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Endovascular repair during complex thoracic aortic dissection using a micropore stent graft: Midterm follow-up clinical outcomes

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Abstract

Objective: This study explored the clinical efficacy and hemodynamic effects of the micropore stent graft (MSG) that could promote aortic remodeling and preserve important organ branches.

Methods: We conducted a retrospective analysis of 26 patients who underwent endovascular repair using an MSG for DeBakey types I and III TAD at our center between December 2014 and December 2017. The main efficacy parameters were rupture of the false lumen or dissection-related death, conversion to open repair, secondary reintervention, branch vessel patency, and the hemodynamic effects of TAD at 12 months.

Results: Dissection rupture, dissection-related mortality, conversion to open repair, and secondary reintervention rates at 12 months were 0, 3.9, 0, and 0%, respectively. In the 24 patients with more than 6 months of follow-up, micropore stents were implanted to cover 39 openings in aortic arch branches, 91.7% (22/24) presented with complete thrombosis in the false lumen, 8.3% (2/24) presented with partial thrombosis in the false lumen, 35.2% (6/17) presented with a thrombus in the false lumen that was completely absorbed, and all 39 branches were patent. After surgery, pressure peak value and fluctuation along with the degree and range of unstable blood flow in the aortic lumen decreased.

Conclusions: For type I and type III thoracic artic dissection, endovascular treatment with an MSG may be a safe and effective treatment option with a good midterm outcome.

KEYWORDS
endovascular repair, hemodynamics, micropore stent graft, patency rate, thoracic aortic dissection

1 | BACKGROUND

Aortic dissection (AD) is the most devastating complication of thoracic aortic disease.[1] AD can cause aortic rupture, insufficient perfusion of important organs, myocardial ischemia, aortic retrograde flow,

pericardial tamponade, and tissue ischemia, and its mortality rate is extremely high.[2] Thoracic endovascular aortic repair has become an accepted alternative to surgery for the treatment of AD.[3] This strategy is suitable for most patients because it is a minimally invasive procedure with fewer perioperative complications and lower mortality rates. However, endovascular treatment is not suitable for all patients. According to the literature, the current management of complex thoracic aortic dissection (TAD) requires a hybrid approach for acceptable early and midterm major morbidity and mortality (12%); however, there is still a high rate of reintervention (24%) and endoleak (18%).[4] Endovascular repair for aortic arch disease remains challenging because of the limited length of the landing zone while preserving the supra-aortic branch blood flow.[5] To more effectively address this patient population, the micropore stent graft (MSG) was independently developed in China to treat complex TAD. This membrane-covered stent has micropores on its wall, and the principle underlying the application of this type of stent is similar to that of the multilayer flow modulator (MFM) stent (Cardiatis, Isnes, Belgium). The concept of flow diversion involves a commercial multilayer MFM stent that has been used to treat TAD in situations where the patients were not suitable for standard endovascular repair.[6] Unlike a conventional stent graft, flow diversion acts as a passive barrier by reducing blood flow into the false lumen and subsequently creates a natural hemodynamic environment to promote false lumen thrombosis, which is conducive for the activation and aggregation of platelets within the false lumen.[7,8] Moreover, the stent can fully maintain the patency of important branch vessels and avoids organ ischemic infarction and spinal ischemia. The purpose of the current study was to analyze midterm follow-up outcomes in 26 patients who were treated for DeBakey type I and type III TAD using MSG. This study also explored the clinical efficacy and hemodynamic effects of novel treatment regimens that could promote aortic remodeling and preserve important organ branches.[9,10]

2 | METHODS

2.1 | Ethics statement

This study was approved by the Ethical Committee of the First Affiliated Hospital of Chongqing Medical University (2017-179). All patients had a good understanding of the study and signed written informed consents.

We conducted a retrospective analysis of 26 patients who underwent endovascular repair via MSG for DeBakey type I and type III TAD at our center between December 2014 and December 2017 (Table 1). Four out of 26 patients were chronic TAD. A total of 22 out of 26 patients were acute TAD. Patients with ruptured false lumens, occlusion of the aortic branches (i.e., the blood vessels of the head and neck), previous graft infection, myeloproliferative disorders, coagulopathy, or a life expectancy less than 6 months, and those choosing open or conservative treatment were excluded. Patients recruited to this study had unstable TAD during the (1) acute phase, when the patients presented with (a) uncontrolled pain,

TABLE 1 Demographics of the 26 patients

Age (year)	59.46 ± 13.05 (31–77)
Sex	
Male	23 (88.5%)
Female	3 (11.5%)
Body weight index (BMI)	24.24 ± 3.23 (16.23–32.01)
Accompanied disease	
Hypertension	19 (73.1%)
Diabetes	6 (23.1%)
Coronary heart disease	2 (7.7%)
Myocardial infarction	0 (0%)
Hyperlipidemia	4 (15.4%)
Renal insufficiency	0 (0%)
Takayasu's arteritis	1 (3.8%)
Shock	0 (0%)
Personal history	
Smoking	18 (69.2%)
Drinking	16 (61.5%)
Aortic surgery	3 (11.5%)
Infectious disease (syphilis)	0 (0%)
Dissection type	
DeBakey I	3 (11.5%)
DeBakey III	23 (88.5%)

