Early survival benefit of a low-profile endograft in blunt traumatic aortic injury

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ABSTRACT

Objective: The aim of this study was to demonstrate the safety and effectiveness of a low-profile thoracic endograft (19-23 French) in subjects with blunt traumatic aortic injury.

Methods: A prospective, multicenter study assessed the RelayPro thoracic endograft for the treatment of traumatic aortic injury. Fifty patients were enrolled at 16 centers in the United States between 2017 and 2021. The primary endpoint was 30-day all-cause mortality.

Results: The cohort was mostly male (74%), with a mean age of 42.4 ± 17.2 years, and treated for traumatic injuries (4% Grade 1, 8% Grade 2, 76% Grade 3, and 12% Grade 4) due to motor vehicle collision (80%). The proximal landing zone was proximal to the left subclavian artery in 42%, and access was primarily percutaneous (80%). Most (71%) were treated with a non-bare stent endograft. Technical success was 98% (one early type Ia endoleak). All-cause 30-day mortality was 2% (compared with an expected rate of 8%), with an exact two-sided 95% confidence interval [CI] of 0.1%, 10.6% below the performance goal upper limit of 25%. Kaplan-Meier analysis estimated freedom from all-cause mortality to be 98% at 30 days through 4 years (95% CI, 86.6%-99.7%). Kaplan-Meier estimated freedom from major adverse events, all-cause mortality, paralysis, and stroke, was 98.0% at 30 days and 95.8% from 6 months to 4 years (95% CI, 84.3%-98.9%). There were no strokes and one case of paraplegia (2%) during follow-up.

Conclusions: RelayPro was safe and effective and may provide an early survival benefit in the treatment of blunt traumatic aortic injury. (J Vasc Surg 2024;80:678-84.)

Keywords: Blunt aortic injury; TEVAR; Endovascular; Endograft; Low profile

Thoracic endovascular aortic repair (TEVAR) is now established as first-line treatment for blunt traumatic aortic injury (BTAI) primarily because it is very effective in addressing focal aortic pathologies, and it offers a simpler operation to patients whose condition is often complicated by multiple concomitant injuries.[1] The particular challenges of patients with BTAI (smaller aortic diameters, higher aortic arch angulation, and treatment at a much younger age) have also been the focus of endovascular design improvements over the past decade in terms of conformability and durability.[2]

RelayPro (Terumo Aortic) is one of the latest generation stent grafts and comes with some features that might benefit patients with BTAI. A 19 French (F) delivery sheath size should facilitate safe percutaneous access in small access vessels. The smallest diameter (22 mm) and covered length (90 mm) increase sizing options and reduce the risk of overtreatment. A non-bare stent (NBS) configuration allows approximation to the head vessels without bare metal (Fig 1). A dual-sheath delivery system means only a soft inner sheath goes into the distal arch/proximal thoracic aorta. Increased distance between the stents allows for better flexibility and conformability. A spiral support strut (S-bar) is outside the seal zone and provides longitudinal support to resist shortening, migration, and kinking during healing and

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remodeling. This pivotal study resulted in United States (U.S.) Food and Drug Administration (FDA) approval (March 2023), and early outcomes are presented here; durability will be assessed in follow-up to 5 years and will be reported in time and join an increasing body of longer-term evidence.

PATIENTS AND METHODS

This is a prospective, multicenter, single-arm, non-randomized pivotal study (NCT03090230) designed to evaluate the safety and effectiveness of RelayPro for the treatment of patients with BTAI. Adult patients with traumatic injury of the descending thoracic aorta within the previous 30 days were included in 16 U.S. centers between November 2017 and June 2021. Excluded were patients with planned coverage of the left carotid or celiac arteries, prior open or endovascular thoracic aortic surgery, known or suspected connective tissue disorder, and less than 2 years life expectancy.

The study was conducted in accordance with the Declaration of Helsinki (1986) and in compliance with 21 CFR parts 812 and any other applicable FDA regulations, local and institutional regulations, and Institutional Review Board requirements. All patients consented to participate.

