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Review article

Emergent endovascular treatment options for thoracoabdominal aortic aneurysm

Alessandro Grandi[a], *Andrea Melloni*[b], *Mario D'Oria*[c], *Sandro Lepidi*[c], *Stefano Bonardelli*[b], *Tilo Kölbel*[a], *Luca Bertoglio*[b,*]

[a] *Department of Vascular Medicine, University Heart and Vascular Center Hamburg, University Medical Center Hamburg-Eppendorf, Hamburg, Germany*

[b] *Division of Vascular Surgery, Department of Clinical and Experimental Sciences, University of Brescia School of Medicine, ASST Spedali Civili of Brescia, Brescia, Italy*

[c] *Division of Vascular and Endovascular Surgery, Cardiovascular Department, University Hospital of Trieste Azienda sanitaria universitaria Giuliano Isontina, Trieste, Italy*

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ABSTRACT

For a long time, parallel grafting, physician-modified endografts, and, more recently, in situ fenestration were the only go-to endovascular options for ruptured thoracoabdominal aortic aneurysm, offered mixed results, and depended mainly on the operator's and center's experience. As custom-made devices have become an established endovascular treatment option for elective thoracoabdominal aortic aneurysm, they are not a viable option in the emergency setting, as endograft production can take up to 4 months. The development of off-the-shelf (OTS) multibranched devices with a standardized configuration has allowed the treatment of ruptured thoracoabdominal aortic aneurysm with emergent branched endovascular procedures. The Zenith t-Branch device (Cook Medical) was the first readily available graft outside the United States to receive the CE mark (in 2012) and is currently the most studied device for those indications. A new device, the E-nside thoracoabdominal branch endoprosthesis OTS multibranched endograft (Artivion), has been made commercially available, and the GORE EXCLUDER thoracoabdominal branch endoprosthesis OTS multibranched endograft (W. L. Gore and Associates) is expected to be released in 2023. Due to the lack of guidelines on ruptured thoracoabdominal aortic aneurysm, this review summarizes the available treatment options (ie, parallel grafts, physician-modified endografts, in situ fenestrations, and OTS multibranched devices), compares the indications and contraindications, and points out the evidence gaps that should be filled in the next decade.

1. Introduction

Ruptured thoracoabdominal aortic aneurysm (rTAAA) is a catastrophic event burdened by a > 20% mortality rate in patients arriving alive at the hospital [1,2]. In the last several years, a paradigm shift towards an "endovascular first" approach for rTAAAs has been taking place in high-volume centers [3–6]. If custom-made devices (CMDs) have become an established endovascular treatment option for elective TAAA, their use in the emergency setting is still limited by manufacturing times of up to 4 months [7,8]. To date, no proper guidelines have focused on the best treatment options

* Corresponding author
E-mail address: luca.bertoglio@unibs.it (L. Bertoglio).

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for rTAAA. For a long time, parallel grafting (PG), physician-modified endografts (PMEGs), and, more recently, in situ fenestration (ISF) were the only go-to endovascular options for rTAAA. Development of off-the-shelf (OTS) multibranched devices with a standardized configuration has allowed the treatment of rTAAA with emergent branched endovascular procedures [4,5,9]. The Zenith t-Branch device (Cook Medical) was the first readily available graft outside the United States to receive the CE mark (in 2012) and is currently the most studied device for those indications [1,4,5,10–14]. A new OTS device, the E-nside thoracoabdominal branch endoprosthesis OTS multibranched endograft (Artivion) has been made commercially available [15], and the GORE EXCLUDER thoracoabdominal branch endoprosthesis (TAMBE) OTS multibranched endograft (W. L. Gore and Associates) [16,17] is expected to be released in 2023. As more devices and surgical strategies are being made commercially available for rTAAA treatment, clear guidelines should be published to help physicians in their clinical practice choices. We analyzed the available treatment options for rTAAA, with a particular focus on the OTS devices, including both commercially available and investigational endografts, compared their anatomic limitations, and then illustrated the clinical data available to date.

2. Parallel grafting

The snorkel/chimney technique (PG) was first described by Greenberg et al [18] in 2003. It consists of placing parallel stent-grafts into target renal or visceral arteries to maintain vital organ perfusion and successful aneurysm sac exclusion. Most data on this technique were gathered via the PERICLES Registry [19], which recently published updated results for 517 patients [20]. All-cause mortality at the latest follow-up was 25.5% (n = 132), with estimated patient survival rates of 87.6%, 74.4%, and 66.1% at 1, 3, and 5 years, respectively. A subgroup of 244 patients with 387 chimney grafts placed (335 renal arteries [RAs], 42 superior mesenteric arteries [SMAs], 10 celiac trunks [CTs]) and follow-up for more than 30 months was used to analyze specific anatomic and device predictors of adverse events. In this subgroup, the technical success was 88.9% and the primary patency rates were 94%, 92.8%, 92%, and 90.5% at 2.5, 3, 4, and 5 years, respectively. Chimney endograft occlusion had occurred in 24 target vessels (6.2%). Late open conversion was required in 5 patients (2%). The absence of an infrarenal neck was significantly associated with long-term device-related complications (odds ratio = 2.86; 95% CI, 1.32–6.19; $P = .007$). A sealing zone diameter > 30 mm was significantly associated with persistent or late Type Ia endoleak (odds ratio = 4.86; 95% CI, 1.42–16.59; $P = .012$). The PG strategy is plagued by many inherent device-related complications, such as "gutter" leaks, proximal seal failure, and early branch occlusions. A recent multicenter study found higher rates of early failure, morbidity, and mortality with PG compared with other complex endovascular methods [21]. Moreover, most published data on PG report results for infrarenal pathology and its use in proper thoracoabdominal aneurysms is far from being universally accepted and practiced. Analysis of 813 patients undergoing TAAA repair with PMEG (n = 387) and PG (n = 426) strategies from the Vascular Quality Initiative demonstrated reduced Type Ia endoleak incidence, improved survival, and increased freedom from aortic-related mortality at 1 year with PMEG [22]. This supports the idea that the more vessels are treated with PG, the greater the risk for gutter and endoleaks, therefore, treatment of TAAA that involves all visceral vessels at once would be better treated with other strategies. The sandwich technique [23] has been proposed to try and solve this problem, but most of the same drawbacks as other PG techniques still apply. The specific advantage of this approach is its feasibility, as it is based entirely on devices readily available in stock: a standard range of self- and balloon-expandable bridging stents and a choice of thoracic endografts could fit most of the anatomies, although at least one viable upper extremity access is necessary for renovisceral stent delivery. Clinical studies available for PG have been summarized in Table 1 [24–30].

