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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Experimental study of a canine model for a newly designed adjustable prefenestration aortic stent graft

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PURPOSE

When performing thoracic aortic endovascular repair (TEVAR) on lesions of the aortic arch, physician-modified fenestration or *in situ* fenestration is often used to maintain patent branches. We designed a new adjustable prefenestration aortic stent graft that can both isolate pathologies in the aortic arch and obtain patent branches simultaneously. In this study, we use this new type of stent to perform fenestrated TEVAR in a canine's aorta. This study aims to evaluate the safety and feasibility of the new device, which may provide preliminary data for potential human application.

METHODS

Eight Labrador Retriever canines underwent fenestrated TEVAR using the new stent device. Digital subtract angiography (DSA) was performed before and after fenestrated TEVAR to evaluate the safety and feasibility of the procedure. For the device deployment, at the "large curvature" side in the endograft, there is a rectangular prefenestration area (2 × 5 cm) without the polytetrafluoroethylene membrane, and at both longer side edges of the fenestration, there are two slide rails. A moveable membrane that covers the same area as the prefenestration area is initially set at the prefenestration position. A stay line is connected from the distal site of the moveable membrane that controls it to the distal position along the slide rail, which releases the fenestration. After the positioning of the prefenestration is determined, the outer sheath of the delivery system is released, and the stay line at the end of the delivery system is pulled outside the body. The animals were divided into a 1-month group (n = 4) and a 3-month group (n = 4) after the fenestrated TEVAR. Computed tomography (CT) was performed before euthanasia, and video of the DSA during the procedures and CT angiography (CTA) images were then studied.

RESULTS

The procedure success rate was 100%, but the total survival rate was only 87.5%. There were no aortic-related deaths during follow-up, and during the operation, there were no stent-graft-related accidents. In addition, no stent-graft migrations were observed in the CTA, and all branch arteries were kept patent by the adjustable fenestration. Finally, histological examination and electron microscope results showed no obvious vascular injury or inflammation.

CONCLUSION

Based on the results of this study, we judge the safety and feasibility of the use of the newly designed adjustable prefenestration aortic stent graft in a fenestrated-TEVAR canine model to be acceptable. Our preliminary data may serve as an initial reference for evaluating the potential application of the new stent in humans.

KEYWORDS

Thoracic aortic endovascular repair, fenestrated thoracic aortic endovascular repair, adjustable prefenestration aortic stent graft, canine, aortic arch

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Thoracic aortic endovascular repair (TEVAR) is the most successful minimally invasive treatment for aortic pathologies developed in the past 3 decades. Currently, there is also a "hybrid operation" involving TEVAR and extra-anatomic bypass for lesions involving the aortic arch, which is even more minimally invasive and may reduce complication rates compared with open surgery under extracorporeal circulation.[1,2] At present, the most difficult issue for the use of TEVAR in the aortic arch is simultaneously isolating the pathologies without endoleak and keeping the superior arch branches patent; fenestration in the stent graft is often used to meet both of these objectives.

The fenestration technique falls into two categories, physician-modified graft fenestration (PMGF)[3,4] and *in situ* fenestration.[5] The former involves relatively simple manipulation but carries with it the possibility of misfitting the fenestration and branch orifices. The latter method requires a large number of endovascular devices. However, both these techniques share a common shortcoming-the modification of the structure of the endograft may result in physical and dynamic risk. Therefore, TEVAR for proximal aortic arch lesions must be evaluated carefully through further studies with long-term timeframes and specific standardized designs.[6]

Physicians treating aortic arch lesions with an endograft may significantly benefit from an adjustable fenestration device that can adapt to the orifices of the branches. To this end, we designed a method using prefenestration in the stent graft and made its position and area adjustable. The new device was fabricated by APT Medical (Xiangxiang, China, 411400), and we have already tested it in a fluid-dynamic mimic tube system (Figure 1). In this paper, we further examine its safety and feasibility in a canine model based on fenestrated TEVAR.

