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Experimental evaluation of homemade distal stent graft fenestration for thoracic endovascular aortic repair of type A dissection by a transapical approach

Thomas Gandet, MD, Anis Seghrouchni, MD, Baris Ata Ozdemir, MRCS, Guillaume Captier, MD, PhD, Roland Demaria, MD, PhD, Pierre Alric, MD, PhD, Bernard Albat, MD, PhD, and Ludovic Canaud, MD, PhD, Montpellier, France

ABSTRACT

Objective: The use of off-the-shelf stent grafts for thoracic endovascular aortic repair of type A dissections is limited by variability in both the length of the ascending aorta and the location of the proximal intimal tear. This experimental study aimed to assess the feasibility of using a physician-modified thoracic aortic stent graft to treat acute type A dissection by a transapical cardiac approach.

Methods: The experiments were performed on six cadaveric human heart, ascending aorta, aortic arch, and descending aorta specimens. Fenestration was fashioned in each standard tubular Valiant thoracic stent graft (Valiant Captivia; Medtronic Vascular, Santa Rosa, Calif) to match the anatomy of each specimen. Stent grafts of sufficient length were selected to cover the entire ascending aorta and aortic arch. Stent graft diameters in proximal sealing zones were oversized by 5% to 10%. The length of the fenestration was the distance between the left subclavian artery and the proximal edge of the origin of the brachiocephalic trunk with an additional 10 mm. The diameter of the scallop was that of the brachiocephalic trunk with an additional 5 mm on all sides. The length of the covered portion of the stent graft was the distance between coronary arteries and the proximal edge of the origin of the brachiocephalic trunk. Two lateral radiopaque markers were positioned to delineate the distal and lateral edge of the scallop. Another 3-cm radiopaque marker was sutured onto the sheath to ensure accurate radiologic positioning of the scallop on the outer curve of the aorta. The left ventricle and the thoracic aorta were connected to a benchtop aortic pulsatile flow model. A 5-mm 30-degree lens was introduced through the left subclavian artery to monitor the procedure. The customized stent graft was deployed by a transapical approach under fluoroscopic control.

Results: Median duration of stent graft modification was 21 minutes (range, 17-40 minutes). All attempts to deploy the homemade proximal scalloped stent graft by a transapical approach were successful. Completion angiography demonstrated patency of the supra-aortic trunks and of the coronary arteries in all cases. Macroscopic evaluation did not identify any deterioration of the customized stent graft.

Conclusions: The use of physician-modified stent grafts is feasible for thoracic endovascular aortic repair of type A dissection by a transapical approach in this model. (J Vasc Surg 2017;■:1-8.)

Clinical Relevance: So far, the endovascular revolution has not included the routine management of type A dissection. We confirm with this experimental study the feasibility of physician-customized proximal scalloped stent grafts by a transapical approach. This methodology enhances accurate positioning of the scallop, provides a rapid and suitable strategy using an "on-the-shelf" endograft, and allows coverage of a greater proportion of dissected aorta and intimal tear from the sinotubular junction to the descending aorta.

Standard treatment of type A aortic dissection is replacement of the ascending aorta during hypothermic circulatory arrest with antegrade cerebral perfusion. If the tear extends to the arch, combined

replacement of the ascending aorta and transverse arch with great vessel reimplantation is often required. Mortality and morbidity associated with this approach, in the standard-risk population, have decreased during the past decades as various modifications of surgical technique have been introduced but remain at 20% to 25%.¹ Despite these recent advances, surgery remains a challenge, particularly in elderly patients or in those with pre-existing comorbidities. Furthermore, some of these patients are deemed unsuitable for open repair.²

Simultaneously, thoracic endovascular aortic repair (TEVAR) has revolutionized the management of complicated type B aortic dissection, and the treatment of descending thoracic aortic disease has resulted in progressive use of endovascular grafts around the aortic

From the Department of Cardiac and Vascular Surgery, Arnaud de Villeneuve Hospital.

