 factors were identified as potential root causes and considerations to minimize the incidence of narrowing: device size selection, arch anatomy, and surgical manipulation, specifically tension on the distal anastomosis.

Three patients (3.2%) patients underwent unanticipated aortic reoperation due to progression of aortic disease. In the 2 cases of total arch repair using a frozen elephant trunk technique, the procedures and extensions were deployed successfully through the existing AMDS without the need for explant. These early results suggest that AMDS might not be the ideal treatment strategy in patients with either primary tear in the arch (an exclusion criterion in the study) or extensive distal secondary reentry tear in the distal aorta; total arch repair would be a reasonable approach.[2]

One limitation of this study is the short follow-up. In addition, this is a single-arm study and not randomized, and therefore the reference publications were not identical to study patients. Nonetheless, this study is unique owing to its prospective design and large sample size of almost 100 patients. The majority of ADTI studies reported in the literature are retrospective, single center, and of limited size.

The minimal additional circulatory arrest time for device implantation and simplicity of deployment are distinct from complex total arch reconstruction. The device can be successfully implanted by all cardiac surgeons treating ADTI patients and is not limited to subspecialized high-volume aortic surgeons.

CONCLUSIONS

These early PERSEVERE study results in ADTI patients with preoperative malperfusion demonstrate a considerable improvement in clinical outcomes compared to the literature. Study design assumptions were met. The AMDS procedure is safe and effective, adds minimal time to ADTI repair, and does not add significant technical complexity. Data collection is ongoing. Although data on aortic remodeling for comparison are scarce, the early data suggest positive aortic remodeling after treatment with AMDS. Future studies will assess the relationships between aortic remodeling, presence of secondary entry tears, and the need for additional aortic procedures. Long-term follow up data are needed to confirm outcomes and treatment durability.

Webcast

You can watch a Webcast of this AATS meeting presentation by going to: https://www.aats.org/resources/aortic-arch-remodeling-followi-8304.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: acute aortic dissection, hemiarch, aortic remodeling, malperfusion

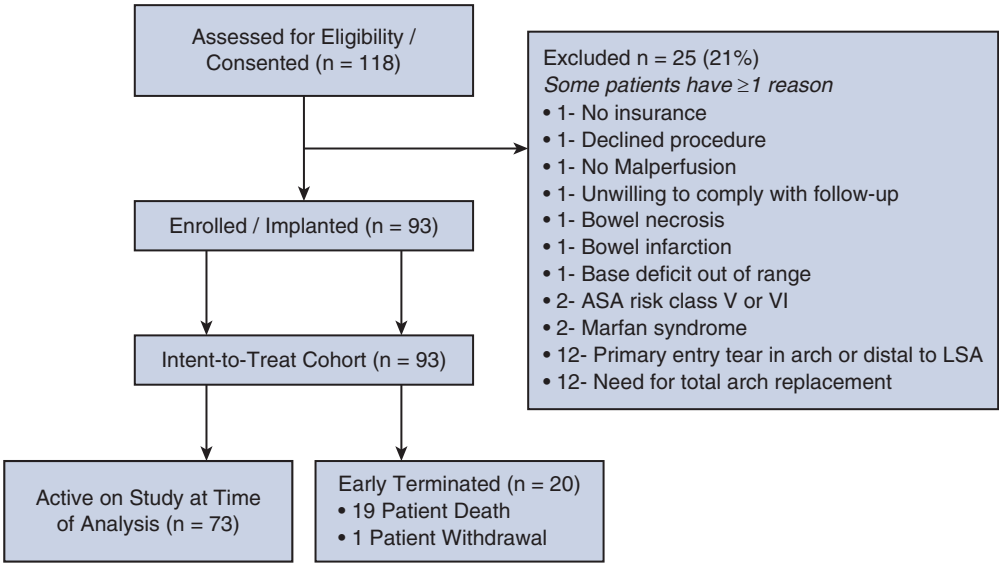

FIGURE E1. CONSORT diagram. *ASA,* American Society of Anesthesiologists; *LSA,* left subclavian artery.

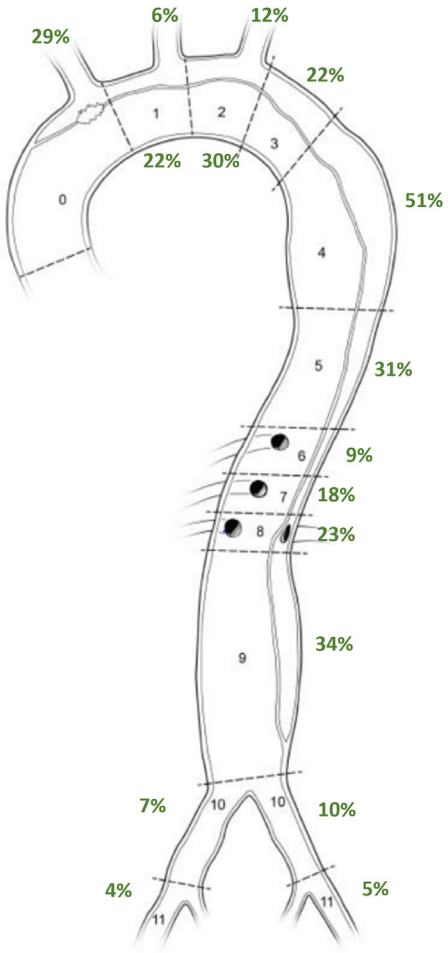

FIGURE E2. Rates of any preoperative secondary entry tears by zone, documented by the core lab.

