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CUTTING-EDGE TECHNOLOGY

A Novel Endovascular Double-Disc Implant for Sealing Intimal Tears in Aortic Dissection

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ABSTRACT

Postdissection thoracoabdominal aortic aneurysm incidence after thoracic endovascular aortic repair for type B aortic dissection is high, with residual distal tears being a major reason for persistent blood flow in the false lumen. The EndoPatch is an endovascular double-disc implant for sealing re-entry tears in aortic dissection, isolating blood flow in the false lumen and promoting thrombosis formation. Compared with conventional endovascular treatment techniques, this endovascular double-disc implant's small size and minimal working space requirements may reduce the risk of spinal ischemia and offer flexible vascular access. Although several barriers still impede this endovascular device's broad application, its innovative design, flexible vascular access, and streamlined surgical process make it a promising alternative for managing intimal tears in aortic dissection, either alone or as a supplementary method combined with conventional endovascular techniques. (Guo's Entry Tear Repair: The First in Man Study of Endopatch System; NCT04745039) (JACC: Asia 2023;3:937–941) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

According to the international registry of acute aortic dissection report, the incidence of postdissection thoracoabdominal aneurysm after thoracic endovascular aortic repair (TEVAR) for type B aortic dissection is alarmingly high, at 62.7%.[1] The re-entry tears in aortic dissections serve as the blood inflow channel for the false lumen and are a major reason for persistent blood flow in false lumen.[2,3] The EndoPatch (Endonom Medtech) is an endovascular double-disc implant specifically designed for intimal tears in postdissection thoracoabdominal aortic aneurysm, aiming to isolate the blood flow in the false lumen, and promote thrombosis formation in the aortic false lumen.

DEVICE DESIGN, WORKING MECHANISM, AND TREATMENT INDICATIONS

This endovascular double-disc implant consists of 2 discs, a central rod, and polytetrafluoroethylene fabric within the discs (**Figure 1**). The intended position of this device after implantation is that the 2 discs are in the true and false lumen, respectively, with the central rod locking the 2 discs onto the intimal flap. The polytetrafluoroethylene fabric within the discs is used to fill the gaps in the nitinol metal wires of the discs, reducing the likelihood of endoleak. This device is equipped with a delivery device, which contains a steel cable connected to the central rod. By tightening the slider and rotating the knob on the delivery device handle, the discs can be locked and released. The delivery system requires a steerable sheath (9-F to 10-F) to deliver the discs to the tear site. The diameter of discs ranges from 6 to 30 mm (in 2-mm increments).

The structure of the endovascular double-disc implant is similar to those of ventricular/atrial septal defect (V/ASD) occlusion devices, but their working principles are significantly different. The main distinction lies in the fact that the V/ASD

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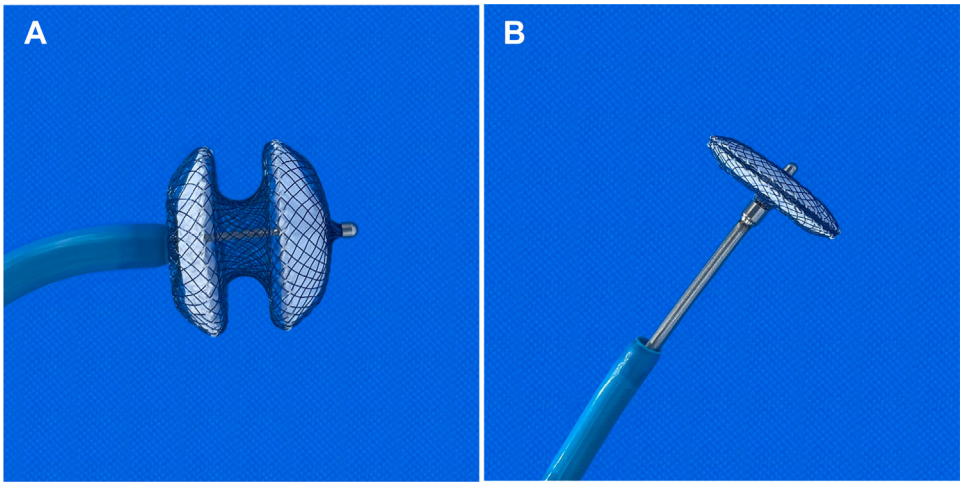
FIGURE 1 Ex Vivo Profiles of the Endovascular Double-Disc Implant



(A) The self-expanding discs, which are filled with polytetrafluoroethylene fabric, exhibit a symmetrical gourd-like shape before the locking mechanism is engaged. (B) The discs transform into a flattened configuration after being securely locked.

occlusion devices rely on its waist to seal the ventricular defect, while the endovascular double-disc implant depends on the clamping force between the 2 discs to achieve a sealing effect. The ping force could reduce the working space and enable it to be fixed more securely on the intimal flap.

