Clinical trial outcomes and thoracic aortic morphometry after one year with the Valiant Navion stent graft system

Fabio Verzini, MD, PhD, FEBVS,[a] Nimesh Desai, MD, PhD,[b] Frank R. Arko III, MD,[c] Jean M. Panneton, MD,[d] Fabien Thaveau, MD, PhD,[e] Francois Dagenais, MD,[f] Jia Guo, PhD,[g] *and* Ali Azizzadeh, MD, FACS,[h] *Turin, Italy; Philadelphia, Pa; Charlotte, NC; Norfolk, Va; Strasbourg, France; Quebec City, Quebec, Canada; and Santa Rosa and Los Angeles, Calif*

ABSTRACT

Authors' Note: *On February 17, 2021, Medtronic Incorporated issued a global voluntary recall of the Valiant Navion Thoracic Stent Graft System (the device under study in the Valiant Evo Global Clinical Program that is the subject of this publication), and instructed physicians to immediately cease use of the Valiant Navion system and return any unused product. Medtronic initiated the recall in response to three clinical trial subjects recently observed with stent fractures, two of whom have confirmed type IIIb endoleaks. The data collection, analysis, and manuscript submission occurred before the notice of this recall, and, specifically, the 100 procedures reviewed for this series were free of events at 1 year related to the reason for this device recall. The authors of this article and the manufacturer were unaware of the recently detected adverse events at the time of the preparation of the manuscript, and the 1-year trial results, and imaging-based analyses described are unchanged.*

Management of thoracic aortic aneurysms continues to be a challenging problem and outcomes are dependent on patient *anatomy. The present publication focuses on the importance of achieving proximal and distal seals and the consideration of the temporal changes of the aortic morphology as a part of the TEVAR planning process. The authors believe there is still scientific merit in disclosing this information, despite the current nonavailability of the Valiant Navion system.*

Objective: The Valiant Navion stent graft system (Medtronic Inc, Santa Rosa, Calif) is a third-generation device with improved conformability. We have reported the 1-year clinical trial outcomes, with a focus on an imaging-based analysis of the aortic morphology. We assessed the effects of graft implantation on the native anatomy and the effects of the 1-year changes in thoracic aorta morphology on the original seal zones of the stent graft.

Methods: A total of 100 subjects were enrolled in a prospective single-arm clinical trial investigating the Valiant Navion stent graft system. An independent core laboratory (Syntactx, New York, NY) assessed the anatomic characteristics and performance outcomes.

Results: Through 1 year of follow-up, the freedom from all-cause mortality, aneurysm-related mortality, and secondary procedures was 89.8%, 97.0%, and 94.8% respectively. Of the 100 patients, 5 had undergone a total of six secondary procedures, and 9 patients had developed an endoleak (type Ia and Ib in 1, type Ia in 1, type Ib in 3, and type II in 4 patients) within the first year. After 1 year, 2 of 76 patients (2.6%) had had an increase in their maximum aneurysm diameter of ≥5 mm, 62 (81.6%) had had stable sacs, and 12 (15.8%) had experienced sac shrinkage. Although no deployment failures had occurred, 36 of the 100 proximal (36%) and 31 of the 100 distal (31%) attachment zones were considered short according to our definitions. The stent graft had conformed to the native anatomy at implantation, because the preprocedural thoracic aorta tortuosity (1.45 ± 0.02) had not significantly changed at 1 month after implantation (1.46 ± 0.02). Despite a natural increase in thoracic tortuosity after 1 year (1.49 ± 0.02), wall apposition had been maintained over time, as evidenced by the low endoleak rates. Aortic elongation and dilation had occurred at the

From the Unit of Vascular Surgery, Department of Surgical Sciences, University of Turin, Turin[a]; Department of Surgery, University of Pennsylvania, Philadelphia[b]; Department of Endovascular Surgery, Carolinas Medical Center, Charlotte[c]; Department of Vascular Surgery, Eastern Virginia Medical School, Norfolk[d]; Department of Vascular Surgery, Strasbourg University Hospital, Strasbourg[e]; Division of Cardiac Surgery, University of Quebec, Quebec City, Quebec[f]; Department of Clinical Research, Medtronic Inc, Santa Rosa[g]; and Division of Vascular Surgery, Cedars-Sinai Medical Center, Los Angeles.[h]

The Valiant Evo International Clinical Trial (ClinicalTrials.gov identifier, NCT02625324) and VEVO (Valient Evo US Clinical Trial; ClinicalTrials.gov identifier, NCT02652949) were funded by Medtronic, Inc (Santa Rosa, Calif).

Clinical Trail registration: NCT02625324 and NCT02652949.

Author conflict of interest: The institution of F.V. receives consultancy fees from Medtronic Inc. F.R.A. and F.D. is on the speaker's bureau for Medtronic Inc. J.G. is a principal statistician for Medtronic Inc. N.D., J.M.P., F.T., and A.A. have no conflicts of interest.

Presented in part at the 2020 ESVS Annual Meeting - ESVS month, Virtual Meeting, September 29-October 22, 2020.

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

Correspondence: Fabio Verzini, MD, PhD, FEBVS, Unit of Vascular Surgery, Department of Surgical Sciences, University of Turin, A.O.U. Città della Salute e della Scienza, Corso Dogliotti 14, Turin 10126, Italy (e-mail: fabio.verzini@unito.it).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2021.01.047

proximal end of the graft by an average of 1.2 mm and 1.6 mm, respectively. Aortic remodeling was more pronounced at the distal end, with an average increase of 4.2 mm in length and 2.8 mm in diameter.

Conclusions: The included patients had had positive 1-year outcomes with high freedom from mortality, endoleak development, and secondary procedures. Aortic elongation and dilation were more prevalent at the distal end, emphasizing the importance of distal attachment zone consideration as part of preoperative planning. Because aortic remodeling can be expected to continue over time, additional follow-up and imaging analysis in the trial will be necessary to assess the aortic morphology and its effects on stent graft performance. (J Vasc Surg 2021;74:569-78.)

Keywords: Aortic aneurysm; TEVAR; Thoracic aorta; Thoracic endovascular aortic repair; Thoracic stent graft

Patient anatomy can affect the seal created by a stent graft,[1,2] and this is critically important in determining the outcomes after thoracic endovascular aneurysm repair (TEVAR). Anatomic features such as wide necks, short necks, and excessive tortuosity of the aorta have been associated with type IA endoleaks, migration, and other complications.[2-4] At the distal end, inaccurate positioning of the graft has been reported to be associated with migration and the occurrence of type Ib endoleaks.[5] Excessive oversizing can also lead to an increased risk of aortic wall lesions, both proximally and distally.[6]

Changes to the native anatomy immediately after stent graft implantation and aortic remodeling over time are additional anatomic factors that deserve further investigation. Stent graft-induced retrograde dissection is a commonly discussed effect that the graft might have on the native anatomy.[7,8] The placement of a TEVAR device can change the curvature of the aorta,[9,10] which could be a concern for patients with a fragile aorta. Also, a natural increase in the diameter, length, and curvature of the thoracic aorta occurs over time,[11,12] and this remodeling should be considered when planning the initial procedure.

The Valiant Navion stent graft system (Medtronic Inc, Santa Rosa, Calif) is a third-generation device with improved conformability and positive outcomes reported in a 30-day primary end point study.[13] In the present report, we have described the 1-year clinical trial outcomes with an imaging analysis examining the effects of graft implantation on the native anatomy and the effects of 1-year aortic remodeling on stent graft performance.

