Heliyon 10 (2024) e29106

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

Research article

A new minimal invasive technique with in-situ stent-graft fenestration for type A aortic dissection

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ARTICLE INFO

Keywords:
Type A aortic dissection
Aortic arch reconstruction
In-situ stent-graft fenestration technique
Sun's procedure

ABSTRACT

Background: Aortic surgery successfully improves the prognosis of patients with type A aortic dissection. However, total arch replacement and reconstruction remain challenging. This study presents a new surgical modality, the in-situ stent-graft fenestration (ISSF) technique, for simplifying aortic arch reconstruction and assesses its short-term efficacy and safety in patients with type A aortic dissection.
Methods: Data from 177 patients with type A aortic dissection who underwent aortic arch reconstruction were retrospectively analyzed. Sun's procedure was performed in 90 patients and ISSF was performed in the other 87.
Results: The in-hospital mortality rate was 7.8% in the Sun's procedure group and 3.4% in the ISSF group ($p = 0.357$). Compared to the Sun's procedure group, the ISSF group had significantly shorter surgical duration, cardiopulmonary bypass time, circulatory arrest time, mechanical ventilation time, and aortic cross-clamp time ($p < 0.05$). Additionally, intraoperative blood loss was lower in the ISSF group than in the Sun's procedure group ($p < 0.05$). Patients who underwent ISSF also had a lower incidence of postoperative complications, including lung injury, renal failure, peripheral nerve injury, and chylothorax, than those who underwent Sun's procedure ($p < 0.05$). During the 6-month follow-up period after surgery, both groups showed significant improvements in the true lumen diameter of the descending thoracic aorta post-operation compared with the pre-operation measurements; meanwhile, the false lumen diameter decreased ($p < 0.05$).
Conclusions: The ISSF technique appears to be an effective and safe alternative to conventional surgical procedures for patients with type A aortic dissection, with the potential to simplify the procedure, shorten the operation time, and yield satisfactory operative results. However, further investigation is needed to determine its long-term benefits.

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https://doi.org/10.1016/j.heliyon.2024.e29106
Received 13 September 2023; Received in revised form 28 March 2024; Accepted 1 April 2024
Available online 3 April 2024

1. Introduction

Type A aortic dissection (TAAD), a life-threatening vascular disease, presents a significant challenge with high mortality rates of up to 50% within 48 h of onset [1]. The conventional surgical strategy for TAAD involves ascending aorta replacement with or without arch replacement [2–4]. However, surgical intervention for aortic dissection presents two primary difficulties: the deep-positioned nature of the aortic arch and its intricate surrounding anatomy. The aortic arch contains three supra-aortic branches (the brachiocephalic trunk, left common carotid artery, and left subclavian artery) and is surrounded by structures such as the recurrent laryngeal nerve, trachea, and thoracic duct, posing significant challenges for aortic arch reconstruction [5,6].

Sun's procedure, also known as total arch replacement using a four-branched graft with frozen elephant trunk stent implantation, has emerged as the most commonly employed surgical technique for TAAD patients in China [7,8]. Despite its advantages in improving the closure rate of the distal false lumen (FL) and reducing the re-operation rate, Sun's procedure has several limitations. These include complex surgical strategies, the requirement of multi-anastomoses, a high risk of respiratory complications, and high incidence of postoperative malperfusion in vital organs [9]. Additionally, it is also associated with challenges in the suturing of tears and a long learning curve [10,11].

Surgical procedures remain the primary choice for total aortic arch reconstruction as they have proven to be effective in improving the closure rate of the distal FL and expanding the true lumen (TL) of aorta [12]. However, the mainstream surgical approach for the three supra-aortic branches is hindered by complicated procedures, high time consumption, and significant surgical trauma [13]. Previously, our team introduced a simplified total arch reconstruction method for extended aortic arch dilation, which yielded satisfactory operative results [14]. To simplify the procedure and reduce the risk of serious complications associated with TAAD, we designed an innovative in-situ stent-graft fenestration (ISSF) technique for minimally invasive aortic arch reconstruction. Our aim is to provide valuable insights to facilitate its implementation in clinical practice.

2. Methods

This study was approved by the Ethics Committee of the First Affiliated Hospital of Army Medical University. Two independent and experienced cardiac surgery teams performed all surgeries. All patients undergoing the ISSF or Sun's procedure were aware of the surgical process and signed an informed consent form. The preoperative patient characteristics are summarized in Table 1.

2.1. Source of participants

This study enrolled patients with TAAD who underwent aortic arch reconstruction at the First Hospital affiliated with the Army Medical University between February 2018 and January 2022. This study included 177 patients (124 males and 53 females) with ages

Table 1
Baseline characteristics of the participants.

Variables	Group		
	Sun's group (n = 90)	ISSF group (n = 87)	p
Male/female	66/24	58/29	0.333
Age (years)	50.6 ± 12.3	52.7 ± 10.1	0.196
Height (cm)	164.9 ± 9.2	163.9 ± 7.9	0.439
BMI (kg/m^2)	24.2 ± 3.9	24.3 ± 3.4	0.773
From symptom onset to surgery			
Acute (≤14 days) (n, %)	77 (85.6)	78 (89.7)	0.409
Subacute (15 days–1 month) (n, %)	6 (6.7)	4 (4.6)	0.787
Chronic (>1 month) (n, %)	7 (7.8)	5 (5.7)	0.591
Primary entry			
Ascending aorta (n, %)	72 (80.0)	74 (85.1)	0.376
No entry found (n, %)	14 (15.6)	11 (12.6)	0.578
Multiple entry (n, %)	4 (4.4)	2 (2.3)	0.357
Comorbidities			
Hypertension (n, %)	66 (73.3)	65 (74.7)	0.834
Atherosclerosis (n, %)	22 (24.4)	20 (23.0)	0.820
Marfan syndrome (n, %)	8 (8.9)	7 (8.0)	0.840
BAV (n, %)	7 (7.8)	6 (6.9)	0.822
Diabetes mellitus (n, %)	2 (2.2)	3 (3.4)	0.679
Cerebrovascular disease (n, %)	2 (2.2)	2 (2.3)	> 0.99
Chronic kidney disease (n, %)	10 (11.1)	9 (10.3)	0.869
Chronic obstructive pulmonary disease (n, %)	7 (7.8)	8 (9.2)	0.735
Peripheral arterial disease (n, %)	10 (11.1)	8 (9.2)	0.673
Dyslipidemia (n, %)	9 (10.0)	7 (8.0)	0.650
Hypoproteinemia (n, %)	12 (13.3)	21 (24.1)	0.065
Previous cardiac operations (n, %)	3 (3.3)	4 (4.6)	0.717

