In situ diode laser fenestration of aortic arch stent grafts during thoracic endovascular aortic repair of Stanford type A aortic dissection

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This paper also includes supplementary data published online at: http://www.pcronline.com/eurointervention/151st_issue/326

KEYWORDS

• balloon inflation
• innovation
• laser
• thoracic aorta dissection

Abstract

Aims: The aim of the study was to evaluate the feasibility, safety, and effectiveness of *in situ* diode laser fenestration of thoracic endovascular aortic repair (TEVAR) stent grafts to treat Stanford type A aortic dissection.

Methods and results: Fifty-eight patients with acute or subacute Stanford type A aortic dissection treated with *in situ* diode laser fenestration during TEVAR under cerebral circulation protection with an extracorporeal bypass were reviewed retrospectively. Routine postoperative outcomes were recorded and assessed. Computed tomography angiography (CTA) was performed during the follow-up after 3, 6 and 12 months. Procedural success was achieved in 53 patients (91.4%). The average procedure time was 162±36 minutes. One patient died of pericardial tamponade during intervention, and one died of severe pneumonia after the intervention. Except for two minor strokes, no more fenestration-related complications occurred at 30 days and 12 months after the intervention. CTA imaging demonstrated 100% primary patency for the left subclavian artery and carotid arteries with favourable aortic remodelling after TEVAR during the follow-up. Two patients had a type Ia endoleak and one other a type II endoleak.

Conclusions: *In situ* diode laser fenestration during TEVAR for type A aortic dissection was found to be feasible, safe, and effective, and may be beneficial as a less invasive approach.

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Abbreviations

ACP   antegrade cerebral perfusion
CTA   computed tomography angiography
DSA   digital subtraction angiography
LCA   left common carotid artery
LSA   left subclavian artery
PTFE   polytetrafluoroethylene
TEVAR   thoracic endovascular aortic repair

Introduction

Stanford type A aortic dissection involving the aortic arch remains a catastrophic disease due to high mortality and morbidity rates[1,2]. Up until now, open aortic arch reconstruction has remained an irreplaceable therapeutic technique[3,4], although it shows high morbidity and mortality rates for multiple organ failure[5]. Compared with open surgery, thoracic endovascular aortic repair (TEVAR) with branched endografts, chimneys, fenestrations, or hybrid-debranching endovascular aortic repair presents an advanced alternative therapy for Stanford type A aortic dissection, extending the option of TEVAR therapy into the realm of the proximal aortic arch in patients with Stanford type A aortic dissection who may benefit from a less invasive approach[6-8]. Branched-type stent grafts can reconstruct the three branches of the aortic arch[9,10], which are customised and limited to use in emergency situations. Additionally, chimney techniques are accepted during TEVAR, which may increase the risk of endoleaks after the intervention[11]. Furthermore, debranching TEVAR and hybrid-debranching endovascular aortic repair are also available methods; however, they require complex procedures and prolonged intervention times[12,13]. Compared with the above methods, fenestration, as a rapid and reproducible technique of fenestrating the endograft membrane, presents a potential and effective option to reconstruct the supra-aortic branches[14]; however, the related reports are limited[15-17], because revascularising the three branches of the aortic arch effectively during TEVAR is still a big challenge, especially for the Stanford type A aortic dissection. Differently, in our department, an 810 nm diode laser has been used for the past 15 years to cure superficial venous insufficiency and congenital extratruncular venous malformations[18,19]. The present study used this diode laser to fenestrate the membrane of aortic arch stent grafts and showed attractive results in repairing Stanford type A aortic dissections.