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Correspondence: Thomas Gandet, MD, Service de Chirurgie cardiaque et vasculaire, Hôpital A de Villeneuve, 191 av Doyen Gaston Giraud, Montpellier 34090, France (e-mail: thomas.gandet@gmail.com).

arch.³ The basic principle of this approach is coverage of the primary entry tear to re-establish true luminal blood flow and to facilitate false lumen thrombosis.⁴

So far, the endovascular revolution has not included the routine management of type A dissection. The anatomic challenge of endovascular treatment of type A dissection remains formidable. With a mean distance of 32 mm between the primary entry tear and the closest coronary artery, proximal graft fixation is inevitably close to the aortic valve and coronary ostia.⁵ The intimal tear can be on the opposite side of the ascending aorta, close to the innominate artery (IA) or more distal, in the aortic arch or the descending thoracic aorta. With a radical approach, the ideal endovascular repair would cover the entire ascending aorta and aortic arch. An additional major factor limiting the use of “on-the-shelf” endografts to treat type A dissection is the significant variability in ascending aortic length, ranging from 40 to 130 mm.⁶

Access for endovascular treatment of ascending aortic disease is also challenging. As a consequence of the length of catheters required and the double angulation of the arch and ascending aorta, femoral access is problematic. There is loss of accuracy during stent graft deployment and dramatic decrease in the torquability of the catheter, required for accurate positioning of scalloped grafts. Furthermore, type A dissection requires emergent surgery that excludes the use of industry-manufactured custom-made stent grafts. The concept of physician modification of off-the-shelf stent grafts to match individual anatomy is attractive.

The aim of this experimental study was to assess, in a cadaveric benchtop model, the feasibility of complete endovascular repair of the ascending aorta and arch using a physician-modified stent graft by a transapical approach.

METHODS

An institutional review committee approved the study.

Harvesting and preparation of model specimens

Six nonaneurysmal human hearts in continuity with the ascending aorta, aortic arch, and descending aorta (to the end of the thoracic aorta) were harvested from male or female cadavers preserved with zinc chloride. The mean age of the cadavers was 78 ± 6 years, without severe calcifications.

Benchtop model

A previously described benchtop closed-system pulsatile flow model was used to mimic physiologic aortic flow and pressure changes.⁷

Experimental setup

Preparation of aorta. The brachiocephalic trunk, the left common carotid artery, and the left subclavian artery (LSCA) were ligated 3 cm from their origin after harvesting. The pulmonary veins, abdominal aortic branches,

- **Type of Research:** Experiments using human cadaveric model of type A aortic dissection
- **Take Home Message:** In six human cadaveric models of type A aortic dissection, placement of a homemade proximal scalloped stent graft was feasible for thoracic endovascular aortic repair by a transapical approach in all six cases.
- **Recommendation:** Based on cadaver studies, the authors suggest clinical trial of transapical placement of a homemade proximal scalloped stent graft for endovascular repair of type A dissection.

and intercostal and lumbar arteries were oversewn. The left ventricular apex was connected to the closed-system pulsatile flow model using a surgical purse-string. The distal end of the thoracic aorta was then connected to the circuit to allow antegrade circulation into the left ventricle, ascending aorta, and aortic arch during the experiment. Pulsatile flow at 60 pulses/min with a pressure of 150/80 mm Hg was achieved by pump activation (Fig 1).

Stent grafts. The Valiant Captivia stent graft (Medtronic Vascular, Santa Rosa, Calif) is composed of a nitinol stent framework between layers of polyester graft. Individual stents are sutured to the outside of the polyester graft material. The proximal end features an open bare stent segment. Stent grafts of sufficient length were selected to cover the entire ascending aorta from the sinotubular junction, the aortic arch, and at least 1 cm of the descending thoracic aorta.

Planning and preparation of the fenestration based on each anatomy. Procedure planning and device sizing were performed using preprocedural measurement of the length and diameter of the ascending aorta (from sinotubular junction to the origin of the IA) and length of the aortic arch (from IA to LSCA). Stent graft diameters in the proximal sealing zone corresponding to the sinotubular junction were oversized by 5% to 10%.