Continuous variables are expressed as mean ± standard deviation (SD) or median (range). Categorical variables are expressed as number (%). ISSF, in-situ stent-graft fenestration; BMI, body mass index; BAV, bicuspid aortic valve.

ranging from 20 to 76 years. Among them, 90 patients underwent Sun's procedure and 87 underwent ISSF. All patients were diagnosed preoperatively based on clinical manifestations, echocardiography, and aortic computed tomography angiography (CTA). The decision to undergo surgery was based on the patient's clinical condition. When a patient was enrolled in the Sun's procedure group, a matched patient was enrolled in the ISSF group to achieve a 1:1 match. Variables of interest, including age (±5 years), sex (exact), weight (±15 kg), height (±20 cm), and TAAD stage (acute or nonacute), were used for matching.

2.2. Inclusion and exclusion criteria

The inclusion criteria in this study consisted of individuals with a confirmed diagnosis of TAAD as indicated by CTA. Consent to participate in the study and to the surgical intervention was obtained from each patient through the execution of an informed consent form. Surgical procedures for TAAD patients were determined by the cardiac surgery team according to the patients' examination and aortic CTA. The exclusion criteria were listed as follows: (I) Presence of severe comorbid conditions (malignancies, rheumatic immune diseases, severe abdominal organ ischemia, etc.); (II) Concomitance with severe neurological disease, large-scale cerebral infarction, or

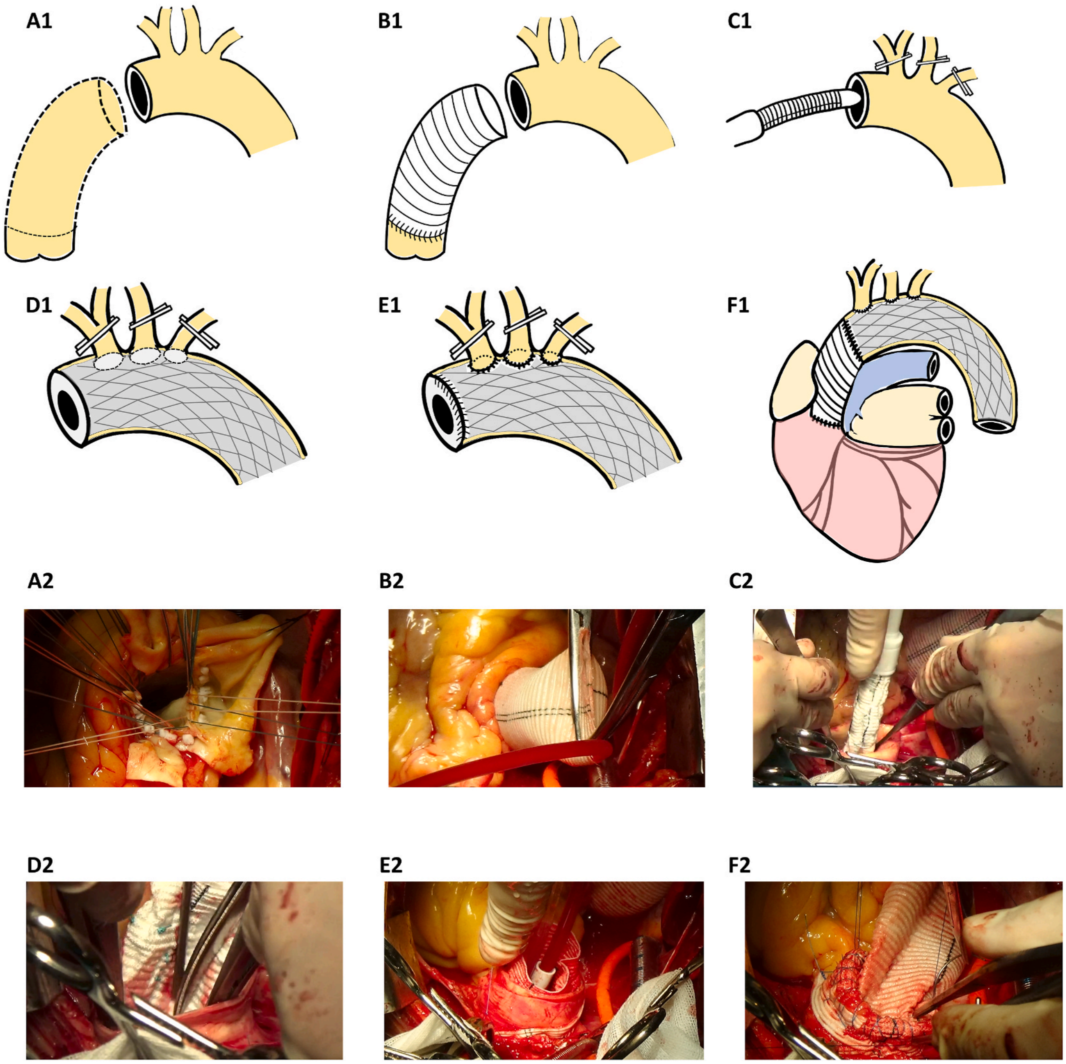

Fig. 1. Procedure of the aortic arch reconstruction utilizing the ISSF technique. **A1**: Transection of the ascending aorta proximal to the innominate artery's origin; **B1**: Replacement of the ascending aorta utilizing a custom-fit surgical graft; **C1**: Positioning and deployment of an appropriate frozen elephant trunk stent within the TL of the aortic arch and descending aorta; **D1**: Crafting of three fenestrations corresponding to the supra-aortic branch openings using surgical scissors post stent graft deployment; **E1**: Suture fixation of the fenestrations to the aortic wall and attachment of the proximal stent end to the native aortic arch; **F1**: Attachment of the distal end of the surgical graft to both the stent graft and the native arch via suturing. **A2–F2**: Sequential surgical images displaying each stage of the ISSF procedure.