METHODS

Trial method. The complete details on the Valiant Evo International Clinical Trial (ClinicalTrials.gov identifier, NCT02625324) and VEVO (Valient Evo US Clinical Trial; ClinicalTrials.gov identifier, NCT02652949) have been previously reported.[13] In brief, the trials were prospective, nonrandomized, single-arm investigations of the performance of the Valiant Navion stent graft system (Medtronic) for the treatment of descending thoracic aortic aneurysms and penetrating atherosclerotic ulcers (PAUs). One detail of the Navion stent graft design relevant to the present study is that the proximal end of the stent graft is available with a bare stent (FreeFlo) and without a bare stent (CoveredSeal). A total of 100 patients were enrolled from 2016 to 2018, with 53 from 18 U.S. sites and 47 from 15 sites outside of the United States. The institutional review board or ethics committee of each site approved the clinical trials, as applicable, which were performed in accordance with the clinical investigation protocol, and all the patients had provided written informed consent. The trials were conducted in compliance with the Declaration of Helsinki (October 2013) and the laws and regulations of the countries in which the clinical trials were conducted.

Clinical trial and imaging data. The definitions of the primary composite end point and other outcomes have been reported in detail in the 30-day study.[13] An independent core laboratory (Syntactx, New York, NY) was responsible for the assessment of the anatomic characteristics and stent graft measurements. For the imaging-based analyses, all diameter measurements were performed from the intima to the intima, with the exception of the maximum thoracic aortic diameter, which was measured from the adventitia to the adventitia, and the iliac minimum diameters, which were luminal. The maximum aneurysm diameter changes at 1 year were assessed using the 1-month imaging findings as the baseline, and the definitions for sac increases, stability, and decreases followed the reported standards for sac dynamics.[14] The aortic measurements were defined as follows (Fig 1):

- Tortuosity: centerline length divided by the straight line length from the proximal to distal end of the arterial segment (the thoracic aorta was defined as the left common carotid artery to the celiac artery and the abdominal aorta as the celiac artery to aortic bifurcation)
- Proximal oversizing: proximal diameter of the proximal stent graft divided by the aortic diameter immediately proximal to the aneurysm, minus one
- Proximal neck length: centerline distance from the proximal edge of the site-specified landing zone to the proximal edge of the aneurysm (aortic diameter increased by 10%) determined from the preprocedural imaging study
- Proximal attachment zone (PAZ) length: centerline distance within the proximal seal zone from the

proximal location at which the graft fabric is apposed 360° to the aortic wall to the distal location at which the graft fabric is apposed 360° to the aortic wall (for our analysis, the recommended PAZ length was ≥20 mm if the most proximal device were a FreeFlo graft and ≥25 mm if the most proximal device were a CoveredSeal graft, in accordance with the neck lengths recommended in the instructions for use [IFU])
- PAZ diameter: diameter at the proximal end of the PAZ
- Distal oversizing: distal diameter of the most distal stent graft divided by the aortic diameter immediately distal to the aneurysm, minus one.
- Distal neck length: centerline distance from the distal edge of the aneurysm to the proximal edge of the celiac determined from the preprocedural imaging study
- Distal attachment zone (DAZ) length: centerline distance within the distal seal zone from the proximal location at which graft fabric is apposed 360° to the aortic wall to the distal location at which the graft fabric is apposed 360° to the aortic wall (for our analysis, the recommended DAZ length was ≥20 mm in accordance with the IFU recommended distal neck length)
- DAZ diameter: diameter at the distal end of the DAZ
- Maximum thoracic aneurysm diameter: maximum major axis of the thoracic aorta perpendicular to the blood flow lumen
- Aneurysm length measured on postimplant images at 1 and 12 months: centerline distance from the distal end of the PAZ to the proximal end of the DAZ

Statistical analysis. Continuous variables are presented as the mean ± standard deviation and categorical variables as proportions of patients. Categorical variables were compared using the Fisher exact test. For continuous variables, a *t* test was used to compare normally distributed data and a Wilcoxon rank sum test for nonnormally distributed data. Estimates and *P* values were calculated from a linear model for repeated measurements. The time to major adverse events, all-cause mortality, and aneurysm-related mortality were analyzed using Kaplan-Meier survival analyses with the Greenwood method used for the standard error estimate. An interval censored survival analysis was used to evaluate the interval to the development of endoleaks The one year primary end point rate was calculated based on the number of patients with events (m) and the number of patients without events (k) following the formula: primary end point rate = m/(m+k). All statistical analyses were performed using SAS, version 9.4 or later (SAS Institute Inc, Cary, NC).

RESULTS

Clinical and imaging follow-up. Of the 100 patients who had undergone implantation with the Valiant Navion stent graft, 1 had died within the first 30 days, for 99 patients eligible for evaluation at 1 month. The 1-month clinical and imaging compliance was 99% (98 of 99) and 98% (97 of 99), respectively. A total of 86 subjects were eligible for 1-year follow-up examination (10 patients had died, 2 patients had withdrawn from the study, and 1 patient was lost to follow-up). In addition, 1 of the 86 patients had not yet completed their 1-year follow-up visit at the time of the present analysis. The 1-year compliance for the clinical and imaging examinations both was 91% (78 of 86). Of the 99 patients eligible for imaging studies at 1 month, 97 (98%) had undergone computed tomography (CT) or magnetic resonance imaging. At the 1-year follow-up, 78 of the 86 eligible patients (91%) had undergone CT or magnetic resonance imaging, although only 76 patient images had appropriate scan quality for the core laboratory assessment.

ARTICLE HIGHLIGHTS

- **Type of Research:** A multicenter, prospective, nonrandomized trial
- **Key Findings:** A total of 100 subjects with a descending thoracic aneurysm or penetrating atherosclerotic ulcer were treated with the Valiant Navion stent graft (Medtronic Inc, Santa Rosa, Calif). The 1-year freedom from all-cause mortality and secondary procedures was 89.8% and 94.8%, respectively. The graft conformed to the native thoracic aorta tortuosity at implant and through 1 year of follow-up. Aortic elongation and dilation had occurred more often at the distal end of the stent graft.
- **Take Home Message:** The 1-year results with the Navion stent graft were positive, and the imaging analysis showed the importance of the seal zone length and oversizing to address the natural changes in aortic morphology.

Baseline patient and anatomic characteristics and procedural outcomes. The demographics and baseline characteristics were similar to those previously reported in the 30-day primary end point study[13] (Supplementary Table I, online only). Of the 100 patients, 24 (24%) had had an abdominal aortic aneurysm and 11 (11%) had had an ascending thoracic aneurysm in addition to their thoracic aortic aneurysm. The proportions of patients with a primary indication for TEVAR and the mean maximum aneurysm diameter for the specific group as specified by the core laboratory (Syntactx) imaging analysis were as follows: fusiform aneurysm, 47% (mean aneurysm diameter, 63.1 ± 9.5 mm); saccular aneurysm, 28% (mean diameter, 53.0 ± 13.2 mm); and PAU, 25% (mean diameter, 44.1 ± 9.3 mm).

