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Two-Year Target Vessel-related Outcomes Following Use of Off-the-Shelf Branched Endografts for the Treatment of Thoracoabdominal Aortic Aneurysms

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AUTHOR CONTRIBUTIONS

Author		All FOUR Criteria are required by EACH author						
		Research (Select one or more)			Manuscript Development (Select one or more)		Approval (Required)	Accountability (Required)
Full author name	Initials	Conception and design	Analysis and interpretation	Data collection	Writing the manuscript	Critical revision	Approval of the manuscript	Agreement to be accountable
Nikolaos Tsilimparis	NT	X	X	X	X	X	X	X
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Chyon Yeh	CY		X			X	X	X
Tilo Kölbel	TK	X	X	X	X	X	X	X

ARTICLE HIGHLIGHTS

Type of Research: Multicenter analysis of retrospectively and prospectively collected data.

Key Findings: Two years following thoracoabdominal aortic aneurysm (TAAA) repair with the off-the-shelf Zenith® t-Branch® Thoracoabdominal Endovascular Graft, Kaplan-Meier (KM) freedom from all-cause and aneurysm-related mortality were 78.5% and 98.6%, respectively. Maximum aneurysm diameter decreased in 84.6% of patients at last available follow-up after 1 year. KM freedom from loss of primary patency at 24 months were 94.8%, 100%, 91.3%, and 89.3% for the celiac (CA), superior mesenteric (SMA), left renal (LRA), and right renal (RRA) arteries, respectively. KM freedom from loss of secondary patency at 24 months in the CA, SMA, LRA, and RRA were 96.3%, 100%, 98.2%, and 98.3%. Four endoleaks involving bridging stents were reported after 12 months: 2 in the CA and 2 in the RRA. KM freedom from secondary intervention was 76.3% at 24 months.

Take Home Message: Favorable primary and high secondary target vessel patency were observed through 2 years in patients treated with the t-Branch graft for symptomatic or asymptomatic thoracoabdominal aortic aneurysms.

Table of Contents Summary

This multicenter study evaluating the t-Branch graft showed rates of mortality, patency, and secondary interventions similar to those reported previously. Freedom from loss of secondary target vessel patency was maintained in over 95% of all target vessels through 2 years.

ABSTRACT

Objectives: To assess clinical outcomes and target vessel patency through 2 years following thoracoabdominal aortic aneurysms (TAAA) repair with the off-the-shelf Zenith® t-Branch® Thoracoabdominal Endovascular Graft (William Cook Europe, Bjaeverskov, Denmark).

Methods: This post-market, observational study was conducted at 3 European sites with ambispective enrollment from 2012-2017. Patients underwent endovascular TAAA repair with the t-Branch graft and bridging stent grafts (BSGs) for the celiac (CA), superior mesenteric (SMA), left renal (LRA), and/or right renal arteries (RRA). Follow-up was through 2 years per sites' standard of care. Procedural and 1-year results were reported previously.

Results: Eighty patients (mean age 71.0±7.4 years, 70.0% men) were enrolled; 6 patients had symptomatic TAAAs and 15 patients had contained ruptures. Technical success was achieved in 98.8% (79/80) of patients. Median follow-up was 22.2 months (IQR: 9.2-25.1 months).

At 24 months, Kaplan-Meier (KM) freedom from all-cause and aneurysm-related mortality were 78.5% and 98.6%, respectively. Beyond 12 months, 38 adverse events occurred in 20 patients, including 2 aortic ruptures (1 study aneurysm and 1 non-study aneurysm) and 6 deaths (none aneurysm-related, as reported by the site). Compared with postprocedure, maximum aneurysm diameter decreased (>5 mm) in 84.6% (44/52), remained unchanged in 3.8% (2/52), and increased (>5 mm) in 11.5% (6/52) of patients with imaging follow-up after 12 months. No conversions to open repair, and no t-Branch graft or other endograft component migration or integrity issues were reported. No loss of patency was reported in the t-Branch or iliac limb grafts throughout the study. Throughout study duration, 4 patients had 5 imaging-reported BSG compressions, none of which required secondary intervention.

KM freedom from secondary intervention was 76.3% at 24 months. Fourteen target vessel-related secondary interventions were performed, primarily consisting of stent placement for endoleak, stenosis, or occlusion. KM freedom from loss of primary patency were 94.8%, 100%, 91.3%, and 89.3% for the CA, SMA, LRA, and RRA, respectively, at 24 months. KM freedom from loss of secondary patency in the CA, SMA, LRA, and RRA were 96.3%, 100%, 98.2%, and 98.3% at 24 months. A total of 298 vessels were targeted of which 12 were occluded over the study period.

Conclusions: Primary and secondary target vessel patency rates through 2 years demonstrated durable repair with the t-Branch graft in patients treated for symptomatic or asymptomatic thoracoabdominal aortic aneurysms.

Keywords: thoracoabdominal aortic aneurysm, endovascular techniques, ruptured aneurysm, aortic dissection

INTRODUCTION

Endovascular repair with branched endografts for patients with thoracoabdominal aortic aneurysms (TAAA) and suitable anatomy has demonstrated promising outcomes in both elective and urgent settings.[1-4] According to the latest guidelines from the European Society for Vascular Surgery (ESVS), complex endovascular repair with off-the-shelf branched endografts may be considered for patients with complex aortic aneurysms based on patient status, anatomy, local routines, team experience, and patient preference.[5] The first off-the-shelf branched endograft for TAAA repair became available in Europe more than 10 years ago.[1] Despite the introduction of this technology, data on real-world use and longer-term outcomes are limited. Additional data regarding the performance of the bridging stent grafts (BSGs), which are often involved in reintervention, are needed.

