From the Society for Vascular Surgery

Standard "off-the-shelf" multibranched thoracoabdominal endograft in urgent and elective patients with single and staged procedures in a multicenter experience

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ABSTRACT

Objective: The objective of this study was to assess immediate and midterm outcomes for urgent/emergent and elective patients with thoracoabdominal aortic aneurysms (TAAAs) treated with the first commercially available "off-the-shelf" multibranched endograft for endovascular aneurysm repair, with a single-step or a staged surgical approach.

Methods: A multicenter, nonrandomized, retrospective study was conducted of TAAA patients grouped by urgent/emergent and elective treatment with multibranched endograft for endovascular aneurysm repair at 13 Italian centers from November 2012 to August 2016. Urgent/emergent repair was classified as rupture in 16%, impending rupture in 9%, pain in 53%, or a maximum TAAA diameter ≥80 mm in 22%. Study end points were technical success, mortality, spinal cord ischemia, target visceral vessel (TVV) patency, and procedure-related reinterventions at 30 days and at follow-up.

Results: Seventy-three patients (274 TVVs) were enrolled. Treatment was performed in elective (n = 41 [56%]) or urgent/emergent (n = 32 [44%]) settings, according to a single-step (n = 30 [41%]) or staged (n = 43 [59%]) approach. Technical success was 92%. Mortality within 30 days was 4% (n = 3 urgent/emergent patients) due to myocardial infarction. Spinal cord ischemia was recorded in two patients (3%; elective group). The primary patency of TVVs was 99% (three renal branch occlusions). Procedure-related reinterventions were required in five cases (7%). At least one adverse event from any cause ≤30 days was registered in 42% (n = 31). At a median follow-up of 18 months (range, 1-43 months), eight (11%) deaths (elective vs urgent/emergent, 2% vs 22%; $P = .018$), three (1%) cases of branch occlusion or stenosis, and five (7%) reinterventions were recorded. A survival of 88% (standard error [SE], 4%), 86% (SE, 4%), and 82% (SE, 5%) was evidenced at 12, 24, and 36 months, respectively. Urgent/emergent repair and female gender were identified as independent risk factors for all-cause mortality ($P < .001$ and $P = .015$, respectively), and the staged approach was identified as protective ($P = .026$). Freedom from reintervention was 86% (SE, 4%) and 83% (SE, 5%) at 12 and 24 months.

Conclusions: The first off-the-shelf multibranched endograft seems safe in both urgent/emergent and elective settings. The staged surgical approach appears to positively influence overall survival. This unique device and its operators will usher in a new treatment paradigm for TAAA repair. (J Vasc Surg 2018;67:1005-16.)

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*The members of the Italian mbEVAR study group can be found in the Appendix at the end of this article.

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Traditional open surgery for thoracoabdominal aortic aneurysm (TAAA) has a consistently high risk of overall perioperative mortality (8.3%-12.1%) and morbidity (cardiac, 14.7%-26%; pulmonary, 35.8%-49%; renal insufficiency, 12%-20.9%; and spinal cord ischemia [SCI], 4.2%-13.2%),[1-3] despite increasing experience of the operators and evolution of instruments in aortic surgery.[1,4] Endovascular therapies with custom-made stent grafts (CSGs) increase the selection of patients to include some patients unfit for surgery,[5,6] with reduced mortality and morbidity rates.[7] However, CSGs have long manufacturing times and are therefore inappropriate for symptomatic and ruptured TAAAs. Hybrid[8] and exclusively endovascular[9] procedures have been offered in urgent/emergent settings, but these techniques are burdened by high morbidity rates (around 35%)[9-11] and overall perioperative mortality (13%).[8]

Sweet et al[12] in 2009 demonstrated that a "standardized" endograft could be applied to 88% of aortic shapes. In 2012, the first "off-the-shelf" multibranched endograft for endovascular aneurysm repair (mbEVAR), the Zenith t-Branch (Cook Medical, Bloomington, Ind), was approved in Europe. The initial clinical experiences showed interesting early results in both elective and urgent settings, but larger cohorts and longer follow-up are needed to verify this device.[13-16]

The Italian mbEVAR study group performed a retrospective study to assess immediate and midterm outcomes for both urgent and elective TAAA patients treated with the first off-the-shelf mbEVAR, with a single-step or staged surgical approach.

METHODS

This multicenter, nonrandomized, retrospective study of TAAA patients treated with the Zenith t-Branch device at 13 Italian centers was approved by the local Ethics Committee (protocol No. 2384) and Institutional Review Board (protocol No. 1698). Written informed consent was collected.

Study population. Consecutive patients treated for TAAA with the Zenith t-Branch device between November 2012 and August 2016 at collaborating centers were included in the study. Three centers contributed 10 to 20 patients, three centers contributed 5 to 10 patients, and seven centers contributed 1 to 5 patients. Most patients were classified as unfit for open surgery (American Society of Anesthesiologists [ASA] grade >3) or refused open repair. The t-Branch device for elective patients was usually selected according to anatomic suitability (indications for use) and cost advantages compared with CSG alternatives. Patients' data were reported by each center in a dedicated database, and the primary authors grouped them according to elective or urgent/emergent approaches.

Device characteristics. Extensive device characteristics have previously been published.[13] Briefly, the Zenith t-Branch is a standard stent graft with four downward cylindrical cuffs: one for the celiac trunk (CT), one for the superior mesenteric artery (SMA), and two for the renal arteries. The cuffs are positioned for the CT, SMA, right renal artery (RRA), and left renal artery (LRA) according to clock positions (Fig 1). The t-Branch has a tapered configuration and a 22F delivery system. The device is commercially available in Europe and is currently undergoing Food and Drug Administration approval in the United States.

