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CLINICAL INVESTIGATION

Implantation of Unibody Single-Branched Stent Graft for Patients with Type B Aortic Dissections Involving the Left Subclavian Artery: 1-Year Follow-Up Outcomes

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Abstract
Objective To report the early results of castor device, a kind of unibody single-branched stent graft, in the treatment of type B aortic dissection (TBAD) involving the LSA.
Methods From April 2013 to February 2014, 21 patients with TBADs underwent TEVAR with LSA revascularization by unibody single-branched stent grafts. Three patients with penetrating aortic ulcers in the aortic arch received additional reconstruction of left common carotid artery with chimney technique. Follow-up evaluations were conducted with computed tomography angiography (CTA) at 6, 12 months and annually after that.
Results All of the proximal entry tears were completely excluded. Good patency of the grafts was found in all cases. A small type I endoleak occurred in one patient during the procedure. Perioperative mortality is null, and there was no occurrence of serious complications. All patients completed the follow-up except one lost contact after discharge. One death occurred within 6 months after the operation, resulting from myocardial infarction, considered unrelated to the stent implantation. No endoleak occurred during follow-up. One compression of a chimney stent and one twist of side branch graft of castor were observed in 2 different patients, respectively. In other cases, CTA scans showed good patency of both the branched and chimney grafts. Two patients had partial thrombosis of the false lumen during follow-up. In other patients, complete thrombosis in the false lumen in thoracic aorta was revealed.
Conclusion The single-branched stent graft was safe and efficient in the 1-year follow-up. Further studies are required to determine its long-term outcomes.

Keywords Aortic dissection · Left subclavian artery · Thoracic endovascular aortic repair · Single-branched stent graft

Introduction

Aortic dissection is a cardiovascular disease associated with high mortality, and the complexities of management make it challenging for surgeons to determine an optimal treatment [1]. Since reports of its encouraging short-term outcomes in 1999, TEVAR has been increasingly applied for patients with TBADs [2, 3]. Most off-the-shelf endovascular devices require a proximal landing zone of healthy and no dissected aorta of at least 20 mm in length for safe deployment and fixation. When there is <20 mm of normal aorta between the lesion and the LSA, intentional coverage of LSA is often performed to obtain an adequate length of the proximal landing zone. However, coverage of the LSA origin without revascularization during TEVAR appears to have increased risk of stroke, upper extremity ischemia and paraplegia [4, 5]. These potentially serious

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adverse events of coverage may be obviated if LSA patency is secured.

From April 2013 to February 2014, we performed TEVAR and along with revascularized LSA for 21 TBAD patients using castor single-branched thoracic aortic stent grafts (Microport Medical, Shanghai, China). In this study, we reported the feasibility and early results of utilizing this novel single-branched stent graft in the treatment of TBADs with primary entry tear adjacent to the LSA.

Methods

Patients Cohort

From April 2013 to February 2014, 21 patients with TBADs were treated by endovascular repair with the castor single-branched stent grafts at two hospitals, including 13 (patients 1–13) in the First Affiliated Hospital of Nanjing Medical University (Nanjing, China) and 8 (patients 14–21) in Nanjing Drum Tower Hospital (Nanjing, China). There were 6 patients with complicated acute TBADs (28.6%), 13 patients with subacute dissections (61.9%) and 2 patients with chronic dissections (9.5%). Table 1 reports the characteristics of these 21 patients. There were 15 men and 6 women with a median age of 64.3 ± 12.2 year (range 42–79 year). All patients had sudden onset of severe chest or back pain lasting from 1 to 26 days before hospitalization. Most patients (16/21) had hypertension, 2 had cerebrovascular accident, 4 had coronary artery disease, and 1 patient underwent TEVAR in 2007. All the cases were diagnosed by high-resolution CT scans (section thickness <1 mm). Axial image data were transferred to a workstation and analyzed with Osirix (version 8.0.1, Osirix Foundation, Geneva). 3D reconstruction of the aorta and branch vessels showed that in all cases the primary tears were within 20 mm from the origin of the LSA and located in zone 3 according to the classification proposed by Ishimaru (Fig. 1A) [6]. All patients underwent TEVAR and LSA reconstruction using castor single-branched stent grafts, and three patients (patients 8, 10 and 12) with penetrating aortic ulcers (PAUs) underwent additional left common carotid artery (LCCA) reconstruction with chimney technique.