Objectives.

The current study reports the 2-year outcomes of a post-market observational study of the Zenith® t-Branch® Thoracoabdominal Endovascular Graft (William Cook Europe, Bjaeverskov, Denmark; herein referred to as the "t-Branch graft") for TAAA. Target vessel patency through 24-month follow-up, including the number of stenoses and occlusions in target vessels (celiac artery [CA], superior mesenteric artery [SMA], left renal artery [LRA], and right renal artery [RRA]) based upon the type of BSG used, are reported. Additional outcomes include 24-month mortality, adverse events, device integrity issues, endoleaks, aneurysm diameter changes, and secondary procedures.

METHODS

Study Design and Definitions.

Patients treated with the t-Branch graft from September 2012 to November 2017 at 3 European centers were enrolled, either prospectively or retrospectively, in this postmarket, observational study. Details of study design, study device, implantation technique, and patient inclusion and exclusion were described previously.[6] As reported in Bosiers et al., 2021,[6] several stents were used during the study procedure for target vessels. Covered stents included Advanta™/iCAST™ (Getinge AB; Getinge, Sweden), BeGraft™ (Bentley Innomed; Hechingen, Germany), E-ventus® (JOTEC, now ARTIVION; Hechingen, Germany), Viabahn® (Gore Medical; Flagstaff, AZ, USA), Covera™ (C.R. Bard; Covington, GA, USA), and Fluency™ (C.R. Bard). Uncovered stents included Genesis™ (Cordis; Santa Clara, CA, USA), Omnilink™ (Abbott; Chicago, IL, USA), Visi-Pro™ (Medtronic; Minneapolis, MN, USA), Flexive™ (Boston Scientific; Marlborough, MA, USA), Complete® (Medtronic), EverFlex™ (Medtronic), Zilver Flex® (Cook Medical, Bloomington, IN, USA), and SMART® (Cordis). The type of bridging stent used was left to the discretion of the physician but, in general, the type of bridging stent used was based on anatomy of the target vessels and available stock. Bridging stents were typically oversized by approximately 1-2 mm to the target vessel. The antiplatelet regime was per the standard-of-care at each institution: Single anti-platelet therapy with aspirin at 2 of the centers; dual antiplatelet therapy for 8 weeks postprocedure, followed by aspirin alone thereafter at 1 center; and double platelet with clopidogrel and aspirin for 6 months followed by aspirin alone 1 center. Written consent was provided by all patients enrolled in the study. The study was conducted according to local regulations and the Declaration of Helsinki and was approved by an ethics committee at each study site. Cook Medical sponsored the study, which is registered at ClinicalTrials.gov (NCT02104089).

Previously reported outcomes included procedure-related mortality and morbidity through 30 days postprocedure, as well as mortality, morbidity, and other clinical outcomes through 12-month follow-up.[6] The objectives of the current study were to assess t-Branch graft and target vessel patency as well as procedure-related mortality, morbidity, and other clinical outcomes through 24-month follow-up. Vessel patency was defined according to the Society for Vascular Surgery (SVS) Reporting Standards.[7] In brief, primary patency was defined as uninterrupted patency in the absence of occlusion or without a procedure to maintain patency of the stent or native target vessel. Primary-assisted patency was defined as endovascular intervention in the presence of stenosis to maintain patency before occlusion. Secondary patency was defined as endovascular restoration of patency of a side branch, stent, or stent-graft after an occlusion had already occurred; therefore, loss of secondary patency would occur because of conversion to bypass or inability to treat an occlusion using endovascular techniques. Endoleaks, aneurysm size changes, and device migration were defined and reported according to the SVS reporting standards of 2002 (the most recent standards available at the time of study design).[8] Aneurysm growth was defined as an increase of >5 mm in diameter from the first postprocedure measurement. Aneurysm shrinkage was defined as a decrease >5 mm in diameter from the first postprocedure measurement. No change was defined as aneurysm diameter that remained within 5 mm of the postprocedure diameter.

Postprocedural follow-up, including imaging was performed per the standard of care at each institution; therefore, the number of patients with data at each follow-up is variable, and not all patients had visits within each prespecified window. Typically, the standard of care at each institution was yearly computed tomography angiography (CTA).

Data Analysis.

Study data were recorded electronically using standardized case report forms by trained site personnel. Data were centrally managed by Cook Research Incorporated (West Lafayette, IN). SAS version 9.3 or higher (SAS Institute, Cary, NC) was used to perform the statistical analyses. Data are presented as mean ± standard deviation for continuous variables and as percentages for categorical variables, unless otherwise indicated. Kaplan-Meier analysis was performed to estimate freedom from all-cause and aneurysm-related mortality, freedom from secondary intervention, freedom from type I/III endoleak, and freedom from loss of primary, primary-assisted, and secondary target vessel patency. Regarding the Kaplan-Meier estimated freedom from loss of patency analysis, only those vessels that were patent at preprocedure were included in the analysis.

RESULTS

A total of 80 patients (mean age: 71.0±7.4 years, 70% men) were enrolled in the study; 77 patients were treated for TAAA (Crawford Type I: n=5, Crawford Type II: n=30, Crawford Type III: n=14, Crawford Type IV: n=28) and 3 patients were treated for aortic dissection. Six patients had symptomatic TAAAs and 15 patients had contained ruptures.

During the study period, approximately 480 patients were treated using custom-made devices, 60 patients were treated using chimney endovascular aortic repair (ChEVAR), 8 patients were treated using parallel graphs, and 5 patients were treated using open surgical repair in the participating centers.