Note: Continuous data are presented as the means ± standard deviation (min–max); categorical data are given as the counts (percentage).
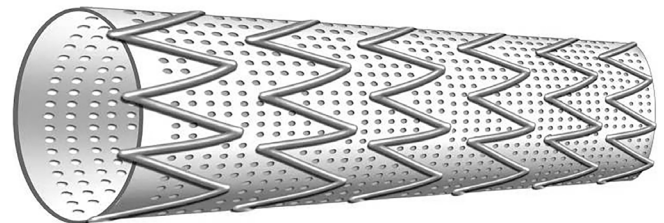

FIGURE 1 Micropore stent graft

(b) progressive enlargement of a hematoma near the aorta or in the mediastinum, and (c) a rapidly increasing TAD diameter, and (d) acute ischemia of branch arteries caused by aortic dissection or during the (2) chronic phase, when the patients presented with (a) persistent chest and back pain, (b) a rapidly increasing TAD diameter (>10 mm per year), and (c) the formation of aneurysms.[11]

2.2 | Stent structure

The MSG (Aortec Technology Co., Ltd., Beijing, China) (Figure 1) is approved by the China Food and Drug Administration to treat TAD and aortic aneurysm in China. Its features include a conical thoracic aortic membrane-covered stent that is suitable for TAD with a compressed true lumen. The stent is based on a porous membrane-covered stent graft and is a cylindrical or conical stent graft designed to seal the main tear in TAD. In this study, the stents were made of a

nickel-titanium alloy, and the surface was covered with a membranous layer of polyester fibers with 1.3 mm micropores (average 3 micropores/cm^2). The lengths of the stents ranged from 80 to 200 mm, the proximal diameters ranged from 22 to 46 mm, and the distal diameters were 3–8 mm smaller than the proximal diameter. A 20F or 22F sheath was required for stent delivery.

2.3 | Diagnosis and treatment

All patients underwent 3D-computed tomography angiography (3D-CTA) of the whole aorta to confirm the diagnosis, obtain the disease classification, and perform a surgical feasibility analysis. The surgical procedures are described below. The femoral artery was incised, and a micropore stent was implanted into the diseased artery. The stent covered a region ranging from the proximal normal aortic docking site to the site above the celiac trunk. The stent was not allowed to cover the openings of the major branch vessels of the abdominal aorta, such as the celiac trunk, superior mesenteric artery, and bilateral renal arteries. If the dissection involved an important branch artery of the abdominal aorta, temporary observation was required. All surgical procedures were performed under general anesthesia.

2.4 | Volume calculated

In the professional workstation, the CTA imaging data in DICOM format were imported into the Mimics 19.0 medical image processing program (Materialise Inc., Belgium) to reconstruct a 3D model of the target vessel and calculate volume.[4]

2.5 | Hemodynamic analysis of the cardiac cycle in individual-based model

This assessment defined the blood as a mobile fluid to study the influence of blood on the blood vessel wall at different phases of the cardiac cycle. The following assumptions were used in the numerical simulation: the blood vessel wall was rigid and no-slip; and blood was incompressible Newton fluid. The movement viscosity coefficient of blood was $u = 0.0035$ Pa·S, the blood density was $p = 1,050$ kg/m^3, and the cardiac cycle was $T = 0.8$ s. As the Womersley number of the thoracic aorta diameter was 19.2 and the mean value of Reynolds numbers of blood flow velocity at the inlet and thoracic aorta diameter was 1,399, less than 2,300, it was defined as laminar flow. In the current research, the blood flow conformed to the law of mass and momentum conservation, that is, the continuity equation and the Navier–Stokes equation. In the calculation process, the entrance condition was based on the given flow velocity curve with a velocity value of 0.8 m/s. The exit condition was set to a pressure outlet with a value of 0 Pa. The distribution of blood flow into the true and false lumens, aortic branch perfusion, and aortic wall pressure was calculated using the ANSYS Fluent CFD (ANSYS, Canonsburg, PA) postprocessor module. Hemodynamic parameters were time functions. Two typical time points were selected for analysis: $T_1 = 0.25$ s, the blood flow velocity was at a fast speed, which was equivalent to the

rapid ejection period of the heart; $T_2 = 0.3$ s, the blood flow velocity reaches the peak, which was equivalent to the maximum systolic period of the ventricle. Hemodynamic analysis of the cardiac cycle were based on data presented by Stefanov et al.[12]

2.6 | Follow-up

Prior to discharge, all patients underwent a physical examination and imaging study to evaluate branch patency. At 1, 3, 6, 12, 24, and 36 months after surgery, the patients underwent routine physical examinations and CTA. SOMATOM Definition Flash CT scanners were used in this study. During the entire follow-up period, branch vessel patency, the true lumen volume, the false lumen thrombus volume, the blood flow volume in the false lumen, all adverse events, and additional surgical details were carefully recorded and reviewed.