The core laboratory measurements of the preimplant vessel diameters are also reported in Supplementary

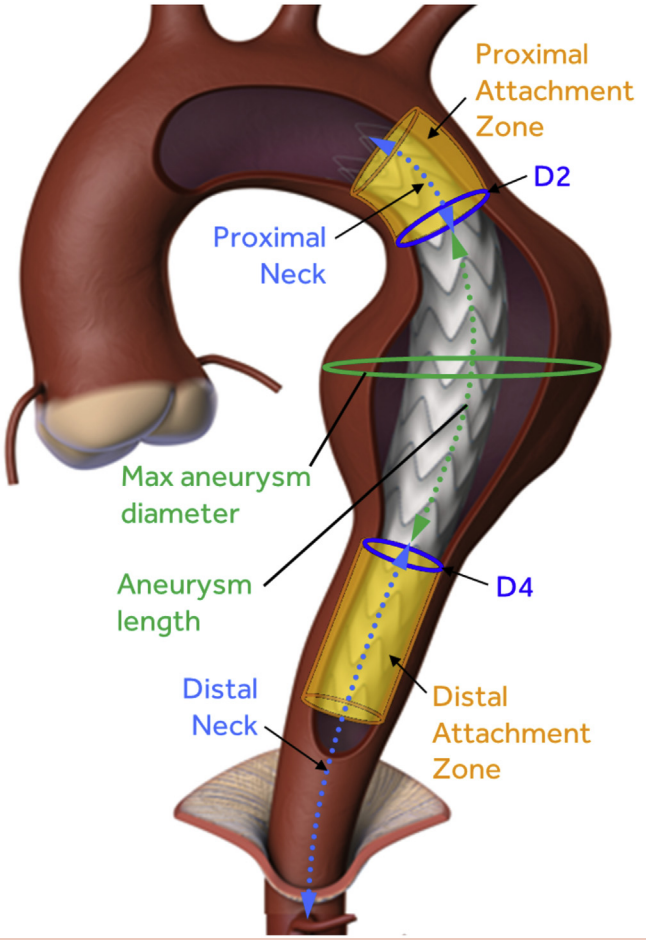


Fig 1. Schematic of seal zone-related measurements. Note that proximal and distal neck lengths were calculated from preprocedural images and attachment zone lengths and diameters were measured after the procedure (1 and 12 months in the present study). *D2,* Aortic diameter immediately proximal to aneurysm; *D4,* aortic diameter immediately distal to aneurysm for oversizing calculations; *Max,* maximum.

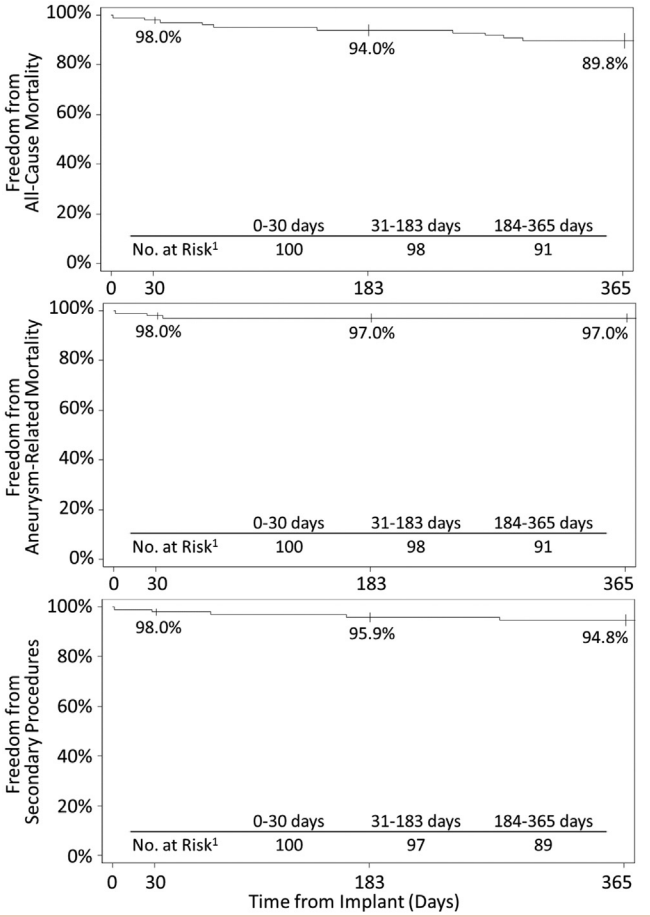


Fig 2. Kaplan-Meier curves for freedom from all-cause mortality, aneurysm-related mortality, and secondary procedures through 1 year. [1]Number of subjects at risk at the beginning of the interval; survival estimates performed at the end of the interval, with the standard error calculated using the Greenwood method.

Table I (online only). Most patients had had only one device implanted (55%), with 38 patients (38%) requiring two and 7 (7%) requiring three or more devices. Of the 100 patients, 73 had received a FreeFlo device (73%) as their proximal graft, with the landing zone distributed as follows: zone 2, 28.8% (n = 21); zone 3, 46.6% (n = 34); and zone 4, 24.7% (n = 18). The other 27 subjects had received a CoveredSeal device as their proximal graft, with the landing zones distributed as follows: zone 2, 7.4% (n = 2); zone 3, 40.7% (n = 11); and zone 4, 51.9% (n = 14).

The acute procedural outcomes were similar to those reported in our primary end point report[13] (Supplementary Table I, online only). No access or deployment failures occurred during the index procedure for any of the 100 subjects. Of the 23 subjects with landing zone 2, 21 had complete coverage and 2 had partial coverage of the left subclavian artery (LSA). The 2 patients with partial LSA coverage did not undergo revascularization, and 19 of the 21 patients with complete LSA coverage had required a revascularization procedure. Our review of the database showed that 13 of the revascularizations were left carotid to left subclavian bypass and 6 were left subclavian transpositions. Of the 19 revascularization procedures, 10 had been performed adjunctively before stent graft implantation and 9 intraoperatively.

Clinical trial outcomes at 1 year. At 1 year, the primary composite end point had been met (one-sided 95% upper confidence interval, 9.99%; $P < .001$), with only 4 of eligible 89 patients (4.5%) experiencing access and/or deployment failure and/or a major device effect. Through the 1-year follow-up, the freedom from all-cause mortality, aneurysm-related mortality, and secondary procedures was 89.8%, 97.0%, and 94.8%, respectively (Fig 2). A review of the database revealed the cause of death for the 10 patients who had died was aneurysm related for 4,

Table I. Major adverse events through 1 year (as reported by site)

MAE	0-365 Days (n = 100)[a]
Any	41 (41/100)
Cardiac disorder	24 (24/100)
Acute myocardial infarction	2 (2/100)
Unstable angina	1 (1/100)
Atrial fibrillation	8 (8/100)
Atrioventricular block	2 (2/100)
Congestive heart failure	10 (10/100)
Left ventricular failure	1 (1/100)
Tachycardia	1 (1/100)
Ventricular tachycardia	2 (2/100)
Nervous system disorder	9 (9/100)
Stroke	7 (7/100)
Paraplegia/spinal cord ischemia	2 (2/100)
Acute kidney injury	7 (7/100)
Respiratory, thoracic, and mediastinal disorder	5 (5/100)
Acute respiratory failure	1 (1/100)
Pulmonary embolism	2 (2/100)
Vascular disorder	7 (7/100)
Aortic dissection	2 (2/100)
Aortic rupture	1 (1/100)

MAE, Major adverse events.
Data presented as percentage (no./No.) of subjects who experienced one or more MAE during the study period; a patient could have had multiple MAE in different categories; thus, the number of patients in each category might not be the sum of those in each subcategory; each patient was counted only once in each category.
[a]Number of subjects at risk at beginning of the interval.

cardiac for 3, cancer for 1, neurologic (Parkinson disease) for 1, and pneumonia for 1 patient. Of the four aneurysm-related mortalities, three had occurred on day 1 (retrograde type A dissection), day 24 (not related to the stent graft but within the first 30 days), and day 35 (aortic arch rupture) after implantation; the details have been reported in the 30-day study.[13] The fourth patient had undergone an indium-111 white blood cell scan, which had revealed findings consistent with stent graft infection on day 268. The patient had failed to progress after treatment for methicillin-resistant *Staphylococcus aureus* sepsis and had died on day 280. Of the five patients who had undergone a total of six secondary procedures, the reason for the secondary procedure was retrograde type A dissection, aortic arch rupture, type II endoleak, infrarenal abdominal aortic aneurysm, type Ia endoleak, and type Ib endoleak. Excluding the PAU subjects and considering only the aneurysm patients in the present trial did not change the survival curves for all-cause mortality, aneurysm-related mortality, or secondary procedures (Supplementary Tables II and III; Supplementary Fig, online only).

