

Novel Application of Custom-Made Stent Grafts with Inner Branches for Secondary Treatment After Stent Graft Migration of Previous Infrarenal Endovascular Aortic Repair

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Purpose: We present a novel application of custom-made stent grafts (CMGs) with inner branches to incorporate target vessels (TVs) as an alternative to fenestrations or directional branches for secondary treatment after stent graft migration of previous infrarenal endovascular aortic repair (EVAR).

Case report: Two consecutive patients with stent graft migration of previous EVAR were electively treated at our institution from January 1, 2018 through December 31, 2018. Stent graft migration was defined as radiologic evidence of stent graft displacement >10 mm. In both cases, a proximal type I endoleak was noted, and the residual infrarenal aorta above the previous endograft was unsuitable as the proximal landing zone for a nonfenestrated cuff. Repair was planned by means of a CMG with 4 inner branches. The procedures were conducted in two-stage fashion to minimize the risk of spinal cord ischemia. The procedures were technically successful with a total of 8 TVs stented. Both patients did not suffer from any early (i.e., up to 30 days) major adverse events, and no access-site complications were noted. At one-year follow-up, computed tomography angiography showed regular placement of the CMGs, widely patent TVs, absence of any type I or III endoleak, and stable sac size. No late reinterventions were recorded.

Conclusions: Secondary treatment of stent graft migration after previous EVAR is safe and feasible using CMGs with 4 inner branches. This technique is effective as showed by stable sac size and 100% freedom from TVI at mid-term imaging follow-up. Larger cohorts and longer follow-up are needed to confirm the preliminary results.

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Fenestrated and branched endovascular aortic repair (F-BEVAR) using custom-made stent grafts (CMGs) has been increasingly used to treat pararenal aortic aneurysms (PRAAs) and thoracoabdominal aortic aneurysms (TAAAs) with high technical success and low mortality and morbidity rates. To address target vessels (TVs), 2 solutions are available: fenestrations and directional branches. Fenestrations work well for TVs that have a close to 90-degree takeoff from the aorta and when the main stent graft is close to the aortic wall, whereas directional branches work well when TVs have a steeper angle of takeoff and there is a longer gap to

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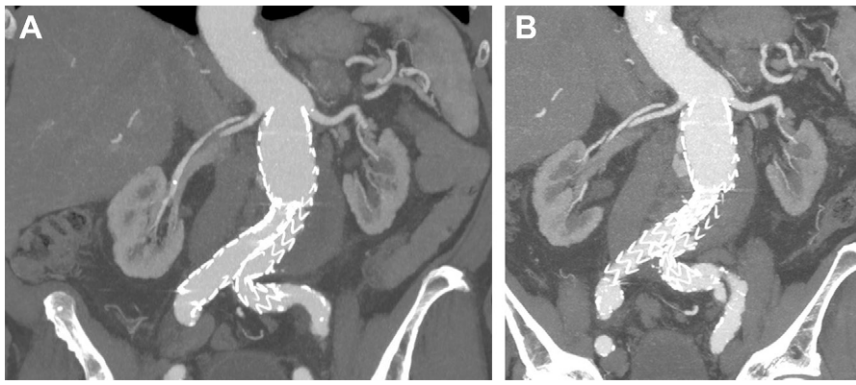


Fig. 1. Postoperative CT scan after initial EVAR. **(A)** At 30 days showing correct placement of the endograft without any endoleak. **(B)** At 1 year showing type Ia

endoleak with the enlarged aneurysm sac. CT, computed tomography; EVAR, endovascular aortic repair.

be bridged.¹ Endografts with inner branch configuration have been widely used mainly in the arch position, thus highlighting the advantage of this configuration when the nonobstruction of the aortic lumen is needed. Indeed, inner branches are advantageous in the aortic arch as they minimize the risk of component interaction that may result from use of directional branches when the TVs are close. However, implementation of inner branches as an alternative to incorporate TVs unsuitable for standard fenestrations or directional branches during F-BEVAR has recently been described.² The aim of our study is to report a novel application of CMSGs with inner branches to incorporate TVs for secondary treatment after stent-graft migration of previous infrarenal endovascular aortic repair (EVAR).