The primary endpoint at 30 days was the rupture of the dissected false lumen or dissection-related death. The main efficacy parameters were dissection rupture, dissection-related mortality, stable thrombus inside the false lumen, conversion to open repair, secondary reintervention, branch vessel patency, and the hemodynamic effects of TAD at 12 months.[13] The secondary endpoints were all-cause death or serious adverse events (i.e., stroke, paraplegia, stent dislocation, or stent fracture). Type II and IV endoleaks have not been reported in this study because they are not applicable to the MSG.[14]

2.7 | Statistical analyses

Kaplan–Meier curves were used to analyze the survival rates and determine the time points that exceeded the standard error by 10%. The branch patency rate was the proportion of the number of branches that did not show stenosis or occlusion after surgery relative to the total number of branches covered by the stent. Volumes are expressed as the means, standard deviations, and medians. Student's t test or the chi-square test was used to compare the changes in continuous or categorical variables, respectively, before and after surgery. Statistical significance was defined as $p < .05$. All analyses were performed using SPSS (version 19; IBM Corporation, Somers, NY).

3 | RESULTS

This study included 26 patients (23 males) with an average age of 59.46 ± 13.05 years old (range: 31–77 years old) (Table 1). All 26 patients underwent stent implantation via a femoral artery approach, and the technical success rate was 100%. A total of 41 stents (range: 1–3 per person) were implanted to cover 41 supra-aortic vessels (range: 1–3 per person). The dissection did not involve all visceral branches in five patients, the superior mesenteric artery or bilateral renal artery in two patients, bilateral renal artery in four patients, and the celiac trunk, superior mesenteric artery, or bilateral renal artery in 15 patients.

One patient died of a sudden cerebral hemorrhage on the 7th day after surgery, and one patient refused follow-up after discharge.

Thus, follow-up data for 24 patients were available for analysis. The average follow-up period was 12.25 months (range: 6–24 months). During the follow-up period, dissection-related mortality, conversion to open repair and secondary reintervention were 0, 3.9, 0, and 0%, respectively (n = 26). No hemorrhagic shock, myocardial infarction, stroke, paraplegia, severe respiratory infection, renal failure, or puncture-related complications were reported for any of the 24 patients. Follow-up imaging studies showed no stent dislocation, rupture, stent thrombosis, false lumen rupture, new onset, or recurrence of dissection. In these 24 patients, 38 stents covered 39 major branch arteries (locations: brachiocephalic trunk, common carotid artery, and left subclavian artery). After 6–24 months of follow-up, no branch artery stenosis or occlusion was observed, and the patency rate was 100%. The result can be found in the Supplementary Materials 1.

The 6-month follow-up results showed that no stroke or paraplegia occurred in the 24 patients. The major branch artery patency rate was 100% (39/39), 12 of the 24 (50%) patients presented with a complete thrombosis in the false lumen, and false lumen thrombi were completely absorbed in five (20.8%) patients.

A total of 13 patients (20 covered branches) completed a 12-month follow-up. The patency rate associated with important branches was 100% (20/20). No stroke or paraplegia was reported. A total of 10 of these 13 (76.9%) patients presented with complete false lumen thrombosis, while three (23.1%) patients had a false lumen thrombus that was completely absorbed and showed aortic remodeling.

Six patients (nine covered branches) completed a 24-month follow-up. The patency rate in important branches was 100% (9/9). No stroke or paraplegia was reported. Five of these six (83.3%) patients presented with complete false lumen thrombosis, and five (100%) had a false lumen thrombus that was completely absorbed and showed aortic remodeling.

