The Advantages of Customized Vascular Implants for Challenging Aortic Anatomy

Case reports and discussion on custom-made endovascular solutions.

BY JAN-PETER GOLTZ, MD, PhD, EBIR, AND SAID ABISI, MD, MS, FRCS

CASE 1: Rescue of Failing Endovascular Infrarenal Aortic Repair Using Customized Aortic Stent Grafts

Jan-Peter Goltz, MD, PhD, EBIR
Senior Physician, Interventional Radiology
Clinic for Radiology and Nuclear Medicine
University Hospital of Schleswig Holstein
Campus Lübeck
Lübeck, Germany
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In many centers, endovascular aneurysm repair (EVAR) is considered the treatment of choice for infrarenal abdominal aortic aneurysms (AAAs) in patients with suitable anatomies.[1] Progressive neck dilatation with a failure of the proximal seal may result in formation of a type Ia endoleak, repressurization of the aneurysm sac, and finally, rupture. For this reason, progressive neck dilatation represents one major concern after EVAR.[2,3]

Other reasons for occurrence of a proximal endoleak are an unsuitable landing zone (too short, too angulated), poor planning (undersized stent graft), or technique (too-low deployment), as well as stent graft migration.[4] Although type Ia endoleaks that are present at the end of a procedure may be self-limiting and therefore do not necessarily demand an immediate secondary intervention, this is definitely not the case with newly diagnosed type Ia endoleaks during follow-up.[5,6]

Because open repair of failing infrarenal grafts has been associated with significant morbidity and mortality, the preferred treatment mode is endovascular.[7,8] Endovascular options depend on the length of the remaining infrarenal landing zone—if the landing zone is long enough, proximal cuff extension might be possible. Utilization of a balloon-expandable bare-metal stent could be an alternative to realign the stent graft with the aortic wall.[9] EndoAnchors (Medtronic) can be used for the same purpose.[10] In the case of an inadequate landing zone relocation above the renal level by use of parallel stent grafts in combination with a cuff, off-the-shelf branched or customized fenestrated/branched EVAR have been described.[3,4,6,11,12] Another option would be embolization of the endoleak using coils and/or the Onyx liquid embolic system (Medtronic).

CASE PRESENTATION

A 71-year-old man underwent EVAR with an iliac branch on the right side to treat an infrarenal AAA with a concomitant common iliac artery aneurysm 4 years

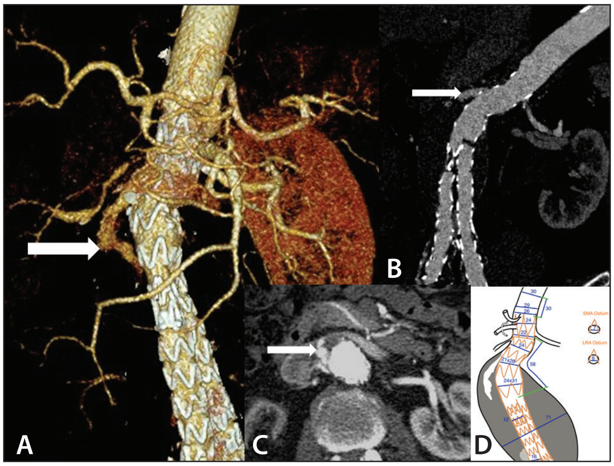

Figure 1. A 3D reformation of a follow-up CT scan acquired 4 years after the index procedure depicts a loss of proximal seal with type Ia endoleak formation (A). A 2D curved multiplanar reconstruction (B) and axial view of contrast within the aneurysm and outside the stent graft (C). The stent graft was in the same position where it was deployed during the index procedure, suggesting progressive neck dilatation was the underlying cause. Using a preoperative CT scan with 1-mm slices, a sketch was produced by JOTEC's E-xtra DESIGN ENGINEERING (D). This sketch was then discussed with the treating physicians before a technical drawing was made.