The major adverse events are listed in Table I. Seven patients experienced strokes, of whom, four recovered without sequelae and three with sequelae. The results of the survival analyses of endoleaks through 1 year of follow-up are listed in Table II. An additional two patients had experienced a type Ib endoleak on days 379 and 423 after implant, which were within the 1-year follow-up window and, thus, were included in the imaging analysis. They were not included in the survival analyses owing to the 1-year cutoff. Of the nine patients with an endoleak, two had undergone a secondary procedure to correct their endoleak. One patient with both type Ia and Ib endoleaks was successfully treated with a Valiant Captivia stent graft (Medtronic) placed proximally and a fenestrated Cook device (Cook Medical, Bloomington, Ind) placed distally. The second patient had a type II endoleak. After embolization of the LSA with a coil, follow-up imaging confirmed the leak had resolved without sequelae.

Aneurysm sac dynamics. Only 2 of the 76 patients with images available for analysis (2.6%) had had an increase in their maximum aneurysm diameter of ≥5 mm after 1 year. Of these two patients with a sac increase ≥5 mm, one had had a type Ib endoleak (Fig 3) and one had not developed any endoleak. Most of the patients had had stable sacs (81.6%; 62 of 76), and 12 (15.8%) had had sac shrinkage of ≤5 mm at 1 year.

Aortic measurements related to seal zones. The results of the imaging analysis of the proximal and distal seal zones are presented in Table III. The mean device oversizing was 17% ± 12% at the proximal end. Although three patients had not met the minimum required proximal neck length according to the IFU, 36 of the 100 patients (36%) had had a short PAZ at 1 month using the study definitions. The mean device oversizing at the distal end was 20% ± 13%. All the patients had met the minimum required distal neck length of 20 mm. However, again, the DAZ length was considered short for 31 of the 100 patients (31%). Of the 25 patients with a PAU, 2 (8%) had had a proximal neck length that did not meet the IFU requirements. In addition, the PAZ was considered short for 15 of these 25 patients (60%) using our definition.

As stated previously, nine patients had developed endoleaks, one of whom had also had a sac increase >5 mm. An additional patient had had a sac increase >5 mm but without an endoleak identified. The seal zones for these 10 patients (for simplicity, the endoleak group) were compared with the patients without an endoleak or with a sac increase of <5 mm (no endoleak group; Table III). With the understanding that this subgroup analysis was limited by the low numbers, 5 of the 10 patients (50%) in the endoleak group had had a short PAZ compared with 31 of the 90 patients (34.4%)

Table II. Interval censored survival analysis of endoleaks

Endoleak	Interval censored estimate	
	0-30 Days	31-365 Days
All	96.0% ± 2.1% (100; 2; 15)	89.6% ± 3.2% (83; 5; 37)
Type I	98.9% ± 1.1% (100; 1; 15)	94.4% ± 2.4% (84; 2; 38)
Type Ia	98.9% ± 1.1% (100; 1; 15)	97.6% ± 1.6% (84; 1; 39)
Type Ib[a]	100.0% ± 0.0% (100; 0; 15)	95.4% ± 2.2% (85; 2; 39)
Type II	98.0% ± 1.6% (100; 1; 15)	95.4% ± 2.1% (84; 3; 40)

Data presented as mean ± standard deviation (no. at risk; no. of events; no. censored).
[a]Two patients had had a type Ib endoleak on days 379 and 423 after implantation, which was within their 1-year follow-up window; however, these were not included in the survival analyses because the interval censored method had a 365-day cutoff point.

in the no endoleak group. Also, of the 10 patients in the endoleak group, 4 (40%) had had proximal oversizing of <10% compared with 29 of the 90 patients in the no endoleak group (32.2%). At the distal end, six patients in the endoleak group (60%) had had a short attachment zone compared with 25 patients in the no endoleak group (27.8%). However, although two patients in the endoleak group (20%) had had <10% oversizing, an additional two patients had had borderline undersizing at 10.3% and 10.7% oversizing. Every patient in the endoleak group had had at least one seal zone characteristic that did not meet the recommendations.

Thoracic aorta morphometry: effect of graft on native anatomy and vice versa. Changes in aortic morphology are presented in Table IV. The tortuosity did not change between the preprocedural and 1-month images. Compared with 1-month images, the thoracic aorta showed a significant increase in tortuosity at 1 year (from 1.46 to 1.49; $P < .001$). At 1 year, an average of 4.2 mm of aortic elongation was found at the distal end of the graft compared with 1.2 mm at the proximal end (Table IV). Similarly, the aortic dilation was more pronounced at the distal end of the graft, with an average increase of 2.8 mm at the DAZ compared with 1.6 mm at the PAZ at 1 year.

DISCUSSION

In the present 1-year analysis of the clinical trials, the patients treated with the Valiant Navion stent graft system (Medtronic) exhibited positive outcomes. The overall survival of near 90% and freedom from aneurysm-related mortalities >95% are in line with reports of other contemporary devices.[15-17] Sac shrinkage is an indication of the successful exclusion of the aneurysm, and most patients had had stable or decreasing sacs at 1 year, similar to the results with other modern grafts.[15,16] Similar to other trials,[16,17] the rates of endoleaks and secondary procedures were also low in the present study. The low mortality, endoleak, and secondary procedure rates support the use of TEVAR as a safe and effective treatment of thoracic aneurysms.

The investigation into the aortic morphology offers several key insights for consideration in clinical practice. Short necks are a risk factor for adverse events,[18] and we often found short seal zones in the patients who had experienced endoleaks or a sac increase of >5 mm. Although the differences in the endoleak and no endoleak group comparisons were not statistically significant, we believe the trends shown are still hypothesis generating. We also quite a disparity in that almost every patient met the IFU requirements for the neck length but one third had had short proximal and/or distal seal zone lengths. The difference in seal zone length and available neck length was unlikely to have resulted from an imprecise landing, because 100% of the patients had had successful advancement and deployment of the graft at the intended landing zone, according to the previous report.[13]

Although we acknowledge the possibility of underreporting of suboptimal deployment, other factors could have led to the "short" attachment zones. The definition of a continuous 360° wall apposition is likely to be interrupted by calcification[19] or thrombus, which would lead to a shorter seal zone length, although not necessarily compromise the performance of the graft. In addition, patients with PAU and isolated lesions might not warrant excessive coverage.[20,21] Thus, at the distal end, physicians might opt for less coverage to mitigate the risk of spinal cord ischemia.[22,23] Despite these possible reasons for the attachment zones measuring short, we place an emphasis on achieving, at a minimum, the recommended seal zone length to minimize the risk of adverse events.[1,24] Physicians can improve the seal zone by increasing the length of seal[25] or improving apposition of the graft to the artery wall.[26]

At 1 year, the trial cohort as a whole had experienced dilation of the proximal and distal attachment zones.[12] In most cases, the aortic diameter remained smaller than the graft diameter, with no loss of seal as evidenced by the low type I endoleak rate. Although undersized grafts are, intuitively, at risk of endoleaks,[27] the radial forces imposed by excessive oversizing are a

