Title

A Single Institution Case Series of Total Endovascular Relining for Type 3 Endoleaks in Traditional EVAR Grafts with Raised Bifurcations

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A Single-Institution Case Series of Total Endovascular Relining for Type 3 Endoleaks in Traditional Endovascular Aneurysm Repair (EVAR) Grafts with Raised Bifurcations

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Background: The endovascular repair of infrarenal abdominal aortic aneurysms can be performed with a wide variety of devices. Many of these grafts elevate the aortic bifurcation which can limit future repairs if the graft material fails thereby creating a type III endoleak to aorto-uniliac grafts. Many manufacturers have grafts susceptible to this, but we have seen this in the Medtronic AneuRx graft. Our goal is to provide technical details and outcomes regarding a novel technique to reline these grafts while maintaining inline flow to the iliac arteries.

Methods: This was a single-institution review of patients who had endoleaks requiring intervention after a previously placed graft with an elevated aortic bifurcation. Primary outcomes included technical success defined as placement of all planned devices, resolution of type III endoleak, aneurysm size at follow-up, and requirement of reintervention. Secondary outcomes included 30-day complications, aneurysm-related mortality, and all-cause mortality. Technical details of the operation include back-table deployment of an Ovation device, modification of the deployment system tether and pre-emptive placement of an up and over 0.014″ wire. The wire is placed up and over and hung outside the contralateral gate. Once the main body is introduced above the old graft, the 0.014" is snared from the contralateral side and externalized. The main body is then able to be seated at the bifurcation as the limb is not fully deployed and then device deployment is completed per instructions for use.

Results: Our study consists of 4 individuals, 3 of which had an abdominal aortic aneurysm initially managed with an AneuRx endovascular aneurysm repair and 1 with a combination of Gore and Cook grafts. All 4 patients were male with an average age of 84.5 years at time of reline. All patients had at least 10 years between initial surgery and reline at our institution. Primary outcomes revealed no type 1 or 3 endoleaks at follow-up, technical success was 100% and 1 patient required reintervention for aneurysm growth and type 2 endoleak. In terms of our secondary outcomes, there was 1 postoperative complication which was cardiac dysfunction

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Disclosures: This manuscript contains off IFU device information that is not FDA approved. ARB: consultant for Endologix.

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secondary to demand ischemia, aneurysm-related mortality was 0% and all-cause mortality was 25% at average follow-up of 2.44 years.

Conclusions: As individuals continue to age, there are more patients who would benefit from less invasive reinterventions following endovascular aneurysm repair. Whether this is due to aortic degeneration, stent migration, or stent material damage is not always known. In this study, we present an endovascular approach to treating type III endoleak patients with a previous graft and elevated aortic bifurcation using Ovation stent grafts and found no evidence of type 1 or 3 endoleaks on follow-up imaging. This approach may allow patients with type III endoleak the option of a minimally invasive, percutaneous approach where they previously would not have had one.

INTRODUCTION

The endovascular repair of aortic aneurysms is a common method for the treatment of abdominal aortic aneurysms (AAA). The Food and Drug Administration released an executive summary indicating that in the United States, 80% of AAAs that require intervention are treated with an endovascular repair.[1] This has been thought to be due to lower early mortality compared to open surgical repair; however, this comes with the added expense of surveillance, endoleaks, and reintervention.[2,3] Many of these grafts elevate the aortic bifurcation which can lead to limited repair options if the graft fails in the future.