The pathology addressed by the endovascular double-disc implant is chronic aortic dissection, regardless of type A or type B aortic dissection after prior surgery. The treatment indications include rapid aortic enlargement (5 mm in the past 6 months), maximum diameter of aorta >55 mm, impending rupture as evidenced by periaortic hematoma or pleural effusion, and symptomatic dissection with thoracic, back, or abdominal pain excluding other causes. This endovascular device also has anatomical requirements for the target re-entry tears: the re-entry tear diameter range is 2 to 20 mm, the distance between the tear and the ostia of the renovisceral arteries should be no less than the radius of the discs used.

POTENTIAL ADVANTAGES OVER EXISTING APPROACHES

False lumen embolization is a conventional technique for blocking the false lumen blood flow, with its working principle being the inducing thrombus formation.[4] However, this technique is criticized for not sealing the intimal tears, leaving the false lumen with the possibility of reperfusion.[5] Secondary TEVAR extension is another technique for occluding the residual re-entry tear. Its limitation lies in its applicability only for occluding distal thoracic aorta and infrarenal abdominal aorta tears, while it cannot be used for tears in the visceral aortic region. Fenestration/multibranched endovascular repair can preserve the blood supply to the renovisceral arteries, making it the current preferred solution for sealing re-entry tears in visceral aortic region. Both aortic stent graft extension and fenestration/multibranched endovascular repair have issues with extensive stent coverage and an increased risk of spinal ischemia.[6] The latter advanced techniques are still limited to experienced centers.

The endovascular double-disc implant has a small size and requires minimal working space, which can undoubtedly reduce the coverage of true lumen-perfused intercostal arteries and consequently decrease the risk of spinal ischemia. Based on our center's ongoing first-in-human clinical trial experience, this device requires only a 2- to 4-mm anchoring margin beyond the tear edge for an effective seal. For example, a re-entry tear with a long-axis diameter of 4 mm can be treated with 8- to 12-mm diameter discs. This can not only reduce the risk of

spinal ischemia, but also, for nonvisceral artery-originating tears in the visceral aortic region, eliminate the need for visceral artery revascularization. The latter is a challenge that must be faced when using stent graft endovascular repair.

This endovascular double-disc implant provides flexible vascular access, as the delivery sheath can be inserted into the false lumen via the true lumen or vice versa. If the true lumen is severely compressed, the discs can be advanced into the true lumen through the targeted intimal tear by way of the false lumen (ie, false to true passage), thereby obtaining additional maneuvering space that permits rotational and craniocaudal movement. If no distal re-entry tear allows access into the false lumen for the delivery sheath, the discs can still be implanted using the true to false passage approach. This differs significantly from conventional stent graft endovascular techniques, which typically can only be performed in the true lumen; when it comes to visceral artery reconstruction, stent graft implantation within a narrow true lumen presents a considerable technical challenge.

PROCEDURE KEY POINTS AND CLINICAL APPLICATION

The key to the implantation of the endovascular double-disc implant lies in the catheterization of the targeted intimal tear, which will significantly affect the time required for disc implantation. The surgeon needs to fully evaluate the morphology, location, and tangential view of the targeted tear before surgery, which helps shorten the operation time and reduce x-ray dosage.

