Proximal landing zone of TEVAR. Are there any limits? A narrative review

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Abstract:

Thoracic endovascular aortic repair (TEVAR) is increasingly utilized for managing thoracic aortic pathologies, necessitating adequate proximal stent graft apposition to healthy aortic wall to optimize outcomes..This review highlights the evolution of TEVAR techniques and devices, emphasizing the importance of anatomical suitability, technical success rates, and the need for a standardized approach to LSA reperfusion.Ultimately, careful patient selection, device choice, and interdisciplinary collaboration are critical to enhancing procedural outcomes and reducing complications in TEVAR.

Thoracic endovascular aortic repair (TEVAR) has gained widespread use in the treatment of acute and chronic pathologies of the thoracic aorta. Optimal outcomes in TEVAR are dependent upon obtaining adequate proximal apposition of stent graft against a healthy aortic wall.[1, 2] According to the instructions for use of the available endografts, this should be at least 15-20 millimeters long. **(Table 1**) In the proximal thoracic aorta, this may require coverage of one or more of the branches of the aortic arch, most commonly the left subclavian artery (LSA) (26-40%).[3-5] However, coverage of the LSA during endovascular repair of the thoracic aorta has been identified in the literature as a significant modifiable risk factor for: cerebrovascular ischemia, stroke (anterior circulation), vertebral ischemia, ischemia of the upper extremities.[3, 4, 6-8] There are also some special cases that make reperfusion of the LSA imperative, such as:

-Presence of a patent coronary bypass between the left internal mammary artery and coronary arteries.

-Termination of the left vertebral artery on the posterior inferior cerebellar artery.

-Absent, hypoplastic or occluded right vertebral artery.

-Presence of a patent arteriovenous dialysis shunt in the left upper limb.

-Planned extensive coverage (20 cm) of the descending thoracic aorta.

-Previous infrarenal aortic surgery with concomitant ligation of lumbar and middle sacral arteries.

-Occlusion of the internal iliac artery.[5, 9, 10]

Based on the above, all current guidelines of the European Society of Vascular Surgery, the Society of Vascular Surgery and the American Heart Association recommend prior or simultaneous reperfusion of the LSA, when coverage is necessary for adequate proximal landing zone achievement, in order to prevent neurological ischemic complications.[9, 11, 12] Traditionally, reperfusion of the LSA was performed with a carotid-subclavian bypass. **(Figure 1)** Alternatively, LSA is transposed to the left common carotid artery (LCCA).[13] **(Figure 2)** Although this technique eliminates the need for a synthetic graft and does not require secondary central embolization, it is contraindicated in cases of early take-off of the left vertebral artery and in the presence of a patent coronary bypass from the left internal mammary artery. Adopting all these open LSA reperfusion techniques, an excellent patency rate of >97% has been described at five years follow-up.[14, 15]

Therefore, arises the question whether there is a need for alternative methods of reperfusion of the LSA. Indeed, in obese patients, open reperfusion of the LSA becomes technically demanding and is associated with an increased risk of local complications, the incidence of which is not negligible; i.e bleeding, (10-20%), peripheral nerve injury (9-25%) and lymph leakage, although relatively rare (3-5%), may require more sophisticated treatment techniques.[15-17] **(Figure 3)**

This was realized by the team of Lawrence-Brown in Liverpool, who first described in 2004 the in-situ creation of a fenestration in a thoracic dacron endograft using the hard tip of a guide wire and the sequential use of cutting balloons so that a covered stent could be placed and blood flow to the LSA could be maintained.[18] While in 2009, the team of Frank Arco from Texas described for the first time the use of an ultraviolet laser catheter to create a fenestration in a Talent thoracic endograft and, after balloon dilation, placed an iCast covered stent in a patient with traumatic thoracic aortic injury.[19] A recent meta-analysis on the use of laser to create fenestrations during the endovascular treatment of aortic arch pathologies identified 6 studies with a total of 247 patients, almost 81% of whom underwent surgery on an emergency or urgent setting. The pooled technical success rate was estimated at 98%, the pooled 30-day mortality rate was estimated at 3.2% and the pooled estimate for stroke was estimated at 4.5%. Regarding the mid-term results, a target-vessel patency rate of 100% and