An endoleak represents persistent blood flow to the aneurysm after an endovascular stent has been placed.[4] The focus of this study was on type III endoleaks, which occur between different components of the stent graft (IIIa) or in areas or fabric fracture or disruption (IIIb). Type III endoleaks are relatively uncommon in current third generation endografts; however, in first and second generation devices, it can represent between 3% and 5% of endoleaks.[5,6]

The AneuRx graft was the first aortic endoprosthesis to receive regulatory approval in both Europe (1996) and the United States (1999). This particular graft was placed in many patients in the early 2000s due to ease of deployment and good short-term outcomes. However, as the graft was followed over time, it was noted to have high migration rates and stent fracture rates leading to type I and III endoleaks (Fig. 1).[7] A single-institution review of the AneuRx graft found a type III endoleak rate as high as 8%.[8] This traditionally has been repaired with an aorto-uniiliac device and femoral–femoral bypass with good outcomes.

Early detection of type III endoleaks is important as they are associated with a 9-fold increased risk of rupture.[9] Additionally, appropriate treatment is imperative as recurrent rates can be as high as 25%.[8] The goal of this study is to describe a novel technique to reline an elevated aortic bifurcation while maintaining inline flow to the iliac arteries.

METHODS

Cohort

This study was performed at a single-institution tertiary care center. Institutional review board approval was obtained for this study. The primary surgeon was the same for all cases. Each case that was performed represented a type III endoleak from a previous endovascular aneurysm repair (EVAR) with a raised aortic bifurcation (Fig. 2).

Outcomes

Primary outcomes included technical success, resolution of type 3 endoleak, aneurysm size at follow-up and any reintervention. Secondary outcomes included 30-day postoperative complications, aneurysm-related mortality and all-cause mortality.

Technique

The goal of this repair is to perform a percutaneous reline of an elevated aortic bifurcation while maintaining inline flow to the iliac arteries. The procedure begins with bilateral percutaneous access. This is performed in the usual fashion. The micropuncture set is then exchanged to bilateral 6-French sheaths over a ‘‘0.035 wire. Nine-French sheaths are placed bilaterally and stiff wires are placed up both sides.

A 26-mm Ovation iX device is then unsheathed on the back table (Fig. 3). The limbs are separated and the tether that holds the contralateral limb is identified. A ‘‘0.014 Nitrex wire is passed up and over the iX port and hung outside the graft for 4 cm. The constraint tether polytetrafluoroethylene is then divided between the 2 limbs of the aortic main body device (Fig. 4). The device is then resheathed and ready to be advanced (Fig. 5).

An Omni flush catheter is placed in the infrarenal aorta and an aortogram is performed to mark the level of the bilateral renal arteries. The previously modified Ovation device is then advanced through a 16-French or 18-French dryseal up the stiff wire.

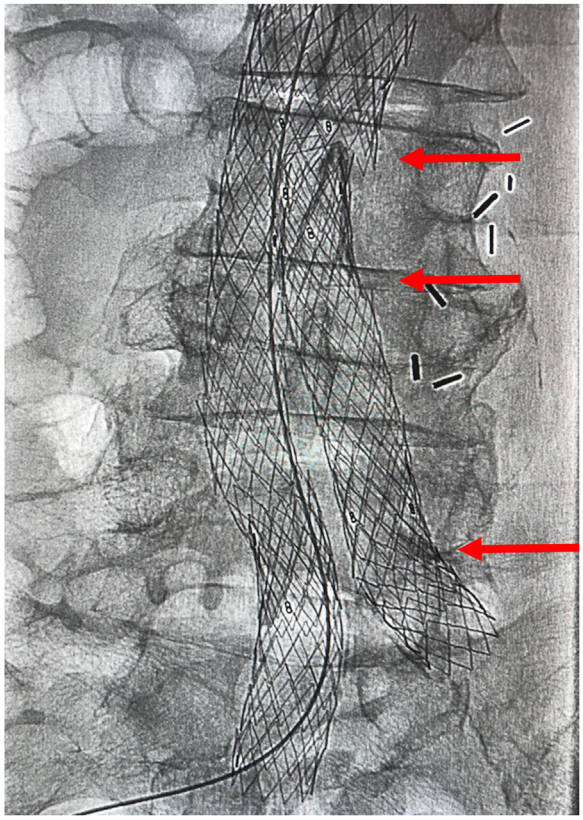

Fig. 1. Stent fracture.