The stent graft was partially unsheathed while holding the proximal tip capture with the barrel of a 5-mL syringe (Fig 2). The fenestration was fashioned to lie on the outer curve of the aortic arch. The margin of the fenestration was marked on the stent graft fabric using a sterile marking pen such that the length was that of the supra-aortic trunks (SATs) with an additional 10 mm and the diameter of the scallop was that of the IA with an additional 5 mm on all sides. The wire components of the stents involved in the area of making the scalloped opening are left intact to preserve the integrity of the graft's shape and size. The length of ascending aorta corresponded to the proximal covered part of the stent graft that was kept sheathed. A No. 11 blade scalpel was used to fashion the scallop.

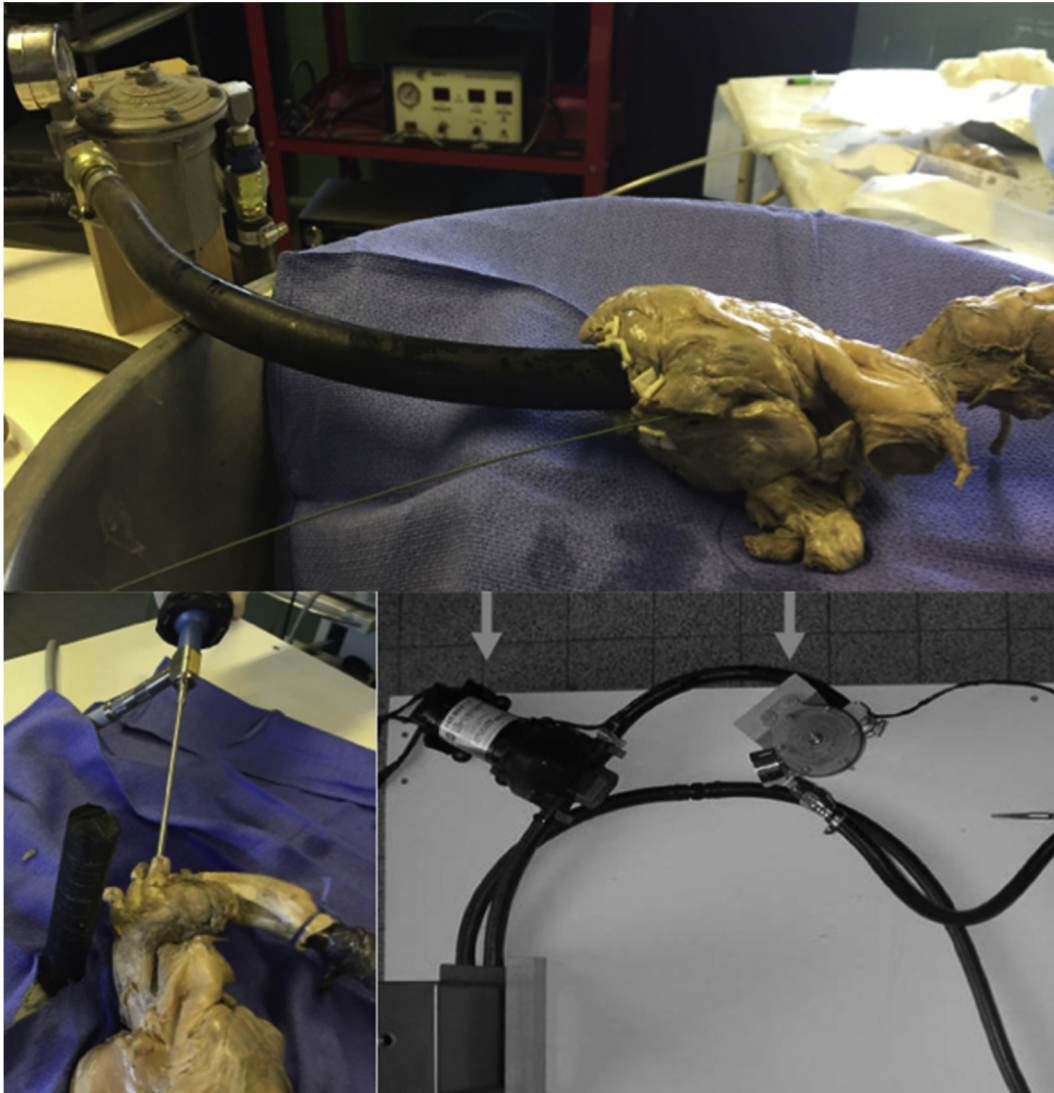


Fig 1. Benchtop closed-system pulsatile flow model. The *arrows* indicate the pump and the sequencer. To monitor the procedure, a 5-mm lens connected to a video camera was introduced into the left subclavian artery (LSCA).