The ratio of the mean true lumen volume to the mean total volume was 0.560, 0.620, 0.684, 0.788, 0.853, and 0.956 before and at 1, 3, 6, 12, and 24 months after surgery, respectively. Figure 2 presents the
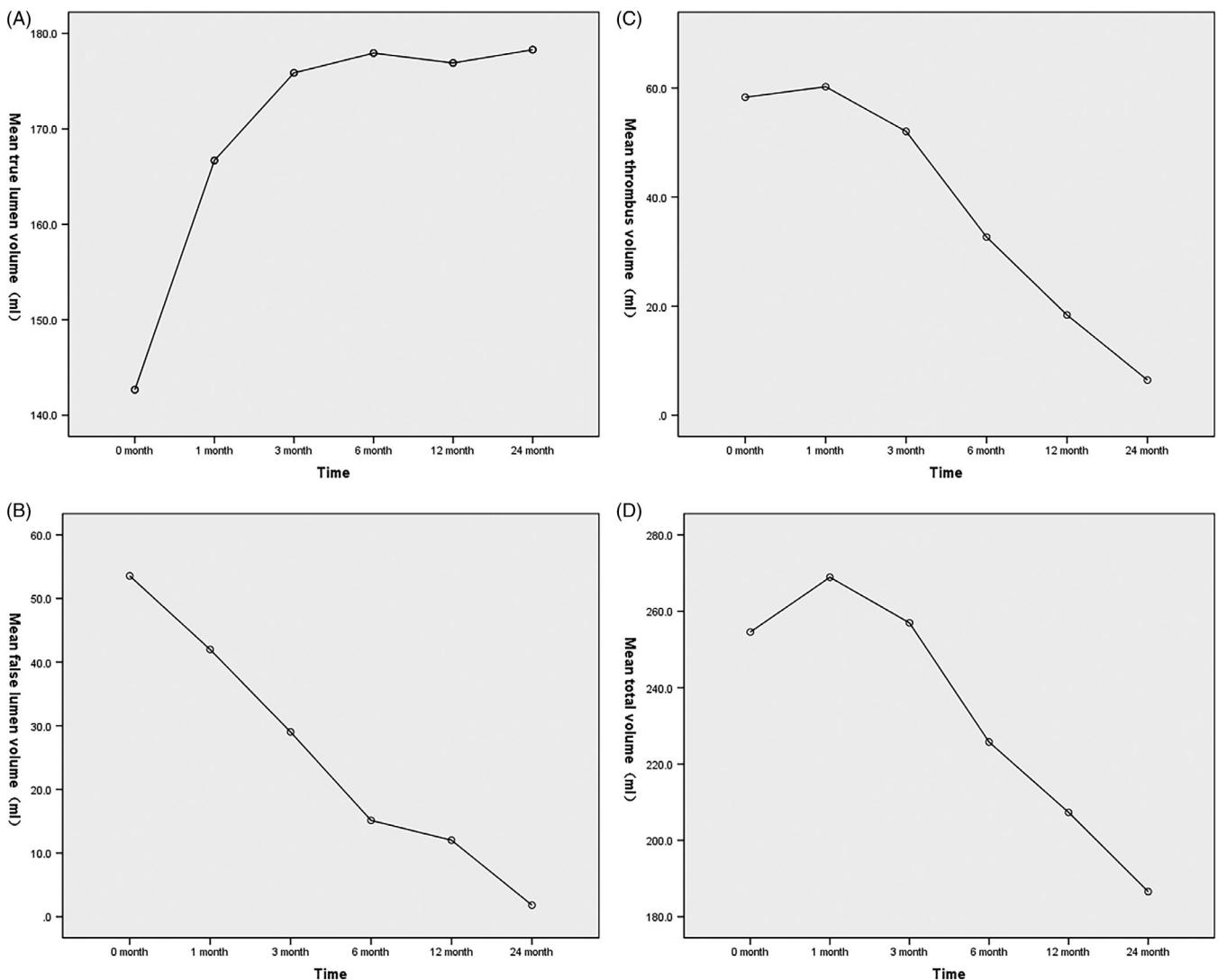

FIGURE 2 Panels A, B, C, and D show the changes in mean true lumen volume, mean false lumen volume, mean thrombus volume, and mean total volume between preoperative and postoperative time points

average volume change of the true lumen, false lumen, residual blood flow, and total volumes.

During the follow-up period, six patients had partial thrombosis. Of these patients, two had a type Ib endoleak, perhaps because the distal portion of the micropore stent was fixed above the celiac trunk due to the involvement of the splanchnic vessels of the abdominal aorta, causing the retrograde flow of the distal abdominal aorta. No type Ia or type III endoleaks were reported in this study.

The changes in pressure on the thoracic aortic wall before and after operation suggested that the wall pressure of the false lumen was higher in phases T1 and T2 and that the wall pressure rapidly and progressively decreased after phase T2. High wall shear stress was observed for intimal tear. High stresses have the potential to cause additional injury to the endothelial cells, thereby potentially leading to tear progression and the creation of additional tears. The thoracic aortic wall of the false lumen was incomplete and weak, and thus led to continuous relaxation and contraction of the wall when continuously supporting the impact of sudden changes in blood flow in the short term. Gradually, continuous relaxation and contraction caused damage to the structure of thoracic aortic wall as the arterial wall became progressively thinner; the wall pressure progressively increased, and consequently led to a higher risk of rupture of the thoracic aortic wall. This study demonstrated that in patients with TAD whose false lumen has a tumor-like change, it was necessary to repair the tear of intima, which could greatly reduce the risk of a rupture. The MSG acts as a passive barrier by reducing blood flow into the false lumen and subsequently creating a natural hemodynamic environment to promote false lumen thrombosis. The velocity and flux of blood flow decreased rapidly in a short time, and the impact on the thoracic aortic wall decreased rapidly. Therefore, the degree of pressure in the false lumen decreased significantly after surgery compared with that before surgery (Figure 3). After the operation, wall shear stress was significantly lower at the direct initial tear and in the false lumen (Figure 4). Before the operation, the vortex and reflux flow appearing in the aorta from the primary entry were increasing. After the operation, the blood flow velocity in the false lumen greatly and progressively decreased (Figure 5). The degree and range of unstable blood flow in the false lumen decreased significantly after surgery compared with those before surgery. As an increasing number of platelets adhered to the inner wall, a thrombus would form in the false lumen, which was beneficial to the self-healing of the intimal tear in the dissection. After the operation, progression from gradual thrombosis to gradual reabsorption corresponded to progression from gradual reduction to complete disappearance of blood flow in the false lumen.