The Ovation body is then advanced outside the sheath. The stent graft is delivered above the previous EVAR flow divider and the contralateral limb wire is snared using a gooseneck snare from the 14-French contralateral sheath (Fig. 6). The EN-SNARE is able to capture the Nitrex wire and externalize it to bring the graft down onto the previously placed graft raised bifurcation.

Once the device is in proper position, the polymer is allowed to fill (Fig. 7). A final completion angiogram is performed that demonstrates patent renal arteries, patent limbs and no evidence of a type 1 or 3 endoleak. Of note, the above described technique is not approved by the Food and Drug Administration and is an off-instructions for use method.

The AneuRx grafts are traditionally more difficult to treat for a variety of factors. The grafts tend to have a short main body generally of 3–4 centimeters, higher propensity for slipping, and higher chance of stent fracture. However, any EVAR that elevates the aortic bifurcation makes it more difficult to preserve a bifurcated endovascular repair if an endoleak develops. The operative technique that we have described allows preservation of a bifurcated repair and avoids large incisions in the groin and a bypass which is required for the traditional aorto-uniiliac repair.

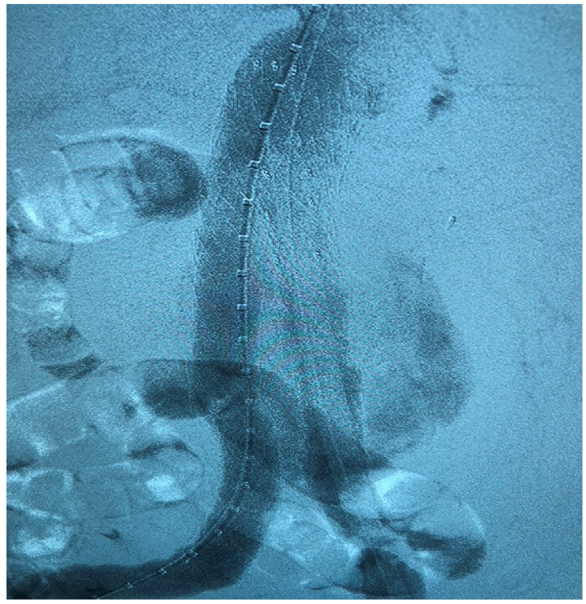

Fig. 2. Previous endovascular aneurysm repair with raised bifurcation.

Statistics

Statistical comparative analyses were not performed in this study. Descriptive statistics were used to discuss primary and secondary outcomes and indications for repair.

RESULTS

Baseline Characteristics

Our study consisted of a total of 4 patients who were treated at either a tertiary care center or university affiliated Veterans Affairs Medical Center. All 4 patients were male with 3 self-identified as White and 1 as mixed race. Baseline characteristics included 50% with coronary artery disease and atrial fibrillation and 100% with hypertension and hyperlipidemia. Three of 4 patients had congestive heart failure and 75% were former smokers with 1 never-smoker. One patient had a history of a popliteal aneurysm and this same patient also had a family history of an aneurysm.

Surgical History

In terms of the surgical history, 3 patients had a previous AneuRx EVAR graft and 1 had a previous combination of Gore and Cook EVAR graft. Table I demonstrates the preoperative information. The