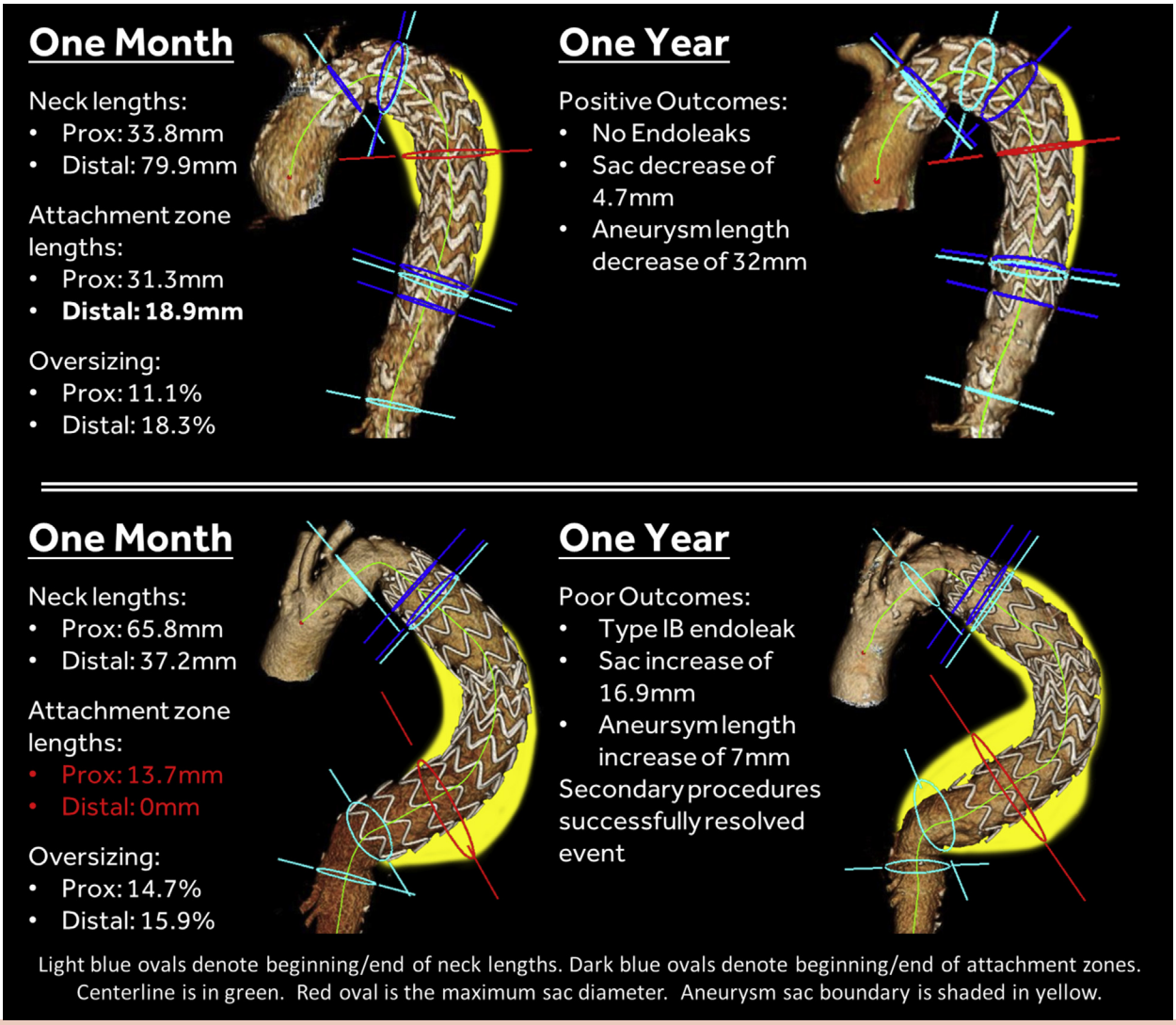


Fig 3. Three-dimensional computed tomography (CT) reconstructions of two patients, both with sufficient neck lengths according to instructions for use (IFU) recommendations. *Top*, A patient with a good proximal attachment zone (PAZ) and close to 20 mm of distal attachment. After 1 year, the patient had no endoleaks and had positive signs of sac regression. *Bottom*, A patient with a short PAZ and no distal seal (0-mm attachment zone length), which resulted in a type Ib endoleak and an increase in both aneurysm sac diameter and length. Although secondary procedures were successful in resolving the event, we believe this situation could have been avoided with better preprocedural planning.

risk factor for early dilation.[28,29] The inclusion of patients with PAU could also have biased the overall oversizing numbers because the recommended oversizing for PAU and other fragile tissues is generally <10%.[30] With an understanding that arterial dilation is naturally occurring, adjunctive procedures to protect against dilation could be considered as a part of the device sizing algorithm.[28,29]

Most of the thoracic aorta lengthening in the present cohort occurred distally.[11,31] Stent grafts also have a tendency to conform to the outer curvature of the aorta, and the combination of aortic elongation and a shift toward the outer curvature can lead to the distal coverage being shorter than expected.[32] Thus, it is important to have a good distal seal zone to limit adverse events.[5,33] Some available options to ensure a good distal seal include using longer or multiple grafts, grafts with distal fixation, or EndoAnchors (Medtronic) to improve distal sealing and fixation.[34] Patient follow-up and monitoring of the seal zones, especially at the distal end, are also recommended.

Finally, the significance of a conformable graft that does not alter the native anatomy immediately after implant should not be understated. Previous studies have reported that stent graft implantation can modify the aortic curvature and lead to increased displacement forces,[9,35] which is especially concerning in fragile aorta scenarios.[30,36] In the present study,

Table III. Seal zone-related measurements

Anatomic measurement	Full cohort (n = 100)	EL or sac increase ≥5 mm (n = 10)	No EL and sac increase <5 mm (n = 90)	*P* value
Proximal seal zone				
PNeck length, mm[a]	62.07 ± 44.20	60.72 ± 35.10	62.22 ± 45.25	.76
Short PNeck per IFU[a]	3.0 (3/100)	0.0 (0/10)	3.3 (3/90)	1.00
1-Month PAZ length, mm	32.25 ± 22.59	25.21 ± 17.87	33.09 ± 23.03	.36
Short PAZ at 1 month	36.0 (36/100)	50.0 (5/10)	34.4 (31/90)	.50
Proximal OS,[a] %	17 ± 12	14 ± 10	17 ± 12	.42
Proximal OS <10%[a]	33.0 (33/100)	40.0 (4/10)	32.2 (29/90)	.73
Distal seal zone				
DNeck length,[a] mm	97.65 ± 66.98	95.53 ± 79.78	97.88 ± 65.92	.73
Short DNeck per IFU[a]	0.0 (0/100)	0.0 (0/10)	0.0 (0/90)	NA
1-Month DAZ length, mm	36.14 ± 28.40	31.33 ± 32.11	36.71 ± 28.08	.30
Short DAZ at 1 month	31.0 (31/100)	60.0 (6/10)	27.8 (25/90)	.08
Distal OS,[a] %	20 ± 13	17 ± 11	20 ± 13	.62
Distal OS <10%[a]	23.0 (23/100)	20.0 (2/10)	23.3 (21/90)	1.00

DAZ, Distal attachment zone; *DNeck*, distal neck; *EL*, endoleak; IFU, instructions for use; *OS*, oversizing; *PAZ*, proximal attachment zone; *PNeck*, proximal neck.
Data presented as mean ± standard deviation or percentage (no./No.).
[a]Neck length and OS calculated from preprocedural imaging measurements.

