Editor's Choice − Outcomes of Off the Shelf Outer Branched Versus Inner Branched Endografts in the Treatment of Thoraco-Abdominal Aortic Aneurysm in the B.R.I.O. (BRanched Inner − Outer) Study Group

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WHAT THIS PAPER ADDS
This multicentre study compared the early and one year outcomes of two commercially available off the shelf branched endografts, namely the inner branched E-nside (Artivion) and the outer branched Zenith t-Branch (Cook Medical). Both endografts provided excellent early and midterm results. The E-nside may require shorter thoracic aorta coverage and bridging length for the renal arteries, and less frequent implantation of a concomitant proximal thoracic or distal abdominal bifurcated endograft, without any significant difference in early or one year outcomes.

Objective: This study aimed to compare two commercially available off the shelf branched endografts for thoraco-abdominal aortic aneurysm (TAAA) repair, namely the E-nside (Artivion) and Zenith t-Branch (Cook Medical) devices.
Methods: This multicentre retrospective study (2020 − 2023) included patients treated by branched endovascular aortic repair (BEVAR) for TAAA using the inner branched E-nside or the outer branched t-Branch. Endpoints were 30 day technical success and major adverse events (MAEs) as well as one year freedom from target vessel instability and main endograft instability.
Results: The study included 163 patients: 79 (307 target vessels) treated with E-nside and 84 (325 target vessels) with t-branch. Aneurysm extent was I − III in 91 patients (55.8%; 47% of E-nside and 66% of t-Branch) and IV in 72 patients (44.2%; 53% of E-nside and 34% of t-Branch) ($p = .011$). An adjunctive proximal thoracic endograft was used in 43% of E-nside $vs.$ 69% of t-Branch ($p < .001$), with less frequent thoracic endografting (14% $vs.$ 76%; $p < .001$) and shorter length of coverage ($p = .024$) in extent IV TAAA treated by E-nside. E-nside cases had shorter renal artery bridging lengths (66 ± 17 mm $vs.$ 76 ± 20 mm; $p < .010$) and less frequent use of a distal bifurcated endograft (53% $vs.$ 80%; $p < .001$). Comparing 30 day results, the mortality rate was 1% $vs.$ 2% ($p = .62$), any MAE occurred in 18% $vs.$ 21% ($p = .55$), the stroke rate was 3% $vs.$ 0% ($p = .23$), and the elective spinal cord ischaemia rate was 5% $vs.$ 8% ($p = .40$) for E-nside and t-Branch, respectively. At one year, freedom from target vessel instability was 96 ± 3% for E-nside and 95 ± 3% for t-Branch ($p = .58$), and freedom from endograft instability was 98 ± 2% $vs.$ 97 ± 3% ($p = .46$), respectively.
Conclusion: Both off the shelf devices provided excellent early and one year results. The E-nside may require shorter thoracic aortic coverage and bridging length for the renal arteries, and less frequent implantation of a concomitant proximal thoracic or distal abdominal bifurcated endograft. However, these aspects did not determine significant differences in clinical outcomes.

[†] A list of the B.R.I.O. (BRanched Inner − Outer) Investigators is included in Appendix A.

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INTRODUCTION

Thoraco-abdominal aortic aneurysm (TAAA) repair has evolved progressively towards a minimally invasive endovascular approach for most patients, reserving total open repair for selected cases.[1–4] Over the last 20 years, different types of endografts have been developed for incorporation of the visceral and renal vessels through directional branches.

More recently, off the shelf branched endografts have been commercialised. The first commercially available device was the Zenith t-Branch (Cook Medical, Bloomington, IN, USA), which was introduced in 2012 and consists of a single conformation main endograft with four outer, downward oriented, directional branches. In 2020, the E-nside (Artivion; Kennesaw, GA, USA) received the CE mark and became commercially available. It is available in four sizes, with four pre-loaded, downward oriented inner branches. Although the outer branched off the shelf conformation demonstrated excellent results even in complex anatomies,[5,6] the inner branched design along with the pre-loaded system has primarily been developed to facilitate the procedure and improve technical success, as well as to expand feasibility in cases with specific anatomical challenges such as a narrow or tortuous aorta.

These two different standardised endograft solutions carry the similar advantage of a readily available device that can be implanted in symptomatic, urgent, or emergency cases. On the other hand, their different geometric structure and implantation procedures may lead to different indications and outcomes. Being commercially available for more than 10 years, several single and multicentre experiences have described excellent outcomes for t-Branch both in elective and urgent settings.[6–11] More recently, excellent outcomes have also been reported with the E-nside endograft.[12]

However, to date, no studies have been reported comparing the clinical outcomes between t-Branch and E-nside devices. The aim of this multicentre study was to compare early and midterm outcomes of these two off the shelf devices.

METHODS

Study design

A multicentre retrospective study was conducted including consecutive patients treated in 11 Italian vascular centres. The study was physician initiated and not sponsored. Centres were included only if using both E-nside and t-Branch devices throughout the study period. To account for the later introduction to the market of the E-nside (2020), only patients treated during the period 2020 – 2023 were included in the analysis. Only patients with a TAAA were included, while patients treated for a pararenal or juxtarenal aortic aneurysm were excluded. Institutional review board and ethics committee approval were required by each participating institution.

Peri-operative patient management

Decisions on surgical indications, patient and device selection, surgical technique, and peri-operative care were not standardised and were at the discretion of the treating centre. Bridging stents were self expandable (Gore Viabahn, Bard Covera, Scitech Solaris) or balloon expandable (Gore VBX, Getinge Advanta, Bentley BeGraft/BeGraft+, Artivion Eventus, other). Spinal cord protection was generally based on current recommendations on neuromonitoring, haemoglobin level, and arterial pressure control. Surgical staging was performed for I – III TAAA if clinically possible, either via thoracic endovascular aortic repair (TEVAR) followed by branched endovascular aortic repair (BEVAR), or by temporary aneurysm sac perfusion. Prophylactic drainage was not routinely used but was considered for extensive I – III TAAAs.[1,13,14] Therapeutic drainage was adopted in the case of spinal cord ischaemia (SCI). Dual antiplatelet therapy was usually prescribed for at least one month after the procedure.