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Table 1: Anatomic requirements for the proximal landing zone of the available thoracic stent-grafts

MANUFACTURER	NAME	PROXIMAL LANDING ZONE	
		Diameter (mm)	Length (mm)
W. L. Gore & Associates	Conformable Thoracic Aortic Graft (c-TAG)™	16-42	≥20
Medtronic	Valiant Captivia™	18-42	≥20
Cook Medical	Zenith Alpha™	22-42	≥20
Terumo Aortic	Relay™	19-42	15-25
Lifetech Scientific	Ankura™	18-44	≥15

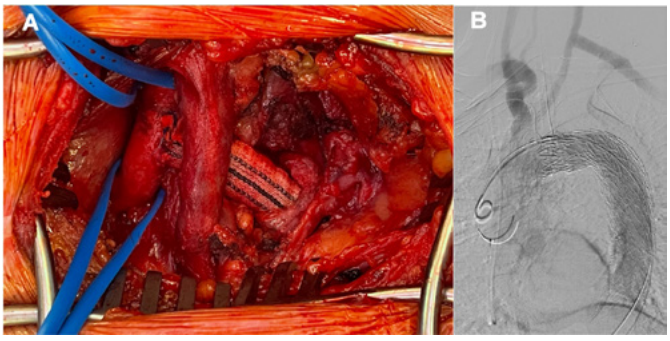

Figure 1: Left common carotid - left subclavian artery bypass. A: intraoperative view. B: angiographic view

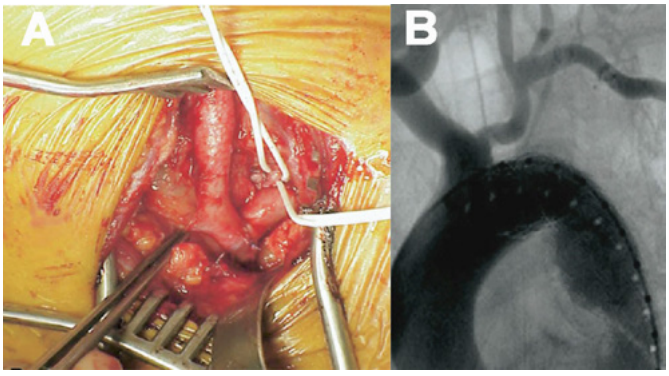

Figure 2: Transposition of the left subclavian artery. A: intraoperative view. B: angiographic view

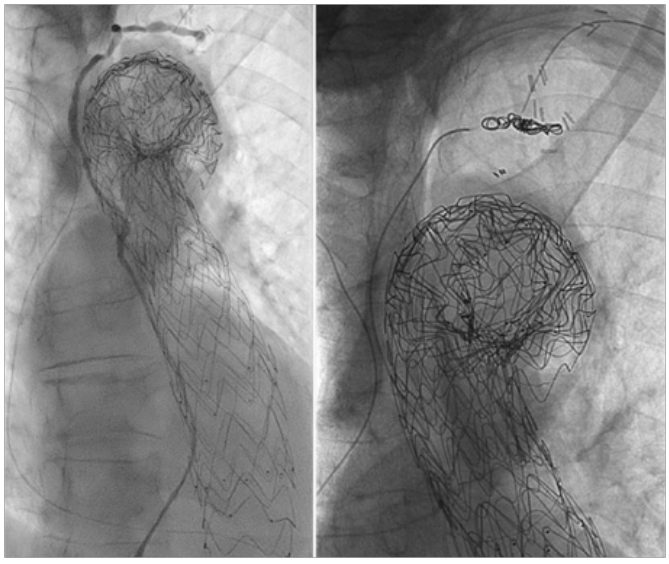

Figure 3: Embolisation of the the thoracic duct due to persistent chylous leak after a LCCA-LSA bypass

a reintervention rate of 6% during a median follow-up period of 12 months was recorded.[20] The recently published early results of the multicenter LIFE (Laser In Situ Fesnestrated Endograft) confirmed the feasibility of the technique with a perioperative mortality and neurologic risk profile that is comparable to standard techniques, but with a modest (9.8% within 15 months) reintervention rate.[21]

