



Anatomic feasibility of off-the-shelf thoracic single side-branched endograft in patients with blunt traumatic thoracic aortic injury

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ABSTRACT

Objective: The advent of thoracic single side-branched endograft (TSSBE) has provided a treatment option to obviate the need for open cervical debranching of the left subclavian artery (LSA), thereby enabling total endovascular incorporation of the LSA during thoracic endovascular aortic repair (TEVAR). In a previous study of patients with type B aortic dissection who had required zone 2 TEVAR, the anatomic feasibility of this device was demonstrated to range from 28% to 35%, suggesting limited applicability of the currently available designs. The objectives of the present study were twofold: (1) to evaluate the anatomic feasibility of TSSBE in blunt traumatic thoracic aortic injury (BTAI) patients who would require LSA revascularization; and (2) to describe the anatomic characteristics of the supra-aortic arch branches that could be used to improve future device design.

Methods: A retrospective review was performed of BTAI patients who had undergone TEVAR at a single institution from November 2013 to October 2018. Preoperative computed tomography angiograms were analyzed using three-dimensional reconstruction to quantify the aortic diameter, distance and arc length between branch vessels, and the LSA diameter and length. We calculated the proportion of patients who had met all aortic and LSA anatomic requirements for TSSBE proposed by investigational protocols. We also assessed the effect of anatomic requirement modifications on device suitability. Finally, we assessed the local anatomic relationship between the supra-aortic branches.

Results: A total of 41 patients (63% men; median age, 39 years; range, 23-88 years; 68% normal aortic arch pattern, 32% bovine aortic arch pattern) with BTAI who had required TEVAR involving the LSA and were, thus, considered potential candidates for TSSBE were included. Of the 41 patients, 13 (32%; 7 with a bovine aortic arch and 6 with a normal aortic arch) had met all proposed aortic and LSA anatomic requirements for TSSBE. An appropriate aortic diameter, LSA diameter, and LSA length to its first branch were observed in 100%, 95%, and 66% of the patients, respectively. An insufficient distance between the arch branch vessels, observed in 41%, was the most common exclusionary criterion. The median clock-face position of the LSA was 12:00 (interquartile range, 30 minutes) in the normal arch group and 11:45 (interquartile range, 15 minutes) in the bovine arch group.

Conclusions: Despite the numerous potential advantages of TSSBE, only 32% of patients with BTAI requiring LSA revascularization had met all the aortic and LSA anatomic requirements, justifying the need for additional designs. Better characterization and mapping of the aortic arch branches will improve future device design and application. (*J Vasc Surg* 2021;74:1456-63.)

Keywords: Blunt traumatic thoracic aortic injury; Left subclavian artery; Off-the-shelf; TEVAR; Thoracic single side-branched endograft

Thoracic endovascular aortic repair (TEVAR) has been widely accepted as the primary treatment choice for blunt traumatic thoracic aortic injury (BTAI).¹⁻⁴ BTAI occurs most commonly at the aortic isthmus, 10 to 20 mm distal to the origin of the left subclavian artery

(LSA).⁵⁻⁷ This location implies that endograft coverage of the origin of the LSA could be required during TEVAR to secure an adequate proximal fixation and seal.

Intentional coverage of the LSA is possible; however, because of the extensive perfusion through the LSA,

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ischemic complications, including acute left arm ischemia, claudication, posterior stroke, and/or left subclavian steal syndrome, are possible consequences.^{5,8} Additionally, in patients with previous cardiac bypass surgery that had used the left internal mammary artery as a conduit, coverage of the LSA during acute TEVAR can result in cardiac ischemia and arrest. Furthermore, BTAI patients present with a wide range of concomitant injuries, and the risk of injury progression to dissection, pseudoaneurysm, and rupture remains poorly quantified. Thus, the current Society for Vascular Surgery guidelines for BTAI have recommended urgent repair with selective revascularization of the LSA.² However, in acute multiple trauma settings, LSA revascularization before TEVAR or concurrently might not be feasible. Furthermore, this subset of patients requiring urgent treatment will not be able to wait for a customized graft. These potential issues with LSA coverage and revascularization, and the need for immediate endograft availability, can be addressed using an off-the-shelf LSA-branched endograft.

At present, efforts are underway to create platforms for off-the-shelf arch fenestrated endografts to allow for endovascular supra-aortic revascularization during acute TEVAR. The thoracic single side-branched endograft (TSSBE; W.L. Gore and Associates, Flagstaff, Ariz) is a novel endograft device for zone 2 deployment with a side branch for LSA reconstruction.⁹ Intended as an off-the-shelf device, the TSSBE was initially studied for the treatment of thoracic aneurysms and is now in its pivotal trial phase with added trial arms for additional pathologies, including dissection and traumatic injuries.