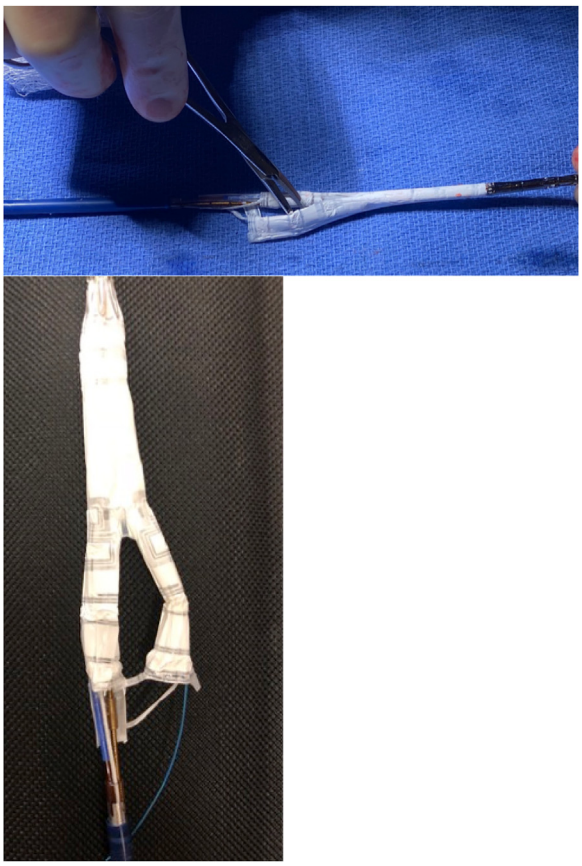

Fig. 3. Back-table modification of Ovation graft.

patients were on average 84.5 years old at time of reline procedure and the average age of the EVAR at time of repair was 13.25 years. Three of 4 patients had aneurysm sac expansion, 3 of 4 had previous reinterventions, and all 4 had a type III endoleak with a raised aortic bifurcation at time of reline surgery.

Operative Details

All 4 cases were performed with percutaneous ultrasound groin access. The Ovation iX system was used in all cases, 2 performed with the traditional device and 2 with the Alto device. Average contrast use was 112 cc, average air kerma was 1,907 Gy, 39 min of fluoroscopy, 215.6 min of operative time, and an average length of stay of 2.75 days. There were no patients treated with alternative techniques during our study period.

Outcomes

Primary outcomes revealed 100% technical success in our reline procedure. There was no evidence of type I or III endoleak on follow-up imaging. One patient required reintervention for aneurysm growth secondary to a type II endoleak. On secondary outcomes, there was 1 incident of 30-day complications, which was cardiac dysfunction secondary to demand ischemia. There was no incidence of aneurysm-related mortality and 1 patient passed away from unrelated reasons during the 2.44 year follow-up. The most recent follow-up for each patient was: patient #1—1.6 years, patient #2—3.5 years, patient #3—4.0 years and for patient #4—0.6 years from surgery date. Successive imaging has also demonstrated decrease in aneurysm sac over follow-up (Fig. 8).

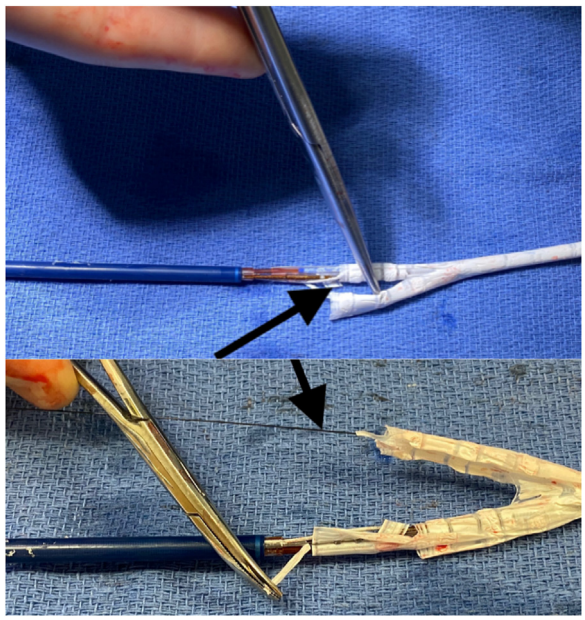

Fig. 4. Dividing constraint tether.

