

# Late Gore Excluder endoprosthesis fabric tear leading to abdominal aortic aneurysm rupture 5 years after initial implant

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Endoprosthesis fabric tear leading to abdominal aortic aneurysm rupture is a rare event. In this report, we describe a patient who presented with an abdominal aortic aneurysm rupture after a tear in the fabric of the Gore Excluder endoprosthesis (W. L. Gore and Associates, Flagstaff, Ariz) 5 years after implantation. The reason for the fabric tear was unknown. The complication was successfully treated by relining the endograft with an aortic cuff and two iliac limbs. The patient experienced an uneventful recovery after the intervention. (*J Vasc Surg* 2013;57:221-4.)

Since its introduction in 1991, endovascular aneurysm repair (EVAR) has become widely popular in the management of abdominal aortic aneurysms (AAAs) and ensures clear short-term advantages over open repair.<sup>1</sup> But there are doubts about the long-term outcome because it is associated with complications such as graft migration, endoleaks, increasing aneurysm size, and eventually, death. Continuous monitoring of patients who have undergone EVAR is necessary because long-term durability of the graft fabric is largely unknown.

Here we describe the case of ruptured polytetrafluoroethylene (PTFE) graft material of an Excluder bifurcated endoprosthesis (W. L. Gore and Associates, Flagstaff, Ariz) ~5 years after implantation. The Gore Excluder graft is fabricated from expanded PTFE with an outer self-expanding nitinol support structure without the use of any suture. The graft comes as a trunk-ipsilateral leg endoprosthesis. A contralateral leg endoprosthesis is then added.

Although type III endoleaks (modular separation and fabric disruption) have been reported with the three commercially available endoprostheses, delayed AAA rupture after fabric tear after 5 years of initial implant has never been reported for the Gore Excluder system.<sup>2-5</sup>

## CASE REPORT

A 71-year-old man was referred to Emory University Hospital with an AAA. On physical examination and computed tomography (CT) scan, the AAA was confirmed starting at the level of the right

renal artery with involvement of the left renal artery. His medical history was significant for hypertension, chronic obstructive pulmonary disease with forced expiratory volume in 1 second <1.2 liters, mild renal insufficiency with a preoperative creatinine of 1.3 mg/dL, chronic heart failure secondary to ischemic cardiomyopathy, and a recent history of coronary artery bypass grafting with a fixed deficit on his echocardiography. The patient was prescribed warfarin therapy by the cardiac surgery service after this procedure.

He had a history of smoking for many years and continued to smoke 1/2 pack of cigarettes a day. An open repair was considered, but the patient's significant comorbidities precluded open repair with aortic cross-clamping at a reasonable risk. The approach of debranching of the left renal artery and aortic stenting across it was believed to reduce the operative stress for the patient compared with an open repair.

An angiogram showed the anatomy of the aneurysm was suitable for repair with the Gore Excluder endoprosthesis, with an infrarenal AAA of 6.7 cm in maximal diameter, neck length of ~15 mm below the right renal artery, and neck diameter of 22 mm at the parallel portion of the landing zone. The left renal artery, however, was coming right off the aneurysm, and despite multiple views, its origin could not be adequately identified (Fig 1, A). The patient also had second right renal artery. Pelvic diagnostic angiogram showed normal common, external, and internal iliac arteries bilaterally.

Because of the prohibitive risk for open repair, it was decided to proceed with endovascular repair of the AAA, with planned coverage of the left renal artery and left renal artery bypass. The patient was placed under general anesthesia, and a left subcostal incision was made. The left femoral artery was exposed, and the inguinal ligament was mobilized to identify the left external iliac artery for left iliorenal bypass by using 6-mm ringed PTFE. Then, after a bilateral femoral cutdown, the 18F, 28-cm-long Gore DrySeal Sheaths were advanced in the iliac arteries to the level of the common iliac artery. The main body of a 26-mm-diameter × 14-mm × 18.5-mm Gore Excluder stent graft was introduced over the DrySeal sheath from the right side to minimize ischemia in the left kidney that could be caused by an occlusive sheath. No resistance was encountered at any point during advancement of the main body of the stent graft.

