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Aorta: Research

One-Year Results of a Low-Profile Endograft in Acute, Complicated Type B Aortic Dissection

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ABSTRACT

BACKGROUND The safety and effectiveness of the RelayPro endograft (Terumo Aortic) was assessed for the treatment of acute, complicated type B aortic dissection (TBAD).

METHODS A prospective pivotal trial analyzed a primary end point of all-cause mortality at 30 days. Secondary end points included technical success, major adverse events (disabling stroke, renal failure, and paraplegia/paralysis), endoleaks, patency, rupture, device integrity, false lumen perfusion, reinterventions, aortic expansion, and migration evaluated to 5 years.

RESULTS The study involved 22 United States centers and enrolled 56 patients (mean age, 59.5 ± 11.4 years) from 2017 to 2021; of whom, 73.2% were men and 53.6% were African American. TBAD was complicated by malperfusion of the kidneys (51.8%), lower extremities (35.7%), and viscera (33.9%), and rupture (10.7%). Dissection extended proximally to zones 1/2 (14.3%) and zone 3 (78.6%) and distally to the iliac arteries (67.3%). Most procedures were percutaneous (85.5%). Technical success was 100%. Median hospitalization was 7 days (interquartile range, 5-12 days). All-cause mortality at 30 days was 1.8% (1 of 56; upper 95% CI, 8.2%; $P < .0001$). Seven major adverse events occurred in 6 patients (10.7%), consisting of paraplegia (n = 3), paraparesis (n = 2), disabling stroke (n = 1), and renal failure (n = 1). All paraplegia/paraparesis resolved with lumbar drainage. Kaplan-Meier analysis estimated a freedom from major adverse events of 89.1% at each interval from 30 days to 3 years. There was 1 endoleak (Type Ia), 2 retrograde dissections, and aortic diameter growth occurred in 2. There has been no rupture, fistula, component separation, patency loss, stenosis, kinking, twisting, bird beak, loss of device integrity, or fracture.

CONCLUSIONS RelayPro is safe and effective in acute, complicated TBAD. Follow-up is ongoing to evaluate longer-term outcomes and durability.

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Thoracic endovascular aortic repair (TEVAR) for acute, complicated type B aortic dissection (TBAD) has been shown to be beneficial vs open surgical repair in mortality, paraplegia, and stroke, and is now first-line treatment.[1,2] The immediate

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objectives of endovascular repair are to cover the primary entry tear, redirect flow to the true lumen, depressurize the false lumen, and resolve malperfusion; longer-term objectives include positive aortic remodeling and a low rate of secondary interventions.[3]

RelayPro (Terumo Aortic) is a low-profile stent graft approved by United States Food and Drug Administration in 2021 for the treatment of aneurysms and penetrating atherosclerotic ulcers and in 2023 for dissection and transection.[4] Some unique features of the device are a 19F-23F delivery sheath size to facilitate safe percutaneous access in small or diseased iliofemoral arteries, a nonbare stent (NBS) proximal configuration that enables proximal deployment with greater conformability, dual-sheath deployment, and a range of diameters, lengths, and tapering.

RelayPro comprises self-expanding electropolished nitinol, sinusoidal stents that are sutured to a tightly woven, multifilament polyester graft fabric for profile reduction. The wire diameter and design are identical to the previous iteration (RelayPlus) where no stent fractures were observed at 5-year follow-up.[5] A distinguishing characteristic of the system is that deployment comprises 2 stages: the first with a thin-wall, coiled outer sheath that advances to the abdomen; the second allows partial expansion (and release of spring tension) of the stent graft within a flexible inner sheath that advances further up the thoracic aorta. Deployment is proximal to distal.

PATIENTS AND METHODS

This is a prospective, multicenter, single-arm, pivotal study (NCT03033043) to evaluate the safety and effectiveness of RelayPro in the treatment of acute, complicated TBAD with an hypothesis-driven 30-day primary end point of all-cause mortality. Although the study was designed before current Society for Vascular Surgery (SVS) reporting standards, this end point is equivalent to early dissection-related death, defined as all deaths within 30 days of symptom onset or the index procedure or during hospitalization.[6] Secondary end points include technical success, major adverse events (MAEs) of disabling stroke, renal failure, paraplegia, and paraparesis, aortic diameter growth (>5 mm) or rupture, false lumen perfusion, endoleaks, patency, integrity, migration (>10 mm), and secondary interventions.