In a recent study of patients with type B aortic dissection who required zone 2 TEVAR, the anatomic feasibility of the TSSBE was demonstrated to range from 28% to 35%,¹⁰ suggesting limited applicability of the currently available designs. Additionally, most of the BTAI patients will usually be younger than those requiring TEVAR for aneurysmal disease. With increasing age, the aortic diameter expands, and the aortic arch angulation decreases¹¹⁻¹³; therefore, the anatomic feasibility of TSSBE for patients with BTAI could differ.

The objectives of the present study were twofold: (1) to evaluate the anatomic feasibility of TSSBE for BTAI patients who would require LSA revascularization; and (2) to describe the anatomic characteristics of the aortic arch branches in this typically younger population that could be used to improve future device design.

METHODS

The present study was a retrospective analysis of single-institution data collected at the University of California, Davis. A total of 41 consecutive BTTAI patients who had undergone TEVAR and required LSA coverage from November 2013 to October 2018 were included. All patients had undergone preoperative computed

ARTICLE HIGHLIGHTS

- **Type of Research:** A retrospective analysis of single-institution data
- **Key Findings:** Only 32% of patients with blunt traumatic thoracic aortic injury requiring left subclavian artery revascularization during thoracic endovascular aortic repair had aortic anatomic features suitable for treatment with a novel thoracic single side-branched endograft. An insufficient distance between the arch branch vessels was the most common exclusionary criterion.
- **Take Home Message:** To improve future device design and application, better characterization and mapping of the aortic arch branches are needed.

tomography angiography (CTA). The CTA scans were de-identified for all patients. Next, three-dimensional centerline reconstruction was performed using a dedicated three-dimensional workstation and Aquarius iNtution software (TeraRecon, Foster City, Calif). The BTAI grade was assigned in accordance with the Society for Vascular Surgery guidelines: grade I, intimal tear; grade II, intramural hematoma; grade III, pseudoaneurysm; and grade IV, rupture.^{2,14} The demographic data were recorded from the medical records. The University of California, Davis, institutional review board approved our retrospective review and waived the requirement for written informed consent.

Device design and proposed instructions for use anatomic criteria. The device design and proposed anatomic criteria have been previously described in detail.^{9,10,15} In brief, this modular stent graft system consists of a main aortic component and a side branch component. The aortic component has one integrated portal, through which a side branch component is placed into the LSA with a retrograde orientation. Two portal options are available: 12 mm and 8 mm. Given that the 8-mm portal device is typically used for a zone 2 landing and further considering that no patient had met all the criteria for the 12-mm portal configuration in a previous study by Magee et al,¹⁰ the present study was performed using the anatomic requirements for the device with the 8-mm portal configuration for all the patients.

To be deemed suitable for the 8-mm portal device, independent of the underlying pathology, the following aortic and LSA anatomic criteria must have been met: (1) an aortic diameter of 16 to 42 mm at the proximal landing zone (PLZ); (2) a distance between the LSA and the next most proximal supra-aortic branch of ≥ 15 to 20 mm (to accommodate the covered stent graft lengths, proximal to the side-branch portal, which ranged from 15 to 20 mm); (3) an LSA diameter of 6 to 15 mm; and (4) a ≥ 30 -mm distance between the origin

of the LSA and the left vertebral artery (LVA) origin. In the present study, the access vessel diameter criterion (range, 7.5-9.5 mm) was not assessed during the anatomic feasibility analysis because this challenge can be surmounted with an adjunct access procedure.

Measurements and assessing device suitability. For each patient, the following measurements were performed: the aortic diameter at the PLZ and at the ostia of the innominate artery (IA), left common carotid artery (LCCA), and LSA; the distance and arc length between the LSA and the next most proximal supra-aortic branch (ie, LCCA in a normal aortic arch; IA in a bovine aortic arch); the distance between the ostium of the LSA and the origin of the LVA; and the clock-face position of the LSA, LCCA, and IA.

The diameter of the aorta at the ostia of the IA, LCCA, and LSA was measured from inner wall to inner wall at the level of the center of each branch vessel in the orthogonal plane to the manually adjusted centerline. The diameter of the LSA was measured from the inner wall to the inner wall at the level of sealing. The distance from the LSA origin and the next most proximal supra-aortic branch vessel was measured from the distal edge to the distal edge using the centerline adjusted at the outer curve of the aortic arch. The proportion of patients who had met all the aortic and LSA anatomic requirements proposed by the investigational protocols was calculated. Next, the effect of the anatomic requirement modifications was assessed.