Data collection and definitions

Anonymised data were entered by delegates from each participating centre. Data for all patients were collected on an intention to treat basis in a combined database. Demographics, clinical and anatomical characteristics, peri-operative data, 30 day results, and one year outcomes were collected. Aneurysm classification was based on extent of aneurysmal disease evaluated by computed tomography angiography (CTA) according to the Society for Vascular Surgery reporting standards.[2] Other pre-operative anatomical characteristics, such as maximum aortic diameter, minimum aortic lumen diameter at the visceral level, and iliac access size, were assessed on the pre-operative CTA. Pre-operative aortic angulation was assessed as previously reported.[15] Proximal aortic length coverage was measured on the post-operative CTA as the centreline distance covered by the endograft above the level of the coeliac trunk ostium. The branch length was measured as the distance between the branch proximal radiopaque marker and the distal edge of the covered bridging stent along the branch centreline.[16]

Major adverse events (MAEs) included severe acute kidney injury, new onset dialysis, myocardial infarction, respiratory failure requiring prolonged mechanical ventilation or re-intubation, paraplegia, stroke, bowel ischaemia requiring surgical resection or intensive medical care, and estimated blood loss > 1 L. Spinal cord ischaemia was classified according to the current reporting standards.[2] Follow up imaging was left to the treating centre but generally included CTA within one month, at six and 12 months, and yearly thereafter.

E-nside

The graft design and step by step operative technique have been described previously.[12,17] The device is a nitinol inner branched endograft with a 24 Fr outer diameter delivery

Table 1. Demographics and clinical characteristics of 163 patients with thoraco-abdominal aortic aneurysm (TAAA) treated with off the shelf inner branched E-nside or outer branched t-Branch endografts.

Characteristic	Overall				Extent I–III TAAA			Extent IV TAAA		
	E-nside (n = 79)	t-Branch (n = 84)	Total (n = 163)	p	E-nside (n = 36)	t-Branch (n = 55)	p	E-nside (n = 43)	t-Branch (n = 29)	p
Age − y	74.0 ± 8.8	74.0 ± 8.2	74.0 ± 8.5	.96	72.9 ± 9.8	73.2 ± 8.5	.86	74.8 ± 7.8	75.5 ± 7.6	.71
Male sex	57 (72)	62 (74)	119 (73.0)	.81	21 (58)	36 (65)	.49	36 (84)	26 (90)	.47
BMI − kg/m^2	26.7 ± 5.2	25.4 ± 4.6	26.2 ± 5.0	.19	25.8 ± 3.9	25.4 ± 4.6	.71	27.4 ± 6.0	25.0 ± 4.7	.39
Coronary artery disease	26 (33)	34 (40)	60 (36.8)	.31	11 (31)	21 (38)	.45	15 (35)	13 (45)	.39
Chronic heart failure	10 (13)	19 (23)	29 (17.8)	.076	4 (11)	12 (22)	.17	6 (14)	7 (24)	.21
Hypertension	72 (91)	79 (94)	151 (92.6)	.47	33 (92)	52 (95)	.58	39 (91)	27 (93)	.71
Hypercholesterolaemia	54 (68)	59 (70)	113 (69.3)	.79	22 (61)	40 (73)	.24	32 (74)	19 (66)	.41
Tobacco use	51 (65)	47 (56)	98 (60.1)	.39	20 (56)	29 (53)	.86	31 (72)	18 (62)	.63
COPD	38 (48)	34 (40)	72 (44.2)	.32	14 (39)	16 (29)	.33	24 (56)	18 (62)	.59
Peripheral arterial disease	9 (11)	8 (10)	17 (10.4)	.69	4 (11)	5 (9)	.75	5 (12)	3 (10)	.86
Diabetes mellitus	10 (13)	13 (15)	23 (14.1)	.60	3 (8)	9 (16)	.26	7 (16)	4 (14)	.77
Stroke or TIA	10 (13)	9 (11)	19 (11.7)	.58	3 (8)	5 (9)	.71	7 (16)	4 (14)	.77
ASA classification	3.0 ± 0.7	3.0 ± 0.7	3.0 ± 0.7	.81	2.9 ± 0.7	2.9 ± 0.7	.81	3.0 ± 0.7	3.1 ± 0.7	.35
Genetically triggered aortic disease	2 (3)	1 (1)	3 (1.8)	.52	2 (6)	1 (2)	.32	0 (0)	0 (0)	.099
Prior open abdominal aortic repair	23 (29)	19 (23)	42 (25.8)	.34	14 (39)	13 (24)	.11	9 (21)	6 (21)	.98
Prior endovascular abdominal aortic repair	18 (23)	26 (31)	44 (27.0)	.24	8 (22)	18 (33)	.28	10 (23)	8 (28)	.68
Prior thoracic repair	8 (10)	4 (5)	12 (7.4)	.24	7 (19)	4 (7)	.11	1 (2)	0 (0)	1.0

Data are presented as *n* (%) or mean ± standard deviation. TAAA = thoraco-abdominal aortic aneurysm; BMI = body mass index; COPD = chronic obstructive pulmonary disease; TIA = transient ischaemic attack; ASA = American Society of Anesthesiologists.

system, available in four different sizes (proximal diameter 38/33 mm; distal diameter 30/26 mm). All inner branches are pre-cannulated with a polyimide tube that can be loaded with a 0.018″ wire from the handle system and snared from above the top of the graft using an upper limb or contralateral femoral approach. According to the manufacturer's instructions for use, the device should land on a thoracic endograft, but in clinical practice it has also been safely used without TEVAR.[12] Potential advantages are conformability to different aortic diameters, easy cannulation of the pre-loaded branches, and adaptation to a narrow aortic diameter.

t-Branch

The t-Branch is a stainless steel graft with a single version (34 mm proximal diameter, 18 mm distal diameter, and four outer branches), in a 22 Fr internal (24 Fr external) delivery system. The endovascular procedure is intended to be completed by distal deployment of a bifurcated Zenith Universal Distal Body Endovascular Graft (Unibody; Cook Medical) landing in the iliac arteries. The potential advantages are easier advancement in challenging iliac access and a traditional pull back deployment mechanism.