TABLE E1. Reference cohort MAE rates

Characteristic	Zindovic (2019)[4]	Pacini (2013)[5]	Girdauskas (2009)[6]	Geirsson (2007)[7]	Bossone (2002)[8]
Number of sites	8	1	1	1	1
Time period	2005-2014	2000-2008	1994-2008	1993-2004	1996-1999
Study design	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective
DeBakey I dissection	329 (86.4)	100% type A	100% type A	52 (88.1%)	NA
Sample size	Total: 1159	Total: 502	Total: 276	Total: 221	Total: 513
	MPS: 381	MPS: 103	MPS: 93	MPS: 59	MPS: 154
	N-MPS: 778	N-MPS: 399	N-MPS:183	N-MPS: 162	N-MPS: 359
Age, y, mean ± SD	60.9 ± 10.6	61.9 ± 12.0	59.9 ± 11.3	59.0 ± 14.4	59.9 ± 13.5
Male sex, n (%)	268 (70.3)	72 (69.9)	62 (67)	41 (69.5)	119 (77)
Hypertension, n (%)	207 (54.3)	81 (78.6)	77 (83)	41 (69.5)	92 (64.0)
Coronary artery disease, n (%)	NA	NA	15 (16)	7 (11.9)	NA
Diabetes mellitus, n (%)	9 (2.4)	NA	NA	4 (6.8)	3 (2.0)
History of stroke, n (%)	17 (4.5)	NA	NA	2 (3.4)	NA
CKD/renal failure, n (%)	5 (1.3)	NA	NA	4 (6.8)	NA
Mortality, n (%)	110 (28.9)*	45 (43.7)	27 (29.0)	18 (30.5)	63 (40.9)
Stroke, n (%)	74 (19.4)	17 (16.5)	20 (21.5)	7 (11.9)	54 (35.1)†
Dialysis, n (%)	66 (17.3)‡	NA	40 (43.0)	7 (11.9)	NA
Myocardial infarction, n (%)	41 (10.8)	7 (6.8)	NA	9 (15.3)	14 (9.1)
Total events, n (%)	291 (76.4)	69 (67.0)	87 (93.5)	41 (69.5)	131 (85.1)

MAE, Major adverse event; *NA*, not available; *MPS*, malperfusion; *CKD*, chronic kidney disease. *30-day mortality data. †Including all neurologic deficits. ‡Including other renal replacement therapy.

TABLE E2. All-cause mortality through follow-up

Patient	Cause of death	Days postprocedure
1	Multisystem organ failure	1
2	Liver failure	1
3	Bowel ischemia	2
4	Multisystem organ failure	2
5	Cardiogenic shock	9
6	Multisystem organ failure	11
7	Septic shock/multisystem organ failure	24
8	Ventricular fibrillation leading to cardiac arrest	25
9	Cardiac arrest	26
10	Cardiac arrest	49
11	Refractory vasoplegia	54
12	Multi system organ failure	66
13	Septic shock	103
14	Severe sepsis and septic shock	181
15	Unknown	196
16	Unknown	208
17	Respiratory distress with worsening hypoxia	267
18	Unknown	281
19	Cardiac arrest	326

TABLE E3. Secondary endpoint event rates

Secondary endpoint	Value
Technical success, n (%)*	92 (98.9)
Procedural success, n (%)	76 (81.7)
Cumulative event incidence, n (%)	
Total all-cause mortality	19 (20.4)
New disabling stroke	11 (11.8)
New nondisabling stroke	5 (5.4)
New renal failure requiring dialysis	19 (20.4)
Myocardial infarction	2 (2.2)
Aortic rupture	0 (0.0)
Pseudoaneurysm	1 (1.1)
Unanticipated aortic reoperations	3 (3.2)
New postoperative paraplegia or paraparesis	0 (0.0)
Respiratory failure	17 (18.3)
Recurrent laryngeal or phrenic nerve injury	0 (0.0)
Radiological†	
DANE tears	0 (0.0)
d-SINE	1 (1.1)
Occlusion of supra-aortic vessels	0 (0.0)
Device migration	0 (0.0)
Stent fracture, kink, or twist	0 (0.0)
Stent narrowing‡	5 (5.4)

DANE, Distal anastomotic new entry; *d-SINE*, distal stent-induced new entry. *Defined as the successful delivery and accurate placement of the AMDS, patency of the device and aortic arch vessels, and freedom from unanticipated or emergent surgery related to device malfunction or complication. †N = 91 with ≥1 postoperative diagnostic image(s). ‡Defined as a > 50% reduction in inner diameter compared to expanded portions of the implant proximal and distal to the narrowed portion.

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TABLE E4. Unanticipated aortic reoperations

Patient	Indication	Type of procedure	Surgery status	Description of procedure	Days after procedure
1	Descending aorta thrombus	Open	Unanticipated	Thoracoabdominal aorta replacement	3
2	Aortic arch aneurysm	Open	Unanticipated	Total arch replacement	125
		Endovascular	Anticipated	TEVAR and left subclavian embolization	155
3	Ascending pseudoaneurysm	Open	Unanticipated	Total arch Replacement	129
		Endovascular	Anticipated	TEVAR extension	146
		Endovascular	Anticipated	Coil embolization of the left subclavian artery	200

TEVAR, Thoracic endovascular aortic repair.