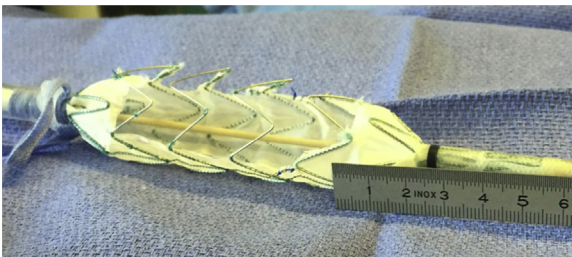


Fig 2. Homemade distal scalloped stent graft based on individual aortic anatomy.

a continuous locking 5-0 polypropylene suture. The modified stent graft was then reloaded in the existing sheath using a temporary vessel loop to collapse each stent. Another 3-cm radiopaque marker (using the loop of a snare) was sutured with 5-0 polypropylene and part of an incision drape onto the sheath to ensure accurate radiologic positioning of the scallop on the outer curve of the aorta (Fig 3).

Monitoring of the procedure. To monitor the procedure, a 5-mm 30-degree lens (Richard Wolf, Vernon Hills, Ill) connected to a video camera was introduced into the LSCA. Fluoroscopic control was used for deployment.

Stent graft placement. The left ventricle was punctured, and an ultrastiff wire was inserted from the apex to the descending aorta. Angiographic runs were performed through a 6F sheath placed in the LSCA. The Valiant thoracic stent graft was then introduced, and

Radiopaque markers. Two lateral radiopaque markers were positioned to delineate the distal and lateral edge of the scallop (Fig 3). Each radiopaque marker consisted of the loop of a snare (Amplatz GooseNeck; Covidien, Minneapolis, Minn), secured on the fabric with

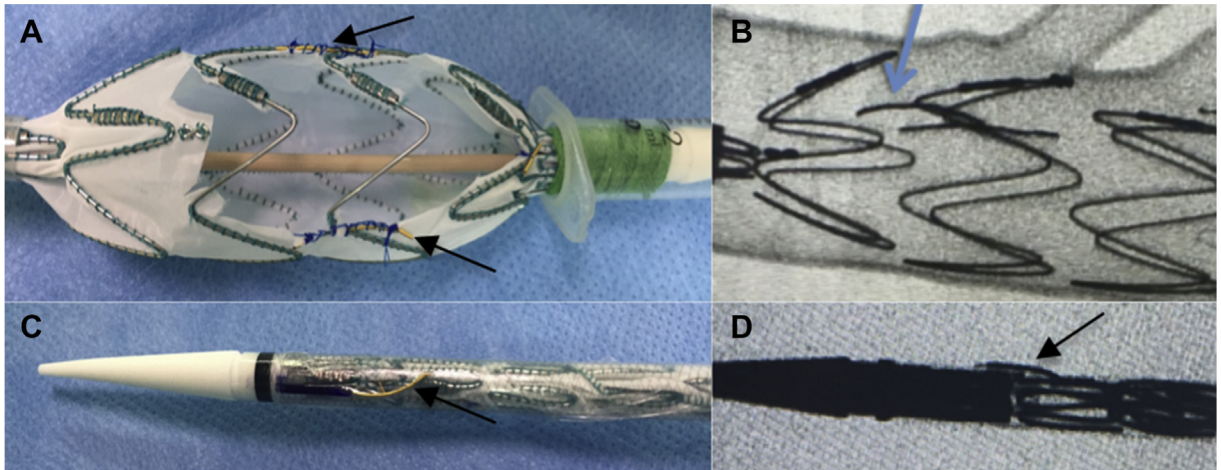


Fig 3. Positioning of the radiopaque markers indicated by arrows: Two lateral radiopaque markers (A), under fluoroscopic vision (B); sheath marker (C), under fluoroscopic vision (D).