4 | DISCUSSION

Endovascular repair has become the preferred treatment for TAD. However, patients with complex TAD, in which the lesions are adjacent to the major branch arteries and the stent docking area is less than 1.5 cm, are not indicated for conventional endovascular repair. Therefore, for complex TAD that involves important organ branches,
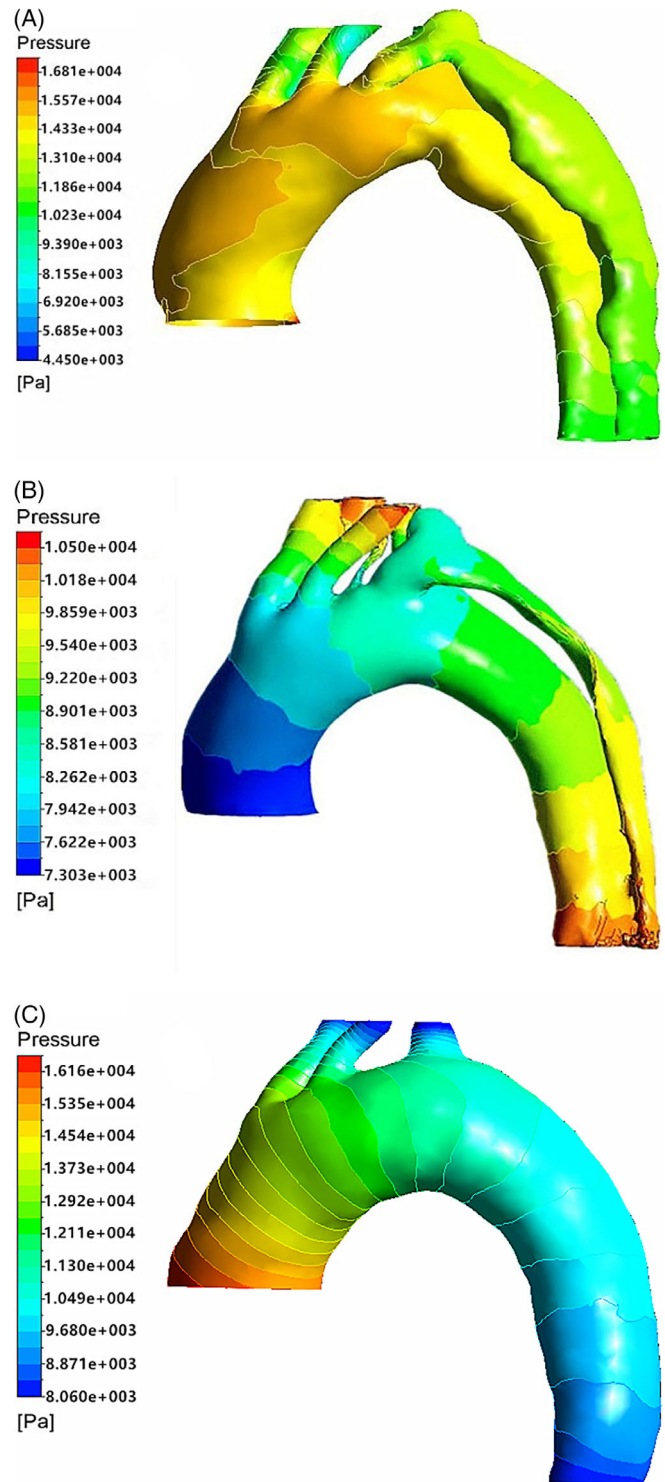

FIGURE 3 The analysis of pressure before and after stent-graft placement. Case A represents the preoperative lumen; case B represents the postoperative lumen at 3 months after surgery; and case C represents the postoperative lumen at 6 months after surgery