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Methods

PATIENT SELECTION

The study protocol was approved by the Committee for the Protection of Human Subjects at the Shanghai Jiao Tong University, School of Medicine (Shanghai, China). Informed consent was obtained from each patient involved in this study. This was a retrospective observational study. From April 2014 to May 2018, 58 patients with Stanford type A aortic dissection who underwent TEVAR combined with *in situ* laser fenestration from a zone 0 landing were retrospectively analysed. Patients with aortic artery diseases were included in this study according to critical inclusion criteria, including the damage to the aortic branches and intimal tears adjacent to the aortic/coronary ostia or the proximal seal zone more than 15 mm. The exclusion criteria were as follows: 1) patients with cardiopulmonary and renal insufficiency intolerant to general anaesthesia (the criteria according to the anaesthetist); 2) less than 15 mm distance (seal zone) between intimal tears and coronary ostia; and 3) coronary ostia or cardiac vesicle affected by the dissection. None of the patients had aortic valve failure, pericardial effusion, or other complications.

All procedures were performed under general anaesthesia in a digital subtraction angiography (DSA) operating room. Both carotid arteries, the left brachial artery, and the left or right femoral artery, were exposed surgically under sterile conditions and cannulated with a 6 Fr sheath, 8 Fr sheath, and a 10 Fr sheath (Terumo Corp., Tokyo, Japan), respectively. Intravenous heparin 5,000 U and a 30 U/min drip infusion of heparin were administered. A 100 cm 5 Fr pigtail catheter (Cook Medical, Bloomington, IN, USA) was advanced over a 0.035-inch stiff guidewire (Terumo Corp.) through the femoral artery to the ascending aorta-adjusted coronary ostia, which is an important marker to show the valve location for the next procedure. A 16 Fr sheath (DrySeal Sheath; W.L. Gore & Associates, Inc., Flagstaff, AZ, USA) and a 6 Fr sheath (Terumo Corp.) were inserted into the proximal and distal innominate arteries on different orientations, respectively. Of note, when the 16 Fr sheath core arrived at the tip of the pigtail catheter (15 mm above the coronary ostia), it was pushed forward in tandem with pulling back the sheath core in the ascending aortic arch until next to the coronary valve (15 mm). Then, an 8 Fr sheath (Terumo Corp.) was inserted into the distal part of the 16 Fr sheath, and a 12 Fr sheath (DrySeal Sheath) was inserted into the left common carotid artery (LCA) following the same procedure as the 16 Fr sheath. Cerebral blood perfusion and brain protection were established by an extracorporeal bypass through a vascular shunt connection of the bilateral sheath **(Supplementary Figure 1)**, giving time for the following laser fenestration. Under these systemic circulatory arrests, antegrade and retrograde cerebral perfusions were initiated in the following steps by changing different angles for the blood perfusion.

LASER FENESTRATION PROCEDURE

The diameters of the ascending aorta and arch branches were measured using angiography and computed tomography angiography (CTA) **(Figure 1)**, and the thoracic endografts were delivered via the femoral artery access using the double-curved Lunderquist® wire (Cook Medical), which arrived at the level of the coronary ostia according to the tip of the pigtail catheter (a marker, as previously mentioned). The 21-24 Fr sheath (DrySeal Sheath) was inserted from the femoral artery, and a TAG® or conformable TAG (cTAG) endograft (W.L. Gore & Associates, Inc.) was passed into the descending and ascending aortas. Immediately after the TAG or cTAG endograft had been deployed to cover the dissection tears, a balloon catheter of 4×40 mm (Mustang™; Boston Scientific, Marlborough, MA, USA) was inserted using an 810 nm optical
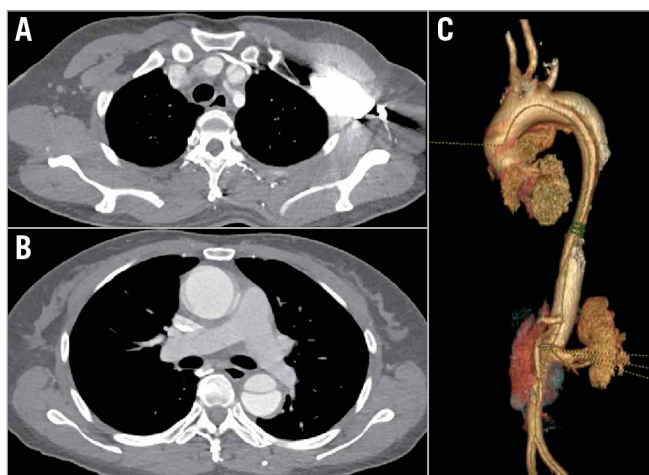
Figure 1. *CTA before treatment. A) Cross-section of CTA showing intimal tear location in the aortic arch. B) Cross-section of CTA showing the tear involving the ascending aorta. C) Three-dimensional volume image showing intimal tear at the aortic arch.*