The study was conducted in accordance with the Declaration of Helsinki (1986) and in compliance with 21 CFR parts 50, 54, 56, 812, and any other applicable Food and Drug Administration regulations, local and institutional regulations, and Institutional Review Board requirements at 22 hospitals in the United States (see Supplemental Material). All patients consented to participate in this study.

A Clinical Events Committee and Data Safety Monitoring Board with independent physicians (and a biostatistician in the case of the Data Safety Monitoring Board) oversaw the study, adjudicated all adverse events and classified them as related or not related to the device or procedure, and ensured the study was conducted ethically and that the health and welfare of each patient was protected. A core laboratory assessed all imaging outcomes.

Adult patients with acute (symptom onset to diagnosis within 2 weeks), complicated (clinical or imaging evidence of malperfusion or aortic rupture) TBAD were included. Exclusion criteria were traumatic injury or transection, significant stenosis (>50%), calcification, thrombus (that would compromise fixation or seal), or tortuosity, connective tissue disorders, recent stroke, and/or myocardial infarct.

The study data were analyzed using SAS 9.4 software (SAS Institute, Inc), with descriptive summary statistics of all data points, including number of observations, mean ± SD, and median (minimum and maximum) for continuous variables, and numerator, denominator, and percentage for categorical variables. Exact *P* values and 95% CIs were calculated using the exact method for appropriate variables, based on a binomial distribution (nonnormal). The primary end point was compared with performance goals based on 30-day outcomes of comparable pivotal studies. These end points were binary proportions with 95% CIs tested against a performance target of 25%.[6]

RESULTS

From September 2017 to September 2021, 56 patients were included. At the time of this primary analysis, 1-year follow-up was complete, and 36 patients (69.6%) were active in the study. Table 1 details patient demographics and medical history, a population largely male (73.2%), African American (53.6%), and predominately young (two-thirds were aged <65 years, and the mean age was 59.5 ± 11.4 years). Comorbidities included hypertension (89.3%), history of smoking (82.1%), hypercholesterolemia (37.5%), coronary artery disease (21.4%), gastrointestinal disease (19.6%), diabetes mellitus (17.9%), renal insufficiency (12.5%), and previous vascular intervention (12.5%).

All 56 patients had acute TBAD complicated by malperfusion (51.8% renal, 33.9% visceral, 35.7% lower extremity, 1.8% spinal) or rupture (10.7%) (Figure 1). Malperfusion was present in >1 site in 16 patients

TABLE 1 Patient Demographics and Medical History

Variable	Data Value (N = 56)
Male	73.2 (41)
Age, y	59.5 ± 11.42
Median (IQR)	59.5 (51-68)
Race/ethnicity	
African-American	53.6 (30)
White	42.9 (24)
Asian	1.8 (1)
Comorbidities and complications	
Renal malperfusion	51.8 (29)
Lower-extremity malperfusion	35.7 (20)
Visceral malperfusion	33.9 (19)
Rupture	10.7 (6)
Spinal cord malperfusion	1.8 (1)
Pain at presentation	14.3 (8)
Hypertension	89.3 (50)
Smoking	82.1 (46)
Current	47.8 (22/46)
Hypercholesterolemia	37.5 (21)
Antiplatelets/anticoagulants	37.5 (21)
Coronary artery disease	21.4 (12)
Gastrointestinal complications	19.6 (11)
Diabetes mellitus	17.9 (10)
Renal insufficiency	12.5 (7)
Vascular intervention	12.5 (7)
Limb ischemia	8.9 (5)
Peripheral vascular disease	7.1 (4)
Impotence (men)	2.4 (1/41)

Data are presented as % (n or n/N), mean ± SD, or as indicated otherwise. IQR, interquartile range.