Main points

- When performing thoracic aortic endovascular repair (TEVAR) on lesions of the aortic arch, fenestration techniques require structural modification of the stent graft.
- We designed a new adjustable prefenestration aortic stent graft that can simultaneously isolate pathologies in the aortic arch and obtain patent branches. In this study, we used this new type of stent to perform fenestrated TEVAR in canine aortas.
- Based on the results of this study, we judge the safety and feasibility of the newly designed adjustable prefenestration aortic stent graft in a fenestrated TEVAR canine model to be acceptable. Our preliminary data may provide a first reference for evaluating the new stent's potential use in humans.

Methods

This study was approved by the Ethics Committee of the Second Xiangya Hospital (ethics approval number: 2018-S034) and it is also obeyed the laboratory animals practice guidelines of China (YY/T1754.1-2020 pre-clinical animal experiment of medical device). The total number of experimental animals was 8, and their specific type was Labrador Retriever (experimental animal quality certificated number, 370825210100047374, Advanced Medical, Shenzhen, China). There were 3 females and 5 males, and the average weight of the 8 animals was 25.8 ± 3.5 kg.

Device description

The stent graft is composed of a nickel–titanium (NiTi) alloy scaffold and an expanded polytetrafluoroethylene membrane woven to the surface of the scaffold structure. At the "large curvature" side in the endograft, there is a rectangular prefenestration area (2 × 5 cm) without the polytetrafluoroethylene membrane, and at both longer side edges of the fenestration, there are two slide rails. A moveable membrane in the same area as that of the prefenestration is initially set at the position of the prefenestration (Figure 1). A stay line is connected from the distal site of the moveable membrane that controls it to the distal position along the slide rail, which releases the fenestration (Figure 1). The stay line is connected to the moveable membrane by a fixed device, and the moveable membrane can be moved backward when the stay line is pulled back. There are also radiopaque markers in the tip head of the delivery system that can show the direction of the fenestration and a radiopaque marker in the middle of the movable membrane that can show the position of the membrane (Figures 1, 2).

The implantation procedure

All the fenestrated-TEVAR procedures using this new stent graft were performed at Advanced Medical's digital subtraction an-