Endpoints

Primary study endpoints were technical success and 30 day survival. Device technical success was defined by successful aneurysm exclusion without type I or III endoleak, conversion to open repair, or intra-operative death.[7] Branch technical success was defined by successful catheterisation and stent placement in all intended target vessels, without occlusion, severe kink or stenosis, component separation, or type Ic or III endoleak.[2] Secondary endpoints were target vessel instability and endograft instability at one year. Target vessel instability was defined by any target vessel related complication leading to aneurysm rupture, death, occlusion, component separation, or re-intervention to maintain target vessel patency or to treat a target vessel related component separation or endoleak.[2] Endograft instability was defined by any event related to the aortic graft component that was associated with patient death, aneurysm rupture, infection, or re-intervention, excluding target vessel related events, which are described under the definition of target vessel instability.[2]

Statistical analysis

Results are reported as number and percentage for categorical variables and as mean ± standard deviation or median and interquartile range for continuous variables. Continuous variables were compared with the Wilcoxon rank sum test or *t* test, as appropriate. Pearson's χ^2 test and Fisher's exact test were used for analysis of categorical variables. Time dependent variables were estimated using Kaplan–Meier curves and were compared with the log rank test. A *p* value of .050 was used to determine statistical significance. R 4.3 software (R Foundation for Statistical Computing, Vienna, Austria) was used for statistical analysis.

Table 2. Anatomical characteristics of 163 patients with thoraco-abdominal aortic aneurysm (TAAA) treated with off the shelf inner branched E-nside or outer branched t-Branch endografts.

Characteristic	Overall				Extent I–III TAAA			Extent IV TAAA		
	E-nside (n = 79)	t-Branch (n = 84)	Total (n = 163)	p	E-nside (n = 36)	t-Branch (n = 55)	p	E-nside (n = 43)	t-Branch (n = 29)	p
Aortic pathology				.005			.042			.068
Degenerative aneurysm	65 (82)	78 (93)	143 (87.7)		30 (83)	50 (91)		35 (81)	28 (97)	
Acute or subacute dissection	1 (1)	5 (6)	6 (3.7)		1 (3)	5 (9)		0 (0)	0 (0)	
Chronic dissection	6 (8)	1 (1)	7 (4.3)		5 (14)	0 (0)		1 (2)	1 (3)	
Pseudoaneurysm	6 (8)	0 (0)	6 (3.7)		0 (0)	0 (0)		6 (14)	0 (0)	
IMH/PAU	1 (1)	0 (0)	1 (0.6)		0 (0)	0 (0)		1 (2)	0 (0)	
Aneurysm type				.011			—			—
Extent I–III	36 (46)	55 (65)	91 (55.8)		36 (100)	55 (100)		—	—	
Extent IV	43 (54)	29 (35)	72 (44.2)		—	—		43 (100)	29 (100)	
Largest diameter of aortic aneurysm – mm	74.0 ± 8.8	74.0 ± 8.2	74.0 ± 8.5	.61	72.9 ± 9.8	73.2 ± 8.5	.72	74.8 ± 7.8	75.5 ± 7.6	.39
Status of aneurysm				.051			.017			.61
Asymptomatic, non-ruptured	62 (78)	67 (80)	129 (79.1)		26 (72)	44 (80)		36 (84)	23 (79)	
Symptomatic, non-ruptured	16 (20)	10 (12)	26 (16.0)		10 (28)	6 (11)		6 (14)	4 (14)	
Contained rupture	1 (1)	7 (8)	8 (4.9)		0 (0)	5 (9)		1 (2)	2 (7)	
Aortic diameter at CT level – mm	26.7 ± 5.2	25.4 ± 4.6	26.2 ± 5.0	.76	25.8 ± 3.9	25.4 ± 4.6	.13	27.4 ± 6.0	25.0 ± 4.7	.027
Aortic diameter at SMA level – mm	3.0 ± 0.7	3.0 ± 0.7	3.0 ± 0.7	.39	2.9 ± 0.7	2.9 ± 0.7	.64	3.0 ± 0.7	3.1 ± 0.7	.17
Aortic diameter at RRA level – mm	65.7 ± 14.3	66.8 ± 13.3	66.3 ± 13.8	.44	64.1 ± 10.3	65.0 ± 13.8	.080	67.1 ± 17.0	70.3 ± 11.8	.059
Aortic diameter at LRA level – mm	37.8 ± 11.5	37.1 ± 10.8	37.5 ± 11.3	.86	43.6 ± 12.7	39.1 ± 10.3	.20	32.8 ± 7.4	25.0 ± 3.5	.041
Minimum visceral aortic diameter – mm	36.0 ± 11.2	38.1 ± 12.5	36.7 ± 11.6	.53	38.6 ± 11.6	40.0 ± 12.6	.81	33.8 ± 10.6	27.2 ± 3.7	.039
Minimum iliac access diameter – mm	8.7 ± 2.1	8.6 ± 1.7	8.7 ± 2.0	.78	8.6 ± 1.6	8.4 ± 2.1	.81	8.9 ± 2.3	8.8 ± 2.0	.94
Aortic infrarenal angle – °	37.6 ± 11.7	38.0 ± 13.8	37.7 ± 12.3	.69	36.3 ± 10.5	40.2 ± 14.0	.85	38.7 ± 12.7	27.5 ± 6.3	.45
Aortic pararenal angle – °	32.0 ± 8.3	31.0 ± 8.5	31.6 ± 8.4	.98	33.7 ± 9.3	33.1 ± 9.2	.89	30.6 ± 7.2	26.3 ± 3.9	.39
Aortic supracoeliac angle – °	8.7 ± 2.1	8.6 ± 1.7	8.7 ± 1.9	.81	8.6 ± 2.2	8.4 ± 1.8	.82	8.8 ± 2.0	9.0 ± 1.2	.38

Data are presented as *n* (%) or mean ± standard deviation. TAAA = thoraco-abdominal aortic aneurysm; IMH/PAU = intramural haematoma or penetrating aortic ulcer; CT = coeliac trunk; SMA = superior mesenteric artery; RRA = right renal artery; LRA = left renal artery.

RESULTS

Patient population

There were 163 patients treated in 11 centres (mean of 15 patients per centre), comprising 79 patients (48.5%) treated with E-nside and 84 patients (51.5%) treated with t-Branch. The mean age was 74.0 ± 8.5 years, and 119 patients (73.0%) were male. Demographics, risk factors, and clinical data are described in Table 1. The mean largest aneurysm diameter was 74.0 ± 8.8 mm in the E-nside group and 74.0 ± 8.2 mm in the t-Branch group (*p* = .61). Aneurysm anatomical classification was extent I – III in 47% and extent IV in 53% of patients in the E-nside group, and extent I – III in 66% and extent IV in 34% of patients in the t-Branch group (*p* = .011).