3. Physician-modified endograft

The term *physician-modified endograft* was coined by Dr. Benjamin Starnes to describe back-table modification of commercially available aortic stent-grafts by the creation of reinforced directional branches or fenestrations that replicate the same principles applied for sizing and implantation of CMDs [31]. PMEGs were introduced as an alternative for higher-risk patients, but due to limited access to CMDs, have been widely used in intermediate-risk patients as well. This treatment option has also been adopted in patients who require emergent repair for exceedingly large, symptomatic, or ruptured aneurysms that could not be treated with OTS devices [32,33]. Despite widespread use, given the unregulated and "homemade" nature of PMEGs, outcomes regarding efficacy and durability remain limited. A recent systematic review and meta-analysis of PMEG for TAAA by Gouveia e Melo et al [34], which included 27 studies and 909 patients, reported an emergent setting in 36% of the cases, a major adverse event rate of 15.5% (24.6% in emergent cases), and a technical success rate of 97.2%. A recent study from Chait et al [35] reported acceptable long-term graft outcomes and vessel patency, at a mean ± SD follow-up of 49 ± 38 months in 156 patients (24%) treated with PMEG (121 were male patients; mean ± SD age, 75 ± 8 years) for a total of 452 renal-mesenteric targets (mean ± SD, 3.1 ± 1.0 vessels/patient) incorporated. Technical success was higher in patients treated for complex AAAs (99% *v* 91%; $P = .04$). Thirty-day and/or in-hospital mortality rate was 5.7% and was significantly lower for complex AAAs compared with TAAAs (2% *v* 10%; $P = .04$), with 3 of 9 early mortalities (33%) among patients treated emergently. Mean ± SD primary and secondary target vessel patency rates were 91% ± 2% and 99% ± 1%, respectively, although the 5-year patency rate was 41%. Patients treated for complex AAAs had higher 5-year freedom from aortic-related mortality ($P = .016$), and target artery instability ($P = .05$), endoleak ($P = .01$), and secondary interventions ($P = .05$) with a higher, but nonsignificant freedom from sac enlargement ≥ 5 mm ($P = .11$).

The major advantage of PMEGs is the ability to perform a fast and patient-specific repair, avoiding the need to wait for the graft to be manufactured; however, several limitations should be taken into consideration. There is a total absence of centralized oversight and quality control, a benefit associated with OTS and CMDs, which leaves all responsibility in the

Table 1 – Literature review of clinical studies available for parallel grafting.

Study, first author	Year	n	Age (y) mean ± SD	Aortic diameter (mm) mean ± SD	Urgent/ emergent n(%)	Technical success n(%)	30-d mortality n(%)	AKI n(%)	SCI n(%)	Any complication n(%)	LOS (d)	Branch patency (%)	Survival (%)
Cherfan [24]	2022	58 (47 men) TAAA: 12	76.8 ± 7.8	71 ± 2	21 (36.2)	58 (100)	4 (6.8)	18 (30.9)	—	47 (81)	—	1 y: 82.8 5 y: 73.6	1 y: 61.3 5 y: 27
Alfawaz [25]	2021	79 TAAA: 60	74	71	30 (38)	79 (100)	6 (8)	1 (1)	2 (3)	9 (12)	—	1 y: splanchnic: 100 Renal: 95	1 y: 85
Rinaldi [26]	2020	20 (16 men) TAAA: 8	68 (47–89)	—	20 (100)	20 (100)	1 (5)	0 (0)	0 (0)	—	7.4	100	22 mo: 90
Bannazadeh [27]	2020	38 (23 men) TAAA: 38	76.5	63	0 (0)	—	1 (2.6)	0 (0)	1 (2.6)	1 (2.6)	—	97.3	2 y: 73
Bin Jabr [28]	2016	51 (35 men) TAAA: 5	77 (72–81)	—	51 (100)	42 (82)	5 (10)	0 (0)	0 (0)	4 (8)	9 (5–15)	1 mo: 95	7.5 y: 43
Pecoraro [29]	2011	9 (9 men) TAAA: 6	72 ± 14	94.8 ± 39.9	9 (100)	8 (89)	1 (11)	—	—	1 (11)	—	100	10 mo: 56
Kolvenbach [30]	2010	5 TAAA: 5	—	65 (59–80)	5 (100)	5 (100)	0 (0)	—	1 (20)	1 (20)	—	6 mo: 94	6 mo: 100

Abbreviations: AKI, acute kidney injury; LOS, length of stay; SCI, spinal cord ischemia; TAAA, thoracoabdominal aortic aneurysm.