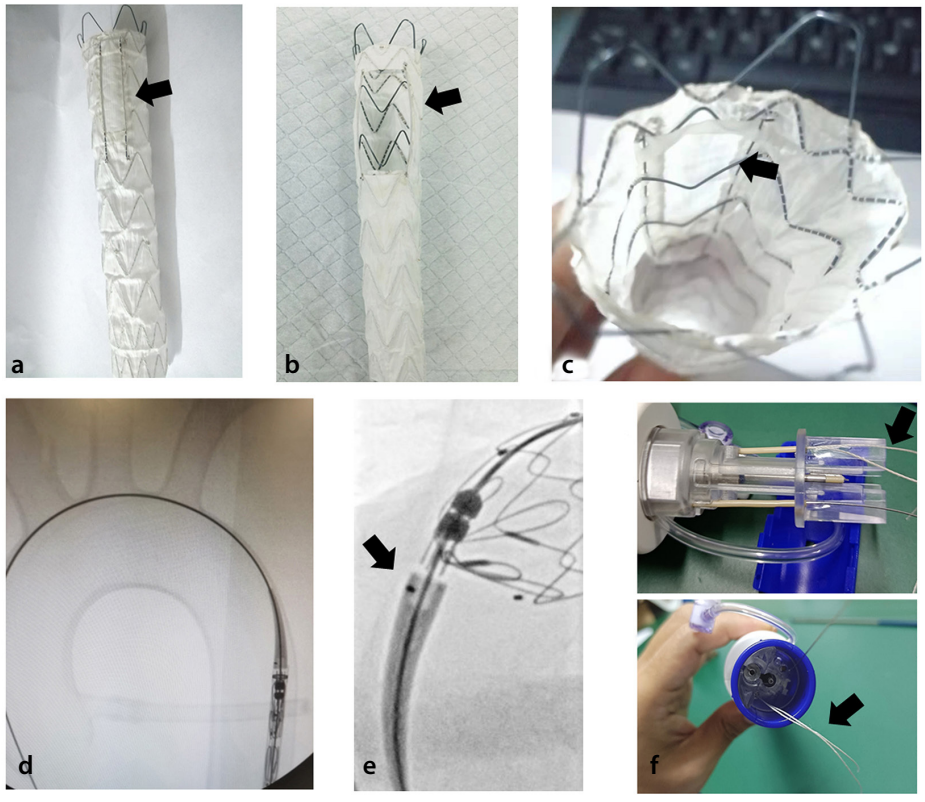

Figure 1. Adjustable prefenestration stent graft. **(a)** Black arrow shows the prefenestration sealed by a membrane patch. **(b)** Black arrow shows the fenestration already opened by the membrane patch moving distally. **(c)** View from the inner angle of the adjustable prefenestration stent graft; black arrow shows the initial situation of the fenestration. **(d)** X-ray screening of the device by mimicking deployment in a digital subtract angiography operation room. **(e)** Black arrow shows the radiopaque marker in the tip of the stent graft. **(f, g)** Black arrows show the stay line at the end of the delivery system that can be loaded in an independent tube.

giography (DSA) theater. The details of the procedures (Figure 2) are as follows. (1) The dogs were placed in a supine position with their extremities fixed. General anesthesia with intubation was then administered, the fur was removed from the groin area, and the exposed skin was sterilized. (2) An incision was then made to the femoral artery on one side using an arterial tourniquet control. After this, the femoral artery was punctured and a 5-French sheath was inserted. (3) The animal was then given 200 IU/kg of heparin, and the 5-French Pigtail catheter (William Cook Europe Aps, Sandet 8 DK-4832 Bjaeverskov, Denmark) was sent to the ascending aorta. Subsequently, DSA was performed to show the aorta and the configuration of its branches. (4) Next, the Lunderquist super stiff guide wire (William Cook Europe) was exchanged through the pigtail catheter, and the sheath was withdrawn. The adjustable prefenestration stent-graft system was then sent to the aortic arch, and the X-ray radiopaque marker in the tip of the head was observed to ensure that the fenestration was in the right position at the aortic "greater curvature" side. (5) The outer sheath of the delivery system was released, and the stay line at the end of the delivery system was pulled outside the body. The radiopaque marker at the movable membrane was used to adjust the position of the fenestration. (6) After the fenestration position and release were deemed satisfactory, the rear-release apparatus was unlocked and the entire delivery system was withdrawn. (7) Another DSA was performed to clarify the position of the stent graft/fenestration and the patency of the branches. (8) Finally, the femoral artery was sutured using 6-0 Prolene sutures, and the incision was closed.

All 8 animals were then divided into a 4-week and 12-week follow-up group, at which times computed tomography angiography (CTA) was performed before euthanasia. The specimens of the aortae with the stent grafts were dispatched for pathology and electron microscope assay.

Histological treatment, examination protocol, and electron microscope examination protocol

For the examination of the specimens, we used the following procedures. (1) The tissue was fixed with formalin, dehydrated with gradient alcohol, soaked with polymeric solutions I and II, immersed in an embedding solution, placed under a vacuum to complete plastic embedding, sliced with a precision cutting machine (to a thickness of approximately 200 μm), polished, and, finally, dyed with hematoxylin and eosin (H&E). (2) The tissue samples were then fixed with formalin, and 5 mm-thick slices were cut from each specimen. These were then dehydrated with gradient alcohol, soaked in paraffin for embedding, and sliced with a Leica 2135 slicer (Leica Biosystems Nussloch GmbH Postfach 1120 D-69222 Nussloch) using the conventional method (5 μm thickness). (3) Next, these sections were scanned with a digital pathology scanner, and the following indicators were determined using image analysis software: lumen area (LA), neointima thickness, and internal elastic membrane area (IEMA). From this, the additional indicators of neointima area (NA) (NA = IEMA – LA) and occlusion % (NA / IEMA × 100%) were calculated. (4) Finally, the blood vessels at the implantation site were fixed using glutaraldehyde, and the surface attachments were analyzed through electron microscopy after alcohol gradient dehydration.