Table. Aortic and stent graft (SG) characteristics

	Length, mm			Diameter, mm	
	AA/covered SG	SAT island	Scallop	STJ	Endograft
1	50	40	60	24	152 × 26 mm
2	65	45	65	30	152 × 34 mm
3	110	55	75	34	200 × 38 mm
4	80	50	70	27	152 × 30 mm
5	60	60	80	25	152 × 28 mm
6	70	55	75	29	152 × 32 mm

AA, Ascending aorta; SAT, supra-aortic trunk; STJ, sinotubular junction.

the radiopaque marker of the sheath was aligned to the outer curve of the aortic arch. The deployment was started and continued until the distal marker of the scallop was visualized. Alignment of the markers was achieved just distal to the LSCA. The stent graft was adjusted to ensure that the scallop side markers were positioned on either side of the LSCA before completion of stent graft deployment.

Explantation of stent grafts. Macroscopic qualitative evaluation of the fenestrations and proximal landing zone of the stent graft was performed after longitudinal opening of the aorta.

RESULTS

Aortic characteristics. Six human cadaveric combined heart and aorta specimens were harvested from three men and three women. The length of the ascending aorta varied from 5 to 11 cm. The mean aortic diameter measured at the sinotubular junction was 28 mm (range, 24-34 mm). The length of the SAT island varied from 40 to 60 mm (Table).

Preparation of the fenestration. Median duration for stent graft modification was 21 minutes (range, 17-40 minutes). The length of the stent graft was 152 mm for

five patients and 200 mm for one patient. The mean stent graft diameter was 31 mm (range, 26-38 mm; Table).

Stent graft deployment. All six deployments by a transapical approach were successful. The transapical approach facilitated catheter control during the procedures. Optimal repositioning of the scallop was easy to obtain after visualization of the distal radiopaque markers. Completion angiography demonstrated the patency of the SATs in all cases. Postprocedural evaluation with the aortic camera demonstrated a free aortic valve, the patency of the coronary arteries, and the patency of the SAT in all experiments (Fig 4; Video, online only).

Stent graft explantation. Stent graft explantation confirmed satisfactory positioning of the stent graft respecting the orifices of the SATs, the aortic valve, and the coronary arteries in all deployments. We did not identify any deterioration of the customized stent graft, and markers did not move during the procedures (Fig 5).

DISCUSSION

The goal of endovascular repair of an acute aortic dissection is to cover the entry tear and ideally all of