Table 2 – Literature review of clinical studies available for physician-modified endografts.

Study, first author	Year	n	Age (y) mean ± SD	Aortic diameter (mm) mean ± SD	Urgent/ emergent n(%)	Technical success n(%)	30-d mortality n(%)	AKI n(%)	SCI n(%)	Any complication n(%)	LOS (d)	Branch patency (%)	Survival (%)
Chait [35]	2023	156 (121 men) TAAA: 67	75 ± 8	70 ± 13	28 (18)	149 (96)	9 (6)	26 (17)	5 (3)	40 (26)	7.4 ± 9.2	91 ± 2	5 y: 41 ± 4
Torrealba [39]	2022	2 (2 men) TAAA: 2	73.5	64	2 (100)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	6.5	100	—
Manunga [40]	2021	4 (4 men) TAAA: 2	76	73	3 (75)	4 (100)	0 (0)	0 (0)	0 (0)	0 (0)	—	100	25 mo: 100
Yang [41]	2020	16 (12 men)	75.3	71 ± 15	—	55 (98.2)	1 (6.3)	—	—	—	—	98.1	100
Han [42]	2020	20 (10 men) TAAA: 16	73 (68–78)	70 (63–88)	10 (50)	20 (100)	0 (0)	6 (30)	1 (5)	12 (60)	7 (5–11)	100	5 mo: 100
Sénémaud [43]	2019	28 (24 men) TAAA: 17	73 ± 11	74 ± 19	13 (46)	22 (79)	4 (14)	0 (0)	2 (7)	7 (25)	—	100	—
Singh [44]	2018	8 (7 men) TAAA: 4	65	49	8 (100)	8 (100)	0 (0)	0 (0)	0 (0)	0 (0)	10	100	44 wk: 100
Dossabhoy [45]	2018	41 (27 men) TAAA: 18	75	65	9 (22)	—	—	—	—	25 (61)	3 (1–6)	93	1 y: 83
Tsilimparis [46]	2017	21 (16 men) TAAA: 11	70	74 ± 23	21 (100)	21 (100)	1 (5)	2 (10)	2 (10)	7 (35)	19	100	11 mo: 81

Abbreviations: AKI, acute kidney injury; LOS, length of stay; SCI, spinal cord ischemia; TAAA, thoracoabdominal aortic aneurysm.

Table 3 – Literature review of clinical studies available for in situ fenestration.

Study, first author	Year	n	Age (y) mean ± SD	Aortic diameter (mm) mean ± SD	Urgent/ emergent n(%)	Technical success n(%)	30-d mortality n(%)	AKI n(%)	SCI n(%)	Any complication n(%)	LOS (d)	Branch patency (%)	Survival (%)
Le Houérou [51]	2023	44 (32 men) TAAA: 5	75.1 ± 10	—	17 (39)	43 (97)	2 (4.5)	6 (13.6)	0 (0)	14 (32)	7 (6–14)	86	3 y: 60.6
Dean [50]	2023	15 (11 men) TAAA: 7	76	52 (44–69)	15 (100)	26/27 (96.2)	1 (6.7)	1 (5)	3 (20)	12 (80)	6.5	100	168 d: 86
Pyun [2]	2022	18 (13 men) TAAA: 14	73 ± 13	85 ± 29	18 (100)	—	2 (11)	10 (56)	4 (22)	12 (67)	14.4	83	—
Leger [52]	2019	20 (15 men) TAAA: 5	69 (68–78)	57 (54–68)	4 (20)	18 (90)	2 (10)	0 (0)	0 (0)	8 (40)	9 (8–17)	—	—

AKI, acute kidney injury; SCI, spinal cord ischemia; LOS, length of stay; TAAA, thoracoabdominal aortic aneurysm.

hands of the operator. Potentially catastrophic complications can derive from poor decision making regarding patient selection, sizing, design, and implantation [36,37]. Device modification, depending on design complexity and experience of the operator, can take up to 2 hours, which precludes the use of PMEGs for patients *in extremis*. Unlike CMDs, which can be customized to nearly any diameter and length, and tapered to fit a patient's aorta, PMEGs are limited to the dimensions of commercially available endografts, which were not originally developed and tested for this application. Furthermore, a more pressing issue may relate to the importance of the learning curve and the adequate training needed to properly perform a PMEG. The quality of the modification depends largely on the preoperative planning, which is directly related to the experience accumulated with manufactured devices. A fenestration created in the wrong location or a device deployed improperly leads to an exceedingly difficult operation with a long operating time and poor outcome. Therefore, it is imperative that physicians learn these techniques in well-organized, advanced endovascular aortic programs that integrate clinical practice, research, and education [38]. Clinical studies available for PMEG have been summarized in Table 2 [35,39–46].