fibre and gently advanced close to the LCA thoracic endograft. Importantly, the fibre tip was beyond the tip of the 1 cm balloon catheter. When the fibre touched the TAG membrane, the resistance of its delivery could be perceived. Then, laser energy was applied with 18-watt energy for 3 seconds to create fenestration without any fibre movement. The laser energy was activated, and an *in situ* fenestration hole was created. Either the whole laser fibre or the Hi-Torque Supra Core® wire (Abbott Vascular, Santa Clara, CA, USA) was passed through the newly created hole. The balloon catheter was then advanced into the aortic lumen over the fibre. Alternative wires, such as 0.035-inch or 0.018-inch wires (Boston Scientific), were passed through the balloon catheter after withdrawing the laser fibre into the ascending aorta. A 100 cm 5 Fr pigtail catheter (Cook Medical) through the fenestration was used, sometimes followed by rotating multiple angles to judge the true lumen to guarantee the balloon catheter of 4×40 mm in the aortic lumen. After confirming the reverse blood flow, balloon dilatation was performed to enlarge the fenestration using 6 to 8 mm balloons (Sterling™; Boston Scientific). After a 0.035-inch Hi-Torque Supra Core guidewire exchange and endograft predilation using an 8 mm balloon (Mustang), a covered stent (10-13.5 mm in diameter, FLUENCY® Plus; Bard Peripheral Vascular, Inc., Tempe, AZ, USA) was placed through the fenestration, and an angioplasty balloon with a 10 to 14 mm diameter was used to "flare" the branched stent graft portion. After changing the angle of the vascular shunt, DSA angiography was performed to demonstrate the aortic stent and LCA fenestration patency. Innominate artery fenestration was also performed using the above method. After confirming the reverse blood flow, balloon dilatation was performed to enlarge the fenestration and a FLUENCY covered stent of 13.5×40 mm (Bard Peripheral Vascular) was placed and a 12 mm diameter balloon was used to "flare" the branched stent. If the diameter of the innominate artery was larger than 13.5 mm, a modified Talent™ (Medtronic,

Minneapolis, MN, USA) leg stent graft was used because no such large stent for the innominate artery was available on the market. After placing the branch stent to prevent bubble stroke, a 50 mL syringe with saline-dilated heparin was used to draw out 50 mL of blood through the carotid artery, which was transfused back. After the aforementioned fenestration, a 6 Fr, 55 cm Cook sheath (Cook Medical) was introduced over a stiff wire to the origin of the left subclavian artery (LSA) by angulation and directional control to fenestrate the LSA in a similar manner **(Figure 2)**. A stable branch reconstruction was confirmed using DSA.

Finally, the incisions were closed. The patients were then placed under intensive care after the intervention, transferred to a peripheral ward two days after the intervention, and discharged home in good clinical condition.

After the intervention, the technical success, intervention times, clinical outcomes, number of fenestrations of the intimal flap per patient, and complications were recorded. Routine postoperative follow-up CTA imaging was performed to evaluate TEVAR and fenestration patency, endoleaks, and dissection or aneurysm exclusion formation 3, 6 and 12 months after the intervention.

STATISTICAL ANALYSIS

Patient demographics, the morphological presentation of aortic arch arteries, intervention information, clinical outcomes, complications, and follow-up data were analysed using SPSS software, Version 18 (SPSS Inc., Chicago, IL, USA). Data were expressed as mean values ± standard deviation.