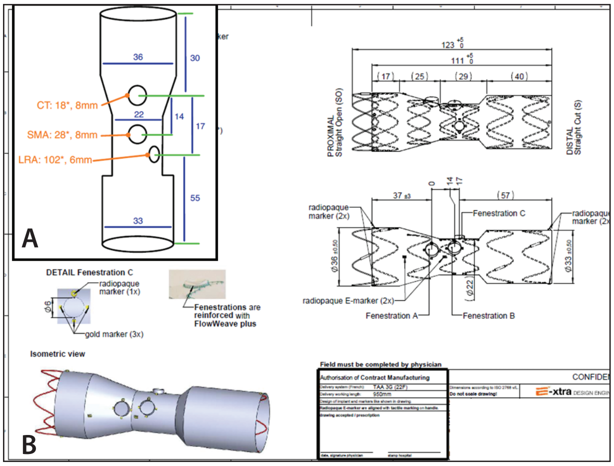

Figure 2. After the sketch (A) was discussed with physicians and engineers, a technical drawing (B) was made. Specifications of the fenestrated stent graft are depicted, and this drawing is delivered with the tailor-made stent graft. Because it is sterilized, the physician can use it during the procedure.

prior. During follow-up, he underwent embolization of the inferior mesenteric artery for type II endoleak with sac expansion 2 years after the index procedure. After

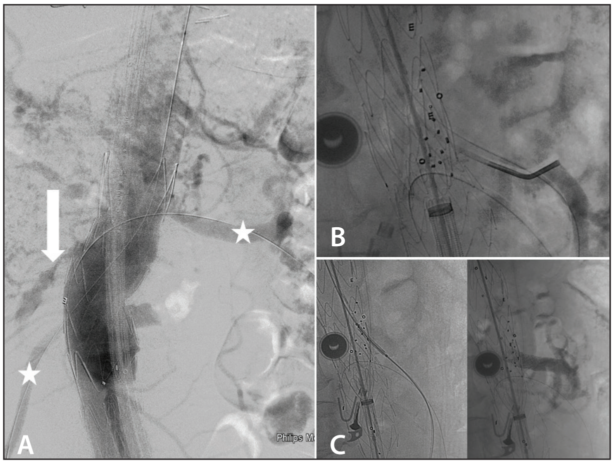

Figure 3. Intraprocedural images from fenestrated EVAR. Digital subtraction angiography (DSA) depicting the endoleak (arrow). Marker wires (asterisks) within the left renal and superior mesenteric arteries (A). Via the transbrachial access, the fenestration as well as the superior mesenteric artery itself are selected. Confirmation of the correct position of the selective catheter by DSA (B). A 10- X 27-mm balloon-expandable stent graft (E-ventus®, JOTEC) is ready to be deployed into the superior mesenteric artery fenestration, and DSA confirms sufficient position after deployment (C).

4-year follow-up, a type Ia endoleak was diagnosed by CT scan (Figure 1). After interdisciplinary discussion and consultation with the patient, it was decided to treat the endoleak by implanting a customized stent graft with three fenestrations for the celiac trunk, superior mesenteric artery, and left renal artery (the right renal artery had a high-grade chronic stenosis; the organ was small compared to the contralateral one, and a preoperative scintigraphy had revealed that the remaining parenchyma was without relevant residual function). After planning the case (Figure 2), the customized stent graft was manufactured within 3 weeks of the order placement.

PROCEDURAL DESCRIPTION

With the patient under general anesthesia, percutaneous access was achieved in both common femoral and left brachial arteries. Two Perclose ProGlide devices (Abbott Vascular) were used for the right femoral access and one was used for the left femoral access. Next, 5,000 units of heparin was given. From the left femoral access, the left renal artery was probed and marked with a guidewire, and from the brachial artery, the superior mesenteric artery was probed and marked. The custom-made stent graft had an outer diameter of 22 F and was delivered percutaneously via the right femoral access.