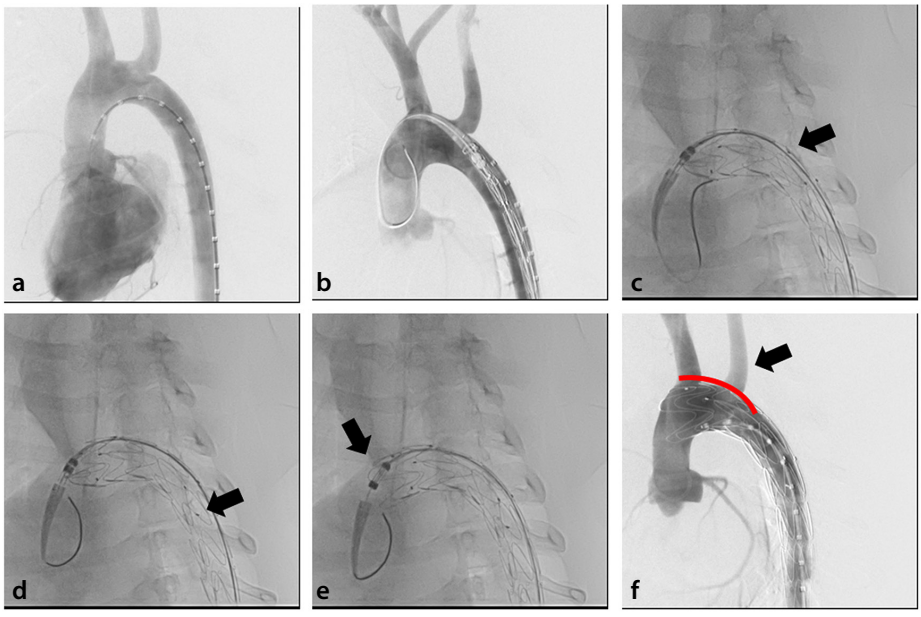

Figure 2. Operation steps performed during canine-fenestrated thoracic aortic endovascular repair (TEVAR) using the adjustable prefenestration stent graft. **(a)** Digital subtract angiography (DSA) before TEVAR. **(b)** When the stent graft approaches the aortic arch, DSA is performed again to check the location of the branches. **(c)** Outer sheath is already pulled distally, and main body of the stent graft is deployed; pulling the membrane patch distally makes it move distally. Black arrow shows the radiopaque marker on the membrane patch at its initial site. **(d)** Black arrow shows the radiopaque marker on the membrane patch at its final site. **(e)** Black arrow shows that the fenestration location is satisfactory and that the rear-release lock is unlocked. **(f)** DSA after the operation was completed; black arrow shows that both branches on the aortic arch remained patent; red curve shows the rough location of the fenestration.

Results

The technical success rate of the fenestrated TEVAR was 100%. The procedure time was 54 ± 32 min, with a radiation exposure time of 16 ± 8 min. There were no major bleeding events in any of the procedures, and no cardiovascular or cerebral events occurred during the procedures. Furthermore, no limb ischemia or instant retrograde dissection occurred after the procedures. The stent-graft delivery processes were all successful, and fenestration release obstruction did not occur. The adjustment of the movable membrane was smooth in every case. All the stent-graft delivery systems were withdrawn safely. In both the 4-week and 12-week groups, the fenestration was selected to preserve only one branch artery on the aortic arch in one of the 4 animals. In the rest of the animals, the fenestration was released to keep both branches on the arch.

One animal died of an infection condition that was not aortic related; the total survival rate for follow-up was therefore 87.5%. The CTA results of both groups show that there was no stent-graft migration in any of the remaining 7 animals. In addition, at the proximal and distal sites of the stent graft, we observed no retrograde or distal dissection, and no pseudoaneurysms were found around the stent graft or fenestration. All the branch arteries reserved by the fenestration were patent in the CTA results, with no dissections observed in any of the patent branch arteries (Figure 3). Finally, no thrombosis was observed at the branch arteries or the location of the fenestration. The above information and stent-type information are summarized in Table 1.