Technical success was achieved in 98.8% (79/80) of patients. Hypertension (83.8%, 67/80), coronary artery disease (35.0%, 28/80), chronic renal insufficiency (30.0%, 24/80), and chronic

obstructive pulmonary disease (22.5%, 18/80) were the most common comorbidities reported. Half of the patients were previous or current smokers. Delivery of the t-Branch graft was achieved percutaneously in 55.0% (44/80) of patients, via cutdown in 40.0% (32/80) of patients, and via conduit in 5.0% (4/80) patients. Full demographic and procedural outcomes were described previously.[6] Median follow-up time was 22.2 months (IQR: 9.2-25.1 months). There were a total of 298 vessels targeted: 68 CAs, 79 SMAs, 75 LRAs, and 76 RRAs. Therefore, 12 CAs, 1 SMA, 5 LRAs, and 4 RRAs were not targeted. The branches of all untargeted vessels were routinely plugged. The number and combination of covered and uncovered bridging stents placed in each target vessel are shown in Table I.

All-cause and Aneurysm-related Mortality.

There were no procedural deaths and a single death due to multiorgan failure within the first 30 days postprocedure. An additional 7 patients died within the first year postprocedure for various reasons, including hypoxia, myocardial infarction, sepsis, hemorrhagic shock, stroke, heart failure, and unknown causes, as described previously.[6] Kaplan-Meier estimates for freedom from all-cause and site-adjudicated aneurysm-related mortality are summarized in Figure 1A. Estimated freedom from all-cause mortality was 88.4% ± 3.9% at 12 months and 78.5% ± 5.4% at 24 months, and estimated freedom from aneurysm-related mortality was 98.6% ± 1.4% at both 12 and 24 months. Six deaths occurred after 12 months. These 6 deaths were attributed to congestive heart failure (2 patients), severe pulmonary problems after aortic rupture (1 patient), uncontrolled bleeding after coil embolization and partial conversion to open surgery for removal of thrombus from the aneurysm sac to treat a type III endoleak two days before death (1 patient), multiorgan failure (1 patient), and unknown cause (1 patient).

Adverse Events.

There were 38 adverse events in 20 patients after 12 months, as shown in Table II. One patient experienced myocardial infarction and was treated with a new medication and the placement of a coronary stent. Two patients experienced stroke; both were treated with medication. One patient experienced renal failure that required thrombectomy for left and right renal stenosis. One patient experienced multiorgan failure that required permanent dialysis and medication; this patient died on postprocedure day 611. One patient experienced aortic dissection that required surgical replacement of the aortic arch and ascending aorta.

No conversions to open surgical repair with explantation of the t-Branch graft were reported during follow-up. Aortic rupture was reported in 2 patients after 12 months. One patient with a nonjunctional type III endoleak of the RRA stent (BeGraft covered balloon-expandable stent, [BES]) experienced an aortic rupture on postprocedure day 467. A new stent was successfully placed in the RRA. The patient developed severe pulmonary problems after the procedure and required intubation and ventilation. The patient subsequently died on postprocedure day 472 due to pre-existing chronic obstructive pulmonary disorder (COPD). The second patient presented with occlusion of the RRA and LRA and an aortic rupture on postprocedure day 702. The site reported that the rupture was proximal to the t-Branch graft and thus unlikely to be related to the initially-treated aneurysm. The occlusion was treated with thrombectomy. The aortic rupture was treated using surgical bypass of the descending aorta to the Zenith TX2 Endovascular Graft (Cook Medical), which was placed proximal to the t-Branch graft. Both procedures were considered successful.

Branch vessel occlusions were reported in 10 patients over the 2-year study period, and further information on the associated adverse events is provided elsewhere in this article (see *Patency* section).

Secondary Interventions.

A total of 13 patients required 14 secondary interventions after 12 months, and Kaplan-Meier estimate for freedom from secondary intervention is shown in Figure 1B. Freedom from secondary intervention was 88.8% ± 3.5% at 12 months and 76.3% ± 4.8% at 24 months. Details on the reasons for secondary intervention, as well as the interventions performed for each patient, are provided in Table III. Most secondary interventions (64.3%, 9/14) were performed for treatments of stenosis, occlusion, or endoleak.

Endoleaks.

KM estimate freedom from type I or III endoleak was 84.1% ± 4.5% at 12 months and 74.2% ± 6.6% at 24 months, as shown in Figure 1C. After 12 months, there were 4 type Ia endoleaks: 2 involving the TX2 proximal component (Cook Medical), 1 involving the TX2 proximal extension (Cook Medical), and 1 involving the t-Branch graft. There were 2 type Ib endoleaks: 1 at 18 months involving a Zenith® Spiral-Z® AAA iliac leg graft (Cook Medical) and 1 at 24 months involving a Zenith TX2 distal graft. There were also 4 type III endoleaks reported after 12 months. Two type III endoleaks were due to graft joint overlap; one, located at the CA branch, involved an Advanta covered BES and SMART uncovered SES and the other, located at the RRA branch, involved a BeGraft covered BES. Two additional type III endoleaks were due to broken stents, both were BeGraft covered stents, 1 in the CA and the other in the RRA. There were also 13 type II endoleaks in 12 patients after 12 months. No type IV endoleaks were reported for this period.

Patency.

Graft patency of the t-Branch device was maintained in all patients throughout the study. Likewise, patency of the limb grafts was maintained in all patients throughout the study. One patient experienced stenosis in the left internal iliac artery on postprocedure day 19 which was successfully treated with additional stent placement. Issues with target vessel patency are described below, and target vessel statuses (i.e., stenosed or occluded) by device type through 24 months are summarized in Table IV.