CASE REPORT

Patients

Two consecutive patients with stent-graft migration of previous EVAR were electively treated at our institution from January 1, 2018 through October 31, 2019 (During this period, there was no any other unsuccessful attempt to use the technique, nor any other patient who was evaluated for the technique and withdrew before attempted implantation.) Stent-graft migration was defined as radiologic evidence of stent-graft displacement >10 mm; it was always associated with type IA endoleak and sac expansion. In both cases, the residual infrarenal segment above the previous stent graft was unsuitable for a standard aortic cuff. Both patients were judged to be high-risk candidates for open surgery because of age (78 and 81 years, respectively), comorbidities (American Society of Anesthesiologists score 3 in both), and anatomical complexity (need for suprarenal clamping.) High-resolution computed tomography angiography (CTA) was acquired

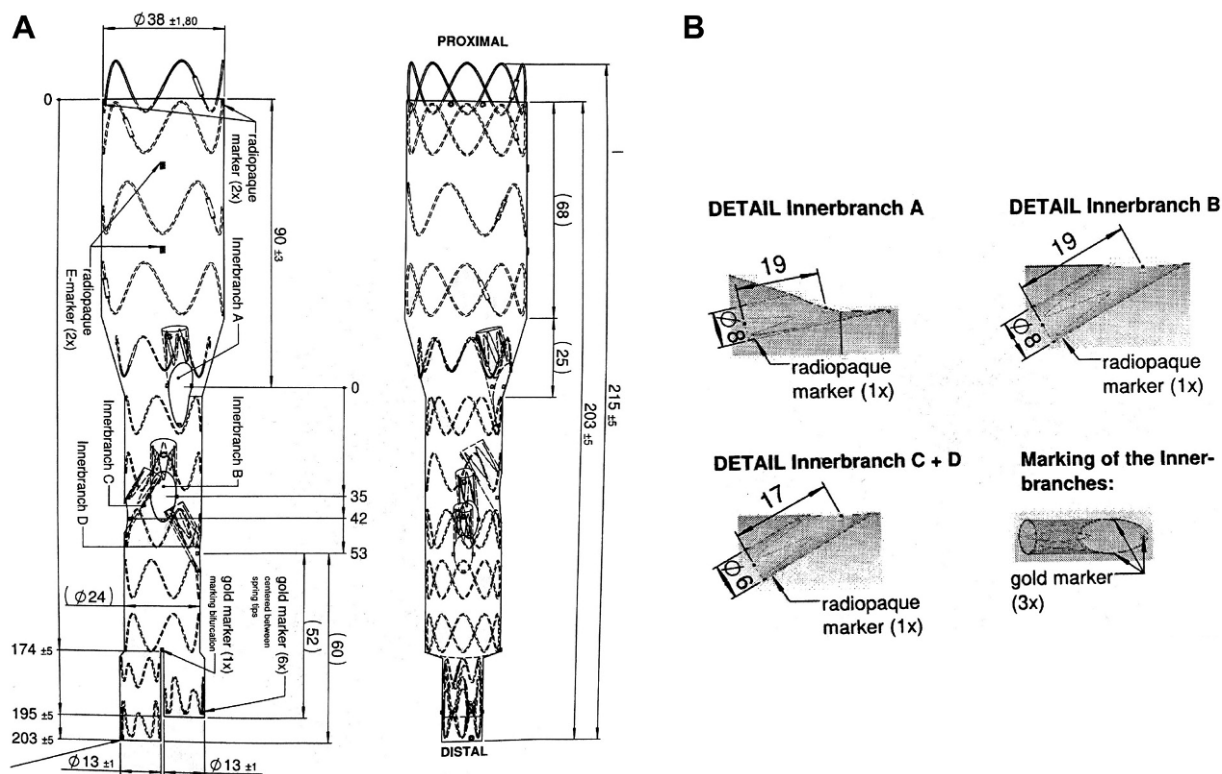
with 1-mm sections of the entire aorta from the neck to the groin to delineate aneurysm morphology (including full evaluation of TV anatomy) and evaluate the iliofemoral access vessels (Fig. 1).