In 2021, the Fu-through™ in situ needle fenestration system in combination with the Fustar™ steerable guided sheath and the Ankura™ thoracic endograft (Lifetech Scientific, Shenzhen, China) were introduced in Europe and received CE mark. This system allows stabilizing and centralizing the 20G puncture needle, which is designed with 3 puncture depths and is convenient for 0.018" guidewire to go through and PTA balloon can be used for rapid dilation. In a single-center retrospective study on 52 TEVAR patients, an anatomic feasibility rate of 61.5% (32/52) was found based on the aortic arch morphology. The LSA angulation was identified to be the most important and limiting anatomical constraint.[22] The experience so far, mainly from China, has shown excellent results in terms of technical success, 30-day mortality and the occurrence of cerebrovascular events.[23-27] **(Table 2)**

Various other techniques for in-situ fenestration of thoracic endografts such as the use of recanalization catheters, or wire connected to electrodiathermy have been suggested. However, all of them are characterized by a lack of standardization, a combination of many materials and technologies and of course the absence of long-term results. Thus, the need for a standardized endovascular method for reperfusion of the LSA arises.

The solution to this need aspires to be the single-branch stent-grafts. Currently available in Europe is the GORE TBE™ (W. L. Gore & Associates, Newark, DE, USA) (MDR CE mark 2024), which is based on the well-known TAG platform and has a retrograde internal branch for the subclavian artery of 8 mm at a distance of 20 to 25 mm from the central end, a 12

mm branch at a distance of 40 mm from the central end. It includes a bridging endograft with diameters of 8 or 12 mm and a length of 6 cm and an aortic extension of 36 to 46 mm. **(Figure 5)** So far, this endograft has been used mainly in the United States of America, where it has been available in clinical studies since 2014 with excellent results.[28-35] **(Table 3)** However, it should be noted that, as with all endografts, there is a limitation of anatomical suitability. In a retrospective single center study of 210 patients who underwent TEVAR in zone 2, only 38.1% of patients met the anatomical criteria for a central landing zone. The left carotid artery - LSA distance being the most frequent factor of anatomic suitability violation.[36]

The second branched thoracic endograft currently available in Europe -in a custom-made platform- is the Castor™ (Lombard Medical Limited, in partnership with MicroPort Endovastec, Newark UK). It is a PTFE-coated nitinol scaffold en-

Table 2: Published results with the Fu-through™ in situ needle fenestration system

	N	Technical success	30-d Mortality	Cerebrovascular events (%)	Follow up (median, months)	Survival
Fan B, et al. 2024[23]	43	99.1%	0.9%	0	50	97.7%
Li G, et al. 2024[24]	115	100%	3.5%	0	31	92.2%
Yu Z, et al. 2024[27]	68	94.1%	2%	3.1%	29.2	98.5%
Usai M, et al. 2023[25]	18	94.4%	0	0	1	100%
Shu X, et al. 2022[26]	51	98.0%	2.0%	4.0%	31	96.0%

