

Late failure of a Nellix endoprosthesis treated with the t-Branch off-the-shelf multibranch stent graft

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ABSTRACT

A 66-year-old man arrived at our emergency department 3 years after an endovascular aneurysm sealing procedure performed at another center. Computed tomography angiography showed distal migration of a Nellix endoprosthesis (Endologix, Irvine, Calif) and a posterior contained rupture. The left kidney was excluded by an occluded iliac-left renal bypass, which was performed at the time of the Nellix implantation because of unintended coverage. A t-Branch (Cook Medical, Bloomington, Ind) was implanted in an emergency, but the delivery caused disruption of the Nellix limb, requiring relining. Target vessels were bridged with VBX stents (W. L. Gore & Associates, Flagstaff, Ariz). The postoperative course was uneventful except for renal function impairment that was restored 2 weeks later. (*J Vasc Surg Cases and Innovative Techniques* 2019;5:576-9.)

Keywords: BEVAR; Nellix; EVAS; t-Branch; Type IA endoleak

In recent years, the Nellix endoprosthesis (Endologix, Irvine, Calif) has been used for the treatment of abdominal aortic aneurysms (AAAs). It represented an alternative endovascular AAA repair by sealing the aneurysm sac instead of excluding it, realizing the so-called endovascular aneurysm sealing. The device is characterized by a particular design that potentially reduces the risk of type I and type II endoleak and endograft disconnection (type III endoleak), even if the lack of an active fixation can be responsible for graft migration over time.¹ We describe the successful treatment of a ruptured AAA previously treated with a Nellix graft using a t-Branch (Cook Medical, Bloomington, Ind) multibranch off-the-shelf thoracoabdominal device. The patient agreed to the publication of this case report.

CASE REPORT

A 66-year-old man presented to the emergency department complaining of undefined back pain for at least 7 days. Three years earlier, he had undergone endovascular aneurysm sealing with a Nellix device for a 6-cm juxtarenal AAA in another hospital. At that time, an emergency surgical revascularization with a

left iliac-left renal bypass for unintended left renal artery coverage was performed.

The medical history of the patient included chronic renal disease (serum creatinine concentration, 3.2 g/dL; estimated glomerular filtration rate <45 mL/min), coronary artery disease with recent myocardial infarction, and hypertension. The patient was hemodynamically stable, and cardiovascular and respiratory examination findings were negligible. His abdomen was soft and slightly painful on palpation with the presence of a pulsatile mass in the lower abdominal quadrants.

Computed tomography angiography (Fig 1) showed a type IA endoleak with distal migration of both Nellix stent grafts and the contained rupture of an AAA measuring 90 mm in maximum diameter. He also presented with evident fluid collections of the mesenteric fat; moreover, the left iliac-left renal bypass was occluded.

Because of severe comorbidities and a previous laparotomy, we judged the patient to be at high risk for an open repair despite his young age. He was referred to the operating room for endovascular correction of type IA endoleak.

A Nellix-in-Nellix² procedure—even if reasonable because of the occlusion of the left renal artery, healthy paravisceral aorta, and adequate distance between superior mesenteric artery (SMA) and celiac trunk—was not possible because of the concomitant Nellix market recall. We did not consider a chimney endovascular aneurysm repair (chEVAR) a valuable option because of the high risk of gutter-related type I endoleak due to the need for a triple chEVAR because of the proximity of the SMA and celiac trunk to the only patent right renal artery.

Under general anesthesia, bilateral femoral and left brachial percutaneous approaches were performed. After the installation of a through-and-through right femoral-left brachial approach, a t-Branch was initially inserted through the right femoral access.

Angioplasty of the right Nellix bag, with an inner diameter of 10 mm, was performed with a Mustang 10- × 60-mm balloon (Boston Scientific, Marlborough, Mass) to facilitate the delivery

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Author conflict of interest: none.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2468-4287

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<https://doi.org/10.1016/j.jvscit.2019.10.004>