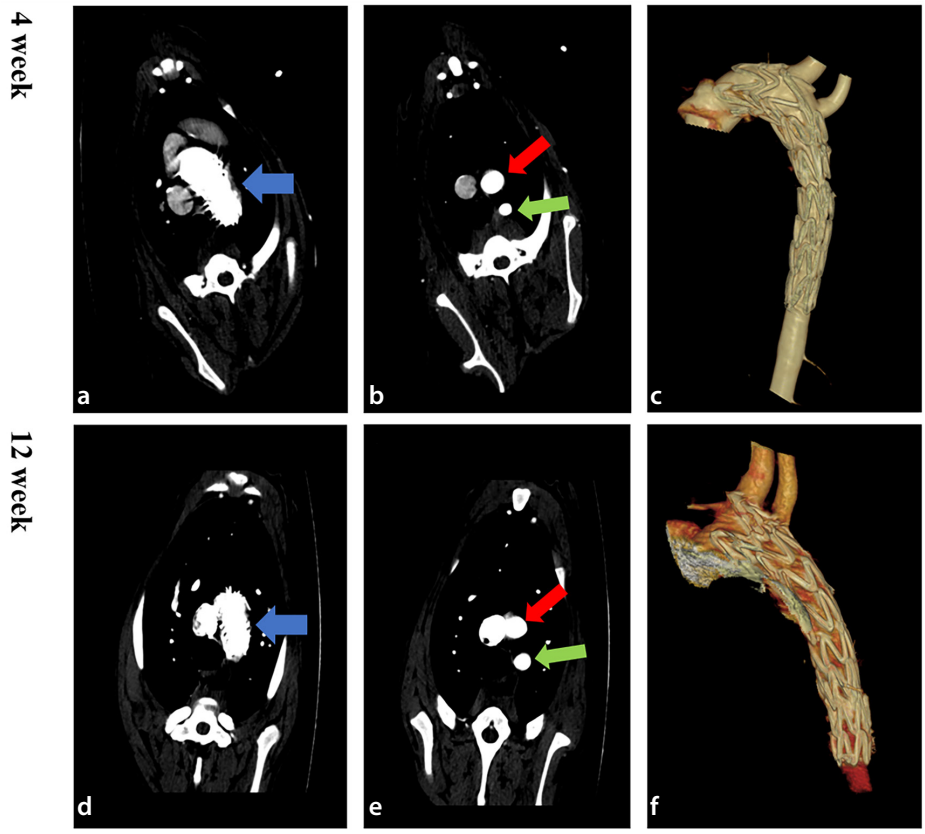

Figure 3. Computed tomography (CT) follow-up results of the canine fenestrated thoracic aortic endovascular repair; **(a-c)** show the 4-week group's CT follow-up results; blue arrow shows the stent graft in the aortic arch, and red and green arrows show the patent branch arteries; **(d-f)** show the 12-week group CT follow-up results; blue arrow shows the stent graft in the aortic arch, and red and green arrows show the patent branch arteries.

Table 1. General information and operation data of the animals

Group (week)	Animal number	Gender	Weight (kg)	Stent-graft size (proximal diameter × distal diameter × length mm)	Outer sheath diameter (French)	Branch preserved by fenestration
4	C642	Female	24.0	24 × 20 × 140	16	Innominate A.+ LSA
4	C646	Female	27.0	26 × 22 × 140	18	LSA
4	C649	Male	23.0	22 × 18 × 140	16	Innominate A.+ LSA
4	C650	Male	28.0	24 × 20 × 140	17	Innominate A.+ LSA
12	C651	Female	26.0	22 × 18 × 140	16	Innominate A.+ LSA
12	C652	Female	24.8	22 × 18 × 140	16	Innominate A.+ LSA
12	C655*	Female	27.4	22 × 18 × 140	16	LSA
12	C656	Male	32.0	24 × 20 × 140	17	Innominate A.+ LSA

*C655 dog died of systemic infection 5 days after surgery. Innominate A., innominate artery; LSA, left subclavian artery.

The histological results (H&E staining) showed no obvious injuries on the stent-graft segments of the aortae. In most parts of the aorta, there were no obvious inflammation reactions (Figure 4). Electron microscope results also showed that the endothelial cells provided effective coverage of the stent-graft surface in all cases (Figure 5).