Table 1 Baseline characteristics of the study cohort ($n = 21$)

Variable	Value
Age, years, mean ± SD	64.3 ± 12.2
Male sex	15 (71.4%)
Hypertension	16 (76.2%)
Previous aortic repair	2 (9.5%)
Tobacco abuse	2 (9.5%)
Chronic obstructive pulmonary disease	0 (0)
Coronary artery disease	4 (19.0%)
Family history of dissection	0 (0)
cerebral vascular incident	2 (9.5%)
Renal insufficiency	3 (14.3%)
Diabetes	1 (4.8%)

Stent-Graft Design

The diameter of LSA orifice, the distance between LSA and LCCA, and the aortic diameters of the proximal and distal landing zones were measured by an experienced surgeon using preoperative CTA. Based on these measurements, the single-branched stent graft was customized for each patient. The castor branched aortic stent graft was a unibody branched graft consisting of a self-expandable nitinol stent and polyester vascular graft fabric (Fig. 2A). It consisted of a main stent graft and a side branch for the LSA, and in consequence, the delivery system was slightly thick with an outer diameter of 24F (Fig. 2B). The side branch graft was 35 mm long with a diameter of 14–16 mm. The distance between neighboring side branch graft and proximal end of main graft was 5 or 10 mm. When the distance between LSA and LCCA is <10 mm, the former (5 mm) is chosen; if the distance exceeds 10 mm, the latter (10 mm) is selected. All stent grafts were oversized 0–10% with respect to the proximal aortic diameter. There is no bare stent at the proximal or distal ends of the stent graft.

Operation Details

All operations under general anesthesia. Initially, an 8-F sheath was inserted percutaneously into the left brachial artery, to provide access to draw the side branch section of the stent graft into the LSA. Through the left brachial artery sheath, a pigtail catheter was advanced into the ascending aorta under fluoroscopic guidance. Then, an aortography was performed to identify the proximal primary tear and to measure the diameter at the relevant segments of the aorta again to ensure that the prepared device was correct (Fig. 1B). After the measurements were confirmed, a small cut down was performed over the femoral artery. The catheter introduced from the left brachial sheath was then manipulated inferiorly toward the femoral artery over a guidewire. Both the guidewire and catheter were exteriorized via the femoral cut down achieving through and through access from the left brachial artery to the femoral artery, thus establishing the traction conduit. The guidewire was removed and the traction wire of the side branch section of the stent graft was threaded through the catheter that was exteriorized at the femoral cut