Each fenestration had four markers (top, bottom, left, and right) and there were two E-shaped markers included in the stent graft. The correct longitudinal position of the stent graft was determined by orienting the fenestration markers along the marker wires within the superior mesenteric artery and left renal fenestrations as well as two subtraction angiographies (lateral and anterior-posterior views) (Figure 3).

The stent graft was deployed in the anterior-posterior position, making sure that both E markers were in line with the stiff guidewire, thereby guaranteeing correct axial orientation of the device and fenestrations. Finally, the fenestrations were selected via the brachial access one after the other, and then balloon-expandable stent grafts (E-ventus®, JOTEC) were implanted. These stent grafts were over-flaired within the fenestrations to ensure a tight connection between the fenestrated cuff and balloon-expandable stent grafts within the visceral arteries. Postdilatation of the overlapping zone with the infrarenal device was performed. Final angiography depicted correct perfusion of the target vessels and exclusion of the type Ia endoleak (Figure 4). This was also confirmed by an additional CT scan prior to discharging the patient on day 5 after fenestrated EVAR. Follow-up CT confirmed freedom from endoleak at 6 and 12 months after the procedure.

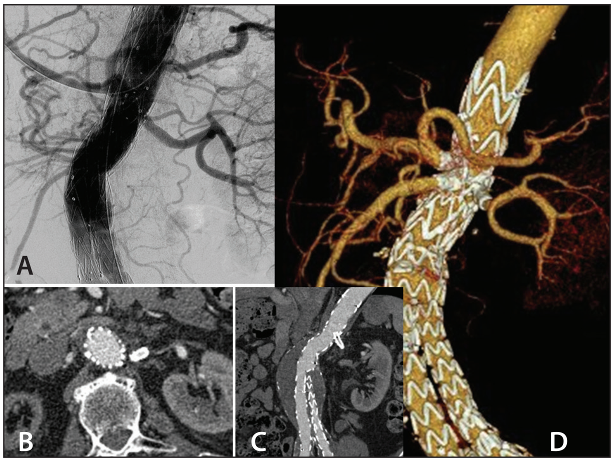

Figure 4. Final angiography confirmed exclusion of the endoleak as well as successful connection to the target visceral vessels (A). Postinterventional CT scan (axial orientation and curved multiplanar reconstruction) prior to discharge confirmed exclusion of the type Ia endoleak (B, C). A 3D reformation of the CT scan confirmed correct position of the connecting stent grafts (D).

DISCUSSION

Currently, EVAR is the most common method used to treat infrarenal AAAs if the vessel anatomy appears to be suitable for an endovascular approach.[1] However, a type Ia endoleak at completion of the index procedure has been described in up to 8% of patients.[5] Moreover, loss of the proximal sealing zone during follow-up has been reported in up to 15.5% of patients with earlier-generation devices and in up to 3% of patients with latest-generation stent grafts.[13] The largest series on late open conversion for type Ia–related endoleak after EVAR reported a mortality rate of 9.9%.[14] Therefore, an endovascular approach seems to be an interesting option.[12] With increasing numbers of EVAR procedures, it seems likely that rescue procedures for type Ia endoleak will represent a relevant part of the EVAR-related endovascular workload.

A Palmaz stent (Cordis, a Cardinal Health Company), proximal cuff extension, and utilization of EndoAnchors may be used in this scenario, but to a certain extent, these depend on an existing infrarenal landing zone. Because many of such cases will present without a suitable neck, different techniques need to be evaluated. In this context, endovascular treatment of type Ia endoleak after EVAR using custom-made fenestrated or branched cuffs has been described in few series. So far, low mortality and morbidity rates, especially where compared to open repair, have been reported. Katsargyris et al and Wang et al reported on the Zenith fenestrated device (Cook Medical) for late type Ia endoleak and reported high technical success (92.3%, 100%), as well as low 30-day mortality rates (0%, 2.2%) together with satisfying patency rates for the connected visceral vessels (100%, 92.3%).[12,15] Furthermore, results from the fenestrated Anaconda (Vascutek) device for this scenario have been reported with a low technical success rate of 58.3%, a 30-day mortality rate of 6.1%, and a patency rate of the connected visceral arteries of 100%.