Discussion

A new adjustable prefenestration aortic stent-graft device was specially designed for aortic arch pathologies. The design allows the device to avoid partially releasing and changing the structure of the endograft in PMGF. In addition, it avoids the need to use a large number of endovascular devices during the *in situ* fenestration procedure. The size and location of the prefenestration are adjustable by moving the membrane distally along the slide rail in the main body of the stent graft. If the proximal site of the membrane is located just distal to the innominate artery orifice, the fenestration release may keep the left subclavian artery patent, and if the proximal site of the membrane is proximal to the site of the innominate artery orifice, the prefenestration release may keep both the innominate artery and left subclavian artery patent.

In humans, the fenestration can be selected to retain 1–3 branch arteries due to the device's proximal membrane edge position. Once the stent-graft delivery and fenestration setup are deemed satisfactory, the stent or stent graft in a branch can be deployed through the same femoral access and further through the fenestration.[7,8] The advantage of this design is that it preserves the patency of the branch arteries and leaves a minimal area of fenestration, which may decrease endoleak risk.

Introduction of the cable release window laminating system

There is a long window preset on the bracket of the device, and the axial sides of the window are provided with a support frame to ensure that the edge of the window is attached to the wall to avoid leakage at this site. The vertices around the window contain X-ray-proof platinum markers to show the window position, and the outer side of the support frame comes equipped with a guide rail located between the metal bracket and the film covering. The window of the device has a movable film covering sheet along the guide rail axial direction with a width greater than the preset window width. The use of metal support and blood vessel wall compression make the mobile film covering sheet and support film form a relative closure, preventing leakage from the window.

A row of holes is arranged on both sides of the mobile film covering sheet for use on the guide rail. At the proximal end of the removable laminate, there is an X-ray-proof platinum marker to move the proximal end of the laminate, and the distal end of the removable laminate sheet is equipped with a V-shaped frame that is used to adjust the window size of the combined conveying system to avoid laminate damage and serious folding during adjustment. The bottom of the V-shaped frame, which has a movable film covering sheet, is fixed to the adjusting line through the core wire. When pulled back, the

adjusting line causes the mobile film to move back. After adjustment, the core wire can be withdrawn to realize the relief of the bottom of the V-shaped frame and adjustment line. Although this type of pre-opening may not guarantee the prevention of leakage, its use in conjunction with a branch bracket with a leak-prevention device can dramatically reduce the risk of leakage.

Safety evaluation of the new stent graft

In this canine fenestrated-TEVAR procedure study, the survival rate was 87.5%. One animal died on postoperative day 5. However, autopsy results showed that the death was not related to the aortic stent-graft implantation but was the result of a severe infection. In the other 7 animals, the rate of branch arteries' patency retained by fenestration was 100% (Figure 3). The patency of branches (both one and two branches) was also maintained. Our observations of one/two-branch patency by fenestration also demonstrated the safety and flexibility of the stent graft, which is possibly better than the current three-branch endograft designs.[9-11] In reviewing the results of the CTA, we found that the branch arteries were all kept patent. None of the surviving animals suffered cerebral vessel events due to thrombosis at the fenestration location.[12-14] In addition, the stent graft was able to smoothly cross the very steep canine aortic arch. There were no aortic rupture events and no access vessel injuries when the delivery systems were withdrawn. Hence, we judge the safety of this new stent graft to be satisfactory.

Feasibility evaluation of the stent graft in fenestrated TEVAR

Here, we summarize our evaluation of the feasibility of our new adjustable prefenestration aortic stent graft. The compliance of the stent graft was good in all 8 cases, despite the steeper nature of a canine's aortic arch curvature compared with a human's. In fact, it is similar to a type III aortic arch in a human.[15] A higher aortic curvature increases the level of difficulty and rate of complications in TEVAR.[16] In this canine study, all the stent-graft proximal sites were located in zone 0. However, all the delivery systems crossed the arch successfully without aortic rupture or other complications. In one case of extremely steep curvature of the aortic arch, the stent graft crossed the arch successfully by partially withdrawing the outer sheath to decrease the friction. This is where the device's X-ray radiopaque marker at the tip of the delivery system came into play. The design aimed to "take the marker out" of the NiTi wire and make it more readily directionally functional. When the marker is viewed as a longitudinal shape, the cephalic direction of the longitudinal axis is the fenestration (Figure 1d, e).