Preoperative preparation of the patient. Routine assessment (clinical, cardiac, and hematologic) examinations were performed. Assessment of the patient's eligibility and procedural planning were performed in all cases with contrast-enhanced computed tomography angiography (CTA) scans. Indications for use included iliac arteries >8 mm or use of a conduit, proximal aortic neck <38 mm with 20-mm landing zone, aorta at branches ≥25 mm, four or fewer target arteries, single-lumen origin of target arteries in cases of dissection,

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective multicenter cohort study
- **Take Home Message:** In 73 patients with thoracoabdominal aortic aneurysms treated in 13 Italian centers with "off-the-shelf" multibranched endografts, 30-day mortality was 4%, all after emergent or urgent repairs. The 3-year survival was 82%. Urgency of repair and female gender predicted all-cause mortality; staged repair was protective.
- **Recommendation:** The authors recommend staged repair of thoracoabdominal aortic aneurysms using off-the-shelf multibranched endografts.

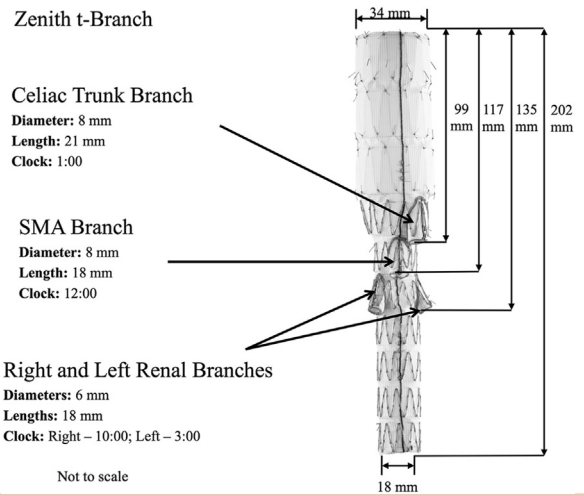

Fig 1. The first off-the-shelf multibranched commercially available endograft (Zenith t-Branch; Cook Medical, Bloomington, Ind). *SMA*, Superior mesenteric artery.

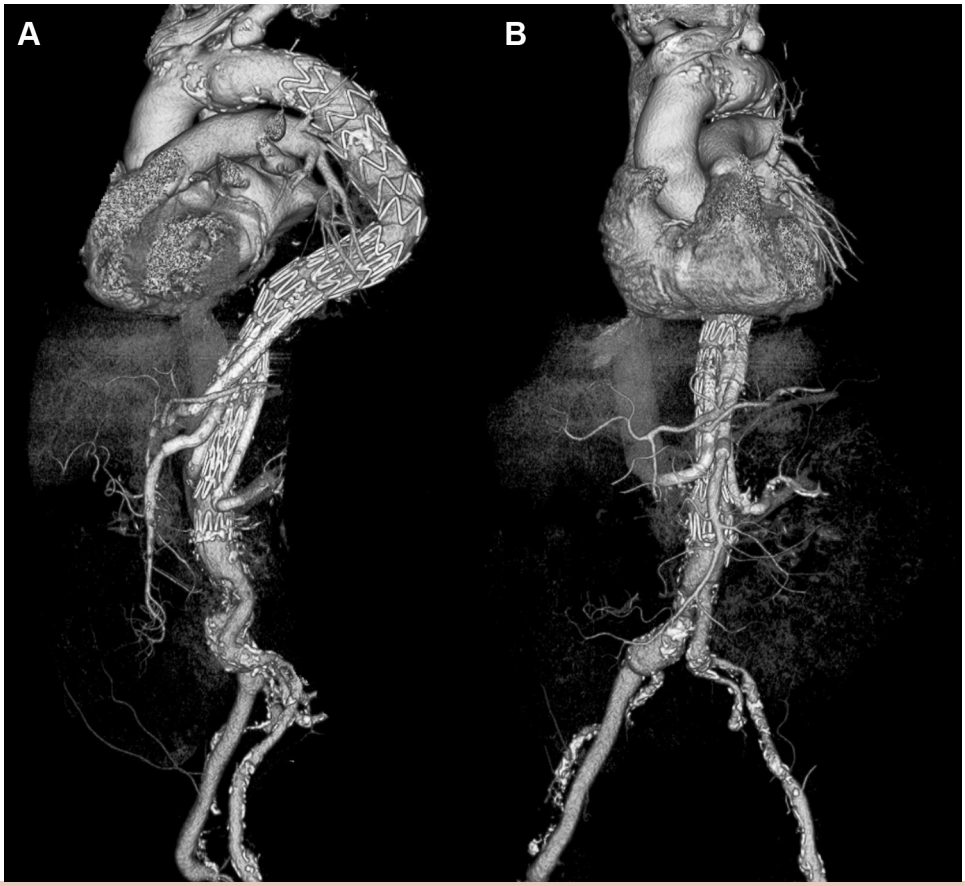

Fig 2. A and **B,** Postoperative computed tomography angiography (CTA), volume rendering of multibranched endovascular aneurysm repair (mbEVAR) of a type I thoracoabdominal aortic aneurysm (TAAA).

renovisceral arteries >4 mm with a <50-mm distance from cuff to orifice, absence of dissection in any downstream implantation sites, and no stenosis or occluded target arteries unless predilation of stenosis is possible.[13,14] Postprocessing of CTA images was performed using the dedicated software 3mensio Vascular (Pie Medical, Maastricht, Netherlands), Aquarius iNtuition (TeraRecon, Foster City, Calif), and OsiriX MD (Pixmeo SARL, Bernex, Switzerland). Eligibility for mbEVAR with t-Branch was mostly assessed by at least two vascular surgeons (or a vascular surgeon and interventional radiologist at two centers). In some minor centers, a manufacturer's specialist assisted in reviewing CTA images.

Implantation technique. All patients were treated in a hybrid or standard operating room under general anesthesia. The C-arms used in a standard operating room were OEC 9900 Elite (GE Healthcare, Chicago, Ill), Alien 3030 (Eurocolumbus s.r.l., Milan, Italy), and Ziehm Vision RFD (Ziehm Imaging GmbH, Nuremberg, Germany).