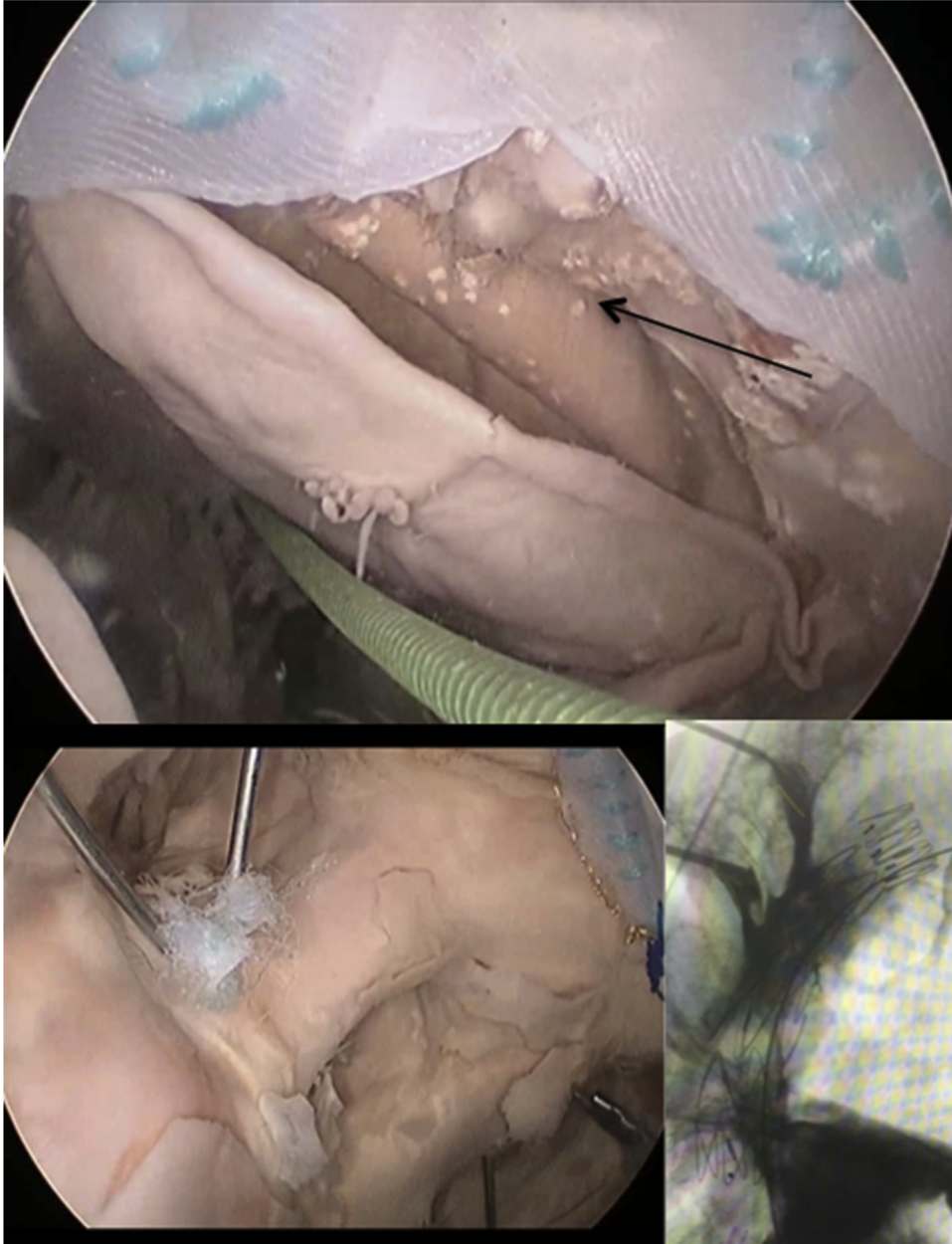


Fig 4. Periprocedural evaluation disclosing a free aortic valve and patency of the supra-aortic trunks (SATs). The ostium of the right coronary artery is indicated by the *arrow*.

the re-entry tears. This redirects the flow into the true lumen while blocking inflow into the false lumen, expanding the true lumen and collapsing the false lumen. The stent graft is not implanted into the aorta to bridge two healthy segments but rather to seal the dissected aorta.

The two major challenges to the endovascular treatment of diseases of the ascending and transverse aorta are the significant variability in length noted from patient to patient and the fact that the outer curve of the aorta naturally is a substantially longer distance than the inner curve, complicating the achievement of a good seal zone with an endovascular graft.

This study reports our experimental evaluation of a physician-modified distal fenestrated stent graft for TEVAR of type A aortic dissection. This approach provides a rapid, reproducible method of scalloping the endograft material. The use of homemade distal fenestrated stent graft is technically feasible and effective for maintaining SAT and coronary vascularization. Fenestration based on individual anatomy permitted coverage of the entire ascending aorta. Dacron graft unraveling was not an issue in our experience, and scalpel was more accurate than cautery devices. The cadaveric model was fixed at the apex (inflow canula) and at the thoracic aorta (outflow canula). The lens inserted in the LSCA stabilized