4. In situ fenestration

ISF is an endovascular technique first described by McWilliams in 2004 for left subclavian artery revascularization [47]. The authors used a needle to puncture the fabric and serial-cutting balloons to enlarge the opening. Subsequently, a covered stent was placed through the created fenestration into the left subclavian artery. In situ laser fenestration (ISLF) offers expedited repair of symptomatic and ruptured aortic aneurysms involving branch vessels, being able to stop the bleeding due to the instantaneous aneurysm exclusion once the endograft is delivered, as opposed to OTS devices, which need target vessels bridging before aneurysm sac exclusion is achieved. However, there are several concerns regarding this technique, including transient renovisceral ischemia time, technically demanding precision needed to align the laser catheter and target vessels ostia, and increased risk of Type IIIa endoleak, given the nonreinforced nature of the fenestration–bridging stent interface, which diverts from the construct of both PMEGs and manufactured devices [48].

A recent systematic review by Prendes et al [49] on ISLF reported a total of 19 clinical studies, including 428 patients (390 cases of supra-aortic trunk ISLF, but only 38 cases of visceral vessel ISLF) with a technical success rate of 95.6% for the visceral vessel ISLF. Most studies had reported $<$ 12 months of follow-up. The most extended available follow-up was in one study at 5 years for left subclavian artery ISLF and 17 months for visceral vessel ISLF. Overall, the quality of the evaluated clinical studies was low. Six experimental studies were included, with the highest level of evidence suggesting fenestration of multifilament polyethylene terephthalate grafts, followed by dilation with either a 6-mm or 8-mm noncompliant balloon. More recent studies were two single-center experiences. Dean et al [50] reported the results of 15 patients treated emergently with ISLF, 7 of which were in the visceral vessels. One endoleak IIIC from a CT, two acute kidney in-

Table 4 – Technical characteristics of three multibranched off-the-shelf devices analyzed in the study.

Variable	t-Branch	TAMBE	E-NSIDE
Main graft			
Total length, mm	202	160	208
Proximal sealing zone length, mm	76	35	48
Proximal end design	Straight cut	Straight cut	Open web
Proximal diameter, mm	34	31 or 37	33 or 38
Visceral portion diameter, mm	18	20	24
Distal diameter, mm	18	20	26 or 30
Branches			
Design (all branches)	Outer	Outer	Inner
Celiac trunk branch			
Length, mm	21	10	20
Diameter, mm	8	8	8
Clock orientation, degree	30	15	23
End to top stent-graft end distance, mm	99	55	101
Superior mesenteric artery branch			
Length, mm	18	10	20
Diameter, mm	8	8	8
Clock orientation, degree	0	345	352
End to top stent-graft end distance, mm	117	55	120
Right renal artery branch			
Length, mm	18	10	20
Diameter, mm	6	6	6
Clock orientation, degree	300	300	288
End to top stent-graft end distance, mm	135	65	136
Left renal artery branch			
Length, mm	18	10	20
Diameter, mm	6	6	6
Clock orientation, degree	90	90	80
End to top stent-graft end distance, mm	135	65	139
End to bottom stent-graft end distance, mm	67	95	68

juries not requiring dialysis, and three cases of spinal cord ischemia were reported in this subset of patients. Globally, during a median follow-up of 168 days (range, 24 to 405 days), no late complications or late endoleaks were reported. One patient died. The second, by Pyun and colleagues [2], described 18 patients who underwent ISF endovascular repair for ruptured suprarental AAAs and TAAAs and acknowledged that ISF "became the most commonly used technique." In-hospital mortality was as low as 11%, but postoperative renal injury, new-onset hemodialysis, and spinal cord ischemia reached 56%, 33%, and 22%, respectively. Moreover, no post-discharge follow-up was provided.

Overall, limitations of this approach are the need for laser-based devices to create the fenestration, and the operator's learning curve with this technique, which is difficult to achieve in elective settings, as the use of ISF in stable patients treatable with CMDs or OTS devices might not be justifiable, given the excellent results of established procedures supported by decades of worldwide experience. Moreover, with fewer than 100 patients published in the available literature, with ultra-brief follow-up, this technique should be relegated to experimental settings in expert hands.

Clinical studies available for ISL have been summarized in Table 3 [2,50–52].

5. Off-the-shelf devices

Each OTS device presents different designs and specific limitations that may influence its anatomic applicability in a real-world setting [53], and their characteristics are summarized in Table 4, while the instructions for use (IFU) have been summarized in Table 5 (Fig. 1). For all devices, upper extremity access is needed to cannulate the branches and deliver the covered stent-grafts. The only exclusion criteria present in the IFU is the need to accommodate a 12Fr introducer sheath for the TAMBE and a 10Fr sheath for the E-nside. Nonetheless, in the past year, there has been a paradigm shift in which all complex aortic procedures have been treated more and more from transfemoral access using steerable sheaths [54–59].

6. Device description

6.1. *t-Branch*

The t-Branch endograft is designed for endovascular repair of complex TAAA with the incorporation of the visceral vessels through four outer branches. It is made of woven polyester supported by a series of stainless-steel Z stents. The t-Branch endograft comes in one configuration of 202 mm in length, tapering from 34 mm proximally to 18 mm distally. The SMA cuff is at 0 degrees. The CT cuff is 30 degrees to the left of the SMA cuff, the right renal artery (RRA) cuff is 60 degrees to the right of the SMA cuff, and the left renal artery (LRA) cuff is 90 degrees to the left of the SMA cuff. The delivery system consists of a 22Fr Flexor (Cook Medical) introducer sheath (7.3-mm inner diameter and 8.5-mm outer diameter) and a Captor

Table 5 – Instructions for use comparison among the three multibranched off-the-shelf devices analyzed in the study.