deep coma; (III) Severe coagulation dysfunction; (IV) Aged over 80 years; (V) Dissection involving the inner layer of the three supra-aortic branches where the tear is proximate to these branches.

2.3. *Outcome measures*

The primary endpoint was defined as all-cause mortality within six months of surgery. Secondary outcomes included intraoperative blood transfusion volume, mechanical ventilation time, cardiopulmonary bypass time, circulatory arrest time, mechanical ventilation time, aortic cross-clamp time, length of postoperative in-Intensive Care Unit (ICU) and in-hospital stay, and incidence of complications (pericardial effusion, stroke, peripheral nerve injury, paraplegia, acute kidney injury, lung injury, poor perfusion, etc.).

2.4. *Surgical process*

The patient was placed in the supine position and administered general anesthesia. Conventional median sternotomy was performed to expose the heart and aorta. Extracorporeal circulation was instituted using the femoral artery, superior vena cava, and inferior vena cava. The innominate artery, the left common carotid artery and left subclavian artery were freed. Subsequently, with the ascending aorta occluded, a histidine-tryptophan-ketoglutarate (HTK) cardiac arrest fluid was perfused through the left and right coronary artery openings, and ice flakes were placed in the pericardial cavity to cool and protect the myocardium. The surgical procedure involving the aortic root repair or the ascending aorta replacement was conducted during the cooling phase (Fig. 1, A1, A2, B1, B2). The circulation was arrested when the nasopharyngeal temperature cooled to 27 °C. After opening the ascending aorta clamp, the anterograde selective cerebral perfusion (SCP) was initiated at a flow of 10 ml/kg/min through the innominate artery cannulation or a combination of innominate artery and left carotid artery cannulation. Subsequently, the patient underwent either Sun's procedure or ISSF technique.

2.4.1. *Ascending aortic replacement and aortic root treatment*

The Bentall, Wheat, David, or Cabrol procedure was chosen based on individual circumstances, CTA results, intraoperative exploration, and relevant patient examinations. The dissected ascending aorta was replaced with a matching surgical graft (Maquet Medical Equipment Co., Ltd., Shanghai, China; diameter:26–30 mm). The graft eversion anastomosis technique was used to achieve a comprehensive exposure of the anastomosis site, ensuring successful anastomosis and reducing vascular injury during suturing. Furthermore, the anastomotic site of the ascending aorta was reinforced with artificial vascular strips to enhance the hemostatic effect.

2.4.2. *Sun's procedure*

The steps in Sun's procedure are similar to those reported previously [7,8]. Briefly, the aortic arch and three supra-aortic branches were exposed (3–5 cm in length) and each branch was individually occluded. SCP was achieved through either sole cannulation of the innominate artery or a combination of innominate artery and left carotid artery cannulation, determined by intraoperative monitoring of cerebral oxygen levels and radial artery pressure. The distal aortic arch was dissected near the origin of the left subclavian artery (LSA), and the three supra-aortic branches were separately transected. A frozen elephant trunk stent, Cronus® (MicroPort Medical Co., Ltd, Shanghai, China; diameter: 26–30 mm, length: 120 mm) was implanted into the TL of the descending thoracic aorta (DTA). This stent features a 10 mm non-metallic mesh fabric on both ends (Fig. S1, supplementary material). Additionally, the stent is self-expanding, enabling the expansion of the TL and compression of the FL of the DTA. A four-branch graft (Maquet Cardiovascular, Wayne, NJ, USA) was sutured to the stent and the aorta. After evacuating the air, circulation to the lower body was resumed, and the corresponding branch of the surgical graft was sutured to the LSA using 5-0 prolene suture (Ethicon, Somerville, NJ, USA). The proximal end of the four-branched graft was sutured to the aorta using 4-0 prolene suture (Ethicon, Somerville, NJ, USA), and the brachiocephalic trunk, left common carotid artery and LSA were sutured end-to-end. The remaining procedures were performed in routine fashion.