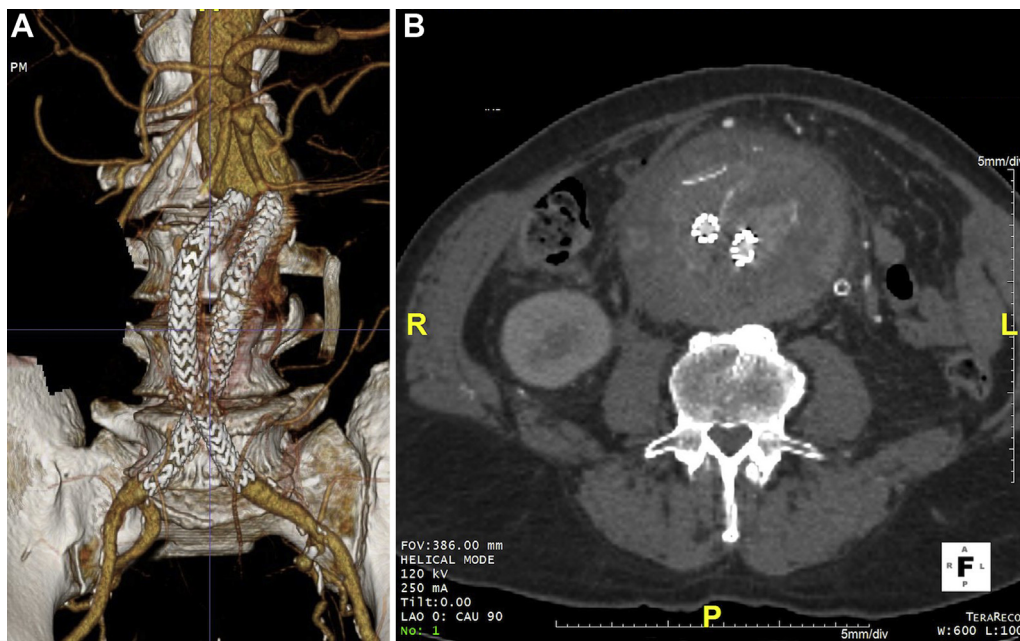


Fig 1. A, Preoperative three-dimensional volume rendered image showing Nellix failure with type I endoleak from associated proximal evolution and endobag distal migration. **B**, Evidence of abdominal aortic aneurysm (AAA) contained rupture at L3 level and the occluded left renal bypass in a preoperative cross-sectional image.

of the t-Branch, which measures 22F in outer diameter. However, during delivery, the t-Branch caused the breakage and distal displacement of the Nellix metallic inner lining in the right external iliac artery. It was therefore necessary to retrieve the t-Branch, to reline the Nellix leg, and to deploy two 9- × 79-mm Gore Viabahn VBX stent grafts (W. L. Gore & Associates, Flagstaff, Ariz) and one 9- × 150-mm Gore Viabahn self-expandable graft up to the common femoral artery as endoconduits. Subsequently, it was possible to successfully deliver the t-Branch to the intended landing zone (Fig 2).

An open conversion of the right femoral access and an end-to-end anastomosis between the endoconduit and the femoral artery were then necessary. The bridging stents used were Viabahn VBX stent grafts, 8 × 79 mm and 8 × 59 mm for the celiac trunk, 9 × 79 mm and 9 × 59 mm for the SMA, and 6 × 79 mm for the right renal artery. The branch of the left renal artery was occluded with a 12-mm Amplatzer Vascular Plug II system (St. Jude Medical, St. Paul, Minn). The implantation was completed with a Unibody 22-8 graft and two ZISL iliac legs (11 × 125 mm and 11 × 93 mm) on the right side and two on the left (11 × 110 and 11 × 77 mm).

In the postoperative phase, the immediate deterioration of renal function required the support of renal ultrafiltration and an intensive care unit stay of 72 hours. The patient did not develop any sign of spinal cord ischemia.

After a period of 2 weeks, renal function improved. Follow-up computed tomography showed complete exclusion of the AAA and patency of the target vessels (Fig 3). The patient was

discharged on postoperative day 17. A 6-month contrast-enhanced ultrasound examination confirmed the absence of endoleak with complete exclusion of the AAA and patency of the visceral and right renal vessels.

DISCUSSION

After the initial clinical experience and the results of the first multicenter post-market study, Nellix appeared to be a promising alternative that seemed to be able to overcome the limitations of current endografts.^{3,4} However, the scarce data available concerning the long-term durability of this approach are not encouraging, mainly owing to the non-negligible migration and sac rupture rate.^{1,5}

Stenson et al⁶ recently published a 295-case single-center experience with Nellix with a median follow-up of 2.4 years. In this series, a non-negligible overall failure rate of 33.2% is reported, with a higher prevalence after 2 years. Significant findings in this experience were an overall rupture rate of 5.4%, a 5-year migration rate of 43.5%, a 5-year sac expansion rate of 38.7%, and a type IA endoleak rate of 38.6% in the subgroup of patients treated in an elective setting.

After these occurrences, it is likely that several Nellix failures will be observed in the future and will require corrections. In the case here described, a Nellix-in-Nellix extension² would have been feasible with a double