All procedures were performed by two experts, endovascular surgeons, with the exception of an endovascular surgeon and an interventional radiologist at two centers. Intravenous administration of heparin was performed (50 IU/kg or a loading dose of 5000 IU). Prophylactic cerebrospinal fluid drainage (CSFD) was used in patients with extensive aneurysm disease or large intercostal arteries observed at CTA. An angiographic evaluation of intercostal and lumbar arteries was performed before implantation. Large collateral arteries arising in the landing zone were not covered where possible, and CSFD and a staged approach were preferred. Prophylactic CSFD was not applied in the following cases: type IV aneurysm with short (<20 cm) supraceliac aortic coverage (n = 14); emergent treatment without CSFD services available (n = 6); and technical issues hindering success of CSFD treatment (n = 6). At three centers, CSFD was preferred for all patients. Femoral access included cutdown procedures and percutaneous techniques. Aortic endografts were introduced through inguinal access over an extrastiff guidewire (Lunderquist; Cook Medical) or through an iliac conduit in a stenotic or occluded iliac artery.

In case of extensive disease, a proximal thoracic segment was deployed for adequate proximal sealing and, if necessary, an abdominal endograft for adequate distal sealing (Fig 2). Implanted thoracic extensions included the TX2 (Cook Medical) and Alpha (Cook Medical); abdominal bifurcated devices included the Zenith t-Branch universal distal body graft (Cook Medical) and AFX (Endologix Inc, Irvine, Calif).

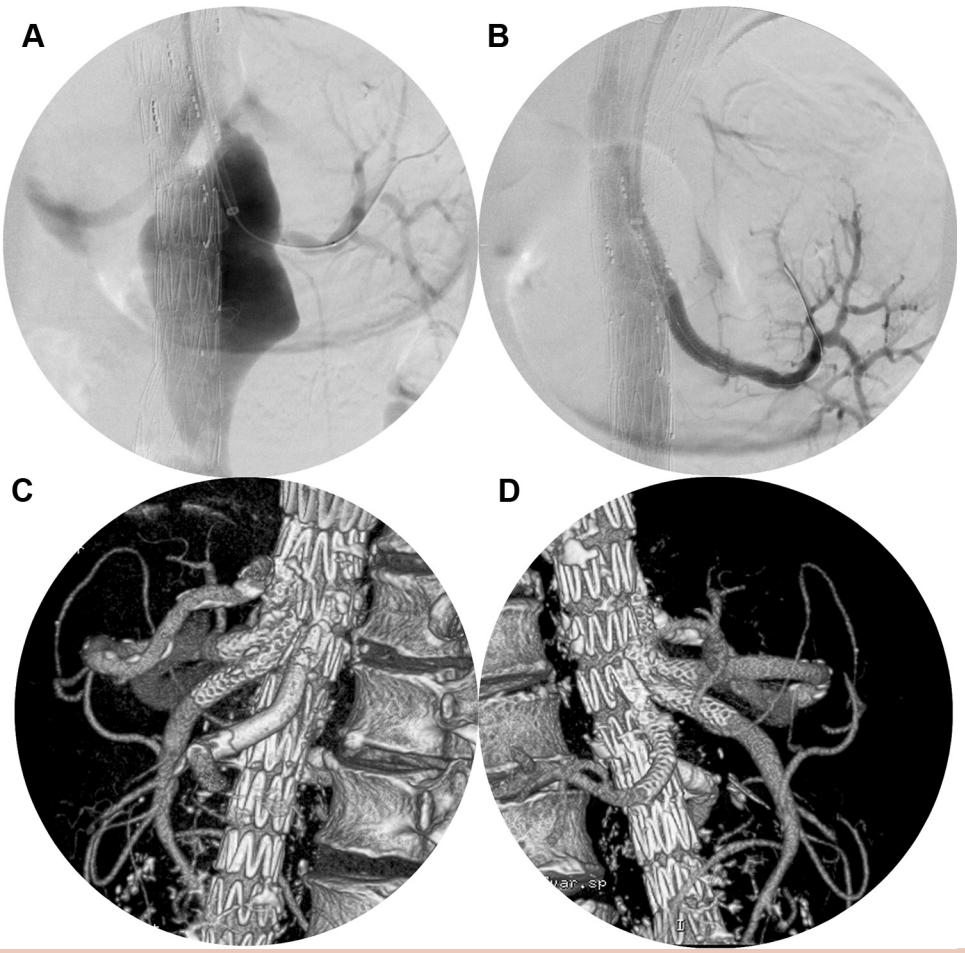

Fig 3. A, Cannulation of the left renal artery (LRA). **B,** Completion angiography after bridging of the LRA. **C** and **D,** Postoperative computed tomography angiography (CTA), volume rendering of the left side **(C)** and of the right side **(D)**.

A single-step or staged approach (elective interval between interventions of around 28 days) was employed according to the surgeons' preferences for elective patients. In urgent/emergent patients without impending rupture or with vital signs of instability (body temperature, pulse rate, respiratory rate, and blood pressure), a procedure was performed and interventions were completed within the first week of symptom onset. All other mbEVAR interventions were scheduled after preoperative preparation.

The staged approach techniques differed among collaborating centers. The aortic endografts (proximal extensions, t-Branch, and distal extensions, when needed) were implanted in the first step in most cases. Bridging, defined as the deployment of a covered stent between the aortic stent graft main body's branches and the native target visceral vessels (TVVs) or renal vessels, was performed either exclusively in the second step or for two or three of the TVVs (usually renal arteries and the SMA) in the first step and the remaining one or two TVVs in a second step (Fig 3). Planned preoperative branch occlusion was performed with a plug, such as an Amplatzer II (St. Jude Medical, St. Paul, Minn).