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 and classified all adverse events (ie, severity, anticipated, device and procedure relationship, and seriousness), assured the study was conducted ethically, and that the health and welfare of each subject was protected. A core laboratory assessed all imaging outcomes.

This was not a hypothesis-driven study. The sample size of 50 subjects is based upon the precision around the estimated 30-day all-cause mortality rate; precision was defined as the half-width of a 95% confidence interval (CI).

The primary endpoint was all-cause mortality at 30 days, which was compared with performance goals based on 30-day outcomes of comparable U.S. Investigational Device Exemption studies, the Gore cTAG and the Medtronic Valiant devices in BTAI populations, where it was reported that all-cause mortality at 30 days was 7.8% (4/51) in the Gore study, and 8% (4/50) in the Medtronic study.[3,4] The primary analysis was performed on all enrolled subjects and is summarized with a two-sided 95% CI and compared with an expected rate of 8%.

Secondary endpoints were analyzed based on descriptive statistics and CIs, with any inferential quantities based on nominal calculations not adjusted for multiplicity. Secondary endpoints include all-cause mortality, aortic-related death, major adverse events (stroke and paralysis), all adverse events, technical success (defined as successful delivery and deployment of the device, including withdrawal of the delivery system), access complications, aortic dilatation (>5 mm), secondary interventions, rupture, aneurysm formation, endoleaks, patency, fractures, compression, erosion, extrusion, migration (>10 mm), and infection. Follow-up is ongoing to 5 years. A Kaplan-Meier analysis estimate of freedom from major adverse events (MAEs) (Fig 2) includes all events of all-cause mortality, stroke, and paralysis.

ARTICLE HIGHLIGHTS

- **Type of Research:** Multi-center prospective clinical trial of a new thoracic aortic device for treating blunt thoracic aortic injury
- **Key Findings:** The RelayPro pivotal transection study demonstrated safety and efficacy in the management of blunt thoracic aortic injuries.
- **Take Home Message:** The RelayPro pivotal transection study demonstrated an early survival benefit; this next-generation thoracic endovascular aortic repair device is unique in that it is low profile and has a non-bare stent configuration.

RESULTS

Fifty patients, predominantly male (74%) and with a mean age of 42.4 ± 17.2 years, were included (Table I). Due to the relatively young age of most of the subjects, few have significant medical history, but comorbidities include hypertension (26%) and a history of smoking (36%). Most subjects (80%) had been involved in a motor vehicle collision and experienced injury at the aortic isthmus (82%) (Table II).

The cohort was complicated with severe polytrauma (mean Injury Severity Score, 30.2 ± 16.3); 4% had grade 1 injury, 8% grade 2, 76% grade 3 and 12% grade 4. With this younger population with relatively few comorbidities, the aortic anatomy was complex only in terms of small access (mean, 8.3 ± 1.3 mm). However, one-quarter (26%) had a bovine arch anatomy.

A total of 56 devices (71% NBS) were implanted during the index procedure, a mean of 1.06 devices per patient; most (88%) requiring the shortest length (100 mm) and 21% receiving the smallest (22 mm) proximal diameter (Table III). Five subjects (10%) had more than one implant for reasons including extent of lesion coverage and device availability. Most procedures (80%) were performed percutaneously. The mean duration of the procedure was 73.5 ± 39.6 minutes, and the mean implantation duration (time from delivery system insertion to withdrawal) was 10.9 ± 6.2 minutes (90% had a single device implanted). Overall blood loss was low, and six subjects (12%) required transfusion.

Median intensive care stay was 70 hours (IQR, 132.5 hours), and mean hospitalization stay was 10 days (IQR, 13 days). One subject had significantly longer intensive care and hospitalization (818 hours and 181 days, respectively); he was a 35-year-old with a complicated clinical

Fig 1. The RelayPro non-bare stent (NBS) configuration has two clasping points located on the outer curve and support wires on the inner for controlled stent graft expansion and alignment with the landing zone.

course after polytrauma that included chronic hypoxemic respiratory failure, anoxic brain injury, bilateral deep vein thrombosis (DVT), recurrent sepsis/septic shock, hypertension, and pneumonia. Nine subjects (18%) required 24 hours or less in intensive care, and two did not require intensive care.

Technical success was 98%: one patient had an early type Ia endoleak associated with retroflex upon deployment and corrected in a secondary intervention (ballooning and proximal extension). There was no collapse of the endograft lumen by maldeployment, and the endoleak was not reported in the injured aortic area. There was one access complication (2%) associated with a Perclose device.

All-cause mortality at 30 days was 2.0% (exact two-sided 95% CI, 0.1%-10.6%). The single mortality in the study to date was a 61-year-old woman after an automobile collision who presented with grade 4 aortic injury and died 12 days after TEVAR due to cardiopulmonary arrest. The Clinical Events Committee adjudicated this event as related to the procedure but not the device. There was a second MAE at 6 months and none since: Fig 2 shows a Kaplan-Meier analysis estimated a freedom from MAEs of 98.0% at 30 days and 95.8% from 6 months to 4 years (95% CI, 84.3%-98.9%).

The second MAE was paraplegia in a 26-year-old woman with grade 3 aortic injury treated with a 24 × 100 × 24-mm device. She developed a left popliteal vein DVT, and imaging revealed thrombus in the stent graft, which was corrected with relining (150-mm device). However, she developed acute paraplegia, renal failure, and coagulopathy. The subject had a history of DVT during pregnancy and was on birth control at the time of the accident. The subject later tested positive for COVID-19, which is known to trigger a hypercoagulable state with a high incidence of thrombotic complications.

There were three early secondary interventions (6%): one to address type Ia endoleak (described above): one left subclavian artery (LSA) coil embolization for type II endoleak; one shortly after the index procedure to address popliteal artery thrombus in the left leg; platelet (not fresh) thrombus was removed and was felt to have likely embolized from the aortic injury.

Although all patients have now completed a 1-year evaluation and the primary analysis of early survival is presented here, follow-up continues in the study, and two have already completed 4-year follow-up. There has been no further mortality (2% overall mortality to date) and two MAEs in total (4% MAE incidence to date).

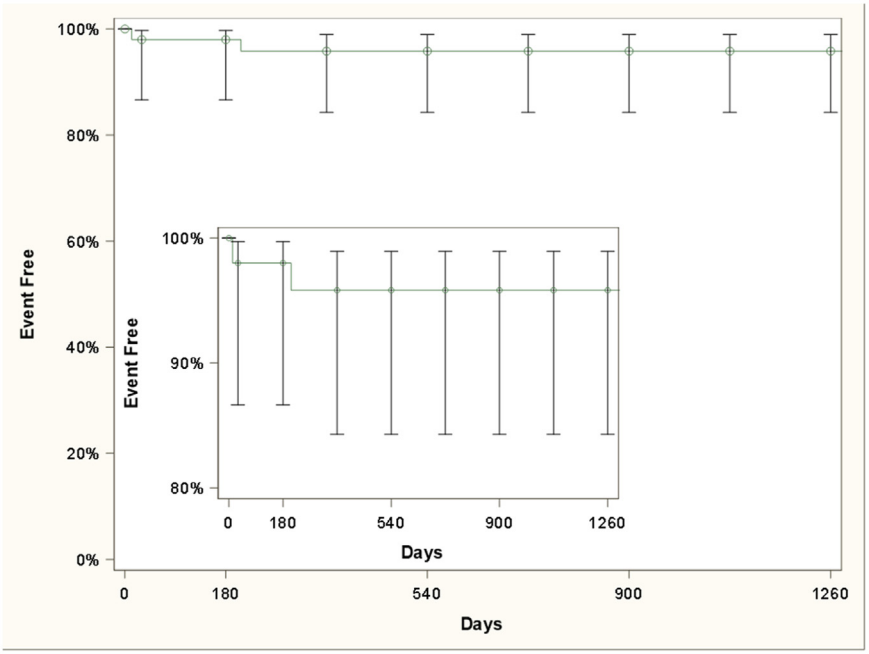
There have been three additional secondary interventions: one case of stent graft thrombosis at 6 months (described above); one stenosis (associated with coarctation physiology) treated successfully with distal extension at 2 years; one remaining intimal flap successfully treated with distal extension at 3 years.

There was one case of stent graft thrombosis (associated with paraplegia, see above). In addition, there were three other cases with mural thrombus within the graft (8% in total, 4% associated with a complication).

There were no aortic ruptures, endograft infections, aortic dilation, migration, compression, twisting, extrusion/erosion, fracture, suture breaks, type Ib endoleaks, or type III endoleaks at any timepoint. There were also no conversions to open surgery reported at any timepoint.

DISCUSSION

TEVAR is now established as the preferred treatment for BTAI, making up three-quarters of all repairs.[5,6] Because many patients with BTAI have very severe polytrauma (Injury Severity Score ≥25), a minimally invasive approach is ideal, especially considering that they will most likely need to undergo several other interventions. Yet transection remains a focus of continuing doubts about endovascular technology because this relatively young population (mean age, 42.4 ± 17.2 years in this study) will have to live with the implant for many decades. Continuing development and improvement of endovascular technology is essential. Early surrogate outcomes are important because so many of these young patients are lost to follow-up. One single-center study



From Day X - Day Y	# Entered	# Censored	# Events	Event-free [%]	Greenwood SE [%]	95% Confidence Interval
0	50	0	0	100.0%	0.0%	
1-30	50	2	1	98.0%	2.0%	86.6%-99.7%
31-180	47	2	0	98.0%	2.0%	86.6%-99.7%
181-360	45	3	1	95.8%	2.9%	84.3%-98.9%
361-540	41	10	0	95.8%	2.9%	84.3%-98.9%
541-720	31	3	0	95.8%	2.9%	84.3%-98.9%
721-900	28	14	0	95.8%	2.9%	84.3%-98.9%
901-1080	14	3	0	95.8%	2.9%	84.3%-98.9%
1081-1260	11	8	0	95.8%	2.9%	84.3%-98.9%

Fig 2. Kaplan-Meier freedom from major adverse events (MAEs).

of 20 years of BTAI experience reported a median follow-up of only 34 months (range, 1-220 months); 80% of patients survived the index hospitalization, and 43% of those were lost to follow-up.[7]

Certainly, this latest generation device is simplifying and shortening the procedure for both patient and surgeon: 80% were percutaneous, the mean duration was 73.5 ± 39.65 minutes, and the mean blood loss was 48 mL (compared with 31%, 106.8 ± 48.6 minutes, and 148 mL for a previous generation device, respectively).[3] RelayPro had already demonstrated safety and effectiveness in 110 patients with thoracic aortic aneurysms and penetrating atherosclerotic aneurysms with a 6.4% MAE rate.[8] In addition, favorable outcomes of 40 patients with BTAI were reported with the previous generation RelayPlus, showing 2.5% early mortality and one late death (5% all-cause mortality).[9]

RelayPro provides a lower profile for the younger BTAI population and associated smaller access diameters while maintaining stent graft integrity and visualization. The study demonstrates shorter procedural time, less blood loss, and shorter stays in intensive care and hospital, which may be related to the low mortality rate when

Table I. Subject characteristics and comorbidities

	No. or mean ± SD	% or median (IQR)
Male	37	74
Female	13	26
Age, years	42.4 ± 17.2	39 (30)
White	33	66
African American	14	28
History of smoking	18	36
Current smoker	11	22
Hypertension (treated or untreated)	13	26
Coronary artery disease	7	14
Gastrointestinal complications	6	12
Antiplatelet/anticoagulant medication	6	12
Hypercholesterolemia	5	10
Diabetes mellitus	4	8
Renal insufficiency	1	2
Impotence (males only, n = 37)	1	3

IQR, Interquartile range; *SD*, standard deviation.

Table II. Traumatic injury characteristics and aortic anatomy

	No. or mean ± SD	% or median (IQR or range)
Automobile collision	33	66
Motorcycle collision	7	14
Fall	5	10
Other traumatic mechanism	4	8
Pedestrian injury from a motor vehicle	1	2
Location of the aortic injury		
Aortic isthmus (distal to LSA)	41	82
Distal DTA	9	18
Extent of aortic injury		
Grade 1	2	4
Grade 2	4	8
Grade 3	38	76
Grade 4	6	12
Injury Severity Score	30.3 ± 16.3	29 (23)
Common origin BCT/LCCA (Bovine arch)	13	26
Intimal tear		
Associated with aortic false aneurysm	28	56
Associated with intramural hematoma	12	24
Alone	6	12
Associated with free rupture	3	6
Total aortic treatment length, mm	83.2 ± 28.0	73.0 (62.8-209.0)
Aortic diameter at LSA, mm	25.0 ± 3.9	24.7 (18.1-35.0)
Maximum thoracic aortic diameter, mm	30.0 ± 5.9	28.6 (20.3-54.3)
Minimum access vessel, mm	8.3 ± 1.3	8.0 (5.7-11.0)

BCT, Brachiocephalic trunk; *DTA*, descending thoracic aorta; *IQR*, interquartile range; *LCCA*, left common carotid artery; *LSA*, left subclavian artery; *SD*, standard deviation.

Table III. Procedural details and early outcomes

	No. or mean ± SD	% or median (IQR)
Percutaneous access	40	80
Cut-down access	10	20
Devices implanted per patient	1.06	–
NBS configuration (n = 56)	40	71
22 mm proximal diameter (n = 56)	12	21
100 mm length device (n = 56)	49	88
Duration of procedure, minutes	73.5 ± 39.65	63 (30)
Landing zone proximal to LSA	21	42
Duration of implantation, minutes	10.9 ± 6.2	9 (9)
Estimated blood loss, mL	48.3 ± 51.5	27.5 (30)
Transfusion	6	12
Intensive care, hours	124.56 ± 148.04	70 (132.5)
Hospitalization, days	16.72 ± 25.72	10 (13)
Technical success	49	98
Mortality	1	2
Paralysis	0	0
Stroke	0	0
Type Ia endoleak	1	2
Type Ib endoleak	0	0
Type II endoleak	3	6
Type III endoleak	0	0
Loss of patency	0	0
Loss of integrity	0	0
Migration	0	0
Misalignment/bird beak	0	0
Access complications	1	2
Secondary interventions	3	6

IQR, Interquartile range; *LSA*, left subclavian artery; *NBS*, non-bare stent; *SD*, standard deviation.

compared with what has been reported in the literature: a large Vascular Quality Initiative analysis of 1311 patients with BTAI reported mortality of 7.2% (grade 3 injury) and 14% (grade 4).[10] Vascular Quality Initiative BTAI TEVAR data indicate an overall 7.3% in-hospital mortality.[11] The early survival benefit is the key takeaway from this pivotal study.

A recent concern has been that patients with BTAI treated with TEVAR develop small mural thrombi at a greater rate than patients with aneurysms (possibly due to aggressive oversizing) with reported incidences of 0.3% to 35% (although few are clinically significant).[12,13] The incidence in this study (8% in total, 4% associated with a complication) appears low in comparison with rates reported in the literature (26% in the TRANSFIX study, although none with clinical sequelae and only one with a secondary intervention).[14] Bero and colleagues reported 19 cases (59%) of mural thrombus formation using a wide range of devices (n = 6 Talent; n = 8 Valiant; n = 1 cTAG; n = 2 Medtronic, n = 1 Zenith Alpha; n = 1 RelayPro NBS [one of the four cases reported here]).[15]

The thrombus events varied between early and late, symptomatic and asymptomatic, involving stenosis/occlusion or not, and requiring intervention or medication or not. Smaller diameter devices and oversizing did not

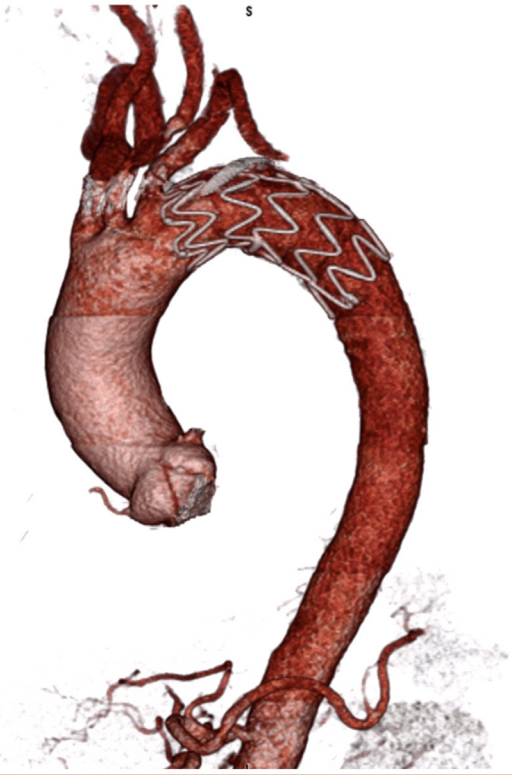


Fig 3. Postoperative three-dimensional reconstruction of a 66-year-old man involved in a high-speed motor vehicle collision with ejection treated with a 100-mm RelayPro non-bare stent (NBS) landing just distal to the left subclavian artery (LSA) in a type III arch with accuracy and good apposition (Courtesy of Jordan Stern, Stanford University, Stanford, CA).

appear to be contributing factors among this small group. However, three (75%) were in obese women, and two (50%) had bovine arch anatomy, which might influence coagulability.[16,17] Three (75%) had LSA coverage without revascularization.

Finally, an encouraging point is the relatively low incidence of all complications associated with inaccurate or poor deployment. Younger patients tend to have more acute curvature of the aortic arch that can compromise stent graft apposition or cause bird beak and increase the risk of endoleak and loss of stent graft integrity.[18] A systematic review of TEVAR in 389 patients with BTAI found a surprising 38.7% incidence of bird beak (although this was defined only as "poor apposition" and not measured objectively or reflected in complications or secondary interventions).[19] Relay has a proximal deployment mechanism for the prevention of bird beak and retroflex on the lesser curvature (42% of deployments in this study were proximal to the LSA) (Fig 3).[20] In one study of 78 patients with different thoracic aortic pathologies, Relay was deployed ≤5 mm from the target vessel in 82% of procedures.[21]

Limitations of this study include some data points that were not captured and could not be analyzed. For instance, delayed TEVAR may improve BTAI outcomes, so timing may be a factor.[22] However, beyond the inclusion requirement of injury within 30 days, this parameter was not analyzed. Neither was LSA revascularization. Finally, this report contains only early outcomes, and longer-term outcomes will be reported in time.

CONCLUSIONS

RelayPro offers some incremental improvements in the endovascular treatment of BTAI (lower profile and NBS configuration) and may provide an early survival benefit.

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AUTHOR CONTRIBUTIONS

Conception and design: BS, RR, PR, MS
Analysis and interpretation: BS
Data collection: BS, RR, PR, NS, JBG, JCh, NN, MS, VK, JS, NK, JCo
Writing the article: BS, RR, PR, NS, MS, JS, NK
Critical revision of the article: BS, RR, PR, NS, JBG, JCh, NN, MS, VK, JS, NK, JCo
Final approval of the article: BS, RR, PR, NS, JBG, JCh, NN, MS, VK, JS, NK, JCo
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BS and RR contributed equally to this article and share co-first authorship.

DISCLOSURES

All authors were principal investigators in the study and as such received research grants to conduct the study. B.S. has been paid a consulting fee by Terumo Corporation for an unrelated project.

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Additional material for this article may be found online at www.jvascsurg.org.

APPENDIX (online only).

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