regardless of the surgical method chosen, the major problems remain the high mortality rate, spinal cord ischemia, and the blood supply of the affected branch artery. There is currently no effective treatment regimen for this condition.
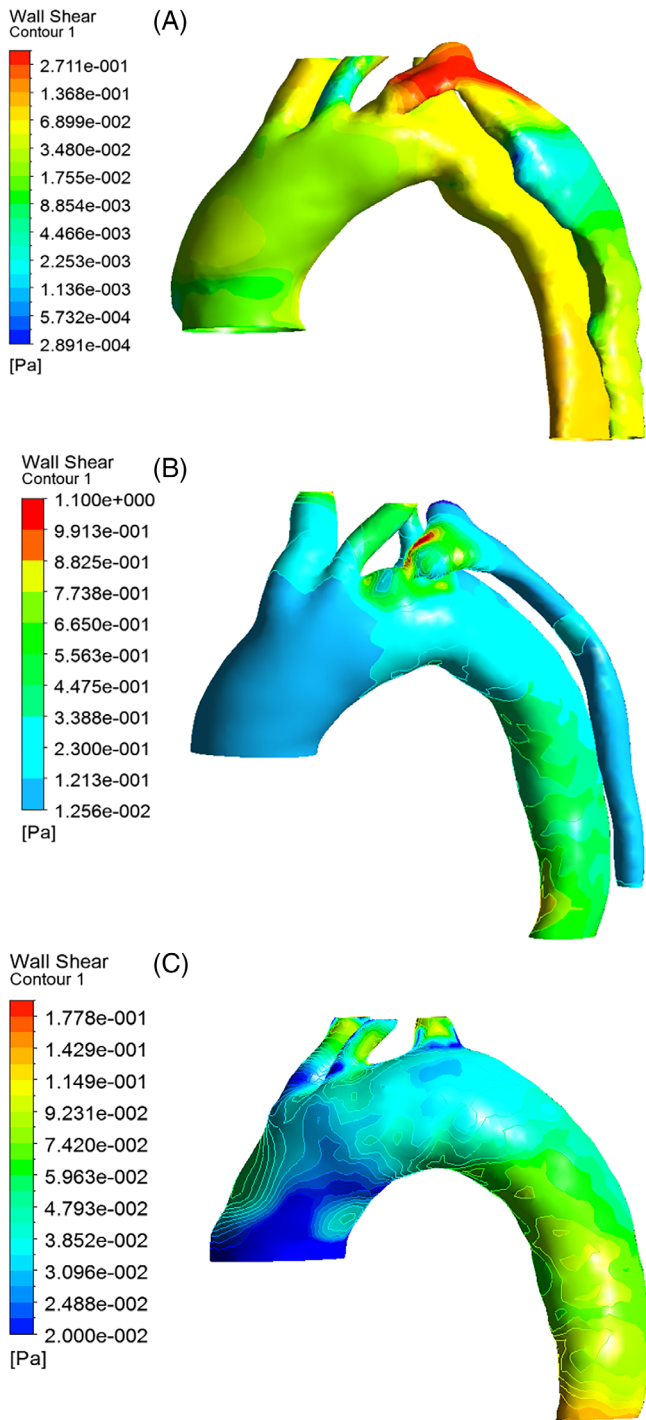
FIGURE 4 The analysis of wall shear stress on the thoracic aortic wall before and after stent-graft placement. Case A represents the preoperative lumen; case B represents the postoperative lumen at 3 months after surgery; and case C represents the postoperative lumen at 6 months after surgery
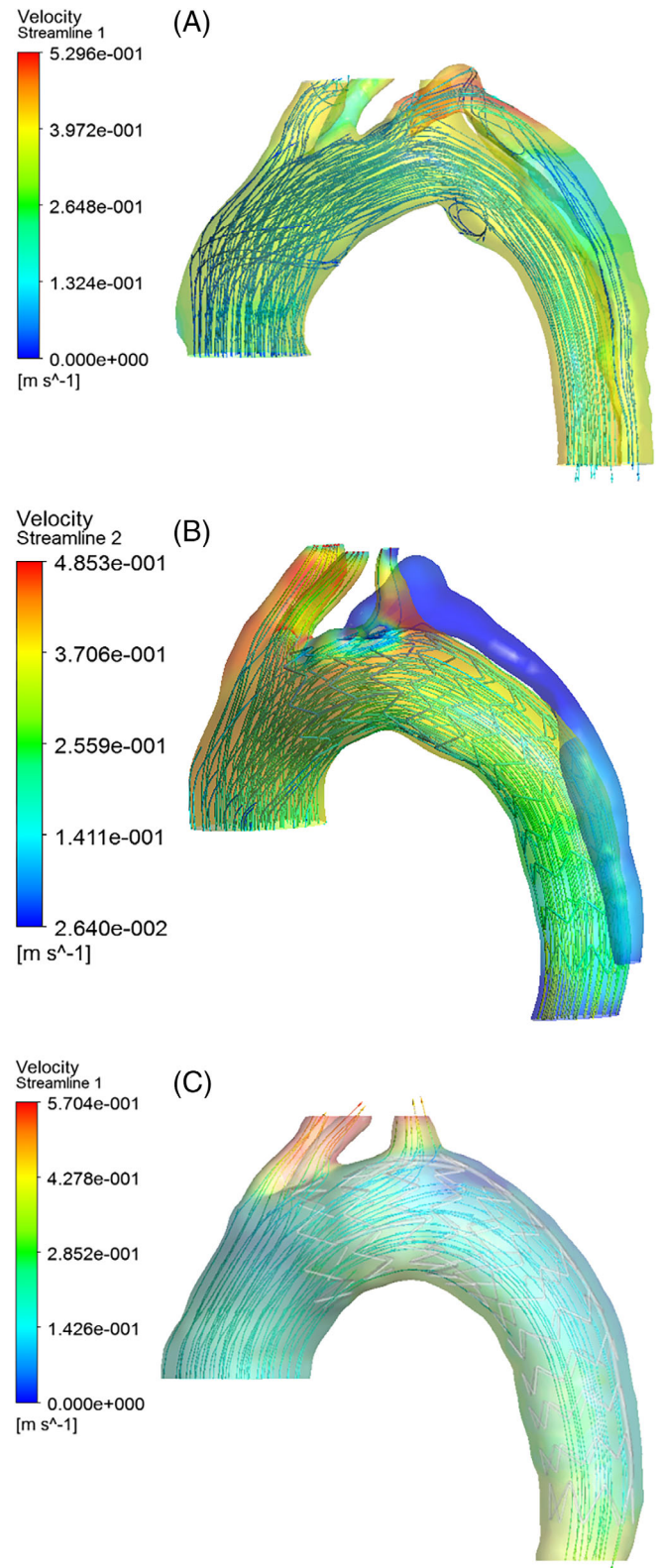
Recently, a growing body of evidence has shown that rather than providing the patient with safe aortic repair, the intraluminal seal of the TAD increases the pressure in the false lumen, leading to an iatrogenic increase in the risk of TAD rupture.[15,16]