Devices

Repair was planned by means of a CMSG with 4 inner branches. The design was selected to incorporate 4 TVs (both renal arteries [RAs], superior mesenteric artery [SMA], and celiac artery [CA]) in both patients. The CMSGs used were based on the Jotec E-extra Design Engineering stent graft (Jotec GmbH, Hechingen, Germany), which has been already proven safe and effective.^{3,4} The customized 22F main delivery sheath is based on the Jotec Squeeze-to-Release delivery system, which enables controlled and accurate release of the endograft.⁵ The devices were constructed by referring to preoperative CTA to achieve a $\geq 15\%$ oversizing of the device as compared with the native aortic diameter at the level of the proximal neck, which was planned in the supraceliac aorta 30 mm above the CA. The inner branches were located inside and fixed at the covering of the stent graft (Fig. 2). Inner branches had a sealing zone (cylinder) length of 20 mm and a diameter of 8 mm (for the SMA/CA) or 6 mm (for the RAs). They had 3 gold markers at the external opening ("fish mouth") and one radiopaque marker at the internal opening.

Procedures

The procedures were conducted in two-stage fashion to minimize the risk of spinal cord ischemia. All the procedures were carried out by 2 vascular surgeons with the aid of a vascular trainee in a fully equipped operating room with portable C-arm. The first stage was carried out under general anesthesia with prophylactic cerebrospinal fluid drainage to reduce the risk of postoperative spinal cord ischemia. The lumbar drain was inserted by a neurosurgeon in the operating room the same day of the procedure.



To further minimize the risk of neurologic complications, the temporary aneurysm sac perfusion technique⁶ was implemented by leaving the CA unstented at the time of the first procedure. Bilateral percutaneous common femoral artery access was obtained under ultrasound guidance with the double ProGlide technique (Abbott Vascular, Santa Clara, CA) on each side as previously described.⁷ A 11 F 45 cm introducer was placed on the contralateral side. Left upper extremity access (UEA) was obtained via surgical exposure of the left brachial artery. The distal arch and descending thoracic aorta (DTA) were selectively catheterized from above using a Cobra C2 catheter (Cordis, Baar, Switzerland), and intravenous heparin (100 UI/kg) was administered to the patients. A 12 F 70 cm Flexor Introducer (Cook Medical, Bloomington, IN) was advanced and positioned in the mid-DTA with a single pass. The hydrophilic guidewire was snared to obtain through-and-through femoral-to-brachial access and then replaced with the Back-Up Meier guidewire (Boston Scientific, Marlborough, MA.) After an initial angiographic run was performed to confirm the exact origin of the RAs, the stent graft was oriented extracorporeally and then advanced under fluoroscopic control to ensure precise positioning with the “fish mouth” distal opening within 1 cm of the intended TV ostia. The stent graft was first only partially deployed (to allow for repositioning if needed), and inner branches of the RAs with their respective TVs were catheterized from the left UEA

using a Rosen guidewire (Cook Medical, Bloomington, IN) with the help of an 8G buddy catheter. The branched component was then opened completely, gentle balloon molding at the level of proximal and distal sealing zones was performed, and the large femoral sheath was removed. This allowed for prompt restoration of blood flow to the pelvis and lower limbs. Subsequently, the SMA inner branch and its corresponding TV were catheterized and stented. The groin accesses were closed using the previously placed ProGlide devices. The left axillary arteriotomy was closed in a transverse fashion with interrupted 6–0 polypropylene sutures.