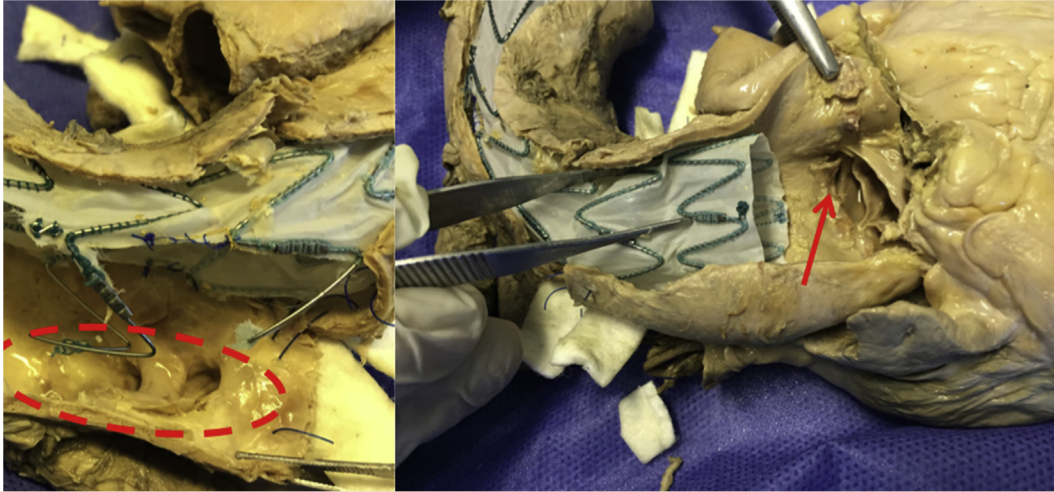


Fig 5. Stent graft explantation after aortic endovascular repair confirming the patency of the coronary arteries (red arrow) and the patency of the supra-aortic trunk (SAT).

the cadaveric model too. Small movement did not impair precision during deployment. Radiopaque markers positioned on the sheath and on the edge of the scallop combined with accurate deployment facilitated by a transapical approach allowed optimal positioning of the fenestration.

Since the 2000s, conventional surgery has drawn inspiration from the endovascular approach. The original elephant trunk technique described by Hans Borst was modified using an aortic handmade stent graft implanted in the descending aorta.^{8,9} This technique was called the frozen elephant trunk. Today, two commercial hybrid grafts are available for acute type A dissection. The 30-day mortality related to the technique is 13% associated with a spinal cord injury rate of 4% and stroke of 12%. The use of this technically demanding technique is limited to high-volume centers.^{10,11}

In parallel, the first case report of complete endovascular treatment of type A aortic dissection was published in 2004. Infrarenal aortic endovascular cuffs have generally been used as they are short enough not to cover the IA, but they are unfortunately limited by relatively short delivery systems.¹²⁻¹⁴ As the indication is off-license, this approach should be used only when all alternative options are excluded. The first report using a made-for-purpose Zenith (Cook Medical, Bloomington, Ind) ascending dissection device was published in 2012.¹⁵ This device, specific to the ascending aorta, is undergoing proof of concept studies, but nothing has been published since. A major limitation to treating type A dissection using on-the-shelf ascending aorta endografts is the variability in the length of the ascending aorta, ranging from 40 to 130 mm.⁶ In addition, these devices cover only the ascending aorta, making them unsuitable when the proximal intimal tear is close to the IA or includes the aortic arch. In this situation, a hybrid approach involving supra-aortic debranching and stent graft

implantation to seal the proximal tear can be used.¹² Recently, Lu et al¹⁶ described seven patients with type A dissection treated by customized branched stent grafts for the aortic arch. However, several limitations exist. Factors such as the delay in device planning and manufacturing limit the widespread availability of this technology, which is unsuitable for acute dissection. Furthermore, target vessel cannulation can be technically challenging and time-consuming even for experienced operators, especially in the presence of complex tortuous anatomy. Despite a custom-made device and extensive preoperative planning, graft rotation and misalignment of the fenestration-vessel ostium interface can still occur. In addition, the aorta may change configuration after insertion of the semirigid stent graft and thus alter alignment of the side branches.

Our strategy of homemade distal scalloped stent graft has several theoretical advantages. Physicians could accommodate the variability in the length of the ascending aorta, with custom fenestration allowing extensive treatment of all entry and re-entry tears in the ascending aorta and the aortic arch. For clinical practice, measurement of the length and diameter of the ascending aorta (from sinotubular junction to the origin of the IA) and length of the aortic arch (from IA to LSCA) can be accurately obtained using a gated chest computed tomography scan. This approach would also reduce the number of catheter and guidewire manipulations required in the aortic arch. The length of coverage possible with this approach should help stabilize the endograft, reducing the amount of oversizing required and therefore intimal trauma. Furthermore, this technique would allow management of dissections with proximal entry tears within 15 mm of the most distal coronary orifice. To ensure that the graft is deployed in the true lumen, one of the best options is systematic use of transesophageal echocardiography to control

positioning of the wire in the true lumen in the ascending and descending aorta. The distal bare-metal stent deployed in dissected descending thoracic aorta can induce a new entry tear in the dissected thoracic aorta, but this issue can be safely treated by TEVAR introduced through the femoral approach.