To determine the location of a branch vessel, both the clock-face position and the arc length are required. In the case of a normal arch, the clock-face orientations of the LSA and IA were determined in reference to the LCCA, such that the LCCA was considered the central position at 12:00 o'clock. In the case of a bovine arch, the IA origin was considered the central position at 12:00 o'clock. The arc length was determined from clock-face position and the aortic diameter. The clock-face positions were converted to degrees, with 12:00 o'clock as 0° for the arc length calculation. An Excel (Microsoft, Redmond, Wash) formula was used to facilitate calculation of the arc length: $\text{arc length} = [(\text{aortic diameter}) \times (\pi) \times (\text{vessel angle})]/360$ (Supplementary Fig 1, online only). A positive or negative arc length was defined clockwise or counterclockwise from the reference vessel centerline at 12:00 o'clock, respectively. All the supra-aortic branch vessels, in relationship to the LCCA and IA for cases with a normal arch and bovine arch, respectively, were plotted.

The results are presented as the median, interquartile range (IQR), and range for continuous variables and as the counts and proportions for categorical variables. For analysis, the Fisher exact test was used for categorical variables and the Mann-Whitney *U* test for continuous

variables. Results were considered statistically significant at a *P* value <.05.

RESULTS

All 41 BTAI patients had had CTA scans with sufficient resolution, enabling assessment of the anatomic details. The median age of the study cohort was 39 years (IQR, 28.5 years; range, 22-93 years), and 63% were men. The branching pattern of the aortic arch was normal in 28 (68%) and bovine in 13 (32%) patients. Grade II to IV aortic injuries were observed in 40 patients (98%). The demographic characteristics are summarized in Table I.

For the overall patient group, the aortic diameter progressively increased from zone 3 to zone 0: 23.4 mm (IQR, 5.0 mm; range, 17.3-30.4 mm) at the LSA, 24.8 mm (IQR, 5.1 mm; range, 19.3-32.7 mm) at the LCCA, and 25.9 mm (IQR, 5.8 mm; range 19.1-35.1 mm) at the IA. The median aortic diameter at the PLZ was 25.0 mm (IQR, 4.8 mm; range, 19.3-32.7 mm). The median distance from the distal edge of the LSA to the distal edge of the next most supra-aortic branch (LCCA in the normal arch group; IA in the bovine group) was 18.0 mm (IQR, 8.1 mm; range 8.7-37.9 mm). The median diameter of the LSA at the seal was 8.6 mm (IQR, 1.3 mm; range 5.3-16.4 mm), and the median length from the LSA ostium to the left vertebral artery origin was 31 mm (IQR, 11.7 mm; range, 15.8-52.9 mm). The individual aortic and supra-aortic branch vessel measurements are summarized in Table II.

When assessing the anatomic feasibility for the TSSBE, the diameter at the PLZ in our cohort ranged from 19 to 33 mm; therefore, all 41 patients (100%) had met this criterion. In contrast, the distance from the LSA to the next most proximal supra-aortic branch was sufficient in 59% of the patients. The LSA diameter was sufficient in 95%, and the LSA length to the LVA origin was sufficient in 66% of the patients. Overall, an estimated 32% of the 41 patients had had aortic anatomic features suitable for treatment with the TSSBE (Table III).

When stratified by aortic arch pattern, the two groups were not significantly different with respect to median age (38 years in the normal arch group; 42 years in the bovine arch group; *P* = .8) and sex (64% male in the normal arch group; 62% male in the bovine arch group; *P* = 1.0). No difference was observed in the median aortic diameter at the PLZ (*P* = .7). Although the median diameter of the LSA was not different between the groups (*P* = .9), the median LSA length from its origin to the LVA origin was significantly shorter in the normal arch group than in the bovine arch group (30.8 mm vs 37.0 mm; *P* = .03). The median distance from the LSA to the first supra-aortic branch was also shorter in the normal arch group than that in the bovine group (16.6 mm vs 19.4 mm; *P* = .4). Because of these longer landing zones, a trend was noted toward increased eligibility for the patients with a bovine arch (53.8% of bovine

Table I. Patient demographics

Characteristic	All	Normal arch	Bovine arch	P value
Patients	41 (100)	28 (68)	13 (32)	
Age, years				.8
Median	39	38	42	
Range	22-93	22-88	23-93	
Male sex	26 (63)	18 (64)	8 (62)	1.0
BTTAI grade				
I	1	0	1	
II	6	3	3	
III	31	23	8	
IV	3	2	1	
II-IV	40	28	12	.3

BTTAI, Blunt traumatic thoracic aortic injury.
Data presented as number (%) or number.