After surgical exposure of the left subclavian, axillary, or brachial artery, bridging for visceral or renal vessels was performed with balloon-expandable or self-expanding covered stents, according to the patients' anatomy and the surgeons' preferences. The covered stents used included Advanta V12 (Atrium Medical Corp, Hudson, NH), Viabahn (W. L. Gore & Associates, Flagstaff, Ariz), Fluency (Bard Peripheral Vascular, Inc, Tempe, Ariz), E-ventus (Jotec GmbH, Hechingen, Germany), and BeGraft (Bentley Innomed, Hechingen, Germany). Relining with bare-metal stent (BMS) was performed in case of short target vessel distal landing zone (<20 mm) or covered stent kinking, and the decision for deployment was based on angiographic results. BMSs used included Complete (Medtronic, Minneapolis, Minn), Protegé (Covidien, Mansfield, Mass), EasyFlype (Alvimedica Group, Saluggia [VC], Italy), and EverFlex (Covidien). CTA scans before the second step ensured correct graft positioning and branch patency.

Table I. Characteristics of the patients

Variable	All (N = 73)	Elective (n = 41 [56%])	Urgent/emergent (n = 32 [44%])	*P* value
Age, years, mean	72 ± 7	72 ± 8	71 ± 7	.617
Age ≥75 years	30 (41)	18 (44)	12 (38)	.637
Male gender	54 (74)	34 (84)	20 (63)	.062
Smoke	46 (63)	23 (56)	23 (72)	.223
Hypertension	68 (93)	38 (93)	30 (94)	1.000
Dyslipidemia	47 (64)	27 (66)	20 (63)	.809
CAD	35 (48)	21 (51)	14 (44)	.638
COPD	28 (38)	12 (29)	16 (50)	.092
DM	11 (15)	8 (20)	3 (9)	.328
CKD	20 (27)	9 (22)	11 (34)	.294
Cerebrovascular disease	6 (8)	4 (10)	2 (6)	.689
PVD	8 (11)	5 (12)	3 (9)	1.000
Previous aortic surgery	37 (51)	23 (56)	14 (44)	.350
ASA grade				
All				.477
2	11 (15)	8 (20)	3 (9)	
3	44 (60)	24 (59)	20 (63)	
4	18 (25)	9 (22)	9 (28)	
Aortic dissection	2 (3)	1 (2)	1 (3)	1.000
Crawford classification				
All				.251
I	5 (7)	1 (2)	4 (13)	
II	28 (38)	17 (41)	11 (34)	
III	24 (33)	12 (29)	12 (38)	
IV	16 (22)	11 (27)	5 (16)	
Proximal aortic diameter, mm	32 ± 3	33 ± 3	30 ± 3	<.001
Maximum aortic diameter, mm	67 ± 15	66 ± 10	69 ± 19	.422

ASA, American Society of Anesthesiologists; *CAD*, coronary artery disease; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *DM*, diabetes mellitus; *PVD*, peripheral vascular disease.
Continuous data are presented as means ± standard deviation. Categorical data are given as counts (%).

Follow-up protocol. This study protocol required CTA scans at 1 month and 12 months, with a chest radiograph at 6 months. CTA scans were then repeated annually and assessed by a radiologist and endovascular specialist.

Outcome measures and definitions. Urgent/emergent patients were considered those with rupture (extravasation of blood surrounding the aneurysm confirmed at CTA), radiologic signs of impending rupture (weakness or frailty of the aortic wall: high-attenuating crescent, focal discontinuity of intimal calcification, tangential calcium sign, and draped aorta),[17] thoracic pain (cardiac and other causes excluded), or a maximum diameter of ≥80 mm.

Technical success was defined as successful graft deployment and successful bridging of all target vessels, with aneurysm exclusion, without conversion to open surgery, evidence of TVV or iliac occlusion, or signs of type I or type III endoleak at intraoperative completion angiography. SCI was classified as either paraplegia (points 0-2) or paraparesis (points 3 or 4).[18] Primary patency was maintenance of TVV patency after bridging. Secondary patency was maintenance of TVV patency after reintervention for primary patency failure. Procedure-related reinterventions were defined as unprogrammed secondary interventions required for restoration of TVV patency or ongoing aneurysm sac exclusion.

Early events were defined as complications ≤30 days from surgery (mortality, SCI, acute kidney injury [AKI], respiratory [respiratory failure—gas exchange failure, pneumonia, acute pulmonary edema], cardiac [myocardial infarction, atrial fibrillation], neurologic, and hematologic). AKI was defined as a serum creatinine increase of ≥0.3 mg/dL (≥26.5 mmol/L) ≤48 hours, a serum creatinine increase ≥1.5 times baseline, or urine volume of 0.5 mL/kg/h ≥6 hours.[19] Temporary dialysis was recorded when renal replacement therapy was interrupted because of kidney function recovery. Permanent dialysis was determined as ongoing replacement therapy. Survival was considered the time between surgery and final follow-up or death from any cause.

Table II. Operative data

Parameters	All (N = 73)	Elective (n = 41 [66%])	Urgent/emergent (n = 32 [44%])	*P* value
Technical success	67 (92)	39 (95)	28 (88)	.394
Prophylactic CSFD	47 (64)	21 (51)	26 (81)	.013
Iliofemoral bypass	4 (6)	3 (7)	1 (3)	.626
Proximal thoracic endograft	41 (56)	23 (56)	18 (56)	1.000
Aortic coverage above CT, cm	193 ± 89	192 ± 87	197 ± 95	
Abdominal endograft	63 (86)	39 (95)	17 (55)	<.001
Tube	26 (41)	16 (39)	10 (31)	
Bifurcated	37 (59)	23 (56)	14 (44)	
Staged	43 (59)	22 (54)	21 (66)	.345
Two steps	35 (81)	18 (82)	17 (81)	
Three steps	8 (19)	4 (18)	4 (19)	
Operating time, minutes				
Single step	331 ± 126	378 ± 64	285 ± 153	.002
Staged, step 1	317 ± 222	163 ± 73	403 ± 221	<.001
Staged, step 2	237 ± 77	246 ± 81	232 ± 74	.444
Staged, step 3	144 ± 102	73 ± 29	238 ± 86	<.001
Fluoroscopy time, minutes				
Single step	96 ± 36	100 ± 40	87 ± 21	.078
Staged, step 1	24 ± 27	28 ± 31	17 ± 3	.029
Staged, step 2	60 ± 46	80 ± 49	43 ± 34	<.001
Staged, step 3	22 ± 7	21 ± 7	23 ± 6	.193
Contrast material volume, mL				
Single step	228 ± 105	232 ± 125	218 ± 45	.510
Staged, step 1	204 ± 125	202 ± 133	205 ± 116	.918
Staged, step 2	234 ± 155	326 ± 123	156 ± 136	<.001
Staged, step 3	78 ± 46	86 ± 38	69 ± 50	.116