Celiac Artery

Kaplan-Meier estimated freedom from loss of primary, primary-assisted, and secondary patency are shown in Figure 2. Freedom from loss of primary patency in the CA was 94.8% ± 3.0% at both 12 and 24 months. Freedom from loss of primary-assisted patency and secondary patency were 96.3% ± 2.6% at both 12 and 24 months. CA occlusion was reported in 2 patients on postprocedure days 166 and 354. In 1 patient, a Fluency covered self-expanding stent (SES) was used during the index procedure, and in the second patient, a Fluency covered SES and a Genesis uncovered BES were used during the index procedure. Secondary interventions were not performed in either patient (i.e., secondary patency was lost in both vessels). In another patient, celiac stenosis was reported on postprocedure day 9. This patient received a Fluency covered SES and a Genesis uncovered BES during the index procedure. Primary patency was lost, but the CA stenosis was successfully treated with additional stent placement, thus preserving primary-assisted patency.

Superior Mesenteric Artery

KM estimate for freedom from loss of primary, primary-assisted, and secondary patency in the SMA was 100% ± 0% at both 12 and 24 months, as shown in Figure 2. No occlusions or stenoses of the SMA were reported throughout the course of the study.

Left Renal Artery

KM estimate for freedom from loss of primary patency was 96.9% ± 2.3% at 12 months and 91.3% ± 4.0% at 24 months, as shown in Figure 3. Freedom from loss of primary-assisted patency was 98.6% ± 1.4% at 12 months and 93.1% ± 3.6% at 24 months. Freedom from loss of secondary patency was 100% ± 0% at 12 months and 98.2% ± 1.8% at 24 months. LRA occlusion was reported in 4 patients at postprocedure days 24, 380, 466, and 514. Secondary patency was lost in 1 patient that was initially treated with a BeGraft covered BES, as no secondary intervention was performed in this patient. Primary-assisted patency was lost in 3 patients with LRA occlusions, all of whom were successfully treated with thrombectomy. One of these patients was initially treated with a Fluency covered SES and an EverFlex uncovered SES; the second patient was treated with a Fluency covered SES, a Genesis uncovered BES, and an EverFlex uncovered SES; and the third patient was treated with an Advanta covered SES and an EverFlex uncovered SES. Furthermore, LRA stenosis was reported in 1 patient who was initially treated with an Advanta covered BES. This patient was treated with two secondary interventions on postprocedure day 325 and again on day 694. Primary patency was lost, but covered stent placement (type of stent was not reported) successfully treated the stenosed vessel, thereby restoring primary-assisted patency after each secondary intervention.

Right Renal Artery

KM estimate for freedom from loss of both primary and primary-assisted patency was 95.4% ± 2.7% at 12 months and 89.3% ± 4.7% at 24 months, respectively (as shown in Figure 3). Freedom from loss of secondary patency was 98.3% ± 1.7% at both 12 and 24 months. RRA occlusion was reported in 6 patients at postprocedure days 24, 211, 288, 384, 514, and 598. Secondary patency was lost in 1 patient who initially received an Advanta covered BES and a SMART uncovered SES, as no secondary intervention was performed on this patient. Primary-assisted patency was lost in the remaining 5 patients with RRA occlusions. Two of these patients were treated with Advanta covered BES and Complete uncovered SES; the third patient was treated with a Covera covered SES; and the remaining 2 patients were treated with 3 stents each: a Fluency covered SES, a Genesis uncovered BES, and an EverFlex uncovered SES. All 5 occlusions were successfully treated; 3 occlusions were treated using thrombectomy, 1 with the placement of an additional stent, and 1 with thrombectomy and stent placement.

Aneurysm Size.

Compared with postprocedure, aneurysm growth (>5 mm) was observed in 11.5% (6/52) of patients at last available follow-up after 12 months. Growth was associated with a type II endoleak in 2 patients, proximal type Ia endoleak in 1 patient, and endotension (type V endoleak) requiring thoracotomy with thrombectomy in 1 patient. Growth was not associated with endoleak or issues with device integrity in the remaining 2 patients. Aneurysm shrinkage (>5 mm) was observed in 84.6% (44/52) of patients at last available follow-up after 12 months.

Device Integrity and Migration.

Five instances of imaging-reported BSG compression were observed in 4 patients throughout the study. One patient experienced compression of a Fluency covered SES in the LRA at 12-month follow-up. Another patient experienced compression of an Advanta covered BES in the LRA at

both 12- and 24-month follow-up. One patient experienced compression of a Fluency covered SES and Visi-Pro uncovered SES in the celiac artery at 24-month follow-up. The fifth compression occurred in a patient who had compression of a Fluency covered SES in the celiac artery at 12-month follow-up. None of these stent compressions required secondary interventions. As described in the adverse events section, outside of the 5 explicit reports of device integrity issues, 1 patient had a type III endoleak requiring intervention caused by a ruptured covered BeGraft BES in the RRA, thereby implying a device integrity issue of the stent. There were no reports of device kinks, barb separations, or stent fractures. Additionally, no instances of device migration were reported.