DISCUSSION

Endoleak detection constitutes a major driving force behind post EVAR surveillance plans. Prompt recognition and treatment of type III endoleaks is critical as they can lead to aneurysmal rupture. The EUROSTAR registry found a 12.7% type III endoleak rate in first and second generation endografts, compared to 1.2% in newer third generation devices and an estimated 9-fold increased risk of rupture in type III endoleaks.[9,10] This is believed to be due to increased pressurization in the aneurysmal sac that if not addressed will continue to enlarge with potential catastrophic consequences. Additional risk factors associated with the development of type III endoleaks are nonproprietary extension, angulated necks, and calcified necks.[11]

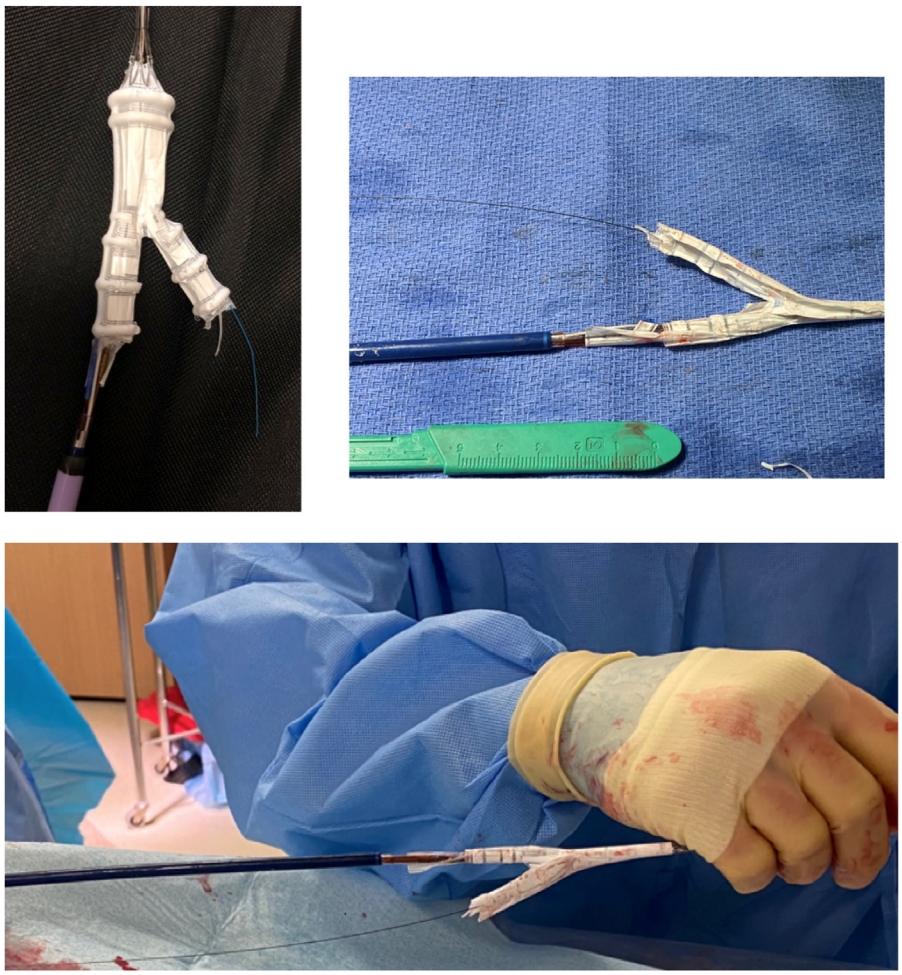

Fig. 5. Final device before deployment.

Given this, the Society for Vascular Surgery advocates for all type III endoleaks to be treated.[4] However, even though consensus exists about the gravity of type III endoleaks, standardized treatment plans are lacking. The literature is heterogenous with treatments involving endovascular approaches, open surgical approaches or hybrid interventions, but none have been widely accepted as a preferred approach.[12–15] Endovascular repairs are favored, but have been classically limited due to anatomic factors such as unfavorable location of the endoleak or short distance between renal arteries and the flow divider. The technique described in this manuscript is meant to overcome such challenges. Open surgical or hybrid techniques are also acceptable; however, they come with the risk of major surgery on patients who presumably were not good surgical candidates at the time of initial EVAR.