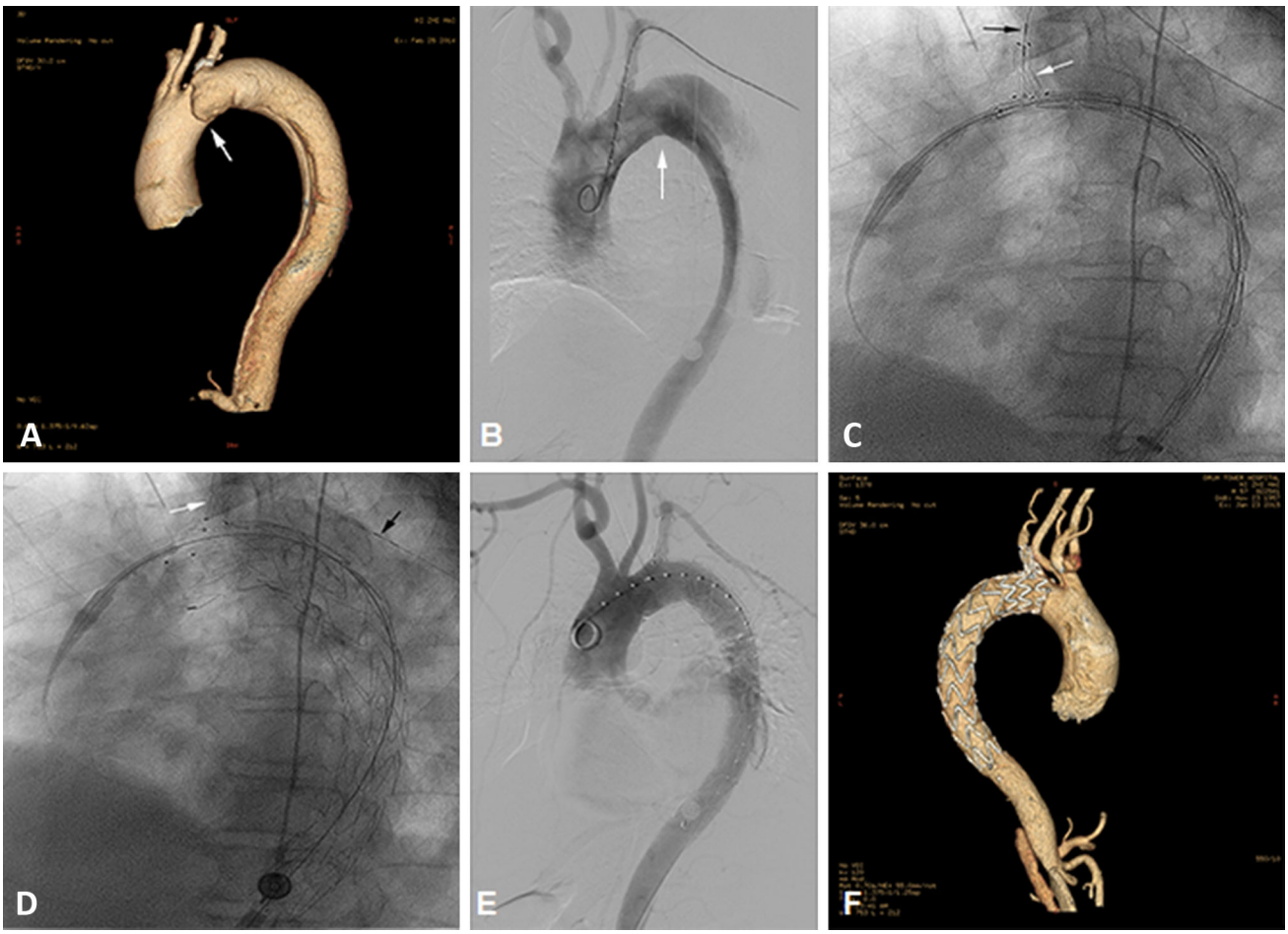

Fig. 1 Implantation of the single-branched stent graft (using patient 14 as an example). **A** 3D reconstruction showing the primary tear located close to the LSA (*white arrow*). **B** Intraoperative aortogram showing the primary tear (*white arrow*). **C** Delivering the stent graft to the planned position. *White arrow* showing the branch and *black arrow* showing the traction wire. **D** Releasing the stent graft. *White arrow* indicating the branch and *black arrow* indicating the traction wire. **E** Final aortography showing complete seal of entry tear. **F** Good patency of the graft during follow-up

down (traction conduit). The traction wire was advanced along the catheter and exited through the left brachial sheath. This enabled the side branch section to be pulled into the LSA subsequently. Another catheter was inserted into the femoral artery cut down alongside the traction wire and advanced superiorly over a guidewire into the ascending aorta. The guidewire was exchanged for a super stiff guidewire, and the stent graft delivery system was advanced over the super stiff guidewire until the lower descending aorta. With the outer sheath remaining in the descending aorta, the stent graft within the soft sheath was advanced over the super stiff guidewire into the arch (Fig. 1C, D). The traction wire was withdrawn superiorly in tandem as the stent graft delivery catheter was advanced superiorly. Once the stent graft was delivered to the planned location in the arch, the soft sheath was removed. The side branch section inside its cap was pulled into the LSA by retracting the traction wire. The stent graft main body was quickly deployed by withdrawing the trigger wire. Only after removal of the trigger wire was the cap of the side branch section unlocked and removed by withdrawing the traction wire, which deployed the side branch section. These steps are illustrated in Fig. 3. Immediate aortography was performed to evaluate the patency of the side branch and to confirm whether endoleak occurred and whether the entry tear was sealed.

Three patients with PAUs in the aortic arch underwent additional revascularization of LCCA using chimney technique. After puncturing the LCCA, a 6-F sheath was inserted into the LCCA to facilitate introduction of the chimney stent. A pigtail catheter and a supper stiff guidewire were advanced into the ascending aorta under fluoroscopic guidance. Then, the catheter was removed, and the chimney stent was delivered into the LCCA over the guidewire. After the deployment of the single-branched stent graft, the chimney stent was rapidly deployed parallel