Table 3: Published results with the GORE TBE™ stent-graft

	Aneurysm	Dissection	Traumatic transection	Other isolated lesion	Total
N of enrolled subjects	84	132	9	13	238
Procedure time (min)	154.5	129.0	109.0	142.0	132.5
Contrast use (mL)	139.0	126.8	74.4	96.1	127.7
Technical success	77/84 (91.7%)	129/132 (97.7%)	9/9 (100%)	13/13 (100%)	228/238 (95.8%)
Permanent Paraplegia	1/84 (1.2%)	0/132 (0.0%)	0/9 (0%)	0/13 (0%)	1/238 (0.4%)
Disabling Stroke	4/84 (4.8%)	3/132 (2.3%)	0/9 (0%)	1/13 (7.7%)	8/238 (3.4%)
Type I/III EL	8/82 (9.8%)	5/121 (4.5%)	0/9 (0%)	0/13 (0%)	13/225 (5.8%)
30-d Mortality	0/84 (0%)	2/132 (1.5%)	0/9 (0%)	1/13 (7.7%)	3/238 (1.3%)
12-month lesion related mortality	0/80 (0%)	3/132 (2.3%)	0/9 (0%)	1/13 (7.7%)	4/234 (1.7%)
12-month LSA patency	67/67 (100%)	96/96 (100%)	8/9 (88.9%)	12/12 (100%)	183/184 (99.4%)
12-month freedom from type I/III EL	61/66 (92.4%)	92/94 (97.9%)	9/9 (100%)	12/12 (100%)	174/181 (96.2%)
12-month-freedom from reintervention	79/80 (98.7%)	126/132 (95.4%)	9/9 (100%)	13/13 (100%)	227/234 (97.0%)
24-month lesion related mortality	0/74 (0%)	3/132 (2.3%)	0/9 (0%)	1/13 (7.7%)	4/228 (1.75%)
24-month LSA patency	51/51 (100%)	61/61 (100%)	8/9 (88.9%)	12/12 (100%)	132/133 (99.2%)
24-month freedom from type I/III EL	46/51 (90.2%)	117/122 (95.9%)	9/9 (100%)	12/12 (100%)	184/194 (94.8%)
24-month-freedom from reintervention	73/74 (98.6%)	126/132 (95.4%)	9/9 (100%)	12/12 (100%)	220/227 (96.9%)
36-month lesion related mortality	0/40 (0%)	3/132 (2.3%)	0/9 (0%)	1/13 (7.7%)	4/194 (2.0%)
36-month LSA patency	27/27 (100%)	25/25 (100%)	8/9 (88.9%)	12/12 (100%)	72/73 (98.6%)
36-month freedom from type I/III EL	74/82 (90.2%)	117/122 (95.9%)	9/9 (100%)	12/12 (100%)	212/225 (94.2%)
36-month-freedom from reintervention	39/40 (97.5%)	126/132 (95.4%)	9/9 (100%)	12/12 (100%)	186/193 (96.4%)

Table 4: Published results with custom-made fenestrated stent-grafts

	Cook Arch Fen™	Terumo Fen±Scal Relay™	Najuta™ Device
Study design	International, 6 centres, 2014-2020	10 Italian centres 2014 - 2022	21 Italian centres 2018 - 2022
n	108	49	76
Technical success	107/108 (99%)	48/49 (98%)	74/76 (97.4%)
In-hospital mortality	4/108 (3.7%)	0	1/76 (1.3%)
Stroke	8/108 (7.5%)	3/49 (6.1%)	3/76 (3.9%)
rTAAD	3/108 (2.7%)	0	0
Follow up (months)	12	36.3	7
EL type I/II	3.5%	4.2%	2/76 (2.6%)