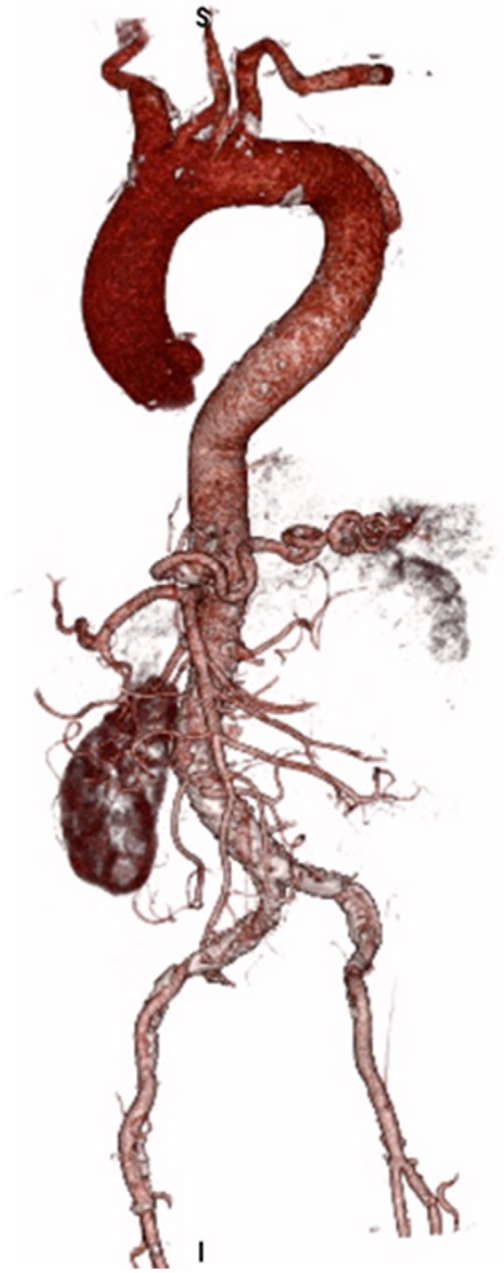


FIGURE 1 Preoperative volume-rendered scan of a 73-year-old man with an acute, complicated type B aortic dissection and a history of diabetes mellitus, hypertension, hypercholesterolemia, smoking, renal insufficiency, limb ischemia (left and right asymptomatic), gastrointestinal complications, bowel obstruction, and vascular intervention.

(28.6%). Proximal extent of the dissection was in zones 1 or 2 in 14.3% and zone 3 in 78.6% (Table 2). Dissection extended distally to the iliac arteries (1 or both) in 67.3%, the abdominal aorta in 25.0%, or was limited to the thoracic aorta in 5.4%.

Most procedures were percutaneous (85.5%) and involved covering all or part of the left subclavian artery (LSA; 58.9%), whereas LSA revascularization was reported in 15 patients (26.8%) (Table 3). One-third (33.9%) had intraoperative cerebrospinal fluid drainage. Median total procedure duration was 100 minutes (interquartile range [IQR], 80-192 min), and the median implantation duration (endovascular part only) was 17 minutes (IQR, 10-26 minutes). RelayPro NBS was used most often of all RelayPro devices implanted (65.3% [64 of 98]). Technical success was 100%. Postoperatively, patients spent a median 81 hours (IQR, 50-142 hours) in intensive care. Median overall hospitalization was 7 days (IQR, 5-12 days).

One death occurred within 30 days (1.8% dissection-related mortality) (Table 4). The patient, a 56-year-old man, was discharged home after a successful procedure but found dead the next morning (postoperative day 8). There was no autopsy, and cause of death is indeterminate. He had a history of lumbar and cervical spine degeneration, hypertension, hypercholesterolemia, smoking, cyclic vomiting, atrial septal defect, and restless leg syndrome, and presented with pain and renal malperfusion. He was treated with a single device covering the LSA.