The difference between type IIIa and IIIb endoleaks is based on etiology and drives treatment. Type IIIa are due to disconnections between modular graft components: main body and contralateral limb or main body and proximal cuff paradoxically placed for other types of endoleaks. These are traditionally repaired by deploying an iliac limb graft to bridge the disconnection. This should provide adequate seal as long as the main body gate is properly cannulated. When the leak is between the main body and aortic cuff, short extensions may not be sufficient and a complete reline such as described in this manuscript is required. Similarly, type IIIb endoleaks are caused by fabric disruption due to excessive pressure during ballooning, chronic shear stress, manufacturing defects or erosion by the tip of a stent in a severely angulated neck.[16,17] The defect is generally at the

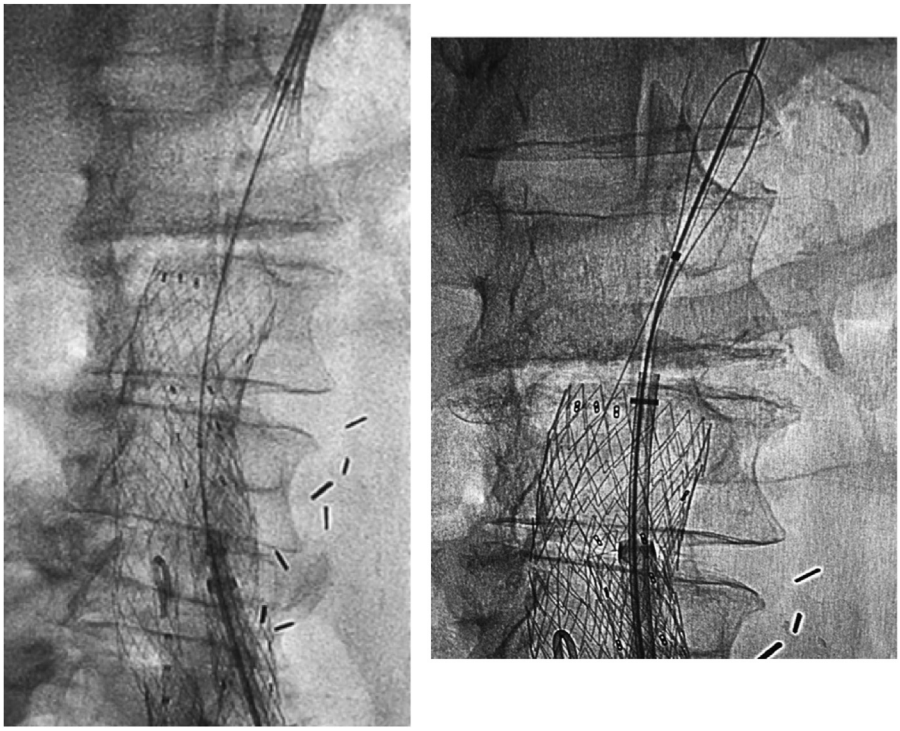

Fig. 6. Snaring new device.

flow divider requiring relining of the graft. Traditionally, this has been resolved with the placement of an aorto-uniiliac stent graft combined with contralateral iliac limb embolization and a creation of a femoro–femoral bypass.[13]

This manuscript describes a technique to treat patients with a type III endoleak in a complete endovascular minimally invasive fashion and therefore avoids any open incisions from traditional repairs. There was 100% technical success in our study and our technique was effective on devices that undoubtedly elevate the aortic bifurcation, such as the AneuRx graft. Since these grafts are quite difficult to reline, we believe this technique could be used for many other devices. We utilized the Ovation iX device due to its expanded instructions for use and its ability to work on hostile anatomy; such features translate into ease of navigation and secure deployment inside another graft that has already shortened landing zones.