Results

PATIENT DEMOGRAPHICS AND PRESENTATION

The procedural success of *in situ* diode laser fenestration during TEVAR of Stanford type A aortic dissection was achieved in 53 of 58 patients (91.4%). Further, 21 patients with acute (≤14 days) Stanford type A aortic dissection were treated, eight of them within 48 hours after the initial admission, depending on the patient symptoms, condition change, and aortic lesion characteristics. Thirty-seven (37) patients were treated in the subacute phase by controlling blood pressure. Two LSA fenestrations were abandoned due to the highly tortuous LSA, with an acute angle between its origin and the aortic arch. Two fenestrations were not achieved due to an acute early take-off of the innominate artery in a type III aortic arch. One patient died of pericardial tamponade during the intervention and one due to severe pneumonia after the intervention, leading to the 3.5% in-hospital mortality rate. No additional deaths occurred during the follow-up **(Table 1)**. All patients complained of severe chest and back pain upon admission. This disappeared two weeks to six months (average, three months) after the intervention during the postoperative follow-up. No patient showed aortic valve failure or other complications.

All the patients underwent TEVAR with *in situ* diode laser fenestration to revascularise the LCA, innominate artery and LSA under an acute or a subacute emergency situation. **Table 1** shows the indications for TEVAR and relative data. Except for stroke occurring
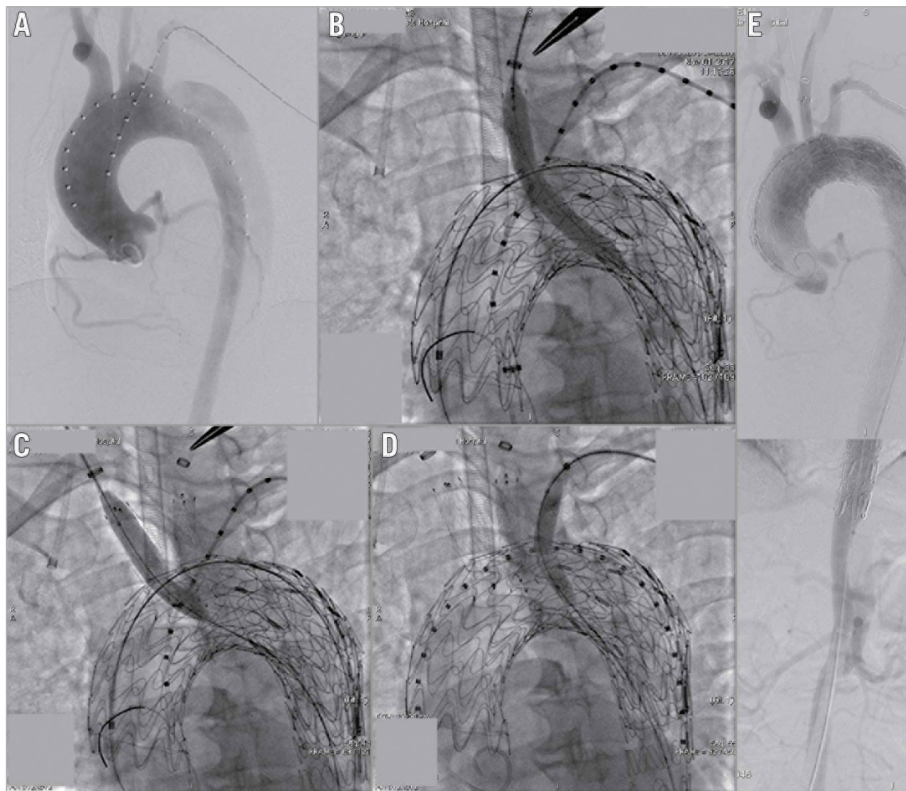
Figure 2. *In situ diode laser fenestration of the LCA, innominate artery, and LSA during TEVAR. A) DSA images in the left anterior oblique view. B) In situ diode laser fenestration of the LCA, and one stent implanted in the LCA. C) In situ diode laser fenestration of the innominate artery, and one stent implanted and balloon dilatation performed to enlarge the fenestration. D) In situ diode laser fenestration of the LSA, and one stent implanted and balloon dilatation performed to enlarge the fenestration. E) DSA showing the patency of aortic arch branches.*