Table II. Individual aortic and branch vessel measurements and thoracic single side-branched endograft anatomic requirements for 8-mm portal configuration

Variable	Anatomic requirement, mm	All (n = 41)	Normal arch (n = 28)	Bovine arch (n = 13)	P value
Aortic diameter, mm	NA				
IA		25.9 (5.8; 19.1-35.1)	25.9 (5.7; 19.1-35.1)	25.9 (7.3; 22.2-30.6)	
LCCA		NA	24.8 (5.1; 19.3-32.7)	NA	
LSA		23.3 (5.0; 17.3-30.4)	22.9 (5.0; 17.3-30.4)	23.4 (4.9; 18.9-29.4)	
PLZ	16-42	25.0 (4.8; 19.3-32.7)	25.0 (4.8; 19.3-32.7)	25.6 (5.9; 20.6-30.6)	.7
Distance from LSA to first supra-aortic branch	≥15-20	18 (8.1; 8.7-37.9)	16.6 (8.9; 8.7-37.9)	19.4 (8.1; 12.1-24.6)	.5
LSA diameter	6-15	8.6 (1.3; 5.3-16.4)	8.7 (1.3; 5.3-16.4)	8.6 (1.7; 8.0-10.7)	.9
LSA length	≥30	31 (11.7; 15.8-52.9)	30.8 (8.6; 15.8-51.8)	37 (11.6; 27.1-52.9)	.03

IA, Innominate artery; LCCA, left common carotid artery; LSA, left subclavian artery; NA, not applicable; PLZ, proximal landing zone.
Data presented as median (interquartile range; range).

arch group vs 21.4% of normal arch group; $P = .07$; Table III).

The clock-face positions and arc lengths of the supra-aortic branch vessels are summarized in Table IV. In the normal aortic arch group, using the LCCA position as the reference (12:00 o'clock position), the median clock-face position of the LSA was 12:00 o'clock (IQR, 30 minutes; range, 11:30-12:45). The clock-face positions for the LSA were most frequently distributed at 12:00 ($n = 8$; 28.6%) and 12:15 ($n = 7$; 25.0%). Most patients ($n = 20$; 71.4%) had had a clock-face position of the LSA from the LCCA within 15 minutes in either direction (Fig 1). In the bovine arch group, the median clock-face position was 11:45 (range, 11:00-12:00). The most commonly encountered LSA clock-face position was 11:45 ($n = 7$; 53.8%; Fig 2). The clock position of the LSA was less often clockwise in the bovine arch group than in the normal arch group.

The supra-aortic branch vessels were further mapped by measuring the arc length from the reference

vessel: the LCCA in the case of a normal arch and the IA in the case of a bovine arch. The median arc length from the LSA to the first supra-aortic branch in the normal arch group and bovine arch group was 0 mm (IQR, 3.15 mm; range -3.3 to 5.1 mm) and -1.8 mm (IQR, 1.9 mm; range, -6.4 to 0 mm), respectively. The absolute position of the individual supra-aortic branch vessels in terms of the distance and arc length between the branch vessels relative to the LCCA and IA in the 0 axis for the normal aortic and bovine arch groups is shown in Supplementary Figs 2 and 3 (online only), respectively.

DISCUSSION

The establishment of anatomic eligibility for the TSSBE depends on the aortic diameter at the PLZ, the distance between the LSA and the first proximal supra-aortic branch, and the LSA diameter and length. In our cohort, 32% patients had met these proposed instructions for use (IFU) anatomic eligibility criteria.

Table III. Patient suitability results stratified by IFU and modified anatomic criteria requirements

Anatomic criteria	Patients meeting criteria			P value
	All (n = 41)	Normal arch (n = 28)	Bovine arch (n = 13)	
Aortic diameter at PLZ				
IFU requirement (16-42 mm)	41 (100)	28 (100)	13 (100)	1.0
Distance from LSA to LCCA				
IFU requirement (≥ 15 -20 mm)	24 (59)	15 (54)	9 (69)	
Modified requirement (≥ 10 mm)	38 (93)	25 (89)	13 (100)	.5
LSA diameter				
IFU requirement (6-15 mm)	39 (95)	26 (93)	13 (100)	1.0
LSA length to LVA origin				
IFU requirement (≥ 30 mm)	27 (66)	16 (57)	11 (85)	
Modified requirement (≥ 20 mm)	40 (98)	27 (96)	13 (100)	.1
Meeting all criteria				
IFU requirements (16-42 mm, ≥ 15 -20 mm, 6-15 mm, ≥ 30 mm)	13 (32)	6 (21)	7 (54)	.07
Modified requirements				
16-42 mm, ≥ 10 mm, 6-15 mm, ≥ 30 mm	23 (56)	12 (43)	11 (85)	
16-42 mm, ≥ 15 -20 mm, 6-15 mm, ≥ 20 mm	23 (56)	10 (36)	13 (100)	
16-42 mm, ≥ 10 mm, 6-15 mm, ≥ 20 mm	35 (85)	22 (79)	13 (100)	

IFU, Instructions for use; LCCA, left common carotid artery; LSA, left subclavian artery; LVA, left vertebral artery; PLZ, proximal landing zone. Data presented as number (%).