Variable	t-Branch	TAMBE	E-nside
Access requirements			
Iliac/femoral, mm	> 8.5	> 8.2	> 8.5
Axillary/brachial, mm	Available	> 4.7 mm (12Fr)	Available (10Fr)
Aortic requirements			
Length proximal neck, mm	≥ 25 (50 preferred)	≥ 20	≥ 30
Aortic diameter proximal aortic neck, mm			
Without proximal thoracic stent-graft	24–30 (OD)	22–34 (ID)	Not allowed
With proximal thoracic stent-graft	24–38 (OD)	19.5–32 (ID)	24–39 (ID)
Proximal sealing zone aortic angle, degree	≤ 90	≤ 60	≤ 75
Minimum aortic lumen in the visceral segment, mm	≥ 25[a]	≥ 20	≥ 24[a]
Distance between celiac trunk and aortic bifurcation, mm	≥ 51	≥ 95	≥ 98
Length of infrarenal neck, mm[b]	≥ 25	—	≥ 30
Minimum infrarenal aortic diameter, mm[c]	≥ 20	≥ 20	21
Common iliac artery diameter, mm	8–20 (OD)	8–25 (ID)	8–24 (ID)
Length of sealing zone in iliac artery, mm	≥ 10	≥ 10	≥ 15
Visceral requirements			
No. of visceral vessels	4	4	4
Renal arteries diameter, mm	4–8 (ID)	4–10 (ID)	> 4 (ID)
Celiac trunk and superior mesenteric artery diameter, mm	6–10 (ID)	5–12 (ID)	> 4 (ID)
Length of visceral vessel landing zone, mm	Any	≥ 15	Any
Branch distance (above) from target vessel, mm	≤ 50	10–30	10–50
Angle between the branch cuff and the visceral ostium			
Celiac trunk/superior mesenteric artery, degree	≤ 90 (45 + 45)	Any	≤ 50 (25 + 25)
Renal arteries, degree	≤ 90 (45 + 45)	Any	≤ 7 (35 + 35)

Abbreviations: ID, inner diameter; IFU, instructions for use; OD, outer diameter.
[a] Not specified in the IFUs but derived from manufacturer or literature [4,10–13,21].
[b] If sealing within the infrarenal aorta is planned.
[c] If the bifurcated distal component is planned

(Cook Medical) hemostatic valve. The company also provides a universal distal body of four different sizes (proximal diameter is always 22 mm; lengths of 81, 98, 115, and 132 mm; 20Fr introduction system).

6.2. *E-nside*

The E-nside is a commercially available endograft for endovascular repair of complex TAAAs made of polyester and self-expanding nitinol stents with the incorporation of the visceral vessel through four precannulated inner branches. It comes in four configurations of 222 mm in length, but variable proximal diameters (38 mm and 33 mm) and distal diameters (30 mm and 26 mm). The openings are at 352 degrees for the SMA, 23 degrees for the CT, 288 degrees for the RRA, and 80 degrees for the LRA. The LRA branch is 3 mm lower than the RRA branch. The device delivery system is an 8.2-mm (outer diameter) hydrophilic sheath with four precannulation tubes (one for each inner branch, compatible with 0.018″ wires.

6.3. *TAMBE*

The TAMBE stent-graft is an investigational aortic graft for endovascular repair of complex TAAAs with the incorporation of visceral vessels through four preloaded inner branches and it is based on the GORE EXCLUDER AAA platform using a nitinol stent frame and conformable expanded polytetrafluoroethylene technology. The initial TAMBE design also included a configuration with two upward-facing branches for the RAs, but only the configuration with four downward branches made it to the later stages of trials and production. The device has two proximal diameter configurations (31 mm and 37 mm), a length of 160 mm, and a distal diameter of 20 mm. it requires a 22Fr inner-diameter introducer femoral sheath, depending on the proximal graft diameter and a 12Fr (inner diameter) brachial or axillary artery sheath to access the antegrade portals.

7. Feasibility and clinical studies

7.1. *T-Branch*

For the t-Branch endograft, numerous feasibility studies have been published [60–64] and are summarized in Table 6. In a total of 578 patients, the theoretical anatomic feasibility ranged between 32% and 88%, and increased to 47% to 88% if adjunctive maneuvers were performed, such as carotid–subclavian bypass, iliac bypass, or the use of low-profile devices.

For the t-Branch stent-graft, numerous clinical studies have been published [1,5,9,12,65–72] and are summarized in Table 7. In a total of 391 patients, the technical success ranged between 63% and 100% with 30-day mortality ranging between 0% and 28%.

A recent meta-analysis from Konstantinou et al [73] identified seven retrospective studies published between 2014 and

Table 6 – Literature review of anatomic feasibility study for the three off-the-shelf devices either commercially available or investigational.