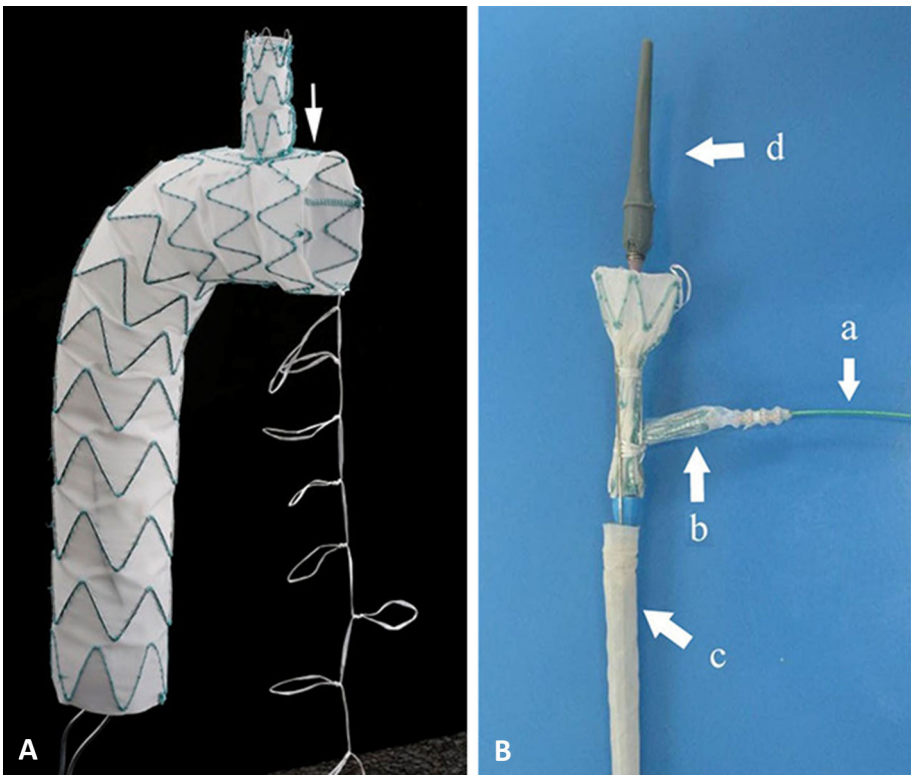

Fig. 2 The 1-piece branched stent graft and the delivery system. **A** The short tube at the proximal end of main graft (*white arrow*), without a bare stent. **B** *Arrow a* pointing to the traction wire, *arrow b* pointing to the side branch graft, *arrow c* pointing to the 24-F outer sheath of the delivery system and *arrow d* pointing to the cone head

to the main stent graft with 0.5 cm of its body protruding proximally. Completion angiogram was performed to identify whether successful proximal fixation of the chimney stent and preserved perfusion of LCCA were achieved.

Balloon catheters were chosen and used at the operator's discretion. All aortic repairs were performed using a castor branched aortic stent graft system (Microport Medical, Shanghai, China), with an oversizing of 7.1–10.3% and a length of 180–200 mm. A self-expanding bare stent (Luminexx, Bard Peripheral Vascular, USA) with a proper size was deployed during each chimney procedure.

Clinical Follow-Up

CT scans were conducted at 6, 12 months and annually thereafter. Aortic morphological remodeling was evaluated at the orifice of LSA (level A), the middle and the distal end of the stent graft (levels B and C) (Fig. 3F). The maximal cross-sectional diameters of the false lumen and the whole thoracic aorta were measured as well. The side branch patency, false lumen thrombosis, endoleak events and patient survival were also recorded.

Statistical Analysis

The data were analyzed with the SPSS version 21 (SPSS Inc., Chicago, IL). Continuous variables were presented as mean ± standard deviation, and categorical variables were recorded as proportions. Diameters were compared by one-way repeated-measures analysis of variance. A P value <0.05 was considered significant.

Results

Perioperative Results

Immediate postoperative aortogram demonstrated successful exclusion of the lesion and good perfusion of LSA in all cases (Fig. 1E). A favorable antegrade blood flow of LCCA was also observed at the end of each chimney procedure. However, a small type I endoleak was noticed in patient 15 at the lesser curvature of the aortic arch, the immediate balloon dilation of the thoracic aorta was performed, but angiogram revealed that the endoleak remained. Therefore, a 32 × 160 mm (Microport Medical, Shanghai, China) stent graft was placed next to the orifice of LSA; however, the existing endoleak was not significantly obviated after second stent graft deployment. Since this patient was asymptomatic after the operation, he did not undergo any further intervention.

Procedural time averaged 139.3 ± 49.3 min (range 85–278 min). A median amount of 100 ml (range 80–160 ml) contrast volume was used. Perioperative