Table IV. Supra-aortic branch vessel clock-face position and arc length

Artery	Clock-face position, hours: minutes		Arc length, mm	
	Normal arch	Bovine arch	Normal arch	Bovine arch
LSA	12:00 (0:30; 11:30-12:45)	11:45 (0:15; 11:00-12:00)	0 (3.15; -3.3 to 5.1)	-1.8 (1.9; -6.4 to 0)
LCCA	12:00 (reference)	12:00	0 (reference)	0
IA	12:45 (0:15; 12:15-13:15)	12:00 (reference)	5.4 (1.75; 1.7-9.0)	0 (reference)

IA, Innominate artery; LCCA, left common carotid artery; LSA, left subclavian artery. Data presented as median (interquartile range; range).

The main reasons for device ineligibility were an insufficient distance from the LSA to the first proximal supra-aortic branch and an inadequate LSA length to the LVA origin, affecting 41% and 34% of our patients, respectively. Our results are in concordance with the findings reported by Magee et al¹⁰ regarding this investigational endograft. Together, these preliminary results show the shortcomings of the TSSBE.

Based on the primary reasons for ineligibility, we identified two possible modifications that would increase the proportion of BTAI patients with anatomy suitable for this device. First, a modification of the distance between the LSA and LCCA is proposed because BTAI is an acute injury of an otherwise healthy aorta; thus, the PLZ will often be sufficient with LSA coverage. Therefore, it can be inferred that the required minimum distance between the LSA and LCCA could be reduced. According to our analysis, a distance of 10 mm would increase the feasibility of the use of the TSSBE from 32% to 56%. Second, by reducing the 30-mm LSA length requirement

for the TSSBE to 20 mm, we estimated that the feasibility in our cohort would increase from 32% to 56%. When applying these two modifications together, a modified TSSBE design with a 20-mm LSA side branch positioned 10 mm from the proximal graft edge, if technically within the manufacturer's capabilities, would expand the applicability of the TSSBE by $\leq 85\%$ in our cohort (Table III).

Compared with the previous TSSBE study by Magee et al¹⁰ of 57 patients who had undergone zone 2 TEVAR for type B aortic dissection, in our cohort of BTAI patients, the distance from the LSA to first supra-aortic branch was shorter (18.4 ± 5.6 mm vs 20 ± 6 mm), and the aortic diameter at the PLZ (23 ± 3 mm vs 35 ± 3 mm) and LSA (8.7 ± 1.7 mm vs 14 ± 3 mm) was smaller. These findings are consistent with those of previous reports of aortic arch morphology. Alberta et al¹⁶ evaluated 210 aortic arches to assess the aortic arch morphology and aortic length in patients with dissection, traumatic injury, and aneurysm undergoing TEVAR. In their study, the mean

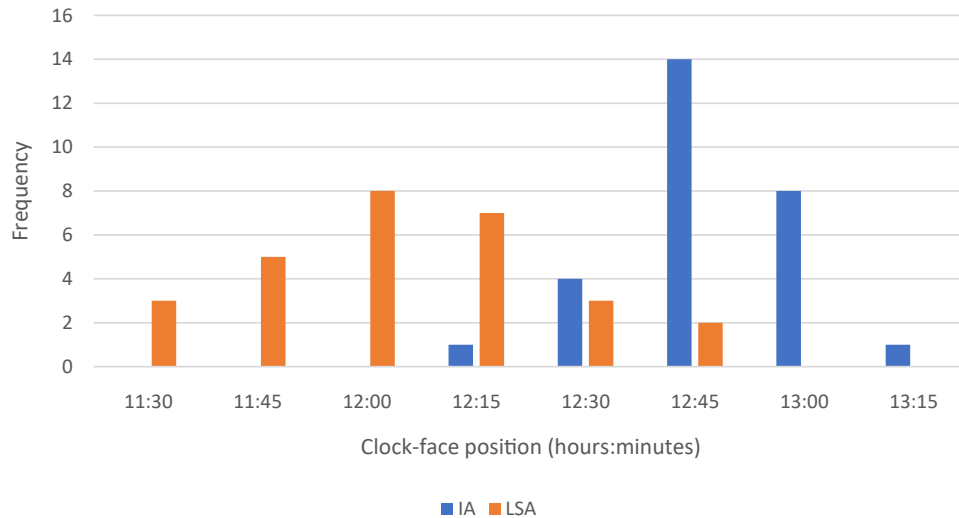


Fig 1. Clock-face position frequency of the innominate artery (IA) and left subclavian artery (LSA) in patients with a normal aortic arch. The clock-face positions of the IA and LSA are in reference to the left common carotid artery (LCCA); the LCCA origin is at 12:00 o'clock.