OTS device	Study, first author	Year	n	TAAA extent	Feasibility	Feasibility with additional maneuvers	Additional maneuvers	Reasons for unfeasibility
t-Branch	Sweet [60]	2009	66 (45 men) Already treated by CMD	I: 4 (6) II: 20 (31) III: 9 (14) IV/pararenal: 31 (49)	58 (88)	58 (88)	—	10: VV
	Bisdas [61]	2013	43 (34 men) Already treated by CMD	I: 1 (2) II: 16 (37) III: 18 (42) IV: 8 (19)	21 (49)	27 (63)	3: TEVAR 3: TEVAR + CSB	17: aorta 3: VV
	Gasper [62]	2013	201 (149 men) Already referred for endovascular treatment	I/V: 18 (9) II: 57 (28) III: 40 (20) IV/paravisceral: 86 (43)	64 (32) Using an LP device	94 (47)	11: visceral artery stenting 4: CSB 17: iliac bypass	36: aorta 65: VV 9: access
	Grandi [63]	2020	268 (199 men) All-comers	I: 13 (5) II: 99 (37) III: 65 (24) IV: 91 (34)	104 (39)	126 (47)	22: LP device	67: VV 98: aorta 59: access
TAMBE	Cambaghi [16]	2020	227 (167 men) All-comers	L-TAA: 61 E-TAA: 166	69 (30)	102 (45)	39: iliac conduit	95: aorta 46: VV 43: access
E-nside	Bilman [15]	2020	268 (199 men) All-comers	I: 13 (5) II: 99 (37) III: 65 (24) IV: 91 (34)	114 (43)	149 (56)	45: iliac conduit	143: aorta 58: VV 59: access
t-Branch TAMBE Valiant	Edman [64]	2020	165 (81 men) All-comers	I: 17 (14) II: 50 (41) III: 19 (16) IV: 36 (30)	18 (15) for at least one device	59 (48) for at least one device	23: iliac conduit 21: VV intervention 11: CSB	71: aorta 26: VV

Categorical variables are presented as n (%). Continuous variables are presented as median (interquartile range) or mean ± SD.
Abbreviations: CMD, custom-made device; CSB; carotid-subclavian bypass; E-TAA, extended thoracoabdominal aneurysm (aneurysm begin ≥ 65 mm from celiac trunk); LP, low profile; L-TAA, limited thoracoabdominal aneurysm (aneurysm begin < 65 mm from celiac trunk); OTS, off-the-shelf; TAAA, thoracoabdominal aortic aneurysm; TEVAR, thoracic endovascular aortic aneurysm repair; VV, visceral vessels.

Table 7 – Literature review of clinical studies available for the three off-the-shelf devices either commercially available or investigational.

Study, first author	Year	n	Age (y)	Aortic diameter	OTS device	Urgent/ emergent	Technical success	30-d mortality	AKI	SCI	Any complication	LOS (d)	Branch patency (%)	Survival (%)	Freedom from reintervention (%)
Bisdas [66]	2014	22 (15 men)	70 ± 8	61 (29–110)	t-Branch	4 (18)	22 (100)	0 (0)	0 (0)	1 (5) paraplegia and 1 (5) paraparesis	SMA dissection relined	12 (8–14)	97 3 renal branches occluded	6 mo: 94	6 mo: 90
Reilly [12]	2012	81 (63 men)	73 ± 8	67 ± 10	t-Branch	2 (2.5)	81 (100)	5 (6.2)	21 (25.9)	3 (3.7) paraplegia	27 (33.3) access complications 14 (4.6) branch injuries	14 ± 17	94.8 9 renal and 2 CT branch occlusions. 4 renal and 1 SMA stenosis	21 ± 17 mo: 93.8	21 mo: 60.5
Silingardi [67]	2018	73 (54 men)	72 ± 7	67 ± 15	t-Branch	32 (44)	67 (92)	3 (4)	15 (21)	2 (2.7) paraplegia	31 (42)	—	99 3 renal branch occlusions	36 mo: 82	24 mo: 89
Bertoglio [68]	2018	18 (14 men)	76 (69–79)	—	t-Branch	0 (0)	18 (100)	1 (5.6)	1 (5.6)	1 (5.6) paraplegia	—	—	—	—	—
Spanos [69]	2018	42 (26 men)	73.3 ± 7	77.7 ± 13.2	t-Branch	42 (100)	39 (93)	6 (14)	10 (23)	5 (12) paraplegia and 4 (10) transient paraparesis	14 (33) pneumonia 16 (38) access complications	20.3 ± 3	99	30 d: 36 84	—
Hongku [1]	2018	11 (4 men)	65 (61-72)	71 (68–86)	t-Branch	11 (100)	7 (63)	3 (27)	4 (37)	3 (27) paraplegia, 2 (18) of which temporary	—	ICU: 5 (4–8)	72 ± 12 2 renal and 2 CT branches occlusions	24 mo: 62.5 ± 17.1	—
Baba [70]	2017	14 (9 men)	74.9 ± 6.8	60.4 ± 7.8	t-Branch	0 (0)	14 (100)	1 (7.1)	0 (0)	5 (37.5) paraplegia	7 (50)	24.6 ± 7.9	—	36 mo: 92.9	36 mo: 92.9

(*continued on next page*)

Table 7 (*continued*)