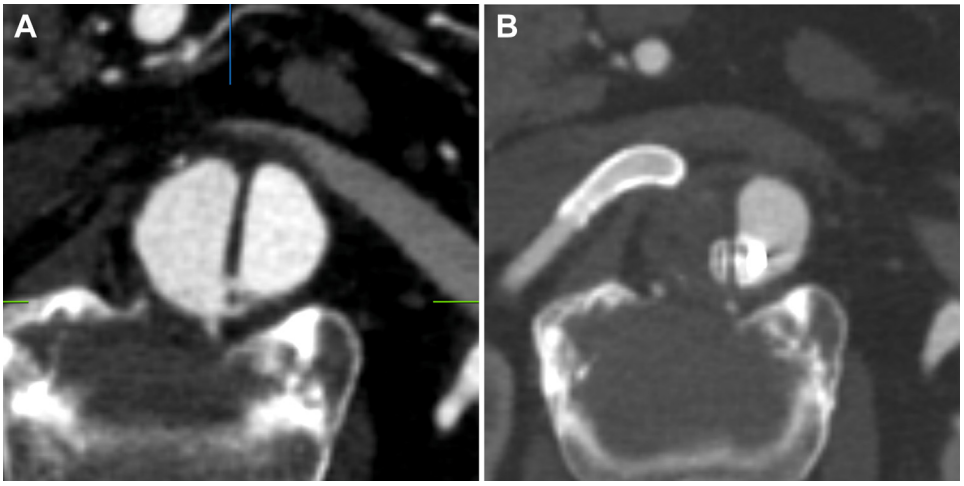
The steps of the disc deployment procedure, called Guo's patch surgery, is descripted as follows. First, after successful catheterization of the intimal tear using the super-slippery guidewire, exchange it for a SupraCore guidewire (Abbott Vascular). Next, advance the steerable sheath over the guidewire through the targeted tear, then withdraw the sheath's core to make room for the disc delivery device. Subsequently, push the disc delivery device into the steerable sheath and advance it to the tip of the sheath. After that, hold the disc delivery device in place and withdraw the sheath to release the first disc into one lumen of the dissection. Then, tighten the slider on the disc delivery device to ensure the first disc is apposed to the intimal flap, followed by a tug test to confirm proper positioning. Afterward, fix the disc delivery device and further withdraw the sheath to release the second disc into the other lumen of the dissection. Next, tighten the slider to ensure the second disc is apposed to the intimal flap. Subsequently, adjust the sheath angle perpendicular to the discs and tighten the slider to lock the discs onto the intimal flap. Finally, rotate the knob on the device to unlock and release the disc.

The innovative design, versatile vascular access, and streamlined surgical process of this double-disc implant presents it as a promising alternative to manage intimal tears in aortic dissection. The double-disc implant can serve as major treatment approach to manage re-entry tears, such as the tears originating from the inferior mesenteric artery or lumbar arteries. Additionally, in cases in which a renovisceral artery-originating tear coexists, this device can also serve as a supplementary method in combination with other conventional endovascular techniques to manage re-entry tears, such as employing the double-disc implant together with a bridging stent for the renovisceral artery (**Figure 2**).

EXISTING EVIDENCE AND ISSUES TO BE ADDRESSED

There have been only a few reports regarding the use of V/ASD occlusion device for intimal tears in aortic dissection, including both primary and distal tears.[7,8] In 15 live pigs, we verified the safety and feasibility of the endovascular double-disc implant in occluding artificially created aortocaval fistulas.[9] Recently, we reported the first human application of this device, which yielded satisfactory early results.[10] Currently, our center is conducting a clinical trial for this device, which was approved by the Institutional Review Board of Chinese PLA General Hospital (approval number, S2020-313; NCT04745039). This clinical trial was planned to enroll 12 aortic dissection patients, with 10 cases completed so far. The technical success rate in these 10 enrolled patients was 100%, although 1 patient died from COVID-19 1 month postoperatively. No patients experienced cardiovascular events, stroke, spinal cord ischemia, renal injury, organ ischemia, or aorta-related secondary surgery during the perioperative period or follow-up. Five patients were followed up for over 6 months postoperatively, aside from the patient who died from COVID-19, and the remaining 4 patients had 6-month postoperative computed tomography angiography. The re-entry closure success rate was 100%, which was defined as no contrast enhancement observed in the false lumen side of the implanted discs on the

FIGURE 2 Endovascular Double-Disc Implant Application for a Postdissection Thoracoabdominal Aortic Aneurysm



(A) Two adjacent intimal tears, originating from the ostia of the first lumbar arteries, communicating the true and false lumens. (B) The 2 small tears are sealed simultaneously with 8-mm-diameter discs; concurrently, the false lumen–perfused right renal artery is bridged using a Viabahn stent graft.

computed tomography angiography scans. It should be noted that the previously referenced data need to be interpreted cautiously, as they are derived from a limited number of patients. The potential clinical implication of this endovascular double-disc implant should be verified in clinical trials with larger sample sizes.

Several barriers continue to impede the broad application of the endovascular double-disc implant. First and foremost, not all intimal tears are amenable to treatment with this device, including those with a long-axis diameter exceeding 20 mm, tears close to the ostia of visceral arteries, and torn ostia of visceral arteries. Moreover, the applicability of this double-disc implant for tears situated at the junction between the intimal flap and the aortic wall remains unclear. In such cases, a significant portion of the discs lacks anchoring margin. Determining the necessary extent of the disc surface securely clamping the dissection membrane throughout the entire 360° circumference to ensure reliable fixation of the discs warrants further investigation. We eagerly anticipate gaining more evidence and insights from the first-in-human clinical trial.

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