DISCUSSION

Endovascular treatment of TAAA with branched or fenestrated endografts is a less invasive alternative to open repair with acceptable results.[9] The t-Branch graft became the first commercially available off-the-shelf endograft in the European Union for the treatment of TAAAs over a decade ago.[1] However, outcomes greater than 12 months and specific outcomes following the treatment of TAAAs with branched endografts are limited. The results of the current study at 24 months show KM estimates for freedom from all-cause and aneurysm-related mortality as 78.5% and 98.6%, respectively, which are comparable to the previously published data.[10-12] Although ruptured TAAAs were included in the analysis, the relative high 2-year mortality rate indicates the severity of the disease and presumably the long-term effects of the patients' cardiovascular comorbidities. An Italian study with 73 patients treated with multibranched endografts placed for endovascular aneurysm repair demonstrated survival rates of 88%, 86% and 82% at 12, 24, and 36 months, respectively, with no data regarding aneurysm-

related mortality.[10] A retrospective single-center study reported 92.9% freedom from aneurysm-related death at 36 months for 14 patients treated with the t-Branch graft.[11] The 18-month overall survival was 75% in a Swedish case series of 11 patients presenting with ruptured TAAA.[12] A recent publication[13] including 65 patients treated with the t-Branch graft reported a 47% survival rate at 24 months with no late aneurysm-related deaths. However, 27 patients (42%) in this study had ruptured TAAAs, which might explain the lower survival rate of 52% when compared with other studies.[13]

In our study cohort, there were no conversions to open repair, and no reports of t-Branch graft migration, integrity issues, or loss of patency. There were 5 reports of BSG compression during follow-up. Freedom from secondary intervention was 76.3% at 24 months, which is a lower than the previously published data.[10,11] Freedom from secondary intervention after 36 months was 92.9% in a single-center study with 14 cases.[11] In the Italian multicenter study, the freedom from reintervention was 86% and 83% at 12 and 24 months, respectively.[10] In a single center Italian study with 65 patients treated with the t-Branch graft, the freedom from reintervention for urgent cases at 24 months was 60%.[13]

Multibranched endografts require longer BSGs because of the distance of branches to target vessels, and this longer BSG length may influence the long-term target vessel patency. The BSGs that were used during the procedures were chosen by surgeon's preference, including balloon-expandable and self-expandable covered BSGs, though only the latter are specified in the IFU for t-Branch. Due to the different types of BSGs used, as well as the multiple combinations of manufacturers, covered and uncovered, self-expandable and balloon-expanding stent types within the same branch, it was not possible to draw conclusions about the

performance of any of the individual stents used. To optimize outcomes in the future, dedicated bridging stents intended for BEVAR are needed.

Multicenter studies with larger cohorts and longer follow-up are not available to compare the patency of the different self-expandable or balloon-expandable BSGs. Retrospective analysis of 62 patients with custom-manufactured devices or the off-the-shelf Zenith p-Branch Endovascular Graft (William Cook Australia, Brisbane, Australia) or t-Branch grafts showed excellent primary patency and similarly low rates of branch-related complications and endoleaks, with no branch-related aortic rupture or death.[14] A systematic review discussing branched endovascular aneurysm repair (BEVAR) showed that SES- and BES-related complications (i.e., occlusion, stenosis, endoleaks, migrations and fractures) following BEVAR are 4% and 3%, respectively.[15] The latest meta-analysis of comparative studies between SESs and BESs in BEVAR concluded that both techniques have similar primary patency rate and branch-related endoleaks during mid-term follow-up (17 months, range 12-35 months), but overall target vessel instability (OR, 0.99; 95% CI, 0.33-1.65; p=.003) and reintervention rates (OR, 1.04; 95% CI, 0.23-1.83; p=.009) seem to favor more positive outcomes with SESs.[16] In this meta-analysis, none of the BESs were among the dedicated BSGs currently seeking approval for the specific indication.[17,18]

In the current study, KM estimate for freedom from loss of primary-assisted patency in the CA, SMA, LRA, and RRA were 96.3%, 100%, 93.1%, and 89.3% at 24 months. The Swedish group reported estimated freedom from branch occlusion of 87.5% ±8.3% and 72.2% ±12.5% at 12 and 24 months, respectively, among 8 surviving patients.[12] However, all of the cases were urgent due to ruptured aneurysm and few patients were included in the study. Target visceral vessel patency at 24 months was 89% in a recent publication[13] of 65 patients who

underwent urgent endovascular repair with the t-Branch graft. In our study, the excellent secondary patency results could be related to the fact that most patients were stable (72.7%, 56/77) upon presentation, with only 7.8% (6/77) symptomatic and 19.5% (15/77) of patients with contained rupture.[6]

The limitations of the present study include the partially retrospective, nonrandomized design. Additionally, consecutive cases were not available to be included because of the inability to obtain consent from all patients treated with the t-Branch graft. These limitations may have contributed to a bias regarding the mortality and morbidity rates. No centralized core laboratory review of the preoperative and postoperative CT scans was performed. Also, some patients had only undergone non-contrast-enhanced CT during follow-up. Therefore, data on branch patency and endoleak were not available for all patients because follow-up was performed per standard of care. The lack of power in the sample sizes of each group and the variety of combinations used, made an adjusted analysis of specific bridging stentgraft outcomes or combinations impossible.

Our results provide information on the real-world, mid-term outcomes of target vessels in patients with TAAAs following repair with the off-the-shelf t-Branch graft. Freedom from loss of secondary patency was high, with low rates of endoleaks and secondary interventions involving BSGs compared with previously published results.

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Table I. Number of covered and uncovered stents used in each vessel