2.4.3. *In-situ stent-graft fenestration (ISSF)*

(I) Vessel dissection: The ascending aorta was carefully transected near the origin of the brachiocephalic artery (Fig. 1, A1, A2). Then the ascending aorta replacement was performed (Fig. 1, B1, B2). Each of the three supra-aortic branches was freed (1–1.5 cm in length) and separately clamped at its respective origin (Fig. 1, C1, C2). (II) Stent selection: the elephant trunk stent used in ISSF group was identical to the one from Sun's procedure (MicroPort Medical Co., Ltd, Shanghai, China; diameter: 26–30 mm, length: 120 mm). The stent selection was based on preoperative CT three-dimensional reconstruction and intraoperative exploration of the aortic arch diameter between the LSA and the Left common carotid artery; (III) Stent implantation: The stent was carefully inserted into the TL of the aortic arch and DTA under direct visualization (Fig. 1, C1, C2). The flexible stent followed the curvature of the aortic arch and DTA, reducing the risk of tears. Once positioned correctly, the stent graft covered the openings of three supra-aortic branches, adjustable as necessary. 37 °C saline was infused to aid stent expansion; (IV) Stent graft fenestration: The stent graft was clamped and its external aspect was manually depressed to create a temporary working space between it and the aortic wall; this enabled direct visualization of the supra-aortic arch branch ostia and reassessment of their sizes and intervening distances. The sizes and distances of the three supra-aortic branch openings were reassessed using direct visualization. The polyester fabric was clamped and pressed downward to reveal the branch openings. The polyester fabric layer was then methodically and gradually removed using surgical scissors, starting with a small opening and progressively enlarging it to match the size of the branch opening. Thermal cautery can be used for deeper LSA openings. In cases where the distance between the branch openings exceeded 1.5 cm, separate stent fenestrations were created for each branch (Fig. 1, D1, D2). However, if the distance between the branch openings is less than 1.5 cm, the fenestration would be adjusted to "island" fenestration (Fig. 2A and B). After fenestration, branch patency was assessed using a nerve hook, while taking care to preserve the vascular intima during the process; (V) Stent graft fenestration anastomosis: After confirming the accurate positioning of the stent graft and fenestration, the anastomosis between the stent graft fenestration and the native aortic arch was performed using 5-0 prolene suture. For the separate stent fenestrations, sutures were taken around each of the three fenestrations individually (Fig. 1, E1, E2). On the other hand, for the "island" fenestration, sutures were taken encircling all three fenestrations (Fig. 2C and D). The first stitch started from the interior of the stent graft and passed through its full layer and the aortic arch. The second stitch entered the exterior of the aortic arch, passed through the full layer, and reached the stent graft interior. The suturing typically began at the LSA. After completing the anastomosis, a double-lumen ureteral catheter or balloon occlusion catheter was carefully inserted into the stent graft to restore lower-body circulation via the femoral artery. Other suturing proceeded simultaneously. (VI) Stent graft and surgical graft anastomosis: The proximal end of the stent graft was securely sutured to the aortic arch using 4-0 prolene suture. The surgical graft was then end-to-end anastomosed distally to the stent graft and the native arch (Fig. 1, F1, F2). (VII) Intraoperative cerebral perfusion: Either via innominate artery cannulation alone or a combination of innominate artery and left carotid artery cannulation, was used to achieve effective anterograde cerebral perfusion. The SCP selection was determined by monitoring of intraoperative cerebral oxygen levels and radial artery pressure.

2.4.4. Follow-up assessment

All patients were followed up for six months after discharge. CTA, chest radiography, and echocardiography were performed after completion of follow-up to assess thrombosis of the residual FL and supra-aortic vessel perfusion. CT was performed in patients with kidney disease who could not tolerate contrast agents. The CTA or CT was performed and evaluated by a radiology team (Fig. 3A–D). A follow-up team was responsible for monitoring, tracking, and collecting data from all patients with TAAD after the surgical procedures.

2.5. Statistical analysis

All statistical analyses were performed using SPSS version 25.0 (IBM Corporation, Armonk, NY, USA). Categorical variables were expressed as numbers (%). The chi-square test and Fisher's exact test were used to compare categorical variables. Continuous variables

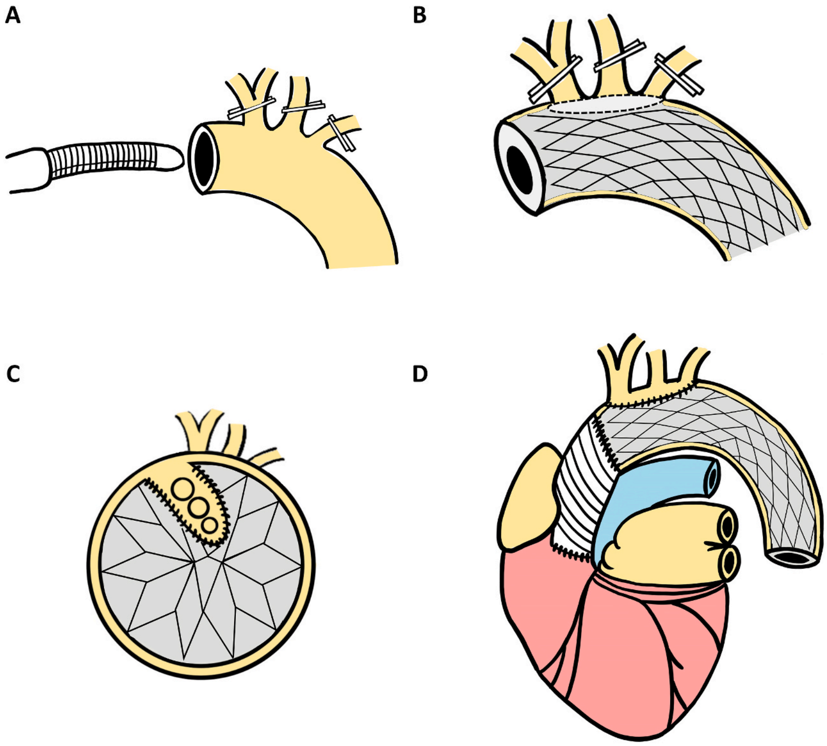

Fig. 2. Procedure of the modified "island" fenestration of ISSF technique. The "island" shaped fenestration method follows the fundamental steps of individual fenestration, differing chiefly in the method of fenestration. **A**: Implantation of a frozen elephant trunk stent in the TL of the aortic arch and descending aorta, with the stent positioned to span the openings of the three supra-aortic branches; **B**: Fabrication of a tailored "island" opening within the polyester fabric of the stent by using surgical scissors, tailored to align with the three supra-aortic branch openings; **C**: Detailed suturing at the "island" fenestration site on the stent graft, ensuring a robust anchorage to the aortic wall; **D**: Suture reinforcement at the proximal end of the stent, with subsequent attachment of the distal end of the surgical graft to both the proximal stent end and the native aortic arch.