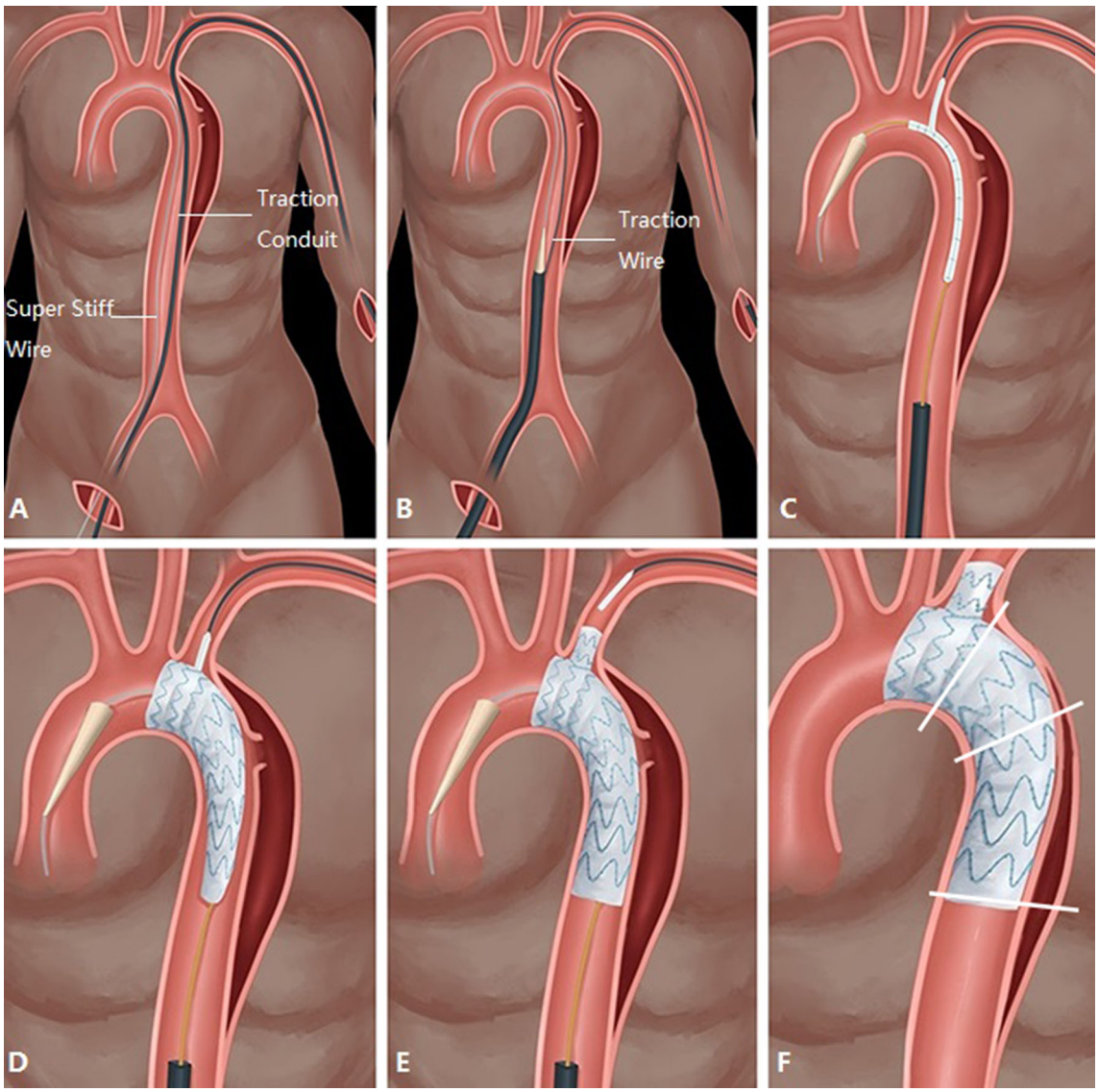

Fig. 3 Endovascular procedure with the use of castor. **A** Establishing the traction conduit. **B** Advancing the stent graft into the descending aorta, with synchronous withdrawal of the traction conduit and traction wire of the branch section. **C** Advancing the stent graft to the target position. The outer sheath remains in the descending aorta. **D** Drawing the branch section into the intended branch artery. The *white arrow* shows that the soft sheath of the stent graft has been removed. **E** Deploying the main body of the stent graft first and then deploying the branch section. The *white arrow* indicates the removed cap. **F** The diameters at levels A, B and C (*white lines*) were measured at the 6- and 12-month follow-up in all patients

mortality was 0, and there were no serious complications such as stroke, acute myocardial infarction, renal failure or left arm ischemia. Median hospitalization time was 8.1 ± 4.4 days (range 3–21 day) (Table 2).

Follow-Up

All patients completed the follow-up visit except patient 15 was out of contact after discharge. One death (patient 7) occurred within 6 months after the operation resulting from myocardial infarction and was considered unrelated to the stent graft implantation. During the follow-up, no more death, left arm ischemia, paraplegia, aortic rupture, conversion to open surgery or secondary endovascular intervention occurred.