Table IV. Vessel tortuosity and aortic morphometry showing effect of stent graft implantation on tortuosity and occurrence of aortic dilation and elongation after 1 year

Anatomic measurement	Before implantation	After implantation	
		At 1 month	At 12 months
Effect of graft implantation on native anatomy			
Thoracic aorta tortuosity	1.45 ± 0.02	1.46 ± 0.02	1.49 ± 0.02[a]
Abdominal aorta tortuosity	1.07 ± 0.01	1.08 ± 0.01	1.08 ± 0.01
Effect of aortic remodeling on graft performance			
LSA to celiac length		272.59 ± 3.52	279.76 ± 4.03[a]
LCC to proximal edge		57.37 ± 4.88	58.60 ± 4.84
Stent graft total covered		161.67 ± 6.19	163.83 ± 6.35
Distal edge to celiac artery		72.36 ± 5.61	76.60 ± 5.60[a]
Aneurysm length		92.22 ± 6.22	82.78 ± 6.49[a]
Maximum thoracic aneurysm diameter		57.21 ± 1.33	55.41 ± 1.41[a]
PAZ length		32.23 ± 2.30	40.80 ± 2.94[a]
PAZ diameter		30.43 ± 0.51	31.98 ± 0.54[a]
DAZ length		36.63 ± 2.89	39.87 ± 3.51
DAZ diameter		30.14 ± 0.54	32.94 ± 0.86[a]

DAZ, Distal attachment zone; *LCC*, left common carotid artery; *LSA*, left subclavian artery; *PAZ*, proximal attachment zone.
Data presented as mean ± standard error, as estimated from the linear model.
[a]Measurement was significantly different from that at earlier measurement (at $P < .05$ significance level); estimates and *P* values calculated from a linear model for repeated measurements.

thoracic aorta tortuosity was not altered as a result of stent graft implantation, showing that the device conforms to the native anatomy. Despite the natural increase in the tortuosity of the thoracic aorta after 1 year, the low rates of endoleaks and secondary procedures also suggest the seal zones were maintained over time. Overall, the graft conformed to the arterial wall with good wall apposition, as have other modern grafts.[37]

STUDY LIMITATIONS

Just as with any single-arm clinical trial, the citations of studies of other stent grafts were simply to place our outcomes in context owing to the

lack of a control group in the present trial. The focus of the present analysis was on the imaging-based parameters, and a slight decrease in the use of CT as the imaging modality had occurred at the 1-year follow-up. In addition, the sample size of the trial was too small to power statistically significant conclusions in the endoleak and PAU subgroup comparisons. Finally, one-quarter of the trial subjects had had PAUs, which is a different disease state than aneurysms. The differences in the outcomes with the exclusion of those with PAUs are presented in Supplementary Tables II and III and the Supplementary Fig (online only).

CONCLUSIONS

In the present 1-year report of the clinical trial of the Valiant Navion stent graft system (Medtronic), the patients had good outcomes, with mortality, endoleaks, and secondary procedures all very low. The imaging analysis showed the role that the length of coverage and oversizing play in achieving a good seal zone. Physicians have a multitude of techniques to choose from to obtain a good seal. Temporal changes in aortic morphology, especially distal aortic elongation and arterial dilation, should be considered during the TEVAR planning process such that the graft will perform well in the long term. Finally, further follow-up will be imperative because morphologic changes are likely to be more significant over time. Thus, follow-up in the present trial is planned through 5 years.

The authors acknowledge the following from Medtronic Inc: Archana Booneti for assistance with the statistical analysis; Brian Glynn, Alessandro Marucchini, Randy Bassett, and Diane Cacho for clinical expertise; and Ming-Jay Chow for preparation of the manuscript.

AUTHOR CONTRIBUTIONS

Conception and design: FV, ND, FA, JP, FT, FD, AA
Analysis and interpretation: FV, FA, JG, AA
Data collection: FV, JG, AA
Writing the article: FV, AA
Critical revision of the article: FV, ND, FA, JP, FT, FD, JG, AA
Final approval of the article: FV, ND, FA, JP, FT, FD, JG, AA
Statistical analysis: JG
Obtained funding: Not applicable
Overall responsibility: FV