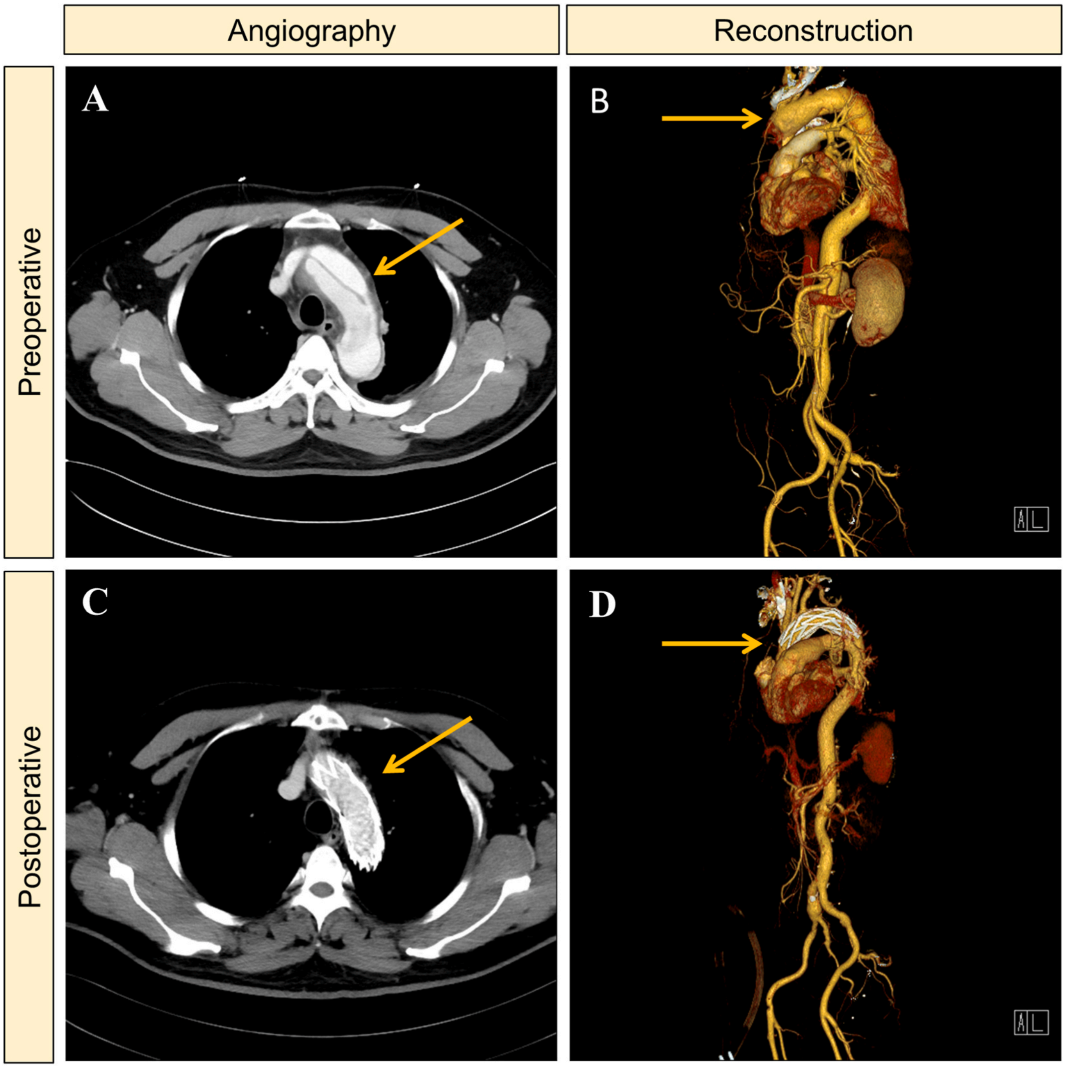

Fig. 3. The CTA of patient with TAAD before and after ISSF technique. **A**: The CTA of a representative patient with TAAD before operation; **B**: Three-dimensional reconstruction of CTA in patient with TAAD before operation; the yellow arrow refers to the FL of the arch; **C**: The postoperative CTA of the patient with TAAD after ISSF technique. The yellow arrow refers to the elephant trunk stent; **D**: Three-dimensional reconstruction of CTA was performed in patient with TAAD after ISSF technique; the yellow arrow refers to the in-situ fenestration of the elephant trunk stent. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

were expressed as mean ± standard deviation (SD) or median (range) according to whether they conformed to a normal distribution, and the normality of each variable was assessed using the Kolmogorov-Smirnov test. Student's t-test or Mann-Whitney *U* test was used for comparisons. A *p*-value less than 0.05 was considered statistically significant.

Table 2
Intraoperative indicators of the two groups.

Variables	Sun's group (n = 90)	ISSF group (n = 87)	*p*
Operative time (min)	406.1 ± 85.6	334.0 ± 64.1	<0.001
Cardiopulmonary bypass time (min)	214.4 ± 48.2	172.1 ± 44.3	<0.001
Aortic cross-clamp time (min)	112 (91, 140)	98 (84, 112)	<0.001
Hypothermic circulatory arrest time (min)	27.0 ± 9.3	22.7 ± 7.4	0.001
Intraoperative blood loss (ml)	640 (800, 1420)	600 (510,780)	<0.001
24-h drainage post-operatively	600 (835, 1200)	500 (325, 900)	<0.001
Intraoperative blood transfusion (ml)	2255 (1475, 3010)	1700 (1210, 2200)	<0.001
Operative deaths (n, %)	0 (0)	0 (0)	> 0.99

Continuous variables are expressed as mean ± standard deviation (SD) or median (range). ISSF, in-situ stent-graft fenestration.

3. Results

In total, 177 patients with TAAD were recruited for this study. The baseline patient characteristics are shown in Table 1. There were no statistically significant differences in baseline characteristics between the two groups.