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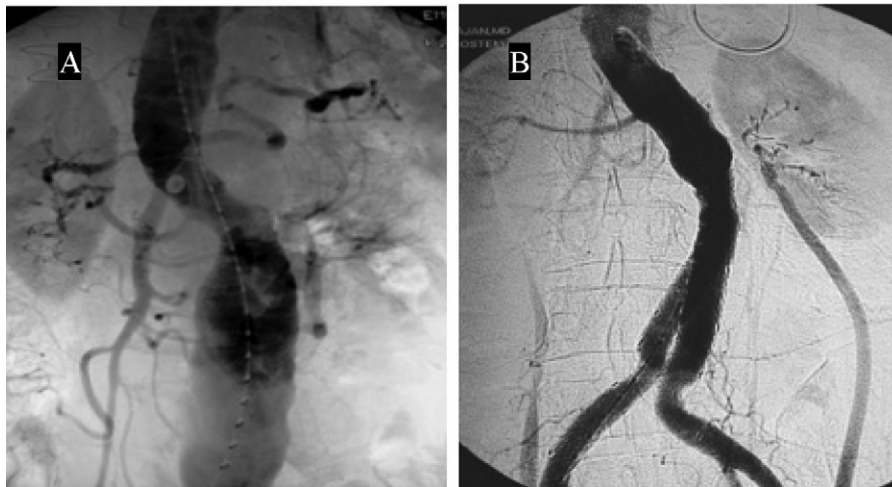
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**Fig 1.** **A,** Preoperative angiogram shows an infrarenal abdominal aortic aneurysm (AAA) at the level of the left renal artery. **B,** Postoperative angiogram shows the iliorenal bypass and the endovascular stent.

Deployment of the stent graft below the origin of the right renal artery was uneventful, covering the origin of the left renal that was involved in the aneurysm. We then placed an 18- × 11.5-mm extension limb on the right side. On the left side, we placed an 18- × 13.5-mm extension limb, followed by another limb, which was 18 × 9.5 mm.

The completion angiogram showed evidence of a type Ia endoleak. This was fixed by performing an aortic angioplasty, followed by placement of a 4010 Palmaz stent (Cordis, Miami Lakes, Fla). The seal and component junction zones of the graft were then angioplastied using an Equalizer balloon (Boston Scientific, Natick, Mass). A repeat angiogram showed excellent flow into the right renal artery and into the left renal artery through the iliac conduit, with no evidence of endoleak (Fig 1, B).

The patient was discharged on postoperative day 4 with a creatinine value of 1.5 mg/dL. The patient had follow-up noncontrast CT with duplex sonography at 1 month, 6 months, and 18 months that did not demonstrate an endoleak. Furthermore, regression of the aneurysm sac from 6.6 to 4 cm advocates against the presence of an endoleak at that point. This was also confirmed by a magnetic resonance angiography performed at an office visit a year before acute presentation with rupture, which excluded the presence of an endoleak and showed a stable aneurysm sac of 4 cm of maximal diameter.

In 2010, the patient presented at another hospital with excruciating lower abdominal and back pain. A CT scan at that hospital suggested a retroperitoneal hematoma that could be associated with an aneurysm rupture due to type III endoleak (Fig 2, A and B). Noteworthy at that point was that his hemoglobin was 7.5 mg/dL, and his international normalized ratio was 5.7 because of the warfarin therapy. After resuscitation and substitution of blood products, the patient was transferred to Emory University Hospital.

He was not in acute distress at arrival but complained of lower abdominal pain. After correction of the international normalized ratio, the patient was emergently taken to the operating room where 8F sheaths were placed through bilateral femoral access. The initial abdominal aortogram showed normal flow in the right renal

artery and an open left iliorenal bypass with the graft showing significant contrast extravasation into the aneurysmal sac at the site of the rupture (Fig 2, C). The exact location of the tear was difficult to identify with absolute accuracy because rapid flow of contrast agent in the aneurysmal sac did not allow this in the CTA or in the intraoperative angiography. On the basis of the preoperative CTA and the intraoperative angiography, the fabric tear was most likely located at the level of the flow divider at the side of the right limb.