For the case described previously, the interventionist used a fenestrated cuff made by JOTEC (E-xtra DESIGN ENGINEERING). The company offers customized fenestrated or branched stent grafts that allow for relocation of the compromised infrarenal neck into a more proximal, healthier vessel segment in case of a failing EVAR or aneurysms of the anastomosis after open repair. To achieve preservation of all visceral vessels even in such complex scenarios, fenestrations, scallops, or multiple branches as well as all types of tapered or reversed tapered designs are offered to work with the individual anatomy. Markers on the device allow for easy orientation of the fenestrations/branches for precise longitudinal orientation, and two clearly visible E markers provide accurate axial orientation of the devices. To date, the published results from the company's E-xtra DESIGN devices for treatment of native thoracoabdominal aneurysms have been promising.[16,17]

CONCLUSION

In conclusion, the endovascular approach toward failing EVAR with type Ia endoleak is the preferred treatment approach. Fenestrated or branched customized stent grafts are available and can be used to safely relocate the landing zone into a healthy juxta- or suprarenal segment. Experience with those devices in this special scenario is limited to only a few series, and more data are needed to define which devices are best in each scenario and to evaluate the durability of this approach. ■

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CASE 2: A Multi-Inner-Branched Endograft for Complex EVAR

Said Abisi, MD, MS, FRCS
Consultant Vascular and Endovascular Surgeon
Guys and St Thomas' NHS Foundation Trust
London, United Kingdom
Disclosures: None.

An increasing number of complex aortic aneurysms are treated using endovascular solutions, with positive outcomes. This trend reflects multifactorial improvements, including better preoperative planning, intraoperative imaging, and above all, overcoming the notable learning curve (eg, improved operator skills and understanding of the anatomic and technical difficulties seen in dealing with complex aortic aneurysms over the last decade). The forward trend in complex endovascular aortic treatment necessitates the evolution of different custom-made designs to accommodate the real-world challenges faced in aneurysm treatment.

Fenestrated and outer-branched endografts can be reasonable options for a large proportion of complex aortic aneurysms, but some cases can benefit from an endograft that incorporates inner branches, such as the thoracoabdominal endograft produced by the E-xtra DESIGN ENGINEERING division at JOTEC/CryoLife. In this article, we discuss a complex aortic aneurysm repair and how a multi-inner-branched endograft adds significant advantages over other potential solutions. To make complex procedures less challenging, it is key for users to assess and select from the vast array of options to suit our specific patients' needs.

CASE REPORT

A 78-year-old man was referred for complex endovascular repair of a large 7.5-cm suprarenal aortic aneurysm associated with a common iliac aneurysm with a narrow lumen to just above the iliac bifurcation. The patient also had an occluded left internal iliac artery and bilaterally tortuous external iliac access vessels (Figures 1 and 2). The adverse anatomy was not suitable for standard fenestrated or outer-branched repair.

A four-inner-branched endograft was designed and manufactured by JOTEC's E-xtra DESIGN ENGINEERING team for this case. Correct deployment is facilitated by the E-shaped marker positioned on the anterior aspect of the graft and the four-inner-branched markers that correlate to the relevant target vessels. Visceral and renal target vessels were cannulated via axillary access, and appropriate kink-resistant, balloon-mounted covered stents were used for bridging. All four covered stents were placed within 90 minutes, a reflection of the clearly

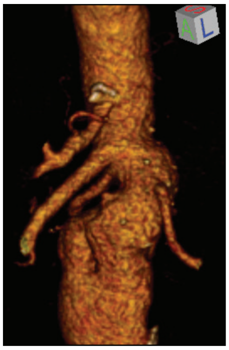

Figure 1. Preprocedural CT scan showing a challenging renal/visceral segment with a narrow aortic lumen not amenable to outer branches.