in two patients (3.5%) after TEVAR, no myocardial infarction, transient ischaemic attacks, cerebral infarction, respiratory system, renal system, or other neurologic complications occurred during the follow-up period. A follow-up CTA (10.6±5.4 months) indicated that two patients had a type Ia endoleak and one other a type II endoleak; no additional fenestration-related endoleaks occurred, and all patients exhibited a reduction in the aneurysm diameter or the thrombosed false lumen **(Figure 3)**. Furthermore, false lumen

thrombosis and subsequent positive remodelling of the aorta were evidenced. All the *in situ* diode laser-fenestrated arteries were patent according to the postoperative follow-up CTA imaging, which was also evidenced by clinical symptoms.

Discussion

The present study shows good technical outcomes with *in situ* diode fenestration of aortic arch stent grafts during TEVAR of
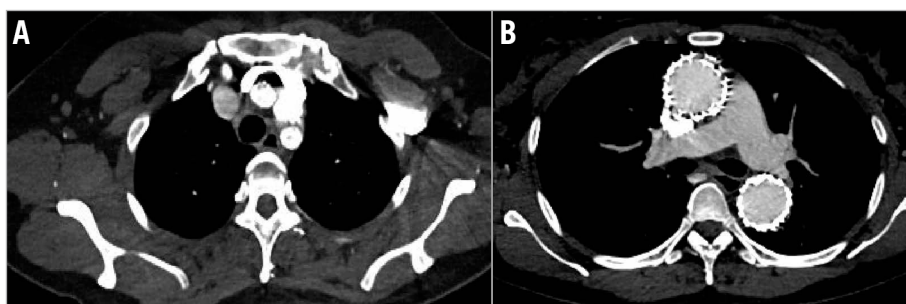

Figure 3. *Postoperative CTA at one year presented the patency of three branches of fenestration and stent placement. A) Cross-section of postoperative CTA showing the patency of in situ laser fenestration of the three branches of the aortic arch. B) False lumen thrombosis and subsequent positive remodelling of the aorta were evidenced.*

Table 1. Baseline characteristics and operative details of 58 patients with in situ diode laser fenestration of aortic arch stent grafts during TEVAR of Stanford type A aortic dissection.

Baseline characteristics	
Age, years	58 (33-67)
Male	32 (55.2%)
Female	26 (44.8%)
Hypertension	42 (72.4%)
Smoking	30 (51.7%)
Diabetes mellitus	33 (56.9%)
Hypercholesterolaemia	16 (27.6%)
Congestive heart failure	10 (17.2%)
Peripheral artery disease	11 (20.0%)
Renal insufficiency	6 (10.3%)
COPD	4 (6.9%)
Marfan syndrome	1 (1.7%)
Operative details	
Proximal diameter, mm	36±8
Operative time, min	162±36
Brain protection time, min	25±13
Contrast, mL	184±20
Length of stay, days	10±2.6
Stroke	2 (3.5%)
Endoleak	3 (5.2%)
Death	2 (3.5%)

COPD: chronic obstructive pulmonary disease; TEVAR: thoracic endovascular aortic repair

Stanford type A aortic dissection under extracorporeal brain protection, which was designed based on the currently available commercial devices and techniques. CTA demonstrated the complete coverage of primary tears, patent *in situ* laser-fenestrated arteries, and remodelling of the aorta 3, 6 and 12 months after the intervention in parallel with no stent graft migration and with complete thrombosis formation in the false lumen.

A well-established procedure has been in use in clinics for treating acute Stanford type A aortic dissection[20,21]. However, conventional surgical procedures are limited for high-risk patients due to high perioperative mortality, such as advanced age, neurological deficits, or other multiple comorbidities[22]. Although TEVAR in descending aortic pathology, such as type B dissection, has shown promising early and midterm results[23], it remains a challenge in type A aortic dissection. Different methods to revascularise the aortic arch branches include elective bypass, transposition of the LSA/LCA, implant of branched or chimney grafts, and fenestrations[7,24,25]. However, revascularisation of the LSA and LCA requires long operative time and presents high risks for artery ischaemic attacks, nerve injury, and other neurological complications.