The second stage was carried out 2 weeks after the first stage. It was performed under local anesthesia, without cerebrospinal fluid drainage, to allow for continuous neurological monitoring while keeping the patient awake. The left brachial artery was surgically exposed, a few centimeters proximally to the previous access. A ten-minute balloon occlusion test of the CA inner branch was performed to assess for any neurological deficit. Given the negative test results, the CA was stented in both patients.

The BeGraft Plus (Bentley Innomed GmbH, Germany) was used as the bridging stent graft (BSG) for TV stenting. A selective angiographic run was performed after each TV was stented to ensure absence of any kink/compression or flow limiting the dissection. After this, completion angiography was performed to assess for technical success.

The patients were admitted to the intensive care unit for 48 hr after each procedure. They were discharged on dual antiplatelet therapy (aspirin 100 mg + clopidogrel 75 mg daily) for 3 months followed by single antiplatelet therapy (aspirin 100 mg daily) lifelong.

Definitions

The following outcomes were recorded: technical success, catheterization time, major adverse events (MAEs), major access-site complications, target vessel instability (TVI), and sac behavior.

- Technical success per patient was defined as successful deployment of the stent graft by endovascular means only, the absence of type I/III endoleaks on completion angiography, and widely patent TVs. Technical success per inner branch was defined as successful catheterization and bridging of the inner branch and respective TV, with widely patent stent graft and absence of type I or III endoleak on completion angiography
- Catheterization time of both inner branches and corresponding TVs was recorded and classified into 3 categories (A: <1 min, B: 1–3 min, C: >3 min.)
- MAEs were defined as composite of any-cause mortality, acute myocardial infarction, stroke, spinal cord ischemia, acute kidney injury, bowel ischemia, estimated blood loss ≥ 1 L, and acute respiratory failure.
- Major access-site complications were defined as ischemia or bleeding of the access site requiring endovascular/surgical therapy, blood transfusion, or rehospitalization.
- TVI was defined as composite of any stent stenosis, separation, or type IC/IIIC endoleak requiring reintervention and stent occlusion, aneurysm rupture, or death due to TV complication.
- Sac behavior was evaluated using the one-year scan. We defined sac expansion as growth ≥ 5 mm compared with pre-operative imaging, sac regression as decrease ≥ 5 mm, and stable sac size as an absolute change <5 mm.

RESULTS

All 4 procedures were technically successful with a total of 8 TVs (4 RAs, 2 SMAs, 2 CAs) stented. Both patients did not suffer from any 30-day MAEs or 30-day major access-site complications. Catheterization time was graded as category B in 6 TVs and category C in 2 TVs (the 2 CAs required <10 min each to achieve catheterization.) Freedom from TVI was 100% at the longest available individual follow-up (one year and 6 months, respectively); CTA showed regular placement of the CMSGs with stable sac size in both patients (Fig. 3).

DISCUSSION

As endovascular treatment options with fenestrated branched stent grafts progressively rival open surgery for PRAAs and TAAAs, pararenal/juxtarenal

endovascular therapy after previous infrarenal repair has also been increasingly performed.^{8,9} Our early experience demonstrates that inner branches may represent a novel solution for this clinical scenario as they proved safe and feasible. Indeed, we achieved a technical success rate of 100% in a total of 8 incorporated TVs (4 RAs, 2 SMAs, 2 CAs.) At midterm follow-up (1 year and 6 months, respectively), effectiveness of treatment was proved by radiologic evidence of the stable sac size in both patients.