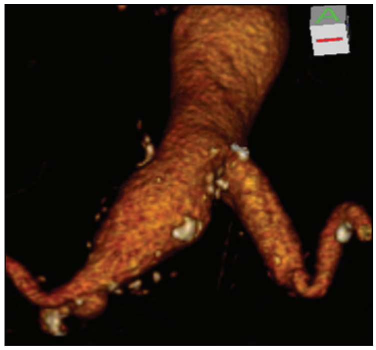

Figure 2. Preprocedural CT scan showing a challenging right common iliac artery aneurysm with a distal lumen that was outside the instructions for use for an off-the-shelf E-liac device.

visible branch markers and the design of the branches, which are sutured to the inner wall of the main graft for stability and have an oval-shaped external opening facilitating access to the target vessels.

It was important to preserve the ipsilateral (right) internal iliac artery, made challenging in this case by the anatomic constraint above the iliac bifurcation that measured only 10 mm. This is below the instructions for use for a standard E-liac branched endograft (JOTEC); therefore, a custom-made bifurcated endograft was designed to allow controlled deployment and subsequent cannulation of the internal iliac via axillary access and bridging with the appropriate covered stent. The custom-made thoracoabdominal and iliac branched devices were bridged with a standard E-tegra stent graft (JOTEC) and contralateral limb. At this point, it was possible to remove the endograft delivery system from the access vessels and restore flow to the pelvis and the lower limbs. Follow-up CT scans showed good seal, patency, and conformability throughout the various components with the relevant vessels (Figures 3 and 4).

DISCUSSION

The inner-branched endograft is an important addition to the interventional tool kit to tackle more complex aortic aneurysms with a minimally invasive technique, particularly those cases that are not suitable for current options of fenestrated and branched repair.

Traditional fenestrated repair is deemed less appropriate in anatomies with downward trajectory target vessels, especially for the renal and visceral arteries. Steep downward target vessels can result in difficulties in cannulation and safe delivery of the necessary sheath and bridging stents, particularly in the presence of iliac access vessel angulations. Vessels with difficult access and prolonged duration of these complex procedures have known consequences of pelvic and limb ischemia resulting in poor outcomes. Preloaded fenestrated endografts can be used as an option in poor-access vessels but have limited availability and applicability in the absence of dedicated suitable catheters and steep downward renal arteries.

Using outer-branched endografts is a good alternative to avoid prolonged procedure time while working through unfavorable access iliac arteries. However, these endografts have a minimal aortic lumen working space requirement (range, 26–28 mm), which is often not feasible as in our case where the inner aortic lumen diameter ranged from 22 to 24 mm, which is the recommended space for inner-branched endografts. The outer-branched design concept also involves longer