In situ fenestrations were employed for the arch arteries and have been reported in both experimental and clinical studies[26,27].

Different fenestration techniques have been reported: RF probes[16], the use of needles or sharp guidewires[28], *in situ* retrograde fenestration, and laser fenestration[15].

On the basis of the study by Murphy et al[15], laser-assisted *in situ* fenestration during TEVAR in this study was applied to treat type A aortic dissection. However, a diode laser was chosen because it cured superficial venous insufficiency and congenital extratruncular venous malformations according to our previous reports[18,19]. The diode laser was more advantageous in terms of biological safety, such as activating a more selective action against blood vessels, compared with previous lasers at wavelengths of 940 or 810 nm, with a selective tertiary haemoglobin peak and a 0.3 mm penetrated depth in the blood. Importantly, the energy generated by this diode laser was absorbed by water and haemoglobin to avoid bubbles, which might cause stroke during fenestration for carotid arteries[19]. After *ex vivo* and *in vitro* experiments, this diode laser was used to fenestrate the stent graft membrane *in vivo*[29]. Although a previous study used 10 W energy[30], this study used 18 W based on previous experiments[29], which might destroy and soften the polytetrafluoroethylene (PTFE) or Dacron fabrics thoroughly. The 810 nm diode laser retained the integrity of the fabric and bare metal portion of PTFE and Dacron grafts and created a round and intact fenestration **(Supplementary Figure 2)**. The soft laser fibre could pass through complex and tortuous aortic arch anatomic variations. In this study, the 810 nm laser provided a rapid and repeatable method for the *in situ* diode fenestration of endografts during TEVAR, which presented a relatively quick and simple intraoperative endovascular treatment for acute thoracic aortic dissection with stable and safe procedures.

Cerebral protection is a huge challenge during TEVAR fenestration, and has been controversial for many years. Lu et al showed that hypothermic circulatory arrest, unilateral antegrade cerebral perfusion (ACP), and bilateral ACP techniques were effective[13]. In this study, the cerebral blood perfusion and brain protection were established by an extracorporeal bypass through the vascular shunt connection of a bilateral sheath between the RCA and LCA. Under these systemic circulatory arrests, antegrade or retrograde cerebral perfusion was initiated. One case of stroke after TEVAR in this study might have resulted because of balloon burst due to oversized inflations during percutaneous transluminal angioplasty (PTA), causing the bubbles to enter the intracranial cavity and leading to cerebral infarction **(Supplementary Figure 3)**. A high-pressure balloon is suggested during the fenestration to avoid balloon burst. A 50 mL syringe was used to draw blood when placing the branched stent graft. No myocardial infarction or respiratory system, renal system, or other neurologic complications were found during the follow-up.

Study limitations

The present study had some inevitable limitations. First, this was a retrospective observational study. Second, this study represented only a single-centre experience and not a multicentre experience

with the lack of longer-term follow-up data. Finally, the advances in anaesthetic, surgical, cerebral protection, and perioperative care therapies might have affected the clinical results to some extent at different time periods.

Conclusions

In situ diode laser fenestration to revascularise the supra-aortic branches is a feasible and effective option during TEVAR for Stanford type A aortic dissection. *In situ* diode laser fenestration under cerebral circulation protection with an extracorporeal bypass presents lower fenestration-related neurovascular complications. The high technical success, low mortality, and high patency have extended this application to more patients with Stanford type A aortic dissection using stable and safe procedures.