Minimum paravisceral aortic diameter (mean 36.0 ± 11.2 mm, range 18 – 57 mm *vs.* mean 38.1 ± 12.5 mm, range 20 – 49 mm; *p* = .53), minimum iliac access diameter (8.7 ± 2.1 mm *vs.* 8.6 ± 1.7 mm; *p* = .78), and aortic angulation were similar in the two groups (*p* = .69), also after stratification by aneurysm extent (Table 2). Minimum paravisceral diameter < 25 mm was present in 28 (35%) E-nside and 19 (22%) t-Branch (*p* = .084).

Peri-procedural data

An urgent or emergency intervention was performed in 35% of patients receiving the E-nside and in 30% of those receiving the t-Branch (*p* = .50); a ruptured TAAA was present in one (1%) E-nside and seven (8%) t-Branch

Table 3. Procedural data of 163 patients with thoraco-abdominal aortic aneurysm (TAAA) treated with off the shelf inner branched E-nside or outer branched t-Branch endografts.

Data	Overall				Extent I–III TAAA			Extent IV TAAA		
	E-nside ($n = 79$)	t-Branch ($n = 84$)	Total ($n = 163$)	p	E-nside ($n = 36$)	t-Branch ($n = 55$)	p	E-nside ($n = 43$)	t-Branch ($n = 29$)	p
Adjunctive TEVAR	34 (43)	58 (69)	92 (56.4)	<.001	28 (78)	36 (65)	.89	6 (14)	22 (76)	<.001
Staged TEVAR	20 (25)	13 (15)	33 (20.2)	.13	5 (14)	8 (15)	1.0	15 (35)	5 (17)	.12
Length of thoracic coverage – cm	171 ± 42.4	186 ± 37.0	179 ± 40.6	.082	211 ± 35	193 ± 46	.089	124 ± 22	183 ± 37	.024
Concomitant EVAR	42 (53)	67 (80)	109 (66.9)	<.001	12 (33)	41 (75)	<.001	30 (70)	26 (90)	.046
Percutaneous femoral access				.11			.53			.079
Unilateral	9 (11)	8 (10)	17 (10.4)		4 (11)	4 (7)		5 (12)	4 (14)	
Bilateral	57 (72)	70 (83)	127 (77.9)		26 (72)	45 (82)		31 (72)	25 (86)	
Brachial or axillary access	68 (86)	51 (61)	119 (73.0)	.002	32 (89)	35 (64)	.001	36 (84)	16 (55)	.014
Coeliac axis				.021			.31			.017
BE bridging stent	54 (68)	50 (60)	104 (63.8)		27 (75)	34 (62)		27 (63)	16 (55)	
SE bridging stent	20 (25)	31 (37)	51 (31.3)		8 (22)	19 (35)		12 (28)	12 (41)	
Intentional occlusion	5 (6)	3 (4)	8 (4.9)		1 (3)	2 (4)		4 (9)	1 (3)	
Coeliac axis stent length – mm	55.3 ± 17.9	59.1 ± 15.9	57.2 ± 15.9	.91	57.2 ± 16.6	58.7 ± 14.8	.32	54.9 ± 17.2	59.9 ± 16.2	.102
Coeliac axis adjunctive BMS	21 (27)	25 (30)	46 (28.2)	.65	6 (17)	15 (27)	.24	15 (35)	10 (34)	.97
SMA				.82			.25			.17
BE bridging stent	53 (67)	55 (65)	108 (66.3)		20 (56)	37 (67)		33 (77)	18 (62)	
SE bridging stent	26 (33)	29 (3.5)	55 (33.7)		16 (44)	18 (33)		10 (23)	11 (38)	
SMA adjunctive BMS	12 (15)	21 (25)	33 (20.2)	.12	2 (6)	13 (24)	.023	10 (23)	8 (28)	.67
SMA stent length – mm	63.9 ± 10.9	62.6 ± 13.4	63.2 ± 12.7	.97	64.2 ± 10.7	63.6 ± 12.6	.97	63.7 ± 10.9	62.4 ± 13.2	.30
LRA				.001			.012			.001
BE bridging stent	23 (29)	53 (63)	76 (46.6)		11 (31)	33 (60)		12 (28)	20 (69)	
SE bridging stent	53 (67)	26 (31)	79 (48.5)		25 (69)	20 (36)		28 (65)	6 (21)	
Intentional occlusion	3 (4)	5 (6)	8 (4.9)		0 (0)	2 (4)		3 (7)	3 (10)	
Stent length – mm	65.5 ± 21.0	76.7 ± 23.5	73.9 ± 22.3	.095	65.5 ± 21.0	75.6 ± 23.5	.91	65.5 ± 21.0	72.7 ± 21.5	.001
Adjunctive BMS	24 (30)	38 (45)	62 (38.0)	.50	12 (33)	24 (44)	.32	12 (28)	14 (48)	.077
RRA				.001			.26			.001
BE bridging stent	24 (30)	48 (57)	72 (44.2)		14 (39)	30 (55)		10 (23)	18 (62)	
SE bridging stent	53 (67)	33 (39)	86 (52.8)		21 (58)	24 (44)		32 (74)	9 (31)	
Intentional occlusion	2 (3)	3 (4)	5 (3.1)		1 (3)	1 (2)		1 (2)	2 (7)	
Stent length – mm	66.4 ± 12.9	76.6 ± 14.7	69.5 ± 13.8	.004	67.1 ± 14.0	78.6 ± 14.6	.001	61.9 ± 13.3	67.6 ± 12.2	.003
Adjunctive BMS	17 (22)	8 (10)	25 (15.3)	.033	7 (19)	7 (13)	.38	10 (23)	1 (3)	.021
Total operating time – min	271 ± 103	264 ± 82	267 ± 74	.12	289.2 ± 90.1	268.5 ± 83.8	.49	260.2 ± 118.3	248.5 ± 72.0	.16
Total contrast used – mL	172 ± 115	196 ± 83	184 ± 96	.042	186 ± 115	224 ± 83	.21	165 ± 108	181 ± 74	.15
Fluoroscopy time – min	95 ± 49	87 ± 39	92 ± 45	.39	100.1 ± 19.9	105.4 ± 17.1	.17	85.1 ± 13.1	79.3 ± 15.3	.12
Radiation dose – Gy·cm^2	312.1 ± 286.3	331.2 ± 267.4	318.7 ± 239.2	.62	319.9 ± 294.8	345.9 ± 290.5	.67	308.9 ± 260.8	325.2 ± 283.5	.43

Data are presented as *n* (%) or mean ± standard deviation. TAAA = thoraco-abdominal aortic aneurysm; TEVAR = thoracic endovascular aortic repair; EVAR = endovascular aneurysm repair; BE = balloon expandable; SE = self expandable; BMS = bare metal stent; SMA = superior mesenteric artery; LRA = left renal artery; RRA = right renal artery.