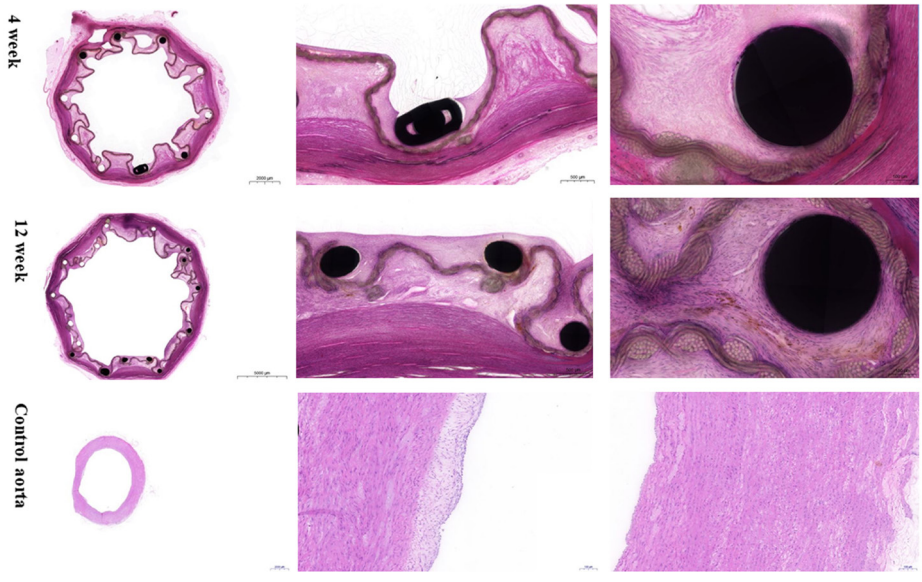

Figure 4. Histological examination (hematoxylin and eosin staining) after stent-graft implantation. Four-week group: there was no vascular injury, and endothelialization of the stent and covered membrane and thrombus organization of the vascular and covered space was observed, as was the proliferation of fibroblasts, scattered infiltration of inflammatory cells, a small number of necrotic cells, and attachment of foreign giant cells on the covered surface. Twelve-week group: slight vascular injury, vascular wall media compression, and intimal hyperplasia were observed, as well as a small amount of inflammatory cell infiltration and hemosiderin powder deposition; blank control group: intima was slightly thickened, and there was no vascular injury, degeneration, or necrosis.

The fenestrations in this study all occurred in the greater curvature of the aorta, and we deemed the reliability of this marker to be satisfactory. The core part of our new stent graft is the movable membrane located and initially overlapped at the prefenestration area. There is also a radiopaque marker at the middle part of the movable membrane. When the stay wire is pulled back at the rear part of the movable membrane, the radiopaque marker indicates where the membrane is and how large the fenestration is (Figure 2c, d). The stay wire, which is the control part of the movable membrane, can be pulled distally at the end site of the delivery system. During the procedures in this study, the stay wire was stable and comfortable during the fenestration-releasing procedure, even in very steep aortic arches. No twining occurred with other parts (Figure 1f, g).

The follow-up data for the 4-week and 12-week groups showed that the branches in all surviving cases remained patent. In addition, no thrombosis was observed in the branch arteries involved in fenestration. To lower the risk of misfitting the fenestration and branch orifices, we designed a relatively large prefenestration area. The area of fenestration could be controlled and adjusted more agilely by physicians based on their specific needs. In addition, our stent graft can potentially be used in repairing proximal arch lesions, as the proximal end can land in the ascending aorta.[17-19]

In the presence of anatomical branch artery variations, the adjustable position and area of fenestration provide a definite advantage over other methods.[20,21] Furthermore, we judge both histological safety and overall healing to be satisfactory based on our H&E staining and electron microscope results. Microvascular injury and minor inflammation reactions were not found in the stent graft. Electron microscope results showed that the endothelial cell cover was also satisfactory (Figure 5).

When designing this device, our primary concern was to create an "off-the-shelf" stent graft that could be used for fenestration without the need to modify the endograft or use multiple steps to puncture the membrane. Accordingly, the use of our device could be indicated for most pathologies in the aortic arch.[4] However, we still have several ideas for improving the design.