CSFD, Cerebrospinal fluid drainage; *CT*, celiac trunk.
Continuous data are presented as means ± standard deviation. Categorical data are given as counts (%).

Statistical analysis. Continuous covariates are summarized as median and interquartile range, categorical covariates as absolute and percentage frequencies. Variables were compared using the Mann-Whitney test (continuous) and Fisher exact test or χ^2 test (categorical). Survival, endoleak, and reinterventions were assessed by Kaplan-Meier analysis, and comparison between groups was performed by log-rank test. All tests are two sided, and *P* value < .05 was considered significant.

RESULTS

Patient cohort. Between November 2012 and August 2016, a total of 73 patients were treated at 13 Italian centers with the Zenith t-Branch. In five cases, the device deviated from the manufacturer's indications for use.

The patients' baseline data are outlined in Table I. Most patients were diagnosed with atherosclerotic aneurysms (n = 71/73 [97%]). Two cases (3%) were chronic aortic dissection (one of which was ruptured).

Asymptomatic patients (n = 41 [56%]) received elective treatment (elective group), and symptomatic and asymptomatic patients (>80-mm aortic diameter; n = 32 [44%]) received urgent/emergent treatment (urgent/emergent group). Indications for urgent/emergent treatment were rupture (n = 5 [16%]), radiologic signs of impending rupture (n = 3 [9%]), thoracic pain (n = 17 [53%]), and maximum aortic diameter ≥80 mm (n = 7 [22%]). Most patients (n = 37 [51%]) had previous aortic surgery for various aortic diseases. A total of 85% (n = 62) were considered at high surgical risk (ASA grade ≥3). Lower risk patients (n = 11 [15%]; ASA grade 2) were urgent/emergent (n = 3), had previous traditional aortic surgery (n = 4), or refused open surgery (n = 4).

The groups did not differ significantly except for a significantly smaller proximal aortic diameter for urgent/emergent patients (*P* < .001; Table I).

In the 73 patients, 274 TVVs (CT, 66; SMA, 73; LRA, 64; RRA, 71) were selected for planned bridging treatment (elective, 156; urgent/emergent, 118). Planned preoperative branch occlusion was performed for 14 patients (18 TVVs: CT only, 3 patients; LRA only, 7 patients; CT + LRA, 2 patients; CT + RRA, 2 patients).

Table III. Outcomes data

Outcomes	All (N = 73)	Elective (n = 41 [56%])	Urgent/emergent (n = 32 [44%])	*P* value
Thirty-day outcomes				
Mortality	3 (4)	—	3 (9)	.080
Branch occlusion or stenosis	3/268 (1)	2/154 (1)	1/114 (1)	1.000
Endoleak				
Ib	1 (1)	—	1 (3)	.438
II	1 (1)	1 (2)	—	1.000
Reinterventions	5 (7)	3 (7)	2 (6)	1.000
Follow-up outcomes				
Mortality	86%	96%	69%	<.001
Branch occlusion or stenosis	3/254 (1)	0/152 (0)	3/102 (3)	.064
Endoleak				
II	97%	95%	100%	.273
III	97%	100%	88%	.105
Reinterventions	83%	87%	72%	.444

Branch occlusion is the No. of occluded branches/total branches in follow-up. Mortality, endoleak, and reinterventions were assessed by Kaplan-Meier analysis at 24 months, and the *P* value was the result of the log-rank test.
Categorical data are given as counts (%).

Operative data. Operative data are outlined in Table II. Overall, 59% (n = 43) of cases were performed in two (n = 35 [81%]) or three (n = 8 [19%]) stages; stage three postponed the bridging of one or more vessels because of technical issues during stage 2. Twenty-one urgent patients (66%) were classified as clinically stable (thoracic pain or maximum aortic diameter ≥80 mm), and a staged approach was preferred to reduce procedural burden. No TAAA ruptures or aneurysm- or graft-related complications occurred between stages, except for two CT occlusions. No cases of intraoperative or intrasurgical stage mortality were registered.

Successful bridging was performed in 98% of the TVVs (268/274). Asymptomatic CT occlusion was observed in two elective patients treated with a staged approach (before bridging). Intentional renal artery occlusion was performed in four branches (urgent/emergent group) because of intraoperative thrombosis or technical impossibility to cannulate.

To avoid kinks and to add stability, 33% (88/268) of TVV stent grafts were relined with a BMS. Routine BMS relining for TVVs was not performed by any participating center.

In 93% (n = 68), one or more additional procedures were required to obtain complete aneurysm exclusion: proximal thoracic endovascular repair (n = 41), distal tube (n = 26) and distal bifurcated (n = 37) abdominal extensions, surgical iliac conduit (n = 4), endovascular hypogastric branch (n = 2), common iliac artery stenting (n = 2), external iliac (n = 1) and CT (n = 1) percutaneous transluminal angioplasty, left carotid subclavian bypass (n = 1), and common femoral artery aneurysm surgical repair (n = 1). In one urgent/emergent patient presenting with four renal vessels arising from the aorta, a surgical iliorenal bypass was required; the contralateral nondominant renal artery was ignored.