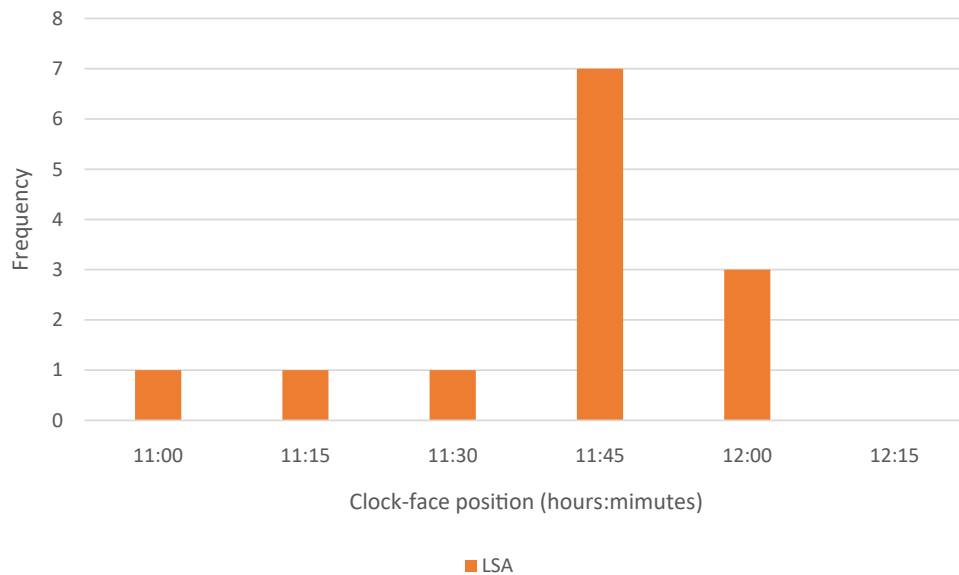


Fig 2. Clock-face position frequency of the left subclavian artery (LSA) in patients with a bovine arch. The clock-face position of the LSA is in reference to the innominate artery (IA); the IA origin is at 12:00 o'clock.

diameters of the branch vessels in the trauma patients were significantly smaller than were the diameters in the dissection and aneurysm patients ($P < .05$).¹⁶ They also observed that the distances from the supra-aortic branch vessels to the celiac artery and from the left main carotid artery to the supra-aortic branch vessels were shorter in the trauma patients than in the dissection and aneurysm patients ($P < .001$).¹⁶ These results were bolstered by the findings from the study by Malkawi et al.¹⁷ The investigators found similar morphologic characteristics in the aneurysm and dissection groups.¹⁷ Taken together, these findings indicate significant morphologic differences in the arch anatomy

between patients with trauma and those with dissection and aneurysms.

The present study compared the measurements from patients with a normal aortic arch and those with a bovine arch. Our results showed that both the median distance from the LSA to the first supra-aortic branch ($P = .4$) and the median LSA length to the LVA origin ($P = .03$) were longer in the bovine arch group, with no significant differences in the aortic diameters between the two groups. A possible explanation for this observation could be the common trunk configuration, with a consequent lengthening of those distances, which resulted in greater anatomic feasibility in the bovine

arch group than in the normal arch group (54% vs 21%; $P = .07$).

In planning a portal for a side target branch and to more accurately designate the position, both the circumferential orientation of the target vessel on the orthogonal cross-section (clock-face position) and its corresponding arc length are required. Our results showed that most patients with a normal arch (71%) had had clock-face positions of the LSA from the LCCA within 15 minutes in either direction (Fig 1), and the clock-face position of the LSA was less often clockwise in the bovine arch group (Fig 2). In the study by Alberta et al,¹⁶ the 12:00 o'clock position was the most common position of the LSA in the trauma and dissection patients. In contrast, in the aneurysm patients, the LSA position was 12:15. Furthermore, the most commonly observed clock positions of the IA were 12:30 and 12:45 in the trauma patients and was 12:15 in the dissection patients.¹⁶ Our results (Table IV; Fig 1) regarding the clock-face positions for the supra-aortic branch vessels in trauma patients are in line with those reported by Alberta et al.¹⁶ Considered collectively, it can be assumed that the clock-face position of the supra-aortic branches will vary among pathologies. As such, data on the varying LSA clock-face positions could provide a framework for improving LSA-branched thoracic endografts.

The concept of a 20-mm proximal seal stemmed from the treatment of aneurysms and has also been adopted for the treatment of BTAI. BTAI is an acute injury; thus, its natural history is likely to be different from that of aneurysmal disease. Thus, the 20-mm recommendation might not be entirely applicable for BTAI. As such, recent reports have suggested that BTAI can be treated with shorter landing zone.⁶ Nevertheless, this hypothesis has not yet been tested in a rigid comparative clinical trial. In addition, some studies have proposed that extension of the PLZ by covering the LSA is safe.⁸ However, the reported incidence of left arm claudication and stroke as a consequence of this strategy has been unsettling. Antonello et al¹⁸ investigated the outcomes of intentional coverage of the LSA in patients who had undergone TEVAR for BTAI and reported moderate claudication in 36%, severe claudication in 32%, and acute ischemia in 1 of their patients immediately postoperatively. At 6 months, 24% of their patients had continued to have claudication.¹⁸ In a systematic review of 1704 BTAI patients, Sepehrpour et al¹⁹ reported a significantly increased prevalence of left arm ischemia (4.06% vs 0.0%; $P < .001$) and stroke (1.19% vs 0.23%; $P = .025$) with LSA coverage compared with no LSA coverage. With the clinical conundrum of intentional LSA coverage and a short PLZ unresolved, the use of the off-the-shelf TSSBE might improve the limitations noted in the treatment of BTAI patients with standard TEVAR.