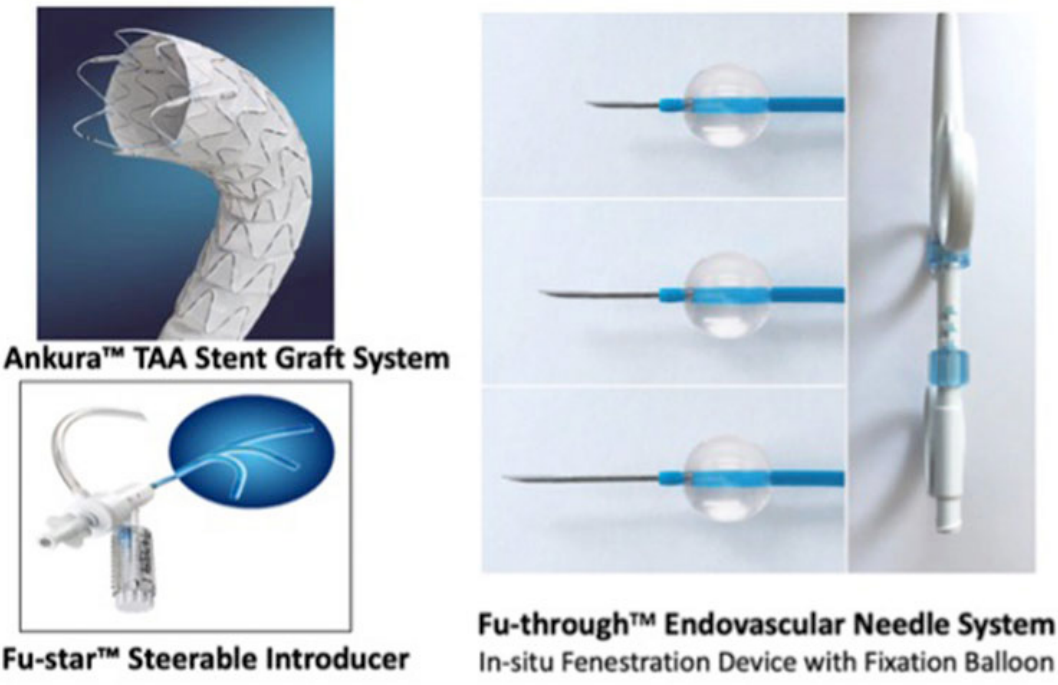

Figure 4: Fu-through™ in situ needle fenestration system in combination with the Fustar™ steerable guided sheath and the Ankura™ thoracic endograft. (Courtesy Lifetech Scientific)

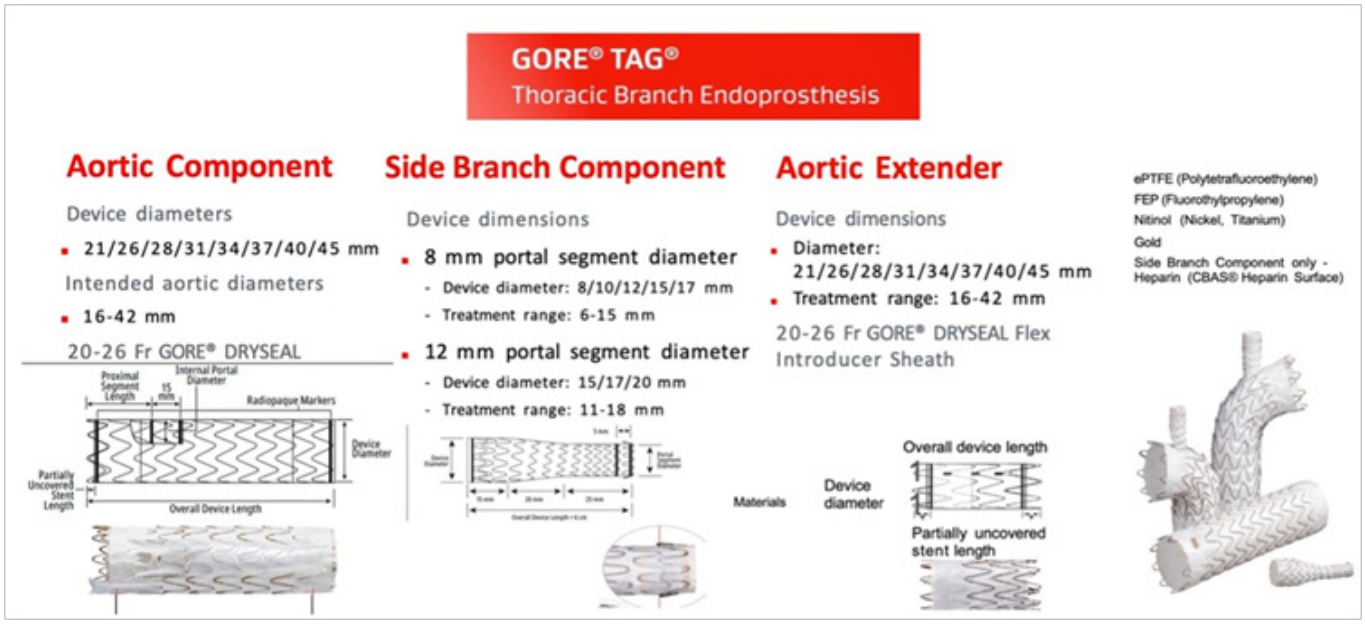

Figure 5: GORE TBE™single-branch stent-graft (Courtesy W. L. Gore & Associates)

dograft with a single branch 6-14 mm in diameter and 25 or 30 mm in length at a distance of 5 to 30 mm from the central tip. **(Figure 6)** The endograft was initially available in China with the indication of type B aortic dissection. A recent meta-analysis identified 11 studies with a total of 415 patients.[37] Technical success was recorded at 97.5%, no postoperative strokes were observed, while the 30-day mortality was almost 1%, while the patency of the LSA branch at 12 months was found to be 95%. Recently the first experience from Europe was published with encouraging results.[38] The second generation of Castor™, Cratos™, which has a redesigned delivery mechanism with a 2 Fr smaller sheath, was recently put into clinical trials in Europe and Japan (ongoing CREATION clinical trial).