Significant differences between the groups' operating and fluoroscopy times and contrast material volume were found (Table II). Of note, at the stages, different procedural tasks were carried out, which obviously influenced standardization of the results.

Thirty-day outcomes. Technical success was 92% (n = 67/73); in six patients, there were two asymptomatic CT occlusions between procedural stages and four renal vessel occlusions (mentioned previously). CT occlusion was treated with a plug and covered stent (both during the second step). Renal vessel occlusions were clinically associated with AKI in one patient (completely recovered), death in one patient (myocardial infarction), and no clinical sequelae in two patients (Tables III and IV).

Immediate mortality (≤30 days) was registered in three cases (4%) for myocardial infarction, all in the urgent group (9%; *P* = .08), on postoperative days 2 and 7 (both diagnosed with rupture at baseline) and 10 (diagnosed with pain at baseline). All other cases had at least 3 months of follow-up.

Two cases (3%) of SCI were reported directly after the procedure and ≤24 hours, respectively. Both, electively treated, were classified Crawford type IV, in the absence of remarkable hypotensive status and prolonged procedures. Neither patient received prophylactic CSFD. Patients were promptly treated with CSFD, hypertensive therapy, and blood transfusion. Improvements were noted from grade 2 to 3 (first patient) and from grade 4 to 5 (second patient).

Table IV. Adverse events within 30 days

Events ≤30 days	All (N = 73)	Elective (n = 41 [56%])	Urgent/emergent (n = 32 [44%])	*P* value
SCI	2 (3)	2 (5)	—	.501
AKI	15 (21)	6 (15)	9 (28)	.243
Dialysis, temporary	3 (4)	—	3 (9)	.080
Dialysis, permanent	2 (3)	—	2 (6)	.189
Respiratory	7 (10)	2 (5)	5 (16)	.228
Cardiac	6 (8)	2 (5)	4 (12)	.394
Myocardial infarction	4 (5)	1 (2)	3 (9)	
Atrial fibrillation	2 (3)	1 (2)	1 (3)	
Neurologic	2 (3)	—	2 (6)	.189
Hematologic	1 (1)	1 (1)	—	.999
Infectious	3 (4)	1 (2)	2 (6)	.584

AKI, Acute kidney injury; *SCI*, spinal cord ischemia.
Respiratory encompasses respiratory failure (gas exchange failure), pneumonia, and acute pulmonary edema. Neurologic encompasses hemorrhagic stroke. The hematologic event is disseminated intravascular coagulation. Infectious encompasses systemic infection and groin wound infections.
Categorical data are given as counts (%).

Of the 268 TVVs treated with bridging, 257 branches were evaluated during the follow-up (11 TVVs were lost to immediate death). TVV primary patency was 99% (254/257) at 30 days. Three (1%) cases of renal artery thrombosis were recorded; two had baseline renal functional deficit; one recovered baseline values ≤30 days and one had a single kidney and required dialysis despite recanalization ≤24 hours of functional deficit.

Overall, reintervention rate ≤30 days was 7% (n = 5). Table V outlines the indications, timing, and types of reinterventions performed. Reinterventions and causes in addition to those already mentioned included successful embolization of a type II endoleak (transealing technique)[20] and endovascular correction of a type IB endoleak.

The overall AKI rate was 21% (n = 15). Dialysis was required in three (4%) cases temporarily and two (3%) permanently (all in the urgent/emergent group). The two cases of permanent dialysis were associated with spontaneous cerebral bleeding and a single kidney with renal vessel occlusion, respectively.

At least one adverse event from any cause within 30 days was registered in 42% (n = 31; Table IV). Coronary artery and chronic obstructive pulmonary diseases were significantly associated with adverse events ≤30 days ($P = .017$ and .048, respectively).

Follow-up outcomes. Median follow-up was 18 months (range, 1-43 months). A total of eight (11%) deaths were reported >30 days. Causes were sepsis (n = 2), myocardial infarction (n = 2), respiratory failure (n = 1), multiorgan failure after spontaneous cerebral bleeding (n = 1) or after bilateral cerebral bleeding (n = 1), and hypovolemic shock (n = 1).

Analyses identified patients treated with urgent/emergent repair and female gender as more likely to die ($P < .001$ and $P = .015$, respectively). The staged approach was identified as the sole protective factor for overall mortality ($P = .026$). This trend was confirmed even among the urgent/emergent subgroup ($P = .009$).

A global survival of 88%, 86%, and 82% was evidenced at 12, 24, and 36 months, respectively (Fig 4). A statistically significant difference according to study groups ($P < .001$) was found (Fig 5). Elective patients' survival (n = 41 [56%]) was stratified according to the procedural approach (Fig 6), with no statistical difference ($P = .282$).

The rate of branch occlusion or stenosis >30 days was 1% (three TVVs); cases are detailed in Table III. TVV primary patency at the end of the study was 99% (n = 225/227). Cumulative TVV primary patency decrease is represented in Fig 7. The cumulative incidence hazard of decreasing TVV primary patency at 12 and 24 months was 3.5% (95% confidence interval, 0.9-14.1), and compared with death as a competing event, it was 3.1% (95% confidence interval, 0.6-9.5). No fractures of the bridging stent graft were reported.

A total of five late reinterventions were required in five (7%) patients; procedural details are outlined in Table III. In addition to the two patients with branch occlusion, three patients required reinterventions for aneurysm sac reperfusion: one distal to the false lumen, one type II endoleak, and one type III endoleak. Freedom from reintervention was 86% and 83% at 12 and 24 months, respectively (Fig 8), with no significant difference between groups (log-rank, $P = .444$).