Two other points are worth mentioning. First, according to our results, 32% of the patients had had a bovine aortic arch. However, the earlier bovine arch prevalence reported has ranged from 10% to 20%.^{20,21} Historically, because aortic arch anomalies have been considered clinically insignificant, they were often not reported. Hornick et al²² reviewed computed tomography and magnetic resonance imaging scans of 1456 patients (612 patients with thoracic aortic disease and 844 patients without) and found that 26% of the patients with thoracic aortic disease had had a bovine arch. In contrast, the radiology reports of the same patient group had cited bovine arch in only 16% of the patients.²² Moorehead et al²³ had also reviewed all serial 817 computed tomography scans performed at their institution and found a bovine arch prevalence of 31%. These reports, consistent with the findings from the present study, have shown that the incidence of a bovine arch is greater than previously reported and thus warrants additional consideration of this patient group in the optimization of the device design. Second, the recent trend in the management of BTAI grade I injuries has been nonoperative treatment. Although it might be contentious up to a point, in our practice, the determination regarding whether a patient with a single grade I injury required treatment was left to the discretion of the treating surgeon. Uncertainty regarding the progression of the injury and the presence long intimal tears or concomitant head injuries are some reported reasons for treating BTAI patients with grade I injury using TEVAR.²⁴

The present study had some limitations. First, our study was a single-center retrospective study that included a relatively small number of BTAI patients who had specifically undergone TEVAR, which might have biased the results. Given that BTAI is a random event, a larger reference general population might have better estimated the feasibility of using the TSSBE. Additionally, we did not consider the access vessel diameter as a factor in the ultimate eligibility for this device because this challenge can be overcome with an adjunct procedure. Furthermore, despite other anatomic features such as tortuosity of the aortic arch that can make device deployment more complicated and difficult, we assessed the anatomic feasibility strictly according to its proposed IFU, which is currently investigational. As such, the feasibility rates could change as the IFU are further refined. Finally, the present study was limited by only one experienced vascular surgeon (W.J.Y.) performing all the measurements. Although measurements are subject to intraexaminer variation, we did not analyze the intraexaminer variability of these measurements.

CONCLUSIONS

Despite the numerous potential advantages of the TSSBE, only 32% of patients with BTAI requiring LSA revascularization had met all the anatomic requirements

in our study, justifying the need for additional designs. To effectively identify the morphologic features that differ among the pathologies and to establish an average morphology among the various patient population groups, better characterization and mapping of the aortic arch branches are needed and will improve future device design and application.