Proper endovascular technique is paramount since reinterventions are not exempt of complications. Maleux et al.[10] reported a 15% rate of adverse events including bilateral lower ischemia, retroperitoneal hematoma and bowel ischemia in type III endoleak treatments. Type III endoleaks have been best described in the AFX endograft. Treatment options include balloon angioplasty, covered stent placement, or open repair.[18] Single-institution studies and case reports have demonstrated treatment success through relining or explant at intercomponent areas or fabric tears.[19,20] The previous described studies including ours do not have comparison groups such as surveillance or open surgery comparisons. Key steps for successful relining include: eliminating parallax; avoiding wireframe entrapment by passing a partially inflated balloon and/or using intravascular ultrasound; performing a provoked angiogram by injecting contrast above balloon occlusion (to reveal occult endoleaks); and relining of the entire endograft to avoid recurrent IIIb fabric tears.[13]

Limitations

This was a retrospective review of a small number of patients. However, it represents proof of concept for a complete endovascular repair of type III endoleaks with raised aortic bifurcations. Our study included patients with relatively straightforward anatomy,

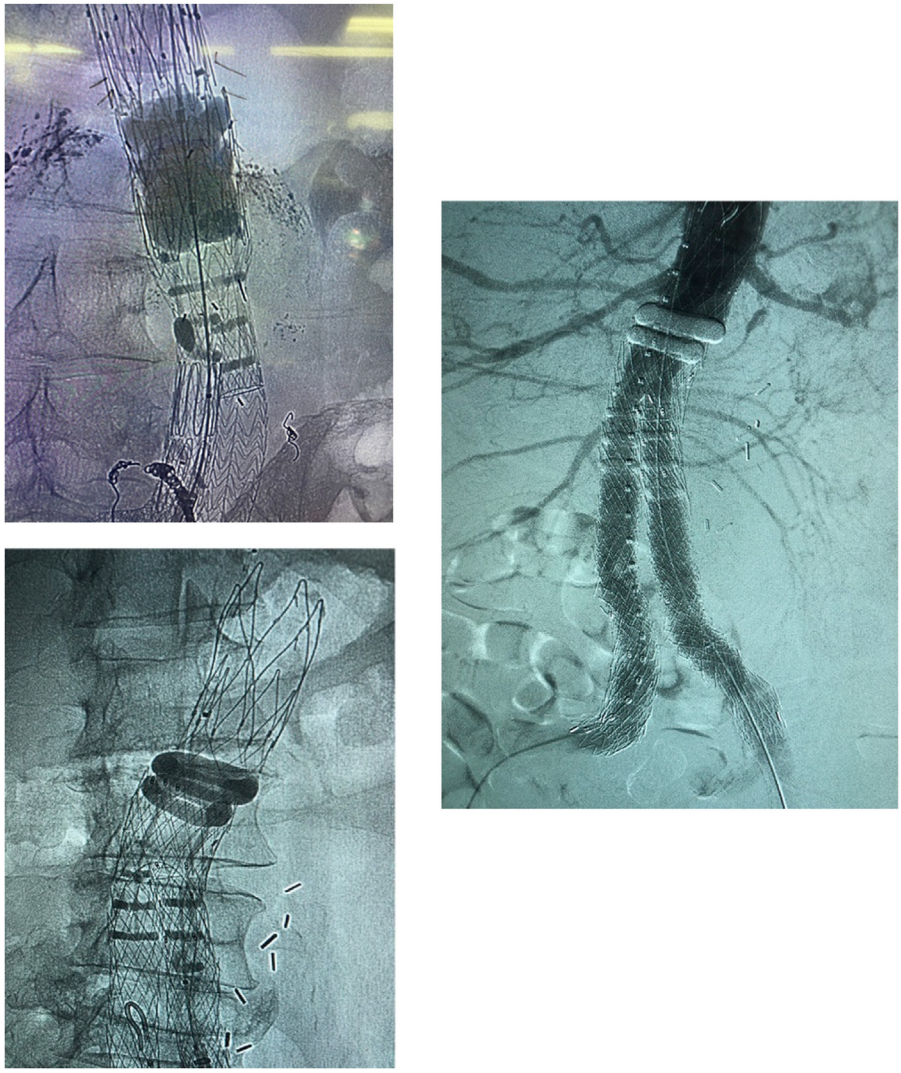

Fig. 7. Polymer fill.

Table I. Preoperative information

Patient	Original EVAR date	Aneurysm size at initial EVAR	Reinterventions before reline surgery	Follow-up aneurysm size	Indication for Reline surgery (type of endoleak)
1	2000	78 mm	Limb extensions	80 mm	IIIb