Study, first author	Year	n	Age (y)	Aortic diameter	OTS device	Urgent/ emergent	Technical success	30-d mortality	AKI	SCI	Any complication	LOS (d)	Branch patency (%)	Survival (%)	Freedom from reintervention (%)
Gallitto [71]	2017	17 (12 male)	73±7	60 ± 19	t-Branch	17 (100)	14 (82)	1 (6)	4 (24)	1 (6) temporary paraparesis	1 (6) access complication	14 ± 5	99 1 renal branch occlusion	12 mo: 82	12 mo: 82
Eleshra [72]	2020	32 (26 men) All previous infrarenal repair	74 ± 7	66 ± 22	t-Branch	9 (28)	31 (97)	4 (13)	8 (25)	7 (32) paraplegia of which 4 temporaries	17 (53)	15 ± 10	97.5	12 mo: 82	12 mo: 90
Fernandez [65]	2016	50 (39 men)	71 ± 7	66.9 ± 9.1	t-Branch	0 (0)	50 (100)	1 (2)	3 (6)	1 (2) paraplegia	2 renal artery injuries	—	93 3 CT, 2 SMA, 8 renal branches occlusions	694 ± 525–d: 45 (90)	694 ± 525 d: 32 (64)
Gallitto [5]	2022	65 (46 men)	73 ± 7	76 ± 20	t-Branch	65 (100)	56 (86)	9 (14)	18 (28)	11 (17)	19 (29)	ICU 6 (5–7)	89	24 mo: 47	—
Ferrer [9]	2022	48 (35 men)	73 ± 8	70 (55–88)	t-Branch	12 (25)	46 (96)	5 (10)	7 (15)	3 (6)	15 (23)	5.7 (4–11)	176/178 (99)	18 (1-63): 39 (91)	—
Eleshra [4]	2022	100 (65 men)	65 ± 10	6.25 (4.8–7.6)	t-Branch	70 (70)	97 (97)	15 (15)	21 (21)	18 (18)	—	17±13	99	24 mo: 87	—
Oderich [17]	2019	13 (11 men)	69 ± 8	61 ± 13	TAMBE	0 (0)	12 (92)	0 (0)	0 (0)	0 (0)	4 (31)	5±3	92 1 renal artery occlusion due to intraoperative dissection	30 d: 100	30 d: 12 (92)
Piazza [74]	2023	79 (53 men)	73 ± 9	68 ± 18	E-nside	19 (24)	75 (95)	4 (5)	0 (0)	5 (6)	10 (12)	—	5 occlusions	—	—

Categorical variables are presented as n (%). Continuous variables are presented as median (interquartile range) or mean ± SD.
Abbreviations: AKI, acute kidney injury; CT, celiac trunk; ICU, intensive care unit; LOS, length of stay; OTS, off-the-shelf; SCI, spinal cord ischemia; SMA, superior mesenteric artery.

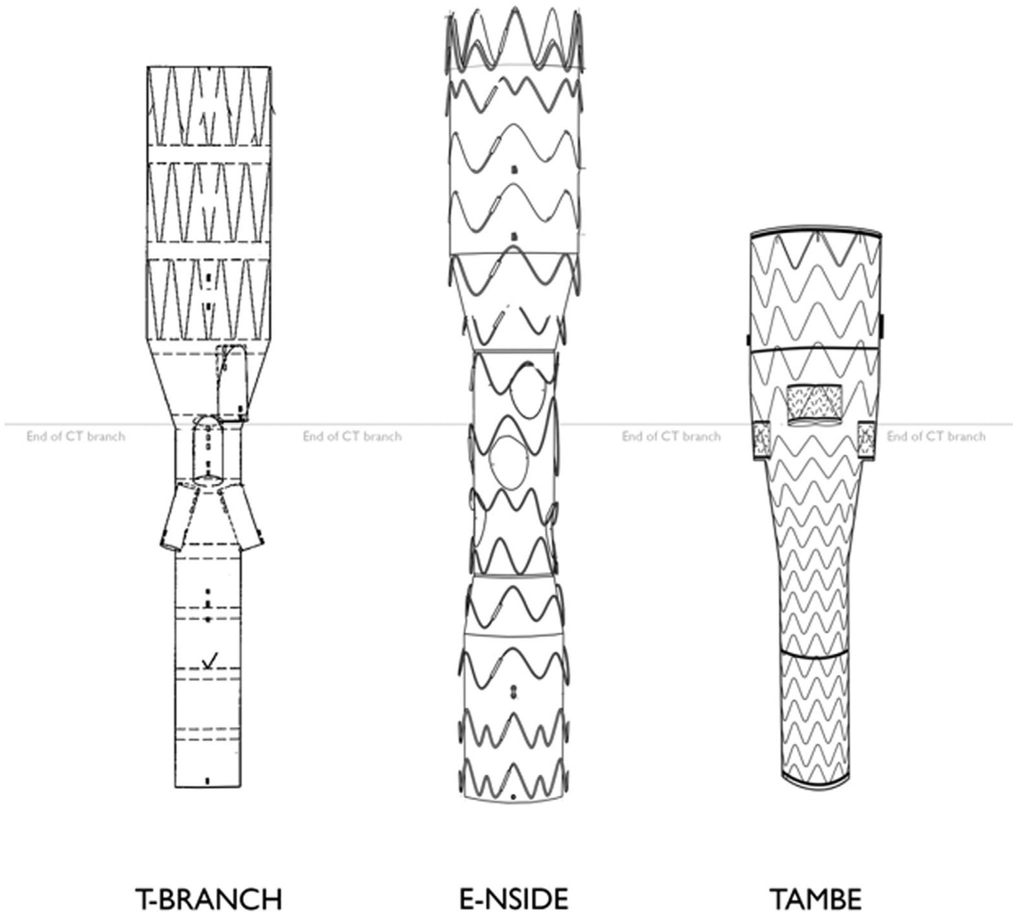

Fig. 1 – Technical scale drawing comparing the three off-the-shelf (OFS) multibranched devices for the treatment of thoracoabdominal aortic aneurysms (TAAAs).