TABLE 2 Aortic and Dissection Characteristics

Variable	Data Value (N = 56)
Proximal extent of dissection	
Zone 1	1.8 (1)
Zone 2	12.5 (7)
Zone 3	78.6 (44)
Zone ≥4	7.1 (4)
Distal extent of dissection	
Thoracic aorta	5.4 (3)
Abdominal aorta	25.0 (14)
Iliac arteries	62.5 (35)
Not reported	7.1 (4)
Common origin BCT/LCCA	23.2 (13)
Aortic diameters, mm	
At proximal end of dissection	33.8 ± 3.4
Median (min, max)	33.45 (25, 42.1)
Maximum aortic diameter	42.2 ± 6.9
Median (min, max)	40.4 (27, 62.7)
Aortic diameter >40 mm	53.6 (30)
Maximum true lumen	18.6 ± 7.8
Median (min, max)	17.8 (3.4, 46.7)
Maximum false lumen	17.7 ± 8.9
Median (min, max)	15.9 (0, 45)
False lumen diameter >22 mm	19.6 (11)
Aortic lengths, mm	
LSA to primary entry tear	39.6 ± 47.5
Median (min, max)	24.7 (−8.37, 198.9)
Total treatment length, mm	207.3 ± 49.5
Median (min, max)	214.5 (108, 281)
Dissection length, mm	442.1 ± 104.9
Median (min, max)	439 (217, 654)

Data are presented as % (n), mean ± SD, or as indicated otherwise. BCT, brachiocephalic trunk; LCCA, left common carotid artery; LSA, left subclavian artery; max, maximum; min, minimum.

TABLE 3 Operative Details

Variable	Data Value (N = 56)
General anesthesia	100 (56)
Cerebrospinal fluid drainage	33.9 (19)
Vascular access	
Left femoral	36.4 (20)
Right femoral	63.6 (35)
Percutaneous	85.5 (47)
Surgical cut down	14.5 (8)
Arch zone <3	58.9 (33)
LSA revascularized	26.8 (15)
Duration of procedure, min	138.4 ± 81.4
Median (IQR)	100 (80-192)
Duration of implant, min	23.9 ± 29.8
Median (IQR)	17 (10-26)
Estimated blood loss, mL	167.2 ± 264.1
Median (IQR)	100 (50-150)
Transfusion	11.1 (6)
Intensive care, h	122.5 ± 201.7
Median (IQR)	81 (50-142)
Hospitalization, d	8.8 ± 4.7
Median (IQR)	7 (5-12)
Vascular access complications	1.8% (1)
Tapered	21.4% (12)
Nonbare stent configuration	65 (64/98)
Technical success	100 (56)

Data are presented as % (n or n/N) or mean ± SD, or as indicated otherwise. IQR, interquartile range; LSA, left subclavian artery.

There were 6 (10.7%) other deaths within 1 year; none was adjudicated as device or dissection related. There have been 2 further deaths (3.6%) during subsequent follow-up to 5 years. Kaplan-Meier curves showed freedom from all-cause mortality of 98.1% at 30 days and 85.0% at 1 year and 2 years (Figure 2).

There were 7 MAEs in 6 patients (10.7%), all within 30 days: paraplegia (n = 3), paraparesis (n = 2), disabling stroke (n = 1), and renal failure (n = 1). All paraplegia and paraparesis resolved with lumbar drainage. No MAEs were reported at later follow-up visits. MAEs are depicted in Figure 3 as a Kaplan-Meier plot and the underlying data. Kaplan-Meier analysis estimated a freedom from MAEs of 89.1% at each interval from 30 days to 3 years.

One patient had 2 MAEs (renal failure and paraplegia) but also a type Ia endoleak and migration. This 42-year-old man, with a history of tobacco and cocaine abuse, presented with acute limb ischemia, renal and mesenteric malperfusion, chest and abdominal pain, and bilateral leg weakness, with almost no movement in the left lower extremity. The dissection extended to zone 2, and the LSA was covered without revascularization and without complete malperfusion resolution. The patient awoke and was unable to move his lower limbs, but this resolved after urgent lumbar drain placement. Postoperative creatinine levels improved with continuous venovenous hemofiltration, and a fasciotomy resolved compartment syndrome. The 6-month follow-up showed type Ia endoleak due to aortic dilatation at the proximal end associated with aortic lengthening (length from the LSA to celiac artery increased from 263 mm at 1 month, to 283 mm at 6 months, and to 290 mm at 1 year). A secondary endovascular intervention was not successful, and the patient was converted to open total arch replacement with a Gelweave (Terumo Aortic) trifurcated graft at 18 months.