As shown in Table 2, patients in the ISSF group had a shorter surgical duration, cardiopulmonary bypass (CPB) time, and circulatory arrest time than those in Sun's group ($p < 0.05$). There were no reported operative deaths in either group. Additionally, the ISSF group had less intraoperative blood loss and shorter aortic cross-clamp time ($p < 0.05$). Table 3 displayed that ISSF group had a shorter mechanical ventilation time, postoperative in-ICU stay, and in-hospital stay compared to the Sun's group ($p < 0.05$). A total of ten patients died during the perioperative period, of whom seven were in the Sun's group (7.8%) and three in the ISSF group (3.4%) ($p = 0.357$).

Six patients died within 6 months after surgery (four in the Sun's group and two in the ISSF group), although no significant difference was observed in the 6-month mortality between the two groups ($p = 0.443$, Table 4). Additionally, there were no significant differences in the incidence of neurological complications, pericardial effusion, paraplegia, or embolism between the two groups ($p > 0.05$, Table 4). ISSF technique exhibited a lower incidence of lung injury, renal failure, peripheral nerve injury, and chylothorax compared to the Sun's group ($p < 0.05$, Table 4). Two cases of endoleakage were reported in the ISSF group, which was not statistically significant compared with Sun's group ($p > 0.05$, Table 4).

A total of 167 patients were discharged from the hospital, with 83 and 84 patients in the Sun's group and ISSF groups, respectively. The CTA results showed that the surgical outcomes of Sun's procedure were satisfactory, with a decreased arch diameter, an expanded TL, and a smaller FL of the DTA ($p < 0.05$, Table 5). Among the 84 patients in the ISSF group discharged from the hospital, complete aortic arch FL closure was found in 74 patients, partial arch FL closure in seven patients, while aortic arch FL in 3 patients was not closed. In patients with complete aortic arch FL closure in the ISSF group, the diameter of the aortic arch at discharge was significantly different from that before operation ($p < 0.01$, Table 5). The DTA diameters at discharge were not significantly different from the preoperative data (p=0.140, Table 5). However, the TL diameter of the DTA after the operation was significantly larger than before the operation ($p < 0.05$; Table 5), whereas the FL diameter was smaller ($p < 0.05$; Table 5). There have been no reports of cardiogenic death, initiation of dialysis, or further surgical interventions in these patients after discharge. Patients in both groups reported no stent shift, obvious aortic arch dilatation, obvious partial arch vascular stenosis, or three-branch opening stenosis caused by stent shift.

CTA was re-assessed at 6-month during follow-up (Table 6). A total of 78 patients in the Sun's group and 77 patients in the ISSF group completed the follow-up CTA. In the ISSF group, 69 patients with complete aortic arch FL closure at discharge underwent follow-up CTA and the FL remained closed. Six patients with the partial closure of the arch FL underwent follow-up CTA. Among them, the arch FL of five patients was closed and that of one patient was not. Two of the three patients with arch FL underwent follow-up CTA, and none of their arch FL was closed. In patients with complete aortic arch FL closure in the ISSF group (Fig. 3), the DTA diameters at 6 months postoperatively were significantly smaller than those before operation ($p < 0.05$; Table 6), which may be partially due to hematoma absorption around the DTA. The TL diameter of the DTA 6 months post-operatively was larger than that before the operation ($p < 0.05$, Table 6), whereas the FL diameter was significantly smaller ($p < 0.05$, Table 6).

4. Discussion

TAAD remains a significant challenge for cardiac surgeons because of the complexity of aortic arch reconstruction and the limited options for the descending aortic path [15]. In China, Sun's procedure is the preferred method for treating TAAD and is applicable in the majority of cases [7]. However, this is often accompanied by a high incidence of intraoperative bleeding, and postoperative neurological and respiratory complications [16]. Inspired by the "in-situ fenestration" in endovascular repair, we have proposed the ISSF technique and applied it in TAAD surgical treatment to achieve "minimally invasive" reconstruction of the aortic arch. Our results showed that ISSF is comparable to Sun's procedure in terms of aortic arch reconstruction but with shorter surgical, CPB, cross-clamp, and mechanical ventilation times. More importantly, patients who underwent ISSF had lower incidences of respiratory insufficiency, renal failure, and nervous system injuries. Considering the generally poor condition of TAAD patients, ISSF would be more preferred for their aortic arch reconstruction.

The ISSF technique presents the following attributes for treating TAAD by implementing in-situ fenestration in open aortic arch surgeries: Firstly, compared to conventional open surgeries, ISSF can not only simplify the surgical procedure and reduce the difficulty of arch reconstruction but can ensure the effect of arch reconstruction with "minimally invasive" endovascular repair. Secondly, ISSF created only three holes in the stent graft coverage without modifying the metal scaffold of the stent graft. This preserves the stent-

Table 3
Postoperative indicators of the two groups.

Variables	Sun's group (n = 90)	ISSF group (n = 87)	p
Hospital stays (d)	14 (13, 19)	14 (12, 17)	0.035
Postoperative ICU stay (d)	6.0 (3.0, 8.0)	4.0 (3.0, 6.0)	0.015
Mechanical ventilation time (h)	59 (33, 100)	45 (28, 76)	0.006
Hospital mortality (n, %)	7 (7.8)	3 (3.4)	0.357

Continuous variables are expressed as median (range). Categorical variables are expressed as number (%). ISSF, in-situ stent-graft fenestration. ICU, Intensive Care Unit.

Table 4
Incidence of complications and 6-month mortality of the two groups.