Impact on daily practice

We evaluated the feasibility, safety and effectiveness of *in situ* diode laser fenestration of thoracic endovascular aortic repair (TEVAR) stent grafts to treat Stanford type A aortic dissection. Our results demonstrated that *in situ* diode laser fenestration was a safe and effective approach when patients were selected appropriately and offered an alternative strategy to open surgery. However, further studies with prolonged follow-up, increased surgical numbers, prospective basic research of fluid mechanic changes, and aortic remodelling after TEVAR are required.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Figure 1. Cerebral blood perfusion and brain protection established by extracorporeal bypass.

Supplementary Figure 2. *In vitro* diode laser fenestration of the PTFE and Dacron stent grafts.

Supplementary Figure 3. A cerebral infarction patient during the *in situ* diode laser fenestration of the innominate artery after TEVAR.

The supplementary data are published online at:
http://www.pcronline.com/
eurointervention/151st_issue/326
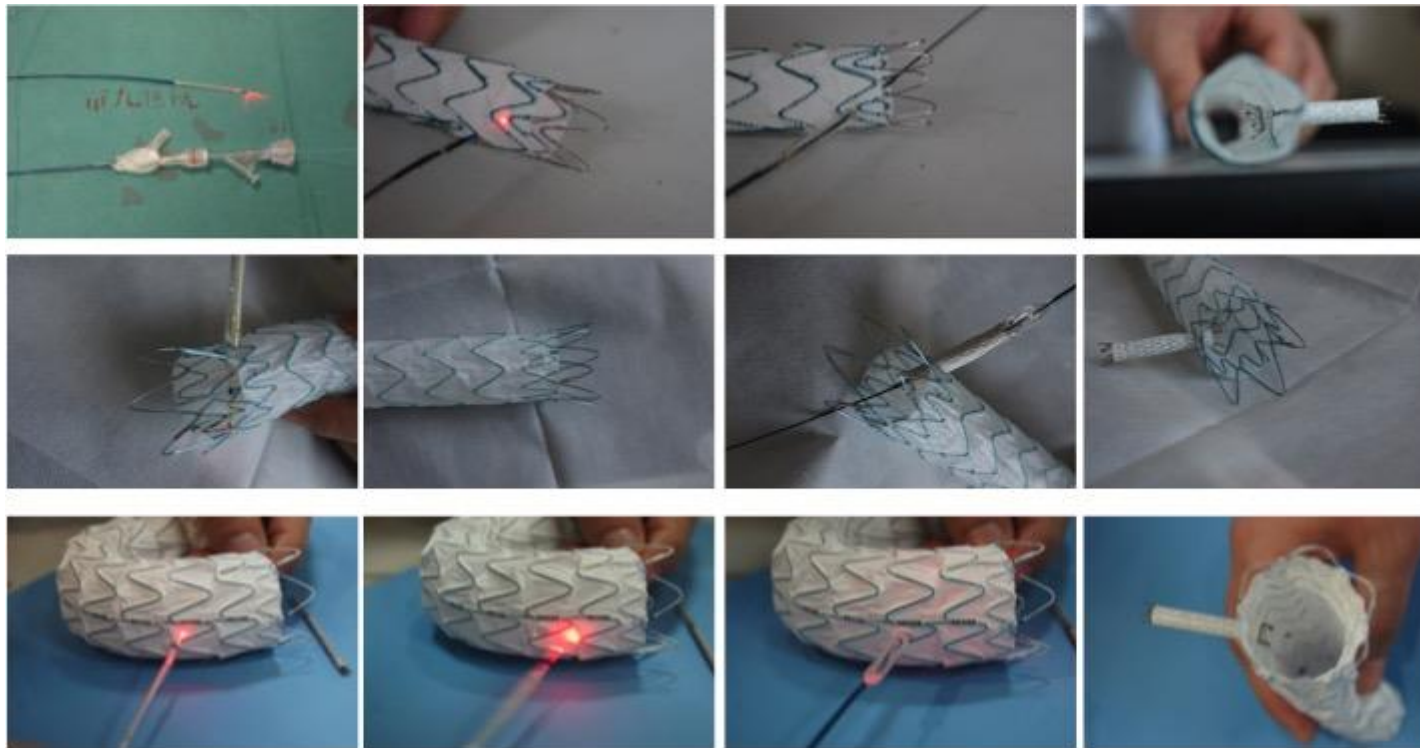
Supplementary data