FIGURE 5 The analysis of streamlined tracking of blood flow velocity field before and after stent-graft placement. Case A represents the preoperative lumen; case B represents the postoperative lumen at 3 months after surgery; and case C represents the postoperative lumen at 6 months after surgery

FIGURE 6 CTA images showing the blood flow in the false lumen before surgery (a). The presence of continuous blood flow in the false lumen 1 month after surgery (b). A thrombus was gradually formed in the false lumen 3 months after surgery (c). The thrombus was completely absorbed, and the false lumen was occluded 6 months after surgery (d)
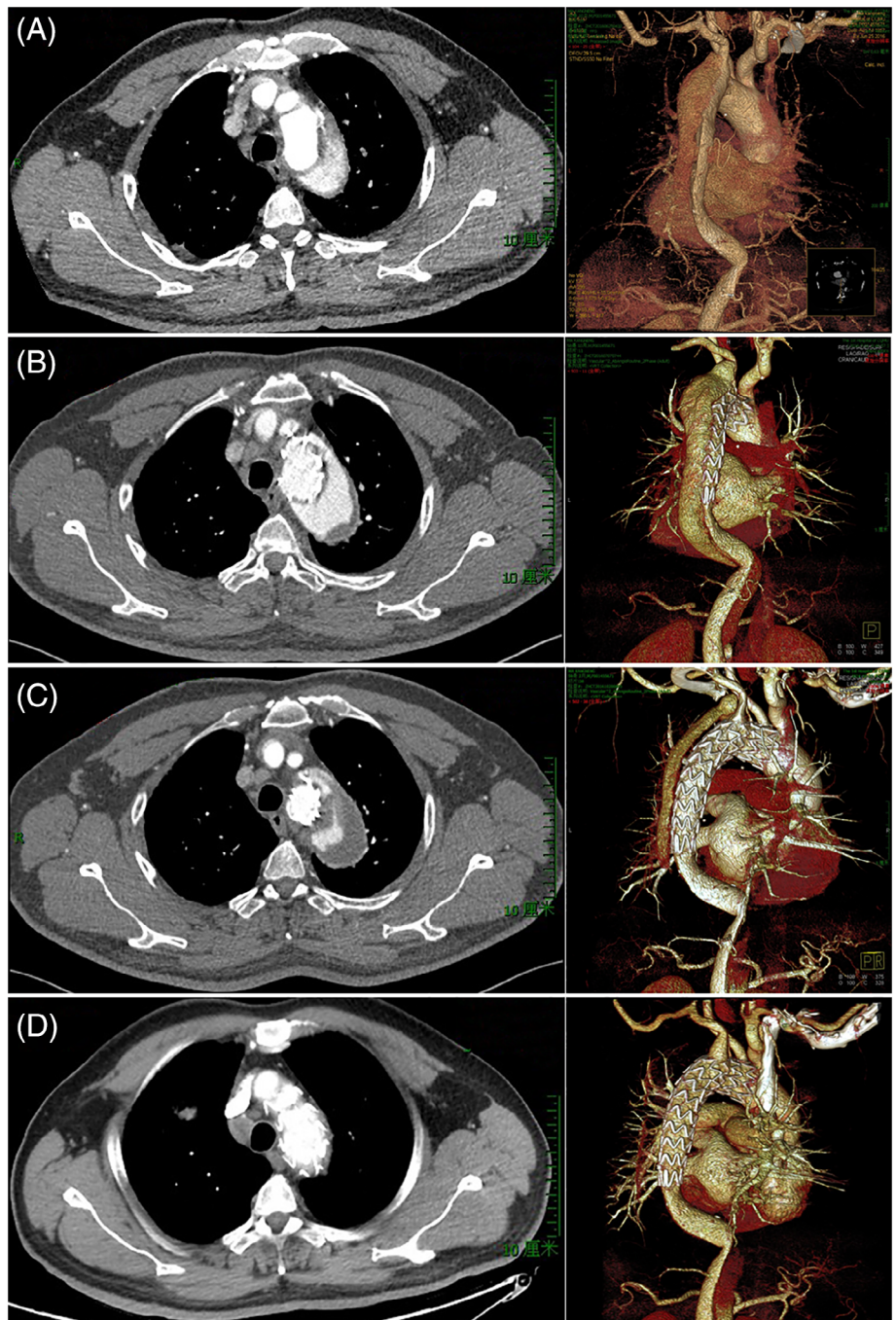
The main purpose of any regimen is to prevent the rupture of the TAD and ensure the patency of the important branch vessels and the perfusion of the corresponding organs.[14,17] A MFM is a multilayer bare stent system used in the endovascular repair of AD. Unlike previous stents, this type does not completely seal the tear in the dissection. Instead, it reduces the shear stress on the vessel wall, and therefore the risk of rupture, by adjusting hemodynamics to delay lesion repair. This type of stent therefore does not affect the blood supply of the branch arteries of the affected organs.[18]