Variables	Sun's group (n = 83)	ISSF group (n = 84)	*p*
Lung injury (n, %)	18 (21.7)	6 (7.1)	0.008
Renal failure (n, %)	11 (13.3)	2 (2.4)	0.009
Central nervous system damage (n, %)	6 (7.2)	3 (3.6)	0.496
Peripheral nerve injury (n, %)	6 (7.2)	0 (0)	0.028
Chylothorax (n, %)	7 (8.4)	0 (0)	0.014
Endoleakage (n, %)	0 (0)	2 (2.4)	0.497
Cerebral infarction (n, %)	1 (1.2)	1 (1.2)	> 0.99
Pericardial effusion (n, %)	3 (3.6)	0 (0)	0.245
Poor perfusion (n, %)	8 (9.6)	2 (2.4)	0.050
Paraplegia (n, %)	2 (2.4)	0 (0)	0.497
Death within 6-month (n, %)	4 (4.8)	2 (2.4)	0.443

Categorical variables are expressed as number (%). ISSF, in-situ stent-graft fenestration.

Table 5
Comparison of aortic arch diameter in patients with complete aortic arch false lumen closure at discharge.

Variables	Sun's group (n = 83)			ISSF group (n = 74)		
	Pre-operation	At discharge	*p*	Pre-operation	At discharge	*p*
AA diameter (mm)	47.0 (42.0, 54.0)	29.0 (27.9, 31.5)	<0.001	46.0 (41.5, 52.0)	29.0 (27.5, 30.5)	<0.001
Aortic arch diameter (mm)	38.8 ± 5.1	34.4 ± 3.4	<0.001	37.8 ± 5.1	34.1 ± 2.7	<0.001
DTA diameter (mm)	34.7 ± 6.4	33.1 ± 5.5	0.076	33.3 ± 5.3	32.2 ± 4.1	0.140
TL (mm)	17.3 ± 7.4	22.4 ± 6.5	<0.001	17.2 ± 7.5	21.1 ± 4.9	<0.001
FL (mm)	15.0 (10.0, 20.0)	10.0 (7.5, 14.0)	0.001	16.0 (12.0, 19.5)	10.5 (8.0, 12.0)	<0.001

Continuous variables are expressed as mean ± standard deviation (SD) or median (range). ISSF, in-situ stent-graft fenestration. AA, ascending aorta; DTA, descending thoracic aorta; TL, true lumen of DTA; FL, false lumen of DTA.

Table 6
Comparison of aortic arch diameter in patients with complete aortic arch false lumen closure at 6th-month of follow-up.

Variables	Sun's group (n = 78)			ISSF group (n = 74)		
	Pre-operation	6-month post-operation	*p*	Pre-operation	6-month post-operation	*p*
AA diameter (mm)	47.0 (41.0, 54.8)	28.5 (27.4, 31.0)	<0.001	46.0 (41.5, 52.0)	28.5 (27.0, 30.5)	<0.001
Aortic arch diameter (mm)	38.2 ± 5.2	29.7 ± 2.3	<0.001	37.7 ± 5.0	30.8 ± 2.5	<0.001
DTA diameter (mm)	34.0 ± 5.8	31.6 ± 4.3	0.005	33.6 ± 5.4	30.3 ± 3.1	<0.001
TL (mm)	16.7 ± 6.8	25.7 ± 3.7	<0.001	17.3 ± 7.4	24.8 ± 4.3	<0.001
FL (mm)	15.0 (10.0, 20.0)	7.5 (5.5, 8.0)	<0.001	15.0 (11.0, 19.0)	6.5 (5.0, 9.0)	<0.001

Continuous variables are expressed as mean ± standard deviation (SD) or median (range). ISSF, in-situ stent-graft fenestration. AA, ascending aorta; DTA, descending thoracic aorta; TL, true lumen of DTA; FL, false lumen of DTA.

graft's ability to conform to aortic arch curvature as well as its self-expanding property which facilitates apposition to the aortic wall and true lumen expansion. Additionally, the stent graft is sutured to the aorta to reinforce the arch, consequently promoting the closure rate of the false lumen and lowering the risk of endoleaks. Considering the rapid progression of TAAD and the possibility of the tearing position differing from the preoperative CTA reconstruction, ISSF allows for timely adjustment of the fenestration based on intra-operative exploration and the relationship of the tears. This enables surgeons to promptly manage unexpected situations, including switching to Sun's procedure, which aligns more closely with current clinical practice. In addition, the ISSF does not require additional sophisticated surgical instruments, making it suitable for widespread adoption and promotion.

One notable benefit of ISSF is its ability to effectively reduce surgical duration, consequently mitigating the potential harm inflicted on vital organs and the central nervous system resulting from CPB and circulatory arrest. In China, Sun's procedure is the first-line option for treating TAAD. However, it requires total arch replacement with a four-branched graft, which requires a long time for SCP and deep hypothermic circulatory arrest, which has profound malignant effects on the function of the organ, especially the nervous system and kidneys [17]. Studies have shown that prolonged CPB time is an independent risk factor for prolonged ventilator assistance, prolonged in-ICU stay, and increased pulmonary infection after cardiac surgery [18,19]. Our results showed that patients who underwent ISSF experienced shorter CPB and circulatory arrest times than those who underwent Sun's procedure. Furthermore, ISSF reduced the incidence of lung injury, renal failure, and central nervous system injuries. These findings suggest that ISSF has the potential to reduce the occurrence of complications by decreasing the CPB time.

ISSF has the potential to effectively reduce postoperative bleeding and minimize the need for intraoperative blood transfusions. Arterial anastomotic bleeding is challenging in aortic arch reconstruction. Patients with acute TAAD are particularly susceptible to anastomotic bleeding due to inflammation, aortic wall edema, and high blood pressure. In this study, although there was no statistically significant difference in the proportion of patients with acute TAAD between the ISSF and Sun's procedure groups, the ISSF demonstrated superior hemostatic capabilities with decreased bleeding. This advantage can be attributed to several factors, including the reduced requirement for aortic arch and arch branch resections, minimized number of anastomoses, and reduced impact of CPB on coagulation function. The prolonged use of CPB can potentially increase the volume of blood transfusions, thus aggravating the risk of complications [20]. Moreover, ISSF offers the added benefit of relocating the distal anastomosis of the aorta closer to the innominate artery, resulting in improved exposure and efficient hemostasis. Conversely, blood transfusion is a known risk factor for postoperative mortality in cardiac surgery [21] as it can lead to excessive expression of pro-inflammatory mediators in the lungs, elevating the risk of lung infections [22]. The ISSF group showed a lower incidence of lung injury, likely due to the reduced volume of blood transfusions.