Number of covered stents	Number of uncovered stents	% Patients (n/N)			
		Celiac Artery	SMA	Left Renal Artery	Right Renal Artery
0	**0**	13.9% (11/79)	0% (0/79)	5.1% (4/79)	3.8% (3/79)
0	**1**	0% (0/79)	0% (0/79)	1.3% (1/79)	0% (0/79)
0	**2**	0% (0/79)	0% (0/79)	0% (0/79)	0% (0/79)
0	**3**	0% (0/79)	0% (0/79)	1.3% (1/79)	0% (0/79)
1	**0**	11.4% (9/79)	8.9% (7/79)	6.3% (5/79)	15.2% (12/79)
2	**0**	6.3% (5/79)	11.4% (9/79)	21.5% (17/79)	11.4% (9/79)
3	**0**	1.3% (1/79)	0% (0/79)	1.3% (1/79)	3.8% (3/79)
1	**1**	46.8% (37/79)	38.0% (30/79)	24.1% (19/79)	30.4% (24/79)
1	**2**	6.3% (5/79)	12.7% (10/79)	8.9% (7/79)	10.1% (8/79)
1	**3**	0% (0/79)	1.3% (1/79)	0% (0/79)	1.3% (1/79)
2	**1**	11.4% (9/79)	24.1% (19/79)	29.1% (23/79)	24.1% (19/79)
2	**2**	0% (0/79)	1.3% (1/79)	1.3% (1/79)	0% (0/79)
3	**1**	1.3% (1/79)	2.5% (2/79)	0% (0/79)	0% (0/79)
3	**2**	1.3% (1/79)	0% (0/79)	0% (0/79)	0% (0/79)

Table II. Adverse events (>365 days).

Outcome	Percent of Patients N=60 % (n)	Events (no.)
All-cause mortality	10% (6)	6
Rupture	3.3% (2)	2
Conversion to open surgery	0% (0)	0
Adverse Events		
Cardiovascular		
Arrhythmia requiring intervention	1.7% (1)	1
Congestive heart failure	3.3% (2)	3
Myocardial infarction	1.7% (1)	1
Cerebrovascular/Neurological		
Stroke	3.3% (2)	2
Paraparesis	0% (0)	0
Paraplegia	0% (0)	0
Pulmonary		
COPD	1.7% (1)	1
Hemothorax	1.7% (1)	1
Pneumonia	5.0% (3)	3
Renal/Urological		
Renal failure	1.7% (1)	1
Renal insufficiency	0% (0)	0
Vascular		
Aortic dissection	1.7% (1)	1
Occlusion of branch vessel(s)	10.0% (6)	6
Miscellaneous		
Multi-organ failure	1.7% (1)	1
Other	18.3% (11)	15

Table III. Secondary Interventions (>365 days)

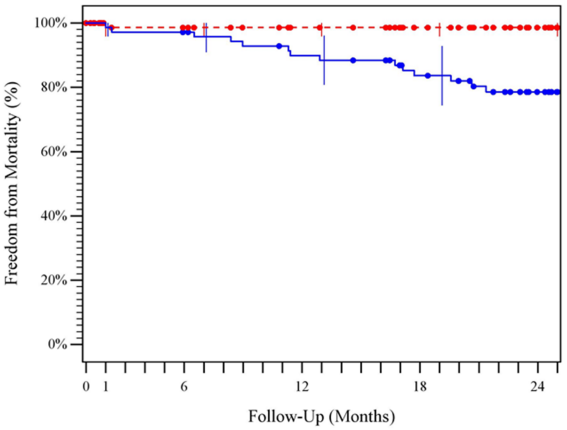
Patient Number	Days After Procedure	Reason	Intervention
1	385	Right renal artery stenosis	Stent placement
2	451	Type II endoleak	Coil embolization and balloon angioplasty
3	467	Right renal artery rupture, stenosis, and type III endoleak	Stent placement
4	482	Type III endoleak	Coil embolization and partial conversion; removal of thrombus from aneurysm sac
5	514	Left and right renal artery occlusion	Thrombectomy
6	554	Thrombus in aneurysm	Thoracotomy
	573	Aneurysm drainage	Aneurysm drainage and placement of thoracic and abdominal Gore stent-graft
7	588	Aneurysm growth	Stent placement in celiac, right renal, and left renal arteries
8	600	Right renal artery stenosis	Thrombectomy
9	615	Right popliteal aneurysm	Stent placement
10	643	Imminent type III endoleak	Stent placement in celiac, right renal, and left renal arteries
11	694	Celiac artery stenosis	Stent placement
12	702	Aortic rupture	Surgical bypass of descending aorta to Zenith TX2 graft
13	828	Type I endoleak	Stent placement

Table IV. Target Vessels Stents in Stenosed and Occluded Vessels through 2-Year Follow-Up.

	CA			SMA			LRA			RRA			TOTAL		
Stent Type	Devices (N)	Stenosed % (n)	Occluded % (n)	Devices (N)	Stenosed % (n)	Occluded % (n)	Devices (N)	Stenosed % (n)	Occluded % (n)	Devices (N)	Stenosis % (n)	Occlusion % (n)	Devices (N)	Stenosed % (n)	Occluded % (n)
Total Covered BES	**45**	**-**	**-**	**63**	**-**	**-**	**62**	**3.2% (2)**	**3.2% (2)**	**56**	**-**	**5.4% (3)**	**226**	**1.1% (2)**	**2.2% (5)**
Advanta/iCAST	36	-	-	61	-	-	48	4.2% (2)	2.1% (1)	45	-	6.7% (3)	190	1.1% (2)	2.1% (4)
BeGraft	9	-	-	1	-	-	11	-	9.1% (1)	9	-	-	30	-	3.3% (1)
E-ventus	0	-	-	1	-	-	3	-	-	2	-	-	6	-	-
Total Covered SES	**41**	**2.4% (1)**	**9.8% (4)**	**45**	**-**	**-**	**52**	**-**	**3.8% (2)**	**47**	**-**	**6.4% (3)**	**185**	**0.5% (1)**	**4.9% (9)**
Viabahn	12	-	-	10	-	-	40	-	-	32	-	-	94	-	-
Covera	1	-	-	0	-	-	1	-	-	4	-	25% (1)	6	-	16.7% (1)
Fluency	28	3.6% (1)	14.3% (4)	35	-	-	11	-	18.2% (2)	11	-	18.2% (2)	85	1.2% (1)	9.4% (8)
Total Uncovered BES	**22**	**4.5% (1)**	**18.2% (4)**	**22**	**-**	**-**	**20**	**-**	**5.0% (1)**	**24**	**-**	**8.3% (2)**	**88**	**1.1% (1)**	**8.0% (7)**
Genesis	19	5.3% (1)	5.3% (1)	20	-	-	16	-	6.2% (1)	18	-	11.1% (2)	73	1.4% (1)	5.5% (4)
Omnilink	2	-	100% (2[a])	1	-	-	0	-	-	0	-	-	3	-	66.7% (2)
Visi-Pro	1	-	100% (1)	1	-	-	4	-	-	4	-	-	10	-	10% (1)
Flexive	0	-	-	0	-	-	0	-	-	2	-	-	2	-	-
Total Uncovered SES	**33**	**-**	**-**	**58**	**-**	**-**	**41**	**-**	**7.3% (3)**	**44**	**-**	**11.4% (5)**	**176**	**-**	**4.5% (8)**
Complete	16	-	-	17	-	-	5	-	-	7	-	28.6% (2)	45	-	4.4% (2)
Everflex	7	-	-	25	-	-	31	-	9.7% (3)	31	-	6.5% (2)	94	-	5.3% (5)
Zilver Flex	0	-	-	0	-	-	2	-	-	0	-	-	2	-	-
SMART	10	-	-	16	-	-	3	-	-	6	-	16.7% (1)	35	-	2.9% (1)