AUTHOR CONTRIBUTIONS

Conception and design: WY, KM, AW, VR, MM

Analysis and interpretation: WY, KM, AW, VR, MM

Data collection: WY

Writing the article: WY

Critical revision of the article: WY, KM, AW, VR, MM

Final approval of the article: WY, KM, AW, VR, MM

Statistical analysis: Not applicable

Obtained funding: Not applicable

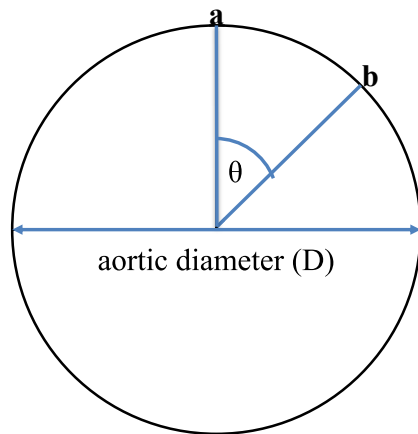
Overall responsibility: WY

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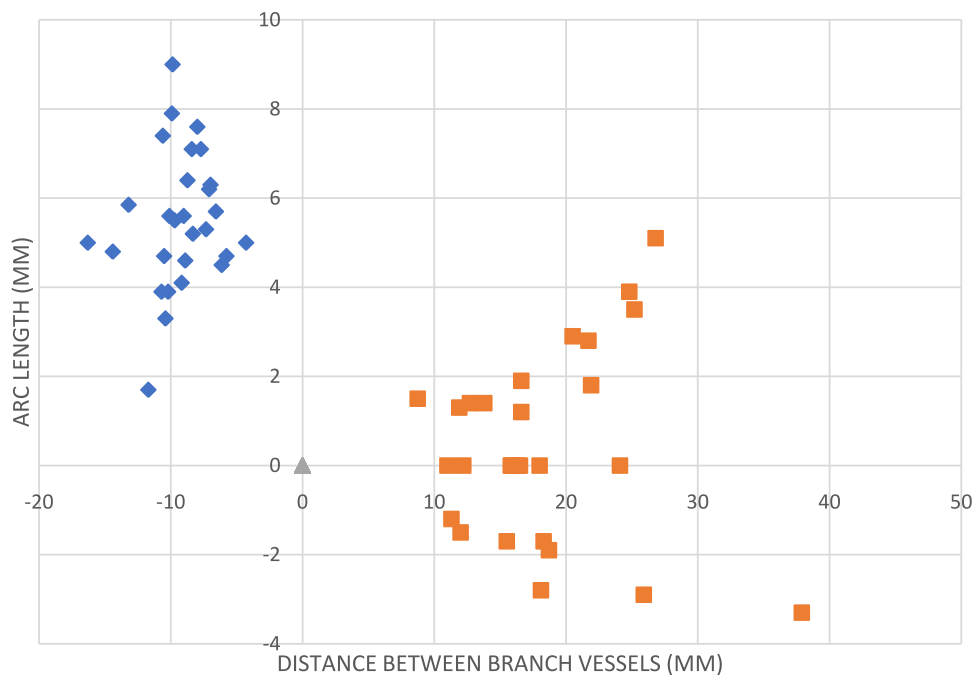
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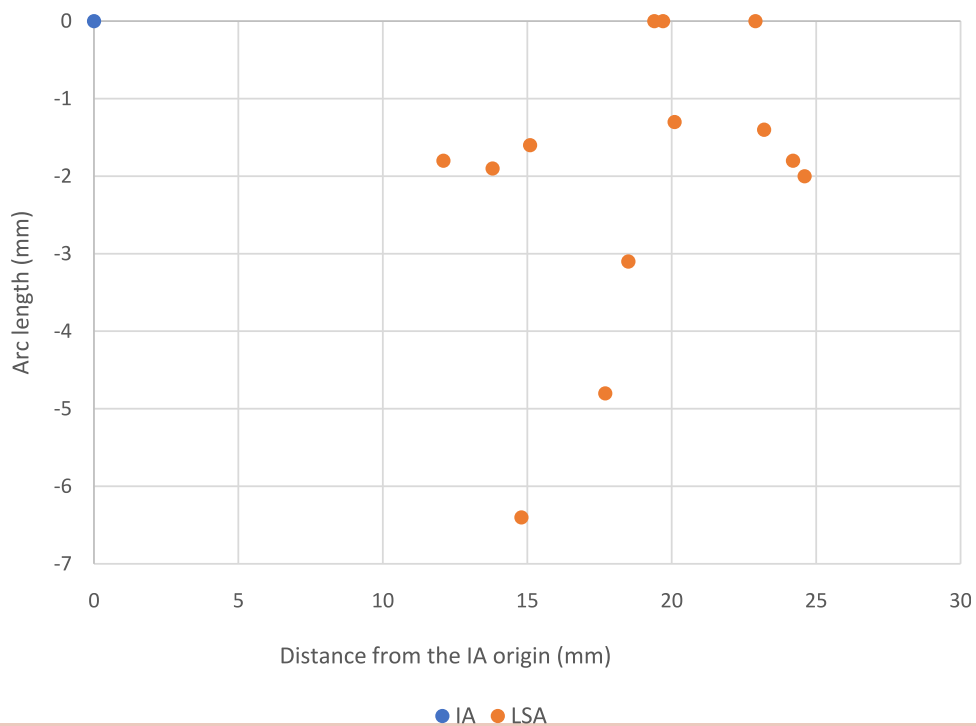
a: reference vessel origin at 12:00 o'clock
 b: target vessel origin
 θ : target vessel angle
 ab: arc length = $(D \times \pi \times \theta)/360$

Supplementary Fig 1 (online only). Schematic showing arc length measurement. Arc length was defined as the distance along the aortic wall from the referent to the center of the target vessel origin.



◆ IA ▲ LCCA ■ LSA

Supplementary Fig 2 (online only). Two-dimensional scatter plot depicting the absolute positions of the innominate artery (IA) and left subclavian artery (LSA) in terms of the distance and arc length, relative to the left common carotid artery (LCCA) in the 0 axis in patients with a normal aortic arch. A positive or negative arc length was defined clockwise or counterclockwise from the LCCA at 12:00 o'clock, respectively.



Supplementary Fig 3 (online only). Two-dimensional scatter plot depicting the absolute positions of the left subclavian artery (LSA) in terms of distance and arc length, relative to the innominate artery (IA) in the 0 axis, in patients with a bovine aortic arch. A negative arc length was defined counterclockwise from the IA at the 12:00-o'clock position.