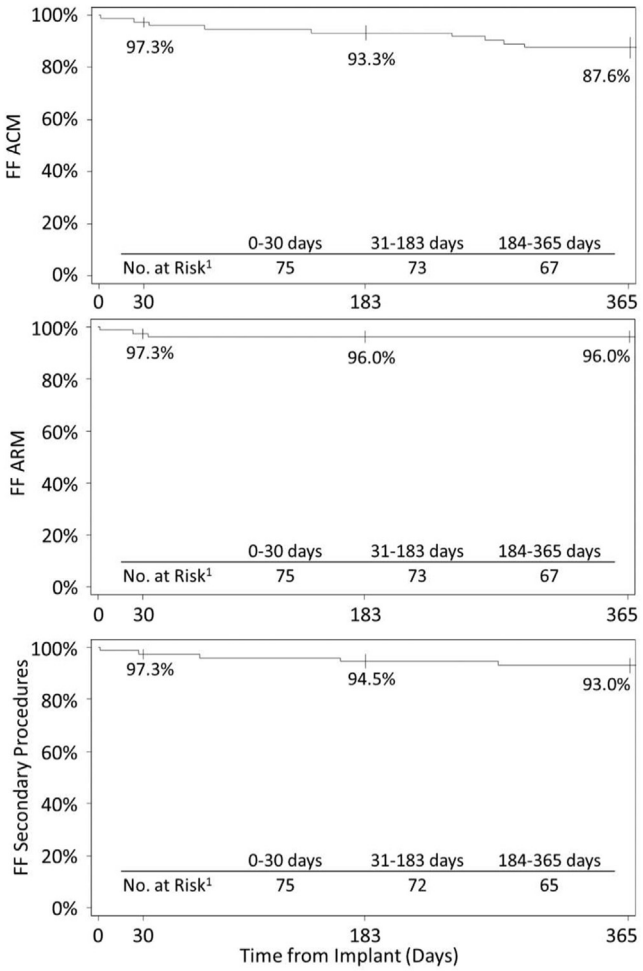
REFERENCESS

1. Nation DA, Wang GJ. TEVAR: endovascular repair of the thoracic aorta. Semin Intervent Radiol 2015;32:265-71.
2. Peidro J, Boufi M, Hartung O, Vernet F, Dona B, Bensoussan D, et al. Complications of the zone of proximal anchoring after TEVAR: role of the aortic anatomy. Ann Vasc Surg 2017;38:e18-9.
3. Schuurmann RC, Ouriel K, Muhs BE, Jordan WD Jr, Ouriel RL, Boersen JT, et al. Aortic curvature as a predictor of intraoperative type Ia endoleak. J Vasc Surg 2016;63:596-602.
4. Nakatamari H, Ueda T, Ishioka F, Raman B, Kurihara K, Rubin GD, et al. Discriminant analysis of native thoracic aortic curvature: risk prediction for endoleak formation after thoracic endovascular aortic repair. J Vasc Interv Radiol 2011;22:974-9.e2.
5. Berezowski M, Morlock J, Beyersdorf F, Jasinski M, Plonek T, Siepe M, et al. Inaccurate aortic stent graft deployment in the distal landing zone: incidence, reasons and consequences. Eur J Cardiothorac Surg 2017;53:1158-64.
6. Lee WA, Matsumura JS, Mitchell RS, Farber MA, Greenberg RK, Azizzadeh A, et al. Endovascular repair of traumatic thoracic aortic injury: clinical practice guidelines of the Society for Vascular Surgery. J Vasc Surg 2011;53:187-92.
7. Chen Y, Zhang S, Liu L, Lu Q, Zhang T, Jing Z. Retrograde type A aortic dissection after thoracic endovascular aortic repair: a systematic review and meta-analysis. Cardiovasc Cerebrovasc Dis 2017;6:e004649.
8. Ma T, Dong ZH, Fu WG, Guo DQ, Xu X, Chen B, et al. Incidence and risk factors for retrograde type A dissection and stent graft-induced new entry after thoracic endovascular aortic repair. J Vasc Surg 2018;67:1026-33.e2.
9. Mestres G, Garcia ME, Yugueros X, Urrea R, Tripodi P, Gomez F, et al. Aortic arch and thoracic aorta curvature remodeling after thoracic endovascular aortic repair. Ann Vasc Surg 2017;38:233-41.
10. Hirotsu K, Suh GY, Lee JT, Dake MD, Fleischmann D, Cheng CP. Changes in geometry and cardiac deformation of the thoracic aorta after thoracic endovascular aortic repair. Ann Vasc Surg 2018;46:83-9.
11. Chen C-K, Chou H-P, Chang Y-Y, Shih C-C. Elongation of the aorta after thoracic endovascular aortic repair: a longitudinal study. Int J Environ Res Public Health 2020;17:1205.
12. Findeiss LK, Cody ME. Endovascular repair of thoracic aortic aneurysms. Semin Intervent Radiol 2011;28:107-17.
13. Azizzadeh A, Desai N, Arko FR III, Panneton JM, Thaveau F, Hayes P, et al. Pivotal results for the Valiant Navion stent graft system in the Valiant EVO global clinical trial. J Vasc Surg 2019;70:1399-408.e1.
14. Ahn SS, Rutherford RB, Johnston KW, May J, Veith FJ, Baker JD, et al. Reporting standards for infrarenal endovascular abdominal aortic aneurysm repair. Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery/International Society for Cardiovascular Surgery. J Vasc Surg 1997;25:405-10.
15. Jordan WD Jr, Rovin J, Moainie S, Bavaria J, Cambria R, Fillinger M, et al. Results of a prospective multicenter trial of CTAG thoracic endograft. J Vasc Surg 2015;61:589-95.
16. Illig KA, Ohki T, Hughes GC, Kato M, Shimizu H, Patel HJ, et al. One-year outcomes from the international multicenter study of the Zenith Alpha thoracic endovascular graft for thoracic endovascular repair. J Vasc Surg 2015;62:1485-94.e2.
17. Tsilimparis N, Debus S, Chen M, Zhou Q, Seale MM, Kölbel T. Results from the study to assess outcomes after endovascular repair for multiple thoracic aortic diseases (SUMMIT). J Vasc Surg 2018;68:1324-34.
18. Ben Abdallah I, El Batti S, Sapoval M, Abou Rjeili M, Fabiani JN, Julia P, et al. Proximal scallop in thoracic endovascular aortic aneurysm repair to overcome neck issues in the arch. Eur J Vasc Endovasc Surg 2016;51:343-9.
19. Lau C, Feldman DN, Girardi LN, Kim LK. Imaging for surveillance and operative management for endovascular aortic aneurysm repairs. J Thorac Dis 2017;9(Suppl 4):S309-16.
20. Eggebrecht H, Plicht B, Kahlert P, Erbel R. Intramural hematoma and penetrating ulcers: indications to endovascular treatment. Eur J Vasc Endovasc Surg 2009;38:659-65.
21. Evangelista A, Czerny M, Nienaber C, Schepens M, Rousseau H, Cao P, et al. Interdisciplinary expert consensus on management of type B intramural haematoma and penetrating aortic ulcer. Eur J Cardiothorac Surg 2014;47:209-17.
22. Dijkstra ML, Vainas T, Zeebregts CJ, Hooft L, van der Laan MJ. Editor's choice – spinal cord ischaemia in endovascular thoracic and thoraco-abdominal aortic repair: review of preventive strategies. Eur J Vasc Endovasc Surg 2018;55:829-41.
23. Awad H, Ramadan ME, El Sayed HF, Tolpin DA, Tili E, Collard CD. Spinal cord injury after thoracic endovascular aortic aneurysm repair. Can J Anaesth 2017;64:1218-35.
24. Ricotta JJ II. Endoleak management and postoperative surveillance following endovascular repair of thoracic aortic aneurysms. J Vasc Surg 2010;52(Suppl):91s-9s.

25. van Bakel TM, de Beaufort HW, Trimarchi S, Marrocco-Trischitta MM, Bismuth J, Moll FL, et al. Status of branched endovascular aortic arch repair. Ann Cardiothorac Surg 2018;7:406-13.
26. Arko FR III, Stanley GA, Pearce BJ, Henretta JP, Fugate MW, Mehta M, et al. Endosuture aneurysm repair in patients treated with Endurant II/IIs in conjunction with Heli-FX EndoAnchor implants for short-neck abdominal aortic aneurysm. J Vasc Surg 2019;70:732-40.
27. Bonci G, Steigner ML, Hanley M, Braun AR, Desjardins B, Gaba RC, et al. ACR Appropriateness Criteria(®) thoracic aorta interventional planning and follow-up. J Am Coll Radiol 2017;14(Suppl): S570-83.
28. Tassiopoulos AK, Monastiriotis S, Jordan WD, Muhs BE, Ouriel K, De Vries JP. Predictors of early aortic neck dilatation after endovascular aneurysm repair with EndoAnchors. J Vasc Surg 2017;66: 45-52.
29. Ribner AS, Tassiopoulos AK. Postoperative aortic neck dilation: myth or fact? Int J Angiol 2018;27:110-3.
30. Patel HJ, Williams DM, Upchurch GR, Dasika NL, Deeb GM. The challenge of associated intramural hematoma with endovascular repair for penetrating ulcers of the descending thoracic aorta. J Vasc Surg 2010;51:829-35.
31. Alberta HB, Takayama T, Panthofer A, Cambria RP, Farber MA, Jordan WD, et al. Thoracic endovascular aortic repair migration and aortic elongation differentiated using dual reference point analysis. J Vasc Surg 2018;67:382-8.
32. Kaladji A, Spear R, Hertault A, Sobocinski J, Maurel B, Haulon S. Centerline is not as accurate as outer curvature length to estimate thoracic endograft length. Eur J Vasc Endovasc Surg 2013;46:82-6.
33. Geisbüsch P, Skrypnik D, Ante M, Trojan M, Bruckner T, Rengier F, et al. Endograft migration after thoracic endovascular aortic repair. J Vasc Surg 2019;69:1387-94.
34. Kasprzak P, Pfister K, Janotta M, Kopp R. EndoAnchor placement in thoracic and thoracoabdominal stent-grafts to repair complications of nonalignment. J Endovasc Ther 2013;20:471-80.
35. Figueroa CA, Taylor CA, Yeh V, Chiou AJ, Zarins CK. Effect of curvature on displacement forces acting on aortic endografts: a 3-dimensional computational analysis. J Endovasc Ther 2009;16: 284-94.
36. Kuo EC, Veranyan N, Johnson CE, Weaver FA, Ham SW, Rowe VL, et al. Impact of proximal seal zone length and intramural hematoma on clinical outcomes and aortic remodeling after thoracic endovascular aortic repair for aortic dissections. J Vasc Surg 2019;69: 987-95.
37. Antonello M, Squizzato F, Dall'Antonia A, Grego F, Piazza M. GORE TAG thoracic endograft with active control system: landing accuracy and wall apposition in an initial clinical experience. Ann Vasc Surg 2019;58:261-9.