Table 4. Early outcomes of 163 patients with thoraco-abdominal aortic aneurysm (TAAA) treated with off the shelf inner branched E-nside or outer branched t-Branch endografts.

Outcome	Overall				Extent I−III TAAA			Extent IV TAAA		
	E-nside ($n = 79$)	t-Branch ($n = 84$)	Total ($n = 163$)	p	E-nside ($n = 36$)	t-Branch ($n = 55$)	p	E-nside ($n = 43$)	t-Branch ($n = 29$)	p
Death	1 (1)	2 (2)	3 (1.8)	.62	1 (3)	1 (2)	.72	0 (0)	1 (3)	.22
Any MAE	14 (18)	18 (21)	32 (19.6)	.55	7 (19)	11 (20)	.67	7 (16)	7 (24)	.41
Estimated blood loss > 1 L	7 (9)	8 (10)	15 (9.2)	.88	3 (8)	5 (9)	.90	4 (9)	3 (10)	.88
Myocardial infarction	1 (1)	1 (1)	2 (1.2)	.96	1 (3)	1 (2)	.76	0 (0)	0 (0)	1.0
Respiratory failure	6 (8)	4 (5)	10 (6.1)	.56	3 (8)	3 (5)	.58	3 (7)	1 (3)	.52
Major stroke	2 (3)	0 (0)	2 (1.2)	.34	1 (3)	0 (0)	.64	1 (2)	0 (0)	.45
Any spinal cord injury*	4 (5)	9 (11)	13 (8.0)	.21	2 (6)	8 (15)*	.17	2 (5)	1 (3)	.80
Elective repair	4 (5)	7 (8)	11 (6.7)	.43	2 (6)	6 (11)	.38	2 (5)	1 (3)	.80
Urgent repair	0 (0)	2 (2)	2 (1.2)	.34	0 (0)	1 (2)	.64	0 (0)	1 (3)	.45
Acute kidney injury	11 (14)	6 (7)	17 (10.4)	.15	5 (14)	4 (7)	.30	6 (14)	2 (7)	.35
Gastrointestinal complication	3 (4)	3 (4)	6 (3.7)	.93	1 (3)	3 (5)	.54	2 (5)	0 (0)	.51
Vascular or access complication	10 (13)	8 (10)	18 (11.0)	.52	5 (14)	5 (9)	.47	5 (12)	3 (10)	.86

Data are presented as n (%). TAAA = thoraco-abdominal aortic aneurysm; MAE = major adverse event.
* In the t-Branch group, two cases were treated in an emergency setting owing to frank aortic rupture.

($p = .051$), and a symptomatic non-ruptured aneurysm was present in 16 (20%) E-nside and 10 (12%) t-Branch cases ($p = .28$). Eight (10%) E-nside and four (5%) t-Branch patients had a prior remote thoracic endograft ($p = .24$). Procedure staging was performed in 82 patients (50.3%), by TEVAR followed by BEVAR (20 E-nside and 13 t-Branch; $p = .080$) or by temporary aneurysm sac perfusion (26 E-nside and 23 t-Branch; $p = .49$); A concomitant TEVAR was performed within the same procedure in 34 (43%) E-nside and 58 (69%) t-Branches ($p < .001$). For extent IV, six (14%) TAAAs treated by E-nside and 22 (76%) by t-Branch required proximal thoracic endografting ($p < .001$), with a mean thoracic aortic coverage of 124 ± 22 mm for E-nside and 183 ± 37 for t-Branch ($p = .024$). For patients with extent I − III TAAA, 28 (78%) E-nside and 36 (65%) t-Branch needed a proximal TEVAR ($p = .24$), with a mean thoracic aorta coverage of 211 ± 35 mm for E-nside and 193 ± 46 mm for t-Branch ($p = .089$) (Table 3).

Upper limb access was used for branch bridging in 69 (87%; 51 from the left side and 18 from the right side) E-nside and 53 (63%; 40 from the left side and 13 from the right side) t-Branch; a total transfemoral approach was adopted in 10 (13%) and 31 (37%) cases, respectively ($p < .001$). Successful catheterisation and stenting of the intended target vessels were performed in 97% ($n = 307$ target vessels) of E-nside and 97% ($n = 325$ target vessels) of t-Branch patients ($p = 1.0$); a successful intentional branch occlusion was performed in seven (2%) inner branches and nine outer branches (3%) (eight pre-operatively occluded coeliac arteries and eight occluded or ≤ 3 mm stenotic renal arteries). Unsuccessful target vessel bridging followed by branch occlusion was performed in three inner branches (one stenotic coeliac artery, two small renal arteries ≤ 4 mm) and two outer branches (two stenotic/small renal arteries) ($p = 1.0$). Characteristics of the bridging stents are shown in Table 3. A balloon expandable stent was used in 154 (50.2%) target vessels with E-nside and 206 (63.4%)

with t-Branch ($p = .009$). Bridging stent reinforcement was more often performed with self expandable stents ($p = .001$); this strategy was more often adopted for the bridging of renal arteries with E-nside ($p = .001$). The total branch lengths in the E-nside and t-Branch groups were 55 ± 17 mm vs. 59 ± 15 mm ($p = .91$) for the coeliac trunk, 63 ± 11 mm vs. 62 ± 13 for the superior mesenteric artery ($p = .97$), and 66 ± 17 vs. 76 ± 20 mm for the renal arteries ($p < .001$). This result was maintained after stratification by aneurysm anatomical classification.

A distal extension with a bifurcated abdominal graft was performed in 53% of E-nside and 80% of t-Branch cases ($p < .001$). Overall, the total operating time was 271 ± 103 minutes for E-nside and 264 ± 82 minutes for t-Branch ($p = .12$); fluoroscopy time was 95 ± 49 minutes vs. 87 ± 39 minutes ($p = .39$), contrast volume was 172 ± 115 mL vs. 196 ± 83 mL ($p = .042$), and radiation dose was 312.1 ± 286.3 Gy·cm^2 vs. 331.2 ± 267.4 Gy·cm^2 ($p = .62$).