Alternatives are also currently available as custom-made stent-grafts: the fenestrated endograft Cook Arch Fen™ (by COOK, Bloomington, IN, USA), the Najuta™ (by B-Kawasumi Laboratories, Inc., Kanagawa, Japan) and the Relay™ (by Terumo Aortic, Inchinnan, UK). All 3 endografts have shown high

technical success rates with a stroke risk of 3.9% to 7.5%.[39-41] However, they set as an anatomical prerequisite the presence of a 2 cm sealing zone (with diameter <40mm) in the mid-aortic arch, which is not always possible, especially in cases of type III aortic arch. In such cases, it is necessary to shift the proximal sealing zone centrally, towards the ascending aorta. Thus, branched aortic arch endografts, the Relay™ (by Terumo Aortic, Inchinnan, UK), Cook Arch Branch™ (by COOK, Bloomington, IN, USA) and the NEXUS™ (by Endospan, Herzlia, Israel) with central sealing zone in the ascending aorta, were developed. **(Figure 7)**

The multicenter postmarket study for Nexus, which in-

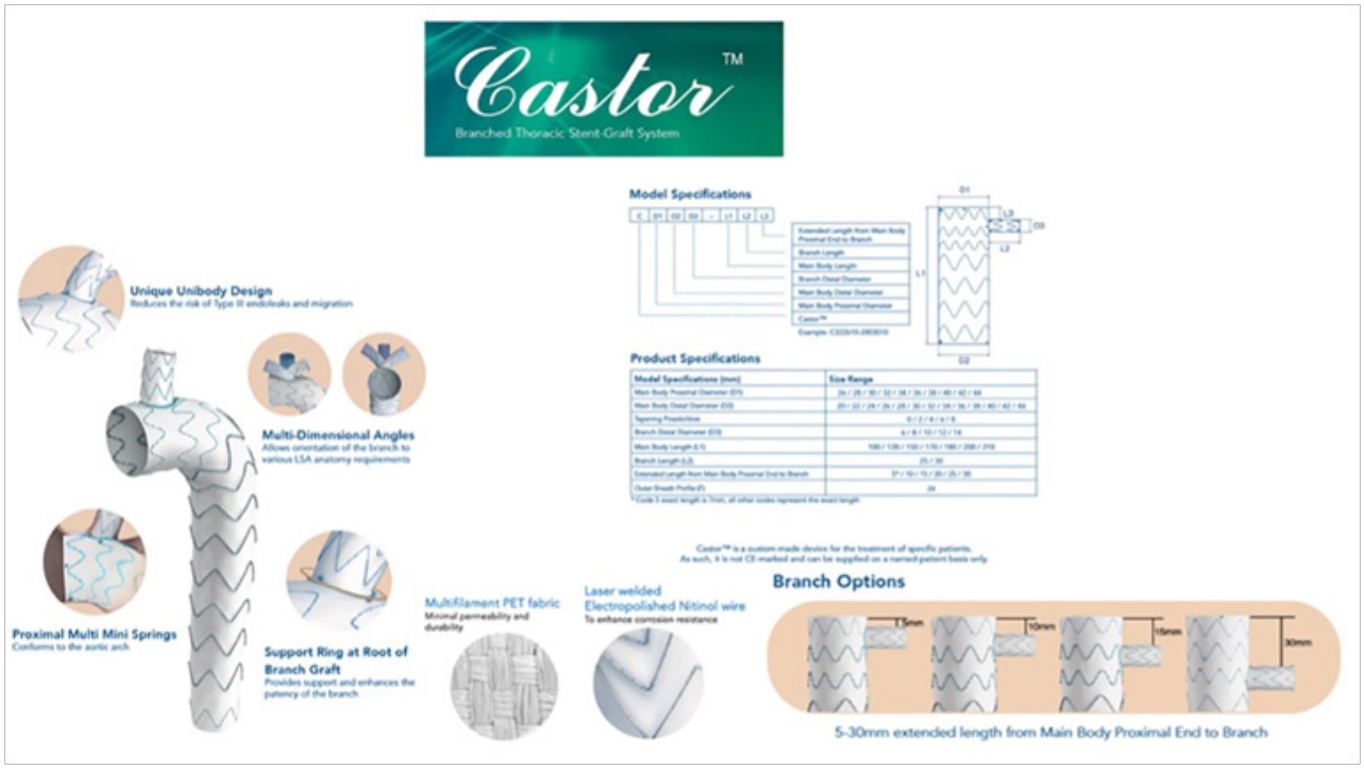

Figure 6: Castor™ branched thoracic endograft (Courtesy Lombard Medical

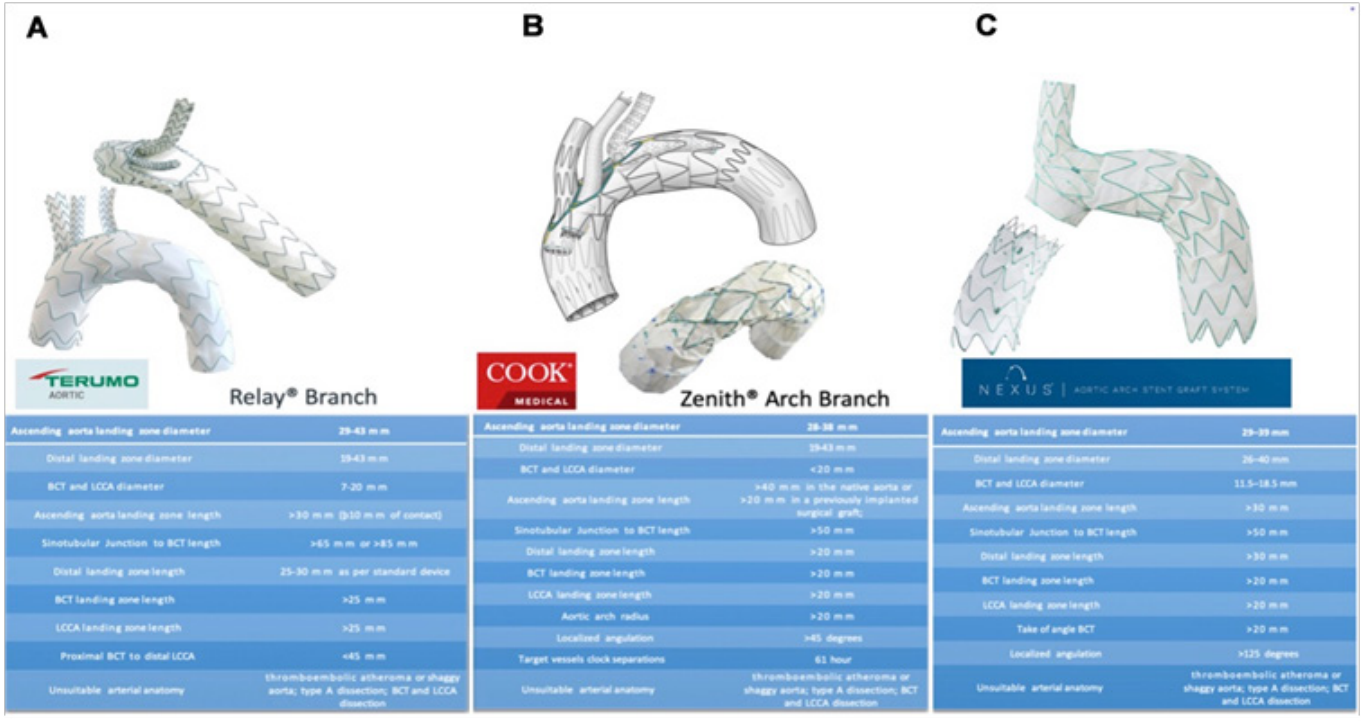

Figure 7: Available in Europe branched aortic arch endografts and their IFUs. A: Relay™(by Terumo Aortic, Inchinnan, UK), B: Cook Arch Branch™ (by COOK, Bloomington, IN, USA) C: NEXUS™ (by Endospan, Herzlia, Israel)s