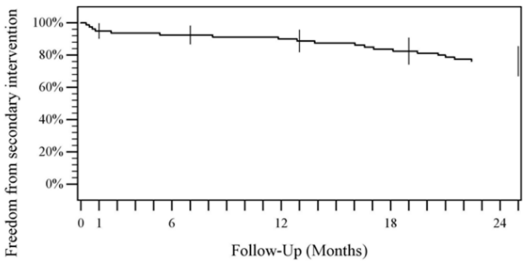
"-" denotes 0% (0). BES, balloon-expandable stent; CA, celiac artery; LRA, left renal artery; RRA, right renal artery; SES, self-expanding stent; SMA, superior mesenteric artery.
[a]A single patient had two Omnilink stents placed.

A



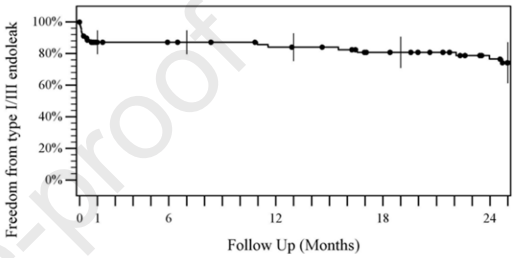
Mortality	Follow-Up (Months)				
	0	1	6	12	24
All-Cause					
No. at risk (cumulative events)	78 (0)	70 (1)	66 (3)	60 (8)	28 (14)
KM estimate (SE)	100% (0%)	98.6% (1.4%)	95.7% (2.4%)	88.4% (3.9%)	78.5% (5.4%)
Aneurysm-Related					
No. at risk (cumulative events)	78 (0)	70 (1)	66 (1)	60 (1)	28 (1)
KM estimate (SE)	100% (0%)	98.6% (1.4%)	98.6% (1.4%)	98.6% (1.4%)	98.6% (1.4%)

B

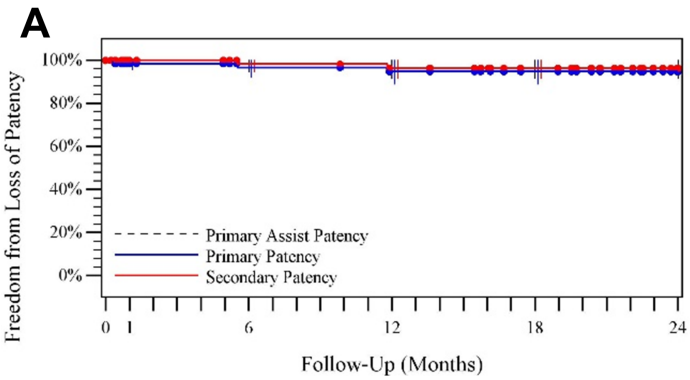


Secondary Intervention	Follow-Up (Months)				
	0	1	6	12	24
No. at risk (cumulative events)	80 (0)	76 (4)	74 (6)	71 (9)	61 (19)
KM estimate (SE)	100% (0%)	95.0% (2.4%)	92.5% (2.9%)	88.8% (3.5%)	76.3% (4.8%)

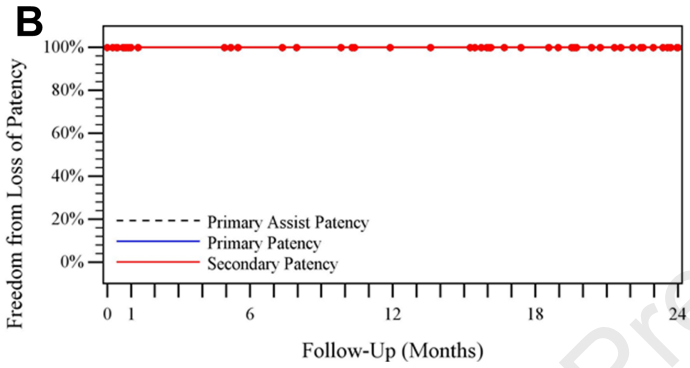
C



Type I/III Endoleak	Follow-Up (Months)				
	0	1	6	12	24
No. at risk (cumulative events)	79 (0)	61 (10)	58 (10)	53 (12)	25 (17)
KM estimate (SE)	100% (0%)	87.2% (3.8%)	87.2% (3.8%)	84.1% (4.5%)	74.2% (6.6%)