No endoleak was observed during follow-up. The 6-month CTA detected a twist of the branch graft in patient 13 (Fig. 4A) and remained unchanged in the 12-month CTA examination (Fig. 4B). No stroke or upper extremity ischemia happened to the patient during follow-up. In patient 10, the 6-month CTA revealed that the chimney stent was compressed by the main stent graft and therefore caused thrombosis and occlusion of LCCA origin (Fig. 4C), but the

Table 2 Clinical data of 21 patients treated with TEVAR

No.	Sex	Age (year)	Operation time (min)	Hospital stay (day)	DMBC (mm)	DANLSAO (mm)	Oversize rate (%)	TCC (day)	TFISTO (day)
1	Male	79	98	3	30	28	7.1	24	46
2	Male	79	106	7	30	28	7.1	21	35
3	Male	73	120	21	36	33	9.1	26	550
4	Female	42	110	4	32	29	10.3	15	27
5	Male	77	121	7	32	29	10.3	1	7
6	Male	56	85	6	34	30	13.3	3	22
7	Male	50	87	6	32	29	10.3	1	13
8	Female	78	110	6	34	31	9.7	1	15
9	Male	47	121	6	34	31	9.7	2	14
10	Male	72	135	7	40	37	8.1	22	51
11	Female	75	93	7	32	29	10.3	8	16
12	Male	63	150	7	38	35	8.6	16	370
13	Male	77	120	5	36	33	9.1	1	15
14	Male	57	195	8	32	29	10.3	15	20
15	Male	61	278	7	30	28	7.1	1	2
16	Female	67	131	9	36	33	9.1	1	15
17	Male	68	210	6	38	35	8.6	2	21
18	Male	42	110	19	30	28	7.1	2	4
19	Female	72	200	9	32	29	10.3	15	24
20	Female	57	155	13	32	29	10.3	5	13
21	Male	59	190	8	34	31	9.7	14	19

DMBC diameter of the main body of castor, *DANLSAO* diameters of aorta near LSA orifice, *TCC* time of chief complaint, *TFISTO* time from initial symptom to operation

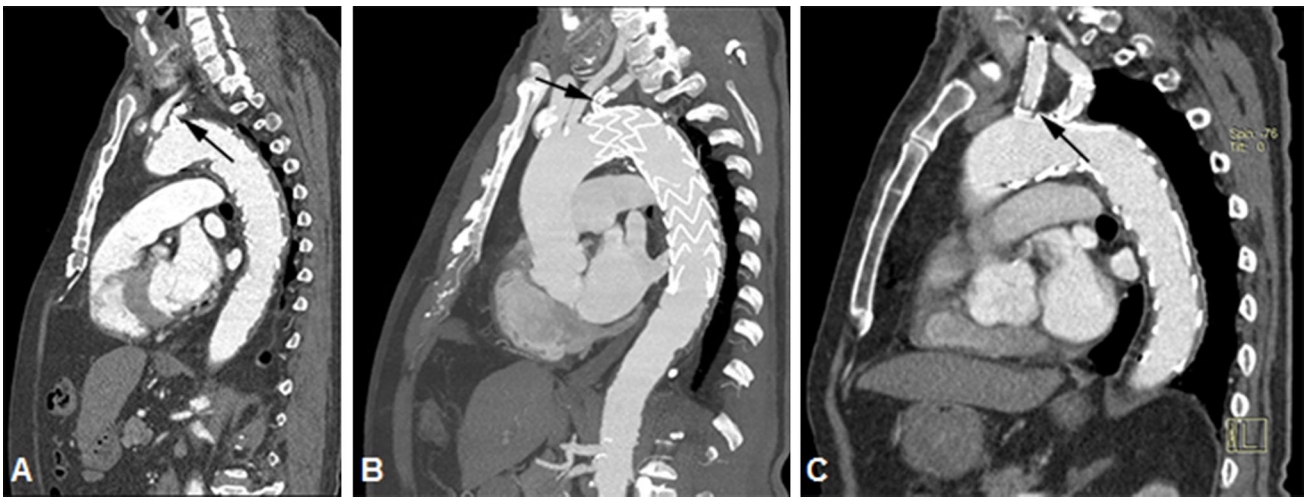

Fig. 4 CTA and 3D reconstruction of the aorta and branch vessels in patient 13 and 10. **A** The tortuous side branched stent in patient 13 (*black arrow*). **B** Imaging showing no significant change of the twist (*black arrow*). **C** Thrombosis and occlusion in LCCA origin in patient 10 (*black arrow*)

patient presented no cerebral symptom. In other patients, CTA all documented good patency of branch grafts and no evidence of device's migration, infolding or fracture (Fig. 1F).