2018, with a total of 197 patients (mean ± SD age, 72.3 ± 7 years; 70% were male) [1,66–71]. Among 165 patients, 45% were symptomatic and 19% were treated for a ruptured aortic aneurysm. In 197 patients, pooled technical success was 92.75% (95% CI, 83.9%–98.7%), and in 10% of the cases, an early endoleak was detected (95% CI, 0%–43.7%). Early mortality was 5.8% (95% CI, 2.5%–10%) and major stroke was observed in 4% of the patients (95% CI, 0.96%–8.40%). The rate of spinal cord ischemia was 12.2% (95% CI, 4.1%–23.2%), with the rate of permanent paraplegia at 1.3% (95% CI, 0%–8.7%). Acute renal failure was 18.7% (95% CI, 9.1%–30.4%), whereas primary branch patency was calculated at 98.2% (95% CI, 96.7%–99.2%). The mean ± SD follow-up was 15 ± 7 months. During this time, midterm mortality (after 30 days) was 6.9% (95% CI, 2.44%–12.8%) and pooled reintervention rate was 5.7% (95% CI, 1.70%–11.4%).

7.2. E-nside

For the E-nside endograft, only one feasibility study has been published. The study from Bilman et al [15] reported a theoretical anatomic applicability of 43% in an all-comer cohort of 268 patients, divided according to access feasibility (78%), aortic feasibility (60%), and visceral vessels feasibility (79%). The main limiting factors were the femoral/iliac access diameter (21%), proximal neck and the inner aortic visceral lumen (16% for both), and inadequate vessel number (7%) or diameter (12%).

For the E-nside stent-graft, only one clinical study has been published [74] and is summarized in Table 7. Piazza et al [74] reported the data on 79 patients treated in 26 Italian centers. The procedure setting was urgent in 19 patients (24%). Thirty-day technical success was 95%, with a 5% (n = 4) mortality rate. Major adverse events were spinal cord ischemia in 5 patients (6%), stroke in 4 patients (5%), and myocardial infarction in 1 patient (1%). There were six target vessel–related events (2%) (five occlusions and one Type IC endoleak) and one Type 1A endoleak needing reintervention.

7.3. TAMBE

For the TAMBE stent-graft, only one feasibility study has been published. The study from Cambiaghi et al [16] showed theoretical anatomic applicability of 30% in an all-comer cohort of 227 patients, divided into access feasibility (81%), aortic feasibility (55%), and visceral vessels feasibility (66%). The main limiting factors were the absence of a tapered thoracic component and, therefore, an inadequate proximal neck (42%), and inadequate vessels number (8%) or length (12%).

For the TAMBE stent-graft, only one clinical study has been published [17] and is summarized in Table 7. Oderich et al. [17] reported the first 13 patients treated with the TAMBE device. A total of 52 renal and mesenteric arteries were incorporated (4 vessels/patient); technical success rate was 92% (12 of 13). One patient had inadvertent occlusion of an RRA due to dissection. There was no mortality, aneurysm rupture, conversion to open repair, dialysis, or spinal cord injury. At the 30-day follow-up, 4 patients (31%) had major adverse events, all were due to procedural blood loss > 1,000 mL. One patient had a Type I endoleak at the distal renal branch, which was treated successfully via placement of an additional renal stent before dismissal and 30-day computed tomography angiography showed patent target vessels and no Type I or Type III endoleak.

8. Future directions

One of the main issues arising from the always increasing use of OTS devices is the additional aortic coverage, which is associated with an increased risk of spinal cord ischemia [7,75,76], especially when treating pararenal aneurysms, compared with CMDs and open surgery [68,77,78]. Because of this, future research should focus on devices for this subset of patients as well, such as the p-Branch device (Cook Medical), which has been found to have similar results as CMDs in the treatment of juxta-renal aneurysms, without the need for manufacturing time [79] and acceptable results in a recent meta-analysis [80].

A second topic of future research will be on the branch design. Comparative studies will be able to tell us in which situations an inner or an outer branch should be used, the same way comparisons between fenestration and branches were performed [81–83].

9. Conclusions

At first, most of those treatment options started as emergency repairs. As the experience grew, they were used in elective settings as well, first following on-label indications, then pushing the envelope further with off-label use to treat a wider percentage of patients. All OTS multibranched endografts are theoretically able to provide endovascular treatment to approximately one-third to one-half of the TAAAs from real-world all-comers cohort of patients. Profile improvements and dedicated thoracic and infrarenal components are warranted to increase the overall feasibility. The t-Branch appears safe and shows optimal results in both elective and urgent or emergent cases, more clinical data are needed for the TAMBE and the E-nside.

When an OTS is not available, PMEG, PG, or ISF, in expert hands, can provide a life-saving alternative. Long-term outcomes of these strategies are burdened by specific technical characteristics, and comparison with branched TAAA repair is limited by the lack of standardization and comparative studies. Open repair or support care are the only options when patient anatomy does not allow endovascular repair.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Prof. Luca Bertoglio and Prof. Tilo are consultant for Cook Medical (Cook, Bloomington, IN, USA), Prof. Luca Bertoglio is consultant for Gore (W. L. Gore and Associates, Flagstaff, AZ, USA).

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