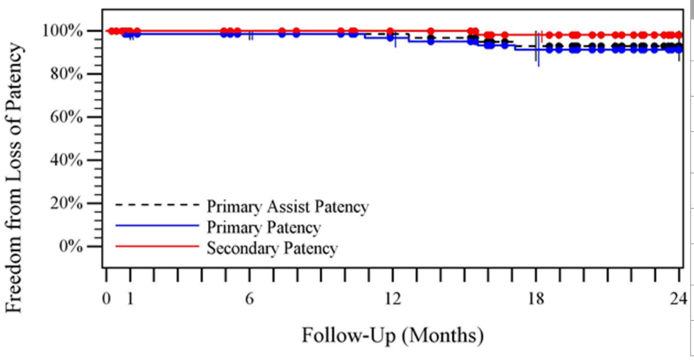


Celiac Artery	Follow-Up (Months) 0	1	6	12	24
Primary					
No. at risk (cumulative events)	67 (0)	58 (1)	53 (2)	50 (3)	28 (3)
KM estimate (SE)	100% (0%)	98.5% (1.5%)	96.7% (2.4%)	94.8% (3.0%)	94.8% (3.0%)
Primary-Assisted					
No. at risk (cumulative events)	67 (0)	59 (0)	54 (1)	51 (2)	28 (2)
KM estimate (SE)	100% (0%)	100% (0%)	98.2% (1.8%)	96.3% (2.6%)	96.3% (2.6%)
Secondary					
No. at risk (cumulative events)	67 (0)	59 (0)	54 (1)	51 (2)	28 (2)
KM estimate (SE)	100% (0%)	100% (0%)	98.2% (1.8%)	96.3% (2.6%)	96.3% (2.6%)



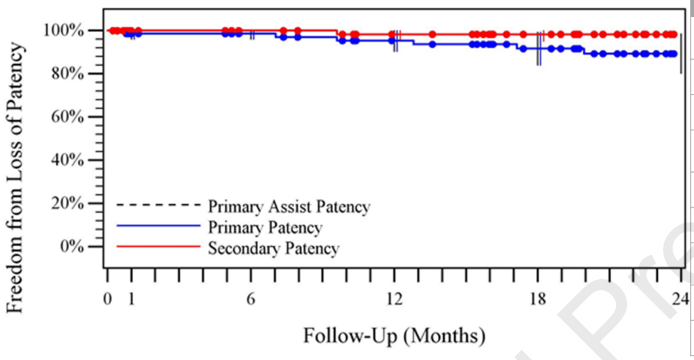
Superior Mesenteric Artery	Follow-Up (Months) 0	1	6	12	24
Primary					
No. at risk (cumulative events)	78 (0)	70 (0)	66 (0)	60 (0)	32 (0)
KM estimate (SE)	100% (0%)	100% (0%)	100% (0%)	100% (0%)	100% (0%)
Primary-Assisted					
No. at risk (cumulative events)	78 (0)	70 (0)	66 (0)	60 (0)	32 (0)
KM estimate (SE)	100% (0%)	100% (0%)	100% (0%)	100% (0%)	100% (0%)
Secondary					
No. at risk (cumulative events)	78 (0)	70 (0)	66 (0)	60 (0)	32 (0)
KM estimate (SE)	100% (0%)	100% (0%)	100% (0%)	100% (0%)	100% (0%)

A



Left Renal Artery	Follow-Up (Months) 0	1	6	12	24
Primary					
No. at risk (cumulative events)	75 (0)	67 (1)	63 (1)	56 (2)	28 (5)
KM estimate (SE)	100% (0%)	98.6% (1.4%)	98.6% (1.4%)	96.9% (2.3%)	91.3% (4.0%)
Primary-Assisted					
No. at risk (cumulative events)	75 (0)	67 (1)	63 (1)	57 (1)	28 (4)
KM estimate (SE)	100% (0%)	98.6% (1.4%)	98.6% (1.4%)	98.6% (1.4%)	93.1% (3.6%)
Secondary					
No. at risk (cumulative events)	75 (0)	68 (0)	64 (0)	58 (0)	31 (1)
KM estimate (SE)	100% (0%)	100% (0%)	100% (0%)	100% (0%)	98.2% (1.8%)

B



Right Renal Artery	Follow-Up (Months) 0	1	6	12	24
Primary					
No. at risk (cumulative events)	76 (0)	67 (1)	63 (1)	55 (3)	27 (6)
KM estimate (SE)	100% (0%)	98.6% (1.4%)	98.6% (1.4%)	95.4% (2.7%)	89.3% (4.7%)
Primary-Assisted					
No. at risk (cumulative events)	76 (0)	67 (1)	63 (1)	55 (3)	27 (6)
KM estimate (SE)	100% (0%)	98.6% (1.4%)	98.6% (1.4%)	95.4% (2.7%)	89.3% (4.7%)
Secondary					
No. at risk (cumulative events)	76 (0)	67 (0)	63 (0)	55 (1)	28 (1)
KM estimate (SE)	100% (0%)	100% (0%)	100% (0%)	98.3% (1.7%)	98.3% (1.7%)

Figure Legend:

Figure 1. Kaplan-Meier estimated freedom from all-cause and aneurysm-related mortality (A), secondary intervention (B), and type I/III endoleaks (C).

Figure 2. Kaplan-Meier estimated freedom from loss of primary, primary-assisted, and secondary patency in the celiac (A) or superior mesenteric (B) arteries.

Figure 3. Kaplan-Meier estimated freedom from loss of primary, primary-assisted, and secondary patency in the left renal (A), and right renal (B) arteries.