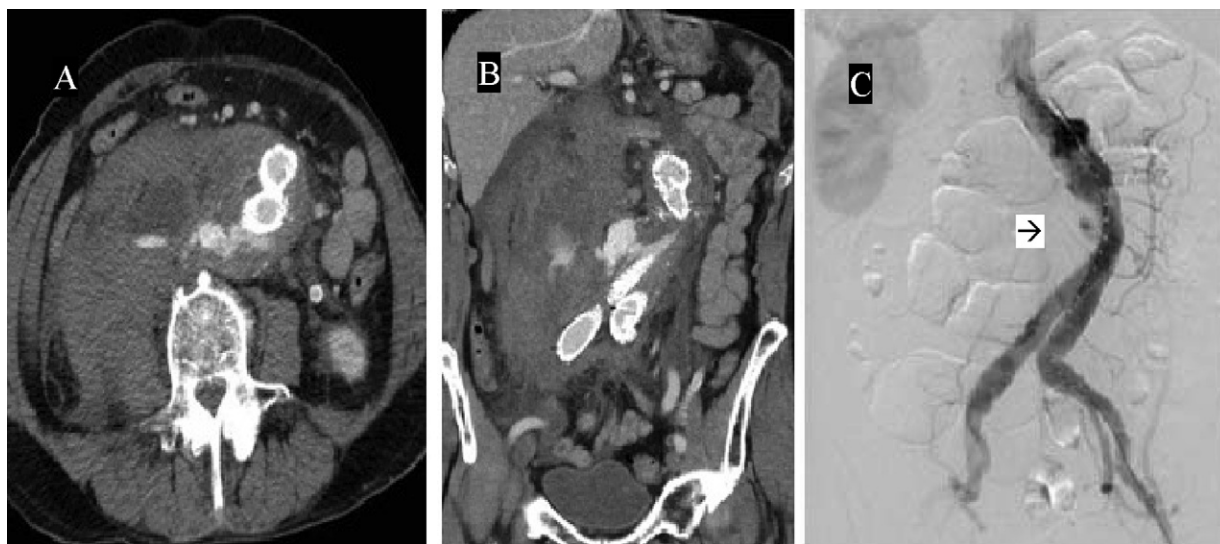
We performed a proximal aortic angioplasty using a 30-mm Z-Med balloon to adequately expand the Palmaz stent that had been previously placed extending into the normal aorta above the endograft, after that proximally, a 28.5-mm cuff and then two 16- × 11.5-mm limb extensions were placed. The entire proximal cuff and the graft were angioplastied using the 30-mm Z-Med balloon (NuMED, Inc, Hopkinton, NY). A repeat angiogram showed total elimination of the endoleak and that good flow into the renal arteries had been preserved (Fig 3, A).

The patient was stable and discharged home on postoperative day 3 with a postoperative creatinine value of 1.3 mg/dL. The patient was subsequently monitored with office visits and duplex ultrasound imaging, which confirmed regression of the aneurysm sac and no signs of endoleak. The patient refused further CT scans due to his compensated renal insufficiency.

## DISCUSSION

As experience with EVAR has increased, this modality of treatment has been offered to a wider population of patients, primarily because of the reported short-term advantages. However, the issue of long-term benefit compared with open repair, as well as the need for reinterventions for complications with EVAR, is still unresolved.<sup>6-9</sup>

Several studies have documented significant changes in aneurysm morphology after aneurysm repair, leading to changes in the configuration of the graft, which could lead to graft distortion and, subsequently, to modular



**Fig 2.** A and B, Computed tomography images show ruptured abdominal aortic aneurysm (AAA) after 5 years due to fabric disruption. C, Angiogram shows significant contrast extravasation (*arrow*) after fabric tear into the aneurysmal sac at the site of the rupture.