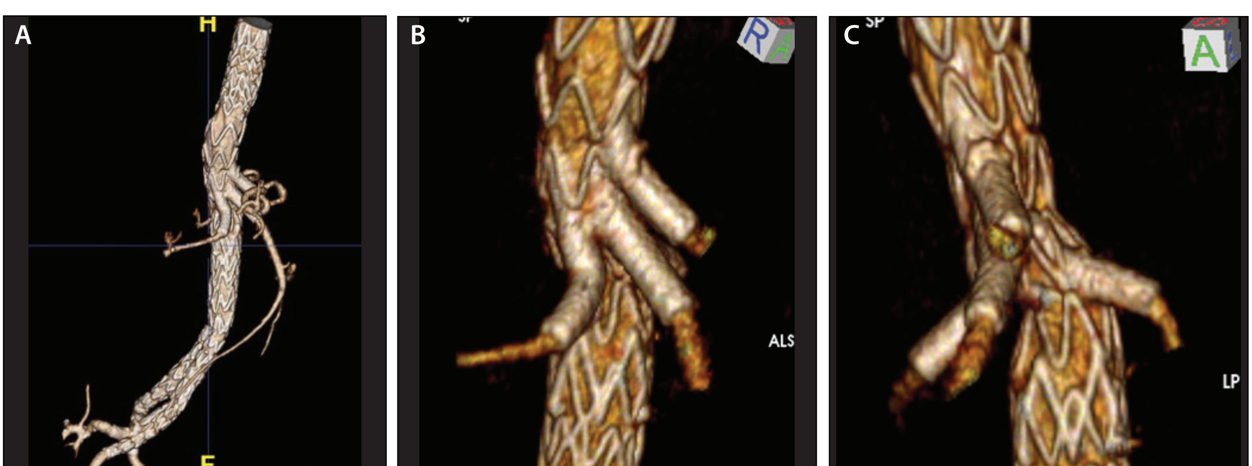

Figure 3. Four-week follow-up CT scan showing good proximal seal, plus seal and patency in all four branch vessels.

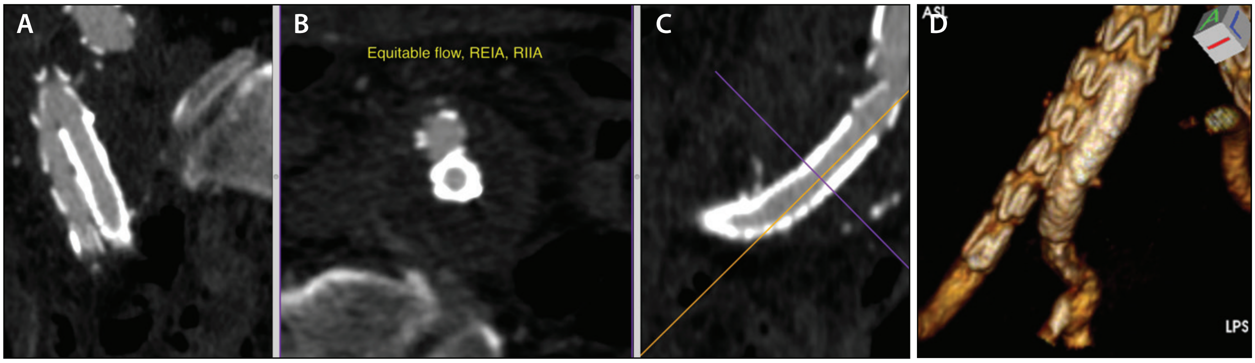

Figure 4. Follow-up CT scan showing the custom-made E-liac and good seal and flow in the right external and internal iliacs.

aortic coverage above the target vessels compared to inner-branched endografts, in which the most proximal inner branch is inside the proximal sealing stents rather than below them.

CONCLUSION

In summary, the inner-branched endograft solution appears to offer wider application of branched repair in narrower aortic lumens around 22 mm. The oval internal branch opening allows flexibility in planning and positioning of the endograft, which may reduce the need for customization, and future designs may allow for off-the-shelf solutions for a wider range of aneurysms. Cannulation appears significantly easier, probably due to the proximity to target vessels and directional guidance provided by the oval-shape exit of the inner branch towards the target vessels, which reduces the procedure time and increases applicability. The design of these inner branches and proximity to target vessels seems to require shorter bridging stents than outer branches. The bridging stents overlap inside the inner branch (inside the main endograft) exiting promptly into the target vessels. There is minimal exposure of the bridging stent in the aneurysm sac in between the aortic wall and the main endograft, theoretically leading to reduced risk of compression or dislodgment.

The inner-branched endograft solution offers a shorter length of aortic coverage, which is a highly relevant factor regarding the reduction of spinal cord ischemia. This can be particularly useful in patients with adverse iliac features (eg, occluded internal iliac artery or occluded contralateral iliac arteries), where complex repair is made possible while keeping aortic coverage to a minimum. It is beneficial to be able to use the option of combining custom-made iliac preservation solutions as well in these cases.

Inner-branched technology is still evolving but is promising, and users are still at the beginning of their experience and learning curve with selection bias for cases not suitable for regular, more traditional complex repair. Therefore, inherently more challenging anatomies are currently treated with inner-branched technology. However, the advantages mentioned herein, applicability, and perhaps future off-the-shelf solutions are factors that are likely to result in a paradigm shift. ■