It is important to acknowledge that the implementation of ISSF technology results in a shorter stent length covering the descending aorta, potentially preventing paraplegia. However, this may also contribute to the increased formation of late-stage aneurysms in the descending aorta. In cases where a single stent was unable to fully cover the aortic dissection rupture based on preoperative evaluation, our team utilized two elephant trunk stents with some degree of overlap. Notably, the majority of patients in this study required only one elephant trunk stent. Additionally, we conducted long-term follow-ups for all patients to enable timely intervention with thoracic endovascular aortic repair (TEVAR) in the event of any complications. This aspect warrants further research as an ongoing focus of our study.

Nervous system complications are common after AD surgery, leading to prolonged hospital stays and increased mortality [23]. Smith et al. and Ma et al. reported neurological injury incidence rates of 3.7% and 5.3%, respectively, in patients with TAAD undergoing Sun's procedure [10,24]. In our study, the incidence of neurological injury in the ISSF group was slightly lower than that in the Sun procedure group (3.6% vs. 7.2%, $p = 0.496$), although the difference was not statistically significant. This may be attributed to the shortened deep hypothermic circulatory arrest in the ISSF group. Additionally, thoracic duct injury and recurrent laryngeal nerve injury are common complications of TAAD surgery, and their rates were remarkably lower in the ISSF group than in the conventional surgery group, which may be due to the minimal extensive dissection of the three super-aortic branches in the ISSF technique. Notably, two cases of postoperative endoleaks were observed in the ISSF group, while it was not reported in the Sun's procedure group. Endoleak, a common complication during complete endovascular treatment of aortic arch lesions [25], can lead to hemodynamic instability in the vascular lumen or even rupture of the dissection in severe cases [26]. The cause of endoleak in the ISSF group could be associated with the positioning of the stent graft and anchoring of the proximal aorta.

Patients with TAAD present with complex conditions associated with high in-hospital mortality rates. A study by Sun et al. reported an in-hospital mortality rate of 3.09% and a long-term mortality rate of 3.73% in 291 patients with AD who underwent Sun's procedure [6]. Another study suggested a higher mortality rate when 20–40% of elderly or high-risk patients were included [27]. A study of 1279 patients undergoing conventional surgical procedure has shown an early mortality of 9.2%, and an overall mortality ($\geq$1 year) of 13.0% [23]. In this study, the in-hospital mortality of patients undergoing ISSF surgery (3.4%) was slightly lower than that of patients undergoing Sun's procedure (7.8%), although the difference was not statistically significant ($p = 0.357$). This could be explained by CPB time, which is closely related to 30-day mortality [10]. Another contributing factor to the lower in-hospital mortality rate in the ISSF group could be the reduced incidence of acute renal failure, as this condition significantly increases the in-hospital mortality rate in patients with TAAD [28,29]. In this regard, the ISSF technique may be a favorable option for elderly patients with TAAD; however, further research is required.

This study has several limitations. First, potential bias is unavoidable due to its retrospective design, although we strictly followed the inclusion and exclusion criteria. Second, the allocation of patients to the two techniques compared in this study was not randomized. Therefore, surgeon preference or anatomical suitability might introduce potential bias in this study. Third, the follow-up duration was short, making it impossible to assess the long-term prognosis and durability of the endovascular stents. Finally, the censored data in the follow-up cohort may have biased the results.

5. Conclusion

We present the ISSF technique as a new surgical approach for treating TAAD. This technique incorporates the advantages of in-situ fenestration into the conventional open surgery. The ISSF technique ensures a definite therapeutic effect while retaining the well-exposed visual field of conventional surgery and completely preserving the arch structure and three super-aortic branches to reduce surgical trauma and duration. The ISSF technique significantly simplifies the aortic arch reconstruction and provides a new and reliable treatment option for TAAD. More well-designed studies are required to further assess its clinical applicability and long-term effects.

Ethical statement

This study was reviewed and approved by the Ethics Committee of the first affiliated hospital of Army Medical University (Third military university) with the approval number: [KY2021058]. Informed consent was obtained from all participants/patients (or their proxies/legal guardians) for their participation in the study and publication of anonymized case details and images. The authors are accountable for all aspects of this study.

Funding

This study was funded by the Foundation of Logistics Support Department (No. 20WQ004), Science-Health Joint Medical Scientific

Research Project of Chongqing (No. 2023MSXM110), University Funded Science and Technology Innovation Capacity Improvement Project (No. 2019XYY13).

Data availability statement

Data associated with this study has not been deposited into a publicly available repository. The study includes original contributions, which are detailed in the article/supplementary material. Additional data used in this study are available from the corresponding author on request.

CRediT authorship contribution statement

Sanjiu Yu: Writing – review & editing, Writing – original draft, Software, Methodology, Data curation, Conceptualization. **Deqing Lin:** Writing – review & editing, Writing – original draft, Methodology, Data curation. **Jianguang Yi:** Writing – review & editing, Writing – original draft, Methodology, Data curation. **Xianpu Zhang:** Writing – review & editing, Methodology, Data curation. **Yongbo Cheng:** Writing – review & editing, Data curation. **Chaojun Yan:** Writing – review & editing, Methodology. **Huajie Zheng:** Writing – review & editing, Data curation. **Lingfeng Tang:** Methodology. **Mei Guo:** Writing – review & editing, Software. **Ping He:** Writing – review & editing, Writing – original draft, Methodology, Data curation. **Jun Li:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Data curation. **Wei Cheng:** Writing – review & editing, Project administration, Methodology, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to thank the researchers and study participants for their contributions.

Appendix ASupplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e29106.

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