Thirty day outcomes

Device technical success was 100% in both groups, with complete final aneurysm exclusion in all cases. Early death occurred in one case (1%) of E-nside (owing to multi-organ failure) and two cases (2%) of t-Branch (one each due to multi-organ failure and sepsis) ($p = .62$) (Table 4). The stroke rate was 3% ($n = 2$) with E-nside and 0% with t-Branch ($p = .23$); both had an ischaemic stroke with permanent deficit, occurring in patients using left brachial access. Spinal cord ischaemia in elective cases occurred in four (5%; two extent I − III and two extent IV TAAAs) E-nside and seven (8%; six extent I − III and one extent IV TAAA) t-Branch ($p = .40$). Two additional patients treated with t-Branch for ruptured TAAA developed SCI, while no case of ruptured TAAA treated with E-nside had SCI. Overall, SCI was permanent in 11 cases (6.7%). An intra- or

post-operative vascular access complication occurred in 13% (seven femoral pseudoaneurysm, one iliac rupture, two femoral dissection or occlusion) of E-nside and 10% (seven femoral pseudoaneurysm, one femoral dissection or occlusion) of t-Branch ($p = .52$), and was successfully treated in all cases. The 30 day re-intervention rate was 13% ($n = 10$; five access related, one type 1a endoleak, and four branch related) for E-nside and 15% ($n = 13$; six access related and seven branch related) for t-Branch ($p = .65$). Other early MAEs, stratified by aneurysm anatomical extent, are detailed in Table 4. In the subset of patients with a paravisceral aorta diameter < 25 mm, technical success was 100% and the MAE rate was 23% for E-nside *vs.* 20% for t-Branch ($p = .74$). There was 100% technical success and no MAE in chronic dissections treated by E-nside ($n = 6$).

One year outcomes

Median follow up duration was 11 months (E-nside, 10 months; t-Branch, 12 months; $p = .21$); 65 patients had their one year CTA and seven patients (4%) were lost to follow up. One year survival was 81% ($n = 11$; 95% confidence interval [CI] $71 - 93$%) for E-nside and 76% ($n = 16$; 95% CI $66 - 87$%) for t-Branch ($p = .31$). There were no cases of aneurysm rupture during follow up. Of the 632

incorporated target vessels (307 E-nside and 325 t-Branch), there were 25 cases of target vessel instability, 15 branch occlusions, and 10 target vessel endoleaks leading to re-intervention. Freedom from target vessel instability at one year was 96% (95% CI $94 - 99$%) for E-nside and 95% (95% CI $93 - 98$%) for t-Branch ($p = .58$). Primary target vessel patency was 97% (four renal and two visceral artery occlusions; 95% CI $95 - 99$%) *vs.* 97% (three renal and four visceral artery occlusions; 95% CI $95 - 99$%) ($p = .80$), and freedom from target vessel endoleaks leading to re-intervention was 98% (95% CI $97 - 100$) *vs.* 98% (95% CI $97 - 100$) ($p = .84$), respectively (Fig. 1). Specific rates of target vessel instability stratified by aneurysm extent are reported in Figure 2. A narrow paravisceral aorta (< 25 mm) did not determine differences between the two endografts in one year target vessel instability (77%; 95% CI $72 - 100$% *vs.* 82%; 95% CI $75 - 100$%; $p = .62$), as well as type of stent.

After one year of follow up there was one endograft related re-intervention in the E-nside group owing to a type 1a endoleak. In the t-Branch group there were two endograft related re-interventions, one for an iliac limb occlusion and one for a type 1b endoleak. The resulting freedom from endograft instability was 98% (95% CI $96 - 99$%) for E-nside and 97% (95% CI $93 - 100$%) for t-Branch ($p = .46$).
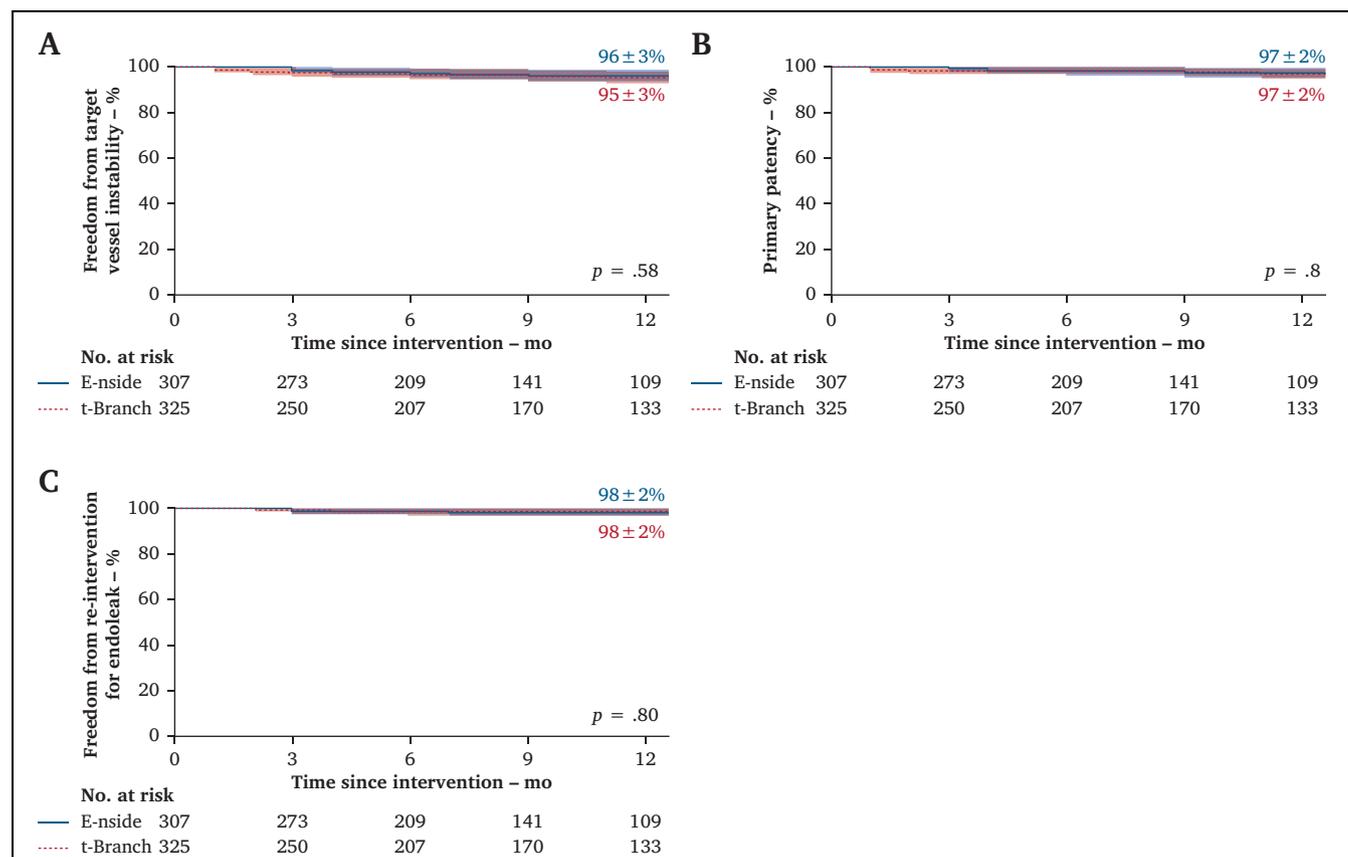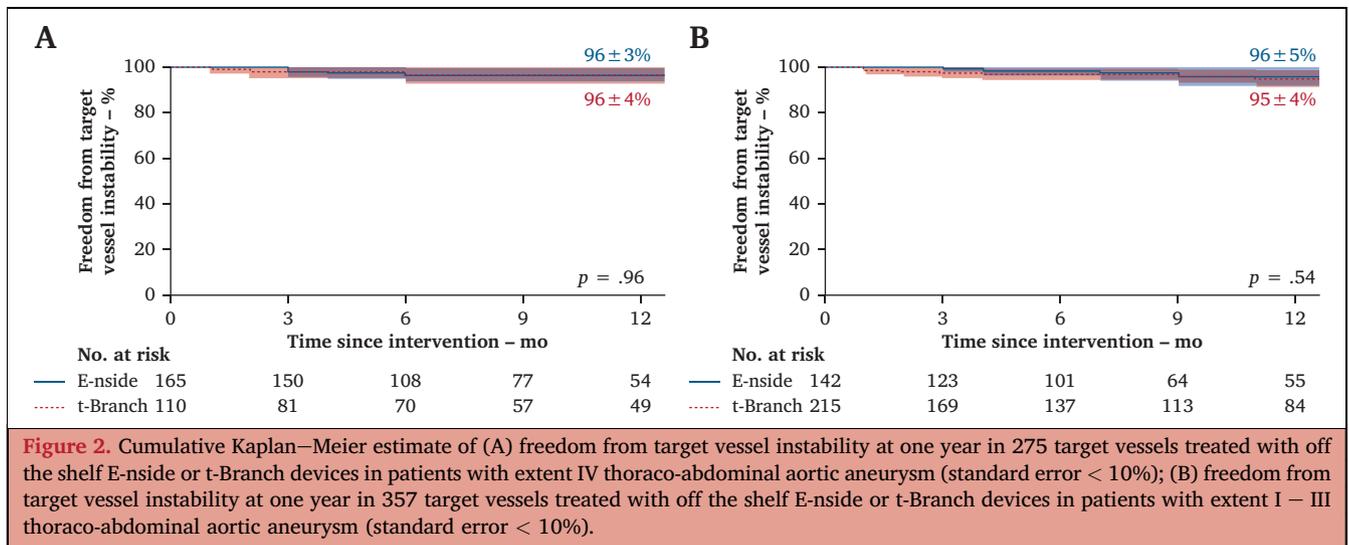