However, the MFM is not yet available in the Chinese market. Hence, in Mainland China, few options are available for treating complex TAD, and MSG remains a feasible and reliable choice for treating

complex TAD in this region. The principle underlying the application of this type of stent is similar to that of the MFM (i.e., the stent treats TAD by modulating the blood flow to avoid occluding important branch arteries or causing ischemic infraction of the corresponding organs).

Our data show that during a follow-up period of 6–36 months, the patency rate of the important branches was usually 100%. The rate of complete false lumen thrombosis was 75% (18/24), the rate of complete absorption of the false lumen thrombus was 45.83% (11/24), and the true lumen volume increased in 100% of treated patients. The volume of residual blood flow in the false lumen was reduced until it was nondetectable, and the volume of the thrombus in the false lumen was reduced or completely absorbed. During the

follow-up period, six of the 24 patients had a partial thrombosis, and no type Ia or type III endoleaks occurred. The result can be found in the Supplementary Materials 2.

We found that the hemodynamic analysis before and after stent-graft placement showed that the pressure of the false lumen was basically equal to that of the true lumen due to the pressure transferred from the intimal tear in the dissection. Continuous relaxation and contraction gradually damages the thoracic aortic wall structure as the arterial wall progressively thins; the wall pressure thus increases, consequently leading to a higher risk of thoracic aortic wall rupture. After stent-graft placement, the pressure in the dissection was transferred to the MSG, and the peak value and fluctuation of the transfer pressure were lower than that of the direct initial tear, which was helpful in reducing the possibility of a dissection rupture (Figure 3). Our study found that the placement of overlapping stents was more effective in reducing flow velocity and shear stress near the thoracic aortic wall (Figures 4 and 5). The results revealed that it could effectively decrease the dissection from the mainstream blood flow, which may induce thrombus formation inside the false lumen. Therefore, this device may induce a shear gradient-dependent platelet aggregation mechanism[19] within the false lumen.

Moreover, these stents do not isolate the false lumen but instead maintain blood communication with the true lumen. Ultimately, the aortic blood flow reaches a dynamic balance, which prevents the pressure on the false lumen from increasing. As the pressure in the false lumen wall decreases, the risk of rupture of TAD is reduced accordingly. Furthermore, decreasing the blood flow velocity in the false lumen and reducing wall shear stress promote thrombosis in the false lumen.[20,21]

These outcomes suggest that the micropore stent is a safe and effective device for treating complex TAD. Compared with traditional endovascular treatments, the micropore stent also provides many other advantages when used to treat complex TAD. For example, it does not require the physician to measure or calculate the position, diameter, or angle of the important branches before determining where to place the stent.

The advantages of the micropore stent are as follows. The stent allows the blood flow of important branch arteries to be maintained and changes the blood flow from a turbulent flow to a laminar flow by altering hemodynamics. These changes reduce the blood flow velocity through the micropores of the stent, thereby reducing the shear stress applied to the wall of the false lumen and promoting thrombosis in the aortic false lumen. We observed thrombus absorbance and in some cases disappearance, indicating that aortic remodeling was complete. Moreover, MSG reinforces the vessel wall and reduces the risk of rupture in the covered vessel.[13,22] Our results are consistent with these conclusions. We found that after the micropore stent was placed, a false lumen thrombus gradually formed, and the volume of the true lumen gradually increased. The volume of the true lumen significantly increased during the first 1–3 months after surgery, after which it increased more slowly. The residual blood flow in the false lumen gradually decreased until it completely subsided (Figure 6). Over time, the relative changes observed in true lumen volume, false lumen residual blood flow, and false lumen thrombus volume

significantly affected the remodeling of the diseased aorta. The thrombus in the false lumen increased until it reached a stable state, after which the absorbance of the thrombus began, and the thrombus then shrank or even disappeared. However, aortic remodeling occurs when the patency of important branch vessels is maintained. Therefore, the micropore stent likely exerts positive effects by reducing the risk of dissection and accelerating aortic remodeling.

5 | CONCLUSIONS

In the current study, we demonstrate that the micropore stent, when used to treat TAD, works by gradually promoting aortic remodeling. The micropore stent is a feasible and reliable option for treating complex TAD in Mainland China. Its application will completely change the treatment methods currently used to repair complex TAD in this region.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.