The patient with a disabling stroke was a 60-year-old man who presented with renal and visceral malperfusion and a dissection extending 65 cm. He was hemiplegic after emergence from anesthesia. Computed tomography showed a right middle cerebral artery distribution infarct secondary to an M1 thrombus, and he underwent mechanical thrombectomy. He was transferred to rehabilitation in a stable condition on postoperative day 14 but died on postoperative day 61 of cardiopulmonary arrest. The Clinical Events Committee

Ann Thorac Surg
2024;117:336-44

TABLE 4 Safety and Effectiveness

Variable	To 30 Days	30 Days to 12 Months	Total
Patients with a major adverse event	10.7 (6/56)	0	10.7 (6/56)
Major adverse events, total	7	0	7
Dissection-related mortality	1.8 (1)	0	1.8 (1)
All-cause mortality	1.8 (1)	10.7 (6)	12.5 (7)
Paraplegia (transient)	5.4 (3)	0	5.4 (3)
Paraparesis (transient)	3.6 (2)	0	3.6 (2)
Stroke (disabling)	1.8 (1)	0	1.8 (1)
Stroke (nondisabling)	5.4 (3)	0	5.4 (3)
Renal failure	1.8 (1)	0	1.8 (1)
Other complications			
Bird beak	0	0	0
Rupture	0	0	0
Migration	0	1.8 (1)	1.8 (1)
Loss of patency	0	0	0
Stenosis/thrombosis	0	0	0
Fractures	0	0	0
Retrograde dissection	3.6 (2)	0	3.6 (2)
Distal stent-induced new entry	0	1.8 (1)	1.8 (1)
Endoleaks			
Type Ia	0	1.8 (1)	1.8 (1)
Type Ib	0	0	0
Type II	0	0	0
Type III	0	0	0
Type IV	0	0	0
Aortic expansion	NA	3.6 (2)	3.6 (2)
Absence of false lumen perfusion	95.7 (45/47)	100.0 (30/30)	NA
Secondary intervention	8.9 (5/56)	8.9 (5/56)	17.9 (10/56)

Data are % (n or n/N). NA, not applicable.

adjudicated this event as disabling (because resolution of stroke symptoms was not documented), related to the procedure, and not related to the device. There were 3 nonpermanent, nondisabling strokes (cerebellar infarction, embolic stroke, ischemic stroke) in patients aged 44, 66, and 70 years, all within 30 days, and all adjudicated as related to the procedure but not the device.

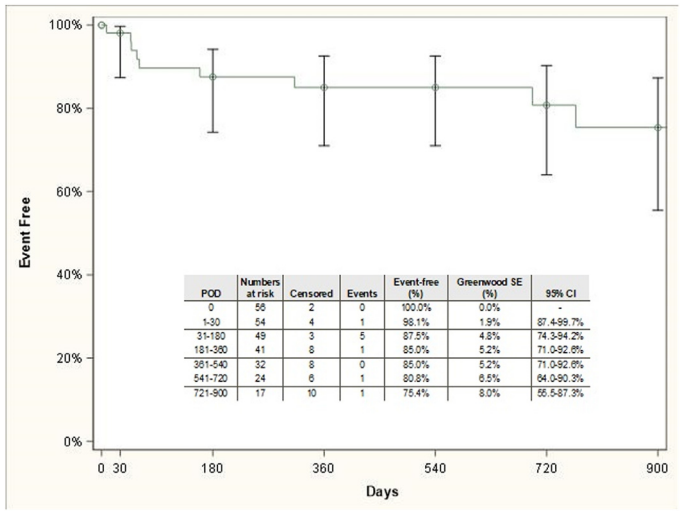


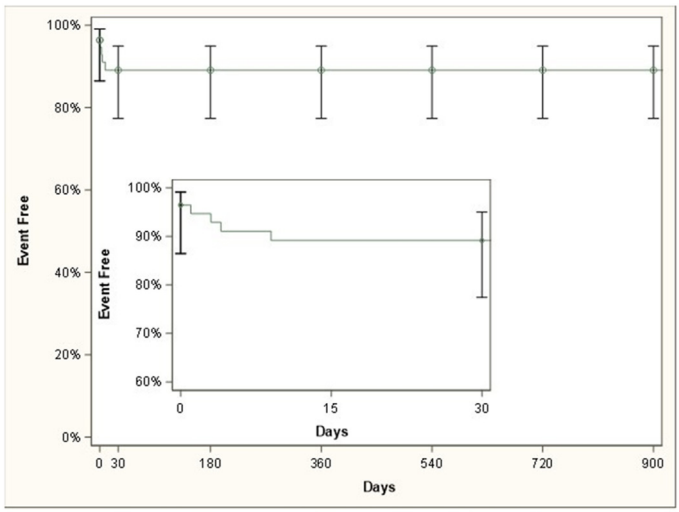
FIGURE 2 Kaplan-Meier freedom from all-cause mortality. Vertical lines indicate the 95% CI. (POD, postoperative day.)