**Fig 3.** A, Repeat angiogram shows total elimination of the endoleak.

separation and type III endoleaks.<sup>10,11</sup> The larger the aneurysm sac, the more space in which the stent graft can move or distort. Tortuosity of the vessels at implantation may be a risk factor for early graft kinking. Time appears

to be a factor as well. All severe conformational changes occurred after 3 years. Umscheid and Stelter<sup>11</sup> reported 30% of the aneurysms did not decrease in length or diameter; however, there were conformational changes in all endografts. Type III endoleak is an unusual complication; however, metal fatigue and fabric erosion can create a type III endoleak, a long-term problem.<sup>12,13</sup> A fracture of the proximal attachment hooks has been also reported.<sup>12</sup> Reports of fabric erosion leading to type IIIb endoleak are rare, whereas type IIIa endoleak, defined as disconnection of the modular limb of a stent graft, is more common and leads to pressurization of the aneurysm sac and risk of rupture and death.<sup>14</sup>

In a 2003 European Collaborators on Stent-Graft Techniques for AAA and Thoracic Aortic Aneurysm and Dissection Repair (EUROSTAR) study,<sup>15</sup> 29% of ruptured AAAs after EVAR had type III endoleaks, so that modular separation or defects in stent graft fabric due to material fatigue remain an issue to be addressed by the industry in stent graft design. The cause of the fabric tear in our patient is unknown, but it is unlikely that the tear was a direct result of the initial procedure. Although it is difficult to speculate on the effect of the initial Palmaz stent placement and the ballooning on a possible damage of the fabric of the stent graft, we are confident as determined on the final angiography of the primary procedure, as well as on the follow-up examinations, that the fabric tear was not caused during the initial procedure.

The angulation between the axis of the aortic neck and the axis of the aneurysm was approximately 45° and could have theoretically contributed to an increased tension on the fabric of the endograft, ultimately leading to material fatigue and local rupture. An endoleak could not be detected postoperatively, however, and the aneurysm sac decreased in size at 1, 6, 18 months, and at 4 years. After 5

years, the patient presented dramatically with rupture of the AAA. Multiple views of fluoroscopy optimized for metal did not reveal stent fracture.

The rupture was treated by placement of a proximal cuff and two extension limbs. The presence of an iliorenal bypass on the left would limit the use of aortouniliac (AUI) graft system to that side, necessitating a femorofemoral bypass to the right side. However, we were concerned that AUI stenting could potentially fail to seal proximally and would require very precise deployment to avoid compromising the iliorenal bypass on the left. The cuff was placed for multiple purposes:

- A seal could be achieved instantly, especially if the tear were at the main part of the graft and above the flow divider.
- Additional expansion to the original stent graft was achieved to prepare the accommodation of the two iliac limbs, thus minimizing the risk of gutters that could occur if only the limbs were implanted.
- Exclusion of the rupture was achieved just by setting the bifurcation of the stent graft higher while preserving antegrade flow to both extremities.

Although type III endoleaks have been reported in all three commercially available endograft systems, this has never been reported after 5 years of initial implant, which makes this case worrisome and raises concern about the long-term durability of stent graft fabrics.<sup>2-5</sup> In the published report of midterm results from the Excluder pivotal trial that led to U.S. Food and Drug Administration approval of the device, there was 0% incidence of type III endoleaks.<sup>16</sup> However, Schanzer et al<sup>17</sup> reported how liberalization of the anatomic characteristics suitable for EVAR has occurred and how this is associated with a significant increase in the incidence of aortic sac enlargement, with AAA enlargement occurring in 40% of patients by 5 years, thereby reducing durability of EVAR. This study was not endograft-specific, and no data related to reintervention were reported.

In our patient, we were fascinated by the fact that 5 years after the initial repair and despite regression of the aneurysm sac and an MRA showing a successful exclusion of the aneurysm, a spontaneous tear of the fabric could occur, leading to rupture. A primary iliorenal bypass as a therapeutic option of debranching for a juxtarenal aneurysm, as well as the management of a rupture with a cuff and two limbs in the presence of a stent graft, is in our eyes, a challenging and interesting case. Implantation of an AUI stent graft is a good alternative in patients in whom insertion of a bifurcated endograft is impossible.<sup>18</sup> However, some type III endoleaks require open surgery.<sup>4</sup>

## CONCLUSIONS

Late type III endoleak from fabric disruption of an endovascular stent graft is a serious and potentially lethal

complication, and given the limited long-term follow-up data in the literature, the current finding is disturbing.

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