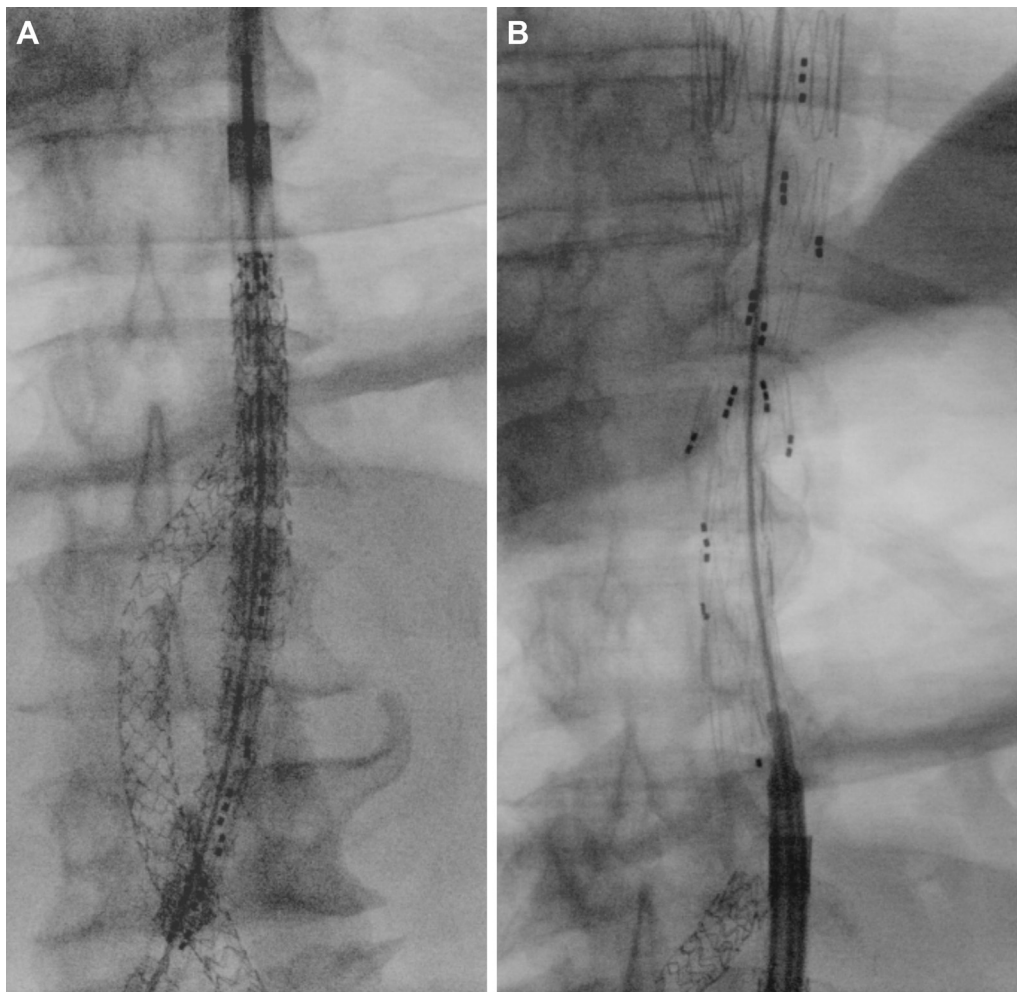


Fig 2. **A,** The t-Branch device is delivered inside the Nellix endograft. **B,** The t-Branch device is released proximal to the right Nellix endobag.

chimney for the right renal artery and SMA but was not preferable after the recent company market recall.

The t-Branch device is an off-the-shelf stent graft with four branches for the renovisceral arteries designed for the treatment of thoracoabdominal aneurysms. It has been shown to be an option in up to 80% of patients with thoracoabdominal aortic aneurysm. It is also described as a safe option in acute cases and in endovascular repair failures.⁷⁻¹³

In this case, the t-Branch was chosen because the anatomy of the three target vessels was favorable. The proximal landing zone, which was in a nonangulated segment of the thoracic aorta, 28 mm in diameter, was suitable for the proper opening of all the branches.¹⁴ One could say that the choice of a t-Branch implied a much greater aortic coverage than a chEVAR procedure would have, but the high risk of gutter-related endoleak in a triple chEVAR procedure was not acceptable in an emergency scenario.

In our opinion, the key point of this case is that despite predilation of the 10-mm Nellix stent graft, the stainless steel balloon-expandable endoskeleton was damaged by the passage of the t-Branch (8.5 mm in outer diameter) and required retrieval and deployment of a provisional endoconduit with an open conversion of the access and an end-to-end anastomosis with the native artery. This consideration should be taken into account in planning a Nellix failure correction with a large-profile device. In light of our experience, a primary through-and-through approach and pre-emptive relining of the Nellix endografts can be a good strategy for the treatment of these cases.

CONCLUSIONS

In the case of favorable anatomy, the Zenith t-Branch device can be used in an acute setting for the treatment of a proximal endoleak due to distal migration of a Nellix endograft.



Fig 3. Postoperative three-dimensional volume rendered image showing the correct t-Branch positioning with the branches' iliac axis patency and aneurysm exclusion.

The authors acknowledge Michael Tarullo, Adjunct Professor, School of Science, Majmaah University, Long Branch, NJ, for language revision.

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Submitted Jul 19, 2019; accepted Oct 6, 2019.