Figure 1. Cumulative Kaplan–Meier estimate of (A) freedom from target vessel instability at one year in 632 target vessels treated with off the shelf E-nside or t-Branch devices. Standard error < 10%; (B) primary target vessel patency at one year in 632 target vessels treated with off the shelf E-nside or t-Branch devices. Standard error < 10%; (C) freedom from re-intervention for target vessel endoleak at one year in 632 target vessels treated with off the shelf E-nside or t-Branch devices. Standard error < 10%.

Figure 2. Cumulative Kaplan−Meier estimate of (A) freedom from target vessel instability at one year in 275 target vessels treated with off the shelf E-nside or t-Branch devices in patients with extent IV thoraco-abdominal aortic aneurysm (standard error < 10%); (B) freedom from target vessel instability at one year in 357 target vessels treated with off the shelf E-nside or t-Branch devices in patients with extent I − III thoraco-abdominal aortic aneurysm (standard error < 10%).

DISCUSSION

Overall, the investigated off the shelf stent grafts were shown to be comparable, with excellent device technical success, branch related technical success, and effective TAAA exclusion, both in elective and urgent cases. The overall MAE rate was 22%, with the main events being represented by SCI (8%), stroke (2%), and vascular access complications (11%) for both endografts.

Nevertheless, the different technical characteristics of the devices influenced some remarkable aspects. Length of aortic coverage is an important point to be considered in thoraco-abdominal endovascular procedures as it may be associated with the risk of SCI.[1,13,18] Proximal aortic coverage is primarily related to the identification of a non-diseased aortic segment above the aneurysm, and also to the presence of a diameter that fits the standardised proximal diameter of these grafts. The t-Branch has a single proximal conformation (34 mm in diameter), and a proximal TEVAR may be required if the aortic diameter is unsuitable. The E-nside has two available proximal diameters (33 mm and 38 mm), thus theoretically increasing the range of aortic size that can be treated without the need for additional proximal endografting. The aortic coverage above the coeliac trunk was about 185 mm for t-Branch and 170 mm for E-nside. Also, in the overall cohort of TAAAs there was a higher number of concomitant TEVARs for t-Branch, which was related to the more frequent use of TEVAR in the subset of type IV TAAAs (14% *vs.* 83%; *p* < .001). Also, length of thoracic coverage was significantly shorter with E-nside in the subset of type IV TAAAs (*p* = .024). The thoracic aorta is generally non-aneurysmal for extent IV and may benefit from the branched device alone without the need for an additional TEVAR.

The concept of aortic coverage has traditionally been put in relation to the proximal thoracic aorta, yet distal coverage may also be important. Data from custom made devices showed that landing in the infrarenal aorta may provide a reduction in procedural metrics, maintaining similar early and midterm results.[19] With off the shelf

devices, the choice to use the infrarenal aorta for distal landing depends on aortic anatomy and available distal device diameter. The t-Branch has a distal 18 mm diameter and usually requires a bifurcated graft to complete the distal sealing. The two different distal conformations of E-nside (26 mm and 30 mm) may enable distal sealing without a bifurcated device in some anatomical situations, thus sparing spinal collaterals and reducing operative metrics. In cases of previous surgical infrarenal aortic repair, or type I TAAA with a non-aneurysmal or just minimally ectatic distal aorta, the E-nside can accomplish distal sealing without bifurcated devices, thus reducing distal infrarenal aortic coverage. The overall number of infrarenal grafts on E-nside was statistically significantly lower compared with t-Branch (53% *vs.* 80%; *p* < .001). However, these differences in length of coverage did not significantly impact the SCI rate, and further studies are needed to clarify this aspect. Operating time was similar between the two groups, but this could be also related to the initial stage of the learning curve for this device in contrast to the many years of experience with t-Branch.