With a mean distance of 32 mm between the primary entry tear and the closest coronary artery, proximal graft fixation is necessarily close to the aortic valve and coronary ostia.⁵ As a consequence, in using the transfemoral approach, the nose of the delivery system must pass through the aortic valve. This can lead to ventricular tachycardia or injury to the ventricular wall.¹³ In addition, as experienced in transcatheter aortic valve implantation (TAVI), femoral access reduces catheter control during deployment, and repositioning of the prosthesis is not accurate. Associated with the development of TAVI, the transapical approach allows secure access to the aortic valve and to the ascending aorta with direct control of the catheter.¹⁷ Few cases using a transapical approach to repair inoperable ascending aortic dissection are reported. Pinaud et al¹⁸ implanted an infrarenal aortic endovascular cuff stabilized with a longer bare stent covering the arch. Kölbel et al¹⁹ modified a commercial stent graft by shortening it from 152 mm to 75 mm. In our study, the transapical approach allowed optimal control during stent graft deployment and positioning of the scallop. Before starting of deployment, rotation of the catheter was easy, allowing a perfect positioning of the sheath marker. Because of the retrograde deployment of the stent graft, early visualization of the distal radiopaque markers made it easier to correctly orient the scallop. There were several other reasons that we adopted transapical access. First, the short length of the delivery sheath prevented a transfemoral delivery. Second, through a femoral access, accurate device control and deployment are hindered by loss of torque control through tortuous iliac vessels into the 270-degree aortic arch. Finally, because transapical access is the most widely used alternative route for TAVI, we became accustomed to this approach. In addition, the transapical access allows drainage of potential pericardial effusions.

Several limitations exist in this experimental study. Pre-clinical testing has limitations regarding the ability to predict clinical failures, in part because of constraints inherent in replicating in vivo conditions. The mechanical properties of the cadaveric aorta conserved with zinc chloride result in loss of elasticity compared with fresh aorta. The use of cadaveric aortas rather than of a non-biologic aortic model is relatively time-consuming and expensive. However, plastic tubing and other substrates bear little resemblance to basic tissue properties, such as compliance, of the human aorta. During experiments, it was impossible to re-create experimental dissection of the ascending aorta. Hence, one weakness of our model is that stent grafts were deployed within nondissected

aortas. Moreover, ligation of the SATs in this model may also be problematic and may affect outcomes because these vessels frequently become dissected in type A aortic dissection and can be a source of endoleaks. In vivo, crossing the aortic valve with the catheter would result in hemodynamic compromise induced by aortic regurgitation. Only six experiments were performed because of the shortage of people who donated their body to science in France.

The technique described is an off-label use of an otherwise approved thoracic endograft. In our view, it should be indicated only for patients with life-threatening ascending aortic disease who are ineligible for open repair. Specific design is required to broaden the applicability.

CONCLUSIONS

This study confirms the feasibility of homemade stent graft fenestration by a transapical approach in this model. This methodology enhances accurate positioning of the fenestration, provides a rapid and suitable strategy using an on-the-shelf endograft, and allows coverage of a greater proportion of dissected aorta and intimal tear from the sinotubular junction to the descending aorta.

AUTHOR CONTRIBUTIONS

Conception and design: TG, BA, LC
Analysis and interpretation: TG, AS, GC, RD, PA, BA, LC
Data collection: TG, AS, BO, LC
Writing the article: TG, BO, LC
Critical revision of the article: TG, AS, BO, GC, RD, PA, BA, LC
Final approval of the article: TG, AS, BO, GC, RD, PA, BA, LC
Statistical analysis: BO
Obtained funding: Not applicable
Overall responsibility: LC

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