There were 2 patients with retrograde dissection (although only 1 was confirmed by the core laboratory) and 1 distal stent graft-induced new entry (not confirmed by the core laboratory). One woman experienced acute-onset chest pain and back pain on postoperative day 40, which was diagnosed as retrograde dissection and repaired with total arch replacement. The second patient, a 63-year-old woman, had TEVAR covering from the left common carotid artery to the celiac artery (with left common carotid artery-LSA bypass). Computed tomography on postoperative day 12 showed a retrograde intramural hematoma at the apex of the aortic arch near the origin of the aortic stent graft. She underwent total arch repair with distal anastomosis to the stent graft.

The single event of distal stent graft-induced new entry was in a 49-year-old woman (also with aortic expansion >5 mm) who was treated successfully by TEVAR extension to zone 5. The other case of aortic expansion was borderline (6 mm) and associated with aortic lengthening and disease progression. No

secondary intervention was required, and surveillance continues. Finally, 1 patient was reported with vascular access difficulties/complications which was due to Perclose (Abbott) failure.

Ten patients (17.9%) had secondary interventions to 1 year and mostly involved the events described earlier, comprising 3 interventions for type Ia endoleaks, 2 for retrograde dissection, and 1 each for type Ia endoleak, type II endoleak, type III endoleak, spinal cord ischemia (SCI), and aortic expansion. Only 1 of these endoleaks was confirmed by the core laboratory, however. This discrepancy may be due to nomenclature, with the core laboratory noting type R entry flow in 10 patients. No types Ib, II, III, IV endoleaks or endoleaks of unknown origin have been reported by the core laboratory at any time point to date.



POD	Numbers at risk	Censored	Events	Event-free (%)	Greenwood SE (%)	95% CI
0	56	2	0	100.0%	0.0%	-
1-30	54	4	1	98.1%	1.9%	87.4-99.7%
31-180	49	3	5	87.5%	4.8%	74.3-94.2%
181-360	41	8	1	85.0%	5.2%	71.0-92.6%
361-540	32	8	0	85.0%	5.2%	71.0-92.6%
541-720	24	6	1	80.8%	6.5%	64.0-90.3%
721-900	17	10	1	75.4%	8.0%	55.5-87.3%

FIGURE 3 Kaplan-Meier freedom from major adverse events. Vertical lines indicate the 95% CI. (POD, postoperative day.)

COMMENT

RelayPro offers a low-profile TEVAR device with NBS configuration (Figure 4; Video).[7] Devices with proximal bare springs or barbs have been associated with a higher incidence of stent-induced aortic wall injury, especially in acute dissection.[8] Combined with the controlled initial expansion of the stent graft (as it exits the stiff outer sheath in the abdominal aorta to enter the thoracic aorta with a soft inner sheath), full deployment of the crown-shaped, covered sealing stent and contact with the native aorta is less traumatic.[9]

Results of this pivotal study show an early survival benefit. As more and more patients survive the acute event, current guidelines are focusing on other considerations and outcomes. A Vascular Quality Initiative analysis of acute TBAD with LSA coverage reported 4% SCI and 7% cerebral stroke; 44% were revascularized, but this did not affect the incidence of SCI, cerebral stroke, or short- or long-term mortality.[10] The incidence of stroke is generally higher in complicated TBAD.[11] In this study, almost two-thirds (58.9%) had LSA coverage, less than one-third (26.8%) were revascularized, and the neurologic event rate was 1.8% disabling and 5.4% nondisabling. All SCI events were transient and resolved with cerebrospinal fluid drainage. The overall rate of 8.9% is consistent with what is seen in both endovascular and open acute TBAD repair.[12,13] SCI rates in previous TEVAR series for this indication are 6% to 8%.[14-16]