The benefits of using a configuration with inner branches in a pararenal/juxtarenal position might be questionable for several reasons, including the need for coverage of a longer segment of the DTA and the stability of a fenestrated design in the pararenal/juxtarenal position. Inner branches in this series were primarily selected because ostia of the RAs had fixation barbs from the previous endografts protruding across them. Therefore, we felt that retrograde catheterization of the RAs through fenestrations would have been very tedious, and we preferred the option of an antegrade approach through branches. However, the use of directional branches was not advisable as there was not enough room to open them at the pararenal/juxtarenal level; this would have required further tapering of the branched component, starting higher in the DTA to achieve effective proximal sealing. With the use of 2 inner branches for the RAs, it was possible to start lower in the DTA and access the RAs inner branches (with respective TVs) from above while keeping the stent-graft diameter wider in the supraceliac aorta thus maximizing the proximal endograft apposition. In our experience, the main advantages of inner branches include greater flexibility of positioning during deployment (as compared with fenestrations) and the ability to incorporate vessels that have origin from narrow aortic segments (in contrast to directional branches.) For these reasons, inner branches might be a valuable alternative solution when the narrow inner aortic space is a significant issue, as in case of secondary rescue after prior infrarenal EVAR or in chronic aortic dissections. Access to the small aortic lumen may be facilitated in these situations with preloaded catheters and guidewire systems,¹⁰ but access to these platforms is not widely available on the market yet.

From a technical standpoint, the internal opening of the inner branches naturally supports the catheter and the guidewire, which resulted in easy and quick catheterization of the TVs (as showed by 6 of 8 cases of category B catheterization.) It also provides a strong support to the BSG, which potentially

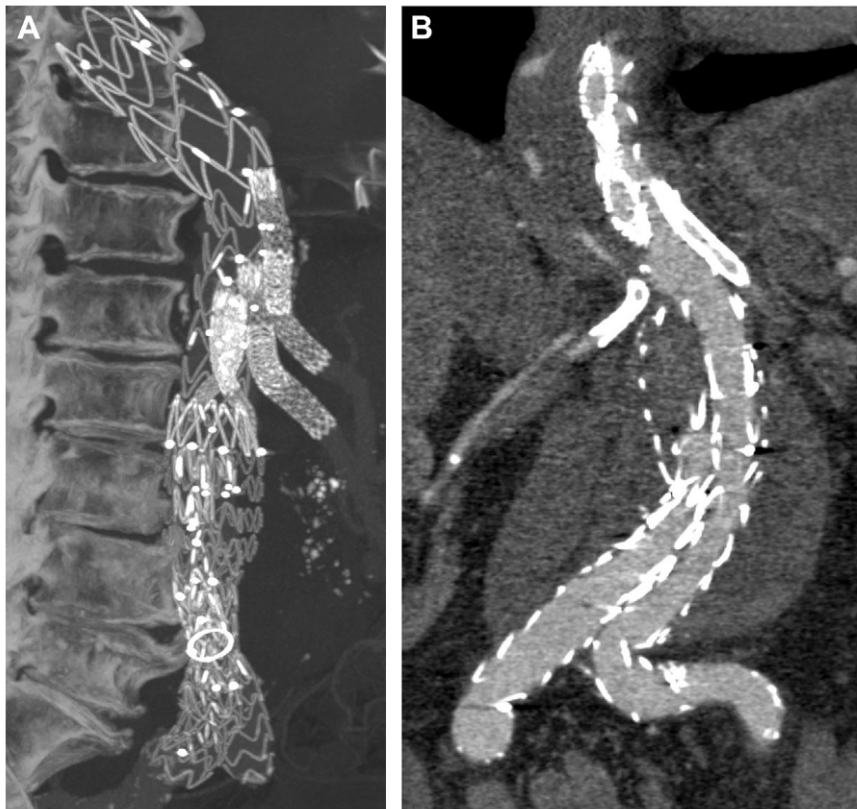


Fig. 3. Postoperative CT scan 12 months after secondary BEVAR. **(A)** Sagittal view showing optimal conformability of the inner branches without any kink/compression.

(B) Coronal view showing correct placement of the endograft without any endoleak and patent inner branches. BEVAR, branched endovascular aortic repair.

reduces not only the long-term risk of migration and disconnection but also of kinking. However, it is well known that renal branches are associated with higher occlusion rates.¹¹ This is the reason why a lot of stent grafts are used with fenestrations for the renal arteries and branches for the CA/SMA. Whether newer more kink-resistant BSGs may help reduce the occlusion rate remains a topic to be cautiously investigated.¹² Indeed, a recent article from the Mayo Clinic group found that outcomes of directional branches were poorer with use of the balloon-expandable Gore VBX endoprosthesis as compared with self-expandable BSGs.¹³ Use of the BeGraft Plus as the BSG in our series resulted in 100% freedom from TVI in all treated TVs ($n = 8$) at one-year and six-month CTA, but more experience with longer follow-up is needed to confirm these findings.