Partial thrombosis of the false lumen was detected in 2 patients (patient 2 and 19) by 6-month CTA scan and remained in 1 patient (patient 19) in 12 months. In other cases, complete thrombosis of the false lumen in the

thoracic aorta was noted by both the 6- and 12-month CTA. Significant morphological changes were observed at 3 designated levels (Table 3). Diameters of maximal false lumen and the false lumens at levels B and C were significantly decreased in the first 6 months ($P < 0.01$), and the true lumens were obviously expanded ($P < 0.001$) (Fig. 5). The diameters of maximal dissected aorta and the aorta at levels A, B and C had no significant changes throughout follow-up ($P > 0.05$).

Discussion

TEVAR is a rapidly developing therapy in the treatment of acute aortic dissections, and many studies have proved its superiority. The IRAD study reported a growing use of TEVAR in patients with acute TBADs, increasing from 7 to 31% in 17 years, with medical treatment decreased from 75 to 57% and traditional surgical management decreased from 17 to 8% [7]. Recent research found that TEVAR had a lower mortality than medical treatment for TBADs over a 5-year period [8, 9]. The INSTEAD study also showed that TEVAR plus optimal medical treatment was associated with improved 5-year aorta-specific survival, improved aortic remodeling and delayed disease progression [10].

However, the necessary of an adequate proximal landing zone (>20 mm) sometimes limited its application in the proximal descending aorta. Fortunately, the development of new endografts and advanced techniques overcame this shortcoming. Currently, there are mainly 3 endovascular techniques for LSA revascularization in TEVAR, i.e., chimney technique, fenestrated and branched stent grafts. Since Criado systemically introduced chimney technique for aortic endovascular repair in 2007, this technique has been widely used in combination with TEVAR [11, 12]. A systematic review suggested that chimney technique had merits of a low short-term mortality and high long-term patency [13]. However, the gutter between the aortic wall and the chimney stent was inevitable and might cause a type Ia endoleak [14, 15]. Fenestration is another reliable technique in endovascular aneurysm repair [16]. Especially, in situ fenestration seems to be a reasonable and effective method for emergent TEVAR procedure [17]. The most concerned issue surrounding this technique is tear propagation of the fenestration leading to a type III endoleak, which would be difficult to treat. In 1999, Inoue firstly designed an unibody branched stent graft to treat distal arch pathologies involving the LSA, but found a relatively high rate of complications, including endoleak and cerebral infarction [18]. Although the result was not encouraging, the unibody single-branched stent graft design was still a very promising proposal. Theoretically, the unibody design could natively avoid the gutter endoleak appeared in chimney technique and avoid loss of alignment due to the anchoring effect of the branch section, which made a contribution to stabilize the entire device.

The castor device employed an easy-to-use unibody design, including a main body and a branch graft to avoid type III endoleaks. Our study demonstrated the castor system was safe and efficient to treat TBADs during the early follow-up. However, this novel device had some deficiencies. The delivery system had a relatively larger external diameter than that of straight stent grafts, leading to a more aggressive intervention. The traction wire could

Table 3 Morphological changes of aorta in the 1-year follow-up

Level	Before endografting, mm	6-month follow-up, mm	*P* value[a]	12-month follow-up, mm	*P* value[b]
Level A					
Aorta	32.0 ± 2.8	33.4 ± 1.3	0.166	33.4 ± 2.4	0.972
Level B					
Aorta	35.2 ± 5.1	36.2 ± 4.4	0.455	36.6 ± 3.7	0.525
True lumen	12.2 ± 4.8	28.6 ± 4.6	<0.001	29.4 ± 4.8	0.027
False lumen	20.9 ± 7.3	6.5 ± 7.4	0.001	5.6 ± 7.3	0.077
Level C					
Aorta	32.2 ± 5.8	30.8 ± 4.9	0.431	31.5 ± 4.5	0.527
True lumen	13.9 ± 4.8	24.6 ± 5.1	0.001	25.5 ± 5.1	0.353
False lumen	17.9 ± 8.7	6.1 ± 8.4	0.006	4.9 ± 7.7	0.082
Maximal false lumen	23.5 ± 8.0	8.1 ± 8.2	0.001	7.1 ± 7.9	0.165
Maximal dissected aorta	40.8 ± 5.9	40.4 ± 5.9	0.793	39.8 ± 5.8	0.161