Adverse events in the study were concentrated in a relatively small number of patients, all with several complicating factors. These patients were disproportionately women, who have been reported to have poorer outcomes compared with men for endovascular procedures.[17,18] The percentage of patients who presented with visceral ischemia (33.9%) was also high. Visceral ischemia is strongly associated with in-hospital mortality, with 1 study reporting 30.8% vs 9.1% without ischemia.[19] In the literature, ~20% of acute TBAD patients are reported to have malperfusion syndrome (5%-7% with visceral ischemia); again, the current study population presented with much higher incidence of 33.9%.[19]

TBAD patients typically experience high 30-day readmission rates of 18.6% for TEVAR and 16.8% for open surgery.[20] The 30-day readmission (21%) and secondary intervention (8.9%) rates in this study appear to be acceptable. In 1 study of acute or subacute TBAD (complicated and uncomplicated), 36.2% had a secondary intervention.[21]

Retrograde dissection is a serious complication of TEVAR, with an estimated incidence of 1.3% to 11%. The incidence in the same patient population in the Gore registry was 4.3%.[22] Risk factors include stent graft oversizing, bare proximal stents, aortic arch dilatation, entry tear within the arch, incomplete apposition, and proximal to zone 3 landing zone.[1] Both cases in this study (1 site-reported only, 1 core laboratory confirmed) were women treated with 2 NBS devices (1 with LSA coverage and revascularized, both covered to the celiac artery) who presented on postoperative days 12 and 40 and underwent total arch repair. Both cases point to extreme fragility of the native aortic walls. Increased analysis of stent-induced aortic wall injury has led to greater awareness of factors such as type III aortic arch and distal oversizing and mismatch and the suggestion that tapering (>4 mm) could help prevention.[23]

FIGURE 4 Volume-rendered follow-up scan at 2 years of the same patient as Figure 1 shows successful repair with 2 RelayPro nonbare stent devices deployed distal to the left subclavian artery.

The limitations of this study reflect the regulatory requirements under which it was designed, and it predates current reporting standards. For example, chronicity is not captured in the same detail as is now required. Similarly, primary entry tear location and the extent of aortic propagation are both known to determine the clinical course, but more sophisticated classification (such as entry tear size) and malperfusion details (eg, dynamic or static, or both) were not part of the study.

In conclusion, the RelayPro Dissection study met its primary end point and performance goal and demonstrated the safety and effectiveness of RelayPro for the treatment of acute, complicated TBAD. The NBS configuration may be a beneficial addition to dissection treatment options.

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DISCLOSURES

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Most Valuable Application of Thoracic Endovascular Aortic Repair: Acute Complicated Type B Aortic Dissection

INVITED COMMENTARY:

Over the past 2 decades thoracic endovascular aortic repair (TEVAR) has become the recommended treatment for acute type B aortic dissection (TBAD) complicated by malperfusion or rupture.[1] In this issue of *The Annals of Thoracic Surgery*, Rossi and colleagues[2] reported the results of a prospective, multicenter, single-arm pivotal study using the RelayPro (Terumo Aortic) for the treatment of patients with acute complicated TBAD. The RelayPro is a low-profile stent graft that comes in a 19- to 23-French delivery sheath size that was previously approved by the US Food and Drug Administration for the treatment of aneurysms and penetrating aortic ulcers. Its non-bare metal stent design provides a true "disease-specific" device for the treatment of acute dissections, because proximal bare metal has been shown to be a risk factor for retrograde type A aortic dissection.[3] Fifty-six patients with malperfusion (89%) or rupture (11%) were treated during this trial with a 30-day dissection-related mortality of 1.8% and a 1-year mortality of 10.7%. The incidence of disabling stroke and renal failure was 1.7%, and 5 patients (8.9%) developed spinal cord ischemia, all of whom had complete recovery of symptoms with cerebrospinal fluid drainage by the time of hospital discharge. Two patients (3.6%) had retrograde type A dissection.

The outstanding results demonstrated in this trial are similar to outcomes in the pivotal trials of other major stent graft devices and provide data to support the use