DISCUSSION

To date, there have been few published studies dedicated to the Zenith t-Branch device in selected patients (most were treated electively)[14,15] or a small cohort (n = 17) of urgent/emergent repair.[16] This study is the largest series of elective and urgent/emergent patients

Table V. Unplanned reinterventions

Time	Indications	Procedure
Elective group		
POD 11	Occlusion of the left renal branch	Fibrinolysis, PTA
POD12	Type II endoleak from intercostal arteries	Transealing
POD 20	Occlusion of the right renal branch	Fibrinolysis and relining with covered stent (Viabahn[a])
POM 3	False lumen distal reperfusion of a chronic dissection	Distal extension with a bifurcated abdominal endograft
POM 8	Type II endoleak from thrombosed CT branch (between stages) not embolized	Endovascular embolization with plug
Urgent/emergent group		
POD 2	Occlusion of the left renal branch	Fibrinolysis and relining with covered stent (Advanta[b]) reinforced by BMS (Protegé[c])
POD 20	Type IB endoleak from distal aortic landing zone	Distal extension with a stent graft
POM 3	Occlusion of the right renal branch	Fibrinolysis, PTA
POM 7	CT and SMA stenosis	Relining with two covered stents (Advanta[b])
POM 19	Type III endoleak (cephalad) disconnection between covered stent and stent graft branch for CT	Relining with covered stent (Viabahn[a])

BMS, Bare-metal stent; *CT,* celiac trunk; *POD,* postoperative day; *POM,* postoperative month; *PTA,* percutaneous transluminal angioplasty; *SMA,* superior mesenteric artery.
[a]W. L. Gore & Associates, Flagstaff, Ariz.
[b]Atrium Medical Corp, Hudson, NH.
[c]Covidien, Mansfield, Mass.

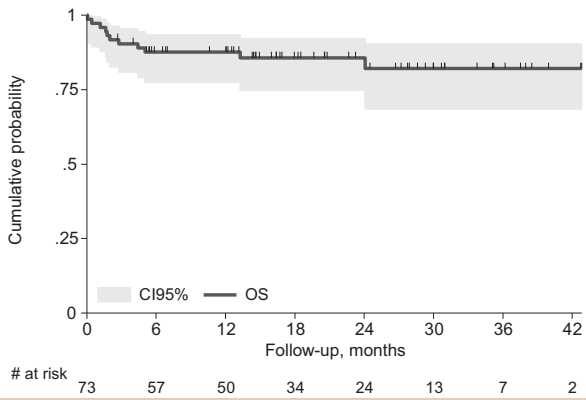

Fig 4. Overall survival (*OS*; N = 73). *CI,* Confidence interval.

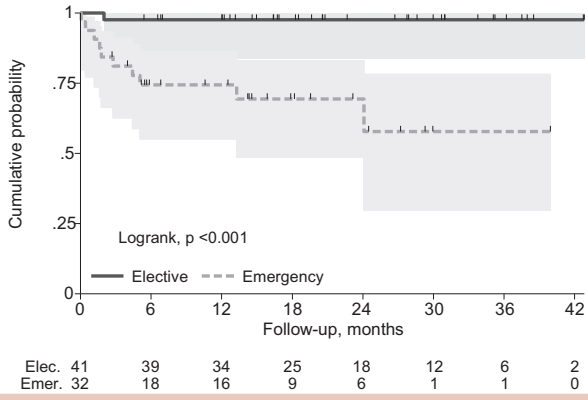

Fig 5. Global overall survival by elective (n = 41 [56%]) and urgent/emergent (n = 32 [44%]) groups.

(n = 32 [44%]) available. The groups were generally similar at baseline, and as is commonly recognized in the literature,[1] urgent/emergent repair was found to increase the risk of both death (by as much as 20 times) and adverse events.

Technical success in this study was encouraging. Overall mortality ≤30 days (4%) was in line with other published series dedicated to the t-Branch device (range, 0%-6%)[14-16] despite the majority of patients electively treated in these studies. The outcome was also lower than in other CSG cohorts (range, 7%-11.6%).[18,21-23]

At a mean follow-up of 18 months, eight (11%) additional deaths of patients were recorded. Independent factors associated with mortality were urgent/emergent repair and female gender. Most deaths were observed within 12 months from the procedure, highlighting the need for strict clinical follow-up, especially within the first 12 months.

O'Callaghan et al[24] demonstrated an improvement in survival associated with the staged approach. Our results confirmed a higher survival rate in patients treated with the staged approach ($P = .026$), but these results may be biased by the high number of symptomatic patients with rupture or impending rupture treated with the single-step approach. In considering only the elective group, no significant improvement in survival was found according to approach ($P = .282$).

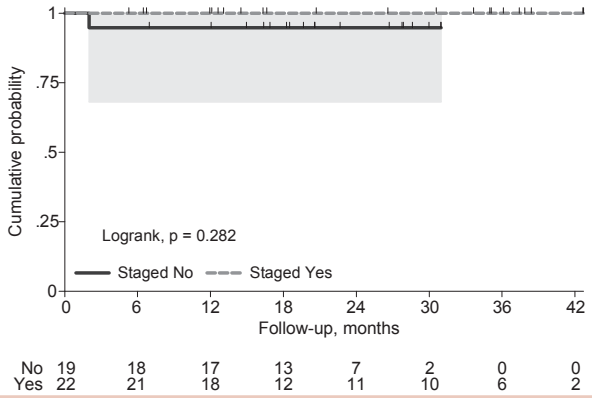

Fig 6. Elective patients' overall survival (n = 41) stratified by procedural approach: staged (n = 22 [54%]) and non-staged/single step (n = 19 [46%]).

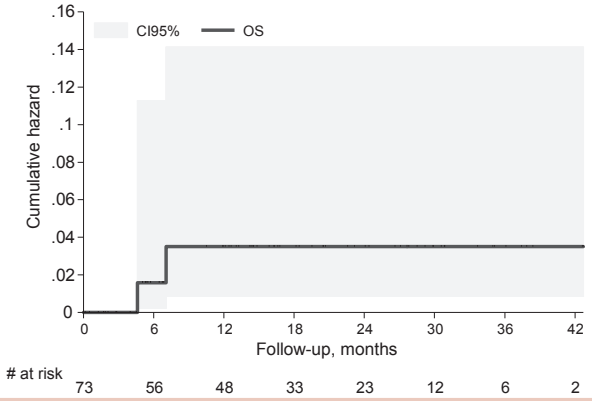

Fig 7. Cumulative incidence of decrease of target visceral vessel (TVV) patency. *CI,* Confidence interval; *OS,* overall survival.