Supplementary Figure 1. Cerebral blood perfusion and brain protection established by extracorporeal bypass.
A) Schematic illustration of the cerebral circulation protection with an extracorporeal bypass. The 16 Fr and 6 Fr sheaths were inserted in the proximal and distal innominate arteries, respectively. The tips of the 16 Fr sheath were placed in the aortic arch region next to the coronary valve (15 mm). An 8 Fr sheath was inserted in the distal part of the 16 Fr sheath, and a 12 Fr sheath was inserted in the LCA. Images of the extracorporeal bypass in side (B) and head position views (C).
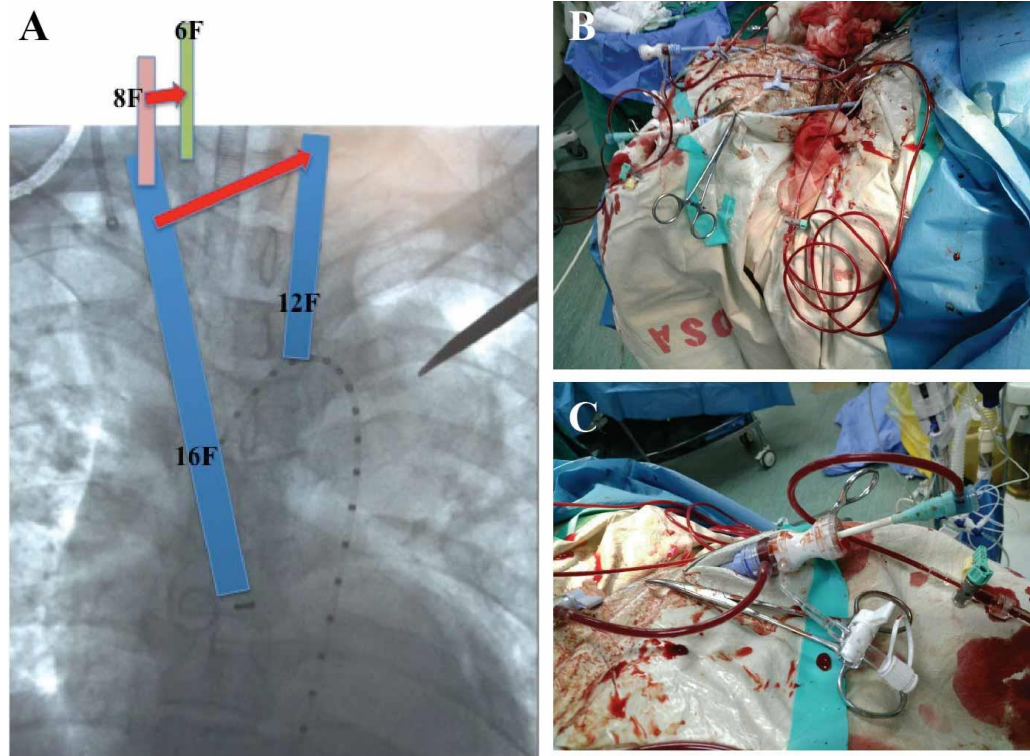
Supplementary Figure 2. *In vitro* diode laser fenestration of the PTFE and Dacron stent grafts.

Prior to clinical application, laser fenestration was evaluated *ex vivo* on the PTFE fabric of the TAG stent grafts and Dacron fabric of a Talent

stent graft, which was completed. Their integrality and spatial structure remained intact after fenestration.

Supplementary Figure 3. A cerebral infarction patient during the *in situ* diode laser fenestration of the innominate artery after TEVAR. This might have been caused by balloon burst due to oversized inflations during PTA, causing the bubbles to enter the intracranial cavity and leading to cerebral infarction.
A) T2-weighted magnetic resonance imaging of cerebral infarction.
B) T1-weighted magnetic resonance imaging of cerebral infarction.