As noted by Katsargyris et al.,² TV catheterization in CMSGs with inner branches only might be challenging. The reason for this was reputed to be the difficulty in visualizing and orientating the inner branches perpendicularly to facilitate

catheterization, in contrast to fenestrations or directional branches. According to these authors, TVs in stent grafts including a combination of fenestrations and inner branches were catheterized more easily because of the benefit of first catheterizing the fenestrations, which orientates the internal opening of the inner branches automatically. Although direct comparison with other stent grafts is not possible, the internal and external openings of the inner branches in our experience were well visible under fluoroscopy and allowed easy and quick alignment with and catheterization of the TVs.

Some technical challenges of secondary F-BEVAR are important to consider before carrying out such advanced procedures. Problems with advancing a stent graft through previously treated limbs can cause difficulties in orientation of the branched cuff. In our experience, the use of brachial-femoral wires counteracts this rotational issue in many cases and avoids excessive traction forces on the device. As said, catheterization of RAs might sometimes be challenging if there are struts crossing the TVs orifices. Indeed, the ability

to push a strut aside to place a sheath and a stent depends on the type of suprarenal stent (as some are very strong and it would be virtually impossible to deform a strut enough to make room) and also on what portion of that stent actually crosses the orifice. Although a single cuff might be sufficient as a secondary repair, we have implemented total relining of the primary repair with a distal bifurcated endograft system to ensure adequate seal below the fenestrated cuff. A limiting factor in this setting would arise when the primary repair is composed of a stent graft with a short main body as is the case with certain specific infrarenal endograft designs. Depending on the length of the main body of the existing stent graft, the secondary repair should be tailored to accommodate this (for instance, using an inverted contralateral limb.)

The main drawback to CMSGs still remains the time delay for device manufacturing and delivering, which has limited the use to elective treatment of stable aneurysms. The time from planning to delivery in our series was 3 weeks for the branched endograft. Available endovascular alternatives for urgent/emergent cases include off-the-shelf multi-branched endografts (MBEs)¹⁴ and physician-modified endografts (PMEGs).¹⁵ However, currently accessible off-the-shelf MBEs might be difficult (or even impossible) to use for secondary relining after previous EVAR for the abovementioned reasons, mainly the recurrent narrow inner aortic lumen, and off-the-shelf MBEs with inner branches are not yet available on the market. On the other side, the feasibility of inner branches incorporation into a PMEG has recently been described.¹⁶ However, such advanced techniques should be used cautiously by adequately trained physicians in patients without other reasonable options, and their broad application cannot be warranted. Finally, parallel grafts have also shown to be a possible alternative for secondary endovascular repair in the pararenal/juxtarenal position,¹⁷ but gutter endoleaks and stent compression still represent significant concerns, particularly in narrow aortic lumens and with >3 chimney stents.¹⁸

An UEA is necessary for endovascular repair with the branched design and deserves specific consideration. We prefer surgical exposure of the UEA site when using larger profile sheaths (≥ 10 F), as this technique is safe and carries a low risk of complications.^{19,20} However, a preliminary experience with percutaneous closure of axillary artery access with the ProGlide device has shown to be clinically safe and technically feasible.²¹ This novel technique might represent a useful alternative, but its

outcomes are still scarce, and its implementation may not be routinely recommended.

CONCLUSION

Secondary treatment of stent-graft migration after previous EVAR is safe and feasible using CMSGs with 4 inner branches. This technique is effective as showed by stable sac size and 100% freedom from TVI at midterm imaging follow-up. Larger cohorts and longer follow-up are needed to confirm the preliminary results.

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