First, we aim to construct more apparatuses to help prevent endoleak around the prefenestration area. Endoleak is the first complication that should be prevented in

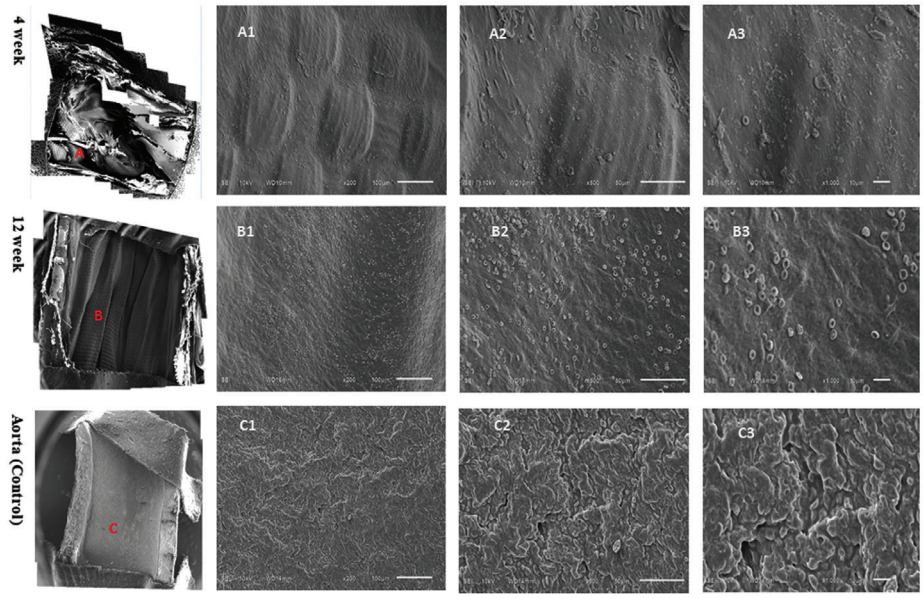

Figure 5. Electron microscope results of 2 groups of canines after stent-graft implantation and a control aorta. All locations in the stent graft or the aorta (red "A, B, C") have been highly magnified at three different powers. Four-week group: stent surface was partially covered by tissue, with a small number of endothelial and red blood cells attached. Twelve-week group: stent surface was completely covered with endothelial cells and a small number of red blood cells. Blank control group: mature endothelial cells can be seen on the surface of blood vessels.

TEVAR, especially under conditions using the chimney or fenestration techniques. In the very early design phase, we did not design extra endoleak prevention apparatuses for our device, since a special gutter-free branch artery stent-graft device already exists,[22,23] and we believe that our fenestration procedure, combined with the new gutter-free branch artery stent graft, can lower endoleak risk. However, if we design more endoleak preventive devices around the edge of the fenestration, the device could be made even more effective at preventing endoleak when combined with a gutter-free branch stent graft. Second, this study only tested the safety and feasibility of the new device in healthy animals and not in pathologic ones.[24,25] Third, there are differences in the anatomical structure of the human and canine aortic arch. Although our new adjustable prefenestration aortic stent graft, used in fenestrated TEVAR to preserve canine branch arteries, achieved satisfactory results, its application to a human aortic arch requires further study. In addition, the follow-up period of this experimental study was short, and the stability of this new adjustable prefenestration aortic stent graft cannot be satisfactorily explained. As such, this study has limitations in terms of demonstrating the effectiveness, safety, and feasibility of our new device for repairing dissection or aneurysm. This remains a topic for future investigation.

In conclusion, we found our new adjustable prefenestration aortic stent graft, used in fenestrated TEVAR to preserve canine branch arteries in the aortic arch, to be satisfactory in terms of both safety and feasibility. During the procedures in this study, the adjustment and manipulation of the position and area of the fenestration were smooth. Furthermore, the results for the stability of the stent graft and the patency of the branch arteries on the aortic arch were also satisfactory. These preliminary data derived from a canine model may serve as a reference for the use of our fenestrated-TEVAR device in humans.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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