Branch design may impact branch related technical success and complications. In this analysis, both inner and outer branched devices demonstrated excellent technical success, with good results also in narrow aorta, with no cuff compression during implantation, and satisfactory branch stability maintained over one year. These results are in line with a previous large, single centre experience with t-Branch by Kölbel *et al.*[7] and with the clinical experience with E-nside.[12,20] On the other hand, branch length was significantly shorter for E-nside especially for the renals. Even though previous studies have reported that higher branch length may increase instability,[16] this was not associated with different clinical outcomes.

Another main difference between the two devices is the presence of pre-loaded branches in the E-nside. This is intended to be used from above and justifies the more frequent use of upper limb access in the case of E-nside. Although this may theoretically increase the risk of stroke,[21]

the number of events was very low in the current series ($n = 2$). Availability of the pre-loaded branches did not significantly impact procedural metrics; however, information about the time needed for each single branch completion is unavailable, and future studies may help understanding. The use of upper limb access also probably influenced the type of bridging stent, with a higher number of self expandable stents in the E-nside group. While the arm access maintains the possibility of using either a balloon expandable or self expandable bridging stent, the use of a balloon expandable stent is nearly mandatory for deployment from below with a steerable sheath (40% of t-Branch cases). Interestingly, endograft design and type of bridging stent did not significantly impact target vessel outcomes at one year.

This study had some notable limitations. The retrospective design, limited number of patients, and baseline differences between the two treatment groups (i.e., aneurysm extent) may have led to inherent bias. It was not possible to assess all comers for TAAA in each centre and their inclusion and the exclusion anatomical criteria for E-nside or t-Branch. The choice of endograft was left to the treating physician, and the implantation technique, peri-operative care, and follow up were not standardised across participating centres. The E-nside has more recently been introduced in the market than the t-Branch, and the reported results may reflect different stages in the learning curve. Also, although all included centres used both E-nside and t-Branch, the availability of the two endografts for emergency situations might have been different among centres. Despite these limitations, this study may help in the choice of the type of off the shelf graft. The use of E-nside may be preferred in cases with good iliac and femoral access, a regular infrarenal aorta with no need for an infrarenal bifurcated endograft, and when available E-nside diameters enable reduced length of aortic coverage. Also, for tortuous target vessel anatomy, use of the pre-loaded branches may be advantageous, while use of a pre-loaded system from above should be avoided for unfavourable aortic arch anatomy because of the risk of stroke. The t-Branch may be favoured for extensive large aneurysms requiring coverage of the entire aorta. The t-Branch is also preferred in the presence of more complex iliac and or femoral access because of better support and pushability.

The strengths of this study were its multicentre design, the selection of a contemporary series, extensive post-operative data collection, and accurate post-implantation CTA analysis for branch stability at one year.

Conclusions

Both the E-nside and t-Branch devices provided excellent early and one year results. The E-nside may require shorter thoracic aortic coverage and renal artery bridging length, as well as less frequent implantation of a concomitant proximal thoracic or distal abdominal bifurcated endograft. However, these aspects did not determine significant differences between the two endografts in early and one year clinical outcomes.

ETHICAL STATEMENT

Institutional review board and ethic committee approval were required by each participating institution.

CONFLICTS OF INTEREST

Michele Piazza: consultant for Artivion*; Giovanni Pratesi: consultant, research support, travel support, and proctoring for Cook; Gianbattista Parlani, consultant for Artivion; Gioele Simonte, consultant for Artivion; and Michele Antonello, consultant for Artivion*. (* All fees paid to the Department of Cardiac, Thoracic, Vascular Sciences and Public Health — Padova University.)

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2024.04.005.

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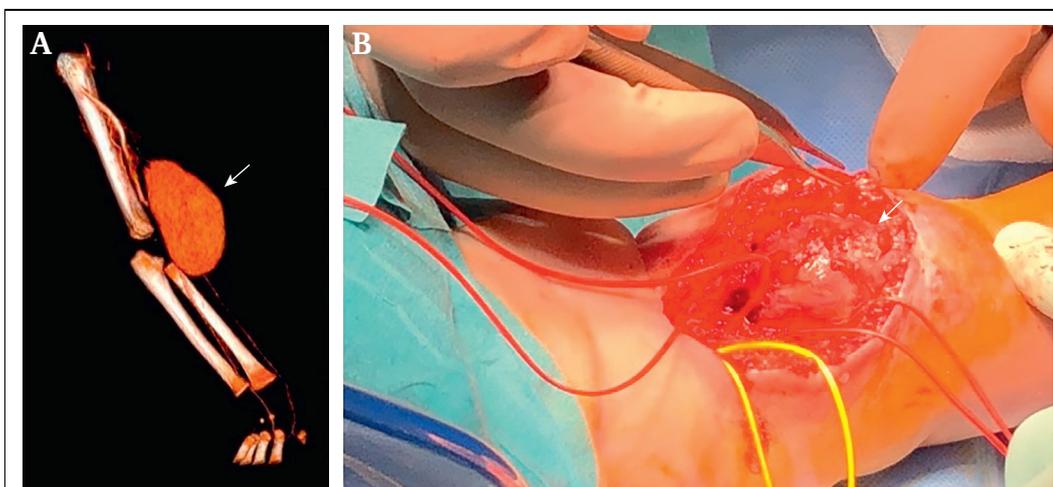
COUP D'OEIL

Giant Pseudoaneurysm of the Brachial Artery in a Newborn

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A one month old boy presented with an anteromedial pulsatile mass in the left upper extremity. He had previously undergone peripheral vein cannulation seven days before. Computed tomography angiography showed a pseudoaneurysm of the distal brachial artery measuring $50 \times 25 \times 30$ mm (A, arrow). Under general anaesthesia, the proximal and distal brachial artery were exposed (B, arrow), the pseudoaneurysm was resected and, after local infusion of heparin, the repair was performed with 9-0 polypropylene interrupted sutures using microsurgical loupes. The patient was discharged on post-operative day 4. He had full range of motion in the extremity without any neurological deficits at follow up two years later.

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