2	2001	68 mm	None	68 mm	I and III
3	2008	63 mm	Coil embolization ×2	89 mm	IIIb
4	2012	Unknown	Coil embolization ×3, reline of limbs, open sacotomy	93 mm	III and V

and therefore a limitation is the lack of evaluation on different patient anatomies. Additionally, access vessels can present a limitation as a 16F sheath is required for this technique. Small access vessels or heavily calcified access vessels may make this technique more difficult. Technical success relies on

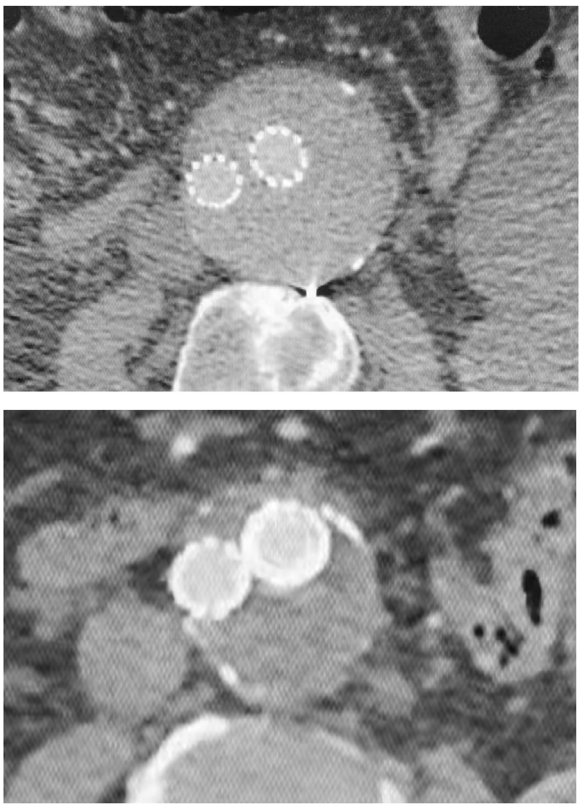

Fig. 8. Follow-up Imaging. **A**: Day of Repair. **B**: 18 Months postop.

minimal aortic tortuosity, so patients with highly angulated aortas or suprarenal tortuosity might have difficulty with this technique. Finally, a minimum distance of 4 cm is required between the aortic bifurcation and renal arteries for proper device placement.

CONCLUSION

First and second generation endografts have a relatively increased incidence of type III endoleaks. As many of these grafts were placed in the early 2000s, many patients who have now been followed for over 10 years are developing type III endoleaks. As these patients age, developing a complete minimally invasive treatment approach is paramount. This manuscript was meant to present an endovascular approach to treating type III endoleaks in patients with an elevated aortic bifurcation. We had 100% technically success with no evidence of type I or III endoleaks on follow-up imaging. This manuscript describes a technique for a total minimally invasive percutaneous approach for treating these patients when previously not available.

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