Values are mean ± SD

[a] Comparison of diameters before endografting and in 6-month follow-up

[b] Comparison of diameters in 6-month follow-up and in 12-month follow-up

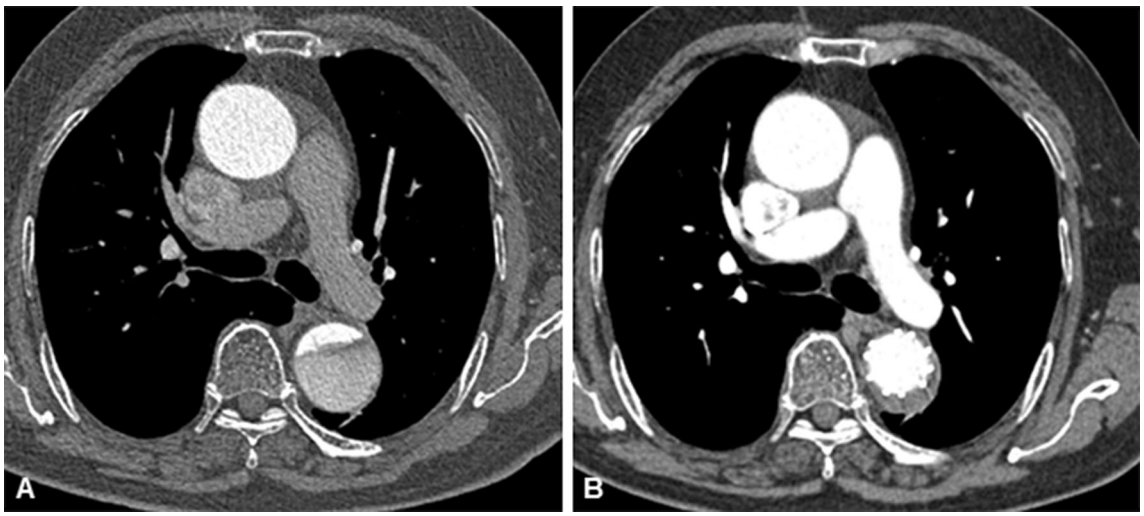

Fig. 5 Cross-sectional view of the thoracic aorta in patient 3. **A** Cross-sectional view before the endovascular procedure. **B** Cross-sectional view in the 6-month examination

be twisted around the super stiff guidewire and caused serious problems during deployment. To solve these problems, better skills and more patience were demanded from the operators. Although castor had employed some designs to avoid device migration, it still happened in 1 case during our follow-up and caused an inevitable twist of a branch graft due to the unibody design. We considered the selection of an inappropriate stent size as the main reason, which might be due to an inaccurate measurement of aortic diameter. In our study, we did not use electrocardiogram-gated CT scan to avoid motion artifact and acquire an accurate imaging of descending aorta. At the proximal end of main graft, there was a short (5 or 10 mm) tube made of sewing Dacron, which provided a relative strong radial expansion force to avoid device migration and type I endoleak. In our study, a chimney stent was compressed by the short tube and consequently caused an occlusion of LCCA. We presumed that the strong radial force and partial coverage of LCCA by main stent graft probably were responsible for the compression of the chimney stent. In our opinion, combining single-branched stent graft with chimney technique to extend proximal landing zone might not be suitable for castor device, but we could seek for the possibility of multi-branched stent graft or combing single-branched stent graft with fenestration technique. Actually, the latter solution has been put into practice by Lu et al. and used to treat complicated aortic dissection involving the arch [19]. As mentioned above, the diameters of whole aorta at levels A, B and C had no significant changes during follow-up. This finding was contrary to the 2-years' results of INSTEAD trial (significant reduction in aortic diameter after TEVAR) [20]. Firstly, we considered the true lumen expanding synchronously with the false lumen shrinking during the first 12 months might lead to this result. Secondly, the small size of sample could also affect the results. At present, this product is custom-made and usually takes a couple of weeks from planning to delivery, which limits its application in emergency situation. However, our recent study showed that 35.4% patients with TBADs could potentially benefit from castor and 20 configurations would treat 54.8% of them [21]. Therefore, we believed that the use of off-the-shelf castor device in emergency settings was possible.

To the best of our knowledge, castor was the first-in-man implantation of LSA branched TEVAR device in China. Other products, such as Valiant Mona LSA (Medtronic Vascular, Santa Rosa, Calif) and Gore Thoracic Branch Endoprosthesis (TBE, WL Gore, Flagstaff, AZ), are under clinical trials and have also achieved favorable early results [22, 23]. For these branched stent graft, however, investigation of their long-term outcomes with further follow-up is in urgent need to assess device durability over time.

Conclusions

Our limited experience showed that the castor branched aortic stent graft system was safe and feasible to obtain an adequate proximal landing zone while maintaining sufficient LSA perfusion during 1-year follow-up. This product provided an attractive alternative to the endovascular treatment of TBADs. However, more experience and studies with longer follow-up are required before this product can be recommended for widespread use.

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Compliance of Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent Assigned informed consent was obtained from all patients.

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