Table 5: anatomical suitability of branched aortic arch endografts

		Cook Zenith Arch Branch™		Terumo Relay Branch™	Nexus™
	N	Double- Branch	Triple-Branch	2-Branch	
Leone N, et al. J Vasc Surg. 2024[54]	120	52.1%		46.6%	
Exelmans W, et al. CVIR Endovascular. 2023[53]	37				40.9%
Benfor B, et al. Eur J Cardio-Thoracic Surg. 2022[52]	90	36%	32%	34%	
Burke CR, et al. J Endovasc Surg. 2020[50]	27	45%			
Smorenburg S, et l. JAHA. 2020[51]	110	11.8%		17.3%	13.6%

cluded 28 patients, showed excellent technical success rates (100%), and extremely low stroke rates (3.6%), but in 29% of patients a reintervention was necessary at 36 months.[42, 43] Similarly, a multicenter study on the Terumo Relay branched endograft, which included 43 patients showed a 30-day mortality of 9%, and 7% disabling stroke rate.[44]

Regarding the COOK endograft, the version with the 2 branches, the initial experience was rather disappointing with a technical success of only 84% and a 30-day mortality at 13% and cerebrovascular accidents at approximately 16%.[45] These results were attributed to the required learning curve and, indeed, in the following series excellent technical success rates were observed, as well as acceptable 30-day mortality rates. However, the risk of stroke remained significant.[45-47] Recently, the international experience with the version with the 3 branches was also published. An improvement was found in terms of the risk of stroke, but the need for secondary interventions was estimated at 31% during a median follow-up period of 3.2 months.[48] Interstingly, a recent study from Hamburg found that the proximal landing zone in the native ascending aorta is associated with high stroke rates (13.5%, 7.9% major) and high need for reinterventions (24-month freedom from rentervention 46.4%).[49]

It should, however, be mentionted that the anatomical suitability of these endografts ranges from 10% to 50%, depending on the population under examination. **(Table 5)** All of studies identified the short length (<5cm) and the large diameter (>40mm) of the ascending aorta as the main factors for limiting the anatomical suitablity.[50-54] Indeed, the presence of a mechanical aortic valve, the short length of the ascending aorta and its severe angulation constitute significant challenges for the use of branched aortic arch endografts. Tsilimbaris et al. proposed the use of a small tip, 35 mm, and its passage lateral to the metallic leaflet, in order to preserve the function of the other one in cases of patients with a metallic aortic valve.[55] A recently published multicentre experience on these patients showed excellent technical success rates. However, it should be mentioned that, the included patients were highly selected and the participating centers were experienced high volume aortic centres.[56] Moreover, in patients with short ascending aorta length, endografts with 3 inverted branches can be used.[57] It should be noted, however, that these endografts are not readily available to everyone, so in selected cases the chimney technique, the in-situ fenestration technique or surgeon-modified endografts can be applied.

Recently, have been published efforts to expand the proximal landing zone in the aortic root. These are based in the combination of fenestrated or branched endografts along with percutaneous aortic valves with encouraging early outcomes for highly selected patients. Long-term follow-up data are, however, needed to assess the persistence of the seal and ongoing durability of this novel technique. [58-62]

In summary, the proximal sealing zone represents the most important factor related to early and long-term results after TEVAR and ensuring its adequate length is the main challenge. Several different technologies have expanded the boundaries of what can be achieved through endovascular techniques worldwide. While the long-term results of the use of branched endografts are pending, most technical limitations are being eliminated and a satisfactory level of technical success has been noted with F/BTEVAR. However, this comes at the cost of increased stroke and reoperation rates. Therefore, patient selection, respecting the anatomical requirements, judicious choice of the most appropriate device considering the pros and cons of each system, in a high-volume centre and by an interdisciplinary team are the keys to minimize complications and achieve an adequate proximal landing zone.

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