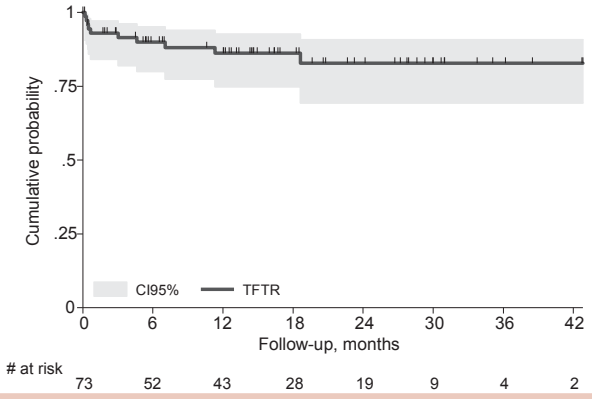

Fig 8. Global time of freedom to reintervention (*TFTR*; N = 73). TFTR was 86% and 83% at 12 months and 24 months. *CI,* Confidence interval.

The SCI rate (3%) reported in this series was lower than the rates reported in literature dedicated to TAAA surgery (range, 5%-13.2%)[1,2] and mbEVAR (range, 5%-17%).[14,16,25] In the two cases of SCI, both patients received minimum aortic coverage (Crawford type IV), and intraoperative prophylactic CSFD was not given. Extended aortic coverage has been identified as one of the most important risk factors for SCI.[26,27] The current series, together with dedicated research,[27] suggests that further investigation of additional risk factors is required. The authors, in accordance with others,[14,27] advise 24- to 48-hour postoperative intensive care for all patients. Interesting techniques designed to reduce SCI risk have been reported,[18,22] including the temporary perfusion sac concept (staged approach)[18] and early perfusion restoration to the pelvis and lower limbs.[22] Furthermore, Bisdas et al[27] demonstrated that prophylactic CSFD did not prevent all cases of SCI. There were no CSFD-related complications, and the low incidence of SCI events does not allow any conclusions in this study regarding single-step or staged procedures and the use of prophylactic CSFD as potential protective factors.

As noted previously,[16,28] the fixed length of the Zenith t-Branch device determines a higher coverage of the nondiseased aorta compared with the CSG and may determine a higher risk, especially in short extended disease. The authors agree with the suggested modifications designed to reduce proximal sealing and to increase the proximal diameter.[28] However, risks for neurologic damage in mbEVAR are still not well understood, and further studies are required.

TVV patency was high, with a low incidence of branch occlusion throughout the follow-up, in line with other t-Branch reported series (range, 2%-7%).[14-16] In contrast with the technique described by Bisdas et al[14] and Fernandez et al,[15] relining of the branches was not routinely performed; some authors[27,29] have found that it may be a risk factor for occlusion. The authors hypothesize a relationship between relining with BMS and TVV occlusion, and this justifies further investigations. Secondary patency was also high; no cases of restenosis or reocclusions were reported in this series. In the literature, most TVV occlusions are encountered within 12 to 24 months,[23,30,31] and therefore the low incidence in this series may be associated with the relatively short follow-up and the mortality rate in the urgent/emergent group. As reported in the literature,[32,33] most common TVV loss is experienced in the renal vessels, which may be due to acute renal angulation, greater motion during respiration, and higher end-organ perfusion resistance.[33] Renal artery bridging is considered the most technically challenging target vessel.[16,29,33] Furthermore, it is plausible that there is a higher burden on the renal vessels with a standard stent graft compared with the CSG, and the authors suggest that dedicated stent grafts for branched endografts are required.

Reinterventions, all successfully performed with endovascular procedures, during the 18-month follow-up were required in 13.7%. This compares favorably with the 36% rate in the study of Fernandez et al[15] at

23 months in elective patients. AKI was reported in 15 patients, five of whom (7%) required dialysis (urgent/emergent group). An incidence of 6% requiring dialysis after standard stent graft mbEVAR has previously been published.[15,16]

Some authors have emphasized current technical issues, such as malorientation, during device implantation.[16] This phenomenon is due to the forces developed during device navigation in a severely angulated aortoiliac axis or through previous aortic grafting.[16,29] Unfortunately, this study did not include aortic and target vessel morphologic appearances, but these should be considered in future research. This is a retrospective nonrandomized design, with a small sample size and relatively short follow-up. Furthermore, data were collected from multiple centers with heterogeneous technical experiences and approaches. Conclusions about the best approach therefore cannot be made. Device implantation was systematically performed by endovascular-experienced operators, but as with all early experiences, the learning curve must be taken into account.

CONCLUSIONS

The first commercially available off-the-shelf multibranched endograft seems safe in both urgent/emergent and elective settings. The staged surgical approach appears to influence overall survival positively. This unique device and its operators will usher in a new treatment paradigm for TAAA repair.

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Conception and design: RS, SG, NL, MG, GF, PC, FV, AI, NT, CR, MA, RC, EM, NM, FS, GV, SB, LM
Analysis and interpretation: RS, SG, NL, MG, GF, PC, FV, AI, NT, CR, MA, RC, EM, NM, FS, GV, SB, LM
Data collection: NL
Writing the article: RS, SG, NL
Critical revision of the article: RS, SG, NL, MG, GF, PC, FV, AI, NT, CR, MA, RC, EM, NM, FS, GV, SB, LM
Final approval of the article: RS, SG, NL, MG, GF, PC, FV, AI, NT, CR, MA, RC, EM, NM, FS, GV, SB, LM
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APPENDIX

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