Submitted Jul 1, 2020; accepted Jan 5, 2021.

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



Supplementary Fig (online only). Survival analyses after removal of patients with penetrating atherosclerotic ulcer (PAU) because previous survival analyses might not have been representative of a typical aneurysm cohort owing to the inclusion of those with PAUs. The all-cause mortality (*ACM*), aneurysm-related mortality (*ARM*), and secondary procedure rates without those with PAU were similar to those that had included the patients with PAUs.

Supplementary Table I (online only). Patient demographics, medical history, preimplant vessel diameters, and acute procedural data

Characteristic	Full trial cohort (n = 100)
Female gender	40 (40/100)
Age, years	70.8 ± 8.9
Cardiovascular	
Carotid artery disease	18.6 (18/97)
Angina	9 (9/100)
Arrhythmia	27 (27/100)
Congestive heart failure	15 (15/100)
Coronary artery disease	33 (33/100)
Myocardial infarction	16 (16/100)
Abdominal aortic aneurysm	24 (24/100)
Ascending thoracic aneurysm	11 (11/100)
Peripheral vascular disease	14.1 (14/99)
Hypertension	87 (87/100)
Cerebrovascular/neurologic	
Stroke/cerebral vascular accident	9 (9/100)
Transient ischemic attack	7 (7/100)
Paraparesis	0 (0/100)
Paraplegia	0 (0/100)
Diabetes	22.0 (22/100)
Hyperlipidemia	69.7 (69/99)
Tobacco use in previous 10 years	50.5 (50/99)
Chronic obstructive pulmonary disease	31.3 (31/99)
Renal insufficiency	22 (22/100)
Cancer	23 (23/100)
ASA physical status classification	
I	8 (8/100)
II	22 (22/100)
III	43 (43/100)
IV	27 (27/100)
Vessel diameter, mm	
D1, aortic diameter 2 cm proximal to aneurysm	29.1 ± 3.6 (100/100)
D2, aortic diameter immediately proximal to aneurysm	31.3 ± 5.0 (100/100)
D3, maximum aneurysm diameter	
Entire cohort	55.5 ± 13.1 (100/100)
Patients with fusiform aneurysm indication	63.1 ± 9.5 (47/47)
Patients with saccular aneurysm indication	53.0 ± 13.2 (28/28)
Patients with PAU indication	44.1 ± 9.3 (25/25)
D4, aortic diameter immediately distal to aneurysm	30.2 ± 5.4 (100/100)
D5, aortic diameter 2 cm distal to aneurysm	28.9 ± 4.7 (100/100)
D6, minimum left common iliac diameter	9.7 ± 2.5 (99/99)
D7, minimum left external iliac diameter	7.6 ± 1.9 (98/98)
D8, minimum left femoral diameter	7.8 ± 1.7 (96/96)
D9, minimum right common iliac diameter	9.8 ± 2.4 (99/99)
D10, minimum right external iliac diameter	7.5 ± 1.8 (98/98)
D11, minimum right femoral diameter	7.7 ± 1.6 (96/96)
Aortic diameter	
At left subclavian artery	29.7 ± 4.2 (100/100)
At 2 cm distal to left common carotid artery	29.5 ± 4.1 (100/100)
At 2.5 cm distal to left common carotid artery	30.2 ± 4.9 (100/100)
At 2.5 cm proximal to aneurysm	29.4 ± 3.6 (100/100)
At 2 cm proximal to celiac artery	28.5 ± 5.4 (100/100)
Maximum infrarenal aortic diameter	26.5 ± 7.9 (100/100)
Acute procedural data	
Duration of procedure, minutes	88.6 ± 54.3 (100/100)
Anesthesia type	
General	90 (90/100)
Local	8 (8/100)
Epidural	0 (0/100)
Spinal	2 (2/100)
Access type	
Surgical cutdown	51 (51/100)
Percutaneous	49 (49/100)
Estimated blood loss, mL	94.4 ± 144.1 (98/100)
Blood transfusion required	2 (2/100)
Volume of blood transfused, mL	600.0 ± 0.0 (2/100)
Volume of contrast, mL	95.3 ± 51.4 (99/100)
Total fluoroscopic time, minutes	12.1 ± 9.0 (99/100)
Radiation exposure, mGy	506.0 (73/100; 31-8502)
ICU stay after index procedure, hours	45.5 (70/100; 14-584)
Hospital stay, days	7.5 ± 7.0 (100/100)

ASA, American Society of Anesthesiologists; *ICU*, intensive care unit; PAU, penetrating atherosclerotic ulcer.
Data presented as mean ± standard deviation (no./No.), percentage (no./No.), or median (no./No.; range).

Supplementary Table II (online only). Seal zone measurements stratified by indication[a]

Anatomic measurement	Indication		*P* value
	Aneurysm (n = 75)	PAU (n = 25)	
Proximal seal zone			
PNeck length,[b] mm	62.85 ± 45.16	59.72 ± 41.96	.57
Short PNeck per IFU[b]	1.3 (1/75)	8.0 (2/25)	.15
1-Month PAZ length, mms	34.20 ± 22.12	26.23 ± 23.46	.05
Short PAZ at 1 month	28.0 (21/75)	60.0 (15/25)	.0032
Proximal OS,[b] %	17 ± 12	18 ± 10	.53
Proximal OS <10%[b]	34.7 (26/75)	28.0 (7/25)	.63
Distal seal zone			
DNeck length,[b] mm	93.32 ± 64.15	110.63 ± 74.70	.32
Short DNeck per IFU[b]	0.0 (0/75)	0.0 (0/25)	NA
1-Month DAZ length, mm	35.79 ± 27.98	37.21 ± 30.27	.85
Short DAZ at 1 month	33.3 (25/75)	24.0 (6/25)	.46
Distal OS,[b] %	19 ± 13	22 ± 13	.22
Distal OS <10%[b]	25.3 (19/75)	16.0 (4/25)	.42s

DAZ, Distal attachment zone; *DNeck,* distal neck; *IFU,* instructions for use; *NA,* not applicable; *OS,* oversizing; *PAU,* penetrating atherosclerotic ulcer; *PAZ,* proximal attachment zone; *PNeck,* proximal neck.
Data presented as mean ± standard deviation or % (no./No.).
[a]Although patients with PAU were included in the clinical trial, they are likely to be treated differently in terms of the choice of oversizing and seal zone length and could have had different changes in their aortic morphometry.
[b]Neck lengths and oversizing were calculated using the preprocedural imaging measurements.

Supplementary Table III (online only). Reassessment of endoleak rates after removal of PAU cohort

Endoleak type	Interval censored estimate	
	0-30 Days	31-365 Days
All	96.6% ± 2.3% (75; 1; 13)	86.7% ± 4.1% (61; 5; 27)
Type I	98.6% ± 1.4% (75; 1; 13)	92.1% ± 3.3% (61; 2; 28)
Type Ia	98.6% ± 1.4% (75; 1; 13)	96.7% ± 2.1% (61; 1; 29)

IC, Interval censored; *PAU,* pensetrating atherosclerotic ulcer.
Data presented as mean ± standard deviation (no. at risk; no. of events; no. censored).
Removal of PAU subjects did not overly change the survival estimates for those with endoleaks; of the 25 patients with PAU, only 1 had developed an endoleak (type Ia); because no patient with PAU